



**Written submission from
Nordion (Canada) Inc.**

**Mémoire de
Nordion (Canada) Inc.**

In the Matter of the

À l'égard de

Nordion (Canada) Inc.

Nordion (Canada) Inc.

Application to renew its Class IB nuclear
substance processing facility licence for a
period of 25 years

Demande visant à renouveler son permis
d'exploitation d'une installation de traitement
de substances nucléaires de catégorie IB pour
une période de 25 ans

Commission Public Hearing

Audience publique de la Commission

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Nordion[®]

A Sotera Health company

Nordion Class 1B Facility

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Nordion Written Submission in
Support of License Renewal

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EXECUTIVE SUMMARY

On May 15, 2024, Nordion submitted an application to renew its current Class 1B Nuclear Substance Processing Facility Operating License, NSPFOL-11A.01/2025.

Nordion manufactures Cobalt-60 sealed sources at its facility at 447 March Road, Ottawa. Cobalt-60 is a critical component of the healthcare supply chain. It is used to sterilize more than 30% of all single-use medical devices globally, and more than 40% in the U.S. This equates to roughly 16 billion medical devices and products annually in the U.S. alone. In fact, some products can only be sterilized with Cobalt-60 due to their design or materials. In addition, Cobalt-60 sealed sources are used in stereotactic radiosurgery for the treatment of brain and breast cancer.

Nordion is the leading manufacturer and supplier of Cobalt-60 sealed sources in the world.

Nordion has been manufacturing Cobalt-60 sealed sources at its facility in Ottawa for over 50 years. The global demand for Cobalt-60 is expected to continue to grow due to factors such as aging demographics, advances in medical technologies, and improved healthcare in emerging markets. Nordion is positioned to meet that growth.

Over its 50+ years of operation, Nordion has developed mature programs that protect employees, the community, and the environment. Nordion has implemented a Management System for Safety and supporting programs to ensure that licensed activities are conducted in accordance with the Nuclear Safety and Control Act ^[1] and corresponding regulations.

Nordion has in place an extensive radiation safety and environmental control and monitoring program. Routine monitoring of personnel and the facility is performed. As a result of these programs, doses to employees and the public remain well below regulatory limits.

Nordion has assessed various possible scenarios and implemented a depth of defense program to minimize adverse effects. An emergency response framework is in place and frequently tested to ensure Nordion personnel are able to respond to any adverse event.

Nordion is committed to continuous improvement of its programs, processes, and equipment.

This written submission, along with the licence application, demonstrate that Nordion is fully qualified to continue to conduct its licensed activities at its Ottawa facility and has made the proper provisions that ensure the protection of people and the environment.

1. INTRODUCTION

This written submission was prepared in support of Nordion's application, submitted on May 15, 2024 with amendments submitted February 21, 2025.

1.1. Background

Nordion's facility is located at 447 March Road, Ottawa, Ontario and is comprised of two buildings: 1) the Kanata Operations Building (KOB) and 2) the Roy Errington (RE) building.

The RE building is a low-rise office structure. No Class 1B activities are undertaken in the RE building.

The KOB was initially built in the early 1970's as the Cobalt Operations Facility (COF). In later years, the Nuclear Medicine Production Facility (NMPF), and the Kanata Radiopharmaceutical Manufacturing Facility (KRMF) were added to create the current KOB.

Although Nordion owns the entire facility, the KRMF and NMPF are leased to BWXT Medical, along with some office space within the KOB. In 2018, Nordion divested the Medical Isotopes business to BWXT Medical. BWXT Medical operates the NMPF and KRMF under their own Class 1B licence.

Nordion operates within the COF portion of the facility under the Nordion operating licence, NSPFOL-11A.01/2025. The COF is dedicated to the manufacturing of high activity radioactive sealed sources.

There are approximately 170 Nordion personnel working at the site. The COF has been in operation for over 50 years.

Nordion's primary business in the COF is the manufacture and shipment of Cobalt-60 (Co-60) sealed sources. Co-60 sealed sources are used in cancer therapy and irradiation technologies. Nordion is the largest, global supplier of such Co-60 sealed sources. Nordion's Co-60 sources for irradiators are used to sterilize medical devices, instruments and supplies for the prevention of disease. Approximately 30-40% of the world's single-use medical supplies and devices are sterilized with this technology. This technology is also used to sterilize a vast array of consumer products, including food, contact-lens solution and cosmetics.

Nordion's Co-60 sealed sources for cancer therapy are used in stereotactic radiosurgery devices for the treatment of inoperable brain cancer and breast cancer.

2. FUTURE PLANS

Nordion's primary business is the manufacture of Co-60 sealed sources for use in industrial irradiation and cancer therapy. Nordion is not expecting changes to its current licensed activities at this time.

The Co-60 industrial sterilization market is expected to grow by approximately 3-5% per year. This would require sealed source production growth to match. Nordion's current facility is well positioned to absorb this growth within the current infrastructure and licencing basis.

The site and production facilities are routinely assessed for improvements and replacement of legacy structures and equipment under Nordion's current licensing basis. This program of facility and equipment improvement and replacement will continue under the renewed licence.

Through continued preventative maintenance and planned replacement of capital assets, the facility and processing equipment are expected to have an operational life extending beyond the requested licensing period of 25-years.

At the end of the proposed 25-year licence period, Nordion anticipates it will seek a licence renewal to continue to operate Co-60 source manufacturing operations. There is no foreseeable shutdown or decommissioning of the facility.

3. JUSTIFICATION FOR RENEWAL PERIOD

Nordion is requesting a 25-year licence and believes that such a licence period is justified.

Nordion has been safely operating the facility at 447 March Road for over 50 years, producing Co-60 sealed sources since the 1970's. Over that time, Nordion has implemented and continuously improved the facility, equipment, and programs in place to protect the health and safety of people and the environment.

Highlights of these programs are described as follows:

1. Nordion has implemented a strong and mature management system for safety program that drives the oversight and continuous improvement of licensed activities. This program meets the requirements of CSA N286:12, "*Management system requirements for nuclear facilities*" [2].
2. The hazards associated with the licensed activity, operation of a nuclear substance processing facility, are well characterized in the Safety Analysis Reports and Fire Hazard Analysis for the facility and their impacts are well predicted. These licensed activities have not substantially changed regarding the production of Co-60 sealed sources, and the risk assessment remains complete and valid and is not expected to change substantially over the 25-year licence period requested.
3. Nordion has implemented a strong radiation protection program that has ensured the protection of its employees and the public. Since the 2015 licence renewal, the highest annual dose to an employee has been 5.49 mSv, which is substantially lower than the regulatory limit of 50 mSv/year, 100 mSv over 5 years. The dose to the public has been less than 0.01 mSv/year from Nordion related activities. This is not expected to substantially change over the requested 25-year licence period.
4. The environmental risk assessment (ERA) shows that Nordion's operations do not negatively impact the surrounding community or environment. Nordion's production facilities have been designed and operated in a manner to prevent radioactive waste being released to municipal solid waste or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the Canadian Nuclear Safety Commission (CNSC). Air and liquid release data since the last licence renewal in 2015 have been annually provided in Nordion's Annual Compliance Report (ACR). From these ACRs, Nordion's air and liquid effluent releases have been shown to be 0.1% or less of the Derived Release Limit (DRL) approved by the CNSC in Nordion License Conditions Handbook. All radioactive waste generated through production operations is collected and sent to licensed radioactive waste management facilities. This is not expected to substantially change over the requested 25-year licence period.
5. Nordion has shown a consistent and excellent history of operating experience and compliance in carrying out the licensed activity. From 2015 to 2024, the CNSC has conducted 27 inspections of Nordion's operations and programs. None of the findings identified by CNSC staff were considered safety significant and Nordion has implemented actions to address each finding in a timely manner.
6. Nordion is continually investing in the facility and making improvements to ensure safety systems are maintained and improved. This is not expected to change over the requested 25-year licence period.
7. Nordion's current programs have proven highly effective in ensuring the protection of people and the environment over the decades that the facility has been in operation. These effective programs will continue under the renewed licence. The issuance of a 25-year licence is justified based on Nordion's decades-long history of protecting people and the environment.

The impact of a 25-year license is summarized in the Table 1 below. A 25-year license period will:

- have no impact on the safe operation of the facility or cost-recovery fees

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- incorporate continued CNSC review
- ensure the same level of scrutiny and oversight as currently provided

Table 1: IMPACT of a 25-YEAR LICENSE	
Issue	Impact
Cost-Recovery Fees Regulations	There would be no impact on Nordion’s compliance to the Cost-Recovery Fees Regulations as Nordion currently pays licensing fees on an annual basis and that would continue for a longer-term license.
Performance Reviews	Currently, Nordion submits an annual compliance report that outlines Nordion’s annual performance. There would be no change to annual reporting under a 25-year licence.
CNSC program evaluations	Currently, CNSC program evaluations are conducted throughout any licence period in the areas deemed priorities by the CNSC. Under a 25-year license period, these program evaluations would continue at a frequency determined by the CNSC.
Preliminary Decommissioning Plan	There would be no impact on the Preliminary Decommissioning Plan. Nordion would continue to update the Preliminary Decommissioning Plan at least every 5 years or when significant changes occur.
Public & Indigenous Engagement	Nordion would continue with its current Public Information Program and Indigenous Engagement which has provisions to address public concerns. Nordion will also continue to increase its efforts to foster a positive relationship with the community and Indigenous Nations and raise awareness of Nordion’s business activities.
Compliance with any changes in existing Regulations or new Regulations	Nordion has a process in place for evaluating compliance with new or changing regulations or other requirements. Under its current 10-year licence, Nordion has already updated various programs and documents to reflect changes to the regulations. This would continue and Nordion would revise its programs and procedures to reflect changes to regulations under a 25-year licence.

The effectiveness of Nordion’s programs in protecting people and the environment provides assurances that a 25-year licence would not negatively impact people or the environment. This is important as a 25-year licence would be beneficial to Nordion and the healthcare sector.

Given the importance of Co-60 to healthcare, and other sectors, a 25-year licence would provide long-term assurance of the stability of supply to the healthcare industry, including the return of disused sources from customers for proper end-of-life management. A 25-year licence would also provide increased confidence for Nordion in planning for long term investments in the facility. Recently, Nordion has made significant investment in facility infrastructure, such as a new hot cell to support recycling efforts. Also, Nordion is investing heavily in new supplies of Co-60 from partners such as Darlington Nuclear Generating Station. Nordion has been producing Co-60 sources for over 50 years and expects that to continue in the decades to come. A 25-year licence would support the long-term commitment Nordion has to healthcare critical Co-60 supply.

In addition, Nordion has implemented a robust Co-60 recycling program. Since 2018, more than 99% of returned Co-60 has been recycled back into new sources. Recycling is a key pillar of Nordion's end-of-life management program for sources. A 25-year licence would ensure that that program remains as a viable option for end-users.

Nordion has safely operated the facility at 447 March Road for decades and expects to continue to operate the facility safely for decades more. The strong programs implemented to date have proven to be effective at protecting people and the environment. A 25-year licence would not negatively impact this program or CNSC's oversight of Nordion's activities. A 25-year licence would provide increased stability to a critical healthcare industry and ensure that recycling and end-of-life options for Co-60 remain viable.

4. SAFETY AND CONTROL AREAS (SCAs)

4.1 Management System

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

4.1.1 General Considerations

Nordion has implemented a Management System for Safety (MSS) that complies with CSA N286:12, "*Management system requirements for nuclear facilities*" [2]. The management system controls work carried out to perform, or in support of, licensed activities from the planning stages to completion. The management system covers the control of activities both at the working level and at the corporate level. The latter ensures the oversight needed to provide corporate direction and maintain overall accountability and ensures that communication between individuals and organizations is effective and in the interest of safety.

Nordion has implemented an Environmental, Health and Safety (EHS) Policy which describes the company's commitment to operate in a safe and responsible manner that respects the environment and the health of employees, customers, and the communities where Nordion operates. The EHS Policy is the foundation of Nordion's environmental, health and safety systems.

Nordion's Environmental Management System (EMS) is certified to ISO 14001, "*Environmental Management Systems – Requirements with guidance for use*" [3], the internationally recognized standard for Environmental Management Systems. Nordion voluntarily maintains this certification to assure customers, regulators, and the community of Nordion's commitment to environmental leadership and continual improvement. In addition to the performance reviews and annual management reviews, each year Nordion's EMS is reviewed by a third party to ensure continual compliance with the requirements of ISO 14001 [3].

The Nordion facility operates under the direction of the Nordion EHS Committee, which is chaired by the Director, Regulatory & EHS or designate. The EHS Committee reviews the operations and approved changes to the facility. The EHS Committee oversees all CNSC related activities, as per Nordion's license conditions, and ensures review of design and safety of operations. Sub-committees are appointed as necessary, to conduct detailed technical reviews and report back to the EHS Committee. The EHS Committee regularly reviews occupational health and safety, radiation safety, and environmental management performance metrics.

Nordion is certified to the ISO 9001, "*Quality Management System*" [4] and ISO 14001 [3] standards.

4.1.2 Organization

Nordion's President is the applicant authority ultimately responsible for Nordion's licence commitments. The various functional groups (Operations, Commercial, EHS, etc.) report directly or indirectly to the President.

The Director, Regulatory & EHS is a member of the senior leadership team and is responsible for implementation and oversight of the MSS. The Director, Regulatory & EHS has been delegated by the President to act on behalf of Nordion with the CNSC.

With respect to the licensed activities, the Nordion facility operates under the direction of the Nordion EHS Committee, which is chaired by the Director, Regulatory & EHS or designate. The EHS Committee reviews the operations and approves changes to the facility.

In addition to the EHS Committee, Nordion has established a Joint EHS Committee with BWXT Medical. Although the EHS Committees for each organization have the responsibility for activities under their respective licences, the Joint EHS Committee provides an opportunity to review and discuss site wide licensing and safety matters, including but not limited to, changes to Final Safety Analysis Reports (FSARs), infrastructure work, and changes to the licensing basis.

4.1.3 Performance Assessment, Improvement and Management Review

Performance reviews of the MSS and the EMS are conducted on a routine basis by the EHS Committee through a review of:

- status of EHS corrective actions and preventive actions;
- results of EHS incidents or investigations;
- operating experience;
- EHS objectives and targets; and
- Internal and external audit and inspection findings.

In addition, the EHS Committee conducts an annual management review of the MSS and the EMS to ensure these programs remain suitable and effective. Results from the annual EHS Performance Report are reviewed. In addition, the management review involves the evaluation of:

- Actions from the previous meeting;
- The EHS Policy;
- Adequacy of resources;
- EHS objectives and targets;
- Changing circumstances; and
- Recommendations for improvement.

Actions and decisions resulting from the EHS Committee review of the MSS and EMS performance are documented in the EHS Committee meeting minutes.

EHS non-conformances and deficiencies are investigated to determine root causes. Nordion has implemented a Corrective and Preventative Actions (CAPA) program to address root causes.

4.1.4 Change Management

Nordion has an established a change control process. All changes to the facility, equipment, processes, documents, and procedures must follow the change control process that includes:

- Justification of change;

- Impacts to existing systems and equipment; and
- Review by technical experts.

The EHS Committee approves all significant changes to facilities.

4.1.5 Safety Culture

Nordion is committed to a strong safety culture. Safety is at the forefront of all the work that is undertaken at Nordion. Nordion employees have performance objectives to work safety at all times, report occurrences of workplace injuries, unsafe conditions, near-misses, and to correct or coach co-workers if working unsafely. Safety culture is embedded in Nordion's programs, standards and procedures and a near-miss reporting program is established.

4.1.6 Business Continuity

Nordion has implemented an Emergency Response Center (ERC) framework to address business continuity from disruptions. In the ERC, an ERC Director is appointed. The ERC director will fill and structure the ERC with appropriate personnel to address the specific disruption and address business continuity.

4.2 Human Performance Management

4.2.1 General Considerations

Nordion has implemented a performance management program that ensures there are sufficient workers with the required knowledge and skills. This starts by defining competency criteria for key positions within the organization.

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

Site security is provided for 24/7. A radiation surveyor is present on-site whenever active area work is occurring.

In the event of an emergency, there is an incident manager available at all times that can be called to site by security. The incident manager can initiate a call-in of all emergency response personnel.

Nordion routinely assesses the availability of qualified staff as part of the Emergency Response Program and through drills and exercises. Nordion tests its emergency call list annually and the results have demonstrated year over year that within one hour of the onset of an emergency, adequate emergency response personnel and at least one representative from each of the key emergency response groups would be available on-site.

As part of continuous improvement and to address any deficiencies in the training program, Nordion conducts a training needs analysis for any high or medium risk EHS incident where training was identified as the root cause.

4.2.2 Human Performance Program

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

Initial selection of qualified personnel is performed through the Human Resources hiring process. Personnel who are assigned responsibilities are competent on the basis of applicable education, training, skills, and experience. Established training programs ensure personnel have the required training to perform their job functions. The employee training programs support the Nordion MSS and ensure that the MSS is understood, implemented and maintained.

4.2.3 Personnel Training

Nordion has implemented a systematic approach to training (SAT) program to meet the requirements of REGDOC-2.2.2, Version 2, "*Personnel Training*"^[5]. Under the SAT program, training is systematically reviewed, designed, developed, documented, and managed to ensure it meets the organization requirements.

Employees who are not classified as Nuclear Energy Workers (NEWs) receive a basic course on EHS, which provides information on the facilities, emergency response procedures and alarms, and basic procedures to follow for safety in the workplace.

NEWs receive additional training on radiation safety and radiation instrumentation usage, depending on their role. To be authorized to enter the Active Area unescorted, the employee must complete and pass a written test, as evidence of understanding the principles of radiation protection and Nordion safe work practices.

Supplementary EHS training programs are provided to all personnel depending on the nature of the job and the requirements specified by their manager. These programs include such topics as:

- Emergency Response Awareness;
- Care and Use of Respirators;
- Material Handling Training; and
- Working Safely with Fume-hoods.

4.3 Operating Performance

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

4.3.1 General Considerations

All work at Nordion is undertaken in a planned and controlled manner through the use of procedures or work permits.

The Building Management System (BMS) monitors the operating conditions of the facility to ensure activities remain within specifications and are carried out safely.

Structures, systems and components (SSCs) are regularly maintained and inspected.

The EHS Committee reviews key facility metrics, such as environmental release data, to ensure operational performance.

When EHS-related non-conformances (i.e. deficiencies in equipment, systems or management processes which were used to carry out, or in support of, licensed activities) are found, they are identified, recorded, reported and corrected as required.

Incidents and non-conformances are identified through the non-conformance procedures, investigations, and internal audits as outlined in the MSS.

Nordion annually conducts internal audits to verify compliance with applicable procedures and requirements. These audits ensure that Nordion's programs and systems are compliant to applicable standards and regulatory requirements, conform to internal policies and procedures, and are properly implemented and maintained.

A process is in place for reviewing and analyzing EHS related non-conformances and CAPAs. Annually, an EHS Performance Report is prepared to document the analysis of data from the previous year. The data is analyzed to determine the presence of any undesirable trends, assess the effectiveness of corrective actions taken and whether additional corrective action is needed. The EHS Performance Report is reviewed by the EHS Committee in the annual Performance Review of the MSS and the EMS.

Corrective actions are issued as required to address incidents and non-conformances. Nordion has a formal process to investigate and identify the root cause of environmental and safety issues and to implement and track corrective actions needed to prevent recurrence. The process is also used to initiate preventive actions to deal with potential problems.

Nordion maintains an inventory of non-production radioactive sources and material.

4.3.2 Conduct of Licensed Activities

Work undertaken at Nordion is planned and controlled. Work activities are identified, sequenced, and defined in approved plans, procedures, instructions, and drawings. Work activities include design control, procurement, operations, shipping, receiving, handling and maintenance. The department and, where appropriate, the position of the person performing the work is also specified. Supervisor acceptance was scheduled as required.

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

The safety analysis report for sealed source manufacturing describes the following:

- Operations within the KOB;
- The potential radiation safety and occupational safety hazards that exist;
- The worst-case accident scenarios; and
- The measures in place to mitigate the consequences of the hazards.

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

4.3.3 Procedures

Nordion ensures that documents are controlled consistent with their intended use to meet the requirements of CSA N286:12 [2]. Documents contain unique identification and are developed by workers with the required knowledge. Documents are reviewed and approved within an electronic document management system and reviewed on a routine basis to ensure they remain current.

4.3.4 Operating Limits and Conditions

Nordion has defined safe operating limits and conditions through the FSARs. These limits are posted at hot cells and pool storage locations. Any exceedance of the operating limits and conditions are investigated to determine root cause and appropriate corrective actions implemented.

4.4 Safety Analysis

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

4.4.1 General Considerations

Safety analysis is performed in accordance with REGDOC-2.4.4, "*Safety Analysis for Class 1B Nuclear Facilities*" [6]. Safety assessments are performed for new Active Area facilities or processes or when changes are to be made to a facility, ventilation system, safety system, equipment, operation or process which could significantly affect the worst-case scenario as outlined in an existing safety analysis. The assessment includes a description of the safety-related systems, features, and administrative controls (i.e. operating procedures, training, etc.) in place to detect, prevent and control hazards to protect the environment and assure adequate safety of employees and the public. Safety analysis of facilities and processes are documented in FSARs. FSARs are prepared by project leaders and approved by the EHS Committee. The FSAR provides the evidence that safety requirements have been met and that the facility, equipment, or operation is safe.

The EHS Committee is responsible for reviewing and approving significant changes to facilities which could alter any conclusions reached regarding the safety of the facility as established in the approved safety analysis. FSARs must be approved by the EHS Committee prior to a new process going into full production or prior to unrestricted production start-up following modifications.

There are two primary FSARs that describe the general operations within the Cobalt Operations Facility and activities related to the storage pools. These FSARs describe the potential radiation safety and occupational safety hazards that exist, the worst-case accident scenarios and the measures in place to mitigate the consequences of the hazards. Secondary FSARs are also prepared to provide analysis of the safety hazards unique to specific areas. Nordion has two secondary FSARs related to waste management. These secondary FSARs are reviewed and approved internally as per an established review schedule. When modifications are made to secondary FSARs, an assessment is performed and details are captured in the primary FSARs, as required. The overall safety case for the facility is reviewed and approved by the EHS Committee.

Nordion's FSARs were revised in 2024 and submitted to the CNSC for review.

4.4.2 Fire Hazard Analysis

Nordion has implemented a Fire Hazard Analysis to assess the potential risks from a fire to personnel safety, property and operations, and the environment. The fire hazard analysis determined that these risks were managed in a manner that minimizes potential impacts. Any changes to the facility that potentially impact fire protection systems are reviewed by a qualified third party to ensure that these changes do not pose a risk to life, safety or the environment. These reviews are submitted to the CNSC.

Nordion reviewed and updated the Fire Hazard Analysis in 2021 and confirmed that it remains valid during this renewal. The Fire Hazard Analysis is undertaken every 5 years and is conducted by a qualified third party.

4.5 Physical Design

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

4.5.1 General Considerations

Nordion has designed its facility, equipment and processes to ensure the safety of the public and the environment in both normal and accident conditions. Through the FSAR process, Nordion identifies SSC's important to safety and ensures such SSCs are maintained and inspected.

4.5.2 Design Governance

Design control is applicable to all process equipment and facilities' buildings, systems and equipment in support of licensed activities. Nordion's design control program ensures that design meets established codes and standards and all applicable requirements. Design requirements are identified, documented and controlled.

Changes to design of existing processing facilities and buildings, systems and equipment are controlled through a formal change control process. The Design Authority ensures that these changes do not impinge on the established safety margin for the protection of health, safety and the environment. The EHS Committee is responsible for approving significant changes to facilities which could alter any conclusions reached regarding the safety of the facility as established in the approved safety analysis. They are responsible for approving any safety systems that are intended to protect the operator, other employees and the public from a radiation hazard. As stated previously, changes to nuclear processing facilities and associated activities are documented in safety analysis reports. EHS Compliance works through the EHS Committee to review and approve the safe design of new and modified facilities.

Nordion has a procedure to ensure that any newly purchased equipment or instruments are identified to the Facilities Department. Procurement and Facilities are responsible for ensuring all outside maintenance or calibration firms being used by Nordion are qualified to carry out the work.

Nordion also has a procedure to define the process for conceptual, ergonomic, and final design reviews, and control of design. Subject matter experts are engaged to ensure a good design based on their knowledge and subject matter expertise that aligns to existing specifications, regulations, and quality requirements.

The EHS Requirements Checklist ensures that changes within Nordion that may have environment, health, and safety impacts are appropriately evaluated by qualified EHS personnel. This applies to acquisitions of capital equipment, new products, materials, or chemicals that are being brought on-site for the first time, and for projects that could have a significant impact on the environment, health and safety (such as the installation of new facilities, the design of new production processes, modifications to existing facilities or processes, and changes to the nuclear ventilation system (NVS)).

4.5.3 Control Facilities

Nordion's infrastructure (i.e. hot cells and storage pools) are designed to provide passive protection of the radioactive material.

Nordion has the ability to remotely monitor the conditions of the facility in the event of an emergency.

Nordion has multiple back-up power supplies to ensure safety critical systems remain operational at all times.

4.6 Fitness for Service

The Fitness for Service SCA covers activities that impact the physical condition of SSCs 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.

4.6.1 General Considerations

Nordion has implemented programs and processes to ensure that the facilities and equipment remain fit for service through our facility maintenance plan and instrument maintenance plan.

Through the FSAR program, Nordion identifies all SSCs important to safety.

Nordion has a system in place for the maintenance and control of equipment that supports the facility. The 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 calibration and maintenance.

Nordion uses a formal system to control Nordion's calibration and maintenance activities referred to as the Advanced Maintenance Management System (AMMS). The AMMS is used to catalogue all equipment requiring calibration or maintenance, record equipment information, schedule maintenance, and issue work orders.

The AMMS provides the necessary oversight to ensure equipment integrity. All equipment inspections and preventative maintenance schedules are managed using the AMMS. Pressure vessels and boilers are authorized under the Technical Standards and Safety Authority (TSSA). Required inspections are performed by Nordion's insurer who provides the inspection reports to the TSSA.

Unscheduled repairs are reviewed on an annual basis by Facilities to assess for trends in equipment failures. Recurring failures are reviewed by EHS Compliance for the determination of any additional corrective actions.

In addition, every year a detailed review is carried out at the senior management level to discuss aging equipment at the Facility. This annual business plan review takes into account criteria such as: safety of facility; regulatory requirements; and site improvements. Projects are prioritized into categories and funds are allocated as required to approved projects.

Maintenance and inspection frequency is identified through the change control process and is administered through the Nordion AMMS.

4.7 Radiation Protection

The Radiation Protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations* [7]. This program must ensure that contamination and radiation doses received are monitored and controlled and maintained as low as reasonably achievable (ALARA).

4.7.1 ALARA Principle

Nordion has measures and systems in place to ensure that radiation exposure to employees and the public are kept as low as reasonably achievable (ALARA). This reflects the commitment to provide employees with a safe and healthy work environment and to protect the public and the natural environment. Nordion's ALARA program includes measures such as:

- management control over work practices;
- personnel qualification and training;
- control of occupational and public exposure to radiation;
- planning for unusual situations; and
- review of radiation doses and trends by the EHS Committee.

4.7.2 Radiation Monitoring

Nordion has established a personnel monitoring program to control radiation exposure. To ensure that the external exposure of NEWs to ionizing radiation from all routine work is kept to a minimum and within safe limits, an intensive program of routine radiation surveys is carried out in all Active Areas.

All employees who regularly work in the Active Area are classified as NEWs and are assigned monthly dosimeters from a dosimetry service company licensed by the CNSC. Nordion refers to these personnel dosimeters as Thermo-luminescent Dosimeters (TLDs) regardless of the technology used.

Employees who normally work outside the Active Area and visit the Active Area on an irregular basis are also classified as NEWs but are assigned quarterly TLDs.

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

Radiation doses to employees are reviewed and assessed in accordance with the ALARA principle by the Radiation Safety Officer and Health Physicist.

Nordion has established CNSC approved Action Levels for radiation exposure. An Action Level is defined as the level which may indicate a loss of control in the radiation protection program. Nordion formally investigates and documents action level exceedances and any corresponding corrective actions. Exceedance of an action level is a reportable event and Nordion notifies the CNSC of all such exceedances.

Nordion has set internal control levels (Administrative levels) for radiation doses below those of our action levels. The administrative levels provide an indication of conditions that may in the future lead to increased doses and allows Nordion to take review and take corrective measures to ensure doses remain low.

Annual maximum whole-body doses to workers and contractors since 2015 are provided in Table 2 below.

Table 2: Whole-body Annual Doses		
Year	Maximum NEW Dose (mSv)	Maximum Contractor Dose (mSv)
2015	5.24	0.13
2016	4.9	0.36
2017	5.49	0.20
2018	4.23	0.25
2019	4.79	0.26
2020	4.92	0.29
2021	4.3	0.3
2022	4.29	0.29
2023	4.58	0.26

4.7.3 Public Doses

The dose to members of the public from Nordion’s potential releases is calculated annually based on the DRL. The DRL was determined for each of the major radioisotopes processed in the facility and then approved by the CNSC. The DRL considers the critical pathway analyses and the most probable location of highest radiation exposure. The DRL uses the 1.0 mSv annual public dose limit as the limiting factor.

Annual dose to the public from Nordion activities are provided in Table 3 below.

Table 3: Annual Doses to the Public	
Year	Annual Dose to Public (mSv)
2015	0.0095
2016	0.0021
2017	0.000052
2018	0.000067
2019	0.00087
2020	0.00122
2021	0.00185
2022	0.00156
2023	0.00095

Annual dose to the public from Nordion activities is well below the 1 mSv CNSC limit.

4.7.4 Contamination Control

Nordion has developed a robust program around contamination control. The primary means of control is the NVS. This system controls the air flow based on various zones defined by potential contamination levels. The system ensures that there are sufficient pressure differentials to control the flow in the direction of less contaminated zones (i.e. non-active areas and office spaces) to zones of higher potential contamination (i.e. hot cells). Air flow is then through High Efficiency Particulate Air (HEPA) filters to capture any Co-60 particulate.

In addition to the ventilation system, Nordion controls contamination through the following means:

- 1) Routine monitoring of areas that have the potential for contamination;
- 2) Use of fume hoods, gloveboxes, and hot cells when performing work that may result in contamination;
- 3) Air sampling at various locations within the active area; and,
- 4) Personnel monitoring at all exits of the active area.

Contamination incidents are investigated and documented as contamination incident reports.

4.8 Conventional Health and Safety

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

4.8.1 General Considerations

Nordion has established an Occupational Health and Safety Program to prevent, manage and respond to potential or actual hazards or emergencies in the workplace. The Program's elements are typically developed and managed under the following headings:

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

The Director, Regulatory & EHS has overall responsibility for the Occupational Health and Safety Program.

The Workplace Health and Safety Committee provides oversight of conventional safety and conducts regular safety inspections. The EHS Committee and the Senior Leadership Team sets targets each year in the areas of Medical Treatment Incidents, Lost Time Incidents, and annually reviews the overall performance of the Occupational Health and Safety Program. Conventional Health and Safety performance is reviewed monthly by senior management and by the applicable health and safety committees.

The Workplace Health and Safety Committee is represented by union and management and typically meets monthly.

Nordion has a program in place to capture potential accidents through unsafe condition and near-miss reporting. Employees are encouraged to report unsafe conditions and near misses, thus allowing prevention or mitigation of potential incidents. Employees have the right to refuse dangerous work.

4.9 Environmental Protection

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

4.9.1 Environmental Management System

Nordion has implemented an Environmental Protection Program to meet the following:

- CNSC REGDOC-2.9.1, "*Environmental Protection Policies, Programs and Procedures*"^[8]
- CSA N288.4, "*Environmental Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills*"^[9]
- CSA N288.5, "*Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills*"^[10]
- CSA N288.6, "*Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills*"^[11]

In addition, Nordion's Environmental Protection Program meets the requirements of ISO 14001^[3].

Nordion has established an Environmental Protection Program to manage actual and potential environmental aspects resulting from activities, products and services.

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

- Airborne effluent;

- Liquid effluent;
- Environmental dosimetry;
- Environmental contamination;
- Hazardous chemical storage and handling; and
- Waste management and disposal.

The Director, Regulatory & EHS has overall responsibility for the Environmental Protection Program.

Nordion's production facilities have been designed and are operated in a manner to ensure that releases to the environment via air or water emissions are within the limits approved by the CNSC and to prevent radioactive waste or hazardous chemicals from being released to municipal solid waste or sewer systems.

An environmental monitoring program has been established to monitor and measure effluent releases and environmental contamination.

4.9.2 Effluent and Emission Control

4.9.2.1 Airborne Effluent

Production operations are contained within hot cells or fume-hoods. Ventilated air from these containment systems is filtered through roughing and HEPA filters. These systems are designed with redundant fan/motor and filtration units that include pre-filters, and primary and secondary filtration units to filter particulates airborne effluent. The NVS has been designed and is maintained to prevent the unnecessary release of radioisotopes and other hazardous materials to the atmosphere.

The program for monitoring airborne effluent includes qualitative continuous monitoring of process ventilation and stack emissions. This is performed with the use of in-situ detectors and data recording.

Quantitative analysis of effluent is performed by weekly air sampling of stack emissions using stack cartridges filters.

Since 2015, the highest annual air release of Co-60 was 0.002% of the DRL.

4.9.2.2 Liquid Effluent

Wastewater which might potentially contain small amounts of radioactive contamination (from emergency showers, personnel wash sinks, water used for routine floor cleaning, etc.) is collected in holding tanks and then sampled and analyzed against DRLs to ensure that it is in compliance with license conditions prior to being released to the municipal sanitary sewer.

Since 2015, the highest annual liquid release of Co-60 was 0.1% of the DRL.

4.9.3 Assessment and Monitoring

Soil and water samples are taken annually from various locations on Nordion property and analyzed for the presence of radioisotopes.

Since 2015, there have been no detectable quantities of Co-60 in the soil or groundwater sampling.

Nordion has an environmental TLD program. Environmental TLDs are located at various locations around the facility and in the community. These results do not quantify the doses to the public, which is assessed based on actual releases and Nordion's DRLs, but rather provides an additional means of ensuring that Nordion's activities are not impacting the community. Since 2015, the environmental TLDs have measured doses below the 1 mSv/year limit.

4.9.4 Protection of People

Limits for radioactive emissions are determined by the DRL. The DRL was determined for each of the major radioisotopes processed in the facility and then approved by the CNSC. The DRL takes into account the critical pathway analyses and the most probable location of highest radiation exposure. The DRL uses the 1.0 mSv annual public dose limit as the limiting factor. The DRL assessment was undertaken in 2017 by a qualified, independent third-party expert. Nordion has reviewed the assessment in subsequent years and determined that there have been no significant changes to operations or surrounding area that would materially affect the 2017 calculations.

4.9.5 Environment Risk Assessment

Nordion undertook an update to its ERA in 2022. In 2024, Nordion hired a third-party consultant to review the 2022 ERA. The third-party consultant confirmed that the 2022 ERA remains sufficient. Nordion's ERA is posted on our website.

4.10 Emergency Management and Fire Protection

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

4.10.1 General Considerations

Nordion has developed emergency management and fire protection programs that meet the requirements of REGDOC-2.10.1, "*Nuclear Emergency Preparedness and Response*" [12] and CSA N393, "*Fire Protect for Facilities that Process, Handle or Store Nuclear Substances*" [13].

Emergency response planning is required to reduce or mitigate operational impacts and potential EHS impacts that may occur in the event of an emergency. Nordion has an extensive emergency preparedness program to respond to various types of emergency situations, including on-site and off-site emergencies. Nordion has established a number of Emergency Response Plans (ERPs) to address various emergency situations, including:

- General Emergency Response;
- Communicable Disease and Bio-Terrorist response plan;
- Chemical spill response plan;
- Transportation ERP; and
- First Aid Program.

These plans outline response actions to be taken to minimize potential EHS impacts. The ERPs are routinely reviewed, updated, and tested in the form of drills, desk top training exercises and full-scale evacuation exercises. Nordion has established a schedule to test each of these plans with a target of testing each plan within a five-year period.

Nordion maintains an inventory of emergency equipment that is routinely inspected.

Emergency response training is provided to workers with emergency response duties.

An Emergency Response Planning Committee has been established and meets on a regular basis to discuss and assess Nordion's emergency planning needs, to plan emergency response exercises and drills to test existing ERPs and as necessary, to review the ERPs for suitability and effectiveness. In addition, emergency response procedures are regularly reviewed and revised, as necessary, in particular immediately following the occurrence of an incident, accident or emergency situation.

Nordion works in partnership with local Fire and Police Departments to ensure safe and appropriate response to potential emergency situations. Nordion provides regular orientation sessions to the local Fire and Police Departments to familiarize them with the facility and to discuss how to work together in an emergency. Nordion invites local emergency response organizations to participate in emergency response drills at the site to test how these types of emergencies would be managed. Emergency response drills have been attended by the local Fire Department, Hazardous Materials (HAZMAT) and Paramedics who participated as exercise players, allowing them and Nordion to improve interoperability of response.

The ERPs outline steps to be taken to notify the surrounding community and businesses in the event of an emergency which could impact the local community. Checks of emergency response equipment are generally managed through the AMMS and/or by Radiation Surveyors. A schedule of drills and exercises is also maintained to ensure testing and exercises are conducted regularly.

4.10.2 Fire Emergency Preparedness and Response

Nordion has implemented a Fire Safety Plan and a Fire Protection Program to minimize the probability and consequences of a fire at Nordion. The objective of this program is 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 program outlined Nordion's commitments to:

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

4.11 Waste Management

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

4.11.1 General Considerations

To minimize potential impacts to the environment, Nordion has established comprehensive waste management programs for managing radioactive, hazardous and non-hazardous waste.

Nordion has established a radioactive waste management program, which complies with applicable laws, regulations and license conditions. Nordion has also established waste diversion programs designed to divert waste below the unconditional clearance levels prescribed in CNSC regulations through conventional waste disposal methods.

4.11.2 Waste Characterization

Waste from the Active Area is categorized into waste types. Routine waste is waste generated from production processes and is routinely shipped to approved external radioactive waste management facilities. Waste generated within the Active Area that meets the CNSC unconditional clearance levels is diverted from the solid active waste stream being sent to licensed radioactive waste facilities and is disposed of by conventional waste disposal methods, such as landfill.

Waste from other radioisotope licensees is not transferred to Nordion for subsequent disposal, except for spent sealed sources that may be returned to Nordion for recycling or other end-of-life management.

4.11.3 Waste Minimization

Nordion encourages and promotes techniques that reduce waste in all areas of operation. Nordion has implemented an Active Area waste diversion program. The waste diversion programs have successfully diverted waste from disposal at a licensed radioactive waste facility to regular landfill through segregation at the source and the use of sensitive monitoring equipment for verification that the segregated waste is below the unconditional clearance levels prescribed in CNSC regulations.

Nordion has implemented a Co-60 recycling program. Returned Co-60 sealed sources are cut open and the Co-60 material is reused to make new sealed sources.

4.11.4 Waste Management Practises

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

Nordion's production facilities have been designed and are operated in a manner to prevent radioactive waste from being released to municipal solid waste or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the CNSC. All radioactive waste that is generated through production operations is collected and sent to a CNSC approved radioactive waste management facility.

Nordion has designated space and processes to store and segregate radioactive waste that is generated in production operations. One room is dedicated for temporary waste storage. Space is also designated for storage of containers and management of waste being prepared for shipment to external waste management facilities.

Non-radioactive chemical waste is consolidated in designated locations. Non-radioactive chemicals are primarily used in the quality control labs for analyses and testing. Waste chemicals are brought to the chemical storage sheds where they are picked up by a licensed waste disposal company for treatment and/or disposal.

Nordion has established programs for managing non-hazardous waste in the Non-Active Areas of the facility to divert waste such as plastics, metals, paper, cardboard, and organics from landfill. Annually Nordion conducts a waste audit of non-hazardous waste to determine diversion program performance.

Nordion also establishes targets to reduce non-hazardous waste sent to landfill. Initiatives to meet these targets include reducing waste, raising awareness of existing recycling programs and looking for further opportunities to divert waste as feasible.

4.11.5 Decommissioning Plan

Nordion has developed a Preliminary Decommissioning Plan (PDP) and has in place a financial guarantee in accordance with REGDOC-2.11.2, "*Waste Management Decommissioning*"^[14] and REGDOC-3.3.1, "*Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*"^[15]. The PDP and Financial Guarantee was approved by the Commission in February 2023 and remains sufficient for the licensed activities.

4.12 Security

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

4.12.1 General Considerations

Nordion has implemented site and transport security programs to meet the requirements of the *Nuclear Security Regulations (SOR/2000-209)*^[16] and REGDOC-2.12.3, "*Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material*"^[17].

4.13 Safeguards and Non-Proliferation

The Safeguards and Non-Proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada and International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*^[18].

Nordion has a program in place for the management of safeguarded material. The program meets the safeguards requirements of specified license conditions, REGDOC-2.13.1, "*Safeguards and nuclear material accountancy*"^[19], CNSC *Nuclear Non-Proliferation Import and Export Control Regulations*^[20], the *Nuclear Safety and Control Act*^[1] and *General Nuclear Safety and Control Regulations*^[21].

Nordion completes a Physical Inventory Taking (PIT) of safeguarded material on an annual basis. The Annual PIT is followed by a CNSC Physical Inventory Taking-Evaluation (PIT-E).

Nordion is fully compliant with REGDOC-2.13.1, "*Safeguards and nuclear material accountancy*"^[19].

4.14 Packaging and Transport

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

4.14.1 Package Design and Maintenance

Nordion has developed a program for the design and maintenance of transport packages.

Changes to package design are done in accordance with Nordion's change control process.

4.14.2 Package and Transport Program

Nordion has implemented a Packaging and Transportation Program that applies to employees involved in 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 all types of packages including Type A, Type B, and Excepted packages. The content of the program was modeled on regulatory requirements listed in the CNSC *Packaging and Transportation of Nuclear Substances Regulations* [22], Transport Canada *Transportation of Dangerous Goods Regulations* [23], IAEA SSR-6, “*Regulations for the Safe Transport of Radioactive Material (1996 Revised Edition)*” [24], US DOT *49 CFR* [25], and US NRC *10 CFR Part 71* [26].

The Packaging and Transportation Program outlined the various processes that are used to monitor and maintain the health of this program.

Some of the elements discussed include:

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

Nordion also has a Transport Package Quality Plan to describe how the quality assurance requirements for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of Nordion radioactive material transport packaging are achieved. It identifies the activities, responsibilities, and actions necessary to ensure that all regulatory, customer, and internal Quality Assurance program requirements are met.

Radioactive materials transport packaging falls within the scope of Nordion’s ISO 9001 [4]. This Quality Plan supplements the Quality Manual where requirements are specific to transport packages.

Compliance with the program document, the quality plan, and any referenced procedures is tracked through Nordion’s Quality Systems (Deviations, Non-Conforming Materials Reports and Customer Complaints). As required, events are investigated, and corrective actions assigned.

4.15 Reporting

Nordion is committed to openness and transparency with the CNSC and has implemented a reporting framework in compliance with REGDOC -3.1.2, “*Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills*” [27].

Nordion has implemented a program for reporting of high activity sealed sources. Nordion notifies the CNSC Sealed Source Tracking System (SSTS) of all transfers of all sealed sources, prior to shipment and and report the receipt of sealed sources within 48 hours of receipt.

4.16 Public Information and disclosure program

Nordion is committed to transparency with the public and has implemented a program that meets the requirements of REGDOC-3.2.1, “*Public Information Disclosure*” [28]. Nordion’s public information program is designed to meet three key objectives:

- To build public awareness about Nordion’s business products, services, operations and that Nordion is a nuclear facility, through timely and ongoing clear, consistent and transparent communications;
- To proactively engage identified stakeholders and utilize available communications tools and channels to foster ongoing public awareness and outreach; and
- To obtain stakeholder feedback and create a two-way dialogue to continuously improve Nordion’s Program.

Nordion reaches out to the local community through the following primary means:

- Public surveys, conducted every 2 years to gauge community interest and concerns;
- Public awareness events and mailings, typically provided every two years, providing information on Nordion’s activities; and
- Posting of event reports and environmental data (via the ACR) to the Nordion website.

As part of our licensing renewal efforts, Nordion has engaged with the local community to inform them of the renewal application and process and address any questions or concerns that are brought forward. A copy of our application has been posted on the Nordion website.

On October 28, 2024, Nordion held a public outreach event at a venue in Kanata, across from the Nordion facility. Approximately 2 weeks prior to the event, mailers were sent to the surrounding community, notifying the community of the Nordion renewal application for a 25-year licence and inviting the community to the outreach event. Approximately 15 members of the public attended the outreach event. Nordion provided an overview of products and safety programs, followed by a Q&A session. Based on the Q&A and subsequent discussions, the following main points were identified from the event:

- Members of the community understood how important Nordion’s products are to the healthcare sector; and
- The community was generally receptive to a 25-year licence.

In November 2024, Nordion conducted its bi-annual telephone survey of the surrounding area. The survey was conducted by Nanos Research and generally followed the same questions asked in previous surveys, with an additional question on the public’s reactions to Nordion’s request for a 25-year renewal. A total of 500 residents were surveyed. The results determined that Nordion’s overall favorability remained high among residents. With respect to the 25-year licence renewal, 51.1% had no view on the renewal, 29.5% were in favor, and only 0.5% felt that 25-years was too long. The remaining 18.9% were unsure, would like additional information, or felt it would depend on the safety and environmental impact.

4.17 Indigenous engagement

The Nordion facility is situated in the unceded territories of the Algonquin Anishinaabe. There are several Indigenous Nations and groups that would have an interest in Nordion activities. Primarily, these are:

- The Algonquins of Pikwakanagan First Nation (AOPFN);
- The Kebaowek First Nation; and
- The Algonquins of Ontario (AOO).

Nordion is committed to engagement with Indigenous Nations.

In 2023, the Nordion Senior Leadership Team attended cultural awareness training with the AOPFN in their community. Also, in 2023, Nordion and BWXT Medical hosted a delegation from the AOPFN at the Nordion facility, providing a tour of the Nordion operations and starting discussions on engagement.

In May 2024, Nordion began discussions with the AOPFN on an engagement plan. Those discussions continue in 2025 and Nordion is working with the AOPFN to host an in-person discussion on Nordion's licence submission within the AOPFN community.

In August 2024, Nordion submitted formal notices of submission of our licence renewal application to the AOPFN, Kebaowek First Nation, AOO, the Metis Nation of Ontario, and the Kitigan Zibi Anishinabeg. The AOO reached out for further information. Introductory calls between Nordion and the AOO were held in August 2024 and February 2025 and Nordion is working to host members of the AOO for a site tour sometime in 2025.

Nordion will continue to reach out to the Indigenous Nations over the period of the licence renewal.

4.18 BWXT Medical

In 2018, Nordion divested the Medical Isotopes business to BWXT Medical. Nordion retained what was referred to as the Gamma Technologies business, which is described as the Nordion activities in our renewal application. BWXT Medical leases NMPF and the KRMF. In late 2021, BWXT Medical received a Class 1B licence to operate their business in the leased portion of the facility. Nordion continues to operate the Gamma Technologies business in the COF under the Nordion Class 1B licence. Nordion remains the owner of the site, and the buildings located at 447 March Road. This arrangement has resulted in two separate Class 1B licensees.

Nordion and BWXT Medical share a number of key programs. The Emergency Response Program is a shared program. For site wide emergencies, a Nordion employee takes the lead as the incident commander. However, the remaining emergency response functions will be called from either BWXT Medical or Nordion personnel, depending on the situation. In the event of a site-wide emergency or other reportable event that occurs in the shared spaces, both Nordion and BWXT Medical provide independent reporting to the CNSC duty officer or respective project officer, as the situation requires.

In addition to emergency response, security is a shared program that is managed by Nordion. Calibration services is a shared program managed by BWXT Medical.

Nordion and BWXT Medical have developed procedures that define the relationship and programs between Nordion and BWXT Medical.

Although Nordion and BWXT Medical share a site and a number of programs, each licensee is responsible for activities under its respective licence.

5 CHALLENGES AND FUTURE PLANS

Nordion has developed robust programs to meet the various CNSC safety and control areas. These programs have been implemented and improved over several decades. The programs have been reviewed by the CNSC during previous licence renewals and on-going CNSC audits. Nordion does not anticipate any challenges with the various SCAs described in this written submission.

Nordion's renewal application requests to continue those activities covered under the current operating licence, NSPFOL-11A.01/2025. Nordion is not requesting any changes to the licensed activities at this time.

6 CONCLUSION

As provided in our application of May 15, 2024 (amended on February 21, 2025), and this written submission, Nordion has developed programs to meet applicable regulatory requirements across the various CNSC safety and control areas. These programs have ensured that Nordion continues to maintain worker and public radiation exposures that are below regulatory requirements, minimizes environmental emissions, and ensures that the public and the environment are protected.

Nordion has been in operation at the site for over 50 years and has applied continuous improvement to the facility and programs and commits to further continuous improvements over the next licensing period.

Nordion is well qualified to continue to operate the licensed activities, ensuring the protection of people, the community and the environment.

7 REFERENCES

Table 4: Reference Documents

Reference	Title
[1]	Nuclear Safety and Control Act
[2]	CSA N286:12, Management System Requirements for Nuclear Facilities
[3]	ISO 14001, Environmental Management Systems – Requirements with guidance for use
[4]	ISO 9001, Quality Management System
[5]	REGDOC-2.2.2 Version 2, Personnel Training
[6]	REGDOC-2.4.4, Safety Analysis for Class 1B Nuclear Facilities
[7]	Radiation Protection Regulations
[8]	REGDOC-2.9.1, Environmental Protection Policies, Programs and Procedures
[9]	CSA N288.4, Environmental Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills
[10]	CSA N288.5, Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills
[11]	CSA N288.6, Environmental Risk Assessment at Class 1 Nuclear Facilities and Uranium Mines and Mills
[12]	REGDOC-2.10.1, Nuclear Emergency Preparedness and Response
[13]	CSA N393, Fire Protection for Facilities that Process, Handle or Store Nuclear Substances.
[14]	REGDOC-2.11.2, Waste Management Decommissioning
[15]	REGDOC-3.3.1, Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities
[16]	SOR/2000-209, Nuclear Security Regulations
[17]	REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources and Category I, II, and III Nuclear Substances
[18]	Treaty on the Non-Proliferation of Nuclear Weapons
[19]	REGDOC-2.13.1, Safeguards and Nuclear Material Accountancy
[20]	Nuclear Non-Proliferation Import and Export Control Regulations

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[21]	General Nuclear Safety and Control Regulations
[22]	Packaging and Transport of Nuclear Substances Regulations
[23]	Transport Canada, Transportation of Dangerous Goods Regulations
[24]	IAEA, SSR-6, Regulations for the Safe Transport of Radioactive Material (1996 Revised Edition)
[25]	US DOT 49 CFR
[26]	US NRC 10 CFR Part 71
[27]	REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills
[28]	REGDOC-3.2.1, Public Information and Disclosure

GLOSSARY

ACR	Annual Compliance Report
ALARA	As Low As Reasonably Achievable
AMMS	Advanced Maintenance Management System
AOPFN	Algonquin of Pikwakanagan First nation
AOO	Algonquins of Ontario
BMS	Building Management System
CAPA	Corrective Action Preventative Action
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
COF	Cobalt Operations Facility
CSA	Canadian Standards Association
DOT	Department of Transport
DRL	Derived Release Limit
EHS	Environmental, Health and Safety
EMS	Environmental Management System
ERA	Environmental Risk Assessment
ERC	Emergency Response Center
ERP	Emergency Response Plans
FSAR	Final Safety Analysis Report
HAZMAT	Hazardous Materials
HEPA	High Efficiency Particulate Air
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
KRMF	Kanata Radiopharmaceutical Manufacturing Facility
KOB	Kanata Operations Building
MSS	Management System for Safety
NEW	Nuclear Energy Worker
NMPF	Nuclear Medicine Production Facility
NRC	Nuclear Regulatory Commission
NVS	Nuclear Ventilation System
PDP	Preliminary Decommissioning Plan
PIT	Physical Inventory Taking
PIT-E	Physical Inventory Taking – Evaluation
RE	Roy Errington
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SSC	Structures, Systems and Component
SSTS	Sealed Source Tracking System
TLD	Thermo-luminescent Dosimeter
TSSA	Technical Standards and Safety Authority