Licence Renewal Application for the Nordion Facility

Nordion (Canada) Inc.

CMD 25 - H6.A

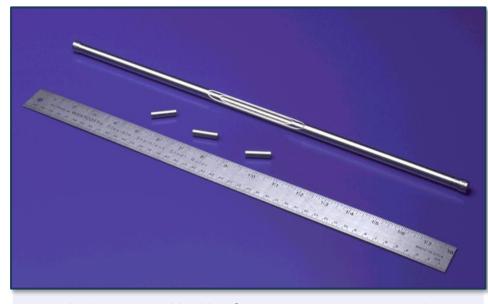
CNSC Staff Presentation

Commission Hearing June 4, 2025



Presentation Outline

- Facility Overview
- Review of the Licence Application
- Regulatory Oversight
- Performance Assessment
- Indigenous and Public Engagement
- Other Matters of Regulatory Interest
- Conclusions and Recommendations



Cobalt-60 pencil holder for sources, Source: Nordion

Purpose of Hearing

Nordion has applied to the Commission to:

Renew Nordion's Class IB Nuclear Substance Processing Facility Operating Licence for 25 years effective November 1, 2025, to October 31, 2050.

Nordion requested no changes to the conditions of the current licence, or to the currently authorized licensed activities.

CMD 25-H6 provides CNSC staff's analysis and recommendations on Nordion's request to renew the Class IB Nuclear Substance Processing Facility Operating Licence.

Current Licence

Authorizes Nordion to:

- Operate a Nuclear Substance Processing Facility, for the purposes of processing and manufacturing nuclear substances and sealed sources used in health sciences and industrial applications.
- Possess, transfer, use, process, import, manage, store, or dispose of, nuclear substances
 that are required for, associated with, or arise from processing and manufacturing
 nuclear substances and sealed sources.
- Possess, transfer, use, import, or service prescribed equipment that are required for, associated with, or arise from processing and manufacturing nuclear substances and sealed sources.
- Possess, transfer, use, service, or import prescribed equipment from clients.
- **Possess and use prescribed information** that are required for, associated with, or arises from the processing and manufacturing of nuclear substances and sealed sources.



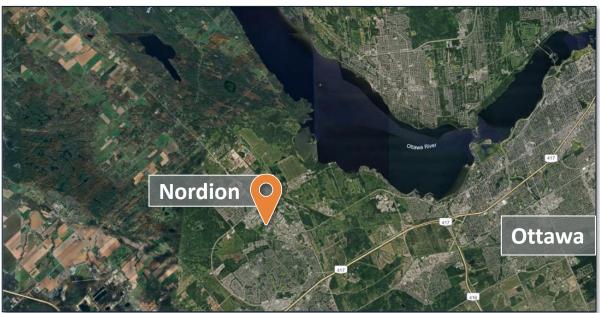
Facility Overview



Location of Nordion Class IB Facility



Aerial view of the Nordion facility outlined in orange (Source: Nordion/Canadian Aerial Photo Corporation)



Google Earth view of the location of Nordion (Source: Google Earth)

Background - Nordion

Nordion is a producer of Cobalt-60.

- Cobalt-60 is used in industrial irradiators to sterilize medical devices, instruments, as well as consumer products such as food, contact lens solution and cosmetics.
- Cobalt-60 sources are also used in medical applications for cancer treatments.



Nordion employee working at a hot cell, Source: Nordion



Review of the Licence Application



CNSC's Review of the Licence Application

CNSC staff:

- **Verified** that the information submitted in support of the application is complete in satisfying CNSC regulatory requirements, including the *Nuclear Safety and Control Act* (NSCA) and associated Regulations, for all 14 safety and control areas (SCAs).
- Assessed all aspects of Nordion's application and proposed licence period.

Nordion's application complies with regulatory requirements



Regulatory Oversight



Compliance Inspections

- The CNSC has a facility assessment and compliance team that oversees all licensed activities.
- CNSC staff established and carried out a riskinformed inspection compliance plan for Nordion.
- 26 inspections conducted over 10 years.
 - covered all 14 SCAs
- Non-compliances tracked by CNSC staff using the CNSC Regulatory Information Bank.

Year	Number of Inspections
2015	3
2016	5
2017	1
2018	4
2019	2
2020	0
2021	2
2022	5
2023	2
2024	2
Total	26

All non-compliances from 2015 to 2024 have been addressed

Event Reporting

•	Licensees must report all events as required	
	the NSCA, associated Regulations, licence	
	conditions and regulatory documents.	

- Nordion provided 77 reportable event notifications:
 - All events were of low safety significance
 - Nordion's event notifications and follow-up reports were acceptable to CNSC staff

Year	Events
2015	2
2016	10
2017	16
2018	8
2019	4
2020	10
2021	7
2022	7
2023	8
2024	5
Total	77

Number of

Nordion met regulatory event reporting requirements



Performance Assessment



Assessment of Safety and Control Areas (SCA)

- CNSC staff assessed 14 SCAs for Nordion's Licence Application.
- Information submitted in support of the application satisfies CNSC requirements under the NSCA and its Regulations.
- Assessment criteria and results are summarized in CMD 25-H6.

Nordion's programs meet regulatory requirements

Safety and Control Areas

Management System

Human Performance Management

Operating Performance

Safety Analysis

Physical Design

Fitness for Service

Radiation Protection

Conventional Health and Safety

Environmental Protection

Emergency Management and Fire Protection

Waste Management

Security

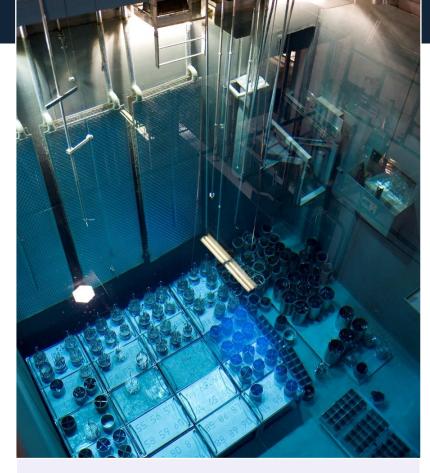
Safeguards and Non-Proliferation

Packaging and Transport

SCA – Safety Analysis

CNSC staff's assessment:

- Nordion has submitted the required safety analysis reports.
- Compliant with CNSC regulatory requirements and reviewed at a minimum every five years.
- Nordion has processes in place to identify and evaluate safety hazards associated with operations.



Nordion Cobalt Storage Pool, Source: Nordion

Nordion's Safety Analysis Reports demonstrate that the facility is operating safely

SCA – Radiation Protection

CNSC staff's assessment:

- Nordion's Radiation Protection program is effective at keeping doses As Low As Reasonably Achievable.
- The maximum annual individual effective dose received by a Nuclear Energy Worker in the licence period was 11% of the annual regulatory dose limit.
- Radiological surveys and contamination controls are used to monitor and minimize radiological hazards in the facility.

Nordion's Radiation Protection program contributes to the safety of workers



SCA – Conventional Health and Safety

CNSC staff's assessment:

- Nordion has established tools for identifying and controlling hazards.
- Nordion staff are made aware of the conventional health and safety program, as well as workplace hazards, through training and ongoing internal communications.
- Safety is maintained through proper use of personal protective equipment, use of barriers and signage, housekeeping, etc.
- Nordion reported a total of 7 Lost Time Injuries during this licence period.

Nordion implements and maintains an effective health and safety program

SCA – Environmental Protection (1/3)

CNSC's staff's assessment:

- Nordion's Environmental Risk Assessment (ERA), which looks at impacts to the environment and human health, meets regulatory requirements. The ERA is required to be revised every 5 years.
- Nordion's Environmental Protection Program, which includes the control and monitoring of atmospheric emissions and liquid effluent releases to the environment, meets regulatory requirements.



SCA - Environmental Protection (2/3)

Program Highlights:

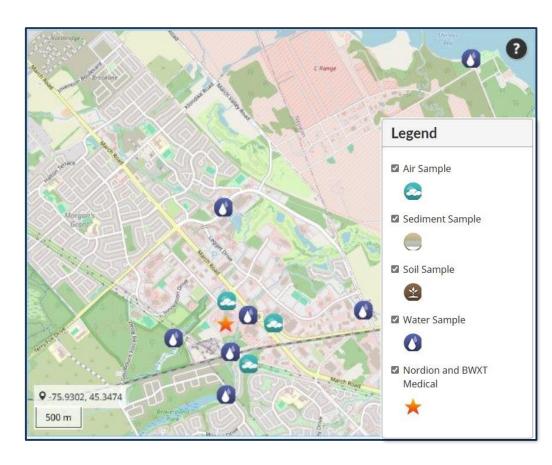
- Air emissions and liquid effluent emissions are very low, with the highest annual emissions being 0.0024% and 0.11% of the regulatory limits, respectively.
- Environmental monitoring provides confirmation that releases from the facility are adequately controlled.
 - Groundwater is monitored every year
 - Soil sampling is conducted every 2 years
 - Environmental dosimeters are positioned at nearby businesses and residences
- During the licence period, the maximum estimated dose to a member of the public was ~1% of the annual regulatory limit of 1 mSv.

Nordion's operations adequately protect the environment and human health



SCA – Environmental Protection (3/3) Independent Environmental Monitoring Program

- The IEMP objective is to build Indigenous and public trust in the CNSC's regulation of the nuclear industry.
- Conducted at the Nordion site during the licence period in 2016, 2018 and 2023.
- Samples included soil, sediment, air, and water.
- The IEMP results are published on the CNSC's website.



SCA – Waste Management

CNSC staff's assessment:

- Nordion has an effective program covering the characterization, segregation, and minimization of radioactive wastes generated on site.
- The Waste Management Program applies to all aspects of waste management at the site, including all the waste materials generated, received, handled, stored at the facility, recycled and/or transferred/removed to an appropriate waste management or other facility.
- Nordion has a program which is designed to reduce the volume of waste currently being shipped to external radioactive waste management facilities.

Nordion manages and implements an effective waste management program



Indigenous and Public Engagement



United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

The CNSC is committed to supporting the Government of Canada's whole-of-government approach to implementing UNDRIP through the United Nations Declaration Act (UNDA), 2021, and the 2023-2028 UNDA Action Plan, where it intersects with the CNSC's mandate.

The principle of Free, Prior and Informed Consent (FPIC) is an integral aspect of UNDA that is reflected in the 2023-2028 UNDA Action Plan.

The CNSC's approach to consultation and engagement with Indigenous peoples is mindful of and consistent with the principles articulated in UNDA.

CNSC staff engage and collaborate with Indigenous Nations to understand and address their concerns, including those related to their consent position for a given nuclear project or licence application that may impact their right and interests.

CNSC provides funding through the Participant Funding Program (PFP) and the Indigenous and Stakeholder Capacity Fund (ISCF) to support meaningful participation in Commission proceedings and ongoing regulatory work in order to help inform the Commission's decision-making process.

Indigenous Engagement

CNSC staff engagement activities included:

December 2024	Letters of notification that included PFP deadline with follow-up phone calls/emails
	Provision of information during regular meetings with Nations with terms of reference for long term engagement*
	Provision of information in meetings with other Nations and communities
November 2024 to April 2025	Follow up on intervention deadlines and hearing details and encouraged participation in the hearing process
	Correspondence providing information about the March 25th public webinar

Indigenous Nations and communities:

- The Algonquins of Pikwakanagan First Nation*
- Kitigan Zibi Anishinabeg
 First Nation
- Kebaowek First Nation*
- The Algonquin Anishinabeg
 Nation Tribal Council
- Algonquins of Ontario
- Mohawks of the Bay of Quinte
- Métis Nation of Ontario*

Participant Funding Program

Funding was provided to assist Indigenous Nations and communities and members of the public in providing valuable information directly to the Commission.

CNSC awarded approximately \$41,000 to the following recipients:

- Algonquins of Pikwàkanagàn First Nation
- Kebaowek First Nation



Public Information and Disclosure Program

CNSC staff have reviewed Nordion's Public Information and Disclosure Program 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 including Indigenous Nations and communities, elected and government representatives, Nordion's employees, media, business leaders, interest groups, and community organizations.
- Provides contact information for members of the public who want to obtain additional information.

CNSC's Public Engagement

Event	Date
Announcement for Notice of Hearing and PFP	November 4, 2024
CNSC Webinar	March 25, 2025



Interventions

A total of 10 interventions were received, 8 of them support Nordion's licence renewal application.

Key themes from interventions:

- Indigenous engagement and consultation
- Licence period
- Transport of nuclear substances
- Emergency preparedness
- Environmental monitoring
- Waste management and decommissioning



Other Matters of Regulatory Interest

Financial Guarantee

CNSC staff's assessment:

- Nordion maintains a financial guarantee (FG) to fund the activities described in its preliminary decommissioning plan (PDP).
 - The FG instruments (stand-by letter of credit, surety bond) total CAD \$35,003,045
 - The current FG was accepted by the Commission on February 16, 2023
- The PDP captures strategies, activities and cost estimates for decommissioning of the Nordion facility.
- The next FG review is expected in 2027.

The financial guarantee is valid, enforceable and sufficient to fund Nordion's decommissioning strategy



Recommendation for Licence Period (1/2)

CNSC staff recommendation for licence period is based on the following conclusions:

- Nordion's programs and processes assure safe conduct of licensed activities
- Nordion has demonstrated satisfactory performance across all SCAs during the previous licensing period
- Nordion has and will continue to be required to undertake periodic reviews of key licensing basis documentation
- Nordion's future plans (i.e., continued operations) align with the requested licence period



Recommendation for Licence Period (2/2)

CNSC staff recommendation for licence period is based on the following conclusions:

- CNSC's mature and agile regulatory oversight that allows for effective compliance verification and enforcement regardless of licence period
- CNSC staff commitment to maintain ongoing engagement and consultation with Indigenous Nations and communities and the public
- Ability of Indigenous Nations and communities and the public to bring concerns to CNSC staff at any time
- Continued Commission engagement through:
 - Scheduled (e.g. Regulatory Oversight Report) and unscheduled (e.g., event initial reports) reporting to the Commission
 - Commission reviews that are required of financial guarantee updates and any licensee proposals beyond the licensing basis
 - CNSC staff's recommendation that should the Commission approve the requested licence period, two performance updates be provided by Nordion



Conclusions and Recommendations



Based on the technical assessment of Nordion's application and supporting information, CNSC staff conclude that:

- The application complies with the regulatory requirements
- The licensee's performance during the current licence period was satisfactory and met regulatory requirements

Recommendations

CNSC staff propose that the Commission:

- Conclude, pursuant to paragraph 24(4)(a) and (b) of the NSCA, that Nordion:
 - i. Is qualified to carry on the activities authorized by the licence
 - ii. 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
- **Renew** the operating licence for a period of 25 years, expiry date being October 31, 2050.
- Impose a requirement for the licensee to provide two performance updates to the Commission during the licence term.
- **Delegate authority** as set out in CMD 25-H6.



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