



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

447 March Road
Ottawa, ON Canada K2K 1X8

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.

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

	REQUIREMENTS	SCA ¹	Response
<i>General Nuclear Safety and Control Regulations</i>			
3(1)	An application for a licence shall contain the following information:		
3(1)(a)	the applicant's name and business address;		<p>Nordion (Canada) Inc. 447 March Road Ottawa, ON K2K 1X8</p> <p>Applicant authority: Riaz Bandali President (613) 592-3400 ext. 2589 riaz.bandali@nordion.com</p>

¹ See acronyms at the end of the table.

	REQUIREMENTS	SCA¹	Response
3(1)(b)	the activity to be licensed and its purpose;		<ul style="list-style-type: none"> • Nordion (Canada) Inc. is a nuclear processing facility situated at the location named in Section 3(1)(a) of this table under the <i>General Nuclear Safety and Control Regulations</i> and comprising the facilities described in the “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12) and “Final Safety Analysis Report for Cobalt Pools”, IN/SR 2638 Co60 (4). • Nordion (Canada) Inc. is applying for renewal of the Facility Operating Licence for a period of 25 years, from November 1, 2025 to October 31, 2050. • Activities to be licenced: <ul style="list-style-type: none"> a) Operate a nuclear substance processing facility at the location named in Section 3(1)(a) of this table under the <i>General Nuclear Safety and Control Regulations</i>, for the purpose of processing and manufacturing nuclear substances and sealed sources used in health sciences, health care, and industrial applications. b) Possess, transfer, use, process, import, manage, store, and dispose the nuclear substances that are required for, associated with or arise from the activities described in a); c) Possess, transfer, use, import, and service prescribed equipment that is required for, associated with, or arises from the activities described in a); d) Possess, transfer, use, service, or import prescribed equipment from clients; e) Possess and use prescribed information that is required for, associated with, or arises from the activities described in a).
3(1)(c)	the name, maximum quantity and form of any nuclear substance to be encompassed by the licence;	SA	<ul style="list-style-type: none"> • $>1 \times 10^{15}$ Bq per calendar year Co-60 in solid, liquid or gaseous form. • Various other radioisotopes atomic numbers between 1 to 103 in quantities of $<1 \times 10^{15}$ Bq per calendar year in solid, liquid or gaseous form that arise from the Nordion’s activities.

	REQUIREMENTS	SCA¹	Response
3(1)(d)	a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence;	SA	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), previously submitted May 14th, 2024 (current version under review by CNSC) and “Final Safety Analysis Report for Cobalt Pools”, IN/SR 2638 Co60 (4) July 22nd, 2020. • “KOB GROUND FLOOR LICENSED NUCLEAR FACILITY”, PEAE-61266 Version 12, previously submitted May 8th, 2023. • “KOB SECOND FLOOR LICENSED NUCLEAR FACILITY”, PEAE-61267 Version 5, previously submitted September 23rd, 2020. • “KOB BASEMENT LICENSED NUCLEAR FACILITY”, PEAE-61278 Version 4, previously submitted November 12th, 2018. • “HEATING PLANT BASEMENT LICENSED NUCLEAR FACILITY”, PEAE-40093 Version 3, previous submitted May 26th, 2017. • “HEATING PLANT FUEL OIL TANK LICENSED NUCLEAR FACILITY”, PEAE-40094 Version 4, previously submitted May 26th, 2017. • “HEATING PLANT GROUND FLOOR LICENSED NUCLEAR FACILITY”, PEAE-40095 Version 6, previously submitted November 21st, 2017. • “SITE PLAN KANATA LICENSED NUCLEAR FACILITY”, PEAE-70027 Version 4, previously submitted May 26th, 2017. • “KANATA SITE BLDGS AND TUNNEL LOCATION LICENSED NUCLEAR FACILITY”, PEAE-70028 version 3, previously submitted May 26th, 2017. • Gammacell 220 (GC-220) Irradiator Serial Number 59 used for dosimeter calibrations and materials irradiation, containing Co-60 sealed sources. • Any Gammacell 220 Irradiators for dosimeter calibrations and materials irradiation. • GE Homeland Protection Mobile Trace electron capture detector Serial Number 160783 used for explosives detection, containing a Ni-63 source. • Security sensitive information including security response plans and procedures and CNSC security correspondence.

	REQUIREMENTS	SCA¹	Response
3(1)(e)	the proposed measures to ensure compliance with the <i>Radiation Protection Regulations</i> and the <i>Nuclear Security Regulations</i> ;	RP/NS	<p><i>Radiation Protection Regulations</i>:</p> <ul style="list-style-type: none"> • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) <ul style="list-style-type: none"> • organization and administration for RP Refer to organizational charts • RP training and qualification Refer to Section 4(a)(ii) of this table under <i>Radiation Protection Regulations</i> “Radiation Surveyors On-the-Job Training Program”, SE-TRN-001 (19) for Radiation Surveyors and Monitors “Cobalt Monitor On-the-Job Training Program”, CO-MD/OP-0028 (8) for Sterilization Monitors • classification of areas and local rules “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11) Section 4.4 • radiation exposure and dose control “Keeping Radiation Exposures and Doses “As Low as Reasonably Achievable (ALARA)””, SE-RP-002 (8), previously submitted April 29th, 2024 (current version under review by CNSC) • RP equipment and instrumentation Refer to Section 3(1)(i) of this table under <i>Nuclear Substances and Radiation Devices Regulations</i> • radiation monitoring and dose assessment “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11) Sections 5.6, 5.7, and 6 • contamination control “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11) Section 7 • planning for unusual situations Refer to Section 4(a)(iv) of this table under <i>Radiation Protection Regulations</i>

	REQUIREMENTS	SCA ¹	Response
3(1)(e), continued			<ul style="list-style-type: none"> RP program oversight EHS Committee - “Nordion Environmental, Health & Safety Responsibilities and Committees”, CPM-6-19 (21) RP program oversight is provided by the EHS Committee. In addition, an EHS regulatory Compliance audit is performed at least once every 3 years by an external 3rd party. This audit is conducted to review all aspects of EHS, including Radiation Protection and is a requirement of Nordion’s EHS Management Systems and Nordion’s Board of Directors. <p><i>Nuclear Security Regulations:</i></p> <ul style="list-style-type: none"> “2024 Security Report”, submitted March 1st, 2024. This report contains the Nordion Security Plan covering all aspects of the security program. This is prescribed information. “Physical Security Threat Assessment”. Updated annually and available to CNSC Security Division review on site at request, as per normal protocol. (Refer to Section 6(l) of this table under Class I Nuclear Facilities Regulations)
3(1)(f)	any proposed action levels for the purpose of section 6 of the <i>Radiation Protection Regulations</i> ;	RP	<ul style="list-style-type: none"> Sections 5.6, 5.7, 9.5 and 10 of the “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) “Keeping Radiation Exposures and Doses “As Low as Reasonably Achievable (ALARA)””, SE-RP-002 (8), previously submitted April 29th, 2024 (current version under review by CNSC)
3(1)(g)	the proposed measures to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information;	NS	<ul style="list-style-type: none"> “2024 Security Report”, submitted March 1st, 2024. This report contains the Nordion Security Plan covering all aspects of the security program. This is prescribed information. “Physical Security Threat Assessment”. Updated annually and available to CNSC Security Division review on site at request, as per normal protocol.
3(1)(h)	the proposed measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information;	NS	<ul style="list-style-type: none"> “2024 Security Report”, submitted March 1st, 2024. This report contains the Nordion Security Plan covering all aspects of the security program. This is prescribed information. “Physical Security Threat Assessment”. Updated annually and available to CNSC Security Division review on site at request, as per normal protocol.

	REQUIREMENTS	SCA¹	Response
3(1)(i)	a description and the results of any test, analysis or calculation performed to substantiate the information included in the application;	SA	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), Section 9, previously submitted May 14th, 2024 (current version under review by CNSC) and “Final Safety Analysis Report for Cobalt Pools”, IN/SR 2638 Co60 (4) July 22nd, 2020.
3(1)(j)	the name, quantity, form, origin and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including waste that may be stored, managed, processed, or disposed of at the site of the activity to be licensed, and the proposed method for managing and disposing of that waste;	WM	<ul style="list-style-type: none"> • Annual Compliance and Operational Performance Reports • “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) • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 13 • “Chemical Handling and Storage”, SE-HS-008 (10) • “Waste Management Program”, SE-ENV-022 (7)
3(1)(k)	the applicant’s organizational management structure insofar as it may bear on the applicant’s compliance with the Act and the Regulations made under the Act, including the internal allocation of functions, responsibilities and authority;	MS	<ul style="list-style-type: none"> • “Nordion Environmental, Health & Safety Responsibilities and Committees”, CPM-6-19 (21) • Organization charts for Environment, Health & Safety (EHS) & Regulatory and Executive Management Team
3(1)(l)	a description of any proposed financial guarantee relating to the activity to be licensed; and	OMRI	<ul style="list-style-type: none"> • Nordion has in place a financial guarantee that is acceptable to the CNSC.
3(1)(m)	any other information required by the Act or the Regulations made under the Act for the activity to be licensed and the nuclear substance, nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.	OMRI	As requested.

	REQUIREMENTS	SCA¹	Response
3(1.1)	The Commission or a designated officer authorized under paragraph 37(2)(c) of the Act, may require any other information that is necessary to enable the Commission or the designated officer to determine whether the applicant (a) is qualified to carry on the activity to be licensed; or (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.	OMRI	As requested.
3(2)	Subsection (1) does not apply in respect of an application for a licence to import or export for which the information requirements are prescribed by the <i>Nuclear Non-Proliferation Import and Export Control Regulations</i> , or in respect of an application for a licence to transport while in transit for which the information requirements are prescribed by the <i>Packaging and Transport of Nuclear Substances Regulations</i> .	N/A	Not applicable.
5	An application for the renewal of a licence shall contain:		
5(a)	the information required to be contained in an application for that licence by the applicable Regulations made under the Act; and		

	REQUIREMENTS	SCA¹	Response
5(b)	a statement identifying the changes in the information that was previously submitted.	MS	<p>The organization of the Facility has changed since the last application. Refer to the attached Organization Charts.</p> <p>All programs and procedures have been revised with the exception of the following documents:</p> <p>“Gammacell 220 Spare Parts List”, IN/DS 1087 GC220 (5)</p> <p>“Installation Procedure for Gammacell 220 Irradiators”, IN/IN 0060 GC220 (2)</p> <p>“Gammacell-220 Inspection Procedure - Field Function Only”, IN/IM 0062 J0300 (2)</p> <p>“Inspection Procedure for GC-220 Irradiators Returned for Source Loading”, IN/IM 0114 J0300 (1)</p> <p>“Radiation Survey Report for the GC-220”, IN/IM 0308 GC220 (6)</p> <p>“Radioactive Source Storage in Transport Packages”, CO-GEN/GD-0003 (2)</p> <p>“Shipping Procedure for the Cobalt Operations Shipper/Receiver”, CO-SR/OP-0002 (3)</p> <p>“Helium Leak Testing of Sub-Assemblies and Capsule Components”, CO-PNG/IT-0001 (2)</p> <p>The changes to each of the procedures have been administrative or a result of improvements to the programs.</p>
7	An application for a licence or for the renewal, suspension in whole or in part, amendment, revocation or replacement of a licence may incorporate by reference any information that is included in a valid, expired or revoked licence.	N/A	See individual sections, as applicable.

	REQUIREMENTS	SCA¹	Response
15	<p>Every applicant for a licence and every licensee shall notify the Commission of:</p> <p>(a) the persons who have authority to act for them in their dealings with the Commission;</p> <p>(b) the names and position titles of the persons who are responsible for the management and control of the licensed activity and the nuclear substance, nuclear facility, prescribed equipment or prescribed information encompassed by the licence; and</p> <p>(c) any change in the information referred to in paragraphs (a) and (b), within 15 days after the change occurs.</p>	MS	<p>Applicant authority:</p> <p>Riaz Bandali President (613) 592-3400 ext. 2589 riaz.bandali@nordion.com</p> <p>Signing authorities:</p> <p>Richard Wassenaar (613) 592-3400 ext. 2539 richard.wassenaar@nordion.com</p> <p>Sabrina Sng (613) 592-3400 ext. 2286 sabrina.sng@nordion.com</p>
<i>Class I Nuclear Facilities Regulations</i>			
3	An application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the following information in addition to the information required by section 3 of the <i>General Nuclear Safety and Control Regulations</i> :		
3(a)	a description of the site of the activity to be licensed, including the location of any exclusion zone and any structures within that zone;	SA/PD	<ul style="list-style-type: none"> Refer to Section 3(1)(d) of this table under the <i>General Nuclear Safety and Control Regulations</i> “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), previously submitted May 14th, 2024 (current version under review by CNSC) and “Final Safety Analysis Report for Cobalt Pools”, IN/SR 2638 Co60 (4) July 22nd, 2020.

	REQUIREMENTS	SCA¹	Response
3(b)	plans showing the location, perimeter, areas, structures, and systems of the nuclear facility;	PD	<ul style="list-style-type: none"> • Refer to Section 3(1)(d) of this table under the <i>General Nuclear Safety and Control Regulations</i> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12): <ul style="list-style-type: none"> ○ The building name, its principal uses, number of floors and basic construction (e.g., steel frame, reinforced concrete, wood frame, etc); (Sections 5.1 General Description, 5.3 Nordion Facilities, and 5.4.1 Structure) ○ Identification of the boundaries of the Nordion facility encompassed by the licence; (Section 5.3 Nordion Facilities) ○ A description of the facility ventilation, heating and cooling systems, electrical circuits, fire protection features, systems and equipment, emergency lighting and location of emergency exits; (Sections 5.6 Site Services, 5.6.2 Electrical, 5.7 Ventilation System, 7.3.4 Fire Detectors, and 7.4 Control) ○ A description of building and laboratory hazards including such things as natural gas pipes, compressed gas storage, significant combustible inventories and water mains that are a potential flooding hazard. (Section 9 Hazard Analysis and Safety Assessment) • “Final Safety Analysis Report for Cobalt Pools”, IS/SR 2638 Co60 (4)
3(c)	evidence that the applicant is the owner of the site or has authority from the owner of the site to carry on the activity to be licensed;		<ul style="list-style-type: none"> • Refer to attach City of Ottawa Property Tax 2024 – Interim bill
3(d)	the proposed quality assurance program for the activity to be licensed;	MS	<ul style="list-style-type: none"> • “Management System for Safety”, SE-LIC-001 (17), previously submitted February 14th, 2022
3(e)	the name, form, characteristics and quantity of any hazardous substances that may be on the site while the activity to be licensed is carried on;	WM	<ul style="list-style-type: none"> • Chemical inventory available upon request • SDS sheets for all substances available upon request • “Asbestos Management Program”, SE-HS-013 (8) • Asbestos Inventory Report – a record of the locations of friable material containing asbestos in the building. Report available upon request.

	REQUIREMENTS	SCA¹	Response
3(f)	the proposed worker health and safety policies and procedures;	CHS	<ul style="list-style-type: none"> • “Nordion Environmental, Health and Safety Policy”, CPM-6-06 (11) • Safety and Environment Health and Safety Procedures, SE-HS-XXX series of procedures • “Fire Safety Plan”, SE-ERP-001 (8), previously submitted December 12th, 2022 • "Nordion Environmental, Health & Safety Responsibilities and Committees", CPM-6-19 (21) • “External Personal Radiation Monitoring”, SE-RP-004 (11) • “Protective Clothing and Gloves in Active Area Laboratories”, SE-RP-005 (4) • “Keeping Radiation Exposures and Doses “As Low as Reasonably Achievable (ALARA)”, SE-RP-002 (8), previously submitted April 29th, 2024 (current version under review by CNSC)
3(g)	the proposed environmental protection policies and procedures;	EP	<ul style="list-style-type: none"> • “Nordion Environmental, Health and Safety Policy”, CPM-6-06 (11) • “Nordion Environmental Protection Program”, SE-ENV-015 (8), previously submitted April 29th, 2024 (current version under review by CNSC) • “Environmental Management System Manual”, SE-ENV-001 (12), previously submitted June 10th, 2022
3(h)	the proposed effluent and environmental monitoring programs;	EP	<ul style="list-style-type: none"> • “Nordion Environmental Protection Program”, SE-ENV-015 (8), previously submitted April 29th, 2024 (current version under review by CNSC) • “Environmental Management System Manual”, SE-ENV-001 (12), previously submitted June 10th, 2024 • “Soil Monitoring Program”, SE-ENV-017 (6) • “Non-Radiological Environmental Monitoring Program”, SE-ENV-021 (4) • “Radiation Protection Manual - Ottawa Site”, SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) • “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)

	REQUIREMENTS	SCA¹	Response
3(i)	if the application is in respect of a nuclear facility referred to in paragraph 2(b) of the <i>Nuclear Security Regulations</i> , the information required by section 3 of those Regulations;	N/A	Not applicable.
3(j)	the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the activity to be licensed; and	OMRI	<ul style="list-style-type: none"> • “Nordion Public Information Program”, SE-LIC-010 (15), previously submitted January 8th, 2021
3(k)	the proposed plan for the decommissioning of the nuclear facility or of the site.	WM	<ul style="list-style-type: none"> • “Preliminary Decommissioning Plan for Class 1B Facility (KOB)”, SE-LIC-009 (6), previously submitted December 10th, 2021
6	An application for a licence to operate a Class I nuclear facility shall contain the following information in addition to the information required by section 3 of the <i>Class I Nuclear Facilities Regulations</i> :		
6(a)	a description of the structures at the nuclear facility, including their design and their design operating conditions;	PD	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), Section 5.4
6(b)	a description of the systems and equipment at the nuclear facility, including their design and their design operating conditions;	PD	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), Sections 5.6, 5.7 and 9

	REQUIREMENTS	SCA¹	Response
6(c)	a final safety analysis report demonstrating the adequacy of the design of the nuclear facility;	SA	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12)
6(d)	the proposed measures, policies, methods, and procedures for operating and maintaining the nuclear facility;	OP/FS/EM/M S	<ul style="list-style-type: none"> • “Management System for Safety”, SE-LIC-001 (17), previously submitted February 14th, 2022 <p>Sections 4, 5 and Appendix A of SE-LIC-001 (17)</p> <p>“EHS Regulatory Reporting and Notifications”, SE-EHS-009 (11)</p>
6(d), continued			<ul style="list-style-type: none"> • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) • “Fire Protection Program – Nordion Ottawa Site”, SE-EHS-007 (7), previously submitted February 28th, 2022 • “Facilities Maintenance Master Plan”, R-Master (15), previously submitted February 19th, 2024 • “Calibration Master Plan”, CP-001 (1), previously submitted April 1st, 2023 • Schedules for performing all routine maintenance available upon request • “Site Emergency Response Plan”, SE-ERP-002 (12), previously submitted May 31st, 2022 • “Radiation Emergency Response Plan”, SE-ERP-011 (7) • “Change Control Procedure”, QAP AP-45 (32)

	REQUIREMENTS	SCA¹	Response
6(e)	the proposed procedures for handling, storing, loading, and transporting nuclear substances and hazardous substances;	WM/PT/OP	<ul style="list-style-type: none"> • “Management System for Safety”, SE-LIC-001 (17), previously submitted February 14th, 2022 • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) • “Requirements for the Transport of Radioactive Materials”, 000079.SOP (5) • “Transport of Radioactive Material Program”, SE-OP-036 (6), previously submitted March 22nd, 2024 • “Receiving Radioactive Material”, SE-OP-015 (7), previously submitted May 10th, 2023 • “Shipping Radioactive Material”, SE-OP-014 (11), previously submitted May 10th, 2023 • “Shipping Procedure for the Cobalt Operations Shipper/Receiver”, CO-SR/OP-0002 (3) • “Chemical Handling and Storage”, SE-HS-008 (10) • “Sealed Source Reporting”, SE-OP-079 (24), previously submitted May 14th, 2024
6(f)	the proposed measures to facilitate Canada’s compliance with any applicable safeguards agreement;	SG	<ul style="list-style-type: none"> • “Safeguards Program”, SE-LIC-016 (14)
6(g)	the proposed commissioning program for the systems and equipment that will be used at the nuclear facility;	PD	<ul style="list-style-type: none"> • “Management System for Safety”, SE-LIC-001 (17), Section 5.19
6(h)	the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;	SA/EP	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), previously submitted May 14th, 2024 (current version under review by CNSC) • “Nordion Environmental Protection Program”, SE-ENV-015 (8), previously submitted April 29th, 2024 (current version under review by CNSC) • “Environmental Management System Manual”, SE-ENV-001 (12), previously submitted June 10th, 2022 • “Preliminary Decommissioning Plan for Class 1B Facility (KOB)”, SE-LIC-009 (6), previously submitted December 10th, 2021

	REQUIREMENTS	SCA¹	Response
6(i)	the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;	EP/WM	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), previously submitted May 14th, 2024 (current version under review by CNSC) • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 9 for airborne effluent • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 10 for liquid effluent • “Nordion Class 1B Facility Derived Release Limits”, REP-EHS-009 (1), Section 10 for derived release limit for air and liquid releases
6(j)	the proposed measures to control releases of nuclear substances and hazardous substances into the environment;	EP/WM	<ul style="list-style-type: none"> • “Nordion Environmental Protection Program”, SE-ENV-015 (8), previously submitted April 29th, 2024 (current version under review by CNSC) • “Environmental Management System Manual”, SE-ENV-001 (12), previously submitted June 10th, 2022 • “Soil Monitoring Program”, SE-ENV-017 (6) • “Non-Radiological Environmental Monitoring Program”, SE-ENV-021 (4) • “Radiation Protection Manual - Ottawa Site”, SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) • “Chemical Handling and Storage”, SE-HS-008 (10) • “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)

	REQUIREMENTS	SCA¹	Response
6(k)	<p>the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including measures to:</p> <p>(i) assist off-site authorities in planning and preparing to limit the effects of an accidental release,</p> <p>(ii) notify off-site authorities of an accidental release or the imminence of an accidental release,</p> <p>(iii) report information to off-site authorities during and after an accidental release,</p> <p>(iv) assist off-site authorities in dealing with the effects of an accidental release, and</p> <p>(v) test the implementation of the measures to prevent or mitigate the effects of an accidental release;</p>	EM	<ul style="list-style-type: none"> • Nordion periodically meets with the local Fire, Paramedics, Police, and Ottawa Hospitals to review Nordion emergency management protocols, provide site familiarization, and to review roles of off-site authorities during on-site emergencies. • “Site Emergency Response Plan”, SE-ERP-002 (12), previously submitted May 31st, 2022 • “Radiation Emergency Response Plan”, SE-ERP-011 (7) • “Emergency Response Training and Testing”, SE-ERP-010 (13) • “Fire Safety Plan”, SE-ERP-001 (8), previously submitted December 12th, 2022 • “Fire Safety Plan – Firefighters Copy”, SE-SC-016 (7), 017 (6) and 018 (6)
6(l)	<p>the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts;</p>	NS	<ul style="list-style-type: none"> • “2024 Security Report”, submitted March 1st, 2024. This report contains the Nordion Security Plan covering all aspects of the security program. This is prescribed information. • “Physical Security Threat Assessment”. Updated annually and available to CNSC Security Division review on site at request, as per normal protocol.

	REQUIREMENTS	SCA¹	Response
6(m)	the proposed responsibilities of and qualification requirements and training program for workers, including the procedures for the requalification of workers; and	HP	<ul style="list-style-type: none"> • Job descriptions are available for all Active Area Operations employees. • For professional and administrative support staff, Nordion uses a system of job families to describe job responsibilities and the minimum education requirements. General responsibilities for EHS professionals are described in the Quality, Regulatory Affairs/EHS job family description. • “Management System for Safety”, SE-LIC-001 (17), Sections 4 and 5.6 • “Systematic Approach to Training System”, SE-TRN-006 (9), previously submitted on July 17th, 2023 • “Compliance Environment, Health and Radiation Safety Training”, SE-TRN-003 (16) defines the available EHS training, training frequencies and who requires the training. • Departmental training programs define the initial and continuing training requirements. These are available upon request.
6(n)	the results that have been achieved in implementing the program for recruiting, training and qualifying workers in respect of the operation and maintenance of the nuclear facility.	HP	<ul style="list-style-type: none"> • There are currently 128 Nuclear Energy Workers (NEWs) working in the licenced facility. In the past year, EHS Compliance training has been provided to meet the training frequency described in “Compliance Environment, Health and Radiation Safety Training”, SE-TRN-003 (16). • Training is assigned and tracked electronically in an Electronic Quality Management System (EQMS) that incorporates training management.
<i>Radiation Protection Regulations</i>			
4	Every licensee shall implement a radiation protection program and shall, as part of that program,		
4(a)	keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account, through the implementation of	RP	<ul style="list-style-type: none"> • Radon progeny is not applicable to Nordion

	REQUIREMENTS	SCA¹	Response
4(a)(i)	management control over work practices,	RP	<ul style="list-style-type: none"> • "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002 (8), Section 4.1 • "Nordion Environmental, Health & Safety Responsibilities and Committees", CPM-6-19 (21) • "Management System for Safety", SE-LIC-001 (17), previously submitted February 14th, 2022 • "Radiation Protection Manual - Ottawa Site", SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) • "Work Permit Authorization Program", SE-HS-009 (13)
4(a)(ii)	personnel qualification and training,	RP	<ul style="list-style-type: none"> • "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002 (8), Section 4.2 • "Management System for Safety", SE-LIC-001 (17), Sections 4 and 5.6 • "Compliance Environment, Health and Radiation Safety Training", SE-TRN-003 (16) • "Radiation Surveyors On-the-Job Training Program", SE-TRN-001 (19) for Radiation Surveyors and Monitors • "Cobalt Monitor On-the-Job Training Program", CO-MD/OP-0028 (8) for Sterilization Monitors
4(a)(iii)	control of occupational and public exposure to radiation, and	RP	<ul style="list-style-type: none"> • "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002 (8), Section 4.3 • "Radiation Protection Manual – Ottawa Site", SE-RP-001 (11), Sections 5.6 and 5.7

	REQUIREMENTS	SCA¹	Response
4(a)(iv)	planning for unusual situations; and	RP	<ul style="list-style-type: none"> • "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002 (8), Section 4.4 • "Safety Analysis Reports", CPM-6-20 (18), previously submitted April 8th, 2024 • "Site Emergency Response Plan", SE-ERP-002 (12), previously submitted May 31st, 2022 • "Radiation Emergency Response Plan", SE-ERP-011 (7) • "Nordion Environmental, Health & Safety Responsibilities and Committees", CPM-6-19 (21), Section 5.3 • "EHS Requirements Checklist", SE-EHS-014 (7) • "Change Control Procedure", QAP AP-45 (32) • "External Personal Radiation Monitoring", SE-RP-004 (11) • "Protective Clothing and Gloves in Active Area Laboratories", SE-RP-005 (4) • "Respirator Protection Program", SE-HS-014 (4) • "EHS Committee Approved Activity Limits for Facilities", SE-LIC-007 (23), previously submitted March 18th, 2022 • "Work Permit Authorization Program", SE-HS-009 (13)
4(b)	ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity (i) by direct measurement as a result of monitoring, or (ii) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the quantity and concentration using that method, by estimating them.	RP	<ul style="list-style-type: none"> • "Nordion Environmental Protection Program", SE-ENV-015 (8), previously submitted April 29th, 2024 (current version under review by CNSC) • "Environmental Management System Manual", SE-ENV-001 (12), previously submitted June 10th, 2022 • "Radiation Protection Manual – Ottawa Site", SE-RP-001 (11), Sections 9 and 10 • "Daily Workstation Air Monitoring", SE-OP-007 (19) • "Weekly Environmental Equipment Testing", SE-OP-027 (26) • "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)

	REQUIREMENTS	SCA¹	Response
5(1)	For the purpose of keeping a record of doses of radiation in accordance with section 27 of the Act, every licensee shall ascertain and record the magnitude of exposure to radon progeny of each person referred to in that section, as well as the effective dose and equivalent dose received by and committed to that person.	RP	<ul style="list-style-type: none"> Radon progeny is not applicable to Nordion
5(2)	A licensee shall ascertain the magnitude of exposure to radon progeny and the effective dose and equivalent dose (a) by direct measurement as a result of monitoring; or (b) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the amount of exposure and doses using that method, by estimating them.	RP	<ul style="list-style-type: none"> Radon progeny is not applicable to Nordion
7(1)	Every licensee shall inform each nuclear energy worker, in writing,		
7(1)(a)	that he or she is a nuclear energy worker;	RP	<ul style="list-style-type: none"> “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 5.1 and NEW Acknowledgement forms Appendix H NEW acknowledgement forms, available upon request
7(1)(b)	of the risks associated with radiation to which the worker may be exposed in the course of his or her work, including the risks associated with the exposure of embryos and foetuses to radiation;	RP	<ul style="list-style-type: none"> “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Sections 5.6 and 5.7, and Appendix B “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Sections 5.1 and NEW Acknowledgement forms Appendix H

	REQUIREMENTS	SCA¹	Response
7(1)(c)	of the applicable effective dose limits and equivalent dose limits prescribed by sections 13, 14 and 15; and	RP	<ul style="list-style-type: none"> • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 5.6 • Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 5.1 and NEW Acknowledgement forms Appendix H
13(1)	Every licensee shall ensure that the effective dose received by and committed to a person described in column 1 of an item of the table to this subsection, during the period set out in column 2 of that item, does not exceed the effective dose set out in column 3 of that item.	RP	<ul style="list-style-type: none"> • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Sections 5.6 and 5.7 • “Keeping Radiation Exposures and Doses “As Low as Reasonably Achievable (ALARA)”, SE-RP-002 (8), previously submitted April 29th, 2024 (current version under review by CNSC)
14(1)	Every licensee shall ensure that the equivalent dose received by and committed to an organ or tissue set out in column 1 of an item of the table to this subsection, of a person described in column 2 of that item, during the period set out in column 3 of that item, does not exceed the equivalent dose set out in column 4 of that item	RP	<ul style="list-style-type: none"> • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Sections 5.6 and 5.7

	REQUIREMENTS	SCA¹	Response
20(1)	<p>No person shall possess a container or device that contains a radioactive nuclear substance unless the container or device is labelled with the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT – DANGER – RADIATION"; and</p> <p>the name, quantity, date of measurement and form of the nuclear substance in the container or device.</p> <p>(2) Subsection (1) (2) Subsection (1) does not apply in respect of a container or device</p> <p>(a) that is an essential component for the operation of the nuclear facility at which it is located;</p> <p>(b) that is used to hold radioactive nuclear substances for current or immediate use and is under the continuous direct observation of the licensee;</p> <p>(c) in which the quantity of radioactive nuclear substances is less than or equal to the exemption quantity; or</p> <p>(d) that is used exclusively for transporting radioactive nuclear substances and labelled in accordance with the Packaging and Transport of Nuclear Substances Regulations.</p>	RP	<ul style="list-style-type: none"> • "Radiation Protection Manual – Ottawa Site", SE-RP-001 (11), Section 4.4.4.1 • "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)

	REQUIREMENTS	SCA¹	Response
21(1)	<p>Every licensee shall post and keep posted, at the boundary of and at every point of access to an area, room enclosure or vehicle, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT – DANGER – RADIATION"; if</p> <p>(a) there is a radioactive nuclear substance in a quantity greater than 100 times its exemption quantity in the area, room, enclosure or vehicle; or</p> <p>(b) there is a reasonable probability that a person in the area, room, enclosure or vehicle will be exposed to an effective dose rate greater than 25 µSv/hr.</p>	RP	<ul style="list-style-type: none"> • "Radiation Protection Manual – Ottawa Site", SE-RP-001 (11), Section 4.4.4.1
22	<p>22. Whenever the radiation warning symbol set out in Schedule 3 is used,</p> <p>(a) it shall be</p> <p>(i) prominently displayed,</p> <p>(ii) of a size appropriate for the size of the container or device to which it is affixed or attached, or of the area, room, enclosure or vehicle in respect of which it is posted,</p> <p>(iii) in the proportions depicted in Schedule 3, and</p> <p>(iv) oriented with one blade pointed downward and centred on the vertical axis; and</p> <p>(b) no wording shall be superimposed on it.</p>	RP	<ul style="list-style-type: none"> • "Radiation Protection Manual – Ottawa Site", SE-RP-001 (11), Section 4.4.4.1

	REQUIREMENTS	SCA ¹	Response
<i>Nuclear Substances and Radiation Devices Regulations</i>			
3(1)	An application for a licence in respect of a nuclear substance or a radiation device, other than a licence to service a radiation device, shall contain the following information in addition to the information required by section 3 of the <i>General Nuclear Safety and Control Regulations</i> :		
3(1)(a)	the methods, procedures and equipment that will be used to carry on the activity to be licensed;	OP	<ul style="list-style-type: none"> • “Management System for Safety”, SE-LIC-001 (17), previously submitted February 14th, 2022 • “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), previously submitted April 29th, 2024 (current version under review by CNSC) • Procedures associated with the licensed activity fall into the following categories: <ul style="list-style-type: none"> - EHS procedures which cover radiation protection, chemical handling, calibration, environmental protection, emergency response - Operating procedures for Cobalt processing - Operating procedures for production of Medical Isotopes products - Packaging of nuclear substances - Shipping - Waste handling - Maintenance - Security <p>Environmental, health, and safety procedures are submitted with this application. Other procedures are available upon request.</p>

	REQUIREMENTS	SCA¹	Response
3(1)(b)	the methods, procedures and equipment that will be used while carrying on the activity to be licensed, or during and following an accident, to		
3(1)(b)(i)	monitor the release of any radioactive nuclear substance from the site of the activity to be licensed,	EP	<ul style="list-style-type: none"> “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Sections 9 and 10
3(1)(b)(ii)	detect the presence of and record the radiation dose rate and quantity in becquerels of radioactive nuclear substances at the site of the activity to be licensed,	RP/EP	<ul style="list-style-type: none"> “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 12
3(1)(b)(iii)	limit the spread of radioactive contamination within and from the site of the activity to be licensed, and	EP	<ul style="list-style-type: none"> “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 7 and 14
3(1)(b)(iv)	decontaminate any person, site or equipment contaminated as a result of the activity to be licensed;	RP/EP	<ul style="list-style-type: none"> “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 7 and 14 “Investigations”, SE-RP-003 (17), Section 5.2.1 and Appendix A
3(1)(c)	a description of the circumstances in which the decontamination referred to in subparagraph (b)(iv) of the <i>Nuclear Substances and Radiation Devices Regulations</i> will be carried out;	RP/EP	<ul style="list-style-type: none"> “Radiation Protection Manual – Ottawa Site”, SE-RP-001 (11), Section 7 and 14
3(1)(d)	the proposed location of the activity to be licensed, including a description of the site;	PD	<ul style="list-style-type: none"> “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), previously submitted May 14th, 2024 (current version under review by CNSC)
3(1)(e)	the roles, responsibilities, duties, qualifications, and experience of workers;	HP	<ul style="list-style-type: none"> “Management System for Safety”, SE-LIC-001 (17), Sections 4 and 5.6
3(1)(f)	the proposed training program for workers;	HP	<ul style="list-style-type: none"> “Management System for Safety”, SE-LIC-001 (17), Section 5.6 “Systematic Approach to Training System”, SE-TRN-006 (9), previously submitted July 17th, 2023

	REQUIREMENTS	SCA¹	Response
3(1)(g)	the proposed instructions for dealing with accidents, including fires and spills, in which the nuclear substance may be involved;	EM	<ul style="list-style-type: none"> • “Site Emergency Response Plan”, SE-ERP-002 (12), previously submitted May 31st, 2022 • “Radiation Emergency Response Plan”, SE-ERP-011 (7) • “Fire Safety Plan”, SE-ERP-001 (8), previously submitted December 12th, 2022 • “Fire Safety Plan – Firefighters Copy”, SE-SC-016 (7), 017 (6) and 018 (6) • “Chemical Spill Response Plan”, SE-ERP-1-005 (5) • “Procedure for Containment of Sprinkler Water”, SE-ERP-015 (2)
3(1)(h)	the proposed inspection program for the equipment and systems that will be used to carry on the activity to be licensed;	FS	<ul style="list-style-type: none"> • “Facilities Maintenance Master Plan”, R-Master (15), previously submitted February 19th, 2024 • “Calibration Master Plan”, CP-001 (1), previously submitted April 1st, 2023
3(1)(i)	the methods, procedures and equipment that will be used to calibrate radiation survey meters in accordance with these Regulations;	FS	<ul style="list-style-type: none"> • “Calibration of Survey Meters”, SE-CA-002 (17) • “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)
3(1)(j)	the methods, procedures and equipment that will be used to calibrate and verify the calibration of dosimeters referred to in paragraphs 30(3)(d) and (e) of the <i>Nuclear Substances and Radiation Devices Regulations</i> ;	FS	<ul style="list-style-type: none"> • “Testing of Direct Reading Dosimeters”, SE-CA-008 (6) • “External Personal Radiation Monitoring”, SE-RP-004 (11)
3(1)(k)	the methods, procedures and equipment that will be used to conduct the leak tests and surveys required by these Regulations;	FS	<ul style="list-style-type: none"> • “Radioactive Material Inventory”, SE-LIC-015 (21), Section 13 • “Underwater Source Swipe Tests for Detection and Isolation of Leaking Source Capsules in Pool #13”, CO-PRD/OP-0072 (5) • “Operation of Varian Leak Detection Software”, CO-C5/IT-0004 (7) • “Ultrasonic Effluent Test Procedure”, CO-PRD/OP-0033 (10) • “Dry Wipe Test”, CO-PRD/TP-0003 (5) • “Helium Leak Test of Sub-Assemblies and Capsule Components”, CO-PNG/IT-0001 (2) • “Outer Capsule Welding and Leak Testing for Elekta Process Using Mini-Trays”, CO-C5/OP-0019 (9)

	REQUIREMENTS	SCA¹	Response
3(1)(l)	where the application is in respect of a nuclear substance that is an unsealed source and that is to be used in a room, the proposed design of the room;	PD	<ul style="list-style-type: none"> • “Final Safety Analysis Report for Cobalt Operations”, IS/SR 1057 Z000 (12), previously submitted May 14th, 2024 (current version under review by CNSC) • “Final Safety Analysis Report for Cobalt Pools”, IN/SR 2638 Co60 (4) July 22nd, 2020
3(1)(m)	if the application is in respect of a nuclear substance that is contained in a radiation device, the brand name and model number of the radiation device, and the quantity of the devices;	PD	<ul style="list-style-type: none"> • Gammacell 220, Serial Number 59. • Any serial number of Gammacell 220 devices brought to the facility for refurbishment and use or for servicing.
3(1)(n)	where the application is in respect of Category I, II or III nuclear material, as defined in section 1 of the <i>Nuclear Security Regulations</i> ,	N/A	Not applicable
3(1)(n)(i)	the measures that will be taken to prevent nuclear criticality, and	N/A	Not applicable
3(1)(n)(ii)	the information required by section 3 or 4 of the <i>Nuclear Security Regulations</i> , as applicable;	N/A	Not applicable
3(1)(o)	if the applicant will be manufacturing or distributing radiation devices referred to in paragraph 5(1)(c) of the <i>Nuclear Substances and Radiation Devices Regulations</i> or section 6 or 7 of the <i>Nuclear Substances and Radiation Devices Regulations</i> , or check sources mentioned in section 8.1 of the <i>Nuclear Substances and Radiation Devices Regulations</i> , the proposed procedure for the disposal of each radiation device or check source or for its return to the manufacturer.	WM	Not applicable

	REQUIREMENTS	SCA¹	Response
4.	An application for a licence to service a radiation device shall contain the following information in addition to the information required by section 3 of the <i>General Nuclear Safety and Control Regulations</i> :	N/A	Not applicable
4.(a)	the brand name and model number of the device or the number of the certificate relating to the device;	SA	<ul style="list-style-type: none"> • Gammacell 220 Irradiator
4(b)	a description of the nature of the servicing proposed to be carried on;	SA	<ul style="list-style-type: none"> • Servicing of the Gammacell 220 consisting of the following: <ul style="list-style-type: none"> ○ Source removal and reloading ○ Surveying ○ Wipe tests ○ Routine preventative maintenance ○ Maintenance as required for repairs (e.g. replacement of broken switches, motor repairs) • Servicing of any Gammacell 220 Irradiator at the Nordion Ottawa location. The devices would be brought to the facility to refurbish and use at the Nordion Ottawa location or to service and return to the customer.
4(c)	the proposed methods, procedures and equipment for carrying on the servicing;	SA	<ul style="list-style-type: none"> • “Gammacell 220 Spare Parts List”, IN/DS 1087 GC220 (5) • “Installation Procedure for Gammacell 220 Irradiators”, IN/IN 0060 GC220 (2) • “Gammacell-200 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)
4(d)	the proposed qualification requirements and training program for workers; and	SA	<ul style="list-style-type: none"> • “Installation and Service Technician Training Program”, IN/OP 2642 Z000 (4)
4(e)	the proposed procedures to be followed after completion of the servicing to confirm that the device is safe to use.	SA	<ul style="list-style-type: none"> • “Gammacell-220 Inspection Procedure – Field Function Only”, IN/IM 0062 J0300 (2) • “Radiation Survey Report for the GC-220”, IN/IM 0308 GC220 (6)

	REQUIREMENTS	SCA ¹	Response
<i>Nuclear Security Regulations</i>			
41	An application for a licence in respect of a nuclear facility shall contain, in addition to the information required by sections 3 to 8 of the <i>Class I Nuclear Facilities Regulations</i> , a description of the physical protection measures to be taken to ensure compliance with sections 42 to 48.	NS	<ul style="list-style-type: none"> • “2024 Security Report”, submitted March 1st, 2024. This report contains the Nordion Security Plan covering all aspects of the security program. This is prescribed information. • “Facility Access Security Clearance”, SE-SC-005 (4) • “Security Guard Vehicle Inspection Post Orders”, SE-SC-014 (6). This is prescribed information. • “Written Arrangements between Nordion (Canada) Inc. and the Ottawa Police Service pursuant to Section 47 of the Canadian Nuclear Security Regulations”. This is prescribed information.

ACRONYMS

SCA	Safety and Control Area	EP	Environmental Protection
MS	Management System	EM	Emergency Management and Fire Protection
HP	Human Performance Management	WM	Waste Management
OP	Operating Performance	NS	Security
SA	Safety Analysis	SG	Safeguards
PD	Physical Design	PT	Packaging and Transport
FS	Fitness for Service	OMRI	Other Matters of Regulatory Interest
RP	Radiation Protection	N/A	Not Applicable
CHS	Conventional Health and Safety		

Attachment 2: Summary of Facility and Program Improvements Since 2015

SCA	FACILITY AND PROGRAMS IMPROVEMENTS: 2015 to 2023
Management System	<ul style="list-style-type: none"> • The Management System for Safety (MSS) (previously known as Quality Assurance (QA) Program for Safety) and the internal audit program were expanded to include other program areas following Canadian Nuclear Safety Commission (CNSC) guidance • Management System for Safety was revised to align with the new CSA Standard N286-12, “Management System Requirement for Nuclear Facilities” • MSS Program was revised to add details as per CNSC comments to further align with the CSA Standard N286-12, “Management System Requirement for Nuclear Facilities” • Nordion implemented a behavioral based safety awareness program to encourage safety discussions within the organization and to encourage employees to report near misses and hazard identifications • Revised procedure for management of work in the Medical Isotopes Facility to reflect that work is sub-contracted to BWXT. The revision captured the changes made for the management of documents, work procedures, drawings, software, dosimetry, training and use of a standalone IT Common Business System (CBS), and to add details regarding workflow for design drawings changes, training, communications, problem identification and resolution and operations • Revisions to update the MSS Program were initiated in 2021 and completed in early 2022 due to BWXT obtaining an operating license and to update the associated procedures, roles and responsibilities within the stand-alone Nordion MSS Program
Human Performance Management	<ul style="list-style-type: none"> • Completion of the SAT Job Task Analysis (JTA) and the revision of the training programs for the following positions where the core duties of the positions are safety related: <ul style="list-style-type: none"> ○ Cobalt Monitors ○ Installation and Service Technicians ○ Surveyors. <p>JTA was also completed for numerous positions that have embedded safety related tasks, but where their core role is not a safety function.</p> • Modification of various safety training programs from in-class to self-directed training • Improved Contractor training by transitioning from read and understand training to annual in-class training • Assessment of all key occupational health and safety courses
Operating Performance	<ul style="list-style-type: none"> • Creation and implementation of two compliance awareness courses for personnel with roles related to reporting to the CNSC Sealed Source Tracking System • Modified where the tracking system retrieved the export license number within the electronic databases management system preventing duplication and reducing error associated with manual entries • Implemented a process for reporting amendments to the export license number to the CNSC • Improved manual reporting process to ensure reporting of all the required

SCA	FACILITY AND PROGRAMS IMPROVEMENTS: 2015 to 2023
Operating Performance (cont'd)	<p>information within the required timeframe</p> <ul style="list-style-type: none"> • Implemented monitoring of sealed source receipts/imports and an electronic alert message to advise when sources are received into the building, but not yet entered into the tracking system • Introduced verification steps for the following manual entries: updating shipment date in tracking system by Forecasting & Planning Department, manual reporting of amendments to the Export License number, and manual revisions of the bulk file • Revised process for review of domestic site licenses to ensure the most recent radioactive material licenses are reported • Simplified process for routine waste shipments by changing responsible department for revising shipment dates in the tracking system • Streamlined the sealed source reporting procedure and developed a Job Aid for the SSTS Bulk Upload to the CNSC web portal • Various continuous improvements were completed in 2021, including but not limited to procedural changes to provide additional guidance to personnel for confirming sender information for SSTS reporting for received sources, and for confirming sender/recipient license information for SSTS reporting of domestic transfers of sources • The internal processes for reallocated Co-60 sources to a different end user after SSTS reporting has been completed were improved in 2022
Safety Analysis	<ul style="list-style-type: none"> • Modification in the KOB Mechanical room to meet seismic requirements • Created Cobalt Pool Safety Analysis Report • Nordion undertook a gap analysis of its safety analysis program against REGDOC-2.4.4, "Safety Analysis for Class 1B Nuclear Facilities". Minor, administrative changes are being made to Nordion's program based on this gap analysis
Fitness for Service	<ul style="list-style-type: none"> • Installed permanent in-pool deionizer system • Installed new Miura boiler in Mech Room 5 • Replacement of the KOB lower roof • Installation of a manual transfer switch for redundancy between the three emergency power generators • Installed stack 2 manual transfer switch • Replacement of breakers and cradles in the KOB electrical power distribution system • Modifications to improve HVAC to Human Resources area • Replaced a medium voltage load breaker switch in the Kanata Operations Building (KOB) electrical room • Upgraded motor controls on plant chillers to variable frequency speed control • Installation of reheat coil for air handling unit (AHU) #40 • Installation of re-circulation pumps (glycol) at AHU #1 and #3 • Chiller Upgrade in Heating Plant; refurbishment project as part of necessary maintenance • Chiller Upgrade included replacement of chiller starters with Variable Frequency Drive controlled chiller starters • Installed secondary water main on Solandt Road

SCA	FACILITY AND PROGRAMS IMPROVEMENTS: 2015 to 2023
Fitness for Service (cont'd)	<ul style="list-style-type: none"> • Repaired air conditioner in Roy Errington (RE) basement phone room • Replacement of dock levelers on Shipping Door 6-9 and Door 6-7 • Replacement of Motor Controls on Chilled Water Condenser Pump • Upgraded condenser pump controls for the chilled water system (to Variable Frequency Drives) • Installed back flow preventers at the KOB, Kanata Radiopharmaceutical Manufacturing Facility (KRMF) and RE buildings • Replaced domestic water line in KOB Active area, no structural changes to designated Active areas • Upgraded valves and valve operators for the chilled water system • Replacement of culvert on March Road • Relocation of Bell Services from RE Building • Retrofitted facility for BXWT separate access • Relocated rooms and modified fire doors to security equipment as a result of sale to BWXT • Installed new milling machine in Cobalt Machine Shop • Modified ventilation in Room 1132 (Cobalt) fume hoods to the new sectioning saw • Cell 1 demolition and site preparation • Construction work continued for new hot cell (Cell 1) in the COF that was started in 2020 and completed in 2023 • Introduced new TIG brush cleaning unit for cleaning contaminated equipment • Installed Cell 1 • Installed Cell 1 Nuclear Ventilation System tie-in • Replacement of roof on the Cobalt building • Installed new industrial style 3D printer in Room 1139B (Active Lab) • Implemented Hytorc electric torque tool to help reduce ergonomic strain injuries from torquing • Rerouted Cobalt washing machine to low level liquid waste • Implemented in-cell probe in Cell 2 • Upgraded BMS (hardware and software) • Installed a storage mezzanine in the Cobalt Shipping area • Upgraded Liburdi welding cabinets
Radiation Protection / ALARA	<ul style="list-style-type: none"> • Installed new airflow monitoring detectors in Cobalt to improve measurement of stack flow at air release compliance monitoring sampling points • Created a new procedure to outline the necessary steps to maintain and use Nordion's database for creating calibration certificates for over 800 radiation detector calibrations performed annually • Efforts to monitor and track unreturned dosimeters • Purchased a new source for the radiation survey meter calibrations (SN 3007GG). The new higher activity source ensured compliance with precision in distance requirements • Designed, built, and installed a shield for the Cobalt whole-body scanner in men's change room to lower background radiation levels and increase sensitivity and reliability of performance • An analysis of doses to Cobalt operations personnel was performed to determine if there were any trends that could lead to further improvements. The analysis found that doses were well controlled. • Updated radiation protection program to reflect changes to the Radiation

SCA	FACILITY AND PROGRAMS IMPROVEMENTS: 2015 to 2023
Radiation Protection / ALARA (cont'd)	<p>Protection regulations</p> <ul style="list-style-type: none"> • Installed a new whole-body scanner in the women's change room in Cobalt operations
Conventional Health and Safety	<ul style="list-style-type: none"> • Developed a back awareness training challenge • A new document was created to outline biosafety guidelines • Created a series of stretch videos to help teach employees about various stretches that they can perform at various times throughout their shift • Routine "Safety Focus Talks" were created for managers to provide to their teams • An EHS compliance management software was implemented for incident, near miss and hazard identification reporting and all employees were trained on its use • A formal site-wide reassessment was completed related to designated substances and materials containing asbestos • A formal occupational health and safety manual was developed • A formal pre-start health and safety review procedure was established • Safe handling of silica and mercury programs were established • Improvements were made to the Asbestos Management Program and an Asbestos Inventory was established • Nordion's Confined Space assessment was reassessed and updated • Improvements were made to on-site chemical spill kits • Improvements were made to facility eyewash stations • Improvements were made to hoisting safety program • Improvements were made to respirator protection program • Chemical awareness training was updated to include reference to WHMIS 2015 • Updated the Right to Refuse Dangerous Work procedure • Introduction of a behavioural based safety awareness program • Improvements were made to the Lead Control Program and training was updated and provided to applicable employees • Reviewed and updated Fall Protection training and provided to applicable employees. Some equipment specific training was also conducted • Implementation of the WHMIS 2015 requirements • Completion of Chemical Spill Response training • Rolled out of Canada Labour Code Part II training for managers • Implementation of a Working Alone procedure • Implementation of a Bio-Safety procedure • Updated the departmental Job Hazard Analysis and Risk Assessment process • Improvements were made to documents for reporting of occupational injuries, and work reintegration • Improvements were made to the Work Permit procedure • Improvements were made to the Manual Material Handling procedure • Improvements were made to the Respirator Program • Created a Machine Guarding Program • Improvements were made to the Hearing Conservation Program • Creation of COVID related programs/processes (education, response, decontamination) • Installed new Safety Boards in key locations throughout the site • Developed safety scorecard to track leading and lagging metrics

SCA	FACILITY AND PROGRAMS IMPROVEMENTS: 2015 to 2023
Conventional Health and Safety (cont'd)	<ul style="list-style-type: none"> • Developed a Hand Protection Policy
Environmental Protection	<ul style="list-style-type: none"> • Implementation of the CSA standards N288.4, N288.5, and N288.6 which included developing a formal Environmental Risk Assessment, revising Nordion's Derived Release Limits and developing Nordion's Environmental Monitoring Program. • Initiated changes to the Environmental Management System (EMS) to meet the requirements of ISO 14001:2015 • Implemented changes to the EMS System to meet the requirements of ISO 14001:2015 • Updated risk assessments for lead, silica, and mercury • Undertook a comprehensive review and implemented improvements of sanitary release program
Emergency Management and Fire Protection	<ul style="list-style-type: none"> • Developed a Transient Combustible Materials Management Program with the assistance from a third party • Revised documents and practices to align with N393-13, "Fire Protection for Facilities that Process, Handle, or Store Nuclear Substances" • Developed training for all employees on fire prevention and safety • Provided Fire Watch training to applicable staff • Generated new documents and revised existing emergency management program documents and all sub-plans to reflect the updated program and incorporate Incident Management System. The revised program documentation incorporated the elements of REGDOC 2.10.1 "Nuclear Emergency Preparedness and Response". • Revised Nordion's Fire Safety Plan (SE-ERP-001) to align with Incident Management System protocol • Completion of project to replace halon fire suppression in hot cells with argon, or in some instances, removed in-cell fire suppression as for some cells, combustible loading is minimal • Implemented Fire Watch and Fire Extinguisher Training for applicable staff • Completed program enhancements to address minor areas for improvement identified in exercises and drills and other continuous improvements included: <ul style="list-style-type: none"> ○ Designed and implemented minor revision to the program to address items identified during the 2016 major exercise ○ Designed and implemented a two-way radio training program for responders ○ Provided orientation visits to approximate 90 fire fighters from two responding stations. ○ Onboarded 3 new Incident Managers ○ Created refresher training courses • Completed a fire response training needs analysis for the Fire Protection Program • Completed a Fire Response Needs Analysis to meet requirements of CSA Standard N393, "Fire protection for facilities that process, handle, or store nuclear substances" • Implemented Fire Extinguisher Training for applicable staff • Designed and implemented minor plan adjustments related to the sale of the Medical Isotopes business. These were limited to command and control relationships and liaison. The response plans were otherwise unchanged due

SCA	FACILITY AND PROGRAMS IMPROVEMENTS: 2015 to 2023
<p>Emergency Management and Fire Protection (cont'd)</p>	<p>to the sale</p> <ul style="list-style-type: none"> • Created additional refresher training courses using online delivery tool • Held a tabletop exercise involving the Incident Command Post personnel pool as participants or observers • Updated the Fire Safety Plan and Fire Warden and Fire Marshall Responsibilities procedures. • Added “expected Emergency Response Organization activation times” to better define expected response times from key emergency response plan personnel • General update to program documentation to include BWXT personnel and associated contact information in the program • Minor update to contact information for key personnel • Designed and implemented minor revisions to the program to address items identified during the 2019 major exercise • Replaced all combustible strapping for compressed air tanks to a non-combustible alternative • The response to the Covid-19 pandemic was the primary focus in 2020 and 2021. Significant effort was required to maintain a safe facility and to reduce any impacts. Continuous adaptation was required as the external situation and guidelines changed very frequently. These adaptations were active program improvements and Nordion was very successful in mitigating the pandemic’s impact • Initiated updates to the Fire Hazard Analysis in 2020, which was finalized in 2021 • Updated the Fire Safety Plan and Fire Warden and Fire Marshall Responsibilities procedures • Updated the Fire Protection Program • Created a new “Fire Protection System Impairments” procedure to supplement the “Work Permit Authorization Program” • Conducted a revised Code Compliance Review and Fire Hazard Assessment • Updated the Fire Safety Plan • Equipment upgrades, including additional Incident Command Post vests • Actioned on program enhancements to address CNSC recommendations on Emergency Management inspection in 2022 • Conducted Fire Protection Program Audit • Conducted a gap analysis against CSA N393-22, NBCC 2020 and NFCC 2020. • Provided tour/orientation to approximately 80 Ottawa Fire Services personnel
<p>Waste Management</p>	<ul style="list-style-type: none"> • Secured waste bins in the Heating Plant • Worked with the waste service provider to include coffee cups in the organics waste stream, reducing the demand on landfills • Replaced non-radiological waste diversion program signage throughout the facilities in an effort to improve program performance

SCA	FACILITY AND PROGRAMS IMPROVEMENTS: 2015 to 2023
Waste Management (cont'd)	<ul style="list-style-type: none"> • Reduced the amount of waste from Ir-192 process sent to CNL. Several small projects completed to reduce Ir-192 process wastes and to optimise filling of the waste package. This work is related to a Nordion initiative to reduce Ir-192 process wastes and implement the practise of storing Ir-192 process waste for decay and then sending to Energy Solutions Inc. as low-level waste (versus continuing to send to CNL)
Security	<ul style="list-style-type: none"> • Renovation and enhancement of the Security Control Centers • Installation of network security hardware • Upgrading of the Security Systems • Upgrading the Security cameras and alarms • Installation of new lighting in and around the facility
Safeguards & Non-Proliferation	<ul style="list-style-type: none"> • Revised to remove the requirement for submission of two nuclear material accountancy reports following CNSC confirmation that some of the reporting requirements in RD-336 could be reduced • The safeguards program document was revised and reorganized to align with and demonstrate compliance with REGDOC-2.13.1 • Nordion initiated the process to exempt transport containers model number 3300 and 3750 that contained depleted uranium (DU). As of December 31st, 2021, eight containers were granted exemption by the IAEA: one of model number 3300 and seven of model number 3750 • As of December 31st, 2022, an additional ten DU packages were granted exemption by the IAEA: four of model number 3300 and six of model 3750. • The request to exempt the final two DU transport packages model 3300 remains outstanding since January 2022
Packaging and Transport	<ul style="list-style-type: none"> • Updated training to a virtual format
Public Information	<ul style="list-style-type: none"> • Updated the Social Responsibility content on Nordion.com and gave the section greater prominence in the navigation • Added an Emergency Preparedness section to the Nordion website • A comprehensive Virtual Tour was published on the website • Updated the Nordion Public Information Program to align with CNSC REGDOC-3.2.1 • Transitioned to a virtual community outreach event during COVID to ensure community engagement continued



Nordion Class 1B Facility

447 March Road
Ottawa, ON, Canada K2K 1X8

Attachment 3: Supplementary
Report to Support License Renewal

447 March Road

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TABLE OF CONTENTS

1. INTRODUCTION.....	1
1.1 Background	1
2. BUSINESS PLAN.....	1
3. SAFETY AND CONTROL AREAS (SCAS).....	2
3.1 Management System	2
3.2 Human Performance Management	4
3.3 Operating Performance	5
3.4 Safety Analysis	6
3.5 Physical Design	7
3.6 Fitness for Service	8
3.7 Radiation Protection	9
3.8 Conventional Health and Safety	10
3.9 Environmental Protection	10
3.10 Emergency Management and Fire Protection	12
3.11 Waste Management	13
3.12 Security	15
3.13 Safeguards and Non-Proliferation	15
3.14 Packaging and Transport	16
3.15 Reporting	17
3.16 Public Information and disclosure program	17
3.17 Indigenous engagement	18
3.18 BWXT Medical	18
GLOSSARY.....	19

1. INTRODUCTION

This Supplementary Report was prepared to support Nordion's application for operating license renewal. This report was prepared using the document REGDOC 1.2.2, "Licence Application Guide: Class 1B Processing Facilities".

1.1. Background

Nordion is a major global supplier of Cobalt-60 sealed sources used in cancer therapy and irradiation technologies.

Nordion's innovative and industry-leading technologies 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 facility, the Kanata Operations Building (KOB) is located at 447 March Road, Ottawa, Ontario.

The KOB comprises an administrative area known as the "Non-Active Area" and a controlled access production area known as the "Active Area". The Active Area encompasses the Cobalt Operations Facility (COF), the Nuclear Medicine Production Facility (NMPF), and the Kanata Radiopharmaceutical Manufacturing Facility (KRMF).

In 2018, Nordion divested the Medical Isotopes business to BWXT Medical. BWXT continues to lease the NMPF and KRMF portions of the facility at 447 March Road, along with some non-active area office space, from Nordion. 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 sealed radioactive sources.

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

2. BUSINESS PLAN

Today, Nordion's primary business is Gamma Technologies. The Gamma Technologies business is focused on producing high activity sealed sources, primarily for the medical and industrial sterilization markets. The industrial sterilization market is expected to grow by approximately 3-5% per year. This would require sealed source growth to match.

Site and production facilities are routinely assessed for improvement and replacement of legacy structures and equipment under its current licensing basis. A number of improvements have been made during the current licence period (see Attachment 2). 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 is expected to have an operational life extending far beyond the requested licensing period of 25-years.

At the end of the proposed 25-year licence period, Nordion anticipates it will continue to operate. There is no foreseeable shutdown and decommissioning of the facility.

Below is a summary of large projects and significant activities anticipated for the next license period:

- Completion and use of Cell 1
- Upgrade of electrical infrastructure
- Upgrade of Building Management Systems (BMS)

These projects are not expected to have a significant impact on safety and will be undertaken with the framework of Nordion's Management System for Safety.

3. SAFETY AND CONTROL AREAS (SCAs)

3.1. 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.

3.1.1. General considerations

Nordion has implemented an Environmental, Health and Safety (EHS) Policy (CPM-6-06) which described the company's commitment to operate in a safe and responsible manner that respect 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.

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.

The Nordion program is certified to the ISO:9001 and ISO:14001 standards.

3.1.2. Management system

Nordion has implemented SE-LIC-001, "Management System for Safety" (MSS). This program aligns with REGOC-2.1.1, "Management System" and meets the requirements of CSA N286:12, "Management system requirements for nuclear facilities".

Nordion's MSS (SE-LIC-001) and Environmental Management System (EMS) (SE-ENV-001) provide the means of controlling those activities that affect safety of Canadian Nuclear Safety Commission (CNSC) licensed activities. These programs apply to all CNSC licensed activities conducted under the Class 1B nuclear substance and processing facility operating license.

The MSS controls work carried out to perform, or in support of, licensed activities from the planning stages to completion, and covered 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 maintained overall accountability and ensures that communication between individuals and organizations is effective and in the interest of safety.

The EMS is certified to ISO 14001, 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.

3.1.3. Organization

Nordion's senior management organization structure and the EHS organizational structure is provided in the organizational charts (see Appendix A of application).

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 described in section 3.1.1, 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 changes to FSARs, infrastructure work, changes to licensing basis, etc.

3.1.4. Performance assessment, improvement and management review

Performance reviews of the MSS and the EMS are conducted on a routine basis by the EHS Committee. At each EHS Committee meeting, the Committee reviews Nordion's EHS performance, including the status of EHS corrective actions and preventive actions (CAPAs), results of EHS incidents or investigations, status of EHS objectives and targets, internal EHS audit findings, and the status of actions from previous meetings. The EHS Committee reviews the information and documents actions resulting from the review in the meeting minutes.

In addition, the 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 (see section 3.3.1). In addition, the management review involves the evaluation of:

- Actions from the previous meeting
- The EHS Policy (CPM-6-06)
- Adequacy of resources
- EHS objectives and targets
- Changing circumstances
- Recommendations for improvement

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

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

3.1.5. Operating Experience

The EHS Committee has responsibility for conducting reviews of Operating Experience (OPEX). The OPEX process is an information gathering and review process to identify, obtain and evaluate in-house and external experiences related to the operations conducted under Nordion's operating facility license. The analysis of this information is used to take action to improve safety and the management processes.

3.1.6. Change Management

Nordion has established a change control process as part of the MSS (QAP AP-45). This is to ensure any changes are justified, reviewed, and approved by appropriate personnel, and to ensure their effect on existing conditions is assessed. The EHS Committee approves all significant changes to facilities.

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 designs met established codes and standards and all applicable requirements.

3.1.7. Safety culture

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

Nordion typically assesses the health of the safety culture at Nordion every three years.

3.1.8. Configuration management

Configuration management is a component of Nordion's change management program. Any changes to current configurations are reviewed and approved by appropriate personnel (see section 3.1.6).

3.1.9. Records Management

Nordion has implemented a program for the control and retrieval of records management. Requirements and responsibilities for the identification, storage, protection, retrieval, retention and disposal had been established for key licensing records, as described in section 5.8.4 of SE-LIC-001. Nordion continues to migrate to electronic format for key records.

3.1.10. Business continuity

Nordion has implemented an Emergency Response Center (ERC) framework under SE-ERP-002, "Emergency Response Plan" 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.

3.2. Human Performance Management

3.2.1 General considerations

Nordion has implemented a performance management program under SE-LIC-001 that ensures there are sufficient workers with the required knowledge and skills.

Nordion has defined competency criteria for key positions within the MSS. These are described in SE-EHS-024, "EHS Competence Criteria". Job descriptions define the requirements of unionized positions.

The Director and Manager of each department is 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.

There is a minimum of 1, and typically 2 Health Physicists on call to address potential radiation events.

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.

3.2.2 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.

3.2.3 Personnel training

Nordion has implemented a systematic approach to training program described in SE-TRN-006 to meet the requirements of REGDOC 2.2.2, "Personnel Training".

Employees who are not classified as Nuclear Energy Workers (NEWs) receive a basic course on Health, Safety and Environment, which provides information on the facilities, emergency response procedures and alarms, and basic procedures to follow for safety in the workplace. NEWs receive a NEW Indoctrination Course. To be authorized to enter the Active Area unescorted, the employee must complete and pass a written test, as evidence of understanding the principles of radiation protection and Nordion safe work practices. NEW retraining and retesting are conducted on a three-year frequency. In addition, NEWs are provided with a half day Radiation Instrumentation Workshop, dealing specifically with the selection and use of radiation survey and contamination meters for the Active Area.

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:

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

3.2.4 Work Organization and job design

Minimum staff complement is described in section 3.2.1.

3.2.5 Fitness for duty

Nordion is not a high security site and this section does not apply.

3.3. Operating Performance

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

3.3.1. 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 remains with specifications and are carried out safely.

Structures, systems and components (SSCs) are regularly maintained and inspected (see section 3.5).

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 and reported 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, the effectiveness of corrective action taken and whether additional corrective action is needed. The EHS Performance Report is distributed and reviewed by the EHS Committee in the annual Performance Review of the MSS and the EMS (see section 3.1.4).

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

Nordion maintains an inventory of non-production radioactive sources and material under SE-LIC-015, "Radioactive Material Inventory".

3.3.2 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 included design control, procurement, operations, shipping, receiving, handling and maintenance. The department and, where appropriate, the identity of the person performing the work was 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 were identified and scheduled to verify that specific requirements are met. Procedures, instructions, drawings, programs, and tools were identified, prepared and approved for use.

Safety analysis reports for sealed source manufacturing (IS/SR 1057 Z000, "Final Safety Analysis Report for Cobalt Operations") described the following:

- Operations within the KOB
- The potential radiation safety and occupational safety hazards that exist
- The worst-case accident scenarios
- 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.

3.3.3 Procedures

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

3.3.4 Operating limits and conditions

Nordion has defined safety operating limits and conditions through the Final Safety Analysis Reports (FSARs) and in SE-LIC-007, "EHS Committee Approved Activity Limits for Facilities". These limits are posted at hotcells and pool storage locations. Any exceedance of the operating limits and conditions would be investigated to determine root cause and appropriate corrective actions implemented.

3.4 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.

3.4.1 General considerations

Safety analysis is performed according to an established process as outlined in CPM-6-20, "Safety Analysis Reports". Safety assessments are performed for new Active Area facilities or processes or when changes are to be performed on a facility, ventilation system, safety system, equipment, operation or process which will 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.

The safety case for the overall facility is maintained in the COF and the Cobalt Pools FSARs (IS/SR 1057 Z000, "FSAR for Cobalt Operations" and IN/SR 2638 Co60, "FSAR for Cobalt Pools"). These two primary FSARs described the operations within the facility, 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 (IN/SR 1859 C000, "FSAR for Waste Diversion Program" and IN/SR 2315 Co60, "FSAR for Cobalt Operations Radioactive Waste Management") are also prepared to provide analysis of the safety hazards unique to those areas. 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 reviewed and updated the Fire Hazard Analysis in 2021 and remains valid. The Fire Hazard Analysis was conducted by a qualified third party and assessed potential risks from a fire to personnel safety, property and operations, and the environment to ensure these risks 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.

Annually, a third party conducts a compliance review regarding inspection, testing and maintenance of Nordion's Fire Protection System. These reviews are submitted to the CNSC.

3.4.2 Criticality safety

Nordion does not handle fissionable materials.

3.5 Physical Design

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

3.5.1 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.

3.5.2 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 in accordance with Nordion's change control procedure (QAP-AP-45). 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 (e.g. the installation of new facilities, the design of new production processes, modifications to existing facilities or processes, and changes to the Nuclear Ventilation System (NVS)).

3.5.3 Site characterization

The detailed site characterization is provided in the FSARs.

3.5.4 Facility design

The facility is described in both SE-LIC-018, "Facility Description" and the FSARs.

3.5.5 System and component design

The characteristics and major components of the systems applicable to the licenced activities are described in the FSARs.

3.5.6 Waste treatment and control

Wastewater from the active area is collected in delays tanks. The tanks are sampled for radioactivity concentrations and is released only if within the limits set out in the licence.

3.5.7 Control facilities

Nordion's infrastructure (i.e. hotcells 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.

3.5.8 Structure design

The structure is described in the Cobalt Facility FSARs.

3.6 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.

3.6.1 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. Maintenance and inspection frequency is identified through the change control process and is administered through Nordion Advanced Maintenance Management System (AMMS).

3.6.2 Maintenance program

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 AMMS to control Nordion's calibration and maintenance activities. The AMMS is used to catalogue all equipment requiring calibration or maintenance, record equipment information, schedule maintenance, and issue work orders.

Detailed processes and rules governing the preventative maintenance program are available in R-Master, "Facilities Maintenance Master Plan" and CP-001 "Calibration Master Plan".

The AMMS provides the necessary oversight to ensure equipment integrity. All equipment inspections and preventative maintenance schedules are dictated by the use of the AMMS.

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.

3.6.3 Aging management program

Aging management is covered under Nordion's maintenance program (see section 3.6.2).

3.6.4 Periodic inspection and testing programs

Maintenance and inspection of SSC's important to safety performed under the maintenance program (see section 3.6.2). Pressure vessels and boilers are authorized under the TSSA. Required inspections were performed by Nordion's insurer Zurich Canada who provide the inspection reports to the TSSA.

3.7 Radiation Protection

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

3.7.1 General considerations

Nordion has measures and systems in place to ensure that radiation exposure to employees and the public are kept ALARA. This reflects the corporate commitment to provide employees with a safe and healthy work environment and to protect the public and the natural environment as described in CPM-6-06, "Nordion Environmental, Health and Safety Policy", and CPM-6-19, "Nordion Environmental, Health and Safety Responsibilities and Committees".

Nordion has in place a program to keep radiation doses received by workers and members of the public ALARA under SE-RP-001, "Radiation Protection Manual – Ottawa Site" and SE-RP-002, "Keeping Radiation Exposures and Doses ALARA". This program defined requirements for 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. 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 Nuclear Energy Workers (NEWs) and are assigned monthly dosimeters from a dosimetry service company licensed by the CNSC. Nordion refers to these personnel dosimeters as 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. Nordion has also developed approved activity limits for hotcells and storage pools to control employees’ external radiation exposure. Use of activity in excess of these limits is only allowed under approved Work Permit.

Deviations to the radiation protection program are investigated, root causes determined, and corrective actions implemented (SE-RP-003, “Investigations”).

3.8 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.

3.8.1 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
- 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 on a monthly basis.

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

3.9 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.

3.9.1 General considerations

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
- 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 garbage or sewer systems.

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

3.9.2 Effluent and emission control

3.9.2.1 Airborne Effluent

Production operations are contained within hotcells 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, 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.

Ventilation and stack sampling is conducted by using particulate. Particulates are sampled by use of cellulose filter papers and analyzed by gamma measurement.

3.9.2.2 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.) was collected in holding tanks and then sampled and analyzed against derived release limits to ensure that it is in compliance with license conditions prior to being released to the municipal sanitary sewer.

3.9.3 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*"
- CSA N288.4, "*Environmental Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills*"
- CSA N288.5, "*Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills*"
- CSA N288.6, "*Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills*"

In addition, Nordion's Environmental Protection Program meets the requirements of ISO 14001, "*Environmental management systems – Requirements with guidance for use*".

Nordion's environmental protection program is described in SE-ENV-015, "Nordion Environmental Protection Program" and SE-ENV-001 "Environmental Management System". The program ensures the control, monitoring and recording of releases of radionuclides and hazardous substances to the environment.

3.9.4 Assessment and monitoring

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

Nordion monitors groundwater annually for both non-radioactive and radioactive contaminants. This monitoring is done to ensure there are no significant changes in results since the Limited Phase I and Phase II Environmental Site Assessment which was conducted by an environmental engineering company for Nordion in August 2005.

Since 2006, quarterly sampling of the sanitary releases is conducted to analyze for non-radiological contaminants and ensure they remain with the City of Ottawa by-law limits.

3.9.5 Protection of people

Limits for radioactive emissions are determined by the Derived Release Limit (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.

Since 2015, the highest yearly dose to a member of the public from licence activities at the site has been 5.7 uSv.

3.9.6 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 remained sufficient.

3.10 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.

3.10.1 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*" and CSA N393, "*Fire Protect for Facilities that Process, Handle or Store Nuclear Substances*".

Emergency response planning is required to reduce or mitigate operational impacts and potential environmental, health and safety impacts that may occur in the event of an emergency. 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, the primary plan being the SE-ERP-002, "Emergency Response Plan". These plans outline response actions to be taken to minimize potential environmental, health and safety impacts. Depending on the nature and scale of an emergency, the appropriate ERP is activated. 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 the Company's emergency planning needs, to plan emergency response exercises and drills to test existing ERPs and as necessary, to review the emergency response plans 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.

Testing of the Emergency Response Contact List is performed annually to ensure accuracy of off-hour contact information listed, to determine availability of personnel, and to estimate response times.

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 situation. 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 emergency response plans 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.

3.10.2 Nuclear emergency preparedness and response

In addition to the general emergency response procedure described above, Nordion has implemented a radiation emergency response plan to address any radiation related emergencies. During an emergency situation, Nordion has the capability to monitor facility conditions remotely to ensure proper response.

3.10.3 Conventional emergency preparedness and response

In addition to the radiation emergency response plan, Nordion has also implemented:

- Communicable Disease and Bio-Terrorist response plan
- Chemical spill response plan
- Transportation Emergency response plan
- First Aid program

These plan all fall under the general emergency response procedure described above.

3.10.4 Fire emergency preparedness and response

Nordion's Fire Safety Plan (SE-ERP-001) and Fire Protection Program (SE-EHS-007) has been established 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
- Establish and regularly test Fire Safety Plans

3.11 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.

3.11.1 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 CNSC accepted clearance levels for release through conventional waste methods.

3.11.2 Waste characterization

Waste from the Active Area is categorized into waste types, typically : routine waste, non-routine waste, and divertible waste. Routine waste is waste generated from production processes and is routinely shipped to approved external radioactive waste management facilities. This waste has been characterized into repositories, or "Waste Blocks". Radioactive waste that has not been characterized into a waste block is considered non-routine radioactive waste. Non-routine radioactive waste is evaluated for conventional waste disposal or packaged for shipment to a licensed radioactive waste management facility. Waste generated within the Active Area that meets 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, with the exception of spent sealed sources that may be returned to Nordion for recycling or other end-of-life management.

3.11.3 Waste Minimization

To continuously improve performance and to meet the spirit of ISO 14001, Nordion regularly monitors waste and establishes objectives and targets for continuous improvement.

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.

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

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

3.11.4 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 production facilities have been designed and are operated in a manner to prevent radioactive waste from being released to municipal garbage or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the CNSC. All radioactive waste that is generated through production operations 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 all 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 cabinets in the shipping areas. 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.

3.11.5 Decommissioning Plan

Nordion's Decommissioning Plan is described in SE-LIC-009, "Preliminary Decommissioning Plan for Class 1B Facility (KOB)". This plan was approved in February 2023 and remained sufficient for current activities.

3.12 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.

Information regarding the Security safety and control area is considered confidential-prescribed information and will be provided under separate cover.

3.12.1 General considerations

Nordion has implemented robust site and transport security programs to meet the requirements of REGDOC 2.12.3, **Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material**. Nordion has 24/7 on-site security. Security guards are trained in accordance with Nordion's training program. The details of Nordion's security program are outlined in the Nordion Security Plan and the Transport Security Plan that have been submitted to and approved by CNSC staff and will not be described further in this attachment due to the security nature of the information.

Nordion has implemented a cyber security program through its parent company, Sotera Heath. This program is based on the NIST cybersecurity framework. IT assets are managed. Firewalls have been implemented to address security threats. Training on IT security threats and security networks is provided to employees on a regular basis. Testing of potential threat vectors is performed on employees and the results reviewed to implement additional training as may be required.

3.13 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*.

3.13.1 General considerations

Nordion has a program in place for the management of safeguarded material at the Nordion Ottawa site, SE-LIC-016, "Management of Safeguarded Material". The program meets the safeguards requirements of specified license conditions, CNSC regulatory document RD-336, "Accounting and Reporting of Nuclear Material", CNSC *Nuclear Non-Proliferation Import and Export Control Regulations*, the *Nuclear Safety and Control Act* and *General Nuclear Safety and Control Regulations*.

The type of safeguarded nuclear material that Nordion has is primarily depleted uranium, with some small amounts of enriched uranium, natural uranium, plutonium, and thorium. The material is in the form of check sources and standards, and shipping containers with depleted uranium as shielding.

3.13.2 Nuclear accountancy and control

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). Complementary Access Inspections were conducted by the IAEA in 2015, 2017, 2022 and the IAEA also conducted a Physical Inventory Verification in 2019.

Nordion is fully compliant with RD-336, "*Accounting and Reporting of Nuclear Material*".

3.13.3 Access and assistance to the IAEA

Nordion provides access and assistance to the IAEA through requests from the CNSC. Nordion treats these IAEA access requests as a regulatory inspection and ensure facility workers and resources are available, as is done for any CNSC inspection.

3.13.4 Operational and design information

Nordion provides a Design Information Questionnaires (DIQ) and the additional protocol to the CNSC as required. The DIQ and additional protocol are reviewed by appropriate staff to ensure the submissions are accurate.

3.13.5 Safeguards equipment, containment and surveillance

No IAEA equipment is present at Nordion's site.

3.14 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.

3.14.1 Package design and maintenance

Nordion has developed a program for the design and maintenance of transport packages. This program is described in section 3.14.2.

Nordion's transport packages are primarily Type B packages certified by the CNSC.

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

3.14.2 Package and transport program

The Packaging and Transportation Program at Nordion is detailed in SE-OP-036, "Transportation of Radioactive Materials Program", SE-OP-014, "Shipping Radioactive Material", and SE-OP-015, "Receiving Radioactive Material". These procedures provide a high-level overview of Nordion's transportation of radioactive materials program. The program 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 various 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*, Transport Canada, *Transportation of Dangerous Goods Regulations*, IAEA, *TS-R-1 Regulations for the Safe Transport of Radioactive Material (1996 Revised Edition)*, US DOT, *49 CFR*, and US NRC, *10 CFR part 71*.

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
- 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.

This plan is applicable to all Nordion Type A and Type B Transport Packages. Radioactive materials transport packaging falls within the scope of Nordion's ISO 9001 Quality Management System. 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.

3.14.3 Registration for use

All new package designs, or changes to current package designs, follow the change control process. This process contains a checklist that has a specific section related to transport considerations. Appropriate staff review all new designs or changes to current design and assess the regulatory requirements (transport licence amendment, new transport licence, etc).

3.15 Reporting

Nordion is committed to openness and transparency with the CNSC and has implemented SE-EHS-009, "EHS Regulatory Reporting and Notifications" to ensure compliance with REGDOC -3.1.2, "*Reporting Requirements, Volume I: Non-Poer Reactor Class I Facilities and Uranium Mines and Mills*".

Nordion has implemented a program for reporting of high activity sealed sources. This program is described in SE-OP-079, "Sealed Source Reporting".

3.16 Public Information and disclosure program

Nordion is committed to transparency with the public and has implemented SE-LIC-010, "Nordion Public Information Program". This program meets the requirements of REGDOC-3.2.1, "*Public Information Disclosure*". 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;
- 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;
- Posting of event reports and environmental data (via the Annual Compliance Report) to the Nordion website.

As part of our licensing renewal efforts, Nordion will engage 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 will be posted on the Nordion website.

3.17 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
- The Algonquins of Ontario.

In prior years, Nordion would provide these Indigenous Nations and groups invitations, typically via email, to various Nordion outreach events.

In 2023, Nordion began to implement a more robust Indigenous engagement program and reached out directly to the AOPFN. In the same year, 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 late 2023, Nordion hired a consultant to develop an engagement program. Nordion will be reaching out the AOPFN in Spring 2024 with a draft engagement plan for discussion. As part of this engagement plan, Nordion is planning to provide a community event with the AOPFN to discuss the licence renewal.

In Spring 2024, Nordion will also be providing a formal notice to both the Kebaowek First Nation and the Algonquins of Ontario of our application to renew our licence and will be seeking opportunities to discuss concerns or questions they may have.

3.18 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 this renewal application. BWXT Medical leases back the Nuclear Medicine Production Facility and Kanata Radiopharmaceutical Manufacturing Facility. 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.

Procedure SE-LIC-023, "BWXT Medical-Nordion Safety Responsibility" has been developed to 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.

GLOSSARY

AOPFN	Algonquin of Pikwakanagan First nation
ALARA	As Low As Reasonably Achievable
AMMS	Advanced Maintenance Monitoring System
CAPA	Corrective Action Preventative Action
CNSC	Canadian Nuclear Safety Commission
COF	Cobalt Operations Facility
CSA	Canadian Standards Association
DIQ	Design Information Questionnaires
DMS	Document Management System
DOT	Department of Transport
DRL	Derived Release Limit
EHS	Environment, Health and Safety
EMS	Environmental Management System
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
NEW	Nuclear Energy Worker
NMPF	Nuclear Medicine Production Facility
NVS	Nuclear Ventilation System
OPEX	Operating Experience
PIT	Physical Inventory Taking
PIT-E	Physical Inventory Taking – Evaluation
SCA	Safety and Control Area
SSC	Structures, Systems and Component
TLD	Thermo-luminescent Dosimeter
TSSA	Technical Standards and Safety Authority