

May 15, 2024

Canadian Nuclear Safety Commission (CNSC)
280 Slater Street
P.O. Box 1046, Station B
Ottawa, Ontario, K1P 5S9

Subject: Application for Renewal of Nordion Operating License NSPFOL-11A.01/2025

Dear Sir/Madame,

This submission is Nordion's application for renewal of Nordion's Class 1B Nuclear Substance Processing Facility Operating License, NSPFOL-11A.01/2025.

The information required to be contained in a license in respect of a Class I nuclear facility as required by the *Nuclear Safety and Control Act* and Regulations is provided in Attachment 1. A summary of facility modifications and program improvements implemented during the current licensing period is provided in Attachment 2. Supplementary information in accordance with REGDOC 1.2.2 is provided in Attachment 3. A table of supporting documentation is listed in Appendix A and will be provided to CNSC staff through an FTP site, with the exception of prescribed information that will be provided via encrypted email.

Information required to be submitted under Sections 3(1)(e), 3(1)(g), 3(1)(h) of the *General Regulations*, Section 6(e), 6(l) of the *Class I Nuclear Facilities Regulations*, and Section 41 of the *Nuclear Security Regulations* was previously provided directly to the CNSC Nuclear Security Division as this information is Prescribed Information. The Nordion Security Plan was accepted on May 13th, 2024^[1] and the Transportation Security Plan was approved on December 14th, 2023.^[2]

We are requesting the license be renewed for a 25-year period. Justification for this request is provided in Appendix B.

Nordion's Application for License Renewal Commission Member Document (CMD) and presentation will be submitted prior to the Commission hearing to review Nordion's license renewal in consultation with CNSC staff. Representatives from Nordion will attend the CNSC hearings regarding Nordion's license renewal. A presentation before the Commission will be provided by Nordion.

Should you have any questions, please do not hesitate to contact me at (613) 592-3400 extension 2539, or e-mail at richard.wassenaar@nordion.com.

Sincerely,

Richard Wassenaar
Director, Regulatory & EHS

cc: Andrew McAllister, Ismail Erdebil and Jason Duhaime – CNSC
Riaz Bandali - Nordion
Kathy Hoffman – Sotera Health

Enclosure:

Appendix A: List of Supporting Documentation

Appendix B: Justification for 25-Year License Period

Attachment 1: Information Required for the Renewal of the Operating License

Attachment 2: Summary of Facility Modifications and Program Improvement

Attachment 3: Supplementary Report to Support License Renewal

Reference:

- [1] E-mail from Thomas Kirton, CNSC to Michael Durkin, Nordion, "RE: Annual Security Plan Submission", dated May 13, 2024
- [2] e-Doc 7173165, Raphael Duguay, Nuclear Security Division, CNSC, letter to Michael Durkin, Nordion, "Technical Assessment of Nordion (Canada) Inc.'s 2024 Transportation Security Plan – Category 1 Sealed Source", December 14th, 2023.

Appendix A
List of Supporting Documentation

FTP FOLDER LOCATION	DOCUMENT
Management System	Management System for Safety, SE-LIC-001 (17)
Human Performance	Radiation Surveyors On-the-Job Training Program, SE-TRN-001 (19)
	Cobalt Monitor On-the-Job Training Program, CO-MD/OP-0028 (8)
	Compliance Environment, Health and Radiation Safety Training, SE-TRN-003 (16)
	Systematic Approach to Training System, SE-TRN-006 (9)
FSARs/Facility Description	Final Safety Analysis Report for Cobalt Operations, IS/SR 1057 Z000 (12) (current version under review by CNSC)
	Final Safety Analysis Report for Cobalt Pools, IS/SR 2638 Co60 (4)
	Final Safety Analysis Report for Cobalt Operations Radioactive Waste Management, IN/SR 2315 Co60 (3)
	Final Safety Analysis Report for the Waste Diversion Program, IN/SR 1859 C000 (4)
	Facility Description, SE-LIC-018
	The following drawings are prescribed information and will not be transferred to the FTP site:
	Drawing PEAE-61266, Version 12, "KOB GROUND FLOOR LICENSED NUCLEAR FACILITY"
	Drawing PEAE-61267, Version 5, "KOB SECOND FLOOR LICENSED NUCLEAR FACILITY"
	Drawing PEAE-61278, Version 4, "KOB BASEMENT LICENSED NUCLEAR FACILITY"
	Drawing PEAE-40093, Version 3, "HEATING PLANT BASEMENT LICENSED NUCLEAR FACILITY"
	Drawing PEMC-40094, Version 4, "HEATING PLANT FUEL OIL TANK LICENSED NUCLEAR FACILITY"
	Drawing PEAE-40095, Version 6, "HEATING PLANT GROUND FLOOR LICENSED NUCLEAR FACILITY"
	Drawing PEAE-70027, Version 4, "SITE PLAN KANATA LICENSED NUCLEAR FACILITY"
	Drawing PEAE-70028, Version 3, "KANATA SITE BLDGS AND TUNNEL LOCATION LICENSED NUCLEAR FACILITY"
Gammacell 220	Gammacell 220 Spare Parts List, IN/DS 1087 GC220 (5)

Appendix A (cont'd)

FTP FOLDER LOCATION	DOCUMENT
Gammacell 220 (cont'd)	Installation Procedure for Gammacell 220 Irradiators, IN/IN 0060 GC220 (2)
	Gammacell-220 Inspection Procedure – Field Function Only, IN/IM 0062 J0300 (2)
	Inspection Procedure for GC-220 Irradiators Returned for Source Loading, IN/IM 0114 J0300 (1)
	Radiation Survey Report for the GC-220, IN/IM 0308 GC220 (6)
	GC-220 Loading and Unloading Procedure, CO-C6/OP-0014 (11)
	Installation and Service Technician Training Program, IN/OP 2642 Z000 (4)
CPM	Nordion Environmental, Health and Safety Policy, CPM-6-06 (11)
	Nordion Environmental, Health & Safety Responsibilities and Committees, CPM-6-19 (21)
	Safety Analysis Reports, CPM-6-20 (18)
Facilities	Facilities Maintenance Master Plan, R-Master (15)
	Calibration Master Plan, CP-001 (1)
Radiation Protection / ALARA	Radiation Protection Manual – Ottawa Site, SE-RP-001 (11) (current version under review by CNSC)
	Keeping Radiation Exposures and Doses As Low as Reasonably Achievable (ALARA), SE-RP-002 (8) (current version under review by CNSC)
	Investigations, SE-RP-003 (17)
	External Personal Radiation Monitoring, SE-RP-004 (11)
	Protective Clothing and Gloves in Active Area Laboratories, SE-RP-005 (4)
	Radioactive Source Storage in Transport Packages, CO-GEN/GD-0003 (2)
	Cobalt Operations Facility Non-Process Related Waste Handling Procedure, CO-MD/OP-0022 (9)
	Shipping Procedure for the Cobalt Operations Shipper/Receiver, CO-SR/OP-0002 (3)

Appendix A (cont'd)

FTP FOLDER LOCATION	DOCUMENT
Derived Release Limits (DRL)	Nordion Class 1B Facility Derived Release Limits, REP-EHS-009 (1)
Conventional Health & Safety (SE-HS)	Protective Eyewear, SE-HS-002 (4)
	Protective Footwear, SE-HS-003 (3)
	Control of Hazardous Energy - Lockout and Tagout Systems, SE-HS-007 (4)
	Chemical Handling and Storage, SE-HS-008 (10)
	Work Permit Authorization Program, SE-HS-009 (13)
	The Right to Refuse Dangerous Work, SE-HS-010 (2)
	Investigation of Occupational Injuries, Hazardous Occurrences, Near Misses and Hazard Identifications, SE-HS-011 (10)
	Hearing Conservation, SE-HS-012 (3)
	Asbestos Management Program, SE-HS-013 (8)
	Respiratory Protection Program, SE-HS-014 (4)
Environmental Protection	Nordion Environmental Protection Program, SE-ENV-015 (8) (current version under review by CNSC)
	Environmental Management System Manual, SE-ENV-001 (12)
	Daily Workstation Air Monitoring, SE-OP-007 (19)
	Stack Air Sampling, SE-OP-010 (10)
	Water Effluent Monitoring, SE-OP-013 (20)
	Delay and Holding Tank Water Sample Collection Procedure, CO-MD/OP-0007 (9)
	Weekly Environmental Equipment Testing, SE-OP-027 (26)
	Soil Monitoring Program, SE-ENV-017 (6)
	Non-Radiological Environmental Monitoring Program, SE-ENV-021 (4)
	Waste Management Program, SE-ENV-022 (7)
	Nordion ERA memo v1-0
Emergency Management and Fire Protection	Emergency Response Plan, SE-ERP-002 (12)
	Emergency Response Training and Testing, SE-ERP-010 (13)
	Radiation Emergency Response Plan, SE-ERP-011 (7)
	Procedure for Containment of Sprinkler Water, SE-ERP-015 (2)

Appendix A (cont'd)

FTP FOLDER LOCATION	DOCUMENT
Emergency Management and Fire Protection (cont'd)	Chemical Spill Response Plan, SE-ERP-1-005 (5)
	Fire Protection Program – Nordion Ottawa Site, SE-EHS-007 (7)
	Fire Safety Plan, SE-ERP-001 (8)
	Fire Fighters Copy - Fire Safety Plan for the KOB and KRMF, SE-SC-016 (7)
	Fire Fighters Copy - Fire Safety Plan for the RE Building, SE-SC-017 (6)
	Fire Fighters Copy - Fire Safety Plan for the Heating Plant, SE-SC-018 (6)
Decommissioning Plan	Preliminary Decommissioning Plan for Class 1B Facility (KOB), SE-LIC-009 (6)
Security	Facility Access Security Clearance, SE-SC-005 (4)
	Security Vehicle Inspection Post Order, SE-SC-014 (6) (prescribed information, no document will be provided.)
SE-LIC	EHS Committee Approved Activity Limits for Facilities, SE-LIC-007 (23)
	Radioactive Material Inventory, SE-LIC-015 (21)
	Safeguards Program, SE-LIC-016 (14)
SE-EHS	EHS Regulatory Reporting and Notifications, SE-EHS-009 (11)
	EHS Requirements Checklist, SE-EHS-014 (7)
Packaging and Transport	Shipping Radioactive Material, SE-OP-014 (11)
	Receiving Radioactive Material, SE-OP-015 (7)
	Transport of Radioactive Material Program, SE-OP-036 (6)
	Sealed Source Reporting, SE-OP-079 (24)
	Requirements for the Transport of Radioactive Materials, 000079.SOP (5)
Leak Testing	Operation of Varian Leak Detection Software, CO-C5/IT-0004 (7)
	Outer Capsule Welding and Leak Testing for Elekta Process Using Mini-Trays, CO-C5/OP-0019 (9)
	Helium Leak Test of Sub-Assemblies and Capsule Components, CO-PNG/IT-0001 (2)
	Ultrasonic Effluent Test Procedure, CO-PRD/OP-0033 (10)
	Underwater Source Swipe Tests for Detection and Isolation of Leaking Source Capsules in Pool #13, CO-PRD/OP-0072 (5)
	Dry Wipe Test, CO-PRD/TP-0003 (5)
SE-CA	Calibration of Survey Meters, SE-CA-002 (17)

Appendix A (cont'd)

FTP FOLDER LOCATION	DOCUMENT
SE-CA (cont'd)	Source Activity Decay Correction, SE-CA-003 (22)
	General Procedure for the Calibration of Contamination Meters, SE-CA-005 (7)
	Testing of Direct Reading Dosimeters, SE-CA-008 (6)
Change Control	Change Control Procedure, QAP-AP-45 (32)
Public Information Program	Nordion Public Information Program, SE-LIC-010 (15)
Other document(s)	BWXT Medical-Nordion Safety Responsibilities, SE-LIC-023 (2)
Organization Charts	Organizational Charts for Gamma Technologies – Leadership and EHS
Proof of legal status	Corporate Profile report
Owner for the site	City of Ottawa Property Tax 2024 – Interim Bill

Appendix B

Justification for 25-Year License Period

Nordion is requesting a 25-year licence and believes such a licence period is justified for the reasons outlined below.

Nordion has been safely operating the facility at 447 March Rd for over 50 years, producing Co-60 sealed sources since the 1960s. 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 safety program that drivew the oversight and continuously improvement of licensed activities. This program meets the requirement of CSA N286-12.
- 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 are 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 does to an employee has been 5.5 mSv, which is substantially lower than the regulatory limit of 50 mSv/year. The dose to the public has been less than 0.01 mSv/year due to Nordion related activities. This is not expected to substantially change over the requested 25-year licence period.
- 4) Nordion has an environmental protection program to control the release of radioactive and other hazardous substances from the facility. The environmental risk assessment 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 garbage or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the 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 much less than 0.1% 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. Since 2015, the CNSC has conducted 25 inspections of Nordion's operations and programs. An average of 1.8 findings were identified per inspection, with 28% (7 out of 25) of those inspections having no findings. None of the

findings were considered safety significant and Nordion 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. Refer to Attachment 2 for a listing of facility modifications and program improvements since the last renewal in 2015.

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 Table B.1 below. A 25-year license period will:

- have no impact on the safe operation of the facility or cost-recovery fees
- incorporate continued CNSC review
- ensure the same level of scrutiny and oversight as currently provided

Table B.1: IMPACT of a 25-YEAR LICENSE	
Issue	Impact
<i>Cost-Recovery Fees Regulations</i>	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 health care sector.

Co-60 sealed sources are critical to the health care sector. Co-60 sealed sources are used to sterilize more than 30% of all single-use medical devices globally and are used in a wide range of procedures, including orthopedic surgery, cardiovascular procedures, and invasive diagnostic procedures (e.g. endoscopy, biopsy). Co-60 is also used in the treatment of cancer in stereotactic radiosurgery for the treatment of brain cancer. Nordion is the leading global provider of Co-60.

Given the importance of Co-60 to health care, and other sectors, a 25-year licence would provide long-term assurance of the stability of supply to the health care 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 invested millions 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 health care 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 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 for decades more. The strong programs implemented to date have proved 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 health care industry and ensure that recycling and end-of-life options for Co-60 remain viable.