Nordion
A Sotera Health company

February 21, 2025

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

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

Dear Sir/Madame,

This submission is an amendment to Nordion's application for renewal of Nordion's Class 1B Nuclear Substance Processing Facility Operating License, NSPFOL-11A.01/2025, initially submitted on May 15, 2024.[1]

This amendment to our May 15, 2024 renewal submission is a revision to the table of supporting documents listed in Appendix A and referenced in Attachment 1. This revision is being made to focus the supporting documentation on those documents key to our licensing basis, as defined in our current Licence Condition Handbook and has been made in consultation with CNSC staff.

The revised Appendix A and Attachment 1 are enclosed.

The information contained in Appendix B, Attachment 2, and Attachment 3 of our May 15, 2024 renewal submission remains unchanged. These have been included with this amendment for completeness of the record.

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

Sincerely,

Richard Wassenaar
Director, Regulatory & EHS

cc: Andrew McAllister, Michael Davey and Jason Duhaime – CNSC
Sabrina Sng - Nordion

Encosure:
Appendix A: Revised List of Supporting Documentation
Appendix B: Justification for 25-year Licence Period
Attachment 1: Revised Information Required for the Renewal of the Operating Licence
Attachment 2: Summary of Facility and Program Improvements Since 2015
Attachment 3: Supplementary Report to Support License Renewal

Reference:
[1] E-mail from S. Sng, Nordion, to the Commission Registry, CNSC, "Application for Renewal of Nordion's Operating License NSPFOL-11A.01/2025", dated May 15, 2024

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Appendix B
Justification for 25-Year License Period

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

Nordion has been safely operating the facility at 447 March Rd for over 50 years, producing Co-60 sealed sources since the 1960s. Over that time, Nordion has implemented and continuously improved the facility, equipment, and programs in place to protect the health and safety of people and the environment.

Highlights of these programs are described as follows:

1) Nordion has implemented a strong and mature management safety program that drivew the oversight and continuously improvement of licensed activities. This program meets the requirement of CSA N286-12.

2) The hazards associated with the licensed activity, operation of a nuclear substance processing facility, are well characterized in the Safety Analysis Reports and Fire Hazard Analysis for the facility and their impacts are well predicted. These licensed activities have not substantially changed regarding the production of Co-60 sealed sources, and the risk assessment remains complete and valid and are not expected to change substantially over the 25-year licence period requested.

3) Nordion has implemented a strong radiation protection program that has ensured the protection of its employees and the public. Since the 2015 licence renewal, the highest does to an employee has been 5.5 mSv, which is substantially lower than the regulatory limit of 50 mSv/year. The dose to the public has been less than 0.01 mSv/year due to Nordion related activities. This is not expected to substantially change over the requested 25-year licence period.

4) Nordion has an environmental protection program to control the release of radioactive and other hazardous substances from the facility. The environmental risk assessment shows that Nordion's operations do not negatively impact the surrounding community or environment. Nordion's production facilities have been designed and operated in a manner to prevent radioactive waste being released to municipal garbage or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the CNSC. Air and liquid release data since the last licence renewal in 2015 have been annually provided in Nordion's Annual Compliance Report (ACR). From these ACRs, Nordion's air and liquid effluent releases have been shown to be much less than 0.1% of the derived release limit (DRL) approved by the CNSC in Nordion License Conditions Handbook. All radioactive waste generated through production operations is collected and sent to licensed radioactive waste management facilities. This is not expected to substantially change over the requested 25-year licence period.

5) Nordion has shown a consistent and excellent history of operating experience and compliance in carrying out the licensed activity. Since 2015, the CNSC has conducted 25 inspections of Nordion's operations and programs. An average of 1.8 findings were identified per inspection, with 28% (7 out of 25) of those inspections having no findings. None of the

findings were considered safety significant and Nordion implemented actions to address each finding in a timely manner.

6) Nordion is continually investing in the facility and making improvements to ensure safety systems are maintained and improved. Refer to Attachment 2 for a listing of facility modifications and program improvements since the last renewal in 2015.

Nordion's current programs have proven highly effective in ensuring the protection of people and the environment over the decades that the facility has been in operation. These effective programs will continue under the renewed licence. The issuance of a 25-year licence is justified based on Nordion's decades-long history of protecting people and the environment.

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

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

Table B.1: IMPACT of a 25-YEAR LICENSE

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

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

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

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

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

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