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ANNUAL COMPLIANCE MONITORING REPORT

January 1 to December 31
2021

The information contained in this report concerns the performance and operation of BWXT Medical Ltd. Class IB nuclear facility located in Ottawa, Ontario. This report is prepared to meet the requirements of the Class IB Nuclear Substance Processing Facility Licence, NSPFL-15.00/2031, specifically Licence Condition 3.2 regarding reporting requirements. The details provided in this report demonstrate BWXT Medical's commitment to operate a safe Nuclear Medicine Production Facility and to remain compliant with applicable regulatory requirements prescribed by the Canadian Nuclear Safety Commission.

Revision	Description	Prepared by Date	Reviewed by Date	Approved by Date
00	Initial Issue	F. Helmke 2022-03-28	S. Lacasse 2022-03-29	T. Mahilrajan 2022-03-30

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Submitted to:

Jason Duhaime, CNSC Project Officer on 2022-03-31

1. Executive Summary

BWXT Medical Ltd. is a respected supplier of nuclear medicine products used for the prevention, diagnosis and treatment of disease for the lives of millions of people in many countries around the world. Our products are used daily by pharmaceutical and biotechnology companies, medical-device manufacturers, hospitals, clinics and research laboratories. The scope of the manufacturing and product development activities at our site for Medical Isotopes includes: active pharmaceutical ingredients, finished pharmaceuticals, medical devices and contract manufacturing.

The purpose of this compliance report is to demonstrate that BWXT Medical has successfully met the requirements of the Nuclear Safety and Control Act, associated regulations and the Class IB Nuclear Substance Processing Facility Licence, NSPFL-15.00/2031 issued by the Canadian Nuclear Safety Commission (CNSC) on November 1, 2021. Prior to this date, all operations in the Nuclear Medicine Production Facility were carried out under Nordion's Class IB licence. This report was prepared based on the requirements of CNSC Regulatory Document 3.1.2: *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*. Appendices containing confidential, proprietary or prescribed information are submitted to the CNSC separately.

BWXT Medical is committed to continuously improve systems to protect the environment as well as the health and safety of employees and our community. We work to implement programs and processes to prevent pollution and minimize waste. Maintaining a safe and healthy work environment for our employees is a top business priority. BWXT Medical has implemented a management system that includes quality assurance requirements for the licensed activities, which ensures structures, systems and components are designed, installed, operated and maintained in accordance with the Nuclear Safety and Control Act, associated regulations, codes and standards, jurisdictional requirements and best practices.

There were no significant changes to operations in 2021. Facility modifications for the future Tc-99m generator process are substantially complete; validation of the process and addition of an automated packaging line will be completed in 2022.

All radiation doses received by employees and contractors were below regulatory limits (50 mSv/yr for Nuclear Energy Workers and 1 mSv/yr for all other workers), action levels and internal administrative levels.

Releases of nuclear substances to the environment were prevented or controlled, resulting in a negligible estimated dose to members of the public, below 0.0005 mSv for the entire year. There were two releases to the sanitary sewer system that exceeded municipal limits and were self-reported to the City of Ottawa.

There were four (4) medical treatment incidents and one (1) lost time incident in 2021. The majority of the incidents were strain injuries and initiatives are in place to reduce the likelihood and severity of strain injuries moving forward.

BWXT Medical places great importance on its relationships with all levels of local government and residents in the communities in which it operates and works to ensure there is open communication and awareness of BWXT Medical's operating activities. The public information program defines the process for providing information about BWXT Medical operations.

This compliance monitoring report demonstrates that BWXT Medical has successfully met the requirements of the Nuclear Safety and Control Act, associated regulations and Class IB Nuclear Substance Processing Facility Licence conditions.

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List of Acronyms

ALARA	As Low As Reasonably Achievable
AMMS	Advanced Maintenance Management System
BMS	Building Management System
CAD	Charcoal Adsorber
CAM	Continuous Air Monitor
CCR	Code Compliance Review
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association
DRL	Derived Release Limit
ECA	Environmental Compliance Approval
EHS	Environment, Health and Safety
ERA	Environmental Risk Assessment
ERO	Emergency Response Organization
FHA	Fire Hazard Assessment
FSAR	Final Safety Analysis Report
HEPA	High Efficiency Particulate Air
KOB	Kanata Operations Building
KRMF	Kanata Radiopharmaceutical Manufacturing Facility
MCA	Multi-Channel Analyzer
MDA	Minimum Detectable Activity
NEW	Nuclear Energy Worker
NMPF	Nuclear Medicine Production Facility
NPRMI	Non-Production Radioactive Material Inventory
NSPFL	Nuclear Substance Processing Facility Licence
NVS	Nuclear Ventilation System
PIDPIE	Public Information and Disclosure Program and Indigenous Engagement
RP	Radiation Protection
SSC	Systems, Structures and Components
STEM	Science, Technology, Engineering and Mathematics
TI	Transport Index
TLD	Thermo-luminescent Dosimeter

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2. Introduction

The purpose of the annual compliance monitoring report is to demonstrate that BWXT Medical Ltd. has successfully met the requirements of the Nuclear Safety and Control Act, associated regulations and the Class IB Nuclear Substance Processing Facility Licence, NSPFL-15.00/2031 issued by the Canadian Nuclear Safety Commission (CNSC) on November 1st, 2021. Until October 31, 2021, operations in the Nuclear Medicine Production Facility (NMPF) were carried out under Nordion's Class IB licence. This report was prepared to meet the requirements of CNSC Regulatory Document 3.1.2: *Reporting Requirements, Volume I: Non-Power Reactor Class 1 Nuclear Facilities and Uranium Mines and Mills*.

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 acquisition terms provided BWXT Medical a long-term lease of the portions of the Ottawa facility dedicated to the nuclear medicine business. The Nuclear Medicine Production Facility (NMPF) is comprised of a portion of the Kanata Operations Building (KOB) and the entire Kanata Radiopharmaceutical Manufacturing Facility (KRMF), both located on Nordion property situated on 447 March Road, Kanata, ON. The site is a parcel of 56.8 acres located to the southwest of the intersection of Carling Avenue and Solandt Road in the Kanata North Business park.

Figure 1: 447 March Road – Aerial View (BWXT Medical leased area outlined in red)

2.1. Processes and Materials

In 2021, BWXT Medical manufactured two products: Yttrium-90 (Y-90) and Indium-111 (In-111). For both products, irradiated raw material is received, processed, dispensed, sterilized and packaged for shipment to customers.

The Y-90 product is a sterile, active implantable Class III medical device used to treat liver cancer. BWXT Medical is under contract to supply this product. The In-111 product is a diagnostic radiopharmaceutical used for the assessment of inflammation and infection within the body.

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Additionally, BWXT Medical continued its development of the Technetium-99m (Tc-99m) generator program using its patent-pending innovative technology to generate Tc-99m from irradiated molybdenum targets. BWXT Medical seeks to furnish a stable North American-based supply of Tc-99m, the most widely sought-after medical isotope used in the diagnosis of serious illnesses, such as heart disease and cancer.

The facility 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 radiochemical and radiopharmaceutical facilities in the NMPF. The nuclear medicine products manufactured in this facility 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 2 and 3). The hot cell wall shielding (e.g., 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. Fume hoods are generally designed to handle low levels of radioactivity (e.g., Quality Control samples, decontamination of equipment, etc.) and allow easier unrestricted manipulation of parts and chemicals used by the operator while maintaining adequate ventilation to ensure contamination control. 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 2: A hot cell at BWXT Medical

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Figure 3: A fume hood at BWXT Medical

3. Safety and Control Areas

3.1. Management System

3.1.1. Applicable Activities

The Management System for Safety is applicable to all CNSC licensed activities, which predominantly refers to the processing and manufacturing of nuclear substances used in health sciences. Other licensed activities include the possession, transfer, use, storage and disposal of nuclear substances and sealed sources.

3.1.2. Management System for Safety Program Effectiveness

Overall, the management system has proven to be effective as a set of processes to ensure the safety of workers and protection of the environment. This is largely based on the outcome of internal and external audits (Section 3.1.3) and Manager self-assessments, as well as the successful performance of each Safety and Control Area as described in the remainder of this report.

The 2021 Annual Management Review of the Management System for Safety is split into two sessions: the first session was conducted in March 2022 by the BWXT Medical Leadership Team and focused on occupational health and safety; the second session will be completed in April 2022 and will cover all remaining aspects of the Management System for Safety.

The March 2021 session focused on strain injuries, which accounted for the majority of safety incidents, and for which there is a need for improvement. The Leadership Team identified four key corrective actions:

1. Through detailed Job Hazard Analyses, identify work that has the potential to cause a strain injury, evaluate the necessity of task and if it cannot be eliminated, identify alternative, safer methods.

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2. For new or modified manufacturing processes, ensure that ergonomic assessments with end user input are integrated into the design process.
3. Increase employee engagement through focus groups that lead improvement efforts, and frequent direct communication through the use of safety scorecards.
4. Emphasize the importance of immediately reporting discomfort so it can be addressed before it turns into an injury.

3.1.3. Internal and External Audits

Internal and external audits are a key part of the Management System for Safety.

As listed in Table 1, there were 10 internal audits completed in 2021 that pertain to BWXT Medical-licensed activities. These audits included an audit of production areas and supporting functions as well as program audits.

One minor non-conformance was identified in the work management audit related to gaps in pre-use inspection logs of lift devices. Corrective actions were put in place to remind Managers and lift users to perform inspections prior to use.

Another minor non-conformance was identified in the waste management audit. The audit identified that a torque wrench was not used when closing waste drums. Corrective actions include clarifying the requirement in procedures and/or associated forms and ensuring proper training.

Table 1 - Internal audits

Scope	No. of non-conformances
Safeguarded Physical Inventory	0
Non-Production Radioactive Material Inventory (NPRMI)	0
Independent Assessment - EHS Internal Audit Program	0
Research and Development	0
Supplier Audit	0
Business Planning	0
Work Management – Work planning and control	1
Packaging and Transport of Nuclear Substances Program	0
Safeguards, Non-proliferation and import/export Controls program	0
Waste Management	1
Total:	2

In April 2021, an external audit was conducted for the Environmental Management System. Two minor non-conformances were identified: a minor lapse in environmental controls related to outdoor activities performed as part of the facility modification project; and two procedures were not updated to reflect current practice. Corrective action plans were submitted, accepted, and implemented. The audit team concluded that the Environmental Management System meets the requirements of the ISO 14001 standard. In December 2021, a third party conducted the annual facility condition inspection to confirm compliance with the National Fire Code of Canada 2015.

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3.1.4. Management System for Safety Program Improvements

There were no changes to the core BWXT Medical management system processes.

To ensure continued collaboration, awareness and joint decision making where applicable, BWXT Medical and Nordion have established a Joint Environmental Health and Safety Committee, with representatives from both organizations. The Committee reviews, monitors and recommends changes to Environment, Health and Safety (EHS) programs that could impact the safety or security of the site as a whole. This ensures that there is no cumulative effect of operations on the shared site that negatively impacts compliance to regulatory requirements or the protection of workers, public and the environment.

3.1.5. Summary of Organizational Structure and Key EHS Personnel

The President of BWXT Medical has the ultimate responsibility for the organization, ensuring adequate resources and support to deliver on all business, regulatory and community commitments. As shown in Figure 4, the leadership team for BWXT Medical directly reports to the President.

The President has appointed the Senior Manager, Nuclear Regulatory and EHS as the Management System representative, who has the responsibility and authority to ensure that the Management System is established, implemented and maintained. Due to planned retirement, there was a change in the position of Senior Manager, Nuclear Regulatory and EHS effective July 5, 2021.

Together, the Senior Manager, Nuclear Regulatory and EHS and the Senior Manager, Radiation Safety are responsible for the protection of workers, public and the environment. They have the authority to cease operational activities that present unsafe or non-compliant situations.

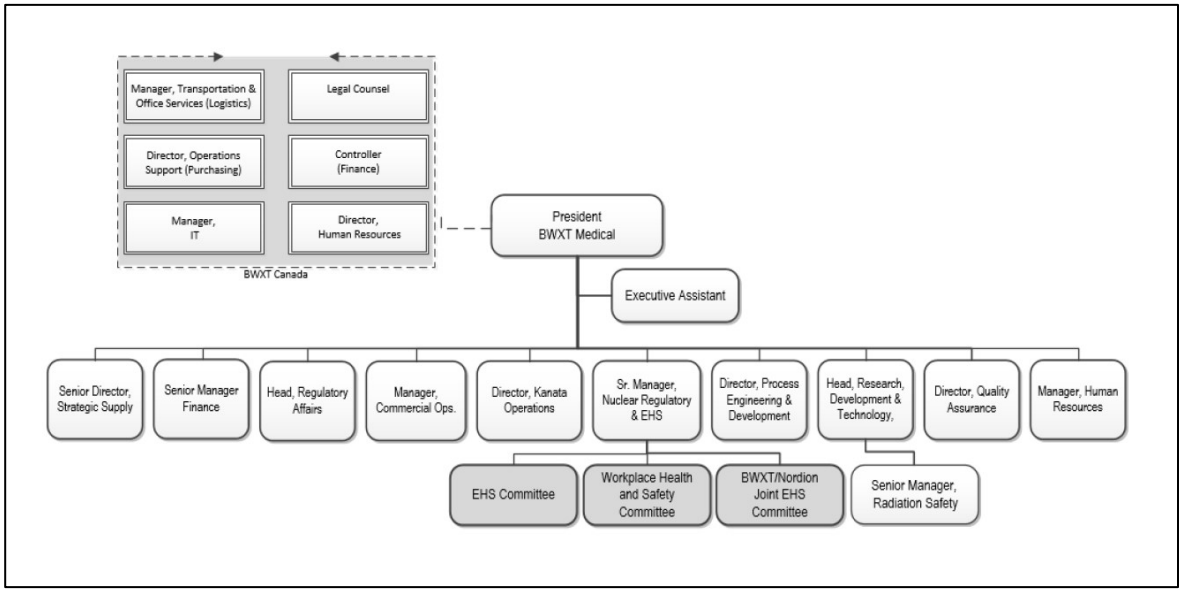

Figure 4: Leadership Organization Chart

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3.2. Human Performance Management

The Human Performance Management Safety and Control Area covers activities that enable effective human performance, through the development and implementation of processes that ensure BWXT Medical staff are sufficient in numbers in all relevant job areas and have the necessary knowledge, skills and tools in place to safely carry out their duties.

Qualifications and training requirements are identified and personnel are given the appropriate training to ensure they are competent at the work they do. This training includes courses related to EHS and radiation safety, as well as on-the-job training. Workers only perform tasks for which they are qualified. As shown in Table 2, training associated with key safety programs were completed as planned in 2021.

The facility is staffed with a sufficient number of qualified workers as well as the minimum number of responsible people to carry on the licensed activities safely and in accordance with the Nuclear Safety and Control Act and associated regulations. EHS and other staff are available after business hours as needed.

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Table 2 - Safety training

Program	Duration	Participants		
		No. required	No. completed	No. not completed
Nuclear Energy Worker (NEW) Indoctrination and NEW Refresher	4 Hours / Self Study	217	217	0
Radiation Instrumentation Workshop	3 Hours	216	215	1*
Transport of Dangerous Goods Level II	1 Hour	10	10	0
Transport of Dangerous Goods Level III	1 Hour	35	35	0
Transport of Dangerous Goods – 4-year refresher	1 Hour	32	32	0
Working with BETA	1 Hour	110	110	0
Crane	Half Day	32	32	0
Working from Heights	Half Day	80	80	0
Confined Space	Half Day	94	94	0
Pallet	Half Day	124	124	0
Pallet Truck – Class III	Half Day	122	122	0
Forklift – Narrow Aisle	Half Day	18	18	0
Forklift – Counter Balance	Half Day	7	7	0
Emergency Response Part 1	2 Hours	24	24	0
Emergency Response Part 2	2 Hours	21	21	0
Emergency Response Part 3	2 Hours	4	4	0
Emergency Response: Monitors	1 Hour	6	6	0
Emergency Communication – 2 Way Radio	1 Hour	20	20	0
SCBA Part 1 – MSA AirHawk	1 Hour	6	6	0
SCBA Part 1 – Chemical Spill	1 Hour	16	16	0
First Aid	2 Day	16	16	0
WHMIS	1 Hour	260	260	0
Fire Watch	2 Hours	27	27	0
Lockout Tagout	2 Hours	93	93	0
TOTAL		**1590**	**1589**	**1**

* Refresher training was due at the end of December 2021 and was completed in January 2022.

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3.3. Operating Performance

The Operating Performance Safety and Control Area covers an overall review of the licensed activities.

BWXT Medical has successfully implemented and maintained programs to ensure safe operation of the licensed activities within the facility as bounded by safety analysis. BWXT Medical has established essential documentation including standard operating procedures and work instructions prescribing the steps required to complete each task. This includes the written work instructions for handling of radioactive materials by workers to ensure activities are conducted in a manner that is protective of workers, the public and the environment; as well as full and accurate records to show the acquisition and inventory of nuclear substances for use or processed by BWXT Medical.

3.3.1. Effectiveness in Carrying out Licensed Activities

Licensed activities were carried out according to BWXT Medical's programs, policies and procedures resulting in no significant unplanned events.

BWXT Medical's programs that are in place for auditing and capturing non-conformances continue to identify issues in areas that require corrective actions. These processes functioned as expected.

The 2021 EHS program objectives and results are shown in Table 3. All EHS objectives related to radiation safety and environmental protection for nuclear substances were met. In general, the objective related to safety culture was also met, with the primary indicator being the number of near misses and concerns reported to EHS.

The number of medical treatments exceeded the target in 2021. Three out of the four medical treatments were in response to strain injuries. There was one lost time incident where an employee overexerted their arm inadvertently attempting to open a hot cell door incorrectly. The incident resulted in a lost time of 3 days. Corrective actions to significantly improve occupational health and safety were the primary focus of the Annual Management Review (see Section 3.1.2).

There were two waterborne releases of hazardous substances that exceeded the City of Ottawa Sewer Use By-law No. 2003-514. These releases are potentially attributable to BWXT Medical operations. The releases have been investigated, and no definitive cause has been identified. The self-reported sanitary releases are being measured using a single grab sample. In 2022, alternative sampling methods such as continuous sampling will be considered to better characterize effluent concentrations. Additionally, a detailed analysis of all hazardous substances within the facility will be carried out to determine the risk of release exceedances due to BWXT Medical operations.

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Table 3 - 2021 EHS Program Objectives and Results

Objective	Measure/Target	Result
Minimize the number and extent of occupational injuries	• The number of medical treatment incidents ≤ 2 • Lost time incidents = 0	• The number of medical treatment incidents = 4 • Lost time incidents = 1
Minimize the use and release of hazardous materials to the environment	• Total release of nuclear substances to the environment is less than 2.0% of the Derived Release Limits (DRL) • Zero reportable releases of hazardous materials to the environment	• 0.05% of the DRL for nuclear substances • Two reportable releases to the sanitary sewer potentially attributable to BWXT Medical: total phosphorus, suspended solids
Maintain radiation doses to employees as per ALARA principle	• Maximum annual employee dose ≤ 7.5 mSv	• Maximum annual employee dose = 2.41 mSv
Maintain a healthy safety culture	• It is unacceptable to take risks in order to get the job done. Safety is every employee's highest responsibility. • Actively participate in regular safety discussions and training. • Immediately report near-misses, hazard identifications, suspected ergonomic symptoms and workplace injuries to your Manager	• Targets established to promote safety culture only (not measured).

3.3.2. Effectiveness in Implementing Operational Controls and Improving Safety Culture

EHS operational controls are documented in program documentation that employees read and understand. Safety critical steps are added into routine production procedures. These procedures are routinely updated using BWXT Medical's change control process when safety improvements are identified or during scheduled document periodic review.

Derived from safety analysis, the fundamental operational limit and condition is that all nuclear substances are processed in a hot cell, glove box or fume hood, which are exhausted to the Nuclear Ventilation System (NVS), and which have established limits for the activity of a given radionuclide. Nuclear substances must be transferred or stored in containers with the appropriate amount of shielding. In, 2021, BWXT Medical ensured that these limits and conditions were fully complied with.

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In 2021, BWXT Medical continued the practice of routine behaviour-based safety awareness campaigns to encourage safety discussions within the organization and to encourage employees to report near misses and safety concerns.

3.3.3. Reportable Events

There were two reportable events in 2021:

1. In January 2021, a Cesium-137 check source could not be located during an internal inventory verification. The room was being architecturally modified at the time and it is likely, although unconfirmed during investigation, that the check source was lost as a result of the renovation. The activity of the source was 157 kBq. The dose rate at 10 cm from the source is approximately 0.001 mSv/hr.
2. In September 2021, a Type A package could not be located during transit and the incident was reported immediately. The package was found and delivered to the end user one day later.

Corrective actions for the first event included improving signage and labelling of wall-mounted sources and implementation of additional procedures during any future architectural modifications to ensure sources are identified and re-located if necessary.

3.3.4. Sealed Source Tracking

There have been no receipts, transfers, exports or imports of sealed sources that require reporting.

3.3.5. Non-Production Sealed and Unsealed Source Inventory

BWXT Medical maintains a program to oversee the inventory of non-production radioactive material (i.e., sealed and unsealed sources).

3.3.6. Annual Production

Activities relating to the procurement, possession, processing and shipping of radioactive materials were conducted under the Nuclear Substance Processing Facility Licence.

Data relating to the production of nuclear medicine products is attached in Appendix A.

3.4. Safety Analysis

The Safety Analysis Safety and Control Area covers the maintenance of the safety analysis which supports the overall safety case for the facility. The safety analysis is a systematic evaluation of the potential hazards associated with the conduct of an activity or facility, and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards. The safety analysis for the Nuclear Medicine Production Facility is documented in a Final Safety Analysis Report (FSAR) that describes the facility and operations, defines the safety requirements and details the hazard analysis. The conclusion of the FSAR is that all safety requirements are met during normal operations as well as during abnormal events.

The safety analysis is underpinned by a robust defence-in-depth strategy. Activity limits for each radionuclide are established based on the systematic evaluation of potential hazards to ensure that safety criteria will not be exceeded during normal operations and credible abnormal events. Passive engineered features such as the hot cells provide a reliable level of containment and shielding for radioactive and other types of hazardous material. Active engineered systems such as the Nuclear Ventilation System, radiation and contamination monitoring systems, and fire protection systems further

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ensure the protection of workers and the environment. Lastly, personal protective equipment and administrative controls provide a final safety barrier.

Modifications to the facility are made in accordance with the Change Control program, which requires review of EHS parameters for any addition to, or modification of existing processes or facility structures, systems or components. Under this process, a proposed modification is screened for potential impact on the facility safety analysis. Where screening 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.).

During the reporting period, a comprehensive update to the FSAR was prepared and submitted to the CNSC. The update included additional information regarding site characteristics, a safety requirements section, removal of discontinued processes, an augmented hazard analysis including the prescription of SSCs Important to Safety, operational limits and conditions, and a description of decommissioning plans. The updates were made in accordance with international guidance for safety analysis at Class IB-type facilities. The assertions made in the safety analysis were validated for normal operating conditions by worker dose data and releases to the environment presented in Sections 3.7 and 3.9 respectively. Additionally, there were no abnormal events with consequences that exceeded the corresponding safety criteria.

There were modifications to the facility for the Tc-99m generator project and for the installation of a semi-automated packaging line for existing products. The Tc-99m generator project included the addition and modification of hot cells and supporting structures, systems and components. In general, the types of hazards associated with these modifications are not dissimilar to the existing types of hazards present in the Nuclear Medicine Production Facility. The major improvement to worker safety is the increased used of automation, which in general reduces the amount of direct worker interaction in the proximity of radioactive materials. Conceptual safety analyses were performed based on detailed design, and have concluded that all safety requirements will be met. This ensures the continued safety of workers and members of the public, as well as the protection of the environment.

3.5. Physical Design

The Physical Design Safety and Control Area relates to activities that impact on the ability of systems, structures and components (SSC) to meet and maintain their design basis, given new information arising over time and taking into account changes in the external environment.

Changes made to the physical facility, equipment, processes, procedures or practices that could adversely affect product quality, employee health and safety, the environment or the public as a result of the operation of BWXT Medical's facilities are assessed through the Change Control program.

During the reporting period, the major modifications to the facility were related to the Tc-99m generator project. This included the continued architectural, mechanical and electrical fit-up of a subsection of the KRMF for radiopharmaceutical production. It also included the installation or modification of hot cells and supporting equipment for radiochemical processing, radiopharmaceutical production, and waste processing.

Additionally, the final packaging system for current manufacturing of Y-90 and In-111 was modified to incorporate further automation to reduce the amount of operator intervention required.

None of the modifications to the facility affected the ability of existing SSCs to function in accordance with their design intent. All modifications were designed in accordance with applicable building and fire codes and standards.

Commissioning of facility modifications and process validations are ongoing, and will be completed in 2022.

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3.6. Fitness for Service

The Fitness for Service Safety and Control Area 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.

3.6.1. Effectiveness of Maintenance and Testing Programs

BWXT Medical ensures fitness for service of facility systems and process equipment. As Landlord, Nordion carries out facility maintenance in accordance with the requirements of the BWXT Medical licence.

The maintenance program provides guidelines for the documentation and maintenance of the system to ensure responsibilities are identified, filing systems are maintained and all necessary controls are in place for facility maintenance and equipment calibration.

The Advanced Maintenance Management System (AMMS) is used to control maintenance and calibration activities. AMMS catalogues all systems and equipment requiring calibration or maintenance, records equipment information, schedules maintenance, issues work orders and retains records of inspections and tests.

Detailed processes and rules governing the preventative maintenance program are available in Facilities Master Plan documents.

The maintenance program continues to prove effective as during 2021, there were no systemic facility or equipment failures that affected BWXT Medical operations, safety or security.

3.6.2. Effectiveness of Aging Management Strategies

Aging of facility structures and systems is jointly monitored by senior leadership at BWXT Medical and Nordion. Where there are concerns, facility or equipment condition assessments are performed, and as necessary, improvement projects are developed and approved.

Aging management continues to prove effective as during 2021, there were no structural or system failures that affected BWXT Medical operations, safety or security.

3.7. Radiation Protection

The Radiation Protection Safety and Control Area covers the implementation of the radiation protection program, in accordance with the Radiation Protection Regulations. BWXT Medical has a well-established and effectively implemented radiation protection program, which includes a commitment to ALARA and continuous improvement. The program addresses the radiation hazards associated with manufacturing processes. This program ensures that surface and airborne contamination, as well as radiation doses to employees and the public are monitored and controlled.

3.7.1. Dose Control Data

Radiation dose refers to the energy deposited or absorbed in materials through which it passes. Equivalent dose is used to assess how much biological damage is expected from the absorbed dose. It takes the properties of different types of radiation into account. Effective dose is used to assess the potential for long-term effects that might occur in the future. It is a calculated value, measured in milliSieverts (mSv), which takes into account the absorbed dose to all organs of the body, the relative harm level of the type of radiation and the sensitivities of each organ to radiation. All radiation exposures received by employees in the reporting period were below Administrative Levels, Action Levels and regulatory limits. Action Levels are site specific and are

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accepted by the CNSC through the facility operating Licence Conditions Handbook. Regulatory limits are specified in the Radiation Protection Regulations.

3.7.1.1. Occupational External Dosimetry

Table 4 provides dosimetry data for employees grouped in various ranges of exposure.

Data on the minimum, maximum and average doses for all employees and contractors are shown in Tables 5, 6 and 7 for effective, skin and extremity doses respectively. Tables are presented as a 5-year dosimetry period beginning January 1, 2021 to facilitate comparison to 5-year regulatory dose limits. In 2021, all contractors were deemed non-Nuclear Energy Workers (NEWs), subject to an effective dose limit of 1 mSv/yr and a skin or extremity dose limit of 50 mSv/yr.

Table 8 provides a summary of the dosimetry data for 2021.

The top 20 doses to employees shown in Appendix C account for 55% of the total collective dose to all employees.

Table 4 - Personnel Dosimetry

Number of Employees															
Dose range (mSv)	**Effective**					**Lens of the Eye**					**Skin**				
	2021	**2022**	**2023**	**2024**	**2025**	**2021**	**2022**	**2023**	**2024**	**2025**	**2021**	**2022**	**2023**	**2024**	**2025**
0	36					36					39				
0.01-1.00	219					219					216				
1.01-5.00	11					11					11				
5.01-10.00	0					0					0				
10.01-20.00	0					0					0				
>20.00	0					0					0				

Number of Employees										
Dose range (mSv)	**Extremity (Left Hand)**					**Extremity (Right Hand)**				
	2021	**2022**	**2023**	**2024**	**2025**	**2021**	**2022**	**2023**	**2024**	**2025**
0	65					71				
0.01-1.00	70					60				
1.01-5.00	21					25				
5.01-10.00	1					1				
10.01-20.00	1					1				
>20.00	0					0				

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Table 5 - Average, Maximum, Minimum Effective Doses

Dose Range (mSv)	BWXT Medical Employees (mSv)				
	2021	2022	2023	2024	2025
Average	0.15				
Maximum	2.41				
Minimum	0				
# NEWs	266				
Dose Range (mSv)	BWXT Medical Contractors (mSv)				
	2021	2022	2023	2024	2025
Average	0.03				
Maximum	0.47				
Minimum	0				
# Non-NEWs	249				

Table 6 - Average, Maximum and Minimum Skin Doses

Dose Range (mSv)	BWXT Medical Employees (mSv)				
	2021	2022	2023	2024	2025
Average	0.15				
Maximum	2.44				
Minimum	0				
# NEWs	266				
Dose Range (mSv)	BWXT Medical Contractors (mSv)				
	2021	2022	2023	2024	2025
Average	0.04				
Maximum	0.95				
Minimum	0				
# Non-NEWs	249				

Table 7 - Average, Maximum, Minimum Extremity Doses

Dose Range (mSv)	BWXT Medical Employees (mSv) Left Hand				
	2021	2022	2023	2024	2025
Average	0.57				
Maximum	12.58				
Minimum	0				
# NEWs	158				
Dose Range (mSv)	BWXT Medical Employees (mSv) Right Hand				
	2021	2022	2023	2024	2025
Average	0.55				
Maximum	10.38				
Minimum	0				
# NEWs	158				

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Table 8 - Summary of Employee doses

Dose Range (mSv)	Effective Dose	Lens of Eye	Skin	Left Hand	Right Hand
0	36	36	39	65	71
0.01-1.00	219	219	216	70	60
1.01-5.00	11	11	11	21	25
5.01 - 10.00	0	0	0	1	1
10.01 - 20.00	0	0	0	1	1
>20.00	0	0	0	0	0
	Effective Dose (mSv)	Lens of Eye (mSv)	Skin (mSv)	Left Hand (mSv)	Right Hand (mSv)
Average	0.15	0.16	0.15	0.57	0.55
Maximum	2.41	2.45	2.44	12.58	10.38
Minimum	0	0	0	0	0
# Monitored	266	266	266	158	158

3.7.2. Significance of Results for the Dose Control Data

Appendix C contains a trending analysis of doses to employees in each functional group.

3.7.3. Dose to the Public

Table 9 shows the maximum radiation dose to the public from 2021 based on releases to the environment as a percentage of the DRL (see Section 3.9.1). The total releases from the site correlate to a maximum dose to a member of the public of 1.85E-03 mSv in 2021. The dose specifically from operations at BWXT Medical and Nordion is 5.1E-04 mSv and 1.35E-03 respectively.

As described in Section 3.9.1, the releases to the environment are over-conservative estimates, largely based on assuming non-detects in liquid effluent have a concentration equivalent to the Minimum Detectable Activity (MDA). For comparison, the Environmental Risk Assessment (ERA) calculates the theoretical dose to public from current BWXT Medical operations (Y-90 and In-111) to be 6E-10 mSv.

Table 9 - Dose to the Public

Year	Maximum dose to the public from BWXT Medical releases (mSv)	Maximum dose to public from Nordion releases (mSv)	Total maximum dose (mSv)
2021	5.1E-04	1.35E-03	1.85E-03

3.7.4. Contamination Control Data

The contamination control program for the Active Area includes routine sampling and monitoring on a daily basis of the floors, benches, fume-hoods, gloveboxes, support/service areas, and on a weekly basis, change-rooms and inactive floors. 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 the

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levels specified in the decontamination procedure. In addition, equipment and personnel leaving the Active Area are monitored for contamination.

The number of contamination incidents in 2021 are shown in Table 10, Table 11 and Figure 5. There was a slight increase in the number of contamination incidents compared to last year, partially due to facility modifications involving entry into historically contaminated hot cells as part of the Tc-99m generator project.

The predominant radionuclides, Y-90 and In-111, are associated with the two manufacturing processes at BWXT Medical. Other radionuclides are largely attributable to facility modifications associated with the Tc-99m generator project.

Table 10 - Contamination Incidents by Contamination Level

Year	Not recorded	<500 cpm	>500 cpm, <2,000 cpm	>2,000 cpm, <10,000 cpm	> 10,000 cpm, < 50,000 cpm	>50,000 cpm	Annual Total
2021	1	3	10	4	3	1	22

Table 11 - Contamination Incidents by Radionuclide

Radionuclide	Number of incidents
Not identified	2
C-14	4
C-60	2
I-125	0
I-131	0
Mo-99	2
Y-90	5
Ir-192	0
Xe-133	0
Sr-82	0
In-111	6
Radon	0
Other	1
Total	**22**

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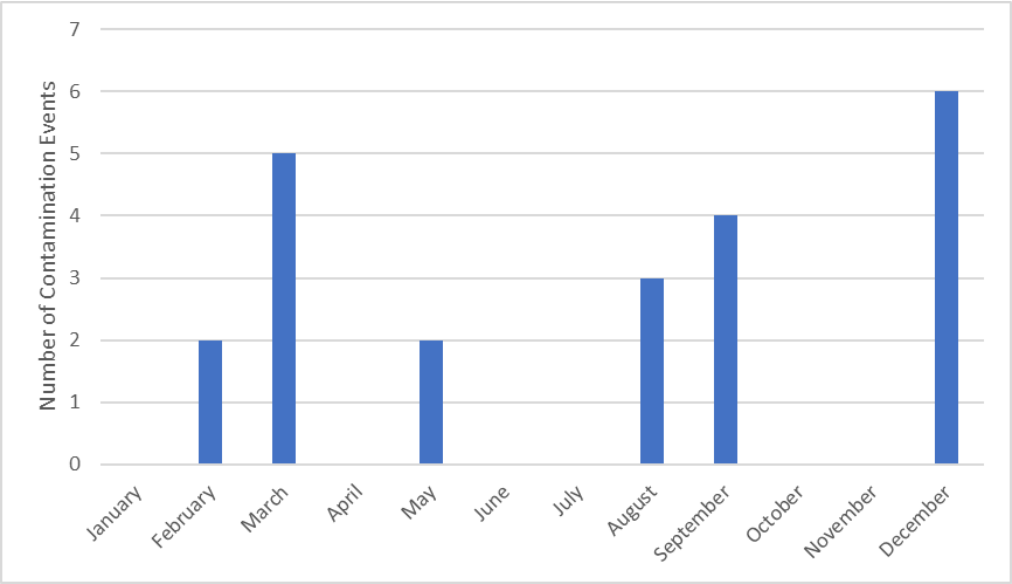

Figure 5: Contamination Incidents by Month

3.7.5. Facility Radiological Conditions

The radiation survey program involves radiation measurements within the Active Area, and on the perimeter and exterior of the KOB. Within the Active Area, radiation surveys are generally conducted daily, throughout all the labs and rooms. Areas where radiation fields are above 2.5 mrem/hr (0.025 mSv/hr) are posted with radiation warning signs, indicating the radiation fields. In addition, surveys are conducted at employee work areas, at cells, glove-boxes, and fume-hoods, during production and test operations, to ensure radiation fields during processing are within acceptable levels. Special surveys are conducted on new processes/equipment to provide information on the safety performance of new operations.

On a monthly basis, radiation surveys have been conducted on the perimeter of the Active Areas, and within the Inactive Office Areas. The monthly survey also includes measurement of radiation fields outside the KOB to ensure conditions have not changed in the operations that may impact the environment/exterior exposure. All the monthly surveys were conducted in 2021.

Breathing air was monitored using Continuous Air Monitor (CAM) 24-hour air samplers. Due to construction activities in the radiochemical production area some CAMs were not accessible to be tested every week, but they were tested routinely throughout the year. In addition to having the capability of alarming locally, CAMs are monitored and logged at the Surveyor's control panel and on the Building Management System (BMS). The 24-hour air filters are measured daily. In 2021, some 24-hour air filters could not be changed out routinely due to construction activities. In all cases this was appropriate as there was no manipulation of radioactive material in the rooms at the time when there was no monitoring present.

For work known to have the possibility of creating radioactive contamination of the breathing air, a zone is demarcated, and signage is posted requiring respirators to be worn. Respirator requirements are removed only once air monitoring measurements are below the required levels. In 2021, all breathing air sampling was performed in accordance with procedures and results indicated that processes were in control.

Facility radiological conditions were very stable and routine throughout the year.

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3.7.6. Exceeding Regulatory Limits or Action Levels

In 2021, there were no exceedances of either regulatory limits or Action Levels.

3.7.7. Radiation Protection Program Effectiveness

The Radiation Protection (RP) Program is reviewed by conducting process audits and process safety audits. Data and performance of the RP Program is also reviewed regularly at EHS Committee meetings. The RP Protection program continued to operate effectively in 2021.

3.7.8. Radiation Protection Program Improvements

The RP Program continues to effectively ensure radiation safety for all workers. No significant improvements to RP processes were made in 2021.

3.7.9. Radiation Protection Program Performance

The objectives, goals and targets of the RP Program are shown in Section 3.3.1. The targets for maximum NEW dose and environmental releases of nuclear substances were met in 2021. These targets are tracked as key performance indicators at EHS Committee meetings and in Monthly Operational reports. The targets are reviewed yearly at the Annual Management System for Safety Review.

For 2022, the target maximum annual dose to an employee will be 5 mSv/yr, a decrease of 33% from the 2021 target.

3.7.10. Continuous Improvements under ALARA Performance

ALARA objectives and performance is reviewed at EHS Committee meetings. Safety is integrated into the design aspects of new builds, from design objectives, design review and to performing Hazard Risk Analysis of process flows.

As examples, two ALARA-based initiatives to reduce doses to workers that were identified and implemented were:

1. Combined packaging line for Y-90 and In-111
    - The handling of packages is known to be the predominant historical contributor to the highest doses to employees. Engineered features were added to the packaging line to automate much of the storage, retrieval and packaging of final product pots. With greater automation and less direct handling, it is expected that doses to employees will be lower during the packaging process.
2. Pre-determined Transport Index (TI) values for packages
    - Y-90 is manufactured in a subset of dose sizes and the total activity in the package is known at the time of shipping. TI values based on the activity of the product vial were established based on statistical analysis of a large data set. The pre-determined TI values were then confirmed periodically with measurements. This improvement led to much less time spent measuring dose rates from the package, resulting in a reduction of total dose.

3.7.11. Radiation Devices and Instruments Performance

As listed below, performance of radiation devices and instruments is checked at various frequencies throughout the year. If operating specifications are not met, corrective maintenance is performed and the device or instrument is verified again prior to its return to service.

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The following have been verified on a routine basis:

- NVS High Efficiency Particulate Air (HEPA) Filter and Charcoal Adsorber (CAD) Testing: all HEPA filters and CADs in the NVS required for operations were tested twice in 2021. The required specification for filtration efficiency was met in all cases.
- Back-up Power: emergency diesel generators were tested monthly and confirmed to be operational.
- Radiation Evacuation Alarms: the intermittent klaxon indicating a high radiation field from Cobalt Operations was tested weekly and confirmed to be operational.
- Radiation Alarms: local radiation alarms at various locations in the manufacturing area are tested on a weekly basis, including a verification of the alarms on the Building Management System (BMS).
- Fire Suppression Systems: sprinkler systems are tested monthly and confirmed to be operational.
- Fire Alarm Panels: fire alarm panels are tested monthly and confirmed to be operational.
- Contamination and Area Monitoring Equipment: preventive maintenance was performed on handheld contamination meters twice in 2021. Hand and foot monitors were calibrated twice in 2021 and tested weekly. Area radiation monitors are verified daily.
- Environmental Monitoring Equipment: air sampling pumps are tested on a weekly basis.
- Radiation Survey Instruments: survey meters are tested on a monthly, bi-annual or annual basis as required.

3.7.12. Radiation Protection Training Program and Effectiveness

Every employee and contractor who works in the Active Area are required to first pass a radiation protection course. The course provides each participant with a detailed description of radiation hazards, the associated potential consequences to human health and the control measures implemented in accordance with the ALARA principle.

All required radiation protection training was completed as required in 2021. Refresher training is provided on a 3-year cycle. Training has proven to be effective in ensuring workers understand the hazard and protect themselves and others accordingly.

3.8. Conventional Health and Safety

3.8.1. Conventional Health and Safety Program Effectiveness

The Conventional Health & Safety Program is reviewed by conducting program audits, process audits, regular inspections by both employees and management, and a review of revised safety programs is performed by the Workplace Health & Safety Committee. The Workplace Health & Safety Committee is also responsible for reviewing the Hazard Prevention Program. In addition, the EHS Committee sets targets each year that are used to monitor the effectiveness of the safety program.

Targets were established for medical treatment incidents (≤ 2) and zero lost time incidents. In addition, Near Miss Reports and Hazard Identification Reports are tracked and are reported monthly to senior management and are provided to the Workplace Health & Safety Committee for review.

Refer to Section 3.1.3 for a list of audits and inspections conducted in 2021.

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Overall, the programmatic elements have proven to comprehensively ensure occupational health and safety. However, given the number and severity of incidents in 2021, the effectiveness of implementation must be improved. A list of improvements initiated in 2021 is provided in Section 3.8.3 and further improvements will be considered in 2022 (see Section 3.1.2).

3.8.2. Conventional Health and Safety Committees

BWXT Medical's objective is to eliminate or minimize as low as reasonably achievable both known and potential environmental, safety and health hazards that could impact our employees and contractors.

BWXT Medical's Workplace Health and Safety Committee is comprised of union and management representatives, and typically meets monthly. Minutes of each meeting are distributed to all employees.

The committee met 11 times in 2021, and accomplished the following:

- Reviewed performance data related to occupational health and safety against objectives and targets (see Section 3.3.1);
- Procured equipment and materials to address identified hazards and concerns;
- Implemented administrative features such as signage and labelling to improve safety;
- Contributed to the development of company policies related to health and safety; and
- Ensured the completion of actions raised during committee meetings.

3.8.3. Conventional Health and Safety Improvements

The most significant improvements to health and safety will correspond to the elimination of hazards or the incorporation of engineered safety features to mitigate hazards. In 2021, this philosophy was executed in the installation of a combined packaging line for the Y-90 and In-111 manufacturing processes. This packaging line automates a number of the formerly manual activities associated with packaging including box erection and taping, and foam compression.

BWXT Medical is committed to the use of technology to further prevent or reduce the likelihood of injuries in the workplace. For example, the packaging line for the Tc-99m generator process currently under development is designed to be fully automated, greatly reducing hazards and improving safety.

Other improvements to the Conventional Health and Safety Program in 2021 include:

- Online ergonomic awareness training;
- Nuclear Culture Spotlight topics for functional group discussions;
- COVID-19 Preparation, Prevention and Response (workplace strategies to prevent transmission, active screening, contact tracing, communications, etc.);
- Electronic Work Permits;
- Machine Guarding Risk Assessments; and
- Hazard Risk Assessments for new processes.

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3.8.4. Conventional Health and Safety Occurrences

During 2021, there were four medical treatment incidents and one lost time injury:

- The lost time incident involved an employee that inadvertently overexerted their arm attempting to open a hot cell door incorrectly. The incident resulted in a lost time of 3 days.
- Three medical treatment incidents were strain injuries; two incidents were due to repetitive motion over time as part of normal duties and the other was due to lifting components above shoulder height.
- One medical treatment incident was for a laceration caused by an exposed sharp object protruding from a carton at the receiving bay.

Medical treatments included physiotherapy and prescription medication.

3.9. Environmental Protection

The Environmental Protection Safety and Control Area covers programs that monitor and control all releases of nuclear and hazardous substances into the environment as well as their effects on the environment as a result of licensed activities.

BWXT Medical has an effective environmental protection program in place which identifies and controls environmental aspects and drives continuous improvement to enhance performance and minimize risk to employees and the public. The facilities have well-established environmental management systems to ensure effective monitoring programs are in place to achieve environmental goals and regulatory compliance.

3.9.1. Air and Water Release Monitoring

The environmental monitoring program is designed to monitor and measure effluent releases to the environment and to determine exterior radiation levels. The program includes the following elements:

a) Continuous monitoring of process ventilation, exhausts ductwork and stack emissions by use of in-situ detectors and samplers and computerized recording

b) Weekly air sampling and analyses for exhaust stack emissions

c) Holding tanks for Active Area liquid effluent to allow sampling, analysis and authorized release of liquid effluent

d) Environmental TLD program

e) Soil sampling

Exhaust stack sampling is conducted by using particulate and/or activated charcoal filters depending on the physical and chemical nature of the radionuclide. Radioiodine sampling involves the use of activated charcoal filter cartridges and analyses by gamma measurement. Particulates are sampled by use of cellulose filter papers and analyzed by gamma measurement.

All production operations are contained within cells, gloveboxes and/or fume-hoods. Ventilated air from these containment systems is filtered through roughing and HEPA filters and, where appropriate, activated charcoal absorbers. These systems are designed with redundant fan/motor and filtration units that include pre-filters, primary and secondary filtration units. The NVS has been designed and is maintained to prevent the unnecessary release of radioisotopes to the atmosphere.

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3.9.1.1. Airborne Emissions

Based on weekly air sampling of all exhaust stacks, there were no detectable airborne releases of nuclear substances to the environment from the BWXT Medical facility in 2021.

For non-radiological, hazardous substances, BWXT Medical operations were well below the production limits specified in the BWXT Medical Environmental Compliance Approval (ECA) from the Ministry of the Environment, Conservation and Parks.

3.9.1.2. Liquid Effluent

Wastewater from the Active Area that could have low-level radioactivity (Emergency showers, Active Area personnel wash sinks, etc.) is collected in underground delay tanks. The wastewater in the tanks is sampled, analyzed and compared to internal administrative levels. All results are reviewed and must be approved by Radiation Safety prior to discharge into the city sewer system. The City of Ottawa is informed whenever a release to the sanitary sewer takes place. In addition, a monthly summary report of the activity levels released is submitted to the city.

In 2021, one measurement of liquid effluent resulted in a concentration above the Minimum Detectable Activity (MDA); 99.8% of the measurements of liquid effluent had no detectable radioactivity. BWXT Medical employs a conservative practice of assuming the concentration is equal to the MDA for non-detects in liquid effluent. Therefore, the total activity in liquid releases closely followed release volumes.

Therefore, the liquid effluent monitoring results indicate a dose to the public that is based on activity values which were over-estimated by a factor of ten (10) at a minimum. Due to the conservative approach, the estimated dose to the public from liquid effluent is greatly over estimated.

For non-radiological, hazardous substances, there were two self-reported City of Ottawa By-law exceedances related to releases to the sanitary sewer system: total phosphorus and suspended solids. See Section 3.3.1 for further detail and corrective actions.

Table 12 - Liquid Releases (GBq)

Liters	β<1MeV*	β>1MeV*	I-125	I-131	Mo-99	Co-60
615219	0.187	0.042	0.071	0.005	0.039	0.006
DRL (GBq/yr)	763	35,000	1,190	389	10,200	35.4
% DRL	2.45E-02	1.19E-04	5.98E-03	1.21E-03	3.79E-04	1.83E-02
*β<1MeV Ni-63 DRL value used, β>1MeV Y-90 DRL used						

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3.9.1.3. Environmental TLDs

Radiation fields at exterior locations both within and beyond the site boundaries, as well as in certain locations inside the KOB are measured using environmental TLDs.

All environmental TLD measurements were well below the annual public limit of 1 mSv. The similarity in the recorded dose in these locations year over year, taken with the absence of any contamination found in soil illustrates that the variation between locations is due to variations in natural background radiation at these locations.

Table 13 - Environmental TLDs

Location		2021 (mSv)
16	RE Building	0.2
17	Pole, North Corner	0.096
18	Heating Plant Roof	0.04
19	Hydro Pole, South West	0.074
20	Local Business	0.065
32	Residence	-0.03
33	Residence	-0.04
38	Residence	0.109
57	Residence	-0.037
58	Local Business	-0.048

3.9.2. Exceeding Regulatory Limits or Action Levels

There were no instances of exceeding CNSC environmental regulatory limits or action levels in 2021.

3.9.3. Spills to the Environment

There were no spills to the environment in 2021.

3.9.4. Environmental Protection Program Effectiveness

Based on the negligible risk to the environment as justified in the BWXT Medical Environmental Risk Assessment (ERA) and confirmed through measurements of nuclear substances in effluent and environmental monitoring, the Environmental Protection Program is effective at preventing pollution and protecting members of the public.

3.9.5. Environmental Protection Program Activities

An external audit was conducted for the Environmental Management System in 2021. See Section 3.1.3 for further details. Additionally, routine environmental inspections were conducted and any concerns were identified and resolved.

3.9.6. Environmental Protection Program Improvements

There were no improvements to the Environmental Protection Program in 2021.

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3.9.7. Environmental Protection Program Performance

The key metrics for the performance of the Environmental Protection Program are presented in Section 3.3.1. As discussed in that section, environmental protection in terms of nuclear substances met the established targets, while there is improvement needed for non-radiological releases to the sanitary sewer against the City of Ottawa By-law.

3.9.8. Soil Sampling

Soil samples are regularly taken and analyzed from various locations on the property to test for the presence of radioisotopes and to detect potential soil contamination.

Soil samples were taken at 19 locations around the site in August 2021. Samples were placed in plastic bags, labeled with the site location and analyzed on the Multi-channel Analyzer (MCA) for 8 hours. Background measurements (no sample, empty chamber) were also taken for reference. There were no gamma-emitting radionuclides detected in any soil samples associated with BWXT Medical operations.

3.10. Emergency Management and Fire Protection

3.10.1. Emergency Preparedness Program Effectiveness

As evidenced by the exercises and drills conducted in 2021, the Emergency Preparedness Program continues to be effective in ensuring that the joint emergency response capability of BWXT Medical and Nordion protects workers, the public, the environment and as much as practicable the facility in the event of an emergency. Further details regarding drills and exercises are provided in the next section.

3.10.2. Emergency Preparedness Program Activities

BWXT Medical has implemented and maintains an Emergency Management Program to meet regulatory requirements. Each drill and exercise is planned with defined objectives, and outcomes are assessed and considered for continual improvement.

As part of the Emergency Management Program, there is an onsite emergency plan and established organizational structure for clear allocation of responsibilities, authorities, and arrangements for coordinating onsite activities and cooperating with external response organizations throughout all phases of an emergency.

During 2021, the following were conducted to test these emergency response plans and response capability:

- Fire drill for the Nordion Heating Plant
- Fire drill in the RE Building
- Incident Command Post exercise for an emergency in the KOB Building

A full-scale emergency response exercise will be conducted in 2022.

In 2021, BWXT Medical hosted Ottawa Fire Services for a familiarization tour and a review of the Fire Safety Plan. The discussion afforded both organizations the opportunity to better understand the mutual context of emergency response considerations in the event of a fire in the BWXT Medical facility.

3.10.3. Emergency Preparedness Program Improvements

There have not been any recent changes to the Emergency Preparedness Program. As in 2020, emergency response efforts were focused on protecting the workplace during the COVID-19 pandemic.

3.10.4. Fire Protection Program Effectiveness

The Fire Protection Program, specifically the elements of fire prevention, proved to be effective as there were no fire incidents in 2021 – a year where there was a significant amount of hot work associated with facility modifications as part of the Tc-99m generator project.

Additionally, as described in the following section, independent third party assessments of the existing facility concluded that fire hazards are adequately mitigated by the existing fire protection systems.

3.10.5. Fire Protection Program Activities

BWXT Medical maintains a Fire Protection Program to meet regulatory requirements. The Fire Protection Program is implemented and integrated into facility operation in a controlled and coordinated manner to ensure that BWXT Medical is able to respond efficiently and effectively to emergency fire situations.

The objective of the Fire Protection Program is to minimize the probability and consequences of a fire and to promote life safety, the conservation of property and essential equipment, the protection of the environment and the continuity of operations through provisions of fire prevention and fire protection measures. This is achieved through appropriate fire protection system design, fire safety analysis, fire safe operation and fire prevention.

Supplementing the Fire Protection Program is a Fire Safety Plan which describes emergency procedures and the Emergency Response Organization (ERO) in the event of a fire.

Under the lease agreement, Nordion maintains all fire protection systems within the BWXT Medical facility. BWXT Medical employees are responsible for following all fire protection procedures.

In 2021, BWXT Medical reviewed and updated the following:

- Fire Hazard Assessment (FHA), which identifies fire hazards and the fire protection features, and demonstrates that the fire protection goals and safety performance criteria are met
- Code Compliance Review (CCR), which systematically confirms compliance with requirements from the National Building Code, National Fire Code and CSA Standard N393

Additionally, Independent Third Party Reviews were conducted for fire suppression and fire alarm modifications to the BWXT Medical facility as part of the Tc-99m generator project.
Fire Inspections for all areas of the leased BWXT Medical spaces are done at least twice a year.
An external Annual Facility Condition Inspection was also conducted in 2021.

3.10.6. Fire Protection Program Improvements

There were no changes to the Fire Protection Program in 2021.

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3.11. Waste Management

The Waste Management Safety and Control Area covers management of radioactive, hazardous and non-hazardous waste as part of facility operations, up to the point where the waste is removed from the facility to an approved waste management facility.

Radioactive wastes are any materials that contain a nuclear substance and which have been declared to be waste. BWXT Medical has an effective radioactive waste disposal program that ensures all radioactive waste disposals are compliant with the Nuclear Safety and Control Act and associated regulations and the facility licence conditions.

3.11.1. Effectiveness of Waste Segregation and Minimization

BWXT Medical's production facilities have been designed and operated in a manner to prevent radioactive waste being released to municipal garbage or the environment as airborne emissions or waterborne effluent. All radioactive waste that is generated through production operations is collected and sent to a CNSC-approved radioactive waste management facility.

BWXT Medical has designated space and processes to store and segregate radioactive waste. Long term decay storage areas are located in the KOB active shipping/receiving facility. Space is also designated for storage of containers and management of waste being prepared for shipment to approved waste management facilities.

BWXT Medical's non-hazardous waste diversion rate in 2021 was 66.3%.

3.11.2. Waste Shipments

Appendix B provides a summary of solid waste material for each of the major radioisotope waste streams and liquid waste shipped to a licensed waste management facility in 2021.

3.11.3. Waste Management Program Performance

The waste management program was internally audited in 2021. See Section 3.3.1 for further details.

3.11.4. Waste Management Program Improvements

BWXT Medical is in the process of transferring legacy solid and liquid radioactive waste sources to a licensed waste management facility. Liquid sources will be concreted prior to transfer. Reducing the amount of radioactive waste stored in the facility is a program improvement.

3.12. Security

The Security Safety and Control Area covers the programs required to implement and support the security requirements stipulated in the regulations and in the facility licence.

The facility maintains a security program in accordance with the General Nuclear Safety and Control Regulations, Class I Nuclear Facilities Regulations, and the Nuclear Security Regulations. The Security Plan outlines the systems, processes and responsibilities for performing security operations with the objective of maintaining safe and secure facilities. The Security Plan describes the physical security features and details the individual roles and responsibilities for implementation and maintenance of the program. The Security Plan is Prescribed Information and confidential and was submitted to the CNSC as part of the BWXT Medical Class IB Licence Application.

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3.13. Safeguards and Non-Proliferation

BWXT Medical has a safeguards program that meets the safeguards requirements of the CNSC regulatory document REGDOC 2.13.1-Safeguards and Nuclear Material Accountancy, CNSC Nuclear Non-Proliferation Import and Export Control Regulations, Nuclear Safety and Control Act and General Nuclear Safety and Control Regulations.

3.13.1. Safeguards Program Effectiveness and Performance

In 2021, BWXT Medical performed accounting and reporting of nuclear material as required. A Physical Inventory Taking of safeguarded material resulted in no non-conformances.

3.13.2. Safeguards Program Improvements

There were no significant improvements to the safeguards program in 2021.

3.13.3. Safeguards Inspections

In 2021, BWXT Medical was not selected for the IAEA Physical Inventory Verification as BWXT Medical was still operating under Nordion's facility licence and not yet designated as a Material Balance Area at the time of the selection.

BWXT Medical hosted the IAEA on two occasions for baseline environmental sampling for the new hot cells as part of the Tc-99m generator project, at the request of the CNSC to establish a reference prior to operation.

3.14. Packaging and Transport of Nuclear Substances

BWXT Medical has a packaging and transport of radioactive materials program that is applicable to the packaging and transport of nuclear substances and radiation devices to and from the licensed facility.

BWXT Medical routinely ships nuclear medicine products in Type A packages. BWXT Medical also ships waste materials in either Type A or Type B packages, and empty containers as Excepted packages. Shipments of BWXT Medical products are made via road and air. Shipments of waste are routinely made via road transport.

The program applies to 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 program meets the regulatory requirements from the CNSC, IAEA, US Department of Transportation, and US Nuclear Regulatory Commission.

In 2021, there was one transport-related non-conformance that was reported to the CNSC and Transport Canada. This non-conformance involved a Type A package that could not be located during transit. See Section 3.3.3 for further details.

4. Other Matters of Regulatory Interest

4.1. Public Information Program

Throughout 2021, BWXT Medical updated its Public Information and Disclosure Program and Indigenous Engagement (PIDPIE) document to best fit the engagement needs of the community. Although the PIDPIE did not officially come into effect until November 1, 2021, BWXT Medical engaged with Indigenous communities, elected officials and community members throughout the year in a variety of ways to ensure there was two-way communication and information sharing.

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4.1.1. Website

BWXT Medical regularly updates its public website (medical.bwxt.com) to ensure current information is made available to the public.

The following items were updated/added to the website in 2021:

- CNSC Notices of Public Hearing, Hearing Agenda and Record of Decision (news release)
- BWXT Medical March 31st Community Webinar (registration link and recording)
- Hearing Documents (BWXT Medical Commission Member Document (CMD), BWXT Medical Presentation, CNSC CMD)
- BWXT Medical Licence Application Briefing Guide
- CNSC April 8th Webinar (registration link)
- Environmental Risk Assessment
- Public Information & Disclosure Protocol
- Indigenous Relations commitment and policy

4.1.2. Engagement

Keeping Indigenous communities, elected officials, community members and stakeholders informed is a priority at BWXT Medical. Throughout 2021, efforts were made to ensure that information was made available to interested parties and that there were opportunities for two-way dialogue.

In 2020, BWXT Medical sent introductory emails to the majority of its target audience in attempt to make a connection and establish a contact at each groups/organization/community. Through this outreach, BWXT Medical developed its contact list, which is used to share regular email updates. The contact list is regularly updated and evaluated each year to ensure it is current. Community members and other interested groups can sign up to join these email updates anytime by contacting the company at isotopequestions@bwxt.com.

In March of 2021, BWXT Medical held a Community Webinar. Invitations to the webinar were sent via email updates, a postcard mailer and targeted Facebook advertising. The webinar was attended by 12 individuals and no concerns were raised. The recording is available on BWXT Medical's public website (medical.bwxt.com) through YouTube and the recording of the webinar currently has over 55 views.

4.1.2.1. Indigenous Engagement

BWXT Medical is committed to communicating and engaging with local, interested Indigenous communities in a timely, transparent and meaningful way.

In early 2021, BWXT Medical sent two updates to Algonquins of Ontario, Algonquins of Pikwàkanagàn First Nation, Métis Nation of Ontario (Region 8) and Algonquin Anishinabeg Nation Tribal Council. In April, once the list of participant funding recipients was made public by the CNSC, BWXT Medical reached out to Kebaowek First Nation to establish a contact and provide information on an ongoing basis. From May to November, BWXT Medical sent three more updates to Algonquins of Ontario, Algonquins of Pikwàkanagàn First Nation, Métis Nation of Ontario (Region 8), Algonquin Anishinabeg Nation Tribal Council and Kebaowek First Nation and offered to meet with each community. BWXT Medical's full PIDPIE document was provided to each community in November. Additionally, BWXT Medical met virtually three times with representatives from Algonquins of Pikwàkanagàn First Nation. BWXT Medical continues to have email discussions with Algonquins of Pikwàkanagàn First Nation and looks forward to

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continuing to develop a meaningful relationship with this community and other interested Indigenous communities.

4.1.2.2. Government Engagement

BWXT Medical engages with all levels of government in the Kanata area to ensure open communication and awareness of the operations in their ridings.

In 2021, BWXT Medical sent four email updates to elected officials. These updates provided information about the June licence hearing, community webinar, recent company announcements and more. Links, invitations and attachments were included in these updates to make sure information was readily available. Additionally, when a new Councillor for the Kanata area was elected, BWXT Medical sent a congratulatory introduction letter and offered to meet. Virtual meetings were held with all other elected officials in late 2020 and no concerns were raised.

4.1.2.3. Community Engagement

Throughout 2021, BWXT Medical utilized a variety of communication channels to provide information to its neighbours, including emails to its contact list (which includes interested members of the public who have signed up for updates), a community mailer, social media, and Facebook targeted advertising. In total, four email updates were sent and provided information about the June licence hearing, community webinar, recent company announcements and more. Links, invitations and attachments were included in these updates to make sure information was readily available.

4.1.3. Public Advertisements & Social Media

BWXT Medical uses a variety of communications tools and methods to ensure information is available to a wide audience. In advance of BWXT Medical's Community Webinar in March 2021, a postcard mailer was sent to over 14,000 neighbours with an introduction to BWXT Medical (following the branding rename from BWXT ITG), webinar registration link and details, contact information and an overview of BWXT Medical's CNSC licence application and hearing. Additionally, BWXT Medical used Facebook targeted advertising to share information about the Community Webinar and the advertisement reached 6,246 community members in only four days.

Social media is another tool used by BWXT Medical. In 2021, multiple posts were shared on BWX Technologies platforms: information on the licence hearing, re-branding to BWXT Medical, recent announcements, YouTube videos, news releases and more.

4.1.4. Community Volunteerism & Investment

Due to the COVID-19 pandemic, volunteer events were held virtually. In April, an employee from BWXT Medical's Kanata facility volunteered as a judge at the University of Ottawa's Design Day. Employees also participated in a virtual Spring Fundraiser to provide donations to local food banks and community centres. In just a few weeks, employees in Kanata raised over $700 for the Kanata Food Cupboard and employees from Vancouver raised over $1300 for the Greater Vancouver Food Bank.

In addition to volunteerism, BWXT Medical provides funding to local organizations in the community. In 2021, bursary awards were created at Algonquin College for students in the Biotechnology – Advanced Diploma program and at University of Ottawa to support students in Mechanical Engineering and Science, Technology, Engineering and Math (STEM) programs.

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4.1.5. Inquiries

BWXT Medical's PIDPIE representatives can be reached via a variety of methods. These methods include the company's toll-free telephone number (1.833.657.4565), designated email address (isotopequestions@bwxt.com), website (medical.bwxt.com), traditional mail, and in person (when applicable). Contact information is included on public mailings and communications.

In 2021, BWXT Medical received two inquiries: one email and one phone call. The phone call was from a neighbour who received BWXT Medical's community mailer in late March and was looking for more information about the company. A BWXT Medical representative called the neighbour back on the same day and answered questions and provided the community member with additional links to more information. The email was from an intervener who was looking for documentation for their intervention. BWXT Medical representatives responded to the email the same day and shared that document summaries would be made available shortly. These summaries were provided the following business day.

4.2. Cost Recovery

The CNSC recovers the cost of regulating from applicants and licensees through the CNSC Cost Recovery Fees Regulations. 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 Guarantees

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. The financial guarantee is distributed in the form of a Letter of Credit and a Surety Bond. The CNSC confirmed receipt of both financial guarantee instruments on November 18, 2021.

BWXT Medical attests that the financial guarantee remains valid, in effect and adequate to fund the full decommissioning of the facility.

4.4. Improvement Plans and Future Outlook

BWXT Medical remains committed to continuously improving its EHS programs to minimize risk to employees, the public and the environment. Overall, commercial operations are projected to remain consistent in 2022, with modest growth.

The primary EHS area for improvement is conventional health and safety. In 2022, all existing manufacturing processes will be examined closely to identify and mitigate hazards that could lead to a strain injury. Wherever possible, alternative, safer methods will be implemented. For new process tasks, ergonomic assessments and end user input will be incorporated into the design process. Lastly, there will be direct engagement with all staff to promote safety improvement and reporting of discomfort before it turns into an injury.

An additional improvement in 2022 will be the sampling method for releases to the sanitary sewer to align with best practices and provide representative concentrations of contaminants in wastewater.

BWXT Medical intends on growing the nuclear medicine business to meet the increasing need in the global market. In 2022, BWXT Medical will complete validation of the process to manufacture Tc-99m generators and intends on beginning commercial production in 2023. The operation of this new manufacturing process has been confirmed to be within the existing licensing basis; and therefore, there will be no significant changes to EHS programs.

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5. Concluding Remarks

BWXT Medical is committed to the establishment and continuous improvement of a healthy safety culture. Safety culture refers to the core values and behaviours resulting from a collective commitment by our company's leaders and individuals to emphasize safety, quality, ethics and security over competing goals to ensure protection of employees, the public and the environment. It is a top business priority to continuously improve our EHS systems to protect fellow employees, the environment, and our communities against environmental, health and safety hazards. BWXT Medical management recognizes, reviews, prioritizes and controls workplace hazards and ensures compliance with applicable regulatory requirements, applicable codes and company policies.

Governed by an integrated management system, conventional health and safety, radiation protection and environmental protection programs are well implemented. All radiation dose measurement results were below internal administrative levels and regulatory limits. Environmental protection programs are well implemented, continuing to ensure negligible risk to the environment and members of the public from BWXT Medical operations.

All production and possession limits were respected. Transportation of dangerous goods was conducted safely between suppliers, customers and waste vendors without risk to workers, the public or the environment.

This annual compliance monitoring and operational performance report demonstrates that BWXT Medical has successfully met the requirements of the Nuclear Safety and Control Act, its regulations and BWXT Medical's CNSC Class IB Nuclear Substance Processing Facility Licence requirements.

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