BWXT Medical Ltd.
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ANNUAL COMPLIANCE MONITORING REPORT

January 1 to December 31
2023

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.

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Submitted to:

Jason Duhaime, CNSC Project Officer on 2024-03-28

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). 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 2023. Commercial manufacturing of Yttrium-90 (Y-90) and Indium-111 (In-111) based products continued as did development work for the Tc-99m generator process.

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), and action levels. One radiation dose to a Nuclear Energy Worker's hand exceeded an internal Administrative Level. The CNSC was informed of the event at the time of occurrence (though reporting was not required). The worker received 45.44 mSv to the right hand during a development activity, this was the subject of an internal investigation and corrective measures have been put in place to prevent a recurrence.

Releases of nuclear substances to the environment were prevented or controlled, resulting in a negligible estimated dose to members of the public, below 0.0002 mSv for the entire year.

There were five (5) medical treatment incidents and two (2) lost time incidents in 2023. While the type of injuries varied, a majority of the causal factors were attributable to unintentional deviation. A Human Performance Program to be initiated in 2024 is expected to substantially lessen the likelihood of these types of injuries.

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 and Disclosure Program defines the process for providing information about BWXT Medical operations.

Additionally, BWXT Medical has established an Indigenous Engagement program that ensures Indigenous Communities are informed and consulted for key developments. In 2023, BWXT Medical supported cultural protection programs and commenced the development of a long-term relationship agreement with the Algonquins of Pikwakanagan First Nation.

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
BMRAM	Blue Mountain Regulatory Asset Manager
BMS	Building Management System
CAD	Charcoal Adsorber
CAM	Continuous Air Monitor
CAPA	Corrective Action and Preventive Action
CNSC	Canadian Nuclear Safety Commission
DRL	Derived Release Limit
ECA	Environmental Compliance Approval
EHS	Environment, Health and Safety
ERA	Environmental Risk Assessment
ERO	Emergency Response Organization
FSAR	Final Safety Analysis Report
HEPA	High Efficiency Particulate Air
INPO	Institute of Nuclear Power Operations
KOB	Kanata Operations Building
KRMF	Kanata Radiopharmaceutical Manufacturing Facility
LTRA	Long Term Relationship Agreement
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
TLD	Thermo-luminescent Dosimeter

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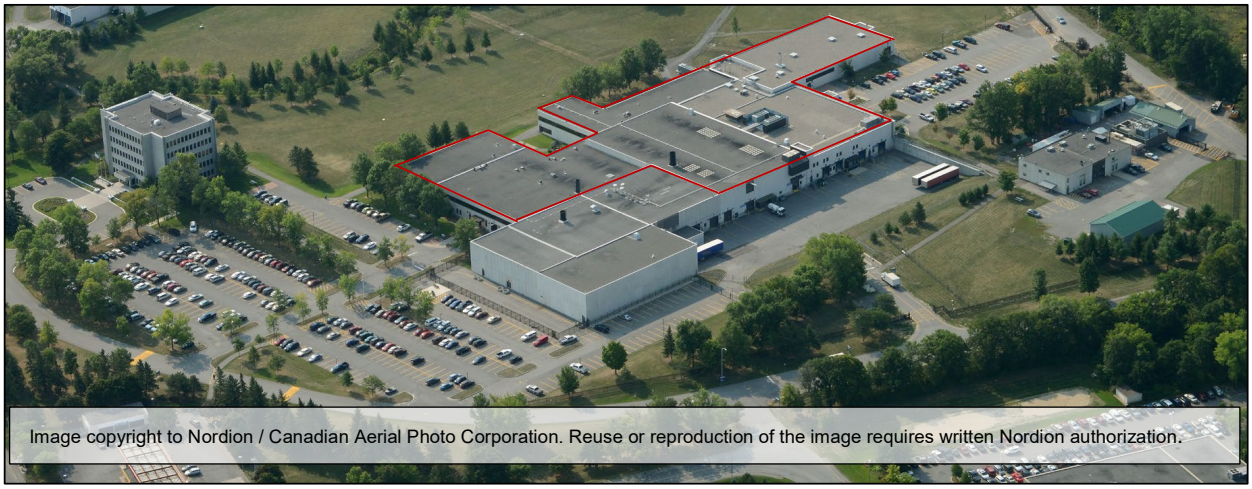
2. Introduction

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). 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*.

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 2023, BWXT Medical manufactured two products using these radionuclides respectively: 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.

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.

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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.

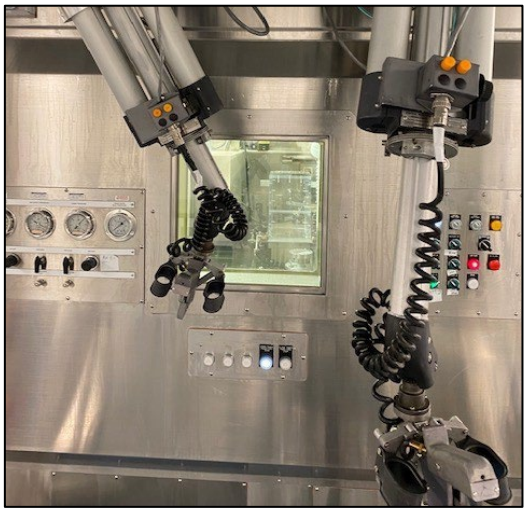

Figure 2: A hot cell at BWXT Medical

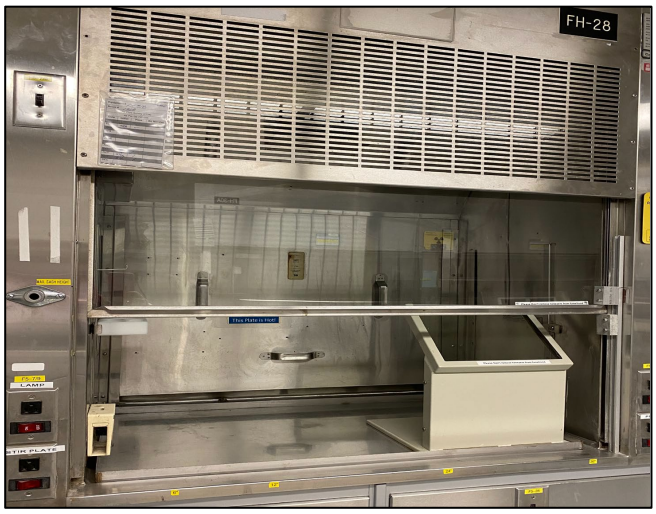

Figure 3: A fume hood at BWXT Medical

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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.

During the 2023 Annual Management Review of the Management System for Safety, the Leadership Team identified the following necessary improvements in 2024:

1. Implement a Human Performance Program, beginning with training employees on the fundamentals of human performance.
2. Improve proactive hazard management through weekly manager field observations and a modified job hazard analysis process.
3. Expand EHS review of safety performance to all management, including near misses and concern reports.
4. Re-assess training requirements and ensure training completion.

3.1.3. Internal and External Audits

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

The audits that were completed in 2023, as per Table 1, included production areas and supporting functions as well as program audits.

There was a total of six (6) non-conformances identified across all audits. Findings were related to the labelling of containers containing hazardous substances, housekeeping near flammable cabinets, documented waste process for mixed waste (radiological and biological), and timeliness of secondary Final Safety Analysis Reports (FSARs).

All of these findings were minor in nature, with no significant impact to the protection of health, safety and the environment. All findings have been appropriately actioned.

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Table 1 - Internal audits

Scope	No. of non-conformances
Environmental Protection	2
Public Information Program	0
Security	1
Waste Management	2
Physical Inventory Taking	0
Air Cargo Security	0
Non Production Radioactive Material Inventory	0
Safety Analysis	1
Radioactive Material Packaging	0
Supplier Audit	0
Total:	6

The CNSC performed the following inspections in 2023:

1. Management System Safety and Control Area; and
2. Physical Inventory Verification of safeguarded material, with the IAEA.

Across both inspections, there was one non-conformance relating to the timeliness of corrective actions. It was deemed to be of low safety significance.

The results of all audits and inspections demonstrate a high level of compliance with EHS programs. Internal and external audits remain a beneficial management system tool for monitoring and continuous improvement.

3.1.4. Management System for Safety Program Improvements

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

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. The leadership team for BWXT Medical directly reports to the President.

The President has appointed the Director, Nuclear Regulatory & EHS as the Management System representative, who has the responsibility and authority to ensure that the Management System is established, implemented and maintained.

Together the Director, Nuclear Regulatory & 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.

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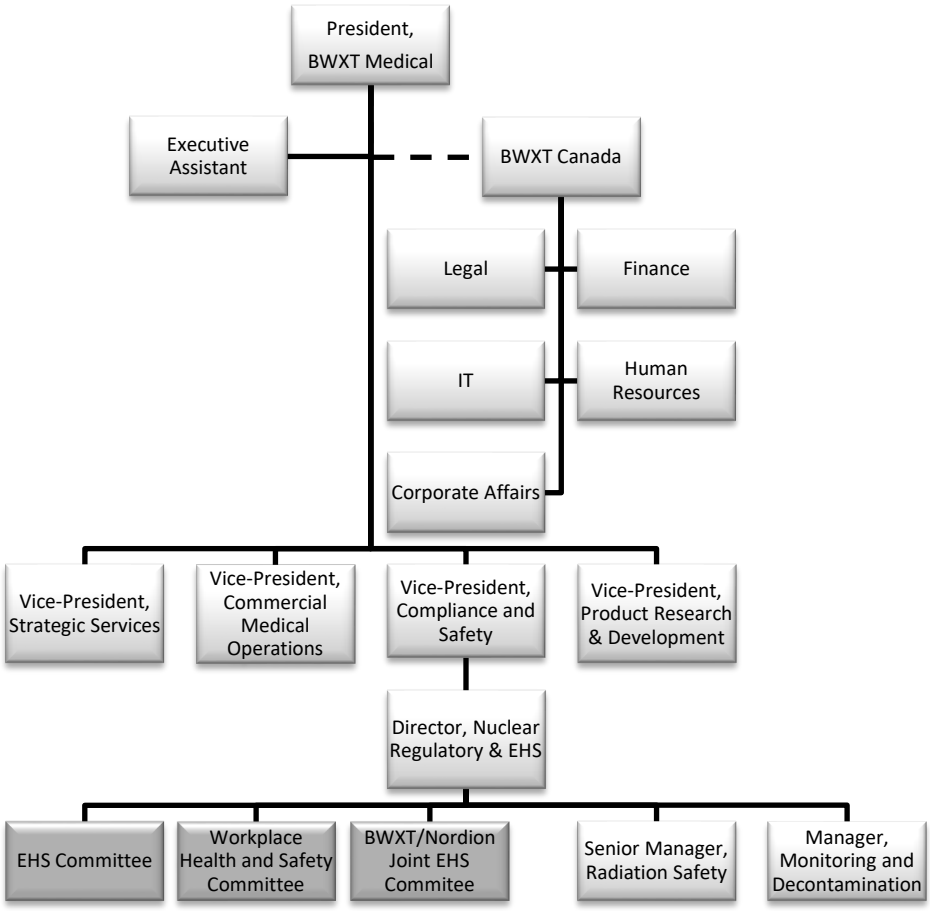

Figure 4: Leadership Organization Chart

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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 required in 2023 with the following to note of the 19 training requirements not completed:

- 2 training requirements were assigned to an off-site employee. They did not require the training for on-site work.
- 15 training requirements associated with pallet truck, confined space, emergency preparedness and response, fire watch and lockout tagout. Employees who did not complete this training did not perform any of the associated job tasks. There were sufficient number of trained employees to perform the same work.
- 2 training requirements were associated with WHMIS. Employees who did not complete this training did not handle chemicals as part of their job tasks.

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

A review of all safety incidents, process deviations, and corrective action and preventive action (CAPA) conclude that training is negligible root cause across the management system. Therefore, the training program has proven to be effective in ensuring that workers are adequately trained and prepared to perform work safely and in compliance with company policies and procedures.

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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	202	201	1
Radiation Instrumentation Workshop	3 Hours	212	211	1
Transport of Dangerous Goods Level III	2 Hours	48	48	0
Working with BETA	1 Hour	140	140	0
Crane	Half Day	39	39	0
Working at Heights	Half Day	75	75	0
Confined Space	Half Day	106	104	2
Pallet Truck – Class III	Half Day	88	87	1
Forklift – Narrow Aisle	Half Day	21	21	0
Forklift – Counter Balance	Half Day	7	7	0
Emergency Response Part 1	2 Hours	17	16	1
Emergency Response Part 2	2 Hours	12	11	1
Emergency Response Part 3	2 Hours	8	7	1
Emergency Communication – 2 Way Radio	1 Hour	26	26	0
SCBA Part 1 – MSA AirHawk	1 Hour	6	6	0
SCBA Part 1 – Chemical Spill	1 Hour	27	21	6
First Aid	2 Day	18	18	0
WHMIS	1 Hour	244	242	2
Fire Watch	2 Hours	39	38	1
Lockout Tagout	2 Hours	80	78	2
TOTAL		**1415**	**1396**	**19**

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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 2023 EHS program objectives and results are shown in Table 3.

There were five (5) medical treatment injuries in 2023, which exceeded the target of two (2), and equalled the totals from the preceding two years.

There were two lost time injuries: a head injury while performing an inspection on a ladder (3 days lost), and an elbow injury after slipping on a wet floor (31 days lost). The total lost time for both injuries was 34 days, corresponding to a severity rate of 14.13 and a frequency rate of 0.83.

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 no exceedances of the Sewer Use By-law during routine sampling of the sanitary sewer.

The radiation safety objective was met; the maximum effective dose to a Nuclear Energy Worker was 2.98 mSv.

Table 3 - 2023 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 = 5 • Lost time incidents = 2
Minimize the release of hazardous substances to the environment	• Zero reportable releases of hazardous materials to the environment	• Zero reportable releases of hazardous materials to the environment
Maintain radiation doses to employees ALARA	• Maximum annual employee dose ≤ 4.5 mSv	• Maximum annual employee dose = 2.98 mSv

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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 2023, BWXT Medical ensured that these limits and conditions were fully complied with.

In 2023, BWXT Medical took steps to improve safety culture following the employee survey in 2022. This included augmenting the means and frequency of communication throughout the company, recognition for raising safety concerns and increasing manager field presence.

3.3.3. Reportable Events

There were ten (10) reportable events in 2023:

- Four (4) incidents of Type A packages or empty Type B packages damaged in transit (Feb, Mar, Apr, May). In all cases, there was no impact to radioactive material and no risk to the safety of people or the environment;
- Three (3) false fire alarms resulting in building evacuation (Sept, Oct, Nov);
- One (1) non-work related illness requiring paramedic response on-site (Feb);
- One (1) near miss with potentially serious consequences involving a ruptured compressed air line (May); and
- One (1) incident when there were emergency vehicles on site responding to an off-site event (Oct).

Corrective actions have been identified and implemented as 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). The effectiveness of the program is verified through routine inventory checks.

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.

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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 ensure the protection of workers and the environment. Lastly, personal protective equipment, administrative controls and training 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, there were no changes to the FSAR, SSCs Important to Safety or the overall safety case for the operation of the NMPF.

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, there were minor modifications to physical design related to the Tc-99m generator project. This included the modification of hot cells and supporting equipment for radiochemical processing, radiopharmaceutical production, and waste processing.

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.

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.

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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 Blue Mountain Regulatory Asset Manager (BMRAM) system is used to control maintenance and calibration activities. BMRAM 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 2023, 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 2023, 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 Action Levels and regulatory limits. Action Levels are site specific and are accepted by the CNSC through the facility operating Licence Conditions Handbook. Regulatory limits are specified in the Radiation Protection Regulations.

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There was one exceedance of an internal Administrative Level in 2023. The CNSC was notified at the time of the occurrence (though reporting was not required). A dose of 45.44 mSv was received to the right hand of a Senior Development Technician performing a development activity to support the Y-90 TheraSphere product. The test required the use of liquid Y-90 purchased from an outside supplier. Meetings were held in advance to plan this activity with the Senior Manager, Radiation Safety. It was planned that the work would be performed under Work Permit in an R&D fume hood using over the wall tools. The FSAR for this facility requires a Work Permit if activities exceed the “Minor Work” limit of 1.45 GBq (0.0392 Ci) Y-90. 37 GBq (1 Ci) Y-90 was ordered for this work. On the day the work was executed, the first step required decrimping of the vial by removing the lead pot lid, but the vial was lower than expected, it was flush with the base of the lead pot. To correct this, and feeling pressed for time, the Senior Technician placed the vial in a shorter lead pot using short tweezers, not over the wall tools. These steps resulted in the high hand dose received (dose recorded agreed with dose calculated, received in seconds). During the investigation it was concluded that if a Surveyor had been present during this step the high hand dose would not have occurred. The correction put in place is any work under the R&D FSAR which exceeds Minor Work Limits automatically requires a Work Permit will now henceforth require a Surveyor to be present for all initial handling of activity. The Technician also recorded 0 mSv body dose, 0.20 mSv to the lens of the eye, 0.44 mSv to the skin and 0.61 mSv to the right hand during this work and for the remainder of the year only recorded an additional 0.01 mSv to the skin.

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. Doses are presented since 2019, the first full year of BWXT Medical’s operation following the acquisition of the medical isotope business from Nordion. In 2023, 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 2023.

Where average doses are calculated, doses of zero (0) mSv are included in the calculation unless otherwise noted.

The maximum individual effective dose for the current 5-year dosimetry period (January 1, 2021 to December 31, 2023 inclusive) is 7.48 mSv (to a Shipper).

The top 20 doses to employees shown in Appendix C account for 61% of the total collective dose to all employees in 2023.

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Table 4 - Personnel Dosimetry

Number of Employees															
Dose range (mSv)	Effective					Lens of the Eye					Skin				
	2019	2020	2021	2022	2023	2019	2020	2021	2022	2023	2019	2020	2021	2022	2023
0	38	63	36	65	71	37	57	36	64	64	33	64	39	65	70
0.01-1.00	116	134	219	214	158	116	140	219	215	165	119	133	216	214	159
1.01-5.00	8	7	11	12	12	9	7	11	12	12	10	7	11	12	12
5.01-10.00	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10.01-20.00	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
>20.00	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Number of Employees										
Dose range (mSv)	Extremity (Left Hand)					Extremity (Right Hand)				
	2019	2020	2021	2022	2023	2019	2020	2021	2022	2023
0	42	49	65	60	90	40	50	71	65	92
0.01-1.00	34	45	70	95	52	29	40	60	83	48
1.01-5.00	18	17	21	29	17	25	21	25	39	19
5.01-10.00	1	1	1	4	3	2	1	1	1	3
10.01-20.00	1	1	1	0	1	0	1	1	0	0
>20.00	0	0	0	0	0	0	0	0	0	1

Table 5 - Average, Maximum, Minimum Effective Doses

Dose Range (mSv)	BWXT Medical Employees (mSv)				
	2019	2020	2021	2022	2023
Average	0.20	0.21	0.15	0.17	0.17
Maximum	1.85	2.23	2.41	3.10	2.98
Minimum	0	0	0	0	0
# NEWs	162	204	266	291	241
Dose Range (mSv)	BWXT Medical Contractors (mSv)				
	2019	2020	2021	2022	2023
Average	0.003	0.012	0.03	0.01	0.01
Maximum	0.07	0.29	0.47	0.36	0.04
Minimum	0	0	0	0	0
# Non-NEWs	70	330	249	161	46

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Table 6 - Average, Maximum and Minimum Skin Doses

Dose Range (mSv)	BWXT Medical Employees (mSv)				
	2019	2020	2021	2022	2023
Average	0.21	0.15	0.15	0.17	0.17
Maximum	1.90	2.28	2.44	3.13	3.00
Minimum	0	0	0	0	0
# NEWs	162	204	266	291	241
Dose Range (mSv)	BWXT Medical Contractors (mSv)				
	2019	2020	2021	2022	2023
Average	0.004	0.014	0.04	0.01	0.01
Maximum	0.08	0.31	0.95	0.37	0.04
Minimum	0	0	0	0	0
# Non-NEWs	70	330	249	161	46

Table 7 - Average, Maximum, Minimum Extremity Doses

Dose Range (mSv)	BWXT Medical Employees (mSv) Left Hand				
	2019	2020	2021	2022	2023
Average	0.78	0.68	0.57	0.64	0.55
Maximum	12.92	16.48	12.58	9.87	15.14
Minimum	0	0	0	0	0
# NEWs	96	113	158	188	163
Dose Range (mSv)	BWXT Medical Employees (mSv) Right Hand				
	2019	2020	2021	2022	2023
Average	0.76	0.67	0.55	0.62	0.74
Maximum	9.37	11.91	10.38	5.17	45.44
Minimum	0	0	0	0	0
# NEWs	96	113	158	188	163

Table 8 - Summary of Employee Doses in 2023

Dose Range (mSv)	Effective Dose	Lens of Eye	Skin	Left Hand	Right Hand
0	71	64	70	90	92
0.01-1.00	158	165	159	52	48
1.01-5.00	12	12	12	17	19
5.01 - 10.00	0	0	0	3	3
10.01 - 20.00	0	0	0	1	0
>20.00	0	0	0	0	1

	Effective Dose	Lens of Eye	Skin	Left Hand	Right Hand
Average	0.17	0.18	0.17	0.55	0.74
Avg. Excluding Zeroes	0.24	0.24	0.24	1.22	1.71
Maximum	2.98	3.01	3.00	15.14	45.44
Minimum	0	0	0	0	0
# Monitored	241	241	241	163	163

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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 2023 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 9.5E-4 mSv in 2023. The dose specifically from operations at BWXT Medical and Nordion is 1.5E-04 mSv and 8.0E-04 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
2022	4.7E-04	1.09E-03	1.56E-03
2023	1.5E-04	8.0E-04	9.5E-04

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 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 2023 are shown in Table 10, Table 11 and Figure 5. There was a decrease in the number of contamination incidents compared to last year, 50 in 2023 versus 86 in 2022.

The majority of the incidents in 2023 were due to the Tc-99m generator development project which accounted for 35 of the incidents. The contamination incidents listed in Table 11 under Mo-99 include Tc-99m and associated impurities (Sb-124, Co-60, Zr/Nb-95, etc.).

The other predominant radionuclides, Y-90 and In-111, are associated with the two commercial manufacturing processes at BWXT Medical. Other contamination incidents were associated with the preparation for disposal of legacy liquid waste.

Of the 50 contamination incidents, 10 involved skin contamination of personnel. The vast majority of contamination incidents involved personnel working at containment facilities (typically fume hoods, under cells or at cell doors – areas of known contamination). Many recorded incidents of contamination involve contamination of workers PPE or clothing, but not the skin. Skin doses varied between 3 µSv to 462 µSv, with an average of 118 µSv. If the duration of skin contamination is uncertain conservative values are applied.

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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
2022	0	34	22	21	7	2	86
2023	3	10	19	14	3	1	50

There were two events resulting in the contamination of floors: 2 and 11 Bq/cm^2. The Active Area Contamination limit is 37 Bq/cm^2, so these are technically not a contamination incident as defined by the Radiation Protection Manual, but it is standard practice to record the discovery of unexpected contamination. There was another instance where 2 scientists were contaminated on PPE with Tc-99m and as the room they worked in was not in regular use it was left for three days to decay and then no contamination was found (the floor was suspected to be contaminated).

Table 11 - Contamination Incidents by Radionuclide

Radionuclide	Number of incidents
Sr-85 (Container Decon)	1
Y-90	10
Mo-99	35
In-111	2
R&D other	2
Total	**50**

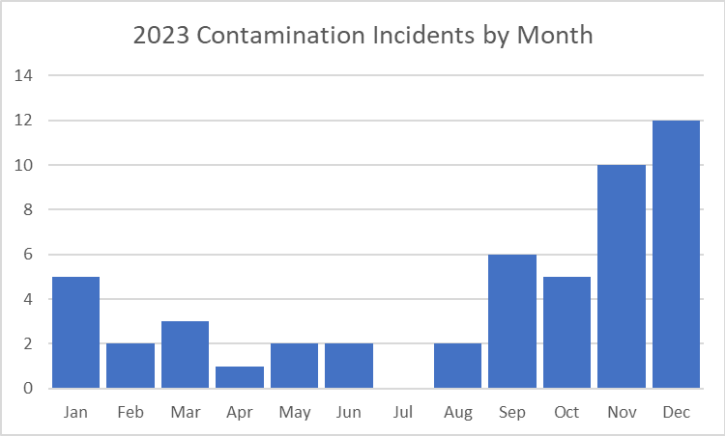

Figure 5: Contamination Incidents by Month

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The frequency of occurrence of contamination events by month closely follows the restart of the Active Mo-99/Tc-99m generator process in the Fall of 2023. If these 35 contamination incidents were removed, the statistics would otherwise be typical of years when just Y-90 and In-111 were being processed. It is worth noting that there has been a large reduction in the number of Mo-99 related contamination incidents in 2023 compared to 2022. This is believed to be in large part due to the equipment and process improvements that were undertaken in late 2022 and the first three quarters of 2023.

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 2023.

Breathing air was monitored using Continuous Air Monitor (CAM) and 24-hour air samplers. 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 2023, some 24-hour air filters were not changed out routinely due to construction activities or the rooms were not in use, but this was a smaller number than in 2022 as construction activities wound up for the Tc-99m generator project. 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. There were multiple instances of airborne in 2023 associated with development runs of Mo-99, however signage was in place prior to the events and personnel were wearing respirators (no measurable inhalation occurred). The airborne concentrations were below investigation levels (<5% DAC). The process was redesigned and it was hoped that the airborne would have been eliminated, but that was not the case. Three additional initiatives have been identified and are planned to be implemented in the first half of 2024 to mitigate room airborne releases from Mo-99 runs. Two of the initiatives are around greater leak tightness around hot cell/equipment interfaces and the third is the redirection of airflow from one piece of equipment inside Hot Cell 9 directly into Nuclear Ventilation (instead of being released to hot cell air).

Respirator requirements are removed only once air monitoring measurements are below the required levels. In 2023, all breathing air sampling was performed in accordance with procedures and results indicated that processes were controlled.

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

3.7.6. Exceeding Regulatory Limits or Action Levels

In 2023, there were no exceedances of either regulatory limits or Action Levels.

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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 2023.

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 2023. See section 3.7.1 regarding improvements made as a result of an internal investigation level being exceeded.

3.7.9. Radiation Protection Program Performance

The objectives, goals and targets of the RP Program are shown in Section 3.3.1. The target for maximum NEW dose was met in 2023. 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 2024, the target maximum annual effective dose to an employee will be 4.5 mSv/yr.

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
    - This was constructed in 2022 and went live in January 2023. There were some learnings and opportunities for improvement as a result of this. The optimization of this process included the addition of localized shielding where packages accumulate. Investigation revealed that instruction/reminders were required to not to store TLDs on lab coats adjacent to package storage locations. An awareness program was also undertaken where workers had to record their Electronic Personal Dosimeter doses versus the number of packages processed in order to improve performance and highlight ALARA practices to optimize use of the new packaging line
2. Multiple improvements to Mo-99 process
    - There were many re-designs of in-cell equipment implemented in 2023 in the Radiochemical part of this process. This resulted in a large reduction in the number of contamination events compared to 2022.

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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.

The following have been verified on a routine basis:

- Existing NVS High Efficiency Particulate Air (HEPA) Filter and Charcoal Adsorber (CAD) Testing: all CADs in the NVS required for operations were tested and passed twice in 2023. All HEPA filters were tested and passed once in the first half of the year. In the second half of the year 257 of the 260 of the in service HEPA filters were tested and passed. The three HEPA filters untested in the second half of the year still meet the minimum annual requirement of being tested once. 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 2023. Hand and foot monitors were calibrated twice in 2023 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 2023. 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.

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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 2023.

Overall, the programmatic elements have proven to comprehensively ensure occupational health and safety. However, given the number of incidents in 2023, the effectiveness of implementation must be improved. A list of improvements initiated in 2023 is provided in Section 3.8.3 and further improvements will be considered in 2023 (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.

The Policy Health and Safety Committee is comprised of union and management representatives, and meets quarterly. This committee addresses company-wide policy or program issues related to health and safety.

The 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 10 times in 2023, and accomplished the following:

- Reviewed performance data related to occupational health and safety against objectives and targets (see Section 3.3.1);
- Performed workplace inspections;
- 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 2023, an engineered system was installed to load and unload containers from a waste bunker. This directly addressed a lost time in injury in 2022, and minimized direct operator interaction.

BWXT Medical took steps to improve safety culture following the employee survey in 2022. This included augmenting the means and frequency of communication throughout the company, recognition for raising safety concerns and increasing manager field presence.

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3.8.4. Conventional Health and Safety Occurrences

There were five (5) medical treatment injuries in 2023, which exceeded the target of two (2), and equalled the totals from the preceding two years.

There were two lost time injuries: a head injury while performing an inspection on a ladder (3 days lost), and an elbow injury after slipping on a wet floor (31 days lost). The total lost time for both injuries was 34 days, corresponding to a severity rate of 14.13 and a frequency rate of 0.83.

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.

There are a number of quality assurance and quality control processes to ensure that accuracy of effluent and environmental monitoring data. For air emissions this includes periodic duplicate analysis of stack air samples using independent methods, data entry verification procedures, and stack leak testing. For water effluent, this includes periodic duplicate analysis of samples using independent methods, data entry verification and approval prior to discharge, and trip blanks and replicate samples when samples are sent for independent analysis.

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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 radioactive material to the environment from the BWXT Medical facility in 2023.

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 2023, there was no detectable radioactivity in liquid effluent. 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.

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.

There were no reportable releases of hazardous (non-radiological) substances to the sanitary sewer based on the City of Ottawa Sewer Use By-law.

We have traditionally reported on liquid releases of β<1 MeV, β>1 MeV, I-125, I-131, Mo-99 and Co-60, however we stopped processing radioiodines in 2016 and C-14 and Ni-63 before then. We have since also done substantial renovations to the facility making it near impossible to have a liquid release of β<1MeV, as there isn't the waste inventory either. We do, however continue to process Y-90, In-111 and Mo-99 – also we note that Mo-99 and Y-90 share the long-lived waste impurity of Co-60. In 2023, all liquid effluent measurements were non-detects; the values reported as releases in Table 12 below are detection limits for In-111, Y-90, Mo-99 and Co-60. Note that gamma emitting radionuclides, were they to be quantifiable in our liquid effluent would be detected and reported (e.g., I-125, I-131).

Table 12 - Liquid Releases (GBq)

Liters	Y-90*	In-111	Mo-99	Co-60
359941	0.033	0.004	0.033	0.005
DRL (GBq/yr)	35,000	10,100	10,200	35.4
% DRL	0.0001%	0.00004%	0.0003%	0.0149%
*For Y-90 β>1MeV is measured via Cernenkov counting on a liquid scintillation counter. Gamma emitters are measured on an HPGe MCA.				

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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		2023 (mSv)
16	RE Building	0.08
17	Pole, North Corner	0.154
18	Heating Plant	0.159
19	Hydro Pole, South West	0.022
20	Local Business	0.085
32	Residence	-0.001
33	Residence	-0.038
38	Residence	-0.045
57	Residence	-0.026
58	Local Business	0.098

3.9.2. Exceeding Regulatory Limits or Action Levels

There were no instances of exceeding CNSC environmental regulatory limits or action levels in 2023.

3.9.3. Spills to the Environment

There were no spills to the environment in 2023.

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

Routine environmental inspections were conducted and any concerns were identified and resolved.

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3.9.6. Environmental Protection Program Improvements

There was a detailed investigation into the characterization of hazardous substances in liquid effluent. This investigation highlighted specific cleaning chemicals that contain contaminants of potential concern when compared to the City of Ottawa Sewer Use By-law. Efforts are underway to determine suitable substitutes.

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.

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 2023. 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 2023, 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.

Three false fire alarms between September and November 2023 provided the opportunity to test the activation of the Incident Command Post, initial response actions by on-site responders and coordination with the local fire department. Overall, these events confirmed preparedness and highlighted areas for continuous improvement.

3.10.3. Emergency Preparedness Program Improvements

There have been no recent changes to the Emergency Preparedness Program. Improvements to the program include improving the timeliness of accounting for personnel during an evacuation.

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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 2023.

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.

Fire inspections for all areas of the leased BWXT Medical spaces are performed at least twice a year.

Additionally, the Annual Facility Condition Inspection performed by an independent third party concluded that there were no unsafe work practices or risk significant fire precursors identified during a facility walkdown. The findings and observations are not considered to present an unreasonable risk to personnel and the environment.

3.10.6. Fire Protection Program Improvements

There were no changes to the overall Fire Protection Program in 2023. To address the false fire alarms: maintenance and communication procedures were updated, and additional training was provided to employees.

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.

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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 2023 was 62.0%.

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 2023.

3.11.3. Waste Management Program Performance

Overall waste is well managed by diverting the majority of waste from landfills, and by characterizing and segregating hazardous and radioactive waste to support optimal disposal methods. Legacy solid wastes have been transferred to a licensed waste management facility in 2023, supporting initiatives to minimize waste stored in the facility.

3.11.4. Waste Management Program Improvements

Additional solid radioactive waste compacting began in 2023, successfully supporting overall radioactive waste volume reduction.

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.

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 2023, BWXT Medical did not have non-conformances related to safeguarded material after conducting a physical inventory.

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3.13.2. Safeguards Program Changes

There were no significant changes to the safeguards program in 2023.

3.13.3. Safeguards Inspections

BWXT Medical was selected for the IAEA Physical Inventory Verification in October 2023. The final statement of conclusions from the inspection is pending.

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.

There were four (4) incidents of Type A or empty Type B packages damaged in transit (Feb, March, April and May 2023). In all cases, there was no impact to radioactive material and no risk to safety or the environment. All incidents were reported to the CNSC as required.

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4. Other Matters of Regulatory Interest

4.1. Public Information Program

Throughout 2023, BWXT Medical carried out the activities listed in the Public Information and Disclosure Program and Indigenous Engagement (PIDPIE) to meet the engagement needs of the community.

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 2023:

- 2022 Annual Compliance Report;
- Disclosure of packaging incidents and building evacuations due to false alarms;
- December 2023 community newsletter; and
- Community survey report.

4.1.2. Engagement

Keeping Indigenous communities, elected officials, community members and stakeholders informed is a priority at BWXT Medical. Throughout 2023, efforts were made to ensure that information was made available to interested parties and that there were opportunities for two-way dialogue.

BWXT Medical maintains its contact list, which is used to share regular email updates. Community members and other interested groups can sign up to join these email updates anytime by contacting the company at isotopequestions@bwxt.com.

4.1.2.1. Indigenous Engagement

Given the operations in the Kanata facility are conducted on the traditional unceded territory of the Anishinaabe Algonquin People, BWXT Medical is committed to communicating and engaging with local, interested Indigenous communities in a timely, transparent and meaningful way.

In June 2023, BWXT Medical hosted a facility tour and meeting with members of the Algonquins of Pikwakanagan First Nation (AOPFN). The first of its kind for BWXT Medical, the opportunity resulted in meaningful discourse and good direction on the path forward for a long-term relationship. Later in the year, the framework for a Long Term Relationship Agreement (LTRA) was initiated, with a goal of establishing the LTRA in 2024. BWXT Medical also met with AOPFN representatives to discuss updates to the facility and its operations, and supported the annual Pow Wow and other cultural programs.

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 2023, BWXT Medical met with elected officials to more comprehensively introduce the company and extend an invitation for a facility visit.

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4.1.2.3. Community Engagement

Throughout 2023, 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 newsletter, social media, and Facebook targeted advertising. Links, invitations and attachments were included in these updates to make sure information was readily available.

BWXT Medical engaged a third party organization to survey the local community within 2 km of the facility between October to November 2023. A total of 165 local residents participated in the survey. The following is a summary:

1. Local residents would like more information on what work BWXT Medical does.
2. Of those who are familiar with BWXT Medical:
    a. Almost half have a positive opinion with the remainder stating that they do not know enough to have an opinion; none have a negative overall impression.
    b. The majority agree that BWXT Medical contributes to the local economy but are less likely to know about processes, preparedness and management.
3. Seven in ten say that they have a more positive view of the facility, after being told that operations are strictly regulated. Just over six in ten say manufacturing and development of nuclear medicine products, funding to local community organizations and local job creation mean they have a more positive view of the facility.
4. Over two thirds of local residents were aware that BWXT Medical has a website for information about the company.

Recommended actions include increasing awareness through the website and through a newsletter or flyer. These actions will be the focus for improvement in 2024.

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. The invitation for the community survey was distributed by mail.

Social media is another tool used by BWXT Medical. In 2023, multiple posts were shared on BWX Technologies platforms: information about the company and its operations, updates on the Tc-99m generator project, recent announcements, news releases and more.

4.1.4. Community Volunteerism & Investment

In June 2023, a group of BWXT Medical employees volunteered their time to support Kanata Race Day, with proceeds going towards a local recreation complex.

Additionally, BWXT Medical provides funding to local organizations in the community. In 2023, bursary awards were issued at Algonquin College and at the University of Ottawa to support students in 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 all communications.

BWXT Medical did not receive any inquires from the public in 2023.

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 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 2024, with modest growth.

The primary EHS area for improvement is conventional health and safety. Key actions include implementing a Human Performance Program and ensuring comprehensive safety oversight through hazard analyses and field observations.

In 2024, BWXT Medical plans to complete validation of the process to manufacture Tc-99m generators and intends on beginning commercial production in 2025. 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 action 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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