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A Licence Renewal

Nordion (Canada) Inc.

Application to Renew Licence for the Nordion Facility

Commission Public Hearing

Scheduled for:

June 4-5, 2025

Submitted by:

CNSC Staff

Renouvellement d’un permis

Nordion (Canada) Inc.

Demande de renouvellement de permis pour l’installation de Nordion

Audience publique de la Commission

Prévue pour :

4-5 juin 2025

Soumis par :

Le personnel de la CCSN

e-Doc 7320108 (WORD)
e-Doc 7460685 (PDF)

Summary

This CMD presents information about the following matters of regulatory interest with respect to Nordion (Canada) Inc.'s:

- Request to renew Nordion (Canada) Inc.'s Class IB nuclear substance processing facility operating licence (NSPFOL-11A.01/2025) for a period of 25 years

CNSC staff recommend the Commission consider taking the following actions:

- Renew the nuclear substance processing facility licence to authorize Nordion to operate its facility until October 31, 2050, with a requirement for the licensee to provide two performance updates to the Commission during the licence term.
- Delegate authority as set out in section 4.4 of this CMD.

The following items are attached:

- the proposed licence NSPFL-11A.00/2050
- the draft licence conditions handbook
- the current licence NSPFOL-11A.01/2025

Résumé

Le présent CMD fournit de l'information sur les questions d'ordre réglementaire suivantes concernant Nordion (Canada) Inc.:

- Demande de renouvellement du permis d'exploitation de l'installation de traitement des substances nucléaires de catégorie IB (NSPFOL-11A.01/2025) de Nordion pendant une période de 25 ans

La Commission pourrait considérer prendre les mesures suivantes :

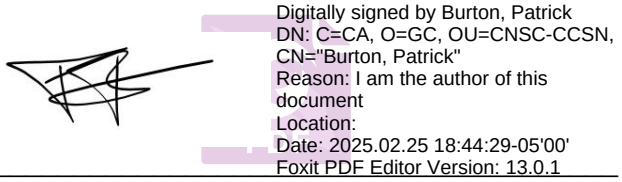
- Renouveler le permis d'installation de traitement des substances nucléaires afin d'autoriser Nordion à exploiter son installation jusqu'au 31 octobre 2050 à la condition que le titulaire de permis soumette à la Commission deux mises à jour de rendement pendant la durée du permis.
- Déléguer les pouvoirs tel qu'il est établi à la section 4.4 du présent CMD.

Les pièces suivantes sont jointes :

- le permis proposé, NSPFL-11A.00/2050
- l'ébauche du manuel des conditions de permis
- le permis actuel, NSPFOL-11A.01/2025

Signed/Signé le

[25 02 2025]



Patrick Burton on behalf of Luc Sigouin

Director General

Directorate of Nuclear Cycle and Facilities Regulation

Directeur général de la

Direction de la réglementation du cycle et des installations nucléaires

TABLE OF CONTENTS

Land Acknowledgement

The Canadian Nuclear Safety Commission acknowledges that Nordion Inc.'s Class 1B facility in Kanata Ontario, is located within the traditional unceded territory of the Algonquin Anishinaabeg peoples.

Plain Language Summary

Nordion (Canada) Inc. owns and operates a Class IB nuclear substance processing facility located at 447 March Road in Kanata, Ontario. Nordion's primary business is Gamma Technologies where Cobalt-60 high activity sealed sources are used in the medical and sterilization markets. Nordion is also a major global supplier of Cobalt-60 sealed sources that are used in cancer therapy and irradiation.

The Cobalt Operations Facility (COF) has been in operations for over 50 years.

In 2018, Nordion divested the Medical Isotopes business to BWXT Medical which is co-located at 447 March Road. BWXT continues to operate this business under their own Class 1B nuclear substance processing facility licence and continues to lease the Nuclear Medicine Production Facility and Kanata Radiopharmaceutical Manufacturing Facility portions of the facility at 447 March Road from Nordion.

Pursuant to subsection 24(2) of the *Nuclear Safety and Control Act* (NSCA) [1], the Commission renewed Nordion's operating licence in November 2015 for a 10-year term that began on November 1, 2015, and will expire on October 31, 2025.

CNSC staff have presented the licensee's compliance performance to the Commission in annual Regulatory Oversight Reports for uranium and nuclear substance processing facilities throughout the period of the current operating licence.

In May 2024, Nordion applied to the CNSC for the renewal of its operating licence. In its application, Nordion requested a 25-year licence to continue operating the Nordion facility with no changes to the authorized activities.

The purpose of this Commission member document (CMD) is to provide comprehensive information on CNSC staff's assessments performed during the current Nordion licence period and to present the rationale for conclusions and recommendations, in order to inform the Commission decision on Nordion's request to renew its operating licence.

This CMD has 2 parts. Part 1 presents CNSC staff's assessment, conclusions and recommendations in respect of Nordion's licence application. CNSC staff have evaluated the licensee's compliance with the requirements of the NSCA and its regulations.

This CMD provides information on CNSC staff's review, with focused highlights on:

- relevant safety and control areas (SCAs)
- other matters of regulatory interest

CNSC staff's assessment of the licensee's regulatory performance concludes that:

- the environmental and radiological risks remain low
- effluent quality and radiation doses are effectively controlled and kept well below regulatory limits
- Nordion's performance in the conventional health and safety SCA demonstrates that hazards and risks are managed and that activities are conducted safely

Therefore, CNSC staff conclude that the licensee's performance during the licensing term was satisfactory and met regulatory requirements.

CNSC staff recommend that the Commission take the following actions:

1. Renew Nordion's nuclear substance processing facility licence for the Nordion facility for a period of 25-years effective November 1, 2025, to October 31, 2050, including two (2) performance updates during the licence term
2. Accept the delegation of authority to CNSC staff as set out in section 4.4 of this CMD

Part 2 of this CMD provides licensing-related documentation pertaining to this hearing, such as the current licence, the proposed licence changes and the proposed licence. A draft licence conditions handbook is also included for information only.

Referenced documents in this CMD are available to the public upon request, subject to confidentiality considerations.

CMD STRUCTURE

This Commission Member Document (CMD) is presented in 2 parts.

Part 1 of this CMD includes:

1. an overview of the matter being presented;
2. overall conclusions and overall recommendations;
3. general discussion pertaining to the safety and control areas (SCAs) that are relevant to this submission;
4. discussion about other matters of regulatory interest; and
5. appendices material that complements items 1 through 4.

Part 2 of this CMD provides all available information pertaining directly to the current and proposed licence if applicable.

1. Overview

1.1 Background

Nordion (Canada) Inc. owns and operates a Class IB nuclear substance processing facility located at 447 March Road in Kanata, Ontario

The facility is situated in proximity of the traditional and treaty territories of many Indigenous Nations and communities including:

- Algonquin Anishinabeg Nation Tribal Council
- Kitigan Zibi Anishinabeg First Nation
- Kebaowek First Nation
- The Algonquins of Ontario
- Algonquins of Pikwàkanagàn First Nation
- The Métis Nation of Ontario

Nordion's primary business is Gamma Technologies where Cobalt-60 (Co-60) high activity sealed sources are used in the medical and sterilization markets. Nordion is also a major global supplier of Co-60 sealed sources that are used in cancer therapy and irradiation.

Figure 1-1: Aerial view of Nordion facility outlined in blue

Nordion's facility is located at 447 March Road, Kanata Ontario, in an industrial zone within the Kanata Research Park. The site has been used for industrial purposes since the 1960's. The surrounding area is a mixture of residential, commercial and industrial zoning.

1.2 Highlights

Nordion's Licence Application Request

The current Nuclear Substance Processing Facility Operating Licence, NSPFOL-11A.01/2025, expires on October 31, 2025.

In May 2024, Nordion submitted an application [2] for the renewal of the Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-11A.01/2025 for the Nordion facility for a term of 25 years with no changes to the authorized activities. In February 2025, Nordion submitted an amended application [3] to the CNSC which included a revised list of supporting documents from the original application. The revision was made to streamline and focus on key documents required for this application. The requested licence period is from November 1, 2025, to October 31, 2050.

Nordion's licence allows it to:

- a) operate the Nordion Nuclear Substance Processing Facility, at the location refereed to in Section II of the licence (hereinafter "the processing facility"), for the purpose of processing and manufacturing nuclear substances and sealed sources used in health sciences and industrial applications;
- b) possess, transfer, use, process, import, manage, store, or dispose, of nuclear substances that are required for, associated with, or arise from the activity described in a);
- c) possess, transfer, use, import, or service prescribed equipment that are required for, associated with, or arise from the activity described in a);
- d) possess, transfer, use, service, or import prescribed equipment from clients; and
- e) possess and use prescribed information that is required for, associated with, or arise from the activity described in a).

Licence Period

In the renewal application Nordion is requesting that its Class IB nuclear processing facilities licence be renewed for a 25-year period. The justification for Nordion's request for a 25-year license period can be found in "*Letter from Nordion- 2025 License Application (cover letter and Appendix A and B)"*. [4] which was submitted to the Commission in support of the application. Nordion's highlights of the justification for a 25-year licence period include:

- Safe operation of the facility at 447 March Road for over 50 years
- Implementation of a strong and mature management safety program that drives the oversight and continuous improvement of licensed activities that meets the requirements of CSA N286-12.

- 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.
- Implementation of a strong radiation protection program that has ensured the protection of its employees and the public. Since the 2015 licence renewal, the highest dose to an employee has been 5.5 mSv, which is substantially lower than the regulatory limit of 50 mSv/year for nuclear energy workers. The dose to the public due to Nordion related activities has been less than 0.01 mSv/year. This is not expected to substantially change over the requested 25-year licence period.
- 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. 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 accepted derived release limit (DRL). 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.
- Nordion is continually investing in the facility and making improvements to ensure safety systems are maintained and improved as provided in its application.

CNSC staff have reviewed Nordion's application and rationale for requesting a 25-year licence term. Further details on CNSC staff's assessment are provided in section 4.3.

CNSC Staff Assessment of Nordion's Licence Application

CNSC staff reviewed Nordion's license renewal application with the requested authorization to operate the Nordion facility and determined that the application complies with regulatory requirements. The assessment evaluated Nordion's programs and past performance to assist the Commission in determining whether Nordion is qualified and capable of performing the activities to be authorized by the Commission.

CNSC staff concluded that Nordion's renewal application contains sufficient information to demonstrate that programs are in place to meet CNSC's regulatory requirements. The CNSC staff assessment is documented in sections 2, 3, 4 and Appendix C of this CMD.

Throughout the previous licence period, CNSC staff have reviewed Nordion's performance and reported results to the Commission in public meetings through the annual Regulatory Oversight Report for Uranium and Nuclear Substance Processing Facilities. CNSC staff's assessments of performance and compliance are based on desktop reviews of Nordion's submissions, including annual compliance reports, event reviews, and results of CNSC inspections. CNSC staff have determined that Nordion's performance during the licensing term was satisfactory and consistently met regulatory requirements.

Based on CNSC staff's assessments of Nordion's past performance and of the licence application, CNSC staff determined that Nordion is qualified and capable of performing the activities authorized in the licence.

Licence Condition Handbook

The draft licence conditions handbook (LCH) associated with the proposed licence provides compliance verification criteria to determine whether the conditions listed in the licence are met. The LCH provides details associated with each licence condition, such as applicable standards or regulatory documents; regulatory interpretation; compliance verification criteria; version-controlled documents; licensee's written notification documents; and guidance. The draft Nordion LCH can be found in Part 2 of this CMD.

CNSC staff update the Commission of any changes to the LCH as well as any facility-specific changes and program documentation updates through the Regulatory Oversight Reports presented to the Commission at public proceedings.

1.3 Overall Conclusions

CNSC staff have reviewed Nordion's licence renewal application and supporting documents. CNSC staff's assessment determined that the application complies with the regulatory requirements and that Nordion's performance during the previous licensing term was satisfactory and consistently met regulatory requirements.

1.4 Overall Recommendations

CNSC staff recommend that the Commission:

1. **Conclude,** pursuant to paragraphs 24(4)(a) and (b) of the *Nuclear Safety and Control Act* **[1] in that Nordion:**

    a) **is qualified** to carry on the activities authorized by the licence

    b) **will 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.

2. **Issue** the proposed 25-year licence Class IB Nuclear Substance Processing Facility Operating Licence NSPFL-11A.00/2050 for operation of the Nordion facility, effective November 1, 2025, to October 31, 2050, with a requirement for Nordion to provide two (2) comprehensive performance updates to the Commission during the licence term.
3. **Delegate** authority as set out in section 4.4 of this CMD.

2. General Assessment of SCAs

CNSC staff review and assess an applicant's proposed measures and controls, and if applicable, a licensee's past performance in each SCA. All 14 SCAs are relevant in this licence renewal application review. It should be noted that the SCA framework does not limit the CNSC in its conduct of regulatory oversight activities. Additional topics or safety areas may be added, as needed, at any time.

The specific areas that comprise the SCAs for Nordion are identified in Appendix C, section C.2. For each specific area that is identified in section 2 as being implicated in the overall conclusions or recommendations for an SCA, provide any detailed data (such as radiation action levels, dose to workers, or environmental releases, that might be helpful to the Commission in making an informed decision). If specific areas are not listed for a given SCA in section 2, then a decision has been made to encompass them in an overall approach to that SCA.

2.1 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.

The specific areas that comprise this SCA at the Nordion facility include:

- Management system
- Organization
- Performance assessment, improvement and management review
- Change management
- Records management
- Management of contractors
- Safety culture

2.1.1 Trends

The following table indicates the overall rating trends for the management system SCA over the current licensing period:

TRENDS FOR MANAGEMENT SYSTEM								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments								

CNSC staff consistently rated the Management System SCA as satisfactory (SA) during the most recent licence period. Nordion has a management system program that complies with CNSC requirements. During the current licensing period, Nordion has continued to improve its processes and their implementation.

2.1.2 Discussion

The *Class I Nuclear Facilities Regulations* [5] require that an application for a licence shall contain the proposed management system for the activity to be licensed, including measures to promote and support safety culture.

The *General Nuclear Safety and Control Regulations* [6] require that a licence application contain the applicant's organizational management structure, including the internal allocation of functions, responsibilities and authority.

To meet CNSC requirements for this specific area, the licensee must implement and maintain the management system requirements set out in Canada Standards Association (CSA) standard N286-12, *Management system requirements for nuclear facilities*. [7] The management system brings together, in a planned and integrated manner, the processes necessary to satisfy the requirements that must be met to safely carry out the licensed activity. During the current licensing period, Nordion implemented and became fully compliant with the requirements in CSA N286-12.

Management System

During the current licensing period, CNSC staff have verified Nordion's management system program through compliance inspections and desktop reviews. All findings issued to Nordion have been addressed to CNSC staff satisfaction. Overall, Nordion's management system continues to meet CNSC requirements.

Organization

Nordion reports to the CNSC on any changes to its organization. The modifications to the organizational structure and the roles and responsibilities of the new positions are documented in Nordion's current management system program document. [8] Through compliance inspections and reviews of Nordion's periodic reports and submissions, CNSC staff confirmed that Nordion's performance in this area is satisfactory.

Performance Assessment, Improvement and Management Review

Nordion continues to demonstrate effective assessments programs (self-assessment and independent assessment). Nordion has several performance indicators that gather information to assess the overall performance and effectiveness of their management system program. This includes, but is not limited to, the review of corrective maintenance work orders, operational deficiencies and results of its self-assessment program. CNSC staff conclude that Nordion's assessment and management review programs are satisfactory.

Change Management

Nordion has a change and design control program to identify risks and ensure adequate mitigation measures are in place prior to modifications to its systems, structures and components. The scope of this program also includes changes to software. The program contains a list of potential hazards to be assessed prior to proceeding with the proposed changes. CNSC staff have confirmed the effectiveness of this program through inspections and desktop reviews. CNSC staff conclude that Nordion's performance in this area is satisfactory.

Records Management

Nordion has a quality record procedure that defines the identification, collection, access, storage, maintenance and disposition of records. CNSC staff have confirmed the effectiveness of this program through inspections and desktop reviews. CNSC staff conclude that Nordion's performance in this area is satisfactory.

Supply and Contractor Management

Nordion has a supply chain management procedure and supplier assessment programs to govern their supply chain and to qualify suppliers/contractors who provide products and services. CNSC staff have confirmed the effectiveness of this program through inspections and desktop reviews. Contractor management was the focus of a management systems inspection during the licence term. CNSC staff conclude that Nordion's performance in this area is satisfactory.

Safety Culture

CNSC REGDOC-2.1.2, *Safety Culture* [9] requires that licensees document their commitment to fostering safety culture in their governing documentation. At the request of CNSC staff, Nordion performed a gap analysis and confirmed implementation in June 2019.

2.1.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.1.3.1 Past Performance

During the licence term, CNSC staff conducted three inspections focused on Nordion's management system and contractor management. No notices of non-compliance (NNC) were raised during the inspections. Through review of Nordion's documentation and CNSC routine compliance inspections, CNSC staff find that Nordion's performance in this area meets CNSC requirements. CNSC staff have rated Nordion's performance for the Management System SCA as satisfactory over the licensing period.

2.1.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in this SCA through regulatory oversight activities including inspections and desktop reviews of relevant program documentation to ensure Nordion continues to meet applicable regulatory documents, codes and standards for the upcoming proposed licence period.

2.1.3.3 Proposed Improvements

There are no improvements proposed for the Management System SCA during the proposed licence period.

2.1.4 Conclusion

CNSC staff have assessed Nordion's program and processes under the Management System SCA and conclude that Nordion's performance is satisfactory.

2.2 Human Performance Management

The human performance management SCA covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

The specific areas that comprise this SCA at the Nordion facility include:

- Personnel Training

2.2.1 Trends

The following table indicates the overall rating trends for the human performance management SCA over the current licensing period:

TRENDS FOR HUMAN PERFORMANCE MANAGEMENT								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments Nordion has implemented and maintains a Systematic Approach to Training (SAT) based training system and programs. The satisfactory (SA) trend for this SCA has remained stable for Nordion over the licensing period. Nordion has ensured that the training programs have been updated and improved over the course of the current licensing period.								

2.2.2 Discussion

Paragraphs 12(1)(a) and 12(1)(b) of the *General Nuclear Safety and Control Regulations* [6] require that a licensee ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the regulations made under the Act and the licence; and shall train the workers to carry on the licensed activity in accordance with the Act, the regulations made under the Act and the licence.

Paragraphs 6(m) and 6(n) of the *Class I Nuclear Facilities Regulations* [5] require that licence applications include the proposed responsibilities of and qualification requirements and training program for workers, including the procedures for the requalification of workers; and 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.

Paragraph 14(2)(e) *Class I Nuclear Facilities Regulations* [5] requires every licensee to keep a record of the status of each worker's qualifications, requalification and training, including the results of all tests and examinations completed in accordance with the licence.

Finally, the licensee shall implement and maintain training programs for workers in accordance with the requirements set out in REGDOC-2.2.2 *Personnel Training* [10].

Nordion maintains training system documentation that address regulatory training and qualification requirements, including processes for implementing the various phases of a Systematic Approach to Training (SAT) training system in accordance with the requirements of REGDOC 2.2.2, *Personnel Training* [10].

Overall, Nordion has provided a robust methodology to assure that workers are qualified to perform their duties safely. CNSC staff conclude that Nordion is performing satisfactorily with respect to this SCA.

2.2.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.2.3.1 Past Performance

Personnel Training

Nordion implements and maintains a (SAT) based training system and program to provide assurance that workers are qualified to perform their duties safely.

Nordion maintains training system documentation that address regulatory training and qualification requirements, including processes for implementing the various phases of a SAT-based training system in accordance with the requirements of REGDOC 2.2.2, *Personnel Training* [10]. A SAT-based training system provides interdependent functions consisting of analysis, design, development, implementation and evaluation.

During the current licensing period, CNSC staff conducted compliance verification activities focused on personnel training as well as numerous document reviews of the training programs at Nordion to ensure that a SAT-based training system was adequately implemented.

During the licence term, CNSC staff conducted two inspections focused on the implementation of Nordion's personnel training program. CNSC staff identified areas of non-compliance with internal documentation and therefore raised six (6) notices of non-compliance (NNC) from both inspections. The NNCs pertained to inconsistencies with regards to accuracy, control, and completeness of some training documents, and implementation of trainer qualification requirements. Nordion's corrective action plans were reviewed and accepted by CNSC staff, and all NNCs have been closed.

Overall, Nordion has provided a robust methodology to assure that workers are qualified to perform their duties safely. CNSC staff conclude that Nordion is performing satisfactorily with respect to this SCA.

2.2.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in this SCA through regulatory oversight activities including inspections and desktop reviews of relevant program documentation.

2.2.3.3 Proposed Improvements

There are no improvements proposed for the human performance management SCA during the proposed licence period.

2.2.4 Conclusion

Overall, Nordion has strengthened the training program over the licensing period and provided a robust methodology to assure that workers are qualified to perform their duties safely. CNSC staff conclude that Nordion is performing satisfactorily with respect to this SCA.

2.3 Operating Performance

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

The specific areas that comprise this SCA at the Nordion facility include:

- Conduct of licensed activities
- Procedures
- Reporting and trending

2.3.1 Trends

The following table indicates the overall rating trends for the operating performance SCA over the current licensing period:

TRENDS FOR OPERATING PERFORMANCE								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments								
The licensee has maintained an operating program in accordance with CNSC requirements during this licence period. Nordion continues to be rated satisfactory (SA) in this SCA.								

2.3.2 Discussion

Nordion is required under licence conditions 4.1 and 4.2 to implement and maintain an operating program, which includes a set of operating limits, and to maintain a program for reporting to the Commission or an authorized person. The CNSC ensures that Nordion has policies, programs, methods and procedures in place for the safe operation and maintenance of its licensed nuclear facilities. The occupational and industrial safety aspects of Nordion's operations are regulated under the *Canada Labour Code* [11], and its associated *Canada Occupational Health and Safety Regulations* [12].

REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills* [13], is also a governing document dealing with reporting to the CNSC.

Verification of the licensee's compliance with the requirements of this SCA are included as part of CNSC's compliance activities ranging from desktop reviews of annual reports, reviews of event reports, related corrective actions and inspections. CNSC staff confirmed through these compliance verification activities that Nordion has implemented and maintained an effective operating program in to ensure licensed activities are conducted safely and in compliance with regulatory requirements.

2.3.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.3.3.1 Past Performance

Conduct of Licensed Activity

During the current licence term, Nordion has shown a consistent and satisfactory history of operating experience. It operated the facility in compliance with its licensing basis. CNSC staff verified Nordion's compliance with the requirements of this SCA as part of compliance activities, which included desktop reviews of

annual reports, operation reports and inspections. Inspections included but were not limited review and implementation of procedures confirming that these procedures are adhered to, up-to-date and, have been through a formal development process which includes validation before the procedure is approved for use. CNSC staff conducted five general inspections during the licence period and found Nordion to be in compliance with the operating performance SCA.

CNSC staff confirmed that Nordion has implemented and maintained an effective operating program, ensuring licensed activities are conducted safely and in compliance with regulatory requirements.

Procedures

Nordion's management system [8] consists of high-level program documents supported by lower-level procedures and work instructions. Nordion maintains a comprehensive suite of procedures across all programs at its facility.

CNSC staff review procedural-level documents as part of ongoing compliance verification activities to ensure proper maintenance of procedures to reflect actual practices as well as procedural adherence by Nordion personnel.
The LCH identifies the information regarding version control of licensing basis documents, including codes, standards or other documents that are used as compliance verification criteria (CVC), and it stipulates requirements for providing change notification, which triggers reviews by CNSC staff. This ensures that changes continue to align with regulatory requirements and the Nordion licensing basis.

Nordion uses a corrective and preventive actions (CAPA) system to address incidents and non-conformances for regulatory actions, and events related to radiation, ALARA, transport, contamination incidents, environmental incidents, fires, occupational injuries, hazardous occurrences, and near misses. CNSC staff have reviewed Nordion's CAPA system and conclude that it meets regulatory expectations.

Based on these reviews, CNSC staff concluded that Nordion adequately maintains its procedures and there were no significant changes to operating procedures with the potential to affect the safe operation of the Nordion facility.

Reporting and Trending

Nordion maintains an Environmental Health & Safety Regulatory Reporting and Notification document [14] to ensure that events are reported in accordance with regulatory requirements. CNSC staff have reviewed this document and consider it acceptable.

During the licence period, Nordion implemented REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills* [13]. CNSC staff concluded that Nordion is currently meeting the requirements of REGDOC-3.1.2. Table 1 lists the number of events reported to the CNSC by Nordion over the licence period.

Table 1: Events reported by Nordion during the current licence period

Year	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Total	2	10	16	8	4	10	7	7	8	1

CNSC staff reviewed all reported events to identify if there are any regulatory concerns and report significant events to the Commission at public meetings of the Commission. All events reported by Nordion during the licensing period were of low safety significance. Nordion utilizes an internal investigation process which is part of their management system to investigate all events and apply corrective actions**.** No significant events were reported during the licence period. CNSC staff are satisfied with Nordion's response and corrective actions and consider all events closed.

Reporting of Sealed Sources

The CNSC has strengthened its regulatory controls on sealed sources, principally through establishment of a sealed source tracking system within an upgraded national sealed source registry and enhanced export and import controls for high-risk sealed sources. High-risk sealed sources are recorded in the CNSC database (the Sealed Source Tracking System) that tracks the location of each significantly hazardous radioactive source (International Atomic Energy Agency (IAEA Category 1 and 2 sources) in Canada.

In 2021, the tracking of imported sealed sources through the Sealed Source Tracking System (SSTS) was brought to Nordion's attention in the context of the IAEA Code of Conduct and its supplementary guidance on import/export controls [15]. In November 2021, CNSC staff and Nordion reached an agreement for Nordion to report manually Cobalt-60 sealed sources received from foreign suppliers. Later, in 2023, Nordion implemented interim controls to ensure reporting of certain imported sealed sources through SSTS.

In 2024, Nordion updated sealed source reporting in alignment with the *IAEA Guidance on the Management of Disused Radioactive Sources* [16], including manually reporting receipts of serialized sources that cannot be electronically reported and manually reporting un-serialized capsules containing Cobalt-60 raw material received from foreign suppliers as required by the CNSC.

As end-of-life management Nordion will also report finished sources used to manufacture Cobalt-60 sources or sources returned to Nordion that may be re-processed or have their inner raw material recovered for subsequent use.

2.3.3.2 Regulatory Focus

CNSC staff continue to monitor Nordion's performance in this SCA through regulatory oversight activities including inspections, desktop reviews of relevant program documentation and periodic reports.

2.3.3.3 Proposed Improvements

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 [17]:

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

These projects are not expected to have an impact on safety and will be undertaken within the framework of Nordion's Management System for Safety [8].

2.3.4 Conclusion

CNSC staff have assessed Nordion's program and processes under the operating performance SCA and have found its performance to be satisfactory. The facility operated safely, in accordance with the procedures and requirements of the licence. Compliance inspections resulted in no major findings. Nordion implements improvements to processes, equipment and programs as part of continuous improvement.

2.4 Safety Analysis

The safety analysis SCA covers the 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.

The specific areas that comprise this SCA at the Nordion facility include:

- Deterministic safety analysis
- Hazard analysis

2.4.1 Trends

The following table indicates the overall rating trends for the safety analysis SCA over the current licensing period:

TRENDS FOR SAFETY ANALYSIS								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments Over this licensing period, Nordion maintained a safety analysis program in accordance with CNSC requirements. CNSC staff consistently rated the safety analysis SCA as satisfactory (SA) during the licence period.								

2.4.2 Discussion

Deterministic safety analysis/Hazard analysis

Nordion has two primary final safety analysis reports (FSARs) [18,19] which are used to maintain the safety case for the overall facility; one for its Cobalt Operations Facility and one for the Cobalt Pools. Their reports include a description of the facility and the measures in place to protect the safety of the workers, the public and the environment, under normal operations, abnormal operations and accident conditions.

During the current licensing period, Nordion's medical isotope business was acquired by BWXT Medical Ltd. in August 2018. Nordion continued to operate the medical isotope facility and maintained the associated FSARs until BWXT Medical obtained a separate Class IB nuclear substances processing facility operating licence in November 2021[20].

CNSC REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear facilities* [21] was approved in October 2022. Nordion carried out a gap analysis of its safety analysis program and documentation against the requirements in REGDOC-2.4.4, which resulted in minor administrative changes to its safety analysis program. CNSC staff reviewed and accepted Nordion's gap analysis and administrative changes. Nordion is fully implementing the provisions of REGDOC-2.4.4.

Under the main Cobalt production operations, there are a number of active processing areas, each with a secondary FSAR that provides an analysis of the specific safety hazards unique to it. Nordion maintains two secondary FSARs to ensure the safe operation of the facility. All the FSARs are written and maintained in accordance with a procedure which establishes the standard guidelines and criteria to be used, as well as the review and approval process. This procedure requires all of the FSARs to be reviewed at a minimum of every five years for accuracy and validity, as per provisions of REGDOC-2.4.4. CNSC staff have assessed Nordion's safety analysis documentation and found it to be acceptable.

2.4.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.4.3.1 Past Performance

Through the review of Nordion's safety documentation during the licence period, CNSC staff conclude that Nordion's safety analysis meets regulatory requirements. CNSC staff rated Nordion's performance for the safety analysis SCA as satisfactory over the licensing period.

2.4.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in the safety analysis SCA through regulatory oversight activities including inspections and desktop reviews of Nordion's compliance reporting and revisions to relevant program documentation pertaining to this SCA.

2.4.3.3 Proposed Improvements

There are no improvements proposed for the safety analysis SCA during the proposed licence period.

2.4.4 Conclusion

CNSC staff have assessed Nordion's documentation and analyses under the Safety Analysis SCA and have found its performance to be satisfactory. Based on the review of the application and supporting documents, CNSC staff are satisfied that Nordion has processes in place to identify and evaluate safety hazards associated with the operations at the facility and continues to maintain its documentation in compliance with regulatory requirements for the Safety Analysis SCA.

2.5 Physical Design

The physical design SCA relates to activities that impact the ability of structures, systems and components to meet and maintain its design basis given new information arising over time and taking changes in the external environment into account.

The specific areas that comprise this SCA at the Nordion facility include:

- design governance
- facility design

2.5.1 Trends

The following table indicates the overall rating trends for the physical design SCA over the current licensing period:

TRENDS FOR PHYSICAL DESIGN								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments CNSC staff consistently rated the physical design SCA as satisfactory (SA) during the licence period. No significant changes were made to the design of the facility.								

2.5.2 Discussion

During the current licensing period, Nordion has not made significant changes to the design of the facility. Any changes to the design of the facility are implemented using Nordion's change control procedure.

CNSC staff confirmed that Nordion has implemented and maintained an adequate physical design program with appropriate change control. CNSC staff concluded that Nordion's physical design measures meet regulatory requirements and when design changes are made within the licensing basis, the licensee has adequate resources in place to manage them and to ensure safety.

2.5.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.5.3.1 Past Performance

Design Governance

Nordion maintains a change control procedure [22]. The change control procedure ensures that changes within the facility are controlled in a fashion that is commensurate with potential risk.

In 2023, construction work for a new hot cell in the Cobalt Operations Facility was completed. The construction work did not impact the overall design basis for the facility.

CNSC staff verified the change control process during a management system inspection in 2022. CNSC staff concluded that Nordion's change control procedure met the requirements of CSA N286-12, *Management System Requirements for Nuclear Facilities* [7].

Facility Design

Information on the Nordion facility design is documented in the Nordion FSAR [18,19]. Information on the Nordion facility systems and components are provided as well as general design aspects such as safety objectives for normal operations as well as emergency conditions. CNSC staff reviewed the FSAR and consider it acceptable.

Through document reviews and onsite inspections, CNSC staff monitor Nordion's implementation of physical design SCA requirements in accordance with CNSC regulatory requirements. Based on the above capabilities and past performance, CNSC staff are satisfied with the licensee's overall performance in this SCA.

2.5.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in this SCA through regulatory oversight activities including onsite inspections and desktop reviews of relevant program documentation, and the third-party reviews of design modifications to the facilities.

2.5.3.3 Proposed Improvements

There are no improvements proposed for the physical design SCA during the proposed licence period.

2.5.4 Conclusion

Based on CNSC staff assessments of Nordion's application, supporting documents and past performance, CNSC staff conclude that Nordion continues to implement and maintain programs for facility design in accordance with regulatory requirements and its performance is satisfactory in this SCA.

2.6 Fitness for Service

The fitness for service SCA covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This area includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

The specific areas that comprise this SCA at the Nordion facility include:

- equipment fitness for service/equipment performance
- maintenance

The following table indicates the overall rating trends for the fitness for service SCA over the current licensing period:

TRENDS FOR FITNESS FOR SERVICE								
Overall Compliance Ratings								
2015	2016	2017	2018	2019	2020	2021	2022	2023
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments CNSC staff consistently rated the fitness for service SCA as satisfactory (SA) during the licence period. Nordion has in place the programs to ensure the facility is appropriately maintained and that remains fit for service.								

2.6.1 Discussion

Nordion is required to implement and maintain a fitness for service program to cover activities that affect the physical condition of systems, structures and components (SSC) to ensure that they remain effective over time.

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* [5] requires that an application to operate a Class I nuclear facility contain the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility. Further requirements are provided under the *National Building Code of Canada, 2020* (NBCC) [23] and the *National Fire Code of Canada, 2020* (NFCC) [24]. Specific aspects of CSA N286-12 *Management System Requirements for Nuclear Facilities* [7] and CSA N393-22, *Fire protection for facilities that process, handle, or store nuclear substances* [25] are also applicable for this SCA.

2.6.2 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.6.2.1 Past Performance

Equipment Performance/Maintenance

Nordion's Maintenance Program [26] details it's preventive maintenance, periodic inspection and testing requirements for equipment at its facility. The maintenance program ensures that equipment functions are designed so that over its lifetime the safety systems remain available, and that equipment failures are minimized. This is accomplished by completion of corrective and preventative maintenance activities along with routine inspection on system components to ensure that they remain in good operating condition.

Nordion's maintenance program has been regularly reviewed through CNSC's routine compliance inspections during the licence period. Inspections of this SCA were conducted in 2016, 2018, 2020, 2023 and most recently in 2024. No notices of non-compliance (NNC) were raised. CNSC staff concludes that Nordion has implemented an effective maintenance program.

Nordion's preventative maintenance program has not been significantly modified during the licence period. CNSC staff confirmed during their compliance inspections that maintenance is performed as required, and that required records for maintenance and calibration are maintained.

2.6.2.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in this area through routine CNSC compliance inspections.

2.6.2.3 Proposed Improvements

There are no improvements proposed for the fitness for service SCA during the proposed licence period.

2.6.3 Conclusion

Based on CNSC staff assessments of Nordion's application, supporting documents and past performance, CNSC staff conclude that Nordion continues to implement and maintain an effective fitness for service program in accordance with regulatory requirements and its performance is satisfactory in this SCA.

2.7 Radiation Protection

The radiation protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations* [27]. The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained as low as reasonably achievable (ALARA).

The specific areas that comprise this SCA at the Nordion facility include:

- Application of ALARA
- Worker dose control
- Radiation protection program performance
- Radiological hazard control
- Estimated dose to the public

2.7.1 Trends

The following table indicates the overall rating trends for the radiation protection SCA over the current licensing period:

TRENDS FOR RADIATION PROTECTION								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments CNSC staff consistently rated the radiation protection SCA as satisfactory. Nordion has implemented and maintained an effective radiation protection program as required by the *Radiation Protection Regulations*.								

2.7.2 Discussion

Application of ALARA

Nordion has a documented ALARA program which was implemented during the licensing period to keep radiation exposures and doses to persons ALARA. This

program integrates ALARA into planning, scheduling and work control, and takes account of industry best practices and operating experience.

Nordion establishes annual performance objectives with the goal of maintaining radiation doses to workers ALARA. Dose trends are analyzed and compared to internal levels and targets as well as the regulatory dose limits. Corrective actions are implemented, as necessary, in a timely manner.

No non-compliances related to the application of ALARA were identified during the radiation protection inspections conducted in the licensing period.

Nordion's ALARA program was updated by Nordion in 2024 and reviewed by CNSC staff and complies with CNSC's requirements.

Worker Dose Control

Nordion utilizes a CNSC licensed dosimetry service to monitor, assess, record and report doses of ionizing radiation received by employees and contractors. Dose records are submitted to the Canadian National Dose Registry. The available types of dosimetry, the criteria and procedures for use at Nordion were assessed by CNSC staff and found to meet regulatory requirements.

Applicable Nordion employees have been designated as Nuclear Energy Workers (NEWs) and are subject to the relevant dose limits prescribed by the *Radiation Protection Regulations* [27]. During the licensing period, Nordion consistently maintained worker doses below its action levels and regulatory limits.

Urine analysis and whole-body counting is available to quantify elevated screening results or if elevated air or surface contamination monitoring indicates a potential intake.

Table 2: Effective dose statistics for all NEWs, Nordion 2015-2023

Dose Data	2015	2016	2017	2018	2019	2020	2021	2022	2023	Regulatory Limit
Average effective dose(mSv)*	0.56	0.75	0.83	0.45	0.48	0.36	0.80	0.71	0.76	N/A
Maximum individual effective dose (mSv)	5.24	4.90	5.49	4.23	4.79	4.92	4.30	4.29	4.58	50 mSv/year
Number of NEWs Monitored	264	267	263	248	278	324	107	131	157	N/A

***** Average effective dose includes zero doses.

Table 2 presents the dose data for Nuclear Energy Workers (NEWs) at Nordion. Average effective doses have remained stable since 2015. The maximum annual individual effective dose received by a NEW in the period 2015-2023 has also remained steady, with a maximum effective dose of 5.24 mSv (11% of the annual regulatory dose limit for NEWs.) As of 2021, BWXT acquired a separate licence for the Nuclear Medicine Production Facility and Kanata Radiopharmaceutical Manufacturing Facility portions of the facility; this is reflected in the decrease in the number of NEWs monitored in 2021 and onward.

Table 3: Effective dose statistics for contractors (non-NEWs), Nordion 2015-2023

Dose Data	2015	2016	2017	2018	2019	2020	2021	2022	2023	Regulatory Limit
Average effective dose (mSv)*	0.03	0.08	0.08	0.05	0.03	0.01	0.04	0.03	0.02	N/A
Maximum individual effective dose	0.13	0.36	0.18	0.25	0.26	0.29	0.30	0.29	0.26	1 mSv/year
Number of NEWs Monitored	46	53	55	45	123	53	53	40	51	N/A

* Average effective dose includes zero doses

Table 3 presents dose data for non-Nuclear Energy Workers (non-NEWs) at Nordion. Average effective doses have remained low and stable since 2015. The maximum annual individual effective dose received by a non-NEW in the period 2015-2023 has also remained steady, with a maximum effective dose of 0.36 mSv in 2015 (36% of the annual dose limit for members of the public.

During a 2023 radiation protection focused inspection, a noncompliance was issued related to Nordion's process for investigating lost dosimeters. Nordion staff confirmed that there were no formal investigations conducted into lost dosimeters.

As a result of this non-compliance, CNSC staff requested Nordion was to document and implement a process for conducting follow up into lost dosimetry. Nordion updated their program document for external personal radiation monitoring, and CNSC staff were satisfied with the response.

CNSC staff are satisfied that doses to workers are being controlled well below the regulatory limits and are maintained ALARA.

Radiological Hazard Control

Nordion has established radiological surveys and contamination controls to monitor and minimize radiological hazards in the facility. These methods include, but are not limited to, contamination control, radiation dose rate control and airborne contamination monitoring and control.

Contamination control at Nordion ensures that contamination is prevented from leaving radiological controlled areas, and that the spread of contamination within these areas is minimized. This is achieved by classifying areas based on the radiological hazards present, establishing radiological zones, ventilation and filtration systems, routine contamination monitoring, signage, access restrictions, and monitoring of personnel and material prior to leaving contaminated or potentially contaminated areas.

Radiological surveys are performed on a routine basis to evaluate changing radiological conditions and to control worker exposure at the facility. Radiological surveys are used in work planning and classifying areas.

Airborne contamination sampling and monitoring are also conducted to monitor the effectiveness of containment systems, identify changing conditions and reduce the likelihood of internal uptakes.

In 2017, a radiation protection focused inspection was conducted at Nordion's facility. During this inspection, a non-compliance was raised against Nordion as workers were found to not be wearing gloves for the collection of filter discs. CNSC staff were satisfied with the response to this NNC.

CNSC staff assessed the specific area of radiological hazard control at Nordion over the licensing period and concluded that radiological hazards are being controlled to ensure the safety of workers and members of the public.

Radiation Protection Program Performance

As of 2021, BWXT acquired a separate licence for the Nuclear Medicine Production Facility and Kanata Radiopharmaceutical Manufacturing Facility portions of the facility. Since this acquisition, Nordion has reviewed their Radiation Protection Program and tailored the contents to reflect the more limited scope of activities under Nordion's licence (i.e., production of Co-60).

Nordion identifies ALARA objectives and performance targets each fiscal year and progress against these targets is routinely reviewed by Nordion's Environmental Health and Safety Management teams. Nordion identifies radiation protection performance indicators for parameters such as worker doses, liquid/airborne effluent releases and radiation incidents. The licensee also performs internal assessments of the various components of the radiation

protection program on a regular basis. Deficiencies are identified and corrected in a timely manner.

In 2017, a radiation protection focused inspection was conducted at Nordion's facility. During this inspection, a non-compliance was raised against Nordion regarding incomplete records related to the radiation protection program. From this finding, Nordion was asked to create an action plan that ensures records related to the radiation protection program are generated. In 2023, a radiation protection focused inspection was conducted at Nordion's facility. During this inspection, a non-compliance was raised against Nordion related to calibration of survey meters in operation with out-of-date calibration stickers. As per Nordion's procedure, the out-of-date sticker must be removed from the meter before it is returned for service. CNSC staff were satisfied with Nordion's corrective actions for both NNCs.

Nordion reviewed its action levels during the licensing period to confirm that they are adequately set to detect the emergence of a potential loss of control of the radiation protection program. Nordion updated their action levels to include limits for effective dose, skin and extremity doses. During the licensing period, Nordion reported 1 action level exceedance.

In March of 2023, a worker was found to have a contaminated pen in their lab coat. The pen was disposed of correctly; however, the associated dose was not noted until the employee's licensed dosimetry report was received. This event resulted in a whole-body dose of 2.05 mSv, which exceeded Nordion's action level of 2 mSv effective dose per reporting period. In accordance with Nordion's corrective action process, investigations were performed for the event that resulted in the exceedance. As a consequence of this event, contamination monitoring procedures have been updated to include monitoring of lab coats. Clear direction has also been added to procedures for when a radiation protection surveyor is to be called for follow up after a contaminated object has been found. The corrective actions were accepted by CNSC staff, and verification of these actions will be performed during follow-up compliance inspections.

CNSC staff have determined through compliance activities that there is an effective system in place to investigate radiation protection incidents, implement corrective actions and avoid reoccurrences. CNSC staff conclude that Nordion's performance of their radiation protection program meets requirements.

2.7.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.7.3.1 Past Performance

Based on the review of Nordion's annual compliance reports and CNSC staff's compliance inspections, CNSC staff have rated Nordion's performance for the radiation protection SCA as satisfactory over the last 10 years.

2.7.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in this area through routine CNSC inspections and documentation reviews.

2.7.3.3 Proposed Improvements

There are no changes anticipated in the near future for the radiation protection SCA.

2.7.4 Conclusion

CNSC staff conclude that Nordion's performance for this SCA is satisfactory. The program for radiation protection and its implementation at Nordion meets regulatory requirements and is effective at keeping radiation doses ALARA.

2.8 Conventional Health and Safety

The conventional health and safety SCA covers the implementation of a program to manage workplace safety hazards and to protect workers.

The specific areas that comprise the SCA at the Nordion facility include:

- Performance
- Practices
- Awareness

2.8.1 Trends

The following table indicates the overall rating trends for the conventional health and safety SCA over the current licensing period:

TRENDS FOR CONVENTIONAL HEALTH AND SAFETY								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments								
CNSC staff consistently rated the conventional health and safety SCA as satisfactory (SA). Nordion has maintained a conventional health and safety program that meets the requirements of the NSCA and is in accordance with CNSC requirements over this licence period. Nordion has continued to demonstrate its ability to keep the workers safe from occupational injuries.								

2.8.2 Discussion

Nordion must have, under the NSCA and its associated regulations, policies, programs, methods and procedures in place for the safe operation and maintenance of its facilities. The *Class I Nuclear Facilities Regulations* [5] require that an application for a licence shall contain, under paragraph 3(f), the proposed worker health and safety policies and procedures.

Conventional health and safety programs at uranium and nuclear substance processing facilities fall under the dual regulatory oversight of the CNSC and Employment and Social Development Canada. Nordion submits hazardous occurrence investigation reports to both regulators, in accordance with their respective reporting requirements. Nordion is obligated under licence condition 9.1, to implement and maintain a conventional health and safety program. Nordion's activities must comply with the *Canada Labour Code* [11], and the associated Canada *Occupational Health and Safety Regulations* [12]. Nordion's occupational health and safety program applies to all work performed by Nordion employees and contractors.

CNSC staff monitor compliance with regulatory reporting requirements through various means including desktop reviews and inspections. Inspections verification activities include proper use of personal protective equipment, use of signage and barriers and ensuring good housekeeping practices in the facility.

2.8.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.8.3.1 Past Performance

Performance

Licensees are required to report to the CNSC as set out under paragraph 29(1)(h) of the *General Nuclear Safety and Control Regulations* [6]. These reports include serious illnesses or injuries incurred or possibly incurred as a result of a licensed activity.

Nordion maintains a Conventional Health and Safety Policy [28]. CNSC staff reviewed these documents and consider them acceptable. These programs incorporate various elements, such as accident reporting and investigation, hazard prevention, preventive maintenance, health and safety committees, training, and personal protective equipment.

The key performance indicators typically reported to the Commission for conventional health and safety are the number of lost-time injuries (LTI) that occur per year, LTI severity and LTI frequency. An LTI is defined as an injury that takes place at work, and results in the worker being unable to return to work and carry on their duties for a period of time. The LTI frequency and LTI severity

are both based on 100 full-time workers (100 FTE = 200,000 hours worked). LTI statistics for the Nordion facility are outlined in table 4.

Table 4: Lost-time injury statistics, Nordion 2015-2023

Year	2015	2016	2017	2018	2019	2020	2021	2022	2023
Lost-time injuries[1]	0	3	1	0	2	0	0	1	0
Severity rate[2]	0	70.04	5.61	0	4.15	0	0	33.88	0
Frequency rate[3]	0	2.32	0.93	0	0.69	0	0	0.65	0

[1] An injury that takes place at work and results in the worker being unable to return to work for a period of time.

[2] The accident severity rate measures the total number of days lost to injury for every 200,000 person-hours worked at the site. Severity = [(# of days lost in last 12 months) /(# of hours worked in last 12 months)] x 200,000.

[3] The accident frequency rate measures the number of LTIs for every 200,000 person hours worked at the site. Frequency = [(# of injuries in last 12 months) / (# of hours worked in last 12 months)] x 200,000.

During the current licence period, Nordion reported a total of 7 LTIs (table 5). CNSC staff have reviewed and are satisfied with the corrective actions taken by Nordion to prevent recurrence of the events.

Table 5: Reported LTIs during the licence period

LTI	Actions Taken
2016: An employee required sutures to forehead when his ladder slipped, and he fell from the third rung of the ladder.	Installation of a new work platform and an access ladder.
2016: An employee sustained a small fracture to right foot when she slipped on the floor. An air cast and modified duties were required.	Regular reminders were sent to employees reminding them to wear proper footwear and to be careful in winter/inclement weather.
2016: An employee sustained a right shoulder injury after using an Allen key to loosen a socket head cap screw. Modified duties were assigned.	Incident was discussed with the team to explore other options. An idea that was raised at the meeting was to use heat on the fastener before unscrewing it to reduce the amount of force required going forward.
2017: Right knee injury sustained when employee stepped off a lawn tractor and	Discussion with employee about dismounting from tractor with care

into a depression in the ground. Grass was long and they couldn't see the depression.	to assess footing and surroundings before proceeding.
2019: Employee sustained a lower back injury when trying to open double lead doors with force. After several attempts the doors would not open. (issue with doors).	An investigation into the incident was performed by the manager and it was determined that the door status was in a "fault condition" which would not allow the door to open. Technicians need to check status of cell doors before attempting to open them.
2019, Employee was removing wood bracing from a sea crate container. When they bent over to pick up a piece of wood they had an immediate pain to the lower back.	Nordion will no longer be removing the blocking and bracing from the ocean containers. Blocking and materials will remain in the containers once the Nordion flasks are removed, with the trucking company now responsible to remove the blocking and bracing materials.
2022, Employee stated they were seated on a chair and when they were getting up from the chair, they stated that they tripped on an ergonomic mat injuring their knee.	All mats were reviewed, and some were disposed of. A dedicated storage area was established for unused mats. A different style of mat was purchased to provide more height and better stability. This was to prevent the stack of ergo mats, which created instability. Training was developed and implemented on proper use of ergo mats.

Practices

Nordion's conventional health and safety program is under the oversight of its Workplace Health and Safety Committee. CNSC staff review the meeting minutes and any associated corrective actions during onsite inspections to ensure that issues are promptly resolved.

Awareness

Nordion continues to maintain a comprehensive occupational health and safety management program for its facility. Workers are made aware of the conventional health and safety program, as well as workplace hazards, through training and ongoing internal communications.

2.8.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in the SCA through regulatory oversight activities including inspections and desktop reviews of relevant program documentation.

2.8.3.3 Proposed Improvements

There are no improvements proposed for the conventional health and safety SCA during the proposed licence period.

2.8.4 Conclusion

Based on CNSC staff assessments of Nordion's application, supporting documents and past performance, CNSC staff conclude that Nordion's performance is satisfactory in this SCA. Nordion continues to implement and maintain an effective conventional health and safety program in accordance with regulatory requirements and CNSC expectations.

2.9 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.

This CMD covers the following specific areas of the environmental protection SCA:

- Environmental risk assessment (ERA)
- Effluent and emissions control (releases)
- Assessment and monitoring
- Protection of people

2.9.1 Trends

The following table indicates the overall rating trends for the environmental protection SCA over the current licensing period:

TRENDS FOR ENVIRONMENTAL PROTECTION								
Overall Compliance Ratings								
2015	2016	2017	2018	2019	2020	2021	2022	2023
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments								
Since 2015, CNSC staff have consistently rated Nordion's Environmental Protection performance as satisfactory (SA). CNSC staff conclude that Nordion's Environmental Protection program continues to effectively control and monitor releases of radioactive substances from the facility to the environment and its Environmental Protection performance meets CNSC's regulatory requirements. During the licence period, the environment and human health in the vicinity of the Nordion facility remain protected.								

2.9.2 Discussion

CNSC regulations require that licensees take all reasonable precautions to protect the environment and control releases of nuclear and hazardous substances to the environment. Licensees are required to implement and maintain environmental protection programs and procedures to ensure the protection of the public and the environment from facility operations.

Nordion's application [2] includes an Environmental Protection Program, Environmental Management System Manual, and a Radiation Protection Manual as the framework for its operational Environmental Protection Program as well as supporting documents within their Environmental Protection Program.

Nordion's Environmental Protection Program documents include a comprehensive Environmental Protection Program and associated processes that cover the following:

- Derived Release Limits (DRLs)
- Radiation monitoring
- Contamination monitoring program
- Soil sampling/monitoring (radiological)
- Air sampling/monitoring programs
- Delay tank sampling/monitoring for wastewater effluent (radiological)
- Groundwater sampling/monitoring (radiological)
- Sanitary sampling for liquid effluent (non-radiological)
- Nuclear ventilation system
- Equipment decontamination and removal from facility
- Waste disposal program
- Hazardous chemical storage and handling
- Non-radiological environmental sampling/monitoring
- Spill containment

CNSC staff assessed Nordion's Environmental Protection Program documents and confirmed they comply with the requirements and principles in the following regulations and standards:

- REGDOC-2.9.1: *Environmental Principles, Assessments, and Protection Measures* [29]
- CSA N288.4-10: *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills* [30]
- CSA N288.5-11: *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills* [31]

- CSA N288.6-12: *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills* [32]
- CSA N288.1-14: *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities* [33]
- CSA N288.7-15: *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills* [34]
- CSA N288.8-17*: Establishing and Implementing Action Levels for Releases to the Environment from Nuclear Facilities* [35]

Nordion's current Environmental Protection Program is acceptable and CNSC staff expect Nordion will make the required program adjustments to align with new and updated CSA standards. Nordion also has derived release limits (DRLs) in place which ensure the protection of the public and the environment [36].

To complement its ongoing compliance activities, CNSC has implemented its Independent Environmental Monitoring Program (IEMP). The IEMP results for Nordion indicate that the public and the environment in the vicinity of the Nordion facility are protected. The IEMP results are published on the CNSC's website: *https://www.cnsc-ccsn.gc.ca/eng/resources/maps-of-nuclear-facilities/iemp/nordion/*

A summary of Nordion's proposed safety and control measures are presented in the following subsections along with a description of the facility's historical performance.

Environmental Risk Assessment ERA

Environmental risk assessment (ERA) is a systematic process used by licensees to identify, quantify, and characterize the risk posed by contaminants and physical stressors in the environment on human and other biological receptors, including the magnitude and extent of the potential effects associated with a facility. The ERA serves as the basis for the development of site-specific environmental protection measures and the results from the ERA updates determine whether the facility's effluent monitoring and environmental monitoring program are effective. The results of these programs, in turn, inform and refine future revisions of the ERA.

REGDOC 2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [29] includes a requirement for an ERA in accordance with CSA N288.6-12, *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills* [32]. Nordion has developed and implemented an ERA in accordance with regulatory requirements.

In 2016, Nordion submitted an ERA which was reviewed by CNSC staff. Nordion addressed staff's comments, and the revised ERA was accepted.

In 2022, Nordion submitted an updated ERA [37] for its facility. Nordion addressed staff's comments and the revised ERA was accepted. CNSC staff

reviewed and determined that Nordion's revised ERA meets the requirements of CSA N288.6-12.

In their licence application for renewal, Nordion included an ERA update memo [2] to confirm that the 2022 ERA is still applicable to their current operations. CNSC staff reviewed the memo and agree with Nordion's conclusions that the 2022 ERA conclusions remain valid, and the environment and the public are protected.

The CSA published a new edition of the N288.6-22, *Environmental risk assessments at nuclear facilities and uranium mines and mills* [32] in February 2022. As per five-year review cycle, Nordion is expected to submit a revised ERA in 2027 in accordance with the new version of the CSA N288.6-22.

Effluent and Emissions Control (Releases)

As part of their application, Nordion's Environmental Protection Program includes the control and monitoring of atmospheric emissions and liquid effluent releases to the environment. CNSC staff confirmed Nordion's program complies with CSA N288.5-11, *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills* [31]. CNSC staff are satisfied with Nordion's measures to control and monitor atmospheric emissions and liquid effluent releases, which are further described below.

In 2016, Nordion ceased the production of the radioisotopes Mo-99, I-125, I-131, and Xe-133, which is reflected in their air emissions and liquid effluent monitoring results starting in 2017 (tables 6 and 7). Since BWXT Medical acquired Nordion's medical isotopes business in 2018 and obtained a Class 1B licence from CNSC in 2021, several radionuclide releases can no longer be associated with Nordion's operations and are now controlled and monitored by BWXT Medical's Environmental Protection Program, which is completely separate from Nordion's Environmental Protection Program. The releases associated with Nordion's Cobalt Operations Facility include Cobalt-60, Niobium-95, Zirconium-95, and Cesium-137. In 2018, Nordion revised the DRLs established for their facility. CNSC staff assessed the DRLs for airborne and liquid effluent and confirmed they meet the requirements in CSA N288.1-14: *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities* [33]. The DRLs ensure that joint releases of radionuclides from the Nordion and BWXT Medical Class IB nuclear facilities will not result in an exceedance of the established regulatory dose limit of 1 mSv/year for members of the public. The joint Nordion-BWXT Medical EHS Committee monitors and ensures that joint releases are being kept below the DRLs and below the regulatory public dose limit.

Nordion's operations include the use of small quantities of non-radioactive hazardous chemicals during processing, testing, decontamination, and cleaning. The handling, storage, and disposal of hazardous chemicals at Nordion aligns with relevant legislation and is included in their Environmental Protection Program and associated operating procedures.

Atmospheric Emissions

Nordion's Environmental Protection Program controls and monitors airborne releases from its facility to prevent unnecessary releases of nuclear substances to the atmosphere and their program includes continuously monitoring their process ventilation and stack emissions. All production work at Nordion is conducted in hot cells or fumehoods and the facility's process air is exhausted through a ventilation system that uses several filtration steps to prevent releases of particulates and gaseous contaminants. The ventilation system includes the use of High Efficiency Particulate Air (HEPA) filters and active charcoal adsorbers to entrap and prevent releases of radioactive particulates to the environment. Over the previous licence term, Nordion's airborne emissions have remained well below their respective regulatory limits and no action levels were exceeded (table 6). The monitoring data demonstrates that releases to the atmosphere from the Nordion facility continue to be effectively controlled.

Table 6: Nordion's air emissions monitoring results, 2015-2023

	Parameter (GBq/yr)					
Year	**Co-60**	**I-125**	**I-131**	**Xe-133**	**Xe-135**	**Xe-135m**
DRL	**70.1**	**4,880**	**3,790**	**61,200,000**	**7,660,000**	**4,600,000**
2015	0.005	0.12	0.15	11,916	8,237	10,758
2016	0.006	0.21	0.35	7,277	4,299	5,421
2017	0.0034	0.0012	0.0008	0	0	0
DRL	**250**	**952**	**686**	**677,000,000**	**102,000,000**	**69,000,000**
2018	0.002	0	0.006	0	0	0
2019	0.00002	0	0	0	0	0
2020	0	0	0	0	0	0
2021	0.00004	0	0	0	0	0
2022	0.0003	0	0	0	0	0
2023	0.000001	0	0	0	0	0

Liquid Effluent

Nordion's Environmental Protection Program controls and monitors liquid releases from its facility. Nordion collects its liquid effluent in holding tanks which provide time for radionuclides to delay and let decay. Nordion and samples and analyzes the effluent for the levels of radiological and non-radiological contaminants. The effluent analysis results are then compared to established DRLs and the City of Ottawa's Sewer Use By-law [38] limits to ensure compliance prior to release to the municipal sanitary sewer. The monitoring data for liquid effluent provided in table 7, shows that liquid effluent releases have consistently been well below their respective regulatory limits and there have been no action level exceedances for their liquid effluent. The monitoring data demonstrates that Nordion's Environmental Protection Program effectively

controls their liquid effluent releases and continues to be protective of the environment and people.

Table 7: Nordion's liquid effluent monitoring results, 2015-2023

	Parameter (GBq/yr)								
Year	**Beta emitters (<1MeV)**	**Beta emitters (>1MeV)**	**I-125**	**I-131**	**Mo-99**	**Co-60**	**Nb-95**	**Zr-95**	**Cs-137**
DRL	**66,000**	**210,000**	**73,600**	**23,300**	**1,120,000**	**155,000**	**558,000**	**749,000**	**137,000**
2015	0.191	0.044	0.111	0.006	0.060	0.019	0.0010	0.0010	0.0004
2016	0.222	0.051	0.144	0.006	0.052	0.026	0.0010	0.0015	0.0007
2017	0.212	0.048	0.145	0.006	0.049	0.022	0.0010	0.0020	0.0007
DRL	**763**	**35,000**	**1,190**	**389**	**10,200**	**35.4**	**3,250**	**2,060**	**24.8**
2018	0.243	0.055	0.146	0.007	0.055	0.027	0.0010	0.0017	0.0007
2019	0.162	0.038	0.063	0.004	0.036	0.020	0.002	0.0019	0.0007
2020	0.226	0.057	0	0	0	0.031	0.0015	0.0013	0.00076
2021	N/A	N/A	0	0	0	0.0046	0.002	0.002	0.001
2022	N/A	N/A	0	0	0	0.038	0.002	0.001	0.001
2023	N/A	N/A	0	0	0	0.026	0.0005	0.0009	0.0006

Assessment and Monitoring

Nordion's application includes an Environmental Monitoring Program to monitor the surrounding environmental media for radioactive and non-radioactive contaminants and to verify the effectiveness of controls in place for airborne emissions and liquid effluent releases. Nordion's environmental monitoring results for soil, groundwater, and gamma radiation exposures using environmental thermoluminescent dosimeters (TLDs) demonstrate that the Environmental Monitoring Program currently in place protects the public and the environment. CNSC staff assessed Nordion's proposed Environmental Monitoring Program and confirm it meets the requirements in CSA N288.4-10, *Environmental Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills* [30]. CNSC staff expect Nordion to continue maintaining and implementing an effective Environmental Monitoring Program.

Groundwater Quality Monitoring

Nordion monitors groundwater at least once a year for hazardous substances such as ammonia, nitrate, dissolved organic carbon, total dissolved solids, iron and total petroleum hydrocarbons. The monitoring is done to ensure that there are no significant changes over time in results. For 2015 through 2023, the results of monitoring demonstrated that there were no significant changes for hazardous substances in the ground water relative to previous license period which were all near the background levels or at the detection limit.

Nordion also performs radiological sampling for groundwater at least once a year. The 2015 to 2023 results showed that only naturally occurring radionuclides were detected which are not processed at this site.

Therefore, the results indicate that releases of nuclear and hazardous substances from the Nordion facility have had no detectable impact on groundwater quality.

Soil Sampling

Nordion conducts soil sampling every two years to determine the levels of radiological contaminants in the soil. Soil sampling was performed from 2015 to 2023, and analysis results showed no nuclear substances attributable to the Nordion licensed activities were detected.

Environmental TLDs

Nordion's Environmental Monitoring Program includes the use of environmental TLDs to monitor gamma radiation around the facility and Nordion has also positioned TLDs at nearby businesses and residences. The TLD monitoring results for all locations for the currently licence term has consistently been well below the public dose limit of 1 mSv/year and this shows that the public is protected from Nordion's operations.

Protection of People

Within the environmental protection SCA, protection of people is included to ensure that members of the public are not exposed to an "unreasonable" risk with respect to nuclear and hazardous substances discharged from nuclear facilities. During Nordion's previous licensing period, there have been no releases of nuclear or hazardous substances to the environment from this facility that would pose a risk to the public or environment. Release data for nuclear facilities is available in the Radionuclide Release Datasets webpage on the CNSC's Open Government Portal, **https://open.canada.ca/data/organization/cnsc-ccsn,** and includes annual estimated public doses from nuclear facilities. Effluent and environmental monitoring results for Nordion is also available in the Regional Information and Monitoring Network webpage on the CNSC's Open Government Portal. The annual estimated public doses for Nordion in Table 8 are well below the regulatory dose limit of 1 mSv/yr. CNSC staff expect Nordion to continue protecting the public and the environment from nuclear and hazardous substances discharged from the facility.

Table 8: Nordion's annual estimated dose to the public, 2015-2023

Estimated Dose to Public (mSv/yr)									
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**Regulatory Limit**
0.0095	0.0021	0.000052	0.000067	0.00087	0.00122	0.00185	0.00156	0.000796	1

Environmental Management System (EMS)

CNSC's REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [29], requires that all licensees maintain an Environmental Management System to describe the integrated activities associated with their facility's protection of the environment. Nordion's licence renewal application includes an Environmental Management System Manual [39], which includes activities such as establishing annual environmental objectives and targets. CNSC staff review and assess these objectives and targets as part of compliance verification activities and CNSC staff expect Nordion to continue maintaining and implementing an effective EMS.

2.9.3 Summary

2.9.3.1 Past Performance

Throughout the licensing period, CNSC staff assessed and rated Nordion's Environmental Protection performance as satisfactory. Nordion's data summarized above demonstrate that airborne and waterborne releases of radioactive and hazardous substances have remained well below regulatory limits and their Environmental Protection Program is effective in protecting the health and safety of the public and environment. Additionally, environmental protection focused inspections at Nordion have resulted in no major findings. CNSC staff are satisfied that Nordion has implemented an effective environmental protection program at the facility.

2.9.3.2 Regulatory Focus

CNSC staff will monitor Nordion's environmental protection performance through regulatory compliance oversight activities including onsite inspections and desktop reviews of relevant program documentation, which includes reviewing monitoring results and reviewing updated Environmental Protection Program documents.

2.9.3.3 Proposed Improvements

Overall, there are no major changes anticipated for the environmental protection SCA for Nordion although CNSC staff expect Nordion will continue to identify

and implement improvements to its Environmental Protection Program documents. Over the next licence period, CNSC expects Nordion to implement REGDOC-2.9.2, *Controlling Releases to the Environmental* [40], which was published in 2024 and to implement newer versions of CSA N288.1, N288.4, N288.5, N288.6 and N288.7. Finally, an update of Nordion's ERA is due in 2027.

2.9.4 Conclusion

Based on CNSC staff's assessment of Nordion's licence renewal application and supporting documents, CNSC staff conclude that Nordion's performance has been satisfactory in this SCA. Nordion has appropriate measures and programs to meet CNSC expectations for the Environmental Protection SCA. CNSC staff conclude that Nordion will make adequate provisions for the protection of the public and the environment.

2.10 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 derived from the participation in exercises.

The specific areas that comprise this SCA at the Nordion facility include:

- Nuclear emergency preparedness and response
- Fire protection

2.10.1 Trends

The following table indicates the overall rating trends for the emergency management and fire protection SCA over the current licensing period:

TRENDS FOR EMERGENCY MANAGEMENT AND FIRE PROTECTION								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments								
CNSC staff consistently rated the Emergency Management and Fire Protection SCA as satisfactory (SA) during the licence period. During the licensing period, Nordion has maintained appropriate programs and measures in place to effectively respond to an unlikely emergency or fire event. Nordion's Fire Protection Program meets the requirements of CSA standard N393-13, Fire Protection for Facilities that Process, Handle, or Store radioactive Substances. CNSC staff continue to incorporate aspects of emergency and fire response and review of fire protection during regular compliance inspections.								

2.10.2 Discussion

Nuclear Emergency Preparedness and Response

During the licence period, Nordion's emergency programs and procedures have been reviewed through routine compliance inspections, emergency preparedness exercises in accordance with REGDOC 2.10.1 *Nuclear Emergency Preparedness and Response* [41].
Nordion's emergency plan relies on external response assistance from the Ottawa Fire Services, HAZMAT and Ottawa Paramedic Services to deal with emergency situations at its facility. Nordion continues to conduct full scale emergency response exercises involving external agencies. During the current licence period, Nordion conducted emergency exercises in 2016, 2019 and 2022.The next exercise is scheduled for 2025. CNSC staff have observed these exercises and conclude that they are meeting requirements to demonstrate an effective, coordinated response. Some deficiencies were noted during the exercises and all actions resulting from these inspections are now closed. CNSC staff also conducted an Emergency Management specific inspection in 2017. All non-compliances were addressed in a timely matter.

Fire Protection

Fire Protection is achieved through the implementation and maintenance of a Fire Protection Program (FPP). Nordion has an acceptable FPP in place to minimize the risk to the health and safety of persons and to the environment from fire, through appropriate fire protection system design, fire safety analysis, fire safe operation and fire prevention. The program has been established to comply with the requirements of the following codes and standard:

- CSA N393-22, *Fire Protection for Facilities that Process, Handle, or Store Radioactive Substances* (N393-22) [24]
- *National Building Code of Canada, 2020* (NBCC) [23]
- *National Fire Code of Canada, 2020* (NFCC) [24]

CNSC staff oversees the implementation of Nordion's FPP through regular compliance verification activities. In March 2024, CNSC staff conducted a compliance inspection and confirmed that the implementation of the fire protection program met regulatory requirements, and the overall condition of the facility is satisfactory with respect to fire protection. Three NNCs were raised during the inspection. Nordion submitted acceptable corrective actions and the NNC's were closed.

During this licence period, Nordion submitted annual third-party review reports of inspection, testing and maintenance of fire protection equipment in accordance with CNSC regulatory requirements. CNSC staff reviewed these reports and confirmed that Nordion continues to meet its licence obligations for fire protection.

2.10.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.10.3.1 Past Performance

Through the review of Nordion's documentation during the licence period and compliance inspections, CNSC staff conclude that Nordion's emergency management program meets regulatory requirements. CNSC staff has rated Nordion's performance for this SCA as satisfactory over the licence period.

CNSC staff monitor Nordion's implementation of its fire FPP through compliance verification activities, and Nordion continues to maintain a satisfactory program over the last 10 years. CNSC staff conclude that the fire protection program at Nordion meets regulatory requirements and Nordion is performing satisfactorily with respect to this SCA.

2.10.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance in this area through regulatory oversight activities including onsite inspections and desktop reviews. CNSC staff will observe Nordion's performance during an upcoming emergency response exercise and verify that the changes made to Nordion's programs were effective in improving its emergency response capability.

2.10.3.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that Nordion will continually identify and implement improvements to its programs.

2.10.4 Conclusion

CNSC staff conclude that Nordion has an acceptable Emergency Management and Fire Protection Program and continues to meet CNSC expectation for this SCAs. Overall, Nordion's compliance with the Emergency Management and Fire Protection SCA has been satisfactory.

2.11 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.

These specific areas that comprise this SCA at the Nordion facility include:

- Waste characterization
- Waste minimization
- Waste management practices
- Decommissioning plans

2.11.1 Trends

The following table indicates the overall rating trends for the waste management SCA over the current licensing period:

TRENDS FOR WASTE MANAGEMENT								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments CNSC staff consistently rated the Waste Management SCA as satisfactory during the licence period. Nordion maintains an adequate Waste Management program. The preliminary decommissioning plan for the facility was revised in 2022 and found to be acceptable by CNSC staff. The next submission is expected in 2027 based on the five-year PDP submission cycle.								

2.11.2 Discussion

Waste Characterization/Waste Minimization

The processes used to store, manage, process, and dispose of radioactive waste are documented in Nordion's Waste Management Program. During the licence period, Nordion has undertaken several initiatives to continually improve its waste management practices. Nordion has a program which is designed to reduce the volume of waste currently being shipped to external radioactive waste management facilities. If the waste's radioactive content meets the release criteria outlined in the *Nuclear Substance and Radiation Devices Regulations* [42] the waste can be released unconditionally from the facility. During the licence period, Nordion implemented this program across the entire facility.

Waste Management Practices

CNSC staff assessed Nordion's application, including waste management programs and procedures, and confirmed that it includes proposed measures to address CNSC requirements concerning waste characterization, waste minimization and waste management practices in accordance with REGDOC-2.11.1 *Waste Management, Volume I: Management of Radioactive Waste* [43]. CNSC staff are satisfied that the applicant's documentation meets CNSC regulatory requirements.

Decommissioning Plan

The decommissioning of a nuclear facility is required to be considered in all phases of the facility's life cycle. Paragraph 3(k) of the *Class I Nuclear Facilities Regulations* [5] , requires that licence applications contain information concerning the proposed plan for the decommissioning of the nuclear facility or of the site. Decommissioning should be conducted in a manner that ensures that the health, safety, and security of workers, the public, and the environment are protected.

The CNSC requires that preliminary decommissioning plans (PDPs) be periodically updated to reflect any changes in the facility or operations at a minimum of every five years or when required by the Commission.CNSC staff reviewed Nordion's PDP in 2022 and found that it meets the applicable regulatory requirements. An updated submission is due to the CNSC in 2027.

2.11.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.11.3.1 Past Performance

Based on the review of Nordion's reports and submissions and CNSC routine compliance inspections, CNSC staff have rated Nordion's performance for the waste management SCA as satisfactory over the current licensing period.

2.11.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance for the waste management SCA through regulatory oversight activities, including inspections and desktop reviews of relevant program documentation.

2.11.3.3 Proposed Improvements

There are no changes anticipated in the near future for this SCA. The PDP must be kept current to reflect any changes in the site or facility. CNSC staff expect Nordion to review and update the decommissioning plan on a five-year cycle as documented in the proposed LCH.

2.11.4 Conclusion

Based on CNSC staff's assessment of Nordion's licence application and supporting documents, CNSC staff conclude that Nordion has proposed appropriate measures and programs to meet CNSC expectations for the waste management SCA. CNSC staff conclude that the submissions made by Nordion in support of its waste management program and decommissioning plan are satisfactory and meet regulatory requirements.

2.12 Security

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

Specific performance evaluation for security is identified as sensitive information and has been designated as prescribed information. This information is not available for public release.

The specific areas that comprise this SCA at the Nordion facility include:

- Facilities and equipment

- Response arrangements
- Security practices

2.12.1 Trends

The following table indicates the overall rating trends for the security SCA over the current licensing period:

TRENDS FOR SECURITY								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
FS	FS	FS	FS	SA	SA	SA	SA	SA
Comments								
Nordion has implemented and maintained a security program that meets regulatory requirements under the General Nuclear Safety and Control Regulations (GNSCR) and Part 2 of the Nuclear Security Regulations (NSR) to prevent the loss, unauthorized removal and sabotage of nuclear substances, nuclear materials, prescribed equipment or information. During the current licence period, CNSC staff rated Nordion's SCA Security as "fully satisfactory" from 2015 to 2018. Starting in 2019, facility performance assessment ratings were simplified and the "Fully Satisfactory (FS)" was replaced by the "Satisfactory (SA)" rating. It is important to recognize that a facility that received an SCA performance rating of FS prior to 2019 and now has a rating of SA, does not necessarily indicate a reduction in performance.								

2.12.2 Discussion

Regulatory Requirements

Nordion is subject to the *General Nuclear Safety and Control Regulations* (GNSCR) [6], which provide obligations for licensees across all SCAs. Specific obligations that distinctly encompass the security SCA include:

- GNSCR par. 12(1) (c) *Every licensee shall take all reasonable precautions to protect the environment and the health and safety of persons and to maintain the security of nuclear facilities and of nuclear substances;*
- GNSCR par.12(1)(g) *Every licensee shall implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, prescribed equipment or prescribed information, or the illegal use of a nuclear facility;*
- GNSCR par.12(1)(h) *Every licensee shall implement measures for alerting the licensee to acts of sabotage or attempted sabotage anywhere at the site of the licensed activity;* and
- GNSCR par.12(1)(j) *Every licensee shall instruct the workers on the physical security program at the site of the licensed activity and on their obligations under that program.*

Furthermore, sections 21 to 23 of the GNSCR provide obligations for all licensees on the identification, storage, handling, and transfer requirements of information designated as "prescribed information".

REGDOC-2.12.3 version 2.1: *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material* [44] provides regulatory expectations and guidance for Nordion regarding the CNSC's expectations under the GNSCR for security.

In addition to the regulatory requirements stipulated in the GNSCR, this facility is identified as a named entity within Schedule 2 of the *Nuclear Security Regulations* (NSR) [45]. As such, and as identified by paragraph 40(1)(b) of the NSRs, Nordion is subject to Part 2 of the NSR, specifically sections 39 to 48.

Nordion has implemented and maintained a security program that meets regulatory requirements under the GNSCR and Part 2 of the NSR and REGDOC 2.12.3 version 2.1 to prevent the loss, unauthorized removal and sabotage of nuclear substances, nuclear materials, prescribed equipment or information. The facility's security program includes administrative and technical measures that meet current CNSC regulatory requirements for nuclear security.

Facilities and Equipment

Nordion satisfactorily maintains the security systems and devices for the facility and the areas with high-risk radioactive sources. In addition, Nordion maintains processes for testing and maintaining the security devices, and assessment and detection systems. Equivalent security measures are also implemented for the secure transportation of high-risk radioactive sources by road. Nordion maintains a general transport security plan for high-risk radioactive sources that meets CNSC requirements. The transport security plan is submitted and reviewed for acceptance by the CNSC annually.

Response Arrangements

Nordion maintains onsite security personnel at all times. Alarm detection and assessment systems are continuously monitored by an on-site security officer. Nordion has established a response protocol with the Ottawa Police Service to ensure response of armed police officers in a timely manner, should a security related incident occur. In 2019 and 2024, Nordion conducted a security exercise with the Ottawa Police Tactical Unit at the facility and a transport security table-top exercise in 2019.

Security Practices

CNSC staff assessed Nordion's implementation of the physical protection program from the access control perspective. Measures for controlling access to persons and vehicles were assessed as being satisfactory. Furthermore, security measures for controlling access to/and from high-risk radioactive source locations are also satisfactory.

The licensee has implemented a satisfactory facility access security clearance process that includes a criminal record name check for individuals with unescorted access to high- risk radioactive sources. In addition, Nordion has a security awareness program for all staff and a supervisory awareness program for managers and supervisors to enhance capabilities in identifying and responding to unusual behaviors that may lead to undesirable activity or violence.

Overall, the facility's physical protection program includes administrative and technical measures that meet current regulatory requirements for security.

2.12.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.12.3.1 Past Performance

During the licence period, CNSC staff performed security inspections (2015, 2017, 2019 and 2023) to verify that the licensee complied with regulations and to assess the effectiveness of the licensee's security measures. 2 NNCs were raised during the inspections. Corrective actions were submitted and accepted by CNSC staff. Both NNCs are closed.

Since 2015, Nordion has maintained at minimum, a SA rating for its security program. During the licensed period, Nordion has maintained an effective security program that meets CNSC regulatory requirements.

2.12.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance for the security SCA through regulatory oversight activities, including on-site inspections and technical assessments of relevant program documentation.

2.12.3.3 Proposed Improvements

In November 2024, Nordion submitted the Nordion Physical Security Report and Plan for 2023. These security improvements noted in the plan are prescribed information and were reviewed and accepted by CNSC staff. CNSC staff expect Nordion to implement these improvements during the proposed licence period.

2.12.4 Conclusion

Based on the review of Nordion's reports and submissions, and CNSC compliance inspections, CNSC staff have rated Nordion's performance for the Security SCA as satisfactory from 2015 to 2023.

CNSC staff concluded that the implementation of the security programs at Nordion meet regulatory requirements in the areas of facilities and equipment, response arrangements and security practices.

2.13 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 safeguards agreement between Canada and the IAEA as well as all other measures arising from the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) [46]. This SCA comprises a safeguards program and non-proliferation requirements, including import and export controls. The export and import of nuclear and nuclear dual-use items and the export of risk-significant sealed sources requires a separate authorization from the CNSC.

The specific areas that comprise this SCA at the Nordion facility include:

- Nuclear material accountancy and control
- Access and assistance to the IAEA
- Operational and design information
- Import and export

2.13.1 Trends

The following table indicates the overall rating trends for the Safeguards and Non-Proliferation SCA over the current licensing period:

TRENDS FOR SAFEGUARDS AND NON-PROLIFERATION								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments Nordion meets CNSC expectations in the safeguards SCA and non-proliferation. CNSC staff consistently rated the Safeguards SCA and Non-Proliferation as satisfactory during the licence period.								

2.13.2 Discussion

Pursuant to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) [46], Canada has entered into a Comprehensive Safeguards Agreement and an Additional Protocol with the IAEA (hereafter referred to as the safeguards agreements). The objective of the safeguards agreements is for the IAEA to provide annual assurance to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there is no indication of undeclared material.

The CNSC provides the mechanism, through the NSCA, regulations and licences, for the implementation of safeguards. Conditions for the application of safeguards are contained in CNSC facility operating licences and the criteria to meet those conditions are contained in the LCH and in regulatory document REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy* [47]. Compliance includes

the timely provision of reports on the movement and location of nuclear material, provision of access and assistance to IAEA inspectors for safeguards activities, support for IAEA equipment, and the submission of annual operational information, additional protocol updates as well as accurate design information.

CNSC REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy* sets out requirements and guidance for safeguards programs for applicants and licensees who possess nuclear material, operate a uranium and/or thorium mine, carry out specified types of nuclear fuel-cycle related research and development work, and/or carry out specified types of nuclear-related manufacturing activities. The requirements and guidance in this document are essential to Canadian compliance with the safeguards agreements entered into with the IAEA and are consistent with modern national and international practices.

CNSC staff are satisfied with Nordion's safeguards program and find the program meets the requirements set out in REGDOC 2.13.1. The program conforms to measures required by the CNSC to meet Canada's international safeguards obligations as well as other measures arising from the Treaty on the Non-Proliferation of Nuclear Weapons [46].

The import and export of controlled nuclear substances, equipment and information prescribed by the *Nuclear Non-proliferation Import and Export Control Regulations* (NNIECR) [48] requires separate licence authorization from the CNSC, consistent with section 26(a) of the NSCA and subsection 3(2) of the *General Nuclear Safety and Control Regulations* [6].

CNSC REGDOC-2.13.2 – *Import and Export (Version 2)* [49] provides further guidance on obtaining and complying with this type of licence authorisation.

Canada has also made a commitment to implement the IAEA *Code of Conduct on the Safety and Security of Radioactive Sources* (Code) [50]

As required by section 26(a) of the NSCA as well as the NNIECR, Nordion has applied for and obtained CNSC Import and Export Licences which provide the necessary authorizations to import/export of nuclear and nuclear dual-use related items. Nordion has a Designated Officer issued export licence EL-11A.01/2025 [51] that is used to for all exports of sources that are not export risk-significant sources. This licence is issued for the duration of the Class IB Nuclear Substance Processing Facility Operating Licence. As required by section 26(a) of the NSCA, as well as the Code, Nordion has applied for and obtained CNSC Export Licences which provide the necessary authorizations to export risk-significant sealed sources. These licences are specific for export of risk-significant radioactive sources.

CNSC staff are satisfied that an effective licensing and compliance program of nuclear and nuclear-related dual-use items, and risk-significant sealed sources has been implemented at Nordion's facility.

2.13.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.13.3.1 Past Performance

CNSC staff are satisfied that an effective safeguards and non-proliferation program has been implemented at the facility and expect this to continue under Nordion. Details pertaining to the specific areas within this SCA are presented in the following subsections.

Furthermore, CNSC staff are satisfied that an effective licensing and compliance program of nuclear and nuclear-related dual-use items and risk-significant sealed sources has been implemented at Nordion's facility.

Nuclear Material Accountancy and Control

CNSC staff determined that the facility has complied with CNSC's regulatory requirements in accordance with REGDOC- 2.13.1, *Safeguards and Nuclear Material Accountancy* [47].

Access and Assistance to the IAEA

CNSC staff confirmed that the facility has granted adequate access and assistance to the IAEA for safeguards activities. During 2015-2025, the IAEA performed inspections and verifications that included one Physical Inventory Verification and one Complementary Access, respectively. In all cases, the facility provided the IAEA with the necessary access and assistance to perform the activities and complied with all regulatory requirements. In all IAEA inspections, the facility had no major issues and the inspection results were satisfactory.

Operational and Design Information

CNSC staff are satisfied that annual operational programs, annual updates to the additional protocol, design information questionnaires, and other required information have been submitted to the IAEA and the CNSC in a timely manner.

Safeguards Equipment, Containment and Surveillance

Not applicable. There is no IAEA safeguards equipment installed at the facility.

Import and Export

The scope of the non-proliferation program under Nordion's licence is limited to the tracking and reporting of foreign obligations and origins of nuclear material. CNSC staff confirm that the CNSC's regulatory requirements in this respect have been met. CNSC staff conducted an inspection in 2023 of Nordion's shipping documentation associated with export licences of risk-significant radioactive sources and found Nordion to be in compliance with no NNCs raised.

2.13.3.2 Regulatory Focus

CNSC staff will continue to monitor and evaluate Nordion's performance through participation in IAEA inspections, CNSC inspections and ongoing assessments of compliance with reporting requirements.

2.13.3.3 Proposed Improvements

There are no major changes anticipated in the near future for this SCA. CNSC staff expect that Nordion will continually identify and implement improvements to its programs.

2.13.4 Conclusion

Based on CNSC staff assessment of the proposed safety and control measures outlined in Nordion's licence renewal application, supporting documents and past performance, Nordion's implementation of the safeguards and non-proliferation SCA is satisfactory and continues to meet all applicable regulatory requirements.

2.14 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.

The specific areas that comprise this SCA at the Nordion facility include:

- Packaging and Transport
- Package Design and Maintenance
- Registration for Use

2.14.1 Trends

The following table indicates the overall rating trends for the Packaging and Transport SCA over the current licensing period:

TRENDS FOR PACKAGING AND TRANSPORT								
Overall Compliance Ratings								
2015	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments								
Nordion has a packaging and transport program that ensures compliance with the *Packaging and Transport of Nuclear Substances Regulations, 2015* and the Transportation of Dangerous Goods Regulations. CNSC staff monitor Nordion's implementation of this program through compliance verification activities and review of annual reports.								

2.14.2 Discussion

Packaging and Transport

Nordion has developed and implemented a packaging and transport program for activities to ensure compliance with the *Packaging and Transport of Nuclear Substances Regulations, 2015* [52] and the *Transportation of Dangerous Goods Regulations* [53].

Nordion's transport program procedures detail requirements and practices. Nordion currently consigns Type B, Type A and excepted packages.

Nordion reported events in a timely matter to the CNSC, as required by the *Packaging and Transport of Nuclear Substances Regulations, 2015.*

During this licence period, CNSC staff conducted five inspections focused on transport and assessed the performance of the licensee through other compliance verification activities, including event reviews and review of annual compliance reports submitted by Nordion. No notices of non-compliance were issued during this licence period.

Packaging Design and Maintenance/Registration for use

Nordion's packaging and transport program covers elements of package design, package maintenance, and the registration for use of certified packages as required by the regulations.

2.14.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

2.14.3.1 Past Performance

Through ongoing compliance oversight, CNSC Staff are satisfied that an effective packaging and transport program has been implemented, ensuring ongoing compliance to all applicable transport regulations.

2.14.3.2 Regulatory Focus

CNSC staff will continue to monitor Nordion's performance for the transport and packaging SCA through regulatory oversight activities, including on-site inspections and technical assessments of relevant program documentation.

2.14.3.3 Proposed Improvements

There are no proposed improvements for this SCA. CNSC staff expect that Nordion will continually identify and implement improvements to its programs.

2.14.4 Conclusion

Based on CNSC staff's assessment of Nordion's application and supporting documents, CNSC staff conclude that Nordion has appropriate programs and procedures in place to meet CNSC expectations for the packaging and transport SCA. CNSC staff conclude that Nordion will maintain an effective packaging and transport program that will ensure compliance with regulatory requirements. CNSC staff rate this SCA as satisfactory.

3. Indigenous and Public Consultation and Engagement

3.1 Indigenous Consultation and Engagement

The common-law duty to consult with Indigenous Nations and communities applies when the Crown contemplates actions that may adversely affect potential or established Indigenous and/or treaty rights. The CNSC ensures that all of its licence decisions under the NSCA uphold the honour of the Crown and consider Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the *Constitution Act, 1982* [54]. CNSC staff's considerations include but are not limited to Indigenous Nations and communities established or potential rights pertaining to lands and waters in relation to the facility and the expected and/or potential impacts of the activities conducted on the site in accordance with a CNSC issued licence.

REGDOC-3.2.2, *Indigenous Engagement* [55], sets out requirements and guidance for licensees whose proposed projects may raise the Crown's duty to consult. While the CNSC cannot delegate its obligation, it can delegate procedural aspects of the consultation process to licensees, where appropriate. The information collected and measures proposed by licensees to avoid, mitigate, or offset potential adverse impacts from the proposed licence renewal may be used by CNSC staff in meeting its consultation obligations.

Based on the information in Nordion's application, CNSC staff found the licence renewal is unlikely to cause new adverse impacts to the exercise of potential or established Indigenous and/or Treaty rights as it would not change the Nordion site characterization or lead to new offsite impacts.

CNSC Staff's Consultation and Engagement Activities

CNSC staff remain committed to building long-term relationships with Indigenous Nations and communities who have interest in CNSC-regulated facilities within their traditional and/or treaty territories. The CNSC's Indigenous engagement practices include sharing information, discussing topics of interest, seeking feedback and input on CNSC processes, and providing opportunities to participate in environmental monitoring programs, such as the CNSC's Independent Environmental Monitoring Program (IEMP). IEMP was conducted at the Nordion site during the licence period in 2016, 2018 and most recently in 2023. CNSC staff reached out to interested Indigenous Nations to participate in the IEMP sampling at the Nordion facility. The CNSC also provides funding support, through its Participant Funding Program (PFP) and Indigenous and Stakeholder Capacity Fund, for Indigenous peoples to meaningfully participate in Commission proceedings and ongoing regulatory activities. Some of the interested Indigenous Nations such as the Algonguins of Pikwàkanagàn and Kebaowek First Nation, regularly intervene in the Regulatory Oversight Report (RoR) in regard to the Nordion facility.

3.1.1 Discussion

CNSC staff identified several Indigenous Nations and communities that may have an interest in the Nordion licence renewal application, due to the proximity of their communities, treaty areas and traditional territories to the Nordion Class IB facility in Kanata, Ontario, or due to previously expressed interest in being informed of CNSC licenced activities occurring in or proximal to their territories or communities.

The Indigenous Nations and communities listed below have been identified based on analysis conducted by CNSC staff using the Aboriginal and Treaty Rights Information System and other mapping tools, as well as through a review of existing CNSC and open resources including records of Indigenous Nations and communities who may have expressed interest in the Nordion facility in the past. Should other Indigenous Nations and communities not included in the list identify interest in the license application moving forward, they will be added as appropriate.

Indigenous Nations and communities with potential or established rights in relation to the renewal of the Nordion facility include:

- The Algonquins of Pikwàkanagàn First Nation
- Kitigan Zibi Anishinabeg First Nation
- Kebaowek First Nation
- The Algonquin Anishinabeg Nation Tribal Council
- Algonquins of Ontario

Indigenous Nations and communities with a potential interest in the Nordion facility include:

- Mohawks of the Bay of Quinte
- Métis Nation of Ontario

The CNSC has signed Terms of Reference (TOR) for long-term engagement with the Algonquins of Pikwàkanagàn First Nation, Kebaowek First Nation and the Métis Nation of Ontario. The CNSC also has regular engagement and meetings with Kitigan Zibi Anishinabeg First Nation and the Algonquins of Ontario and has integrated discussions, and engagement activities on Nordion's licence renewal application as part of regular meetings and discussions with each Nation. The CNSC is open to developing TORs for long-term engagement with other Indigenous Nations and communities as appropriate.

A project notification letter was sent to all identified Indigenous Nations and communities on December 6th 2024. These letters provided information regarding the proposed licence renewal application, opportunities to participate in the Commission's hearing process, and information about the CNSC's (PFP) to facilitate participation in the hearing and regulatory hearing process.

CNSC staff offered to meet with all identified Indigenous Nations and communities to discuss the application and raised Nordion's application in regular meetings with the Algonquins of Pikwàkanagàn First Nation, Kebaowek First Nation, the Métis Nation of Ontario,Kitigan Zibi Anishinabeg First Nation and the Algonquins of Ontario.

CNSC staff followed up with interested Indigenous Nation and communities via phone calls, to discuss intervention deadlines and hearing details and to answer any questions about the licence renewal application,

All of the identified Indigenous Nations and communities have been encouraged to participate in the regulatory review process and in the Commission hearing through interventions to advise the Commission directly of any concerns they may have in relation to this licence renewal application. The Algonquins of Pikwàkanagàn First Nation and Kitigan Zibi Anishinabeg First Nation have received participant funding to intervene in the hearing.

Based on CNSC staff's engagement activities to date, CNSC staff have not been made aware of any specific concerns with regards to potential new impacts to the exercise of rights and interests as a result of the licence renewal. However, the identified Indigenous Nations and communities have been encouraged to notify CNSC staff and the Commission with regards to their position and any concerns in relation to the licence renewal application through their intervention. CNSC staff are committed to working with each Nation to ensure any concerns they may have are addressed through our ongoing engagement and collaboration.

Licensee Engagement Activities

Nordion (Canada) Inc.'s application does not propose a change to the operations of the Nordion Class 1B nuclear substance processing facility and therefore is unlikely to cause new adverse impacts to the exercise of potential or established Indigenous and/or treaty rights. Over the course of Nordion (Canada) Inc.'s licensing period, the licensee has met their regulatory requirements for Indigenous engagement and public outreach while actively working to enhance their efforts. Nordion is focusing on making Indigenous engagement more tailored and direct to better address the needs and preferences of the communities involved.

In 2023 Nordion collaborated with the Algonquins of Pikwàkanagàn First Nation, to enhance Nordion's approach to engagement through more direct interactions. This includes arranging site tours and jointly developing a tailored engagement plan. Nordion is looking to replicate this approach with other Indigenous Nations who may have and interest in their operations, in the coming year, to foster deeper relationships and collaboration.

CNSC staff are satisfied with Nordion (Canada) Inc.'s engagement activities to date and recommend that Nordion (Canada) Inc. continue their efforts to enhance their public and Indigenous engagement programs and activities throughout their licensing term. The licensee is also recommended to continue engaging with Indigenous Nations that have expressed interest in their operations and activities.

3.1.2 Conclusion

As Nordion's licence application does not propose a change to the operations of the Nordion Class 1B nuclear substance processing facility, CNSC staff conclude that Nordion's proposed licence will not cause any new adverse impacts to any potential or established Indigenous and/or treaty rights. For this licence renewal application, both Nordion and the CNSC conducted engagement activities with interested Indigenous Nations and communities, to ensure that each Nation has the ability to express any specific issues or concerns with regards to the licence renewal application and participate in the regulatory review process including the Commission hearing. The CNSC is committed to meaningful, ongoing engagement and collaboration with Indigenous Nations and communities that have an interest in the Nordion facility and activities and encourages Nordion (Canada) Inc. to continue to engage with interested Indigenous Nations and communities during their licensing term and other ongoing activities of interest.

3.2 CNSC Public Consultation and Engagement

The NSCA mandates the CNSC to disseminate objective scientific, technical and regulatory information to the public concerning its activities and the activities it regulates. CNSC staff fulfill this mandate in a variety of ways, including hosting in-person and virtual information sessions and through annual regulatory reports.

3.2.1 Discussion

In accordance with section 17 of the *Canadian Nuclear Safety Commission Rules of Procedure* [56], a Notice of Public hearing was issued and posted on the CNSC website on November 4, 2024, inviting written comments and requests for appearances before the Commission. CNSC staff also informed the public of Nordion's application, the public Commission hearing, and participant funding availability, via the CNSC's website, email subscription list, and social media channels.

CNSC staff annually report to the Commission, the public and Indigenous Nations and communities on the regulatory oversight of all the nuclear processing facilities, including the Nordion facility. The list of regulatory oversight reports is available on the CNSC's website. The public and Indigenous Nations and communities have the opportunity to review, question and comment on the regulatory oversight report. Through CNSC's Participant Funding Program (PFP), financial support was made available for participation in this licence renewal CMD (see section 3.4).

Finally, CNSC staff is anticipating holding a public webinar in March 2025 to discuss Nordion's application, staff's assessment and the public hearing process.

3.2.2 Conclusion

The CNSC is committed to keeping interested communities informed of regulatory activities occurring in regard to the Nordion facility and will continue to look for ways to enhance the involvement of interested groups.

3.3 Licensee Public Information and Disclosure

A Public Information and Disclosure Program (PIDP) is a regulatory requirement for licence applicants and licensees of Class I nuclear facilities, uranium mines and mills and certain Class II nuclear facilities. These requirements are found in REGDOC-3.2.1, *Public Information and Disclosure* [57].

The primary goal of the PIDP is to ensure that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of nuclear facilities are effectively communicated to the public. The program must include a commitment to, and protocol for ongoing, timely communication of information related to the licensed facility during the course of the licence period.

CNSC's expectations of a licensee's public information program and disclosure protocol are commensurate with the public's perception of risk of the facility, as well as the level of public interest in the licensed activities. The program and protocol may be further influenced by the complexity of the nuclear facility's lifecycle and activities, and the risks to public health and safety and the environment perceived to be associated with the facility and activities.

3.3.1 Discussion

CNSC staff have reviewed Nordion's PIDP, submitted as part of its licence application under REGDOC 3.2.1, *Public Information and Disclosure* [57]. CNSC staff regularly monitor Nordion's implementation of its public information and disclosure program to verify that it communicates regularly with its audiences in a way that is open, transparent and meaningful. CNSC staff also review yearly program updates to verify Nordion is taking community feedback into consideration and taking steps to implement PIDP adjustments as needed, to meet evolving needs of its nearby communities as it pertains to communications.

CNSC staff have reviewed Nordion's PIDP and determined that it:

- identifies clear goals and measurable objectives in terms of dissemination of information to targeted audiences
- is available to the public and is posted on the licensee's website
- targets multiple audiences in the surrounding community, elected and government representatives, employees, media, business leaders, interest groups, and community organizations.
- provides contact information for members of the public who want to obtain additional information

CNSC staff will continue to monitor Nordion's compliance with REGDOC-3.2.1 and ongoing implementation of their PIDP.

Communications activities conducted by Nordion included:

- Nordion's website was the primary communications vehicle for disclosed information including its Public Information Disclosure Protocol, nuclear safety and compliance documents (application for renewal of Nordion's operating licence), news releases, virtual tour, education products, FAQ, past links to surveys, and public disclosures.
- Nordion's Virtual Tour was promoted and posted on the website
- Event reports and other required public disclosure information was published to the website including: Annual Compliance Reports and Quarterly Event Reports, both searchable by year back to 2011.
- Surveys were conducted and questions referring to public information were monitored
- News releases were issued to inform the public of company news, achievements and issues, and media was monitored for articles, and analyzed to measure public opinion
- Advertisements targeting key audiences about safety of the community and environment were published

3.3.2 Conclusion

CNSC staff acknowledges that, Nordion has a Public Information and Disclosure Program in place which meets the regulatory requirements of REGDOC-3.2.1 *Public Information and Disclosure* [57].

CNSC staff will continue to oversee Nordion's implementation of the PIDP to ensure that it meets its obligations regarding dissemination and notifying the public and Indigenous communities on its licensed activities.

3.4 Participant Funding Program

The Canadian Nuclear Safety Commission (CNSC) established the Participant Funding Program (PFP) to:

1. enhance individual, not-for-profit organization and Indigenous Nations and Communities participation in the CNSC's environmental assessment (EA) and licensing processes for major nuclear facilities (e.g., uranium mines, nuclear power plants, nuclear substance processing, or nuclear waste facilities)
2. assist individuals, not-for-profit organizations and Indigenous Nations and Communities to bring value-added information to the Commission through informed and topic-specific interventions related to EAs and licensing (i.e., new, distinctive and relevant information that contributes to a better understanding of the anticipated effects of a project)

3.4.1 Groups Awarded Participant Funding

The Notice of Public hearing, posted on November 4, 2024, included notification of PFP opportunity. The participant funding opportunity was also advertised on the CNSC website and was included in notification letters sent to Indigenous Nations and communities. Those interested in obtaining participant funding were able to submit a completed participant funding application from that date until January 17, 2025.

The Funding Review Committee (FRC) reviewed the applications received and made recommendations on the allocation of funding to eligible recipients. Based on the recommendations from the FRC, the CNSC awarded a total of $40,812.34, in funding to the following recipients:

- Algonquins of Pikwàkanagàn First Nation (AOPFN)
- Kebaowek First Nation (KFN)

4. Other Matters of Regulatory Interest

4.1 Cost Recovery

Paragraph 24(2)(c) of the NSCA requires that a licence application is accompanied by the prescribed fee. The *CNSC Cost Recovery Fees Regulations* [58] (CRFR) set out the specific requirements based on the activities to be licensed. An applicant for a Class I facility licence is subject to Part 2 of CRFR, which is based on Regulatory Activity Plan fees.

4.1.1 Discussion

CNSC staff confirmed that Nordion is in good standing with respect to CRFR requirements and has paid their cost recovery fees in full. CNSC staff do not have concerns regarding payment of future cost recovery fees for this licensee.

4.1.2 Conclusion

Based on previous performance there is no concern over the payment of future cost recovery fees.

4.1.3 Recommendation

There are no requirements for any additional licensing activity or any additional licence conditions.

4.2 Financial Guarantees

Under subsection 24(5) of the *NSCA*, the licensee is required to provide a financial guarantee in a form that is acceptable to the Commission. *General Nuclear Safety and Control Regulations* [6], paragraph 3(1)(l) stipulates that, "an application for a licence shall contain a description of any proposed financial guarantee related to the activity for which a licence application is submitted." The

financial guarantee for decommissioning is established to fund the activities described in the Preliminary Decommissioning Plan (PDP). These requirements are found in REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities* [59].

A financial guarantee for decommissioning must be established to fund the activities described in a decommissioning plan. The financial guarantee shall be in a form acceptable to the Commission. Nordion currently maintains a financial guarantee for the decommissioning of their facility as licence condition 1.3 of its current licence, NSPFOL-11A.01/2025

4.2.1 Discussion

Nordion maintains a financial guarantee to fund the activities described in its preliminary decommissioning plan (PDP). Nordion currently has a stand-by letter of credit with the CNSC as the beneficiary, for CAD$6,342,684, as well as a Surety Bond with the CNSC as the beneficiary, for CAD $28,660,361, for this purpose. The financial guarantee instruments total CAD$35,003,045, which is a reduction from the CAD$45,124,748 that was in place from the previous PDP submission. This reduction was driven primarily by the removal of decommissioning activities and costs for which BWXT Medical became responsible.

4.2.2 Conclusion

CNSC staff reviewed the cost estimate and concluded that it was sufficient to decommission the facility. The cost estimate has been made using reasonable costs, including labour costs, decontamination costs, waste disposal costs, licensing costs, the necessary contingency costs, and included five years of escalating costs.

CNSC staff are satisfied that Nordion's financial guarantee, including the selection of financial instruments and estimated costs for future decommissioning of the facility, is consistent with the criteria set out in the Regulatory document REGDOC 3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities* [59].

Following a hearing in writing, in 2023, the Commission accepted [60] the revised financial guarantee proposed by Nordion for its facility.

4.2.3 Recommendation

One standardized licence condition is included in the proposed licence. Standardized licence condition G.3 requires the licensee to maintain a financial guarantee for decommissioning that is acceptable to the Commission.

4.3 Licence Period

The current licence was issued for a period of 10 years. Nordion has submitted an application [2] with a request to renew its CNSC issued operating licence for the

Nordion facility for a period of 25 years. The justification from Nordion for the longer licence period is discussed in section 1.2 of this CMD.

4.3.1 Discussion

As discussed in section 1.2, Nordion submitted justification for a 25-year licence term in Appendix B of "*Letter from Nordion- 2025 License Application (cover letter and Appendix A and B)"*. [4] With over 50 years of operating experience. the Nordion facility hazards are well understood and characterized, and the licensee has well-established and mature programs for their mitigation. 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. CNSC has a standardized licence and LCH framework which provides for effective regulatory oversight of operating facilities. Nordion is required by its licence to report on the performance of the facility through annual compliance reports, including significant changes to its operations. CNSC staff verify compliance with requirements through desktop reviews, inspections, and event reviews.

In 2002, following the coming into force of the Nuclear Safety and Control Act [1], and the evolution of CNSC's licensing process and regulatory framework, CNSC staff reviewed the feasibility of granting longer term licences. As an outcome of this review, CNSC staff developed an approach to recommending appropriate licence periods, which was based on benchmarking with international practices. This approach is outlined in CMD 02-M12 *New Staff to Recommending Licence Periods* [61] and was presented to the Commission in March. 2002. CMD 02-M12 provides a risk-informed process that has been used by CNSC staff to support recommendations regarding licence periods to the Commission in the past.

More recently, CNSC has received applications from licensees requesting renewal of licences with terms in excess of 10 years. In the past few years, the Commission has granted a 20-year licence to Cameco Fuel Manufacturing, McMaster and the RMC SLOWPOKE research reactor. These decisions identified a requirement for a midterm performance update. In addition, in 2023, the Commission granted 20-year licences to Cameco Corporation for its McArthur River, Rabbit and Key Lake Operations but included a requirement for two performance updates over this timeframe.

CNSC staff evaluated the criteria for making recommendations to the Commission on licence periods as per CMD 02-M12 and find that a 25-year licence period is justified considering:

CMD 02-M12 Licence Period Criteria	CNSC Staff Position for 25-year Licence
The recommended duration of the licence should be commensurate with the licensed activity.	Nordion's primary activity is production of high activity sealed sources for the medical and industrial

	sterilization markets. Nordion divested its medical isotopes business in 2018 focusing on its Gamma Technologies business. Nordion has not requested any changes to the specific licensed activities authorized by its licence. (see section IV of the current and proposed licence in Part 2 of this CMD). There is no specific limitation on the licence term on the basis of the licensed activity or facility life stage. Nordion has mature and adequate programs in place to safely manage the hazards associated with the licensed activities at the facility. Preliminary Decommissioning Plan does not identify an end date for the facility.
A longer licence period can be recommended when the hazards associated with the licensed activity are well characterized and their impacts well predicted, and they are within the scope considered in the environmental safety case.	Hazards associated with the licensed activities are well characterized and their impacts are well predicted and within the scope in the environmental safety case. This is documented through Nordion's Safety Analysis Reports [18,19], Environmental Risk Assessment [37] and Fire Hazard Assessment [62]. CNSC staff have reviewed these documents and considered them to be acceptable. These documents are part of the licensing basis for the Nordion facility and are reviewed at a minimum on a 5-year frequency or if there are any significant changes to the facility. CNSC staff will continue to verify and ensure that, through ongoing licensing and compliance activities and reviews, the environment and the health of persons are protected.
A longer licence period can be recommended when licensees have in place a management system, such as a	Nordion has a management system that meets the requirements of CSA N286-12. During the current licence

quality assurance program, to provide assurance that their safety-related activities are effective and maintained.	term, management system focused inspections were performed at Nordion in 2018, 2020 and 2022 and found that it meets the requirements of CSA N286-12.
A longer licence period can be recommended when effective compliance programs are in place on the part of both the applicant/licensee and the CNSC.	The CNSC has a robust and effective compliance verification program to ensure there is adequate regulatory oversight over the licensed activities at Nordion. CNSC staff verify compliance through desktop reviews, inspections and event reviews. CNSC has established, and implemented a compliance strategy for Nordion, which identifies a risk-informed frequency for inspections of each SCA. In total, CNSC staff conducted 23 inspections at Nordion since the beginning of the previous licence term in November 2015. In addition to program documentation reviews, CNSC performs desktop reviews of annual compliance reports submitted by Nordion in accordance with requirements specified in the LCH. CNSC staff also review event reports, which are submitted by Nordion in accordance with requirements specified in REGDOC-3.1.2. CNSC staff review these reports to verify that Nordion implements appropriate corrective actions, where necessary, to prevent recurrence and ensure that adequate provisions ensuring protection of the health and safety of persons and the environment remain in place.
A longer licence period can be recommended when the licensee has shown a consistent and good history of operating experience and compliance in carrying out the licensed activity.	CNSC staff review and assess licensee performance on an ongoing basis. During the previous licence period CNSC staff rated Nordion's performance as satisfactory across all SCA's each year.

	Nordion's operating performance is assessed through the submission of Annual Compliance Reports (ACRs), compliance inspections and reported to the Commission through the *Regulatory Oversight Report for Uranium and Nuclear Substance Processing Facilities* [63]. Worker doses and doses to the public have been kept below regulatory limits at all times (section 2.9.2 of this CMD), and releases to the environment have been maintained at a small fraction of the licensed release limits. Nordion has reported events as per the requirement described in REGDOC-3.1.2. CNSC staff are satisfied with Nordion's reporting and response to events during the previous licence period.
The licence period must be consistent with the requirements of the CNSC Cost Recovery Fees Regulations.	As per section 4.1, Nordion is currently in good standing with the *CNSC Cost Recovery Fees Regulations* [58].
The licence period should take account of the planning cycle of the facility and the licensee's plans for any significant change in licensed activity.	Nordion has been producing Co-60 sources for over 50 years and expects that to continue in the decades to come. Nordion has safely operated the facility at 447 March Road for decades and expects to continue to operate the facility for decades more. Nordion has conveyed in their application that a 25-Year licence term would not have an impact on Cost-Recovery Fees, Performance Reviews, CNSC program evaluations, Preliminary Decommissioning Plan, Public and Indigenous Engagement and Compliance with any changes in existing Regulations or new Regulations. No changes in licensed

	activities were requested in the application.

In addition to the criteria listed above, CNSC staff incorporated other considerations before making a recommendation on the proposed licence period. These include considerations on international practices, CNSC's regulatory oversight framework, ongoing communication and engagement, and Commission engagement opportunities.

International Approach to Nuclear Processing Facility Licensing
Internationally, nuclear processing facilities are issued licences for periods ranging from a few years to the entire life cycle of the facility. [64] The US Nuclear Regulatory Commission(NRC) [65] issues licences for a period of up to 40 years. More recently, the US NRC issued issued a 30-year licence to SHINE Medical Technologies Inc which is a medical radioisotope irradiation and processing facility.

The CNSC's regulatory framework includes requirements for periodic review and updates of essential licensee documentation as recommended in IAEA guidance. Additionally, N286-12, *Management system requirements for nuclear facilities*. [7], which is referenced in the Nordion (LCH), requires that the licensee periodically review and assess all program documentation. When these reviews and updates are carried out, the licensee must notify CNSC staff, who then assess the updated version to ensure continued compliance with the licensing basis. This provides assurance that the licensing basis remains valid and that programs in place are acceptable on a continual basis.

The CNSC is an active participant on the international scene, including with the International Atomic Energy Agency (IAEA), the Organization for Economic Cooperation and Development's Nuclear Energy Agency (NEA), the USNRC and others, which inform CNSC's regulatory framework and licensing recommendations. The CNSC also participates in IAEA's Integrated Regulatory Review Service (IRRS) missions, which help host States strengthen and enhance the effectiveness of their regulatory infrastructure for nuclear safety. The CNSC hosted an IRRS mission to Canada in 2019. The IAEA confirmed that the CNSC has a strong, effective regulatory framework and that the organization demonstrates leadership in multiple areas. The CNSC has the processes in place to achieve safety objectives on a continual basis, which align with international best practices.

CNSC Regulatory Oversight

The CNSC regulatory compliance program is effective and independent of the licence period granted by the Commission. CNSC staff have established a 10-year baseline compliance plan for all nuclear processing facilities. This baseline compliance plan is carried out regardless of licence period and verifies the continued safety through planned inspections, assessments and document reviews. The plan establishes a minimum number of inspections to be carried out at a given facility based on the facility's risk profile.

Each year CNSC staff review the compliance plan as well as the licensee's planned activities to determine if additional verification activities should be added or moved. This approach is flexible and agile to ensure that appropriate, risk-informed regulatory oversight is in place, regardless of the licence period.

CNSC requirements are updated through changes in regulations made under the NSCA and updates to REGDOCs and standards. The LCH process ensures regulatory requirements can be updated within the licence term. LCH updates ensure that modern codes, standards and practices are implemented continually.

Ongoing Communication and Engagement

CNSC remains committed to openness and transparency through effective communication and engagement. Licensing hearings currently represent an opportunity to engage with Indigenous Nations and communities as well as the public (see section 3), although this type of engagement has limitations. Other opportunities for engagement have been implemented such as the RORs. The RORs have proven to be an effective means for Indigenous Nations and communities and the public to engage with CNSC's regulatory process. For nuclear substance processing facilities, the RORs are published on an annual basis. CNSC staff remain committed to collaborating with interested Indigenous Nation and communities, to address any concerns and will continue to provide updates on Nordion, for example, through regular meetings under Terms of Reference for long-term engagement with these nations.

To ensure that an opportunity for meaningful engagement remains available with a longer licence term such as 25 years, CNSC staff recommend that Nordion provide two performance updates to the Commission during the licence period. CNSC staff recommend the performance updates to occur at approximately 8 years and 16 years after the issuance of the licence.

Commission Engagement Opportunities

CNSC's capability to deliver on its mandate is not impacted by a longer licence period. Irrespective of the period of a licence granted by the Commission, the powers of the Commission will not be impacted. The Commission has the

authority to conduct proceedings on any matter within its jurisdiction or any matter relating to the purpose of the NSCA if doing so would be in the public interest. In addition, the Commission may, at any time, amend, suspend, revoke or replace a licence under the conditions prescribed in the GNSCR.

Any concerns identified by CNSC staff can be raised to the Commission for consideration and any requested changes by Nordion that are deemed to be outside the licensing basis are subject to additional Commission approvals, regardless of the licence period. Additionally, for issues raised by members of the public, CNSC has an established external complaint process [66] in place to ensure the issues raised are reviewed and addressed as appropriate.

4.3.2 Conclusion

CNSC staff conclude that the regulatory framework is in place to maintain regulatory oversight of the Nordion facility regardless of the licence term. Based on Nordion's performance over the previous licence term and information submitted in the licence application, their justification for a 25-Year licence is reasonable.

4.3.3 Recommendation

CNSC staff recommend the Commission issue the requested licence for a 25-Year term. If the requested licence term is granted. CNSC staff recommend that Nordion provide two (2) performance updates during the licence term to the Commission.

4.3.4 Improvement Plan and Significant Future Activities

Refer to section 2.3.3.3 for proposed improvements anticipated for the next licence period.

4.3.5 Discussion

The large projects and significant activities described in section 2.3.3.3 are not expected to have a significant impact on safety and will be undertaken within the framework of Nordion's Management System.

4.3.6 Conclusion

CNSC staff have no concerns or recommendations with respect to this matter.

4.4 Delegation of Authority

The Commission may include in a licence any condition it considers necessary for the purposes of the NSCA. The Commission may delegate authority to CNSC staff with respect to the administration of licence conditions, or portions thereof.

There is 1 proposed licence condition in the Nordion operating licence that contains the phrase "the Commission or a person authorized by the Commission":

- LC 4.2 (The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission)

CNSC staff recommend the Commission delegate its authority for the purposes described in the above licence conditions to the following staff:

- Director, Nuclear Processing Facilities Division
- Director General, Directorate of Nuclear Cycle and Facilities Regulation
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch

5. Overall Conclusions and Recommendations

CNSC staff's conclusions and recommendations consider an overall assessment of Nordion's compliance with the NSCA and its regulations during the current licence period (2015-2024). Nordion has programs, resources, and measures in place at the Nordion facility to ensure the health and safety of persons and the environment and of the measures related to security and Canada's international obligations during the proposed licence period.

CNSC staff's assessment determined that the application complies with the regulatory requirements. CNSC staff concluded that Nordion's performance during the current licensing term was satisfactory and met regulatory requirements.

Based on the above conclusions, CNSC staff recommend the Commission:

1. Renew Nordion's nuclear substance facility processing licence for the Nordion facility for a period of 25-years effective November 1, 2025 to October 31, 2050, with a requirement for the licensee to provide two performance updates to the Commission during the licence term.
2. Delegate authority as set out in section 4.4 of this CMD.

References

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2. Nordion (Canada) Inc., Application *for Renewal of Nordion Operating Licence NSPFOL-11A.01/2025,* May 15, 2024

3. Nordion (Canada) Inc., Amendment to Application for Renewal of Nordion's Operating License NSPFOL-11A.01/2025.

4. *Appendix B Letter from Nordion- 2025 License Application (cover letter and Appendix A and B),* May 15, 2024.

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6. *General Nuclear Safety and Control Regulations*

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8. Nordion (Canada) Inc., Management System for Safety, SE-LIC-001, Revision 17.0, February 2022.

9. REGDOC-2.1.2, *Safety Culture*

10. REGDOC-2.2.2 *Personnel Training*

11. *Canada Labour Code*

12. Canada *Occupational Health and Safety Regulations*

13. REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills*

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15. IAEA Code of Conduct and its supplementary guidance on import/export controls

16. *IAEA Guidance on the Management of Disused Radioactive Sources*

17. Nordion (Canada) Inc., *Nordion submission Attachment 3: Supplementary Report to Support Licence renewal*, May 15, 2024.

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19. Nordion (Canada) Inc., Final Safety Analysis Report for Cobalt Pool, IN/SR 2638 Co60, Revision 4, March 2023.

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21. CNSC REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear facilities*

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23. *National Building Code of Canada, 2020* (NBCC)

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25. CSA Group, CSA N393-22, *Fire Protection for Facilities that Process, Handle, or Store Nuclear Substances*, January 2022.

26. Nordion (Canada) Inc., *Facilities Maintenance Master Plan, R-Master*, Revision 15, February 2024.

27. *Radiation Protection Regulations*

28.Nordion (Canada) Inc., *Occupational Health and Safety Management System Manual SE-HS-044*, Revision 1, October 2016.

29. The REGDOC 2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*

30. CSA Group, CSA N288.4-10, *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*, May 2010.

31. CSA Group, CSA N288.5-11, *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills,* April 2011.

32. CSA Group, CSA N288.6-12, *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills,* June 2012.

33. CSA Group, CSA N288.1-14, *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities*, March 2014.

34. CSA Group, CSA N288.7-15, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills,* January 2015.

35. CSA Group, CSA N288.8-17, *Establishing and Implementing Action Levels for Releases to the Environment from Nuclear Facilities*. February 2017.

36. Nordion CLASS 1B Facility Derived Release Limits, Version 4.0, May 2017

37. Nordion Revised Environmental Risk Assessment (June 2022).

38. City of Ottawa's Sewer Use By-law

39. Nordion Environmental Management System Manual, SE-ENV-001, Revision 12, June 2022.

40. REGDOC-2.9.2, *Controlling Releases to the Environmental*

41. REGDOC 2.10.1 Nuclear Emergency Preparedness and Response

42. *Nuclear Substance and Radiation Devices Regulations*

43. REGDOC-2.11.1 *Waste Management, Volume I: Management of Radioactive Waste*

44. REGDOC-2.12.3 version 2.1: *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material*

45. *Nuclear Security Regulations*

46. Treaty on the Non-Proliferation of Nuclear Weapons (NPT)

47. REGDOC- 2.13.1, *Safeguards and Nuclear Material Accountancy*

48. *Nuclear Non-proliferation Import and Export Control Regulations*

49. REGDOC-2.13.2 – *Import and Export (Version 2)*

50. *Code of Conduct on the Safety and Security of Radioactive Sources*

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53. *Transportation of Dangerous Goods Regulations.*

54. *Constitution Act, 1982*

55. *REGDOC-3.2.2, Indigenous Engagement*

56. *Canadian Nuclear Safety Commission Rules of Procedure*

57. REGDOC-3.2.1, *Public Information and Disclosure*

58. *CNSC Cost Recovery Fees Regulations*

59. REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*

60. CNSC, Record of Decision- Nordion (Canada) Inc. Application for Acceptance of Nordion's Revised Financial Guarantee, February 16, 2023.

61. CNSC, CMD 02-M12 *New Staff Approach to Recommending Licence Periods*, March 2002.

62. Nordion *Fire Hazard Assessment,* December 2021.

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64. NEA/CNRA, International Practices with Respect to Licence Periods/Terms for Nuclear Facilities in NEA Member Countries, September 2002

65.The US Nuclear Regulatory Commission

66. CNSC external complaint process

Glossary

For definitions of terms used in this document, see *REGDOC-3.6, Glossary of CNSC Terminology*, which includes terms and definitions used in the *Nuclear Safety and Control Act* and the *Regulations* made under it, and in *CNSC regulatory documents* and other publications.

Additional terms and acronyms used in this CMD are listed below.

Acronym	Term
AANTC	Algonquin Anishinabeg Nation Tribal Council
ALARA	As low as reasonably achievable
AOO	Algonquins of Ontario
ATRIS	Aboriginal and Treaty Rights Information System
BE	Below Expectations
Bq	Becquerel
CAPA	Corrective Action, Preventative Action
CFM	Cameco Fuel Manufacturing
CINFR	*Class I Nuclear Facilities Regulations*
CMD	Commission Member Document
COF	Cobalt Operations Facility
CRFR	*Cost Recovery Fees Regulations*
CSA	CSA Group (formerly Canadian Standards Association)
DRL	Derived Release Limits
ECR	Engineering Change Request
EMS	Environmental Management System
EP	Emergency Preparedness
EPR	Environmental Protection Review
ERA	Environmental Risk Assessment
FHA	Fire Hazard Assessment
FPP	Fire Protection Program
FRC	Funding Review Committee
FS	Fully Satisfactory
FSAR	Final Safety Analysis Report

GBq	Gigabecquerel
GNSCR	*General Nuclear Safety and Control Regulations*
IAA	*Impact Assessment Act*
IAEA	International Atomic Energy Agency
IEMP	Independent Environmental Monitoring Program
LCH	Licence Conditions Handbook
LTI	Lost-time injury
MDA	Minimum detectable activity
MOU	Memorandum of Understanding
mSv	Millisievert
NEW	Nuclear Energy Worker
NNIECR	*Nuclear Non-Proliferation Import and Export Control Regulations*
NBCC	National Building Code of Canada
NFCC	National Fire Code of Canada
NPT	*Treaty on the Non-Proliferation of Nuclear Weapons*
NSCA	*Nuclear Safety and Control Act*
NSPFL	Nuclear Substance Processing Facility Licence
NSPFOL	Nuclear Substance Processing Facility Operating Licence
NSR	*Nuclear Security Regulations*
OPEX	Operating Experience
PFP	Participant Funding Program
PDP	Preliminary Decommissioning Plan
PIDP	Public Information and Disclosure Program
PSV	Post shipment verification
REGDOC	Regulatory Document
RP	Radiation Protection
SA	Satisfactory
SAR	Safety Analysis Report
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SI	International System of Units
SSC	Systems, structures and components

SSTS	Sealed Source Tracking System
TLD	Thermoluminescence Dosimeter
TOR	Terms of Reference
UA	Unacceptable

A. Safety Performance Rating Levels

Satisfactory (SA)

Licensee meets all of the following criteria:

- Performance meets CNSC staff expectations
- Licensee non-compliances or performance issues, if any, are not risk-significant
- Any non-compliances or performance issues have been, or are being, adequately corrected

Below Expectations (BE)

One or more of the following criteria apply:

- Performance does not meet CNSC staff expectations
- Licensee has risk-significant non-compliance(s) or performance issue(s)
- Non-compliances or performance issues are not being adequately corrected

Unacceptable (UA)

One or both of the following criteria apply:

- Risk associated with a non-compliance or performance issue is unreasonable
- At least one significant non-compliance or performance issue exists with no associated corrective action

Note: Starting in 2019, facility performance assessment ratings were simplified and the "Fully Satisfactory (FS)" was replaced by the "Satisfactory (SA)" rating. It is important to recognize that a facility that received an SCA performance rating of FS prior to 2019 and now has a rating of SA, does not necessarily indicate a reduction in performance.

B. Basis for the Recommendation(s)

B.1 Regulatory Basis

The recommendations presented in this CMD are based on compliance objectives and expectations associated with the relevant SCAs and other matters. The regulatory basis for the matters that are relevant to this CMD are as follows.

Management System

The regulatory foundation for the recommendation(s) associated with Management System includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(d), the proposed management system for the activity to be licensed, including measures to promote and support safety culture.
- The *General Nuclear Safety and Control Regulations* require that an application for a licence shall contain, under paragraphs:
  - 3(1)(k), the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the NSCA and the Regulations made under the NSCA, including the internal allocation of functions, responsibilities and authority.
  - 15(a), the persons who have the authority to act for them (the applicant/licensee) in their dealings with the Commission.
  - 15(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.

Human Performance Management

The regulatory foundation for the recommendation(s) associated with Human Performance Management includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 3(d.1), the proposed human performance program for the activity to be licensed, including measures to ensure workers' fitness for duty.
  - 6(m), the proposed responsibilities of and the qualification requirements and training program for workers, including the procedures for the requalification of workers
  - 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.

The *General Nuclear Safety and Control Regulations* require that licensees, under paragraphs:

- 12(1)(a), ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the regulations made under the Act and the licence.
- 12(1)(b), train the workers to carry on the licensed activity in accordance with the Act, the regulations made under the Act and the licence.
- 12(1)(e), require that every person at the site of the licensed activity to use equipment, devices, clothing and procedures in accordance with the Act, the regulations made under the Act and the licence.

Operating Performance

The regulatory foundation for the recommendation(s) associated with operating performance includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence to operate a Class I nuclear facility shall contain, under paragraph:
  - 6(d), the proposed measure, policies, methods and procedures for operating and maintaining the nuclear facility

Safety Analysis

The regulatory foundation for the recommendation(s) associated with safety analysis includes the following:

- The *General Nuclear Safety and Control Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(l)(i), a description and the results of any test, analysis or calculation performed to substantiate the information included in the application
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 6(c), a final safety analysis report demonstrating the adequacy of the design of the nuclear facility.
  - 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.

Physical Design

The regulatory foundation for the recommendation(s) associated with physical design includes the following:

- Paragraph 3(1)(d) of the *General Nuclear Safety and Control Regulations* requires that an application for a licence shall contain a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 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;
  - 3(b), plans showing the location, perimeter, areas, structures and systems of the nuclear facility;
  - 6(a), a description of the structures at the nuclear facility, including their design and their design operating conditions;
  - 6(b), a description of the systems and equipment at the nuclear facility, including their design and their design operating conditions;
  - 6(c), a final safety analysis report demonstrating the adequacy of the design of the facility; and
  - 6(d), proposed measures, policies, methods and procedures for operating and maintaining the facility.

Fitness for Service

The regulatory foundation for the recommendation(s) associated with fitness for service includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
  - 6(d), proposed measures, policies, methods and procedures for operating and maintaining the facility.

Radiation Protection

The regulatory foundation for the recommendation(s) associated with radiation protection includes the following:

- The *General Nuclear Safety and Control Regulations* require, under subsection 3(1), that a licence application contain the following information under paragraphs:
  - 3(1)(e), the proposed measures to ensure compliance with the *Radiation Protection Regulations.*
  - 3(1)(f), any proposed action level for the purpose of section 6 of the *Radiation Protection Regulations.*

- The *Radiation Protection Regulations.*
- The *Class I Nuclear Facilities Regulations* require that an application for a licence to operate a Class I nuclear facility shall contain, under paragraphs:
    - 6(e), the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.
    - 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 measure that will be taken to prevent or mitigate those effects.

Conventional Health and Safety

The regulatory foundation for the recommendation(s) associated with Conventional Health and Safety includes the following:

- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
    - 3(f), the proposed worker health and safety policies and procedures.
- Nordion's activities and operations must comply with the *Canada Labour Code, Part II: Occupational Health and Safety.*

Environmental Protection

The regulatory foundation for the recommendation(s) associated with Conventional Health and Safety includes the following:

- The *General Nuclear Safety and Control Regulations*, under paragraphs 12(1)(c) and (f), require that each licensee take all reasonable precautions to protect the environment and the health and safety of persons, and to control the release of radioactive nuclear substances and hazardous substances within the site of the licensed activity and into the environment.
- The Radiation Protection Regulations prescribe dose limits for the general public, which under Subsection 1(3) is 1 mSv per calendar year.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraphs:
    - 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.
    - 3(g), the proposed environmental protection policies and procedures.
    - 3(h), the proposed effluent and environmental monitoring programs.

- 6(e), the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.
- 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.
- 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.
- 6(j), the proposed measures to control releases of nuclear substances and hazardous substances into the environment.

Emergency Management and Fire Protection

The regulatory foundation for the recommendation(s) associated with Emergency Management and Response includes the following:

- 12(1)(c) of the *General Nuclear Safety and Control Regulations* states that every licensee shall "take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security".
- 12(1)(f) of the *General Nuclear Safety and Control Regulations* states that every licensee shall "take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances within the site of the licensed activity and into the environment of the licensed activity".
- The Class I Nuclear Facilities Regulations require that an application for a licence shall contain, under paragraph:
- 6(k) information on the licensee's proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances of the environment, the health and safety of persons and the maintenance of national security, including measures to:
    - Assist offsite authorities in planning and preparing to limit the effects of an accidental release;
    - Notify offsite authorities of an accidental release or the imminence of an accidental release;
    - Report information to offsite authorities during and after an accidental release;

- Assist offsite authorities in dealing with the effects of an accidental release; and
- Test the implementation of the measures to prevent or mitigate the effects of an accidental release.

Waste Management

The regulatory foundation for the recommendation(s) associated with Waste Management includes the following:

- The General Nuclear Safety and Control Regulations require that an application for a licence include, under paragraph:
  - 3(1)(j), the name, quantity, form 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.

Security

The regulatory foundation for the recommendation(s) associated with Security includes the following:

- It is a requirement of all Class I licensees to comply with the *Nuclear Security Regulations.*

Packaging and Transport

The regulatory foundation for the recommendation(s) associated with Packaging and Transport includes the following:

- The *Packaging and Transport of Nuclear Substances Regulations, 2015*; and
- Transport Canada's *Transportation of Dangerous Goods Regulations*.

Decommissioning Plan and Financial Guarantees

The regulatory foundation for the recommendation(s) associated with Nordion's Decommissioning Plan and Financial Guarantees includes:

- The *General Nuclear Safety and Control Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(1)(l), a description of any proposed financial guarantee relating to the activity to be licensed.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence shall contain, under paragraph:
  - 3(k), the proposed plan for the decommissioning of the nuclear facility or of the site.

Licensee's Public Information Program

- The Class I Nuclear Facilities Regulations require that an application for a licence shall contain, under paragraph:
    - 3(j), information on the licensee's public information program.

B.2 Detailed Summary of CNSC Assessment of Application

CNSC's staff assessment of Nordion's licence application included a completeness check, a sufficiency check, and a technical assessment against regulatory requirements. The completeness check verified whether the application included the prescribed information in accordance with the *Nuclear Safety and Control Act* and applicable regulations. For all facilities (i.e., Class I and Class II facilities), it is important to consider and address all licence application requirements within the applicable CNSC regulations.

The sufficiency check verified whether the application included sufficient and quality information in order for CNSC staff to conduct the technical assessment. The technical assessment verified whether the application included adequate safety and control measures to address CNSC requirements. Documents originally submitted as part of the application may have been revised, updated, or replaced over the course of the assessment to address CNSC requirements.

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by Nordion**	**Complete?**	**Sufficient?**	**Adequate?**
(1) An application for a licence shall contain the following information:				
(a) the applicant's name and business address;	Attachment 1: Information required for the renewal of the Operating Licence Page 1 of 30	Y	Y	Y
(b) the activity to be licensed and its purpose;	Attachment 1: Information required for the renewal of the Operating Licence Page 2 of 30	Y	Y	Y

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by Nordion**	**Complete?**	**Sufficient?**	**Adequate?**
(c) the name, maximum quantity, and form of any nuclear substance to be encompassed by the licence;	Attachment 1: Information required for the renewal of the Operating Licence Page 2 of 30	Y	Y	Y
(d) a description of any nuclear facility, prescribed equipment, or prescribed information to be encompassed by the licence;	Attachment 1: Information required for the renewal of the Operating Licence Page 3 of 30	Y	Y	Y
(e) the proposed measures to ensure compliance with the *Radiation Protection Regulations*, the *Nuclear Security Regulations* and the *Packaging and Transport of Nuclear Substances Regulations, 2015;*	Attachment 1: Information required for the renewal of the Operating Licence Page 4 and 5 of 30	Y	Y	Y
(f) any proposed action level for the purpose of section 6 of the *Radiation Protection Regulations*;	Attachment 1: Information required for the renewal of the Operating Licence Page 5 of 30	Y	Y	Y
(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;	Attachment 1: Information required for the renewal of the Operating Licence Page 5 of 30	Y	Y	Y

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by Nordion**	**Complete?**	**Sufficient?**	**Adequate?**
(h) the proposed measures to prevent loss or illegal use, possession, or removal of the nuclear substance, prescribed equipment, or prescribed information;	Attachment 1: Information required for the renewal of the Operating Licence Page 5 of 30	Y	Y	Y
(i) a description and the results of any test, analysis or calculation performed to substantiate the information included in the application;	Attachment 1: Information required for the renewal of the Operating Licence Page 6 of 30	Y	Y	Y
(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;	Attachment 1: Information required for the renewal of the Operating Licence Page 6 of 30	Y	Y	Y

Pursuant to Section 3 of the *General Nuclear Safety and Control Regulations* Licences – General Application Requirements	**Location in Application or Supporting Document(s) as Noted by Nordion**	**Complete?**	**Sufficient?**	**Adequate?**
(k) the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the [NSCA] and the regulations made under it, including the internal allocation of functions, responsibilities and authority;	Attachment 1: Information required for the renewal of the Operating Licence Page 6 of 30	Y	Y	Y
(l) a description of any proposed financial guarantee relating to the activity to be licensed;	Attachment 1: Information required for the renewal of the Operating Licence Page 6 of 30	Y	Y	Y
(m) any other information required by the [NSCA] or the regulations made under it for the activity to be licensed and the nuclear substance, nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.	Attachment 1: Information required for the renewal of the Operating Licence Page 6 of 30	Y	Y	Y

B.3 Technical Basis

The technical basis for the recommendations presented in this CMD are listed in the table

Applicable Standards and Codes per Safety and Control Area

SCA	Document Title	Sufficient?	Adequate?
Management System	CSA N286-12(R2022) Management Systems Requirements for Nuclear Facilities	Y	Y
	REGDOC-2.1.2 Safety Culture		
Human Performance Management	REGDOC-2.2.2 Personnel Training	Y	Y
Operating Performance	CNSC REGDOC-3.1.2 (2022): Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills	Y	Y
Safety Analysis	REGDOC-2.4.4 (2022): Safety Analysis for Class IB Nuclear Facilities	Y	Y
Physical Design	CSA N393(2022) Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	Y	Y
	National Building Code of Canada 2020		
	National Fire Code of Canada 2020		
Fitness for Service	CSA N393 Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	Y	Y
	CSA N286-12(R2022) Management Systems Requirements for Nuclear Facilities		
Radiation Protection	REGDOC-2.7.1 Radiation Protection	Y	Y
	REGDOC-2.7.2 Dosimetry, Volume I: Ascertaining Occupational Dose		
Conventional Health and Safety	CSA Z94.4 (2011) Selection, Use and Care of Respirators	Y	Y
Environmental Protection	REGDOC-2.9.1(2020) Environmental Principles, Assessments and Protection Measures	Y	Y
	CSA N288.1 (2014) Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operation of Nuclear Facilities		
	CSA N288.4 (2010) Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills		

SCA	Document Title	Sufficient?	Adequate?
	CSA N288.5 (2011) Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills		
	CSA N288.6 (2012) Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills		
	CSA N288.7 (2015) Groundwater protection programs at Class I nuclear facilities and uranium mines and mills		
	CSA N288.8 (2017) Establishing and implementing action levels for releases to the environment from nuclear facilities		
Emergency Management and Fire Protection	REGDOC-2.10.1 (2016) Nuclear Emergency Preparedness and Response	Y	Y
	CSA N393(2022) Fire Protection for Facilities that Process, Handle or Store Nuclear Substances		
	National Building Code of Canada 2020		
	National Fire Code of Canada 2020		
Waste Management	REGDOC-2.11.1 (2021) Waste Management, Volume I: Management of Radioactive Waste	Y	Y
	REGDOC-2.11.2 (2021) Waste Management, Decommissioning		
	CSA N292.0 (2019) General principles for the management of radioactive waste and irradiated fuel		
	CSA N292.3 (2014) Management of Low and Intermediate Level Radioactive Waste		
	REGDOC 3.3.1 (2021) Financial guarantees for decommissioning of nuclear facilities and termination of licensed activities		
	CSA N294 (2019) Decommissioning of Facilities Containing Nuclear Substances		
Security	REGDOC-2.12.3 (2020) Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material Version 2.1	Y	Y
Safeguards and Non-Proliferation	REGDOC-2.13.1 (2018) Safeguards and Nuclear Material Accountancy	Y	Y

SCA	Document Title	Sufficient?	Adequate?
Public Information Program	REGDOC-3.2.1 (2018) Public Information and Disclosure	Y	Y
Financial Guarantee	REGDOC 3.3.1 (2021) Financial guarantees for decommissioning of nuclear facilities and termination of licensed activities	Y	Y
	REGDOC-2.11.2 (2021) Waste Management, Decommissioning		
	CSA N294 (2019) Decommissioning of Facilities Containing Nuclear Substances		

C. Safety and Control Area Framework

C.1 Safety and Control Areas Defined

The safety and control areas identified in section 2.2 and discussed in summary in sections 3.1 through 3.14 are comprised of specific areas of regulatory interest which vary between facility types.

The following table provides a high-level definition of each SCA. The specific areas within each SCA are to be identified by the CMD preparation team in the respective areas within section 3 of this CMD

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
Management	Management System	Covers the framework which establishes the processes and programs required to ensure an organization achieves its safety objectives and continuously monitors its performance against these objectives and fostering a healthy safety culture.
	Human Performance Management	Covers activities that enable effective human performance through the development and implementation of processes that ensure that a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.
	Operating Performance	Includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.
Facility and Equipment	Safety Analysis	Covers maintenance of the safety analysis that supports that 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 preventive measures and strategies in reducing the effects of such hazards.
	Physical Design	Relates to activities that impact on the ability of systems, components and structures to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
	Fitness for Service	Covers activities that impact on the physical condition of systems, components and structures 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.
Core Control Processes	Radiation Protection	Covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. This program must ensure that contamination levels and radiation doses received by individuals are monitored and controlled and maintained ALARA.
	Conventional Health and Safety	Covers the implementation of a program to manage workplace safety hazards and to protect workers.
	Environmental Protection	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.
	Emergency Management and Fire Protection	Covers emergency plans and emergency preparedness programs which exist for emergencies and for non-routine conditions. This also includes any results of participation in exercises.
	Waste Management	Covers internal waste-related programs which 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.
	Security	Covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity.

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
	Safeguards and Non-Proliferation	Covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.
	Packaging and Transport	Covers programs for the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility.

C.2 Specific Areas for this Facility Type

The following table identifies the specific areas that comprise each SCA for Nordion:

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
Management	Management System	▪ Management System ▪ Organization ▪ Performance Assessment, Improvement and Management Review ▪ Operating Experience (OPEX), Problem Identification and Resolution (PI&R) ▪ Change Management ▪ Safety Culture ▪ Configuration Management ▪ Records Management ▪ Supply and Contractor Management ▪ Business Continuity
	Human Performance Management	▪ Human Performance Programs ▪ Personnel Training ▪ Work Organization and Job Design ▪ Fitness for Duty
	Operating Performance	▪ Conduct of Licensed Activity ▪ Procedures ▪ Reporting and Trending
Facility and Equipment	Safety Analysis	▪ Deterministic Safety Analysis ▪ Hazard Analysis
	Physical Design	▪ Design Governance ▪ Site Characterization ▪ Facility Design

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
	Fitness for Service	▪ Equipment Fitness for Service/Equipment Performance ▪ Maintenance ▪ Periodic Inspection and Testing
Core Control Processes	Radiation Protection	▪ Application of ALARA ▪ Worker Dose Control ▪ Radiation Protection Program Performance ▪ Radiological Hazard Control
	Conventional Health and Safety	▪ Performance ▪ Practices ▪ Awareness
	Environmental Protection	▪ Effluent and Emissions Control (releases) ▪ Environmental Management System (EMS) ▪ Assessment and Monitoring ▪ Protection of People
	Emergency Management and Fire Protection	▪ Conventional Emergency Preparedness and Response ▪ Nuclear Emergency Preparedness and Response ▪ Fire Emergency Preparedness and Response
	Waste Management	▪ Waste Characterization ▪ Waste Minimization ▪ Waste Management Practices ▪ Decommissioning Plans
	Security	▪ Facilities and Equipment ▪ Response Arrangements ▪ Security Practices
	Safeguards and Non-Proliferation	▪ Nuclear Material Accountancy and Control ▪ Access and Assistance to the IAEA

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
		▪ Operational and Design Information ▪ Safeguards Equipment, Containment and Surveillance ▪ Import and Export
	Packaging and Transport	▪ Package design and maintenance ▪ Packaging and transport

D. INSPECTIONS

The following table includes inspections conducted at Nordion during the previous licence period.

Inspection Title	SCA(s) Covered
EMPD-NORDION-2016-T01 (5042939)	Emergency management: Nordion exercise
NORDION-2016-02	Operating Performance, Fitness for Service, Radiation Protection, Environmental Protection, Conventional Health and Safety, Waste Management, Packaging and Transport
NORDION-2016-03	Operating Performance - and the review of exports of Category 1 and 2 radioactive sources
NORDION-2017-01	Security
NORDION-2017-02	Radiation Protection
NORDION-2017-03	Environmental Protection
NORDION-2017-04	Human Performance Management
NORDION-2017-05	Emergency Management & Fire Protection
NORDION-2018-01	Management System
NORDION-2019-01	Security
NORDON-2019-02	Packaging and Transport and Operating Performance
NORDION-2019-03	Emergency Management & Fire Protection
NORDION-2019-04	Packaging and Transport
NORDION-2020-01	Management System
NORDION-2020-02	Operating Performance, Fitness for Service, Radiation Protection, Environmental Protection, Conventional Health and Safety and Waste Management
NORDION-2022-01	Management Systems
NORDION-2022-02	Emergency Management and Fire protection
NORDION-2023-01	Security
NORDION-2023-02	Fitness for Service, Operating Performance, Radiation Protection, Environmental Protection, Conventional Health and Safety and Waste Management.
NORDION-2023-03	Human Performance Management
NORDION-2023-04 and 05 (Report was submitted together)	Radiation Protection and Environmental Protection
NORDION-2024-01	Fitness for Service, Operating Performance, Conventional Health and Safety, and Waste Management
NORDION-2024-02	Emergency Management and Fire Protection

PART 2

Part 2 of this CMD provides all relevant information pertaining directly to the licence, including:

1. The current licence;
2. Any proposed changes to the conditions, licensing period, or formatting of an existing licence;
3. The proposed licence; and
4. The draft licence conditions handbook.

Current Licence

The current licence is provided on the following pages of this document.

PDF Ref: e-Doc 5784149
Word Ref: e-Doc 5743436
File / Dossier: 2.02

CLASS IB NUCLEAR SUBSTANCE PROCESSING FACILITY OPERATING LICENCE

NORDION (CANADA) INC.

I) LICENCE NUMBER: NSPFOL-11A.01/2025

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act*, this licence is issued to:

Nordion (Canada) Incorporated
1115250-5
447 March Road
Ottawa, Ontario
K2K 1X8

III) LICENCE PERIOD: This licence is valid from the date signed and remains in effect until **October 31, 2025**, unless otherwise suspended, amended, revoked, replaced, or transferred.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

a) operate the Nordion Nuclear Substance Processing Facility, at the location referred to in Section II of this licence (hereinafter "the processing facility"), for the purpose of processing and manufacturing nuclear substances and sealed sources used in health sciences and industrial applications;

b) possess, transfer, use, process, import, manage, store, or dispose, of nuclear substances that are required for, associated with, or arise from the activity described in a);

c) possess, transfer, use, import, or service prescribed equipment that are required for, associated with, or arise from the activity described in a);

d) possess, transfer, use, service, or import prescribed equipment from clients; and

e) possess and use prescribed information that is required for, associated with, or arise from the activity described in a).

V) EXPLANATORY NOTES:

(a) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and associated Regulations.

(b) The "NORDION LICENCE CONDITIONS HANDBOOK (LCH)" provides:

(i) compliance verification criteria in order to meet the conditions listed in the licence; and

(ii) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

VI) CONDITIONS:

1. GENERAL

1.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations;

(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence;

(iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (hereinafter "the Commission").

1.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

1.3 The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.

1.4 The licensee shall implement and maintain a public information and disclosure program.

2. MANAGEMENT SYSTEM

2.1 The licensee shall implement and maintain a management system.

3. HUMAN PERFORMANCE MANAGEMENT

3.1 The licensee shall implement and maintain a training program.

4. OPERATING PERFORMANCE

4.1 The licensee shall implement and maintain an operating program, which includes a set of operating limits.

4.2 The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.

5. SAFETY ANALYSIS

5.1 The licensee shall implement and maintain a safety analysis program.

6. PHYSICAL DESIGN

6.1 The licensee shall implement and maintain a design program.

7. FITNESS FOR SERVICE

7.1 The licensee shall implement and maintain a fitness for service program.

8. RADIATION PROTECTION

8.1 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

9. CONVENTIONAL HEALTH AND SAFETY

9.1 The licensee shall implement and maintain a conventional health and safety program.

10. ENVIRONMENTAL PROTECTION

10.1 The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

11. EMERGENCY MANAGEMENT AND FIRE PROTECTION

11.1 The licensee shall implement and maintain an emergency preparedness program.

11.2 The licensee shall implement and maintain a fire protection program.

12. WASTE MANAGEMENT

12.1 The licensee shall implement and maintain a waste management program.

12.2 The licensee shall implement and maintain a decommissioning strategy.

13. SECURITY

13.1 The licensee shall implement and maintain a security program.

14. SAFEGUARDS AND NON-PROLIFERATION

14.1 The licensee shall implement and maintain a safeguards program.

15. PACKAGING AND TRANSPORT

15.1 The licensee shall implement and maintain a packaging and transport program.

SIGNED at OTTAWA, this _____ day of _____, 2019

Original signed February 26, 2019

_____
Rumina Velshi, President
on behalf of the Canadian Nuclear Safety Commission

Proposed Licence Changes

Overview

Nordion currently operates the Nordion facility under a Nuclear Substance Processing Facility Operating Licence, NSPFOL-11A.01/2025. The proposed licence incorporates standardized licence conditions in a standard format.

Licence Conditions

The proposed licence incorporates the standardized licence conditions applicable to Nordion as a nuclear substance processing facility as developed by CNSC staff. The only proposed change is the numbering under the General sub-header to align with the formatting of the LCH. The wording of the conditions under the General sub-header remains the same.

PROPOSED LICENCE CHANGES	
General (current licence)	**General (proposed licence)**
1. GENERAL	G. GENERAL
1.1	G.1
1.2	G.2
1.3	G.3
1.4	G.4

Licence Format

Nordion's current licence is written in the current standardized format. The proposed licence will use the same current format; however the GENERAL section will be updated as described above to align with the current LCH format.

Licence Period

Nordion has requested a renewal of its licence for a period of 25 years. As noted in section 4.3, based on CNSC staff's review of Nordion's application, performance history, and supporting information, CNSC staff recommend Nordion's request for a licence period of 25 years to the Commission. Over the proposed 25-year period, CNSC staff would provide regular reporting on regulatory oversight conducted at the Nordion facility in public Commission proceedings.

Proposed Licence

The proposed licence is provided on the following pages of this document.

PDF Ref: e-Doc 7418725
Word Ref: e-Doc 7417092
File / Dossier: 2.02

DRAFT

CLASS IB NUCLEAR SUBSTANCE PROCESSING FACILITY LICENCE

NORDION (CANADA) INC.

I) LICENCE NUMBER: NSPFL-11A.00/2050

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act*, this licence is issued to:

Nordion (Canada) Incorporated
1115250-5
447 March Road
Ottawa, Ontario
K2K 1X8

III) LICENCE PERIOD: This licence is valid from **November 1, 2025**, to **October 31, 2050**, unless otherwise suspended, amended, revoked, replaced, or transferred.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

a) operate the Nordion Nuclear Substance Processing Facility, at the location referred to in Section II of this licence (hereinafter "the processing facility"), for the purpose of processing and manufacturing nuclear substances and sealed sources used in health sciences and industrial applications;

b) possess, transfer, use, process, import, manage, store, or dispose, of nuclear substances that are required for, associated with, or arise from the activity described in a);

c) possess, transfer, use, import, or service prescribed equipment that are required for, associated with, or arise from the activity described in a)

d) possess, transfer, use, service, or import prescribed equipment from clients; and

e) possess and use prescribed information that is required for, associated with, or arise from the activity described in a).

V) EXPLANATORY NOTES:

(a) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and associated Regulations.

(b) The "NORDION LICENCE CONDITIONS HANDBOOK (LCH)" provides:

(iii) compliance verification criteria in order to meet the conditions listed in the licence; and

(iv) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

VI) CONDITIONS:

G. GENERAL

G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations;

(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence;

(iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (hereinafter "the Commission").

G.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

G.3 The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.

G.4 The licensee shall implement and maintain a public information and disclosure program.

2. MANAGEMENT SYSTEM

2.1 The licensee shall implement and maintain a management system.

3. HUMAN PERFORMANCE MANAGEMENT

3.1 The licensee shall implement and maintain a training program.

4. OPERATING PERFORMANCE

4.1 The licensee shall implement and maintain an operating program, which includes a set of operating limits.

4.2 The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.

5. SAFETY ANALYSIS

5.2 The licensee shall implement and maintain a safety analysis program.

6. PHYSICAL DESIGN

6.1 The licensee shall implement and maintain a design program.

7. FITNESS FOR SERVICE

7.1 The licensee shall implement and maintain a fitness for service program.

8. RADIATION PROTECTION

8.2 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

9. CONVENTIONAL HEALTH AND SAFETY

9.2 The licensee shall implement and maintain a conventional health and safety program.

11. ENVIRONMENTAL PROTECTION

10.1 The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

11. EMERGENCY MANAGEMENT AND FIRE PROTECTION

11.1 The licensee shall implement and maintain an emergency preparedness program.

11.2 The licensee shall implement and maintain a fire protection program.

12. WASTE MANAGEMENT

12.1 The licensee shall implement and maintain a waste management program.

12.2 The licensee shall implement and maintain a decommissioning strategy.

13. SECURITY

13.1 The licensee shall implement and maintain a security program.

14. SAFEGUARDS AND NON-PROLIFERATION

14.1 The licensee shall implement and maintain a safeguards program.

15. PACKAGING AND TRANSPORT

15.1 The licensee shall implement and maintain a packaging and transport program.

SIGNED at OTTAWA, this _____ day of _____, 2025.

_____
Pierre Tremblay, President
on behalf of the Canadian Nuclear Safety Commission

Draft Licence Conditions Handbook

The proposed licence conditions handbook is provided on the following pages of the document.

Canada's Nuclear Regulator

e-Doc 7413566 (Word)
e-Doc 7469604 (PDF)

LICENCE CONDITIONS HANDBOOK

LCH-NSPFL-11A.00/2050

NORDION (CANADA) INC.

NUCLEAR SUBSTANCE PROCESSING FACILITY OPERATING LICENCE (NSPFOL)

NSPFL-11A.00/2050

Revision 0

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire
Canada

Licence Conditions Handbook **Effective:**

LCH-NSPFOL-11A.01/2050

Nordion (Canada) Inc.

Nuclear Substance Processing Facility Operating Licence (NSPFOL)

NSPFOL-11A.00/2050

SIGNED at OTTAWA this _____ day of __ , 20

Director
Nuclear Processing Facilities Division
Directorate of Nuclear Cycle and Facilities Regulation
Canadian Nuclear Safety Commission

Revision History:

Effective Date	Rev. #	LCH e-Doc #	Section(s) changed	Description of the Changes	Document Change Record
	0	7413566 (Word) 7106136 (PDF)		Original document	N/A

Table of Contents

PART I: INTRODUCTION

The purpose of the licence conditions handbook (LCH) is to identify the regulatory requirements and other relevant parts of the licensing basis to help ensure that the licensee maintains facility operation in accordance with the licensing basis for the facility and the Nordion Nuclear
Substance Processing Facility Operating Licence, NSPFOL-11A.00/2050. The LCH provides compliance verification criteria for conditions set out in the licence. The LCH should be read in conjunction with the licence.

The LCH typically has three parts under each licence condition (LC): the Preamble, Compliance Verification Criteria (CVC), and Guidance. The Preamble explains, as needed, the regulatory context, background, and/or history related to the LC. CVC are criteria used by Canadian Nuclear Safety Commission (CNSC) staff to verify and oversee compliance with the LC. Guidance is non-mandatory information, including direction on how to comply with the LC.

E-doc numbers indicated in the LCH are references to the internal CNSC electronic filing system, and these documents cannot be opened from outside of the CNSC network.

CNSC documents referenced in the LCH are available through the CNSC Website. Documents listed on CNSC website may contain prescribed information as defined by the *General Nuclear Safety and Control Regulations* (GNSCR). Information in these documents will be made available only to stakeholders with appropriate security clearance with the need to know.

Domestic and international standards, in particular consensus standards produced by the Canadian Standards Association (CSA), are an important component of the CNSC's regulatory framework. Standards support the regulatory requirements established through the *Nuclear Safety and Control Act* (NSCA), its regulations and licences by setting out the necessary elements for acceptable design and performance at a regulated facility or a regulated activity. Standards are used by the CNSC as a reference in evaluating licensees' compliance against certain licensed activities.

The CNSC offers complimentary access to the CSA Group suite of nuclear standards through the CNSC website. This platform allows stakeholders to view these standards online through any device that can access the Internet. Standards applicable to the licensees are documented in the CVC or guidance sections of the LCH as appropriate.

Appendices attached to the LCH provide detailed criteria and clarifications where needed, and are integral and mandatory parts of the LCH.

Several appendices are attached to the LCH. They provide detailed criteria and clarifications where needed and are integral and mandatory parts of the LCH. A short description of the appendices attached to the Nordion LCH is provided below.

Appendix A: provides information on the control of the LCH and includes the LCH Change Request Form.

Appendix B: provides a glossary of terms used throughout the LCH.

Appendix C: provides a list of licensing documents relevant for Nordion. The information regarding editions (revisions) of codes, standards, licensee, and CNSC documents is maintained in an Excel spreadsheet. For convenience of maintenance and updating of the Nordion LCH, and unless the context requires otherwise, these documents are referenced in the applicable criteria throughout the LCH without specifying their revisions.

Appendix D: provides a list of documents used as criteria or guidance.

2. DESCRIPTION OF THE SECTIONS IN THE NSPFL

2.1 Section I: Licence Number

The alpha numeric expression NSPFL-11A.00/2050 stems from the CNSC standard convention for identifying licences. The following table provides a description of each identifier used in the expression:

Identifier	Description
NSPFL	Nuclear Substance Processing Facility Licence
11A	Refers to facility name (11A = Nordion (Canada) Inc.)
00	Licence version number (00 = Initial licence, 01 = Amendment No. 1, etc.)
2050	Expiration year

2.2 Section II: Licensee

This section of the licence provides the name and the address of the corporate entity that holds the licence, which is referred hereinafter as the "licensee". The licensee is:

Nordion (Canada) Inc.
1115250-5
447 March Road
Ottawa, Ontario
K2K 1X8

2.3 Section III: Licence Period

Identifies the duration for which the licence is valid, which in this case, for NSPFL-11A.00/2050, is from November 1, 2025, to October 31, 2050, unless suspended, amended, revoked, replaced, or transferred during the licensing period.

2.4 Section IV: Licensed Activities

The licence identifies the activities that are being licensed. The box below contains a copy of the text in the licence. The authorized activities are from the list of activities described in section 26 of the *Nuclear Safety and Control Act* (NSCA).

Licensed Activities

This licence authorizes the licensee to:

f) operate the Nordion Nuclear Substance Processing Facility, at the location referred to in Section II of this licence (hereinafter "the processing facility"), for the purpose of processing and manufacturing nuclear substances and sealed sources used in health sciences and industrial applications;

g) possess, transfer, use, process, import, manage, store, or dispose of nuclear substances that are required for, associated with, or arise from the activity described in a);

h) possess, transfer, use, import, or service prescribed equipment that are required for, associated with, or arise from the activity described in a);

i) possess, transfer, use, service, or import prescribed equipment from clients; and

j) possess and use prescribed information that is required for, associated with, or arise from the activity described in a).

Nordion operates its facility to process nuclear substances in the manufacturing of sealed sources for medical and industrial applications. Nordion manufactures sealed sources that are installed in prescribed equipment that are either transported to another licensee or packaged and transported to be installed in prescribed equipment at another location or licensee. In addition, Nordion services its own self-shielded irradiator that is used to support the operations of the facility.

This licence also authorizes Nordion to service prescribed equipment from other licensees and clients for which they have provided procedures to the CNSC.

Facility Description: The location of the Nordion's Facility, at 447 March Rd, Ottawa, Ontario, is further defined in Nordion document SE-LIC-018, "Facility Description".

2.5 Section V: Explanatory Notes

This section provides clarification of the licence and introduces the LCH as a compliance tool.

2.6 Section VI: Conditions

This section of the licence lists the LCs.

PART II: FRAMEWORK FOR EACH CONDITION

This section of the LCH provides additional information for each LC including information on the requirements and guidance for meeting each LC. The LCH also provides references to licensee documents submitted to meet the requirements and the compliance verification criteria (CVC) that will be used to verify that the condition is being met and to measure performance.

The information for each LC or group of conditions is organized in the following manner.

Preamble: Provides regulatory context related to the licence condition and provides where applicable, reference to related information including the related regulatory requirements contained in the NSCA and its associated Regulations.

Compliance Verification Criteria: This section identifies the compliance verification criteria or the sources from which the CNSC develops compliance verification criteria. Applicable standards such as Canadian Standards Association (CSA) standards, national codes and guidelines, and/or CNSC regulatory documents are identified. Implementation of programs will be assessed through the CNSC's compliance program and will be measured against performance objectives and regulatory expectations.

The documents that are used to assess compliance with LCs are identified in this section. Compliance verification will be conducted against documents referenced within this LCH. Current versions of documents are tracked and can be accessed through the document "Nordion LCH Written Notice Tracking Sheet" e-Doc 4768292. This document is controlled by the CNSC's Nuclear Processing Facilities Division (NPFD).

Guidance: Guidance is non-mandatory. This section identifies CNSC documents and other documents that provide guidance associated with protection of the environment, health and safety, and other conditions of the NSCA and its associated Regulations. As guidance is
non-mandatory, licensees may propose alternate ways to meet the licence condition.

G. GENERAL LICENCE CONDITIONS

G.1 Licensing Basis

Licence Condition G.1

The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations;

(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence;

(iii) **the safety and control measures described in the licence application and the documents needed to support that licence application;**

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (hereinafter "the Commission").

Preamble

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity, and thus establishes the basis for the CNSC's compliance program with respect of that regulated facility or activity. The degree to which the regulatory requirements are applied to the Nordion facility should reflect their importance to the health and safety of persons, environment, national security, international obligations to which Canada has agreed, licensee's quality and economic expectations, the complexity of facility or activity, and the possible consequences if accidents occur or the activity is carried out incorrectly.

Where the LC requires the licensee to implement and maintain a particular program, the documents submitted by the licensee to support their application that describe and implement the program are part of the licensing basis.

Compliance Verification Criteria

Regulatory Role of the Licensing Basis

The licensing basis is established when the Commission renders its decision regarding the licence application. LC G.1 requires the licensee to conduct the licensed activities in accordance with the licensing basis. For activities that are not in accordance with the licensing basis, the licensee shall take action as soon as practicable to return to a state consistent with the licensing basis, taking into account the risk significance of the situation.

The licensing basis is not intended to unduly inhibit the ongoing management and operation of the facility or the licensee's ability to adapt to changing circumstances and continuously improve, in accordance with its management system.

Part (i) of the Licensing Basis

Part (i) of the licensing basis refers to applicable laws and regulations. There are many federal and provincial acts and regulations, and international laws, agreements, guidelines, etc., applicable to activities performed at the Nordion facility.

The laws, regulations and international agreements for which CNSC has a regulatory role are:

- *Nuclear Safety and Control Act (NSCA)* and its Regulations
- *Impact Assessment Act* and its Regulations
- *Canadian Environmental Protection Act*
- *Nuclear Liability and Compensation Act*
- *Transportation of Dangerous Goods Act* and its Regulations
- *Radiation Emitting Devices Act*
- *Access to Information Act*
- *Canada/IAEA Safeguards Agreements*
- *Canada Labour Code, Part II*

Part (ii) of the Licensing Basis

Part (ii) of the licensing basis refers to the conditions and the safety and control measures included in the licence and in the documents directly referenced in the licence.

Under the standardized format and content, the licence requires the licensee to implement and maintain certain programs. There are no documents directly referenced in the Nordion licence. For the purpose of licence requirements, a program may be a series of documented, coordinated activities, not necessarily a single document.

Part (iii) of the Licensing Basis

Part (iii) of the licensing basis consists of the safety and control measures described in the licence application and in the documents in support of that licence application. The safety and control measures include important aspects of that documentation, as well as important aspects of analysis, design, operation, etc. They may be found in high-level, programmatic licensee documents but may also be found in lower-level, supporting

licensee documentation. LC G.1 requires the licensee to conform to, and/or implement, all these safety and control measures.

Part (iii) of the licensing basis also includes the safety and control measures in the standards, codes and CNSC regulatory documents referenced in the application or in the licensee's supporting documentation. Note, however, this does not mean that all details in these referenced documents are part of the licensing basis. Some of these documents may contain administrative, informative or guidance sections that are not considered to be part of the licensing basis.

Applicable licensee documents are listed in the LCH under the heading "Licensee Documents that Require Notification of Change". Applicable CNSC regulatory documents, CSA standards and other documents are listed in the LCH under the heading "Licensing Basis Publications". The documents listed in the LCH could cite other documents that also contain safety and control measures. Applicable licensing basis publications are listed in tables in this LCH under the most relevant LC. All "shall" or normative statements in licensing basis publications are considered CVC unless stated otherwise. If any "should" or informative statements in licensing basis publications are also considered CVC, this is also explained under the most relevant LC.

Details that are not directly relevant to safety and control measures for facilities or activities authorized by the licence are excluded from the licensing basis. Details that are relevant to a different safety and control area (i.e., not the one associated with the main document), are only part of the licensing basis to the extent they are consistent with the main requirements for both safety and control areas.

In the event of any conflict or inconsistencies between two elements of the licensing basis, the licensee shall consult CNSC staff to determine the approach to resolve the issue.

CNSC Staff's Approach to Assessing the Licensing Basis for Nordion

In accordance with LC G.2, the licensee shall submit relevant documentation for CNSC staff review regarding proposed changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis. This includes, but is not limited to changes to equipment, processes, supporting activities, specific licensee documentation or any other item considered a safety or control measure under the licensing basis. There are specific licensee documents listed in the LCH, which require written notification every time a new version of the document is issued by Nordion. CNSC staff will review the information submitted to confirm that the proposed change remains within the licensing basis. CNSC staff assess whether a proposed change is within the licensing basis based on changes and impact on the overall safety at the Nordion facility. Nordion may proceed with the proposed initiatives if they are found to be within the licensing basis.

Any proposed activity or other change considered to be outside the licensing basis will be referred to the Commission for consideration. If the Commission grants approval to the

change, it will become part of the licensing basis and will be reflected in updates to the LCH as appropriate.

The licensee's safety and control measures are described in the following documentation provided at the time of the licence application, or in support of:

Date	Document Title	e-Doc #
May 15, 2024	Application for Renewal of Nordion Operating Licence NSPFOL-11A.01/2025	7283546

Guidance

Document Number	Document Title	Version
REGDOC-3.5.1	Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills, Version 2.1	2022
REGDOC-3.5.3	Regulatory Fundamentals	2023

When the licensee becomes aware that a proposed change or activity might not be in accordance with the licensing basis, it should first seek direction from CNSC staff regarding the potential acceptability of this change or activity. The licensee should take into account that certain types of proposed changes might require significant lead times before CNSC staff can make recommendations and/or the Commission can properly consider them. Guidance for notifications to CNSC related to licensee changes are discussed under LC G.2.

Licence Condition G.2: Notification of Changes

The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

Preamble

CNSC staff tracks, in e-Doc 4768292 the version history of licensee documents that require notification of change (with the exception of security-related documents).

The objective of the licensing basis, as defined in the LCH under LC G.1, is to set the boundary conditions for acceptable performance at the facility. The licensee is encouraged to make continuous improvements to their programs and documents throughout the licensing period as long as they remain within the licensing basis authorized by the Commission.

Compliance Verification Criteria

Written notification is a physical or electronic communication from a person authorized to act on behalf of the licensee to the CNSC.

Under the licensee's management system, a change control process requires justifying changes and the review of changes by relevant stakeholders. Proposed changes with the potential to negatively impact designs, operating conditions, policies, programs, methods, or other elements that are integral to the licensing basis, are documented and written notification of the change shall be provided to the CNSC. Written notifications shall include a summary description of the change, the rationale for the change, expected duration (if not a permanent change), and a summary explanation of how the licensee has concluded that the change remains in accordance with the licensing basis (e.g., an evaluation of the impact on health, safety, security, the environment and Canada's international obligations). A copy of the revised document shall accompany the notification. All written notifications shall be transmitted to CNSC per established communications protocols.

Many changes for which the licensee shall notify the CNSC are captured as changes to licensee documents under part (iii) of the licensing basis. The LCH identifies specific documents that require written notification under the most relevant LC. However, other documents identified in the application or in the licensee's supporting documentation may require notification of change if they describe safety and control measures applicable to the licensing basis. For example, if a licensee document in the CVC refers to another document, including a third-party document, without citing the revision number of that document, if that document changes and the licensee uses the revised version, the licensee shall determine if it is necessary to notify the CNSC of the change.

The documents needed to support the licence application may include documents produced by third parties (e.g., reports prepared by third party contractors). Changes to these documents require written notification to the CNSC only if the new version continues to form part of the licensing basis. That is, if the licensee implements a new version of a document prepared by a third party, it shall inform the CNSC of the change(s), per LC G.2. On the other hand, if a third party has updated a certain document, but the licensee has not adopted the new version as part of its safety and control measures, the licensee is not required to inform the CNSC that the third party has changed the document.
Licensee documents listed in the CVC of the LCH are subdivided in two groups having different requirements for notification of change:

Category	Definition
PN	Prior notification - The licensee shall submit the notice to the CNSC prior to implementing the change. Typically, the requirement is to submit the proposed changes 30 days prior to planned implementation. However, the licensee shall allow sufficient time for the CNSC to review the change proportionate to its complexity and the importance of the safety and control measures being affected
NT	Notification - The licensee shall submit the notice at time of making the change

Notification of some proposed changes (i.e., engineered physical changes, new processes/activities for the facility) may not be best captured through an update to a licensee document. In these cases, a standalone submission may be made that includes the summary description of the change, the rationale for the change, expected duration (if not a permanent change), and a summary explanation of how the licensee has concluded that the change remains in accordance with the licensing basis.

Changes that are not clearly in the safe direction require further assessment of impact to determine if Commission approval is required in accordance with LC G.1.

Guidance

For proposed changes that would not be in accordance with the licensing basis, the guidance for LC G.1 applies.

G.3 Financial Guarantee

Licence Condition G.3

The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.

Preamble

The *General Nuclear Safety and Control Regulations* requires under paragraph 3(1)(l) that a licence application contain a description of any proposed financial guarantee relating to the activity to be licensed.

LC G.3 requires the licensee to maintain a financial guarantee (FG) for decommissioning that is acceptable to the Commission. The FG shall remain valid and in effect and adequate to fund the activities described in the preliminary decommissioning plan or decommissioning strategy. If the preliminary decommissioning plan is revised and impacts the cost estimate for the FG, the expectation is that the FG is revised and submitted to the Commission for acceptance. In addition, the financial guarantee for decommissioning is to be reviewed and revised by Nordion every 5 years, and when the Commission requires.

Nordion has provided a revised *Preliminary Decommissioning Plan* and an associated cost estimate. CNSC staff deemed these to be satisfactory and the Commission accepted the financial guarantee with the associated cost estimate in 2023. The current cost estimate for decommissioning is $35,003,045. Nordion used a letter of credit to cover the estimated cost
($6,342,684) for placing the facility in a safe state of storage (i.e., transfer of nuclear substances to a licensee authorized to possess them and removal of hazardous material). The remainder of the financial guarantee ($28,660,361) is covered by a surety bond.

Compliance Verification Criteria

1. The licensee shall maintain in effect a financial guarantee for decommissioning acceptable to the Commission which shall remain valid, in effect and adequate to fund the activities described in the preliminary decommissioning plan.

2. The financial guarantee for decommissioning is to be reviewed and revised by Nordion every 5 years, when the Commission requires, or following a revision of the preliminary decommissioning plan.

3. The licensee shall report annually to the CNSC on the status of the financial guarantee to confirm that the financial guarantee remains valid, in effect and adequate to fund decommissioning of the facility.

4. The licensee shall develop its financial guarantee based on the requirements and guidance provided in REGDOC-3.3.1.

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Preliminary Decommissioning Plan for Class 1B Facility (KOB)	SE-LIC-009	PN

Licensing Basis Publications

Source	Document Title	Document #	Effective Date
CNSC	Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities	REGDOC-3.3.1	2021
CSA	Decommissioning of Facilities Containing Nuclear Substances	N294	2019

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Decommissioning	REGDOC-2.11.2	2021

G.4 Public Information and Disclosure

Licence Condition G.4

The licensee shall implement and maintain a public information and disclosure program.

Preamble

The *Class I Nuclear Facilities Regulations* requires that an application for a licence contain 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.

The primary goal of a public information and disclosure program is to ensure that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of the nuclear facilities are effectively communicated to the public. In addition, the program shall include a commitment to a disclosure protocol for ongoing, timely communication of information related to the licensed facility during the course of the licence period.

This LC requires the licensee to implement and maintain a public information and disclosure program to improve the public's level of understanding about Nordion's activities.

Compliance Verification Criteria

Licensee Document that Requires Notification of Change

Document Title	Document #	Notification
Nordion Public Information Program	SE-LIC-010	NT

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Public Information and Disclosure	REGDOC-3.2.1	2018

Guidance

Guidance Publications

None.

1. SCA – MANAGEMENT SYSTEM

1.1 Management System Requirements

Licence Condition 1.1

The licensee shall implement and maintain a management system.

Preamble

The *Class I Nuclear Facilities Regulations* require that a licence application contain information on the proposed management system for the activity to be licensed, including the measures to promote and support safety culture.

The *General Nuclear Safety and Control Regulations* requires that a licence application contain the applicant's organizational management structure, including the internal allocation of functions, responsibilities and authority.

CSA N286 *Management System Requirements for Nuclear Facilities* contains the requirements for a management system throughout the lifecycle of a nuclear facility and extends to all safety and control areas.

CSA N286.0.1 *Commentary on N286-12, Management System Requirements for Nuclear Facilities* provides background information concerning certain clauses and requirements in CSA N286. This background information can help the user clarify the context of the CSA N286 requirements.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Management System for Safety	SE-LIC-001	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Management Systems Requirements for Nuclear Facilities*	N286	2012 (R2022)
CNSC	Safety Culture	REGDOC-2.1.2	2018

***** This document is applicable to all LCs

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Commentary on N286-12, *Management system requirements for nuclear facilities*	N286.0.1	2021
CNSC	Management System	REGDOC-2.1.1	2019

2. SCA – HUMAN PERFORMANCE MANAGEMENT

2.1 Human Performance Management

Licence Condition 2.1

The licensee shall implement and maintain a training program.

Preamble

This LC requires the licensee to develop and implement training programs for workers. It also provides the requirements regarding the program and processes necessary to support qualification and requalification training of persons at the nuclear facility.

As defined by the *General Nuclear Safety and Control Regulations*, a worker is a person who performs work that is referred to in a licence. This includes contractors and temporary employees. Training requirements apply equally to these types of workers as to the licensee's own employees. The GNSCR require that licensees ensure that there are a sufficient number of properly trained and qualified workers to conduct the licensed activities safely.

The *Class I Nuclear Facilities Regulations* require that licence applications include the proposed responsibilities of and qualification requirements and training program for workers, including the procedures for the requalification of workers and 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.

The *Class I Nuclear Facilities Regulations* contain provisions for the certification of persons, and require every licensee to keep a record of the status of each worker's qualifications, requalification and training, including the results of all tests and examinations completed in accordance with the licence.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Systematic Approach to Training System	SE-TRN-006	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Personnel Training	REGDOC-2.2.2	2016

Guidance

None provided.

3. SCA – OPERATING PERFORMANCE

3.1 Operations Program

Licence Condition 3.1

The licensee shall implement and maintain an operating program, which includes a set of operating limits.

Preamble

The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility. The *Nuclear Substances and Radiation Devices Regulations* have requirements for records to be kept and retained for nuclear substances.

An operating program includes an up-to-date set of operating limits for the facility and activities authorized under the licence, which may include: production limits and limits for the possession, use, management, transfer, storage of nuclear substances, and an inventory of nuclear substances possessed under the licensees' operating licence.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
EHS Committee Approved Activity Limits for Facilities	SE-LIC-007	NT
Sealed Source Reporting	SE-OP-079	NT
Radioactive Material Inventory	SE-LIC-015	NT
Management System for Safety	SE-LIC-001	PN

Criteria for Facility Operation:

1. The licensee shall operate its facility using up-to-date procedures that have been through a formal development process which includes validation before the

procedure is approved for use. In addition, such procedures shall be reviewed (and revised, as appropriate) on a regular basis.

2. As part of the operating program, the licensee shall implement and maintain a tracking program for high-risk sealed sources.

3. The licensee shall maintain a record of the nuclear substances and radiation devices in its possession, and provide details to show:

   a. the name, quantity, form and location of the nuclear substance;
   b. where the nuclear substance is a sealed source, the model and serial number of the sources;
   c. where the nuclear substance is contained in a radiation device, the model and serial number of the device, the quantity of the nuclear substance used, and the manner in which the nuclear substance is used; and
   d. any transfer, receipt including acquisition, and disposal of a nuclear substance including:

      - the date of transfer, receipt, disposal
      - the name and address of the supplier or the recipient
      - the number of the licence of the recipient
      - the name, quantity and form of the nuclear substance transferred, received, disposed of
      - where the nuclear substance is a sealed source, the model and serial number of the source
      - where the nuclear substance is contained in a radiation device, the model and serial number of the device.

4. The licensee shall maintain records in accordance with subsection 36(1.1) of *the Nuclear Substances and Radiation Devices Regulations* in respect of each servicing performed on any radiation device containing a nuclear substance.

Change Control

(1) The licensee can make changes to structures, systems and components (SSC) and the facility if these are within the boundary conditions set by the licensing basis (see licence condition G.1). Changes shall be made in accordance with the licensee's change control process.

(2) The change control process shall ensure that all permanent and temporary modifications are properly designed, reviewed, controlled and implemented, and that all relevant safety requirements are met. The change control process, shall include:

   (a) reason and justification for the modification

(b) safety assessment

(c) updating facility documentation and training

(d) fabrication, installation and testing; and

(e) commissioning of the modification.

(3) Changes that would result in an impact on health and safety of persons, environment, national security, or to measures of control and international obligations to which Canada has agreed that is different in nature, greater in magnitude or in probability are considered outside the licensing basis and require prior approval of the Commission or a person authorized by the Commission. The licensee shall submit documents in support of the change, demonstrating that the change has been thoroughly developed, designed, analyzed, reviewed and approved by the licensee, and is in compliance with all regulatory requirements.

(4) The licensee shall review the site description, operating manual and safety analysis report and revise the documents as necessary to reflect changes to structures, systems, equipment, components and procedures.

Guidance

None provided.

3.2 Reporting Requirements

Licence Condition 3.2

The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.

Preamble

This LC requires the licensee to implement and maintain a program for reporting information to the Commission. This includes compliance monitoring, operational performance, responses to unusual events, and notifications of various types.

The Nuclear Safety and Control Act and its applicable regulations describe reporting to the Commission or a person authorized by the Commission. Reporting requirements are found in sections 29-32 of the General Nuclear Safety and Control Regulations and section 27 of the NSCA.

The statement "a person authorized by the Commission" in the LCs or the LCH indicates that the Commission may delegate certain authority to CNSC staff. Unless otherwise specified, the delegation of authority by the Commission to act as a person authorized by the Commission (Delegated Officer) is only applied to the incumbents in the following positions:

- Director, Nuclear Processing Facilities Division
- Director General, Directorate of Nuclear Cycle and Facilities Regulation
- Executive Vice-President and Chief Regulatory Officer, Regulatory Operations Branch

The CNSC has strengthened its regulatory controls on sealed sources, principally through establishment of a sealed source tracking system within an upgraded national sealed source registry and enhanced export and import controls for high-risk sealed sources. High-risk sealed sources are recorded in the CNSC database (the Sealed Source Tracking System) that tracks the location of each significantly hazardous radioactive source (IAEA Category 1 and 2 sources) in Canada.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Sealed Source Reporting	SE-OP-079	NT
Investigations	SE-RP-003	NT
EHS Regulatory Reporting and Notifications	SE-EHS-009	NT

1. The licensee shall, in respect of a radioactive nuclear substance set out in column 1 of the table below, report in writing, according to the reporting schedule as set out in column 2 of the table, any transfer, receipt, export or import of a sealed source (including sealed sources that are imported for further processing)whose corresponding activity is equal to or greater than the value set out in column 3 of the table:

Activity Limits for Sealed Source Tracking

Column 1	Column 2	Column 3
Nuclear Substance	**Reporting Schedule**	**(TBq)**
Americium 241	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Americium 241/Beryllium	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Californium 252	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.2
Curium 244	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.5
Cobalt 60	(a) prior to any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.3
Cesium 137	(a) prior to any transfer, and (b) at least 7 days before any export, and (c) within 48 hours of any receipt of a transfer or import.	1
Gadolinium 153	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	10
Iridium 192	(a) prior to any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.8
Promethium 147	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	400
Plutonium 238	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Plutonium 239/ Beryllium	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Radium 226	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.4
Selenium 75	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	2
Strontium 90 (Yttrium 90)	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	10

OPERATING PERFORMANCE

Thulium 170	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	200
Ytterbium 169	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	3

The written report shall be in a form that includes:

(a) on transfer or export of a sealed source(s),

(i) the date of transfer, or for export, the date the sealed source(s) leaves the facility,

(ii) the export licence number (where applicable),

(iii) the name of the recipient and licence number,

(iv) the name of the importer,

(v) the address of the recipient's or importer's authorized location,

(vi) the nuclear substance (radionuclide),

(vii) activity (radioactivity) (Bq) per sealed source on the reference date,

(viii) the reference date,

(ix) the sealed source unique identifiers, and

(x) where the sealed source is incorporated in a prescribed equipment:

(1) the name and model number of the equipment, and

(2) the equipment serial number

(b) on receipt or import of a sealed source(s),

(i) the date of receipt of a transfer or import,

(ii) the name of the shipper and licence number,

(iii) the name of the exporter,

(iv) the address of the shipper's or exporter's authorized location,

(v) the nuclear substance (radionuclide),

(vi) activity (radioactivity) (Bq) per sealed source on the reference date,

(vii) the reference date,

(viii) sealed source unique identifiers, and

(ix) where the sealed source is incorporated in a prescribed equipment:

(1) the name and model number of the equipment; and

(2) the equipment serial number

2. As part of reporting, the licensee shall provide an annual compliance report by March 31 of each year, covering the operation for the 12-month period from January 1 to December 31 of the previous year. (See REGDOC-3.1.2 for information to include in the report).

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	*Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills*, Version 1.1	REGDOC-3.1.2	2022

Guidance

None provided.

4. SCA – SAFETY ANALYSIS

4.1 Safety Analysis Program

Licence Condition 4.1

The licensee shall implement and maintain a safety analysis program.

Preamble

The *General Nuclear Safety and Control Regulations* requires that a licence application contains information that includes a description and the results of any test, analysis or calculation performed to substantiate the information included in the application.

The *Class I Nuclear Facilities Regulations* requires that a licence application contains information that includes a final safety analysis report demonstrating the adequacy of the design of the nuclear facility, and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

The implementation and maintenance of a safety analysis program includes a process to identify and assess hazards and risks on an ongoing basis. This includes identifying and evaluating new or unforeseen risks that were not considered at the planning and design stages and updating previous risk assessments by replacing important assumptions with performance data. The results of this process will be used to set objectives and targets and to develop preventative and protective measures.

CSA N286-12, *Management System Requirements for Nuclear Facilities*, includes specific requirements related to safety analysis that apply to isotope processing facilities. As such, the licensee's safety analysis process is to be performed and documented for the design and carried through the life of the nuclear facility. CSA N286-12 also requires that the safety analysis is periodically reviewed to ensure it is current.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Safety Analysis Reports	CPM-6-20	NT
Final Safety Analysis Report for Cobalt Operations	IS/SR 1057 Z000	PN
Final Safety Analysis Report for the Cobalt Pools	IN/SR 2638 Co60	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Safety Analysis for Class IB Nuclear Facilities	REGDOC-2.4.4	2022
CSA	Management Systems Requirements for Nuclear Facilities	N286	2012 (R2022)

The licensee shall maintain the safety analysis report to ensure it adequately considers the hazards associated with the facility. The safety analysis shall be a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and consider the effectiveness of preventative measures and strategies in reducing the effects of such hazards.

The licensee shall establish and maintain a process to periodically review and revise existing risk assessments to ensure, at a minimum of every 5 years, new risks and lessons learned are incorporated into an updated safety analysis report. This report shall be provided to CNSC staff for review.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Wet storage of irradiated fuel and other radioactive materials	N292.1	2016

Source	Document Title	Document #	Effective Date
IAEA	Safety of Nuclear Fuel Cycle Facilities	SSR-4	2017

5. SCA – PHYSICAL DESIGN

5.1 Design Program

Licence Condition 5.1

The licensee shall implement and maintain a design program.

Preamble

The *Class I Nuclear Facilities Regulations* require that a licence application contain a description of the structures, systems and components (SSC), and relevant documentation of the facility design.

A design program ensures that the plant design is managed using a well-defined systematic approach.

This licence condition requires that the licensee implement and maintain a design program to confirm that SSCs and any modifications to them continue to meet their design basis given new information arising over time and taking changes in the external environment into account. It also confirms that SSCs continue to be able to perform their safety functions.

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain the proposed measures, policies, methods and procedures to maintain the nuclear facility.

This licence condition requires that the licensee implement and maintain a design control process to ensure that design outputs (both interim and final) are reviewed, verified and validated against the design inputs and performance requirements, and to ensure that the design inputs are selected such that safety, performance and dependability of the design item are achieved.

The licensee is encouraged to make continuous improvements to the design of facilities and equipment, as long as the changes remain within the licensing basis authorized by the Commission.

Compliance Verification Criteria

1. The licensee shall ensure that all SSCs are designed to perform their required functions.

2. The licensee shall ensure that any modifications made to the facility are in accordance with Nordion's Design Control Process of the Nordion's Management System for Safety,
SE-LIC-001, that lists the design control requirements.

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	SE-LIC-001	PN
Facility Description	SE-LIC-018	PN
Code Compliance Review for Nordion (Canada) Inc.	REP-EHS-054	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Management Systems Requirements for Nuclear Facilities	N286	2012 (R2022)
NRC	National Building Code of Canada	NBCC	2020
NRC	National Fire Code of Canada	NFCC	2020
CSA	Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2022

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Boiler, pressure vessel, and pressure piping code	B-51	2014
CNSC	General Design Considerations: Human Factors	REGDOC-2.5.1	2019

6. SCA – FITNESS FOR SERVICE

6.1 Fitness for Service Program

Licence Condition 6.1

The licensee shall implement and maintain a fitness for service program.

Preamble

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed measures, policies, methods, and procedures for operating and maintaining the nuclear facility.

It is expected that the licensee will conduct routine maintenance, inspection and testing to ensure that the availability, reliability and effectiveness of facilities and equipment that may impact the health, safety and protection of the environment.

This condition requires that the licensee implement and maintain a maintenance program to ensure that the operating condition of systems, equipment and devices is preserved so that they can perform their function reliably. Accuracy is maintained by planning and carrying out periodic adjustments, calibrations, repairs and replacement.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	SE-LIC-001	PN
Facilities Maintenance Master Plan	R-Master	NT
Nordion Ottawa Site Instrument Maintenance and Calibration	CP-001	NT

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2022

Source	Document Title	Document #	Revision #
NRC	National Fire Code of Canada	NFCC	2020

1. The licensee shall carry out testing and maintenance sufficient to ensure the reliability and effectiveness of all structures, systems and components, and safety-related equipment.

2. The licensee shall determine the extent and frequency of preventive maintenance, testing, surveillance, and inspection of structures, systems and components through a systematic approach, following operating experience and best industry practices, taking into account:

   a) their importance to safety;

   b) their inherent reliability;

   c) their potential for degradation (based on operational and other relevant experience, research and vendor recommendations);

   d) the consequences of failure;

   e) results of condition monitoring; and

   f) the safety analysis.

3. The licensee shall establish, review and validate procedures for maintenance, testing, surveillance, and inspections.

4. Before any structure, system, equipment or component is removed from or returned to service, the licensee shall ensure full consideration and approval of the proposed reconfiguration, followed by a documented confirmation of its correct configuration and, where appropriate, functional testing.

5. Following any abnormal event due to which the safety functions and functional integrity of any structure, system or component may have been challenged, the licensee shall identify and revalidate the safety functions and carry out any necessary remedial actions, including inspection, testing, maintenance, and repair, as appropriate.

6. The licensee shall ensure that all items of equipment used for examinations and tests, together with their accessories, are qualified and calibrated before they are used.

7. The licensee shall properly identify all equipment in the calibration records and shall establish a calibration program to ensure all equipment remains in calibrated state.

Guidance

None provided.

7. SCA – RADIATION PROTECTION

7.1 Radiation Protection Program

Licence Condition 7.1

The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

Preamble

The *Radiation Protection Regulations* requires that the licensee implement a radiation protection program and also ascertain and record doses for each person who performs any duties in connection with any activity that is authorized pursuant to the *Nuclear Safety and Control Act* or is present at a place where that activity is carried on. This program must ensure that doses to persons (including workers) do not exceed prescribed dose limits and are kept as low as reasonably achievable (ALARA), social and economic factors being taken into account.

The regulatory dose limits are explicitly provided in the *Radiation Protection Regulations*.

Action levels are designed to alert licensees before regulatory dose limits are reached. By definition, if an action level is reached, a loss of control of some part of the associated radiation protection program may have occurred, and specific action is required, as defined in the *Radiation Protection Regulations*. Action levels are not intended to be static and should be adjusted to reflect operating conditions in the facility.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Radiation Protection Manual - Ottawa Site	SE-RP-001	PN
Keeping Radiation Exposures and Doses as Low as Reasonably Achievable	SE-RP-002	PN

1. When the licensee becomes aware that an action level has been reached, it shall notify the CNSC within 7 days.

2. If an action level has been reached, the licensee shall file a final report with the CNSC within 21 days of becoming aware of the matter.

3. The licensee shall review and if necessary, revise the action levels at a frequency of once per 5 years to validate their effectiveness.

The licensee action levels are as follows:

Application	Action Level
Effective Dose	2 mSv/Report 15 mSv/year
Pregnant NEW	1 mSv/balance of pregnancy
Skin	30 mSv/Report 200 mSv/year
Extremity	50 mSv/Report 200 mSv/year
Non-NEW: Effective Dose	0.75 mSv/year

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Radiation Protection	REGDOC-2.7.1	2021
CNSC	Dosimetry, Volume I: Ascertaining Occupational Dose	REGDOC-2.7.2	2021

8. SCA – CONVENTIONAL HEALTH AND SAFETY

8.1 Conventional Health and Safety Program

Licence Condition 8.1

The licensee shall implement and maintain a conventional health and safety program.

Preamble

The *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed worker health and safety policies and procedures.

The regulation of conventional health and safety is governed by the *Canada Labour Code, Part II.* The CNSC also has regulatory responsibilities for the oversight of the protection of the health and safety of workers.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Management System for Safety	SE-LIC-001	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Selection, Use and Care of Respirators	Z94.4	2018

Guidance

Guidance Publications

Document Number	Document Title	Version
REGDOC-2.8.1	Conventional Health and Safety	2019

9. SCA – ENVIRONMENTAL PROTECTION

9.1 Environmental Protection Program

Licence Condition 9.1

The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

Preamble

CNSC Regulatory Document 2.9.1: *Environmental Protection Policies, Programs and Procedures*, requires licensees to establish, implement and maintain an Environmental Management System that satisfies the requirements set by the Canadian Standards Association's (CSA) ISO 14001: 2004, *Environmental Management Systems – Requirements with Guidance for Use*.

Canadian Standards Association N288.1-14 *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities* provides guidelines and a methodology for calculating the upper limits (the Derived Release Limits) for the rate of release of radionuclides discharged into the atmosphere and surface waters, based on limiting radiation exposures to members of the public.

The releases of nuclear substances to the environment from the Nordion Class IB nuclear facility shall not exceed the Derived Release Limits (DRLs) and the sum of all fractional DRL releases must remain less than unity. Any exceedance indicates that the licensee is in non-compliance with the public dose limit of 1 mSv per year as per the *Radiation Protection Regulations*.

The Environmental Management System (EMS) captures the environmental protection policies, programs, and procedures of the licensed activity, and ensures that environmental protection is managed via an integrated set of documented activities that have the support and commitment of all levels of management within the licensee's organization. It shall be designed in a way that is appropriate to the nature, scale and environmental impacts of its activities with a commitment to pollution prevention and

continuous improvement, such that environmental issues are identified, monitored, interpreted and acted upon in a manner that demonstrates “adequate precaution” to protect the environment and the health and safety of persons. Components of an EMS include Environmental Policy, Planning, Implementation and Operation, Checking, and Management Review.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Environmental Management System	SE-ENV-001	PN
Environmental Protection Program	SE-ENV-015	PN
Radiation Protection Manual - Ottawa Site	SE-RP-001	PN
Nordion Class 1B Facility Derived Release Limits	ISR Report 13046-01-02	PN
Nordion Environmental Risk Assessment	Calian Report NORDION-0009-01	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Environmental Principles, Assessments and Protection Measures	REGDOC-2.9.1	2020
CSA	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	N288.1	2014
CSA	Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	N288.4	2010
CSA	Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills	N288.5	2011
CSA	Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills	N288.6	2012
CSA	Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	N288.7	2015

Source	Document Title	Document #	Revision #
CSA	Establishing and implementing action levels for releases to the environment from nuclear facilities	N288.8	2017

1. The licensee's environmental protection program shall ensure the control, monitoring and recording of releases of radionuclides to the environment from the nuclear facility such that the joint releases of BWXT Medical and Nordion do not exceed the release limits specified in the *Nordion Class 1B Facility Derived Release Limits* document.

2. The licensee environmental protection program shall have action levels for releases of radionuclides to the environment. The environmental action levels are:

Environmental Action Levels	
Process	**Air Effluent**
Mo-99	N/A
Co-60	1 MBq/week
I-125	0.1 GBq/week
I-131	0.2 GBq/week
Xe-133	3000 GBq/week

3. When the licensee becomes aware that an action level has been reached, it shall notify the CNSC within seven days. If an action level has been reached, Nordion shall file a final report with the CNSC within 21 days of becoming aware of the matter.

4. The licensee shall review and, if necessary, revise the action levels at least once every 5 years to validate their effectiveness. The results of such reviews should be provided to CNSC staff.

5. The licensee's environmental protection program shall control and monitor the releases of hazardous substances.

6. The licensee's environmental protection program shall conform with the requirements of federal and provincial environmental regulations.

Guidance

Guidance Publications

None provided.

10. SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION

10.1 Emergency Management Program

Licence Condition 10.1

The licensee shall implement and maintain an emergency preparedness program.

Preamble

As part of the emergency management program, the licensee shall prepare an onsite emergency plan and establish the necessary organizational structure for clear allocation of responsibilities, authorities, and arrangements for coordinating onsite activities and cooperating with external response organizations throughout all phases of an emergency.

An effective Emergency Preparedness (EP) program is based on the following 4 components:

1. Planning basis: an analysis of the risks and hazards that the EP program will address.

2. Emergency response plan and procedures: a comprehensive description of how a response will be executed, with accompanying support material.

3. Preparedness: the processes to ensure that people, equipment and infrastructure will be ready to execute a response according to the emergency response plan and procedures.

4. Program management: the management system aspects that assure the effectiveness of the EP program.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Emergency Response Plan	SE-ERP-002	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Nuclear Emergency Preparedness and Response	REGDOC-2.10.1	2016

1. The licensee will run a full-scale exercise at least once every 3 years that includes activation of the Emergency Response Plan.

Guidance

The licensee should test emergency measures listed in its emergency plan over a 5-year period. The licensee's full-scale exercise, conducted at least once every 3 years, should involve any mutual aid partners identified in the emergency plan.

10.2 Fire Protection Program

Licence Condition 10.2

The licensee shall implement and maintain a fire protection program.

Preamble

Licensees shall prepare and implement a fire protection program (a set of planned, coordinated, controlled and documented activities) to ensure that the licensed activities do not result in an unreasonable risk to the health and safety of persons and to the environment due to fire and to ensure that the licensee is able to efficiently and effectively respond to emergency fire situations.

This SCA also includes the requirement for the licensee to have a fire protection program to minimize the risk to the health and safety of persons and to the environment from fire, through appropriate fire protection system design, fire safety analysis, fire safe operation and fire prevention.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Fire Safety Plan	SE-ERP-001	PN
Fire Protection Program	SE-EHS-007	PN
Fire Hazard Assessment for Nordion	SE-EHS-017	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Fire protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2022
NRC	National Building Code of Canada	NBCC	2020
NRC	National Fire Code of Canada	NFCC	2020

Guidance

None provided.

11. SCA – WASTE MANAGEMENT

11.1 Waste Management Program

Licence Condition 11.1

The licensee shall implement and maintain a waste management program.

Preamble

CNSC Regulatory Document REGDOC-2.11.1 *Waste Management, Volume I: Management of Radioactive Waste*, defines radioactive waste as any material (liquid, gaseous or solid) that contains a radioactive "nuclear substance," as defined in section 2 of the NSCA, and which the owner has declared to be waste. In addition to containing nuclear substances, radioactive waste may also contain non-radioactive "hazardous substances," as defined in section 1 of the *General Nuclear Safety and Control Regulations*

Compliance Verification Criteria

1. The licensee shall

   a. ensure that the production, in terms of both rate and volume, of radioactive waste is minimized; and

   b. maintain adequate records of inventory and throughput of radioactive wastes produced.

2. The licensee shall ensure, to the extent reasonably practicable, that

   a. radioactive waste produced is accumulated in a controlled and contained manner such that it cannot escape from such control or containment; and

   b. no leak or escape of nuclear substances or radioactive wastes can occur without being detected.

3. The licensee shall identify the characteristics of all radioactive and hazardous wastes that are produced in the course of the licensed activities.

4. The licensee shall not produce, in the course of the licensed activities, waste for which there is no identified and approved treatment, or storage, or disposal facility.

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Radiation Protection Manual – Ottawa Site	SE-RP-001	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Waste Management, Volume I: Management of Radioactive Waste	REGDOC-2.11.1	2021

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	General principles for the management of radioactive waste and irradiated fuel	N292.0	2019
CSA	Management of Low and Intermediate-Level Radioactive Waste	N292.3	2014

11.2 Decommissioning Strategy

Licence Condition 11.2

The licensee shall implement and maintain a decommissioning strategy.

Preamble

Paragraph 3(k) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed plan for the decommissioning of the nuclear facility or of the site.

This licence condition requires that the licensee maintain a **decommissioning strategy.**

A decommissioning strategy provides an overview of the proposed decommissioning approach that is sufficiently detailed to assure that the proposed approach is, in the light of existing knowledge, technically and financially feasible and appropriate in the interests of health, safety, security and the protection of the environment. The decommissioning strategy defines areas to be decommissioned and the general structure and sequence of the principle work packages. The decommissioning strategy forms the basis for establishing and maintaining a financial arrangement (financial guarantee) that will assure adequate funding of the decommissioning plan.

The decommissioning strategy and estimation of the cost of decommissioning were finalized in the document titled: “Preliminary Decommissioning Plan for Class IB Facility (KOB)”.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Preliminary Decommissioning Plan for Class 1B Facility (KOB)	SE-LIC-009	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Financial guarantees for decommissioning of nuclear facilities and termination of licensed activities	REGDOC 3.3.1	2021
CSA	Decommissioning of Facilities Containing Nuclear Substances	N294	2019

1. The licensee shall maintain a decommissioning plan that reflects any changes in the site or nuclear facility. The decommissioning plan shall be revised at a minimum every 5 years or when required by the Commission.

2. The decommissioning plan was last revised and approved by the CNSC in 2022. The licensee's next scheduled submission of the decommissioning plan is due to the CNSC in 2027.

Guidance

Guidance Publications

None.

12. SCA – SECURITY

12.1 Security Program

Licence Condition 12.1

The licensee shall implement and maintain a security program.

Preamble

The *General Nuclear Safety and Control Regulations* requires that a licence application contain information including the proposed measures to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information.

The *Class I Nuclear Facilities Regulations* requires that a licence application to operate a Class I nuclear facility contain information including the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts.

Part 2 of the *Nuclear Security Regulations* also applies to this licensee, as it is listed in Schedule 2 of these regulations. Part 2 of the *Nuclear Security Regulations* requires that an application in respect of a nuclear facility listed in Schedule 2 contain a description of the physical protection measures to be undertaken to ensure compliance with Part 2.

Part A of Regulatory document REGDOC-2.12.3, Version 2, Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, sets out the minimum security measures that licensees must implement to prevent the loss, sabotage, illegal use, illegal possession or illegal removal of sealed sources during their entire lifecycle, including while the sources are in storage, transport or being stored during transportation. Part B of this document also provides information and guidance on how to comply with the minimum-security measures, including measures related to transport vehicles, containers and security plans for Categories I, II or III Nuclear Material.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Nordion Security Plan (PROTECTED)	n/a	NT
Nordion General Canadian Transportation Security Plan (PROTECTED)	n/a	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material	REGDOC-2.12.3 Version 2.1	2020

1. The licensee shall maintain the operation, design and analysis provisions specified in the security plan, including that they ensure adequate engineered safety barriers are in place for protection against malevolent acts.

2. Technical and administrative security measures shall be documented by the licensee in a site security plan.

3. The licensee shall implement and maintain a facility security plan, and ensure it is designated as prescribed information. The site security plan must be reviewed by the licensee when changes occur within the licensed facility and/or to address an increased threat level and updated if required.

4. The licensee shall implement satisfactory security measures to prevent the loss, sabotage, illegal use, illegal possession, or illegal removal of sealed sources while under licensee's control, including while the sources are in storage, transport or being stored during transportation.

Guidance

None Provided

Guidance Publications

Source	Document Title	Document #	Effective Date
IAEA	Security of Radioactive Material in Transport	Nuclear Security Series # 9	2020
IAEA	Security of Radioactive Material in Use and Storage and of Associated Facilities	Nuclear Security Series # 11	2019
IAEA	Nuclear Security Recommendations on Radioactive Material and Associated Facilities	Nuclear Security Series # 14	2011
IAEA	Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control	Nuclear Security Series # 15	2011
IAEA	Security Management of Radioactive Material in Use and Storage and of Associated Facilities	Nuclear Security Series # 43-T	2022

13. SCA – SAFEGUARDS AND NON-PROLIFERATION

13.1 Safeguards and Non-Proliferation

Licence Condition 13.1

The licensee shall implement and maintain a safeguards program.

Preamble

The GNSCR require the licensee to take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement, and defines reporting requirements for safeguards events.

The *Class I Nuclear Facilities Regulations* require that a licence application contain information on the licensee's proposed measures to facilitate Canada's compliance with any applicable safeguards agreement.

This LC requires that the licensee implement and maintain a safeguards program. Safeguards is a system of inspection and other verification activities undertaken by the International Atomic Energy Agency (IAEA) in order to evaluate a Member State's compliance with its obligations pursuant to its safeguards agreements with the IAEA.

Canada has entered into a Safeguards Agreement and an Additional Protocol (hereafter referred to as "safeguards agreements") with the IAEA pursuant to its obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons* (INFCIRC/140). The objective of the Canada-IAEA safeguards agreements is for the IAEA to provide assurance on an annual basis to Canada and to the international community that all declared nuclear materials are in peaceful, non-explosive uses and that there is no indication of undeclared nuclear materials or activities. This conclusion confirms that Canada is in compliance with its obligations under the following Canada-IAEA safeguards agreements:

- *Agreement between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons*; and

- *Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons.*

These are reproduced in information circulars INFCIRC/164, and INFCIRC/164/Add.1.

In addition, the import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations*, require separate authorization from the CNSC, consistent with subsection 3(2) of the GNSCR.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Notification
Management of Safeguarded Material	SE-LIC-016	PN

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Safeguards and Nuclear Material Accountancy	REGDOC-2.13.1	2018

The licensee shall implement and maintain a safeguards program in accordance with the requirements set out in REGDOC-2.13.1, *Safeguards and Nuclear Materials Accountancy*. According to the criteria set out in that document, Nordion is currently classified as a Location Outside Facility and must comply with the appropriate requirements in REGDOC-2.13.1. Should changes to conditions on the licensed site necessitate a change in safeguards classification, changes to Nordion's safeguards program may be required.

Guidance

None provided.

14. SCA – PACKAGING AND TRANSPORT

14.1 Packaging and Transport Program

Licence Condition 14.1

The licensee shall implement and maintain a packaging and transport program.

Preamble

The *Class I Nuclear Facilities Regulations* requires that a licence application contain information on the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.

Every person who transports radioactive material, or requires it to be transported, shall act in accordance with the requirements of the *Transportation of Dangerous Goods Regulations* (TDGR) and the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR).

The TDGR and PTNSR provide specific requirements for the design of transport packages, the packaging, marking and labeling of packages and the handling and transport of nuclear substances.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Transport of Radioactive Material	SE-OP-036	NT

Document Title	Document #	Prior Notification
Receiving Radioactive Material	SE-OP-015	NT
Shipping Radioactive Material	SE-OP-014	NT

Guidance

Document Number	Document Title	Version
REGDOC-2.14.1	Volume I, Information Incorporated by Reference in Canada's Packaging and Transport of Nuclear Substances Regulations, 2015	2021

APPENDIX A – Definitions and Acronyms

A.1 Definitions

The following is a list of definitions of words or expressions used in the LCH that may need clarification; they are defined for the purpose of the LCH only. All other terms and expressions used in the LCH are consistent with the definitions provided in the NSCA, the regulations made pursuant to the NSCA, or in the CNSC regulatory document REGDOC-3.6, Glossary of CNSC Terminology.

Accept/ed/able/ance – meets regulatory requirements, which mean it is in compliance with the documents referenced in the LCH.

Approval – Commission's permission to proceed, for situations or changes where the licensee would be:

- not compliant with a regulatory requirements set out in applicable laws and regulations;
- not compliant with a licence condition; and
- not in the safe direction but the objective of the licensing basis is met.

Boundary Conditions – procedural, administrative rules and operating limits for ensuring safe operation of the facility based on safety analyses and any applicable regulatory requirements.

Compliance Verification Criteria – regulatory criteria used by CNSC staff to verify compliance with the licence conditions.

Design Basis – the entire range of conditions for which the nuclear facility is designed, in accordance with established design criteria, and for which damage to the fuel and/or the release of radioactive material is kept within authorized limits.

Guidance – guidance in the LCH is non-mandatory information, including direction, on how to comply with the licence condition.

Implementation Date – the date that a given document is implemented by the licensee. If the licensee implemented the document at the time of the LCH revision, then "implemented" will be stated.

Notification Document – a document which is submitted to the CNSC at the time of implementing the change.

Prior Notification Document – a document which is submitted to the CNSC prior to implementing the change.

Program(s) – a documented group of planned activities, procedures, processes, standards and instructions coordinated to meet a specific purpose.

Qualified Staff – trained licensee staff, deemed competent and qualified to carry out tasks associated with their respective positions.

Safe Direction – changes in facility safety levels that would not result in:

(a) a reduction in safety margins;

(b) a breakdown of barrier;

(c) an increase (in certain parameters) above accepted limits;

(d) an increase in risk;

(e) impairment(s) of safety systems;

(f) an increase in the risk of radioactive releases or spills of hazardous substances;

(g) injuries to workers or members of the public;

(h) introduction of a new hazard;

(i) reduction of the defence-in-depth provisions;

(j) causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility.

Safety and Control Measures – measures or provisions which demonstrate that the applicant:

(i) is qualified to carry on the licensed activities; and

(ii) has made adequate provision for the protection of the environment, the health and safety of persons, the maintenance of national security and any measures required to implement international obligations to which Canada has agreed.

Written Notification – a physical or electronic communication between CNSC staff and a person authorized to act on behalf of the licensee.

APPENDIX A

A.2 Acronyms

The following is the list of acronyms used in this document:

AL	Action Level
ALARA	As Low As Reasonably Achievable, social and economic factors taken into consideration
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association
CVC	Compliance Verification Criteria
DNCFR	Directorate of Nuclear Cycle and Facilities Regulation
DRL	Derived Release Limits
EP	Environmental Protection
EMS	Environmental Management System
FG	Financial Guarantee
GNSCR	*General Nuclear Safety and Control Regulations*
IAEA	International Atomic Energy Agency
LC	Licence Condition
LCH	Licence Conditions Handbook
NEW	Nuclear Energy Worker
NPFD	Nuclear Processing and Facilities Division
NSCA	*Nuclear Safety and Control Act*
NT	Notification
PN	Prior Notification
RP	Radiation Protection
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SSC	Structures, systems and components
WN	Written Notification

APPENDIX B – LIST OF VERSION CONTROLLED DOCUMENTS

B.1 Licensee Documents

Document Title	Document #	Notification	Licence Conditions
Facility Description	SE-LIC-018	PN	5.1
Nordion Public Information Program	SE-LIC-010	NT	G.4
Management System for Safety	SE-LIC-001	PN	1.1, 3.1, 5.1, 6.1, 8.1
Systematic Approach to Training System	SE-TRN-006	PN	2.1
EHS Committee Approved Activity Limits for Facilities	SE-LIC-007	NT	3.1
Sealed Source Reporting	SE-OP-079	NT	3.1, 3.2
Radioactive Material Inventory	SE-LIC-015	NT	3.1
Investigations	SE-RP-003	NT	3.2
EHS Regulatory Reporting and Notifications	SE-EHS-009	NT	3.2
Safety Analysis Reports	CPM-6-20	NT	4.1
Final Safety Analysis Report for Cobalt Operations	IS/SR 1057 Z000	PN	4.1
Final Safety Analysis Report for the Cobalt Pools	IN/SR 2638 Co60	PN	4.1
Facilities Maintenance Master Plan	R-Master	NT	6.1
Nordion Ottawa Site Instrument Maintenance and Calibration	CP-001	NT	6.1

Document Title	Document #	Notification	Licence Conditions
Radiation Protection Manual – Ottawa Site	SE-RP-001	PN	7.1, 9.1, 11.1
Keeping Radiation Exposures and Doses as Low as reasonably Achievable	SE-RP-002	PN	7.1
Environmental Management System	SE-ENV-001	PN	9.1
Environmental Protection Program	SE-ENV-015	PN	9.1
Emergency Response Plan	SE-ERP-002	PN	10.1
Fire Safety Plan	SE-ERP-001	PN	10.2
Fire Protection Program	SE-EHS-007	PN	10.2
Preliminary Decommissioning Plan for Class 1B Facility (KOB)	SE-LIC-009	PN	11.2
Nordion Security Plan (PROTECTED)	N/A	NT	12.1
Nordion General Canadian Transportation Security Plan (PROTECTED)	N/A	PN	12.1
Management of Safeguarded Material	SE-LIC-016	PN	13.1
Transport of Radioactive Material	SE-OP-036	NT	14.1
Receiving Radioactive Material	SE-OP-015	NT	14.1
Shipping Radioactive Material	SE-OP-014	NT	14.1

APPENDIX B

B.2 Codes, Standards and Regulatory Documents

Document #	Document Title	L.C.
REGDOC-3.3.1	Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities	G.3, 11.2
REGDOC-2.11.1	*Waste Management, Volume I: Management of Radioactive Waste*	11.1
REGDOC-2.11.2	Decommissioning	G.3
CSA N294	Decommissioning of Facilities Containing Nuclear Substances	G.3, 11.2
REGDOC-3.2.1	Public Information and Disclosure	G.4
CSA N286-12	Management systems requirements for nuclear facilities	1.1, 4.1
CSA N286.0.1	Commentary on N286-12, Management system requirements for nuclear facilities	1.1
REGDOC-2.1.1	Management System	1.1
REGDOC-2.1.2	Safety Culture	1.1
REGDOC-2.2.2	Personnel Training	2.1
CSA N393	Fire protection for Facilities that Process, Handle or Store Nuclear Substances	3.1, 4.1, 5.1, 6.1, 10.2
NFCC	National Fire Code of Canada	3.1, 5.1, 6.1, 10.2
NBCC	*National Building Code of Canada*	3.1, 5.1, 10.2
REGDOC-3.1.2	Reporting Requirements Volume I for Non-Power Reactor: Class I Nuclear Facilities and Uranium Mines and Mills	3.2
CSA N292.1	Wet storage of irradiated fuel and other radioactive materials	4.1
IAEA SSR-4	Safety of Nuclear Fuel Cycle Facilities	4.1
CSA B-51	Boiler, pressure vessel, and pressure piping code	5.1

Document #	Document Title	L.C.
REGDOC-2.7.1	Radiation Protection	7.1
REGDOC-2.7.2	Dosimetry, Volume I: Ascertaining Occupational Dose	7.1
CSA Z94.4	Selection and Use of Respirators	8.1
REGDOC-2.9.1	Environmental Principles, Assessments and Protection Measures	9.1
CSA N288.4	Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	9.1
CSA N288.5	Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	9.1
CSA N288.6	Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills	9.1
CSA N288.7	Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	9.1
CSA N288.8	Establishing and implementing action levels for releases to the environment from nuclear facilities	9.1
REGDOC-2.10.1	Nuclear Emergency Preparedness and Response	10.1
CSA N292.0	**General principles for the management of radioactive waste and irradiated fuel**	11.1
CSA N292.3	Management of Low and Intermediate-Level Radioactive Waste	11.1
REGDOC-2.12.3 Version 2.1	Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material	12.1
IAEA Nuclear Security Series # 9	Security in Transport of Radioactive Material in Transport	12.1
IAEA Nuclear Security Series # 11	Security of Radioactive Material in Use and Storage and of Associated Facilities	12.1
IAEA Nuclear Security Series # 14	Nuclear Security Recommendation on Radioactive Material and Associated Facilities	12.1
IAEA Nuclear Security Series # 15	Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control	12.1

Document #	Document Title	L.C.
IAEA Nuclear Security Series # 43-T	Security Management of Radioactive Material in Use and Storage and of Associated Facilities	12.1
REGDOC-2.13.1	Safeguards and Nuclear Material Accountancy	13.1

Appendix C: provides a list of licensing documents relevant for Nordion. The information regarding editions (revisions) of codes, standards, licensee, and CNSC documents is maintained in an Excel spreadsheet. For convenience of maintenance and updating of the Nordion LCH, and unless the context requires otherwise, these documents are referenced in the applicable criteria throughout the LCH without specifying their revisions.

Appendix D: provides a list of documents used as criteria or guidance.