



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Record of Proceedings, Including Reasons for Decision

In the Matter of

Applicant **Nordion (Canada) Inc.**

Subject **Application to Renew the Nuclear Substance
Processing Facility Operating Licence for
Nordion (Canada) Inc.**

**Public Hearing
Date** **August 19, 2015**

RECORD OF PROCEEDINGS

Applicant: Nordion (Canada) Incorporated

Address/Location: 447 March Road, Ottawa ON K2K 1X8

Purpose: Application to Renew the Nuclear Substance Processing Facility
Operating Licence for Nordion (Canada) Inc.

Application received: November 6, 2014

Supplementary application
received: March 18, 2015

Date of public hearing: August 19, 2015

Location: Canadian Nuclear Safety Commission (CNSC) Public Hearing
Room, 280 Slater St., 14th. Floor, Ottawa, Ontario

Members present: M. Binder, Chair
A. Harvey D. Tolgyesi
S. McEwan R. Velshi

Secretary: M.A. Leblanc
Recording Secretary: M. Hornof
Senior General Counsel: L. Thiele

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Intervenors	Document Number
See Appendix A	

Licence: Renewed

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1.0 INTRODUCTION

1. Nordion (Canada) Incorporated (Nordion) has applied to the Canadian Nuclear Safety Commission¹ for the renewal of the Class IB Nuclear Substance Processing Facility Operating Licence (NSPFOL) for its facility located in Ottawa, Ontario. The current operating licence, NSPFOL-11A.05/2015, expires on October 31, 2015.
2. Nordion processes unsealed radioisotopes, such as iodine-131 and molybdenum-99, for medical applications and also manufactures sealed cobalt-60 sources for health and life sciences applications. Nordion's primary production facility for these licensed activities is the Kanata Operations Building which is located on a parcel of 56.8 acres in Ottawa, Ontario. The closest residence to the facility is approximately 500 metres from the site boundary. Approximately 320 people work in the Kanata Operations Building which has been in operation for close to 50 years.
3. During the current 10-year licence period, the Commission was provided an *Interim Status Report* in June 2009.² The Commission was also provided with updates on Nordion's performance in 2011, 2012 and 2013 through annual CNSC staff compliance reports. Nordion underwent several business and operational changes throughout the current licence period, including its August 2014 acquisition by Sterigenics International LLC (Sterigenics). Nordion's licence was transferred to its new corporate identity as a result of the acquisition by Sterigenics; however, Nordion continued to operate as a stand-alone company with its management, safety and compliance systems unchanged.
4. Nordion originally requested a licence renewal for a period of 20 years. In CMD 15-H7.1, Nordion clarified that it was requesting a licence period of 10 years or more and provided justification for this request. CNSC staff recommended a licence renewal for a period of 10 years based on its evaluation of Nordion's compliance history and Nordion's transition to updated standards and CNSC REGDOCs in the proposed licence period.

¹ The *Canadian Nuclear Safety Commission* is referred to as the "CNSC" when referring to the organization and its staff in general, and as the "Commission" when referring to the tribunal component.

² Minutes of the Canadian Nuclear Safety Commission (CNSC) Meeting held on June 10 and 11, 2009, CMD 09-M23, "Interim Status Report on MDS Nordion Class IB Nuclear Substance Processing Facility located in Ottawa, Ontario", e-Doc 3426325.

Issue

5. In considering the application, the Commission was required to decide, pursuant to subsection 24(4) of the *Nuclear Safety and Control Act*³ (NSCA):
 - a) if Nordion is qualified to carry on the activity that the licence would authorize; and
 - b) if, in carrying on that activity, Nordion 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.

Public Hearing

6. The Commission, in making its decision, considered information presented for a public hearing held on August 19, 2015 in Ottawa, Ontario. The public hearing was conducted in accordance with the *Canadian Nuclear Safety Commission Rules of Procedure*.⁴ During the public hearing, the Commission considered written submissions and heard oral presentations from CNSC staff (CMD 15-H7 and CMD 15-H7.A) and Nordion (CMD 15-H7.1, CMD 15-H7.1A and CMD 15-H7.1B). The Commission also considered oral and written submissions from 14 intervenors (see Appendix A for a detailed list of interventions). The hearing was webcasted live via the CNSC website and video archives are available for a three-month period following the hearing.

2.0 DECISION

7. Based on its consideration of the matter, as described in more detail in the following sections of this *Record of Proceedings*, the Commission concludes that Nordion is qualified to carry on the activity that the licence will authorize. The Commission is of the opinion that Nordion, in carrying on that activity, 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. Therefore,

the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, renews the Class IB Nuclear Substance Processing Facility Operating Licence issued to Nordion (Canada) Incorporated for its facility located in Ottawa, Ontario. The renewed licence, NSPFOL-11A.00/2025, is valid from November 1, 2015 until October 31, 2025.

³ Statutes of Canada (S.C.) 1997, chapter (c.) 9.

⁴ Statutory Orders and Regulations (SOR)/2000-211.

8. The Commission includes in the licence the conditions as recommended by CNSC staff in CMD 15-H7. The Commission also accepts the following modification to the draft licence as presented in CMD 15-H7:
 - The current “Licence Condition 14: Packaging and Transport” will be replaced with “Licence Condition 14: Safeguards and Non-Proliferation” and will read “The licensee shall implement and maintain a safeguards program.”
 - “Licence Condition 15: Packaging and Transport” will be added to the licence and will read “The licensee shall implement and maintain a packaging and transport program.”
9. The Commission notes that CNSC staff can bring any matter to the Commission as applicable. The Commission directs CNSC staff to inform the Commission on an annual basis of any changes made to the LCH.
10. The Commission accepts the revised financial guarantee amount and instruments as presented in CMD 15-H7.1 and CMD 15-H7.1A.
11. With this decision, the Commission directs CNSC staff to provide annual reports on the performance of Nordion, as part of the *Annual Regulatory Oversight Report on Uranium and Nuclear Substance Processing Facilities in Canada*. CNSC staff shall present these reports at public proceedings of the Commission, where requests to intervene from members of the public can be filed.

3.0 ISSUES AND COMMISSION FINDINGS

12. In making its licensing decision, the Commission considered a number of issues relating to Nordion’s qualification to carry out the proposed activities and the adequacy of the proposed measures for protecting the environment, the health and safety of persons, national security and international obligations to which Canada has agreed.

3.1 Management System

13. The Commission examined Nordion’s Management System which covers the framework that establishes the processes and programs required to ensure that the facility achieves its safety objectives and continuously monitors its performance against these objectives, and fosters a healthy safety culture. CNSC staff rated Nordion’s performance in this SCA as “satisfactory” throughout the current licence period.

14. Nordion reported that it had an Environmental, Health and Safety (EHS) Policy which described the company's commitment to operate in a safe and responsible manner and was the foundation of Nordion's environmental, health and safety systems. Nordion further stated that the EHS Policy was supported by a comprehensive document management system that provided the basis of its programs and procedures. Nordion also noted that it used Operating Experience (OPEX) to evaluate in-house and external experience related to Nordion's licensed activities. More information on Nordion's OPEX is available in section 3.3.3.
15. Nordion stated that it now had 50 percent more operational controls to support its management system than it had in 2005 and that these operational controls ensured the regulatory compliance of all of Nordion's processes and procedures.
16. Nordion noted that, following its gap analysis for the transition to CSA N286-12,⁵ CNSC staff had identified several areas where Nordion needed to modify its Quality Assurance (QA) Program for Safety. CNSC staff stated that it had accepted Nordion's transition plan to meet the updated requirements of N286-12 by October 31, 2016 and that the transition plan was included in the proposed LCH as compliance verification criteria related to proposed licence condition 2.1.

3.1.1 Quality Management

17. Nordion reported that its QA Program for Safety and its Environmental Management System (EMS) provided the means of controlling the activities that affected the safety of CNSC-licensed activities. Nordion stated that its EHS Committee conducted annual performance reviews of the QA Program and that, in general, Nordion had met, and in many cases exceeded, the established EHS objectives and targets.
18. Nordion also explained that EHS compliance audits were conducted by a third party every three years, at a minimum, to measure performance against EHS requirements, with the last audit conducted in September 2013. Nordion noted that the scope of performance reviews of the QA Program for Safety and the EMS were proactively expanded during the current licence period. The EHS Committee reviews the EHS Performance Report annually, and also reviews Nordion's EHS performance regularly at EHS Committee meetings. Nordion further noted that it had revised the QA Program for Safety throughout the licence period to address CNSC expectations.
19. CNSC staff reported that, in 2015, it had completed a review of Nordion's assessment programs and identified some areas for improvement. Since that inspection, Nordion had submitted, and CNSC staff had accepted, a corrective action plan. CNSC staff stated that, based on its review of Nordion's overall management system, and the verification of Nordion's QA Program through compliance inspections and desktop reviews, it was of the opinion that Nordion had satisfactorily maintained its QA Program and its implementation over the current licence period.

⁵ N286-12: Management system requirements for nuclear power plants, CSA Group, 2012.

20. The Commission requested additional information about findings and enforcement actions resulting from CNSC QA Program inspections. CNSC staff informed the Commission that all findings had been or are currently being addressed satisfactorily; that none of the enforcement actions presented an impediment to licensing; and that many actions were administrative in nature and related to documentation deficiencies. CNSC staff further noted that it anticipated closing these actions in the near future. The explanation satisfies the Commission on this point.

3.1.2 Organization

21. Nordion reported that, during the current licence period, it had divested itself of four significant product lines to focus on the Gamma Technologies and Medical Isotopes businesses. Nordion further reported on the corporate functions of these two businesses and noted that both businesses operated under the direction of the EHS Committee, which reviewed the operations and approved changes to the facility. Nordion also explained that the EHS Committee regularly reviewed the occupational health and safety, radiation safety and environmental management performance metrics. CNSC staff noted that, through compliance inspections and reviews of Nordion's reports and submissions, it found Nordion's performance in this area satisfactory.
22. Nordion stated that it had recently added a new management position responsible for Transportation Licensing, Import/Export and Gamma Radiation Safety in the EHS Compliance Department. Nordion noted that this change would allow Nordion to better meet CNSC, US Nuclear Regulatory Commission (NRC) and other international regulatory requirements.
23. Nordion explained that it had an established change control process as part of the QA Program, with the EHS Committee responsible for approving all significant changes to processing facilities. Furthermore, Nordion's design control program ensured that the designs met established codes and standards, as well as all applicable requirements. Nordion also stated that, during this licence period, Nordion proactively improved its Change Management process through revisions to its EHS Potential Hazard Checklist and the addition of an EHS Requirements Checklist. CNSC staff confirmed that Nordion had an acceptable change and design control program.
24. The Commission noted that the relationships between the committees within Nordion's Management System were not clear and suggested that Nordion use an organizational chart to clarify these relationships. The Commission also enquired about whether Nordion's staff had the opportunity to participate in the committees. A Nordion representative provided the Commission with additional information about its committees and confirmed to the Commission's satisfaction that employees were involved in many committees alongside Nordion management.
25. The Commission requested additional information about Nordion's parent company, Sterigenics. The Nordion representative responded that Sterigenics operated

approximately 40 medical device sterilization facilities worldwide and that Nordion was a distinct business within Sterigenics, operated independently from its parent company.

3.1.3 Facility Management

26. Nordion reported that it had a mature process in place for the management of licensing records and that, during the current licence period, it had implemented a number of improvements to its processes, including a new Electronic Quality Management System in 2012. CNSC staff confirmed that Nordion had satisfactory procedures in place for records management.
27. The Commission enquired about regulatory approvals, other than CNSC licensing, that were required by Nordion to conduct its business. The Nordion representative responded that Nordion was highly regulated and provided examples of both national and international health, radiological and industrial regulations that applied to its operations.

3.1.4 Safety Culture

28. Nordion reported that it had a strong safety culture that was supported by its programs, standards, procedures and a near-miss reporting program. Nordion stated that two Safety Culture Surveys were conducted during the current licence period with excellent participation and results from its staff. Nordion noted that it planned to assess the health of its safety culture every three years and would continue to ensure that safety culture remained a strong component of the overall Nordion workplace culture.
29. CNSC staff reported that it had assessed Nordion's programs and processes under the Management System SCA and was of the opinion that Nordion's performance was satisfactory.

3.1.5 Conclusion on Management System

30. Based on its consideration of the information presented, the Commission concludes that Nordion has appropriate organization and management structures in place and that the operating performance at the facility in the current licence period provides a positive indication of Nordion's ability to adequately carry out the activities under the proposed renewed licence.

3.2 Human Performance Management

31. Human performance management encompasses activities that enable effective human performance through the development and implementation of processes that ensure licensee staff is sufficient in number in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.
32. CNSC staff found that, during the current licence period, Nordion continued to maintain and implement acceptable training programs addressing all relevant areas of its operations. Through periodic routine compliance inspections and reviews of Nordion's annual reports, CNSC staff verified Nordion's adherence to its training plan and the maintenance of training records. CNSC staff reported that Nordion's current training programs and Nordion's progress toward meeting the updated specifications of CNSC REGDOC-2.2.2, *Personnel Training*⁶ were satisfactory. CNSC staff rated this SCA as "satisfactory" throughout the current licence period. In the next licence period, CNSC staff will continue to monitor Nordion's performance through inspections and documentation reviews.

3.2.1 Personnel Training

33. Nordion provided information about its Compliance Environment, Health and Radiation Safety Training Program and noted that it had training programs for Nuclear Energy Workers (NEWs), for workers not classified as NEWs, as well as for contractors. Nordion noted that it ensured that personnel is given the appropriate training and instruction for the tasks assigned and that training programs, as well as the competency of personnel, are monitored and assessed regularly.
34. Nordion explained that an internal indicator for the human performance SCA is the number and significance of corrective actions related to training. In the past five years, the percentage of EHS corrective actions related to training had significantly decreased from 17% in 2010 to 3% in 2014. Additionally, in 2013, there were no corrective actions related to training.
35. Nordion reported on several improvements that were made to its training programs during the current licence period and stated that, in 2013, it initiated the implementation of a Systematic Approach to Training (SAT)-based program and the revision of its training systems in order to meet the specifications of REGDOC-2.2.2. Nordion added that several milestones of the transition to this program had been reached. CNSC staff noted that the SAT-based training system and the implementation of REGDOC-2.2.2 were progressing on schedule with full implementation planned by December 31, 2016.
36. The Commission requested additional information about testing requirements for Nordion employees. The Nordion representative responded that, although the amount

⁶ CNSC Regulatory Document REGDOC-2.2.2, "Personnel Training", 2014.

of recorded testing is increasing, the principal test that Nordion administered was the Nuclear Energy Worker test and that successful completion of the test was a condition of employment. The Nordion representative added that an employee had two chances to successfully complete the Nuclear Energy Worker test, with mandatory re-testing every three years.

3.2.2 Conclusion on Human Performance Management

37. Based on its consideration of the presented information, the Commission concludes that Nordion has appropriate programs in place and that current efforts related to human performance management provide a positive indication of Nordion's ability to adequately carry out the activities under the proposed licence.

3.3 Operating Performance

38. Operating performance includes an overall review of the conduct of the licensed activities and the activities that enable effective performance as well as improvement plans and significant future activities at Nordion's facility. Throughout the current licence period, CNSC staff rated Nordion's performance in this SCA as "satisfactory".

3.3.1 Conduct of Licensed Activity

39. Nordion reported that, during the current licence period, there were no high risk unplanned events and no major facility or transport non-conformances. CNSC staff confirmed that the operation of Nordion's facility remained within the licensing basis that included the safety analysis.
40. Nordion reported that work undertaken at its facility was planned, controlled and documented in Final Safety Analysis Reports (FSARs). Nordion also stated that FSARs were reviewed and approved on an established review schedule and that CNSC approval was required for the Nuclear Medicine Production Facility and Cobalt Operations Facility FSARs. More information on FSARs is available in Section 3.4.
41. CNSC staff stated that Nordion's renewal application included the in-house servicing of various radiation devices and that, after the evaluation of the required information in Nordion's application, CNSC staff was of the opinion that Nordion had adequate measures in place to carry out this activity.
42. CNSC staff reported that, during the current licence period, the adequacy of Nordion's programs related to the conduct of the licensed activities was assessed through routine compliance inspections and desktop reviews. CNSC staff determined that Nordion continued to operate the facility in a safe and compliant manner and that Nordion adhered to its own procedures.

3.3.2 Reporting and Trending

43. Nordion reported that incidents and non-conformances were identified through non-conformance procedures, investigations and internal audits. As part of its QA Program for Safety, Nordion conducted annual internal audits to verify compliance with applicable procedures and requirements. Nordion also noted that the EHS Committee annually reviewed the EHS Performance Report, which analyzed non-conformance data from the three previous years to determine the presence of undesirable trends, the effectiveness of corrective actions taken and whether additional corrective actions were needed. CNSC staff confirmed that it had reviewed Nordion's EHS Performance Reports and that Nordion was completing actions as required.
44. Nordion reported that a trend in incidents related to Sealed Source Tracking System (SSTS) reporting during import and export was identified from 2011 to 2013, but was mitigated through an in-depth review and the implementation of improvements in the sealed source reporting process. CNSC staff stated that the additional measures implemented by Nordion as a result of its 2014 SSTS review were satisfactory. CNSC staff informed the Commission that, in the next licence period, it would continue to monitor Nordion's compliance with respect to the timely reporting of sealed source movements and to ensure that Nordion's improvements to the SSTS were effective.
45. CNSC staff stated that, in April 2015, Nordion reported to the CNSC that it had not been maintaining up-to-date inventory records for transport packages constructed with depleted uranium for shielding, as required by its licence. CNSC staff reported that Nordion conducted an investigation into its inventory records and identified a number of corrective actions. CNSC staff stated that it would follow up on these actions with additional compliance efforts.

3.3.3 Operating Experience

46. Nordion explained that it had a Corrective Action and Preventive Action (CAPA) process to investigate and identify the root cause of environmental and safety-related issues, to implement and track corrective actions, and to proactively initiate preventive measures. Nordion noted that it had faced challenges with the timely completion of CAPAs, but that it had successfully implemented several improvement strategies and that, in 2014, less than 15% of the CAPAs (the established target) were considered overdue or late, compared with 63% in 2011. Nordion reported that it was investigating the use of an issues management module within the Electronic Quality Management System for CAPAs to improve how CAPAs were managed and to ensure their timely completion. CNSC staff reported that Nordion's CAPA process met CNSC regulatory expectations.

3.3.4 Conclusion on Operating Performance

47. Based on the above information, the Commission concludes that the operating performance at the facility during the current licence period provides a positive indication of Nordion's ability to carry out the activities under the proposed licence.

3.4 Safety Analysis

48. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or the operation of a facility, and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards. It supports the overall safety case for the facility. During the current licence period, CNSC staff rated Nordion's performance in this SCA as "satisfactory".
49. Nordion reported that the safety case for the overall facility was maintained in the Nuclear Medicine Production Facility and Cobalt Operations Facility FSARs and described the Nordion facility operations, potential hazards, worst case accident scenarios and the measures in place to mitigate the consequences of the hazards. Nordion noted that revisions to the primary FSARs were reviewed internally by the EHS Committee and submitted to CNSC staff for final approval.
50. Nordion further reported that secondary FSARs were prepared for each individual production process to provide analyses of the safety hazards unique to those areas and that those secondary FSARs were approved by the EHS Committee. Nordion noted that, during the current licence period, the EHS Committee reviewed the FSARs for several of its processing areas and that, as a result of the reviews, several changes and additional training were implemented to further mitigate the possibility of hazards. Nordion also implemented a Post-Disaster Checklist to verify the safety and operability of the overall facility in the event of a disaster. Nordion reported that, during the next licence period, it planned to revise the safety analysis process to adopt a more systematic approach to the review of hazards.
51. CNSC staff noted that Nordion's procedures required that FSARs be reviewed, at a minimum, every five years. Nordion noted that, since there was a significant effort required in maintaining FSARs, it engaged a third-party contractor to perform several FSAR reviews during the current licence period. CNSC staff confirmed that it had reviewed Nordion's safety analysis documentation, that it met CNSC requirements, and that the overall facility was operating safely. In the next licence period, CNSC staff will continue to monitor Nordion's performance in this area through documentation reviews.

3.4.1 Hazard Analysis

52. Nordion reported that it had completed an NFPA 801:2003⁷ compliant Fire Hazard Analysis in 2009, which was accepted by CNSC staff. Nordion further noted that any changes to its overall facility that could affect fire protection systems were reviewed by a qualified third party and submitted to the CNSC. CNSC staff confirmed that it had accepted Nordion's Fire Hazard Analysis in 2009 and that it is still valid.
53. Nordion stated that, on an annual basis, Nordion's fire protection system underwent a third-party compliance review and that the results were submitted to the CNSC. Nordion reported that minor deviations were noted during the reviews and that corrective actions to address them had been completed. CNSC staff confirmed that it was satisfied with the corrective actions taken by Nordion.
54. Nordion noted that, during the current licence period, it expanded its seismic review process with additional equipment being identified for seismic evaluation and by ensuring that seismic qualification was conducted as part of the safety analysis process. To evaluate the seismic qualification of all office and production equipment on the site, Nordion had a tool developed by a qualified subject matter expert.
55. CNSC staff reported that, after the Fukushima Daiichi accident, CNSC staff directed all Class I licensees, including Nordion, to review their safety case and lessons learned from the event. CNSC staff stated that Nordion re-examined its safety case as it related to seismic evaluations, loss of electrical power, fire protection, flooding, extreme weather and emergency preparedness and, as a result, identified additional enhancements to improve the overall facility. As reported to the Commission in CMD 12-M56,⁸ all actions resulting from Nordion's review were completed before the end of 2012.

3.4.2 Conclusion on Safety Analysis

56. On the basis of the information presented, the Commission concludes that the systematic evaluation of the potential hazards and the preparedness for reducing the effects of such hazards is adequate for the operation of the facility and the activities under the proposed licence.

⁷ National Fire Protection Association NFPA 801: *Standard for Fire Protection for Facilities Handling Radioactive Materials*, 2003 Edition.

⁸ CMD 12-M56, "Commission Request for Information, Status Update on the CNSC Action Plan: Lessons Learned from the Fukushima Accident", October 25, 2012, e-Doc 4013625.

3.5 Physical Design

57. Physical design includes activities to design the systems, structures and components to meet and maintain the design basis of the facility. The design basis is the range of conditions, according to established criteria, that the facility must withstand without exceeding authorized limits for the planned operation of safety systems. The specific areas that comprise physical design are design governance and facility design. Throughout the current licence period, CNSC staff rated this SCA as “satisfactory”.
58. Nordion reported that its Change Control Procedure applied to changes to the designs of existing processing areas, buildings and systems and that the EHS Committee was responsible for approving significant changes to processing areas which could alter conclusions regarding the safety of a facility as established in the approved FSARs. Nordion also noted that it had a procedure in place to ensure that any newly purchased equipment and instrumentation was identified to the Facilities Department, and would be added to the inventory and to the Advanced Maintenance Management System (AMMS).
59. Nordion presented a number of changes that were made to its overall facility during the current licence period, including enhancements to ventilation, security, fire protection and radiation protection. Nordion reported that improvements to its physical design were also enhanced by conducting a Tier 1 seismic assessment of the building in accordance with ASCE/SEI 31-03, “*Seismic Evaluation of Existing Buildings*”.⁹ Nordion further noted that, in the next licence period, it planned to have a Tier 2 seismic assessment of the facility conducted to ensure that the facility maintained its integrity in case of a seismic event.
60. Nordion reported that, in 2008, its licence was amended to include Room 1119 in the Kanata Operations Building as part of the nuclear facility.¹⁰ This was the only change to the licensed facility boundary during the current licence period. Nordion also noted that, in 2014, the classification of Room 1308 within the licensed facility boundary was changed from a Radiation Area to an Active Area to address the concern of migration of a fire from an inactive to an Active Area and in order to meet the requirements of the *National Building Code*, the *National Fire Code* and the *National Fire Protection Association* standards. This reclassification did not require a licence amendment.
61. CNSC staff reported that, in February 2011, a CNSC inspection was conducted to review Nordion’s design and change control processes. Although the inspection found that Nordion used the appropriate change control procedures, some areas for improvement in record-keeping were noted. CNSC staff explained to the Commission that it was satisfied with Nordion’s response to the inspection and that appropriate improvements to the change control process had been made. Furthermore, CNSC staff

⁹ American Society of Civil Engineers ASCE/SEI 31-03, “*Seismic Evaluation of Existing Buildings*”, 2002.

¹⁰ CNSC Record of Proceedings, Including Reasons for Decision – MDS Nordion, “Application to Amend the Nuclear Substance Processing Facility Licence for the MDS Nordion Facility in Kanata, Ontario”, October 31, 2008, e-Doc 3305250.

is of the opinion that Nordion's documented process for design and change control meets regulatory expectations.

3.5.1 Conclusion on Physical Design

62. On the basis of the information presented, the Commission concludes that the design of the Nordion's facility is adequate for the operation period included in the proposed licence.

3.6 Fitness for Service

63. Fitness for service covers activities that are performed to ensure the systems, components and structures at the Nordion facility continue to effectively fulfill their intended purpose. The specific areas that comprise fitness for service at the Nordion facility include equipment fitness for service, equipment performance and maintenance. Throughout the licence period, CNSC staff rated Nordion's performance in this SCA as "satisfactory".

3.6.1 Equipment Fitness for Service / Equipment Performance

64. Nordion reported that a detailed review regarding aging equipment was conducted on an annual basis and that this review took into account the safety of the overall facility, regulatory requirements, and site improvements. Nordion also presented the facility improvement projects that were identified during the current licence period to ensure that the overall facility remained up to date.
65. Nordion explained that unscheduled repairs were reviewed and assessed on an annual basis for trends in equipment failures. Recurring failures were reviewed annually by EHS Compliance for the identification of any additional corrective measures that could be implemented.
66. Nordion reported that, during the current licence period, equipment was available to perform its design function and that, in general, there were no observed trends related to equipment performance, with three exceptions. Nordion presented information on these equipment failures and noted that they did not result in critical safety situations.
67. CNSC staff confirmed that there were no major equipment failures reported during the licence period. Furthermore, CNSC compliance inspections, as well as annual compliance reports, confirmed that Nordion continued to maintain the facility to ensure that its structures, systems and components remained fit for service over time.

3.6.2 Maintenance

68. Nordion explained that it used the Advanced Maintenance Management System (AMMS) to control Nordion's calibration and maintenance activities, while providing the necessary oversight to ensure equipment integrity. Nordion also noted that all equipment inspections and preventive maintenance schedules were managed by the AMMS, that the management structure of its Preventive Maintenance Program had not changed significantly during the current licence period and that, in the next licence period, it would continue to use the AMMS to schedule Nordion's maintenance activities.
69. CNSC staff stated that, throughout the current licence period, Nordion's maintenance program was regularly reviewed through CNSC compliance inspections and that the most recent inspection in 2013 showed that Nordion had implemented an effective maintenance program that included the required maintenance and calibration records.

3.6.3 Conclusion on Fitness for Service

70. The Commission is satisfied with Nordion's programs for the inspection and life-cycle management of key safety systems. Based on the above information, the Commission concludes that the equipment as installed at Nordion is fit for service.

3.7 Radiation Protection

71. As part of its evaluation of the adequacy of the licensee's measures for protecting the health and safety of persons, the Commission considered the past performance of Nordion in the area of radiation protection. The Commission also considered the radiation program at the facility to ensure that both radiation doses to persons and contamination are monitored, controlled and kept as low as reasonably achievable (ALARA), with social and economic factors taken into consideration. During the current licence period, CNSC staff rated Nordion's performance in this SCA as "satisfactory".

3.7.1 Radiation Protection Program

72. Nordion reported that it had a Radiation Protection Program in place to keep radiation doses received by workers and members of the public ALARA and that the EHS Committee provided oversight of the Radiation Protection Program. Nordion also noted that it maintained the external exposure of NEWs to a minimum and within safe limits through an intensive program of routine radiation surveys and the Active Area contamination control program, which employed routine sampling and monitoring through wipe testing and direct measurement. Nordion specified that, should a contamination incident occur, it would be investigated with mitigating measures and

corrective actions applied. Nordion also reported on personnel qualifications, training and work procedures that took into account both existing and potential radiological hazards.

73. Nordion stated that it had developed approved activity limits for hot cells, glove-boxes and fume-hoods to control external radiation exposure. Nordion also detailed the key improvements that had been made to its Radiation Protection Program throughout the current licence period.
74. As part of its Radiation Protection Program, and in addition to its dosimetry program, Nordion explained that it conducted routine thyroid measurements for personnel with a reasonable potential for exposure to radioiodines. Nordion noted that, in the case of a potential internal dose of other radionuclides, urine analysis and whole body counting may be performed.
75. The Commission requested more details about Nordion's thyroid bioassay program. The Nordion representative responded that, depending on an employee's work description, a thyroid bioassay was conducted weekly or biweekly. The Nordion representative added that, in the last year, Nordion had implemented a target of 90% compliance for thyroid bioassay attendance frequency, and that this frequency was reported on monthly.
76. Nordion reported that dosimetry data was routinely reviewed by the EHS Compliance Committee to ensure that doses at administrative and action levels were quickly identified. CNSC staff also reported that Nordion undertook a complete review of its action levels at the beginning of 2015 and that these action levels were currently being reviewed by CNSC staff for eventual incorporation into Nordion's LCH.
77. CNSC staff stated that Nordion's ALARA program complied with CNSC requirements and that radiological hazards were controlled adequately. Furthermore, through compliance activities, CNSC staff determined that Nordion has an effective system in place to investigate radiation protection incidents, implement corrective actions and avoid reoccurrences.

3.7.2 Workers' Radiation Exposure

78. Nordion reported that all employees who regularly worked in the Active Area were classified as NEWs and assigned monthly dosimeters. Nordion also explained that contractors who were given access to the Active Area were identified as "Contractor NEWs" and trained as NEWs, but were subject to the regulatory dose limits of non-NEWs (1 mSv/year) and were also not permitted to handle radioactive material. Nordion noted that, during the current licence period, Nordion used thermoluminescent dosimeters (TLDs) for ring dosimeters, but switched from TLDs to optically stimulated luminescent dosimeters for body dosimeters in 2006. Nordion also improved its TLD storage practices during the current licence period to minimize non-personal doses.

79. Nordion stated that, during the current licence period, several improvements to worker radiation safety were made including reducing radiation dose rates by using additional shielding, replacing radiation monitoring equipment, replacing hand and foot monitors with whole-body contamination monitors, and installing additional airflow samplers at release monitoring points.
80. Nordion reported that the average doses to Nordion Active Area NEWs steadily declined over the current licence period, in part due to the decreased production in Medical Isotopes. During the current licence period, the maximum effective dose received by a NEW was 7.8 mSv and the average dose in the past six years was between 0.6 mSv to 0.7 mSv. Nordion explained that shippers of cobalt-60 packages typically received the highest effective dose and that this dose had decreased due to improved dose management practices, including the installation of additional concrete shielding in the facility and innovative temporary cobalt shipping container shields. CNSC staff confirmed that, during the current licence period, Nordion consistently maintained NEW doses below action levels and regulatory limits (50 mSv/year), and improved its dose management practices.
81. Nordion further reported that the maximum extremity dose recorded for both Active Area and Non-Active Area NEWs during the licence period was 18.0 mSv in 2010 and that it had been, in general, declining since then. Nordion also noted that the average extremity dose during the current licence period was between 0.7 mSv and 1.9 mSv. CNSC staff confirmed that extremity doses to workers at Nordion were being controlled and were well below the regulatory limits of 500 mSv/year and maintained ALARA.
82. Nordion informed the Commission that, in 2006 and 2007, two cases of employees exceeding Nordion's internal dose administrative level of 1,000 Bq¹¹ of iodine-125 or iodine-131 were discovered. Nordion stated that corrective actions were taken, that no dose limits were exceeded and that, for the remaining years during the current licence period, there were no cases of employees exceeding 1,000 Bq or the reportable limit of 10,000 Bq of iodine-125 or iodine-131. CNSC staff confirmed the information provided by Nordion.
83. Nordion stated that, although the regulatory dose limit for contractor NEWs was 1 mSv/year, there were two instances during the current licence period, in 2005 and 2006, when maximum doses of 1.00 mSv and 1.46 mSv were recorded. One dose of 0.88 mSv, which was above the 0.75 mSv/year action level, was also recorded. Nordion explained that these doses were reported to the CNSC, investigated, and found to be non-personal. Nordion further noted that, in recent years, contractor doses had been showing an overall downward trend and had been below the regulatory dose limit. CNSC staff confirmed that the contractor doses in 2005 and 2006 were non-personal in nature and that appropriate corrective actions had been applied to correct problems related to the management of contractor dosimeters. CNSC staff further noted that, since 2008, contractor doses had stabilized, were well below the regulatory limits and

¹¹ The becquerel (Bq) is the SI unit of radioactivity, equal to one transformation (decay) per second.

were maintained ALARA.

84. The Commission requested more information on how Nordion improved its management of contractor dosimeters. CNSC staff responded that Nordion had taken a number of corrective actions in this regard, including the review of all contractor doses back to the late 1990s, the documentation of processes required for the management of contractor dosimeters, and ensuring that contractor dosimeters were returned with a control badge.
85. Nordion reported that, during the current licence period, there were ten Radiation Incident Reports and several ALARA reports. Nordion noted that these incidents were primarily due to TLDs being returned late and processed without control dosimeters, as well as problems with dose control in the iridium-192 facility. Nordion presented the corrective actions that were taken following the events and noted that, throughout the licence period, it had met the established EHS targets for radiation incidents and that, in general, there was a decline in the number of contamination incidents from 2005 to 2014. CNSC staff reported that, during the current licence period, it had evaluated worker dose control through compliance activities and is of the opinion that worker doses were controlled well below regulatory dose limits and ALARA.
86. The Commission noted that the contamination data presented by Nordion did not report separately on the Medical Isotopes and Gamma Technologies business operations and that, as such, it was difficult to determine how the individual business operations were performing. The Nordion representative responded that, since Nordion had a single Radiation Protection Program, the two business operations were reported on jointly. The Commission noted that not having separate contamination data for each business operation could lead to overlooking a serious problem with radiation protection for one of them. The Nordion representative explained to the Commission that Nordion used a defence-in-depth approach with respect to contamination control but agreed that such a breakdown of contamination incidents for each business operation could be presented in the future. CNSC staff added that it had reviewed Nordion's contamination control program and reports in great detail and was satisfied that contamination control in both business operations was adequate.

3.7.3 Public Radiation Exposure

87. Nordion stated that calculations made using the monitoring of air emissions showed that, during the current licence period, the estimated dose to the public ranged between 0.006 mSv/year and 0.042 mSv/year, well below the regulatory dose limit of 1.0 mSv/year. Nordion also noted that the doses to the public for 2005 and 2006 were estimated based on molybdenum-99 production levels because Nordion only began monitoring air emission of carbon-14, xenon-135 and xenon-135m in 2007.

88. CNSC staff reported that, based on the review of dose data, it was satisfied that Nordion was controlling radiation doses to members of the public to levels well below regulatory limits.

3.7.4 Conclusion on Radiation Protection

89. The Commission is of the opinion that, given the mitigation measures and safety programs that are in place or will be in place to control radiation hazards, Nordion provides adequate protection to the health and safety of persons and the environment.

3.8 Conventional Health and Safety

90. Conventional health and safety covers the implementation of a program to manage workplace safety hazards. This program is mandatory for all employers and employees in order to reduce the risks associated with conventional (non-radiological) hazards in the workplace. This program includes compliance with Part II of the *Canada Labour Code*¹² and conventional safety training. CNSC staff reported that it had rated Nordion's performance in this SCA as "satisfactory" from 2005 to 2010 and in 2014, and as "fully satisfactory" from 2011 to 2013. CNSC staff noted that a key performance measure for this SCA was the number of lost-time injuries (LTIs) and that the increased LTIs in 2014 indicated a need for improvement.
91. Nordion reported that it had an established Occupational Health and Safety Program to prevent, manage and respond to potential or actual hazards or emergencies in the workplace, and information about program oversight by staff, as well as by senior management, was provided. Nordion also stated that the overall performance of the Occupational Health and Safety Program was reviewed annually. Nordion has a program in place to capture potential accidents through near-miss reporting and noted that, in general, its Workplace Health and Safety Committee met monthly.
92. Nordion reported on several major improvements that it had implemented in its Occupational Health and Safety Program. Nordion also stated that, during the next licence period, it planned to implement a self-assessed Health and Safety Management System compliant with the upcoming ISO 45001¹³ standard. Although Nordion did not plan to register its program with ISO, the standard would be used for continuous improvement and guidance.
93. Nordion stated that, from 2006 to 2008, the incident rate at the facility was above the EHS targets. As such, improvements were made to ergonomics, the handling of materials and training. Nordion noted that, although for all other years during the current licence period it had met the established EHS targets, it strived to continuously

¹² R.S.C., 1985, c. L-2.

¹³ ISO 45001: *Occupational health and safety management systems – Requirements* (unpublished), International Organization for Standardization, project publication date 2016.

improve these areas.

94. CNSC staff reported that, due to an increase in the incident rates and LTI rates in 2014, Nordion's performance for this SCA was downgraded from "fully satisfactory" to "satisfactory" for that year. Nordion acknowledged this increase in incidents and LTIs, and stated that the majority of the incidents were related to back injuries and/or ergonomics. As such, Nordion implemented various corrective strategies, including Back Safety Awareness Training, as well as increased focus on ergonomic assessments and related training. CNSC staff stated that it found the actions taken by Nordion to be acceptable. CNSC staff further reported that the compliance verification activities conducted at the facility and the corrective actions taken by Nordion confirmed that Nordion had implemented an effective occupational health and safety management program. In the next licence period, CNSC staff will continue to monitor Nordion's performance in this SCA through routine CNSC inspections and documentation reviews.
95. The Commission enquired about the 16 LTIs reported for the current licence period and requested confirmation that Nordion recognized that improvement was required in this SCA. The Commission also noted that Nordion's benchmarking and comparisons for environmental health and safety could be improved. The Nordion representative responded that Nordion's goal was to have zero LTIs and that, through the benchmarking that Nordion performed, it continuously strived to be a leader in health and safety. The Nordion representative explained various strategies that Nordion had adopted to encourage a strong safety culture and emphasized that it was a top priority for the company.
96. The Commission enquired about whether Nordion reported on incidents involving contractors. The Nordion representative responded that any incidents involving contractors were reflected in Nordion's health and safety data.
97. Nordion noted that, in 2013, it was awarded the gold level award as "Canada's Safest Employer" in the manufacturing division by a Canadian occupational safety magazine. The Commission requested additional information about the award. The Nordion representative responded that approximately 180 companies submitted applications for the award and that the application included several years-worth of Nordion's health and safety data, a review of its programs, its past safety culture surveys and an employee survey by Thomson Reuters.
98. Based on the information presented, the Commission is of the opinion that the health and safety of workers and the public was adequately protected during the operation of the facility for the current licence period, and that the health and safety of persons will also be adequately protected during the continued operation of the facility.

3.9 Environmental Protection

99. Environmental Protection covers Nordion's programs that identify, control and monitor all releases of radioactive and hazardous substances, and that aim to minimize the effects on the environment which may result from the licensed activities. It includes effluent and emissions control, environmental monitoring and estimated doses to the public. CNSC staff rated Nordion's performance in this SCA as "satisfactory" from 2005 to 2010 and as "fully satisfactory" from 2011 to 2014.
100. Nordion reported that it had an established Environmental Protection Program and that the Director, QA EHS Compliance had overall responsibility for this Program. Nordion also provided information on eleven environmental incidents that had occurred during the licence period and noted that appropriate notification and corrective actions were carried out.
101. CNSC staff reported that, for this licence renewal application, CNSC staff conducted an environmental assessment (EA) under the NSCA to determine whether Nordion had and would continue to make adequate provision for the protection of the environment and the health of persons. The results of this EA were documented in the *Environmental Assessment Information Report: Nordion (Canada) Inc.* (EA Report), appended to CMD 15-H7, and were based on information submitted by Nordion and reviews completed by CNSC staff.
102. CNSC staff reported that, through the verification of licensee reports, submissions and compliance inspections, it is of the opinion that the Environmental Protection Program at Nordion meets all applicable regulatory requirements.

3.9.1 Effluent and Emissions Control

103. Nordion reported that limits for radioactive emissions were established by the Derived Release Limit¹⁴ (DRL) for each major radioisotope processed in the facility, which takes into account the critical pathway analyses and the most probable location of highest radiation exposure. CNSC staff reported that Nordion was currently compliant with DRLs. CNSC staff also noted that, since the publication of CSA N288.1-08¹⁵ in 2008, Nordion had revised its DRLs to align with the updated standard. CNSC staff noted that it was reviewing Nordion's updated DRL document and that, when it was accepted by CNSC staff, the updated DRLs would be included in Nordion's LCH.
104. CNSC staff explained that, while the DRL was a licence limit, it was not a target for licensees and that action levels below the DRLs were considered to be important limits,

¹⁴ The DRL for a given radionuclide is the release rate that would result in an annual committed effective radiation dose of 1 mSv to the most exposed group of the public (also known as the critical receptor) for that nuclear substance.

¹⁵ N288.1-08: Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities, CSA Group, 2008.

as well. The Nordion representative noted that Nordion's goal was to maintain releases ALARA and well below the DRL.

Air Emissions

105. Nordion reported that, during the current licence period, it had met all of the established EHS targets for airborne releases and that the airborne emissions within the licence period were less than 4.1% of the DRL. Nordion stated that all production operations were contained within cells, glove-boxes and/or fume-hoods with ventilated air from these containment systems filtered through HEPA and charcoal filters. Nordion also reported that the nuclear ventilation system was designed to prevent the unnecessary release of radioisotopes and other hazardous materials to the atmosphere.
106. Nordion stated that it had been reporting carbon-14, xenon-135 and xenon-135m air emissions in annual reports since 2007. Nordion noted that measurement of carbon-14 was discontinued in 2012 since its production stopped in 2008. CNSC staff reported that, even with the addition of the three new radionuclides, no action levels with respect to air emissions were exceeded during the current licence period. In the EA Report, CNSC staff further stated that emissions continued to be effectively controlled and were consistently well below the DRLs in Nordion's licence.
107. Nordion stated that, in 2010, an Emissions Summary and Dispersion Modeling report was completed to assess non-radiological air emissions. This was updated in 2013, as required by Nordion's Certificate of Approval (Air) from the Ontario Ministry of the Environment. Nordion noted that it remained compliant with the Certificate of Approval requirements during the current licence period.
108. The Commission enquired about why there appeared to be an increase in air emissions between 2011 and 2014. The Nordion representative responded that, in 2009 and 2010, supply issues lead to a decrease in production and therefore a decrease in air emissions. When production increased, air emissions increased accordingly; however, the Nordion representative noted that, presently, airborne releases were lower than those prior to 2009.

Liquid Effluent

109. Nordion reported that, during the current licence period, liquid effluent releases were less than 0.008% of the DRL. Nordion explained that waste water that could contain radioactive contamination was collected in holding tanks and analyzed to ensure compliance with licence conditions prior to its release to the municipal sanitary sewer.
110. Nordion stated that, in 2010, increased volumes of water were released from the facility due to a fresh water leak from an autoclave associated with non-active component preparation; however, no radioactivity was detected in the facility effluent

during that year.

111. In the EA Report, CNSC staff confirmed that liquid effluent from Nordion continued to be effectively controlled and that releases were consistently well below the release limits prescribed in Nordion's operating licence, with no action levels exceeded during the current licence period.

3.9.2 Environmental Management System

112. Nordion noted that its EMS was certified under ISO 14001¹⁶ since 2006, that Nordion successfully completed a re-certification audit in May 2015 and that the program was regularly audited by a third party to confirm conformance with the standard. CNSC staff stated that, as part of its compliance verification activities, it reviewed the results of annual EMS reviews and followed up with Nordion on any outstanding items of concern.
113. Nordion stated that, in the next licence period, it planned to align with applicable environmental standards including CSA N288.4,¹⁷ CSA N288.5¹⁸ and CSA N288.6.¹⁹ CNSC staff confirmed that Nordion had reviewed its programs against the requirements in these standards, conducted a gap analysis and committed to transition to the new standards by May 31, 2016.
114. The Commission enquired about whether CNSC staff followed up on ISO audit corrective actions and findings. CNSC staff responded that it reviewed the ISO audits and ensured that findings were addressed appropriately.

3.9.3 Assessment and Monitoring

115. Nordion presented information about its airborne emissions monitoring system and the methods used for sampling. Nordion stated that it had installed environmental TLDs at predetermined locations outside the facility and that this data was compared with facility effluent and other operational data. CNSC staff reported that, to date, the environmental TLD results had shown that gamma radiation at the monitoring locations was in the range of natural background.
116. Nordion reported that soil sampling was conducted at least every two years and that the levels of radionuclides in soil, as well as the radiation doses recorded on the environmental TLDs, were consistent with Nordion's airborne releases. CNSC staff

¹⁶ ISO 14001: *Environmental Management Systems*, International Organization for Standardization, 2004.

¹⁷ N288.4: Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills, CSA Group, 2010.

¹⁸ N288.5: Effluent monitoring at Class I nuclear facilities and uranium mines and mills, CSA Group, 2011.

¹⁹ N288.6: Environmental risk assessment at Class I nuclear facilities and uranium mines and mills, CSA Group, 2012.

confirmed that soil sampling was performed in 2012 and 2014 and that no nuclear substances attributable to Nordion licensed activities were detected.

117. Nordion stated that groundwater monitoring for non-radioactive contaminants was conducted at least once a year and that it expanded its groundwater monitoring program to include potential radioactive contaminants in 2013. Nordion reported that groundwater sampling demonstrated that there had been no significant changes in groundwater since 2005. Nordion also conducted sanitary sewer sampling every two years since 2006, the results of which showed three occasions during which Nordion did not comply with the Ottawa Sewer Use By-law limits. Nordion stated that the non-compliances were reported to the City of Ottawa and that no further action was required. CNSC staff confirmed that Nordion's monitoring results demonstrated that the Nordion facility had no detectable impact on groundwater quality.
118. CNSC staff reported that, as part of CNSC Independent Environmental Monitoring Program, air, soil and vegetation sampling will be done at Nordion in 2016, and that the results would be made publicly available on the CNSC website.

3.9.4 Protection of the Public

119. CNSC staff reported that, during the current licence period and based on Nordion's emissions, the calculated maximum dose to the public during the licence period was 0.042 mSv/year, which was 4.2% of the public dose limit of 1 mSv/year, and that, since 2007, the annual dose to the public showed a consistent downward trend.
120. CNSC staff is of the opinion that Nordion will make adequate provision for the protection of the health of persons and the environment.

3.9.5 Conclusion on Environmental Protection

121. Based on its assessment of the application and the information provided at the hearing, the Commission is satisfied that, given the mitigation measures and safety programs that are in place to control hazards, Nordion will provide adequate protection to the health and safety of persons and the environment.

3.10 Emergency Management and Fire Protection

122. Emergency Management and Fire Protection cover Nordion's measures for preparedness and response capabilities which exist for emergencies and for non-routine conditions at its facility. This includes nuclear emergency management, conventional emergency response, and fire protection and response. During the current licence period, CNSC staff rated Nordion's performance in this SCA as "satisfactory".

123. Nordion reported that it ensured that sufficient responsible personnel were available to provide safety oversight during operations and emergency situations at all times. Nordion had security on site at all times, an on-call incident manager, and radiation surveyors on site during production operations involving nuclear substances. Nordion noted that it also had over 80 fire wardens and marshals, over 80 emergency response personnel, and that it routinely assessed the availability of qualified staff for these roles.

3.10.1 Nuclear Emergency Preparedness and Response

124. Nordion reported that it had an established Emergency Preparedness and Response Program including Emergency Response Plans (ERPs) to address various emergency situations and that the Emergency Response Planning Committee met on a regular basis to discuss and assess Nordion's emergency planning needs. Nordion explained its partnerships with local fire departments, police departments and hospitals, and provided information on emergency exercises that it conducted in conjunction with local first responder organizations during the current licence period, including two full-scale exercises in 2006 and 2011. Nordion noted that the results of these exercises were a key internal performance indicator for this SCA and that both full-scale exercises were considered to be successful tests of the multiple elements of Nordion's ERPs. Nordion also conducted regular Fire Safety Plan and Emergency Response Contact List tests.
125. CNSC staff reported that, during the current licence period, Nordion's ERPs and procedures were reviewed through routine compliance inspections, emergency preparedness exercises conducted at Nordion, during the completion of lessons learned from Fukushima and following the publication of CNSC REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*.²⁰ Based on these regulatory activities, CNSC staff is of the opinion that Nordion demonstrated the ability to effectively respond to and manage an emergency.
126. Nordion reported that, during the current licence period, several improvements to the ERPs were made including training for additional emergency response managers, the adoption of an Incident Management System, improving emergency response communications, and increasing exercise frequency. Nordion also reported that, in 2013, it commissioned a recognized third party expert in emergency management to revise its Emergency Preparedness and Response Program and response structure. Nordion stated that the revised plan represented a significant improvement to emergency planning at Nordion and fully integrated City of Ottawa first responders. Nordion noted that CNSC staff had reviewed the plan and accepted the proposed implementation timeline. CNSC staff confirmed that Nordion's revised Emergency Preparedness and Response Program was compared against the requirements of REGDOC-2.10.1 and was acceptable.

²⁰ CNSC Regulatory Document REGDOC-2.10.1, "Nuclear Emergency Preparedness and Response", 2014.

127. Nordion noted that, in the next licence period, Nordion would increase frequency and robustness of its training and exercise programs, and would also further strengthen its relationship with Ottawa first responders. CNSC staff stated that Nordion had an acceptable Emergency Preparedness and Response Program and that it would continue to monitor Nordion's performance in this area during the next licence period.
128. Nordion stated that, on June 23, 2010, a magnitude 5.0 earthquake took place in Ottawa and that this unplanned event successfully tested the Site ERP, with no reported injuries or damage as a result of the earthquake. Nordion also reported that, on August 6, 2015, the facility successfully implemented its ERPs when a fire was discovered on the roof of its facility. This event is further detailed in section 3.10.2 and was also referenced in the context of an Event Initial Report in the *Minutes of the Canadian Nuclear Safety Commission (CNSC) Meeting held on August 20, 2015*.²¹ CNSC staff confirmed that, during both of these events, Nordion's ERPs were implemented satisfactorily.

3.10.2 Fire Protection

129. Nordion presented its Fire Protection Program which was established to minimize the probability and consequences of a fire at Nordion. Nordion noted that the Fire Safety Plan was tested regularly during which three on-site buildings were evacuated. Nordion also stated that a formal training program for fire wardens and marshals was established during the current licence period.
130. CNSC staff reported that, during the current licence period, Nordion submitted annual third party fire protection review reports of inspections, testing and maintenance, and that these indicated that Nordion was meeting the requirements of its operating licence with respect to fire protection.
131. Nordion reported that, during the next licence period, it would implement CSA N393²² in place of NFPA 801,²³ which was currently in its operating licence. CNSC staff noted that a gap analysis showed that the majority of required elements described in N393 were incorporated in Nordion's existing Fire Protection Program and that Nordion's implementation plan and target completion date of February 19, 2016 was acceptable.

²¹ Minutes of the Canadian Nuclear Safety Commission (CNSC) Meeting held on August 20, 2015,

²² N393: Fire protection for facilities that process, handle or store nuclear substances, CSA Group, 2013.

²³ NFPA 801-2003: Standard for fire protection for facilities handling radioactive materials, National Fire Protection Association, 2003.

Fire at Nordion on August 6, 2015

132. Nordion reported that a fire was discovered on the roof of an office area at Nordion's Kanata Operations Building at approximately 10:02 AM on August 6, 2015 and that Nordion's ERP was activated at approximately 10:07 AM. Nordion representatives described the steps that were taken by its emergency response personnel, as well as by Ottawa Fire Services, to respond to the event and informed the Commission that no employees or members of the community were injured and that there were no radiological releases as a result of the event. Nordion representatives stated that Nordion personnel and guests safely evacuated the facility and that Ottawa Fire Services responded quickly, isolating and extinguishing the fire. The building was returned to Nordion's control at 12:44 PM the same day, after which Nordion was able to confirm that there was no damage to facility safety systems and to restore roof integrity with temporary systems.
133. The Nordion representative informed the Commission that its emergency response proceeded smoothly and that an investigation was initiated immediately into the event, which, at that time, was thought to have occurred during routine roof maintenance performed by a third party that required the use of a blow torch. The Nordion representative further noted that it had engaged third-party experts to assist with identifying the root cause of the fire, to review the emergency response and implement lessons learned to further improve its Fire Protection Plan, and to assist with engineering design of the roof repairs. The Nordion representative assured the Commission that roof maintenance involving hot work had been suspended until a full investigation was completed and that an event report would be submitted to the CNSC within the 21-day prescribed reporting period.
134. CNSC staff confirmed that Nordion's ERP was implemented successfully and noted that a CNSC inspector was on-site during the event to monitor the situation. CNSC staff also stated that air and water samples had confirmed that no nuclear substances were released, and that Nordion staff, members of the public and the environment remained protected during the event. CNSC staff advised the Commission that it would provide the Commission with an update on this event, including root cause information if available, during the presentation of the CNSC staff *Annual Regulatory Oversight Report on Uranium and Nuclear Substance Processing Facilities in Canada: 2014* at the September/October 2015 Public Meeting of the Commission.
135. The Commission enquired about public concern during the event. The Nordion representative responded that many media requests were received and responded to by Nordion throughout the event, and that Nordion updated the public about the situation as it unfolded through its social media accounts and its corporate website. CNSC added that it also kept the public informed through its social media accounts and through the CNSC public website.

3.10.3 Conclusion on Emergency Management and Fire Protection

136. Based on the above information, the Commission concludes that the fire protection measures and emergency management preparedness programs in place, and that will be in place, at the Nordion facility are adequate to protect the health and safety of persons and the environment.

3.11 Waste Management

137. Waste management covers the licensee's site-wide waste management program. CNSC staff evaluated Nordion's performance with regards to waste minimization, segregation, characterization, and storage. Throughout the current licence period, CNSC staff rated Nordion's performance in this SCA as "satisfactory".
138. Nordion reported that it managed its radioactive wastes to ensure conformance with CNSC regulations, and that Nordion processing areas were designed and operated in a manner to prevent radioactive waste from being released to municipal garbage or sewer systems. Nordion presented information about the four main waste types generated in the Active Area. Nordion noted that waste from other radioisotope licensees was not transferred to Nordion for disposal, with the exception of spent sealed sources that may be returned to Nordion.
139. Nordion also provided information about the "Waste Blocks" program that was implemented in 2007 to characterize and identify routine wastes generated during production processes. Nordion noted that high-level liquid waste was typically solidified and included in routine waste. Nordion also stated that routine radioactive waste was collected and sent to a CNSC-approved radioactive waste management facility. CNSC staff stated that the "Waste Blocks" program assisted Nordion in standardizing and identifying routine waste streams in its facility.
140. Nordion noted that waste that was not characterized into "Waste Blocks" was considered non-routine waste. Nordion further explained that some low-level radioactive liquid waste was collected and transported to a licensed disposal facility. With respect to divertible waste, Nordion stated that its facility had a space for its long-term storage, if needed. Nordion also explained that it had well-established programs for chemical and non-hazardous waste management.
141. Nordion presented details on the percentage of diverted waste and reported that, to continuously improve its waste minimization performance and to meet CNSC and ISO 14001 requirements, waste was regularly monitored to ensure that it met established objectives. Nordion noted that waste service providers placed limitations on the types of waste that they accepted and that this proved to be a challenge in waste diversion activities; however, during the next licence period, Nordion indicated that it would continue to improve its waste management programs and find opportunities to continue diverting waste in a safe manner.

142. CNSC staff stated that, over the current licence period, it conducted routine compliance inspections and documentation reviews on Nordion's Waste Management Program and that Nordion continued to manage waste resulting from its licensed activities in accordance to regulatory requirements with an adequate Waste Management Program designed to reduce the volume of waste shipped to external radioactive waste management facilities.
143. The Commission requested additional details about the disposal of Nordion's radioactive waste. CNSC staff responded that, at this time, all routine and non-divertible radioactive waste was sent to a CNSC-licensed facility, including the Canadian Nuclear Laboratories facility at Chalk River, Ontario. CNSC staff also noted that waste disposal cost estimates in the current Preliminary Decommissioning Plan and Financial Guarantee were based on disposal at Chalk River.
144. The Commission requested additional information about Nordion's challenges with the disposal of its three historical neutron sources. The Nordion representative responded that Nordion attempted to dispose of these sources at Chalk River but the facility would not accept them. The Nordion representative added that Nordion is working with CNSC staff to determine how to safely dispose of these sources. CNSC staff confirmed this information and noted that it was uncertain as to why Chalk River would not accept the neutron sources. The Commission requested to be updated on the disposal of the neutron sources when a way-ahead has been determined.
145. Based on the above information and considerations, the Commission is satisfied that Nordion is safely managing waste at its facility.

3.12 Security

146. Security covers the programs required to implement and support the security requirements stipulated in the relevant regulations and the licence. This includes compliance with the applicable provisions of the *General Nuclear Safety and Control Regulations*²⁴ and the *Nuclear Security Regulations*.²⁵ CNSC staff rated this SCA as "satisfactory" from 2005 to 2011 and as "fully satisfactory" from 2012 to 2014.
147. Nordion reported that, throughout the current licence period, it maintained a strong security program and that it underwent annual security inspections by the CNSC and by other Canadian and American authorities. Nordion informed the Commission that US Homeland Security validated Nordion's performance at the top tier level of their Customs-Trade Partnership Against Terrorism, which had only been achieved by the top 2% of organizations.
148. CNSC staff reported that, during the current licence period, a number of security inspections were conducted at Nordion and that the security program was found to be

²⁴ SOR/2000-202.

²⁵ SOR/2000-209.

in compliance with, and in several areas was found to exceed, regulatory requirements. CNSC staff also stated that Nordion's security program had an effective security awareness program for staff and had a physical protection program that included administrative and technical measures that met current CNSC regulatory security requirements.

149. Nordion presented several significant proactive improvements that were made at its facility during the current licence period, including exterior security enhancements, the hiring of an experienced security professional to manage Nordion's security programs, the renovation of the Security Control Centre, upgrading the security systems and the installation of IT network security hardware. CNSC staff confirmed the improvements that Nordion made to its security program during the current licence period and noted that Nordion's updated site security plan, submitted to the CNSC in November 2014, met CNSC requirements.
150. Nordion reported that, in the next licence period, it planned to align with CNSC REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*.²⁶ CNSC staff reported that it had reviewed Nordion's transition plan to REGDOC-2.12.3 and found the target implementation date of December 1, 2015 acceptable.
151. The Commission is satisfied that Nordion's performance with respect to maintaining security at the facility has been acceptable. The Commission concludes that Nordion has made adequate provisions for the physical security of the facility, and is of the opinion that Nordion will continue to make adequate provision for it during the proposed licence period.

3.13 Safeguards and Non-Proliferation

152. The CNSC's regulatory mandate includes ensuring conformity with measures required to implement Canada's international obligations under the Treaty on the Non-Proliferation of Nuclear Weapons. Pursuant to the Treaty, Canada has entered into safeguard agreements with the International Atomic Energy Agency (IAEA). The objective of these agreements is for the IAEA to provide credible assurance on an annual basis to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there is no undeclared nuclear material or activities in this country.
153. The scope of the non-proliferation program for the current licence is limited to the tracking and reporting of foreign obligations and origins of nuclear material. CNSC staff rated Nordion's performance in this SCA as "satisfactory" throughout the current licence period.
154. Nordion reported that a Complimentary Access Inspection was conducted by the IAEA in 2006 and that, in February 2012, it became fully compliant with RD-336,

²⁶ CNSC Regulatory Document REGDOC-2.12.3, "Security of Nuclear Substances: Sealed Sources", 2013.

*Accounting and Reporting of Nuclear Material.*²⁷ Nordion noted that, during the current licence period, the accounting and reporting of nuclear material was performed as required and that Nordion also agreed to participate in the testing of the CNSC's Nuclear Materials Accountancy Reporting (NMAR) e-business system. CNSC staff confirmed that Nordion was compliant with CNSC RD-336.

155. The Commission noted that Nordion volunteered to adopt the NMAR e-business system and enquired about how this transition was progressing. A Nordion representative responded that the NMAR system had streamlined the safeguard reporting process for Nordion. CNSC staff added that, from the CNSC's point of view, the transition had gone smoothly and the CNSC was appreciative that Nordion volunteered to adopt and test the system.
156. CNSC staff reported that CNSC and IAEA safeguards inspections had been performed at Nordion since 2005 and that, during the current licence period, there were no reportable events or action notices issued as a result of the safeguards inspections. During the next licence period, CNSC staff will continue to monitor Nordion's performance in this area through routine CNSC inspections and documentation reviews.
157. The Commission asked about the frequency of IAEA inspections at Nordion. The Nordion representative responded that Nordion conducted a physical inventory of its nuclear material on an annual basis and submitted this information to the IAEA. With respect to IAEA-led inspections, the Nordion representative stated that on-site inspections were conducted on a random basis and that Nordion's last IAEA on-site inspection was in 2006. The Nordion representative also stated that CNSC staff verified Nordion's inventory information and conducted its own nuclear materials inventory annually. CNSC staff confirmed the information provided by Nordion.
158. Based on the above information, the Commission is satisfied that Nordion has made, and will continue to make, adequate provision for safeguards and non-proliferation at the facility that are necessary for maintaining national security and measures necessary for implementing international agreements to which Canada has agreed.

3.14 Packaging, Transport and Export

159. Packaging and transport covers the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility. The licensee must adhere to the *Packaging and Transport of Nuclear Substances Regulations*²⁸ and Transport Canada's *Transportation of Dangerous Goods Regulations*²⁹ for all shipments leaving the facility. CNSC staff rated Nordion's performance as "satisfactory" throughout the current licence period.

²⁷ CNSC Regulatory Document RD-336, "Accounting and Reporting of Nuclear Material", 2010.

²⁸ SOR/2000-208.

²⁹ SOR/2001-286.

160. Nordion informed the Commission about its import and export activities, provided details about its Packaging and Transportation Program, and noted that it had a Transport Package Quality Plan that it applied to its transport packages. Nordion reported that, as a result of an internal audit, the Transport Package Quality Plan was revised to provide clearer requirements.
161. CNSC staff stated that, during the current licence period, it had conducted packaging and transport inspections at Nordion which showed compliance with regulatory requirements and resulted in no major findings. CNSC staff noted that revised *Packaging and Transport of Nuclear Substances Regulations*³⁰ came into force in June 2015 and that CNSC staff will verify that shipments from Nordion continue to be in compliance with the Regulations.
162. Nordion also presented information about reportable events that occurred during the current licence period and stated that many of the reportable events were assessed as low-risk regulatory non-conformances. Nordion stated that, after clarification with respect to reporting obligations was obtained from the CNSC in 2011, Nordion began to report events that it had not been previously reported, resulting in an increase in reportable events. CNSC staff confirmed that Nordion reported all events to the CNSC in accordance with the regulations, that the majority of reportable events during the licence period were low-risk, and that none of the reported events had safety consequences.
163. The Commission enquired about the nature and severity of the reportable transportation events, noting the increase in events in the past several years. The Nordion representative responded that many of the events in the past years were low-risk events that did not involve spills, loss of containment or a vehicular accident, with approximately 50 percent of the events related to non-Nordion carriers. The Commission further enquired about the number of shipments made by Nordion annually. The Nordion representative responded that, between 2011 and 2014, Nordion made approximately 10,000 shipments per year.
164. Nordion also reported that a training program on transport regulations was created in 2011 and that this program had been amalgamated with the Transportation of Dangerous Goods Training Program. Nordion further reported that the roles for Nordion's drivers who transport Class 7 dangerous goods had been consolidated and clarified and that, during the next licence period, an enhanced training program would be put into place to support these requirements.

Export Licence Non-Conformances

165. Nordion reported that, as part of its Gamma Technologies business, it obtained individual CNSC Export Licences, separate from the Class IB NSPFOL that was considered in this hearing, for the exports of Category 1 and 2 sealed sources and that,

³⁰ SOR/2015-145.

between 2010 and 2014, several non-conformances with CNSC requirements for Nordion pre- and post-shipment notifications for the export of these sources were found. As a result, the CNSC issued an Administrative Monetary Penalty (AMP) to Nordion in September 2014, which was paid in full.³¹ CNSC staff provided additional details about the non-conformances and stated that it was satisfied that Nordion had taken appropriate action, including the commissioning of an IT solution that would automate a significant portion of the post-shipment notification process, thus reducing human error. CNSC staff also stated that it was satisfied that Nordion had appropriate procedures in place to ensure that risk-significant radioactive sources were exported appropriately and noted that no additional non-conformances had been reported since the issuance of the AMP.

166. The Commission enquired about why Nordion was rated as “satisfactory” in the Packaging and Transport SCA after the non-conformances leading to the AMP were identified. CNSC staff responded that the AMP was related to reporting requirements under Nordion’s export licences, which were separate from its Class IB licence, and as such, the non-conformances and the AMP did not affect the SCA rating. The Commission expressed concern that, even though the export activities were conducted under different licences, they were related to the transport process under the Class IB licence. CNSC staff responded that, through the identified reporting requirement non-conformances, a gap in Nordion’s Management System was identified whereby the Management System was only being applied to the activities under the Class IB licence and not those under the export licences. CNSC staff indicated the Commission that multiple corrective actions had been taken to close these gaps and that Nordion had improved its Management System to cover all of the activities that it conducted, not partitioned according to licence.
167. The Commission further expressed a concern that such a separation in requirements and licences existed, and fully expects that similar gaps would not reoccur should Nordion’s Class IB licence be renewed. The Nordion representative submitted that, before and following the issuance of the AMP, Nordion conducted an extensive investigation into the non-conformances which resulted in multiple corrective actions. The Nordion representative further noted that it had implemented an increased monitoring and verification process, including performance reviews, and was in the process of launching the pilot phase of an electronic solution with the goal of reducing human and reporting errors to nearly zero. CNSC staff informed the Commission that, in order to ensure Canada’s obligations for import and export of Category 1 and 2 sealed sources, export licences separate from Nordion’s Class IB licence were required but that CNSC staff would ensure that similar situations would not reoccur.
168. Based on the above information, the Commission is satisfied that Nordion is meeting regulatory requirements regarding packaging and transport.

³¹ CNSC Administrative Monetary Penalty and Notice of Violation, AMP-2014-07, Nordion (Canada) Inc., e-Doc 4455793.

3.15 Aboriginal Engagement and Public Information

169. CNSC staff reported that the CNSC had made available up to \$25,000 through its Participant Funding Program (PFP) to assist members of the public, Aboriginal groups and other stakeholders in providing value-added information to the Commission through informed and topic-specific interventions with respect to the review of Nordion's licence renewal application and associated documentation, and to prepare for, and participate in, the Commission's public hearing. The public, Aboriginal groups and other stakeholders were informed of the availability of participant funding through a series of public communications with an application deadline of May 19, 2015; however, no applications requesting participant funding were received.

3.15.1 Aboriginal Engagement

170. The common law duty to consult with Aboriginal communities and organizations applies when the Crown contemplates actions that may adversely affect established or potential Aboriginal or treaty rights. The CNSC ensures that all of its licensing decisions under the NSCA uphold the honour of the Crown and consider Aboriginal peoples' potential or established Aboriginal or treaty rights pursuant to section 35 of the *Constitution Act*.³²
171. CNSC staff informed the Commission that the Algonquin of Ontario (Algonquins of Pikwakanagan), Kitigan Zibi Anishinabeg, Algonquin of Quebec (Algonquin Anishinabeg Tribal Council), and the Métis Nation of Ontario (MNO) had been identified as groups who may have an interest in this licence renewal. CNSC staff had sent information letters to the identified groups in February 2015, providing them with information regarding the licence renewal application, the opportunity to apply for participant funding and details regarding the Commission's public hearing. Follow-up phone calls were conducted to ensure that the information had been received and to answer questions. CNSC staff reported that a response was received from Kitigan Zibi Anishinabeg First Nation expressing concerns related to the environmental impact of Nordion's activities on their claimed traditional territory. CNSC staff followed up with a letter outlining CNSC staff's assessment of Nordion's environmental protection and waste management programs and invited the Kitigan Zibi Anishinabeg First Nation to participate in the hearing process and apply for participant funding. CNSC staff had not been made aware of any concerns related to the licence renewal from other identified First Nations and Métis groups.
172. Based on the information received and reviewed to date, CNSC staff indicated their opinion that the licence renewal is not expected to result in any adverse impacts to any potential or established Aboriginal and/or treaty rights.

³² *The Constitution Act, 1982*, Schedule B to the Canada Act 1982 (U.K.), 1982, c. 11.

3.15.2 Public Information

173. A public information and disclosure program (PIDP) is a regulatory requirement for licence applicants and licensed operators of Class I nuclear facilities. Paragraph 3(j) of the *Class I Nuclear Facilities Regulations*³³ requires that licence applications include “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 program includes a commitment to and protocol for ongoing, timely communication of information related to the licensed facility during the course of the licence period.
174. Nordion provided information regarding its PIDP and the objectives of its Public Disclosure Protocol. Nordion informed the Commission that, in the last year, Nordion had made significant improvements to its PIDP and that the company actively engaged with the public through meetings, community events, its website and social media; responded to requests for information; conducted formal and informal polling; and engaged the public through print ads. Nordion noted that, in December 2014, it hosted a successful Nordion Community Café, which was an information session for the Kanata general public, and that, in 2015, Nordion launched an updated website that gave greater prominence to social responsibility and community outreach. Nordion stated that, in response to public requests, Nordion published its emergency preparedness plan on its website and noted that its future plans for the PIDP included continued public engagement, increased online presence and the development of a virtual tour of the Ottawa facility for the Nordion website. Nordion noted that, in the past three years, the company had received negligible numbers of inquiries from the public.
175. Nordion reported that, in 2014, two community public opinion surveys were conducted and revealed that a baseline awareness level of the facility existed and that, of those in the community who were aware of Nordion, the majority rated Nordion’s facility as safe.
176. CNSC staff informed the Commission that Nordion’s PIDP had been reviewed and assessed against CNSC RD/GD-99.3, *Public Information and Disclosure*.³⁴ CNSC staff stated that Nordion’s PIDP met all expectations outlined in RD/GD-99.3 and noted that, during the current licence period, Nordion had undertaken several improvements to its PIDP.
177. Many intervenors, including municipalities and individuals, expressed the view that there was community support for Nordion, that Nordion was a good corporate citizen that supported environmental, educational and health initiatives in the region, and that Nordion made an important contribution to healthcare worldwide.

³³ SOR/2000-204.

³⁴ CNSC Regulatory Document RD/GD-99.3, “Public Information and Disclosure”, 2012.

178. The Commission enquired about the role that social media played in Nordion's PIDP. The Nordion representative responded that Nordion used social media on a regular basis, primarily to disseminate information to the public. The Commission enquired about whether the public communicated with Nordion through social media. The Nordion representative responded that Nordion monitored its social media accounts on a daily basis but had found that most public inquiries were received through its corporate website and via email.
179. The Commission enquired about public awareness with respect to the importance of gamma sterilization of healthcare products. The Nordion representative responded that, although many of its products directly impacted the health and wellbeing of the public, many people were likely not aware of the contribution that Nordion made in this regard and acknowledged that this awareness should be raised.

3.15.3 Conclusion on Aboriginal Engagement and Public Information

180. Based on this information, the Commission is satisfied that Nordion's public information program meets regulatory requirements and is effective in keeping Aboriginal communities and the public informed of facility plans and operations. The Commission encourages Nordion to continue to create, maintain and improve its dialogue with the neighbouring communities.
181. The Commission acknowledges the efforts made by CNSC staff in relation to the CNSC's obligations regarding Aboriginal consultation and the legal duty to consult. The Commission is satisfied that the proposed licence renewal will not cause any adverse impacts to any potential or established Aboriginal or treaty rights and that the engagement activities undertaken for this licence renewal were adequate, given that no changes to the licensed activities have been requested.³⁵

3.16 Decommissioning Plans and Financial Guarantee

182. The Commission requires that licensees have operational plans for decommissioning and long-term management of waste produced during the life span of the facility. In order to ensure that adequate resources are available for safe and secure future decommissioning of the Nordion facility, the Commission requires that an adequate financial guarantee for realization of the planned activities is put in place and maintained in a form acceptable to the Commission throughout the licence period.
183. Nordion reported that it had a Preliminary Decommissioning Plan (PDP) that had been accepted by the CNSC and that, in April 2015, Nordion submitted a revised decommissioning cost estimate of \$45,124,748, which was accepted by the CNSC staff. Nordion further informed the Commission that it was proposing to use a letter of credit to cover the estimated cost of \$12,252,343 for placing the facility in a state of

³⁵ *Rio Tinto Alcan v. Carrier Sekani Tribal Council*, 2010 SCC 43, [2010] 2 S.C.R. 650 at paras 45 and 49.

safe storage, with the remainder of the financial guarantee – \$32,872,405 – covered by a letter of credit for \$12,872,405 and a surety bond for \$20,000,000. CNSC staff informed the Commission that it had reviewed the value of the financial guarantee and the proposed financial instruments, and that it was of the opinion that they met applicable regulatory requirements under the NSCA. It should be noted that CMD 15-H7 and CMD 15-H7.1 erroneously reported the revised financial guarantee amount as \$45,125,748; however, in CMD 15-H7.1A, Nordion corrected this amount to \$45,124,748, which was accepted by CNSC staff.

184. The Commission enquired about the risk presented by the use of a surety bond for a portion of the proposed financial guarantee instrument. CNSC staff responded that, although this was the first time that a combined letter of credit and surety bond were drafted as proposed financial guarantee instruments, a substantial CNSC staff and legal review determined that the surety bond instrument was a relatively low-risk instrument. CNSC staff added that the letter of credit that was proposed to fund putting the facility in a safe state prior to decommissioning was considered a sound and accepted financial instrument.
185. The Commission enquired about how CNSC staff would ensure that the surety bond was renewed annually and whether CNSC staff would require evidence to that effect. CNSC staff responded that the proposed licence condition 1.3 and the associated section of the proposed LCH included compliance verification criteria allowing for validation of this information by CNSC staff.
186. The Commission further enquired about why Nordion proposed the use of a surety bond for a portion of its financial guarantee. The Nordion representative responded that the use of a surety bond allowed Nordion to have a smaller amount of cash locked in a line of credit, allowing the company to use this cash to carry out its day-to-day operations.
187. The Commission enquired about the level of decommissioning that the PDP and financial guarantee covered. CNSC staff responded that the PDP and financial guarantee assumed a “decommissioning tomorrow” situation which included all of the activities required to immediately shut down the facility and to return the site to a specified end state, including the disposal of any waste on the site and waste generated through decommissioning, the dismantling of facilities and site remediation.
188. CNSC staff reported that Nordion will store sealed sources owned by Best Theratronics Ltd. (BTL) at its facility until BTL implements the full financial guarantee under its CNSC licence. Nordion indicated that the BTL financial guarantee was being implemented in a phased approach³⁶ and that Nordion would only remove these sources and the associated disposal costs from its PDP once BTL’s full financial guarantee was implemented. CNSC staff confirmed that any change to Nordion’s PDP or its financial guarantee would require the Commission’s approval.

³⁶ CNSC Record of Proceedings, Including Reasons for Decision – Best Theratronics Ltd., “Application for the Acceptance of the Financial Guarantee”, March 25, 2015, e-Doc 4706391.

189. Based on this information, the Commission considers that the preliminary decommissioning plans and related financial guarantee are acceptable for the purpose of the current application for licence renewal.

3.17 Cost Recovery

190. Nordion reported that cost recovery fees for regulatory and support activities had been submitted each year and that Nordion is a member of the Cost Recovery Advisory Group. CNSC staff confirmed that Nordion was in good standing with respect to the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*³⁷ requirements and that there was no concern with respect to payment of future cost recovery fees.
191. Based on this information, the Commission is satisfied that Nordion meets regulatory requirements for cost recovery.

3.18 Licence Length and Conditions

192. Nordion requested the renewal of the current operating licence for a period of 10 years or more. CNSC staff recommended the renewal of the licence for a period of 10 years and submitted that Nordion was qualified to carry on the licensed activities authorized by the licence. CNSC staff further stated that this licence period was recommended based on Nordion's compliance history and the requirement for Nordion to transition some of its programs during the proposed licence period to reflect current REGDOCs and standards. CNSC staff also recommended that annual reports on the facility would be provided for consideration by the Commission at public meetings as part of the *Annual Regulatory Oversight Report on Uranium Nuclear Substance Processing Facilities in Canada*.
193. CNSC staff recommended that the renewed licence include a standard LCH that makes reference to licensee programs, compliance verification criteria, recommendations and guidance.
194. The Commission requested additional information regarding the licence period request from Nordion and the CNSC staff recommendation. The Nordion representative responded that it requested a licence period of 10 years or more because, in addition to demonstrating that Nordion had strong corporate programs that evolved as standards changed, the frequency of interaction between Nordion and the CNSC had increased significantly over the current licence period with annual reviews and an enhanced, comprehensive and continuous, rather than periodic, oversight regime. CNSC staff responded that, while Nordion had demonstrated considerable improvement in its performance over the current licence period, CNSC staff also considered Nordion's compliance history and how its performance compared with similar licensees that currently have 10-year licences. CNSC staff noted that, since Nordion's performance

³⁷ SOR/2003-212.

was equivalent to the performance of these licensees, CNSC staff recommended a 10-year licence.


195. The Commission noted that the LCH was designed to provide clarity on compliance assessment and enquired about whether Nordion perceived the LCH as an additional regulatory requirement. The Nordion representative responded that, in the past, CNSC requirements were often discussed via telephone or email, whereas the LCH was a clear explanation of the requirements of the licence, and this should improve their implementation. The Nordion representative noted that, in the next year, Nordion would focus its efforts to ensure that all of its programs met the requirements of the licence.
196. The Commission enquired about the level of effort required for the relicensing of Nordion's facility. The Nordion representative responded that the level of effort required was approximately three to four full-time equivalent staff the year prior to and the year following relicensing. CNSC staff responded that approximately two CNSC full-time equivalent staff were required for relicensing activities, in addition to routine compliance effort.
197. All intervenors expressed support for the Nordion licence renewal. They were of the view that Nordion had safely operated its facility during the current licence period and would continue to do so during the proposed licence period. Many intervenors were also of the view that Nordion played a vital role in health care worldwide.
198. Based on the above information received during the course of this hearing, the Commission is satisfied that a 10-year licence is appropriate. The Commission accepts the licence conditions as recommended by CNSC staff. The Commission is of the opinion that a 10-year licence with annual reporting at public proceedings will allow Nordion to continue with safe operation, to further improve its performance, and to transition to updated regulatory documents while maintaining transparency of operation, public engagement and adequate oversight by CNSC staff.

4.0 CONCLUSION

199. The Commission has considered the information and submissions of CNSC staff, Nordion and all participants as set out in the material available for reference on the record, as well as the oral and written submissions provided or made by the participants at the hearing.
200. The Commission is satisfied that, given the mitigation measures and safety programs that are in place to control hazards, Nordion provides adequate protection to the environment. The Commission notes that the NSCA provides a strong regulatory framework for environmental protection.

201. The Commission is satisfied that Nordion meets the requirements of subsection 24(4) of the *Nuclear Safety and Control Act*. That is, the Commission is of the opinion that Nordion is qualified to carry on the activity that the proposed licence will authorize and that Nordion 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.
202. Therefore, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, renews Nordion (Canada) Incorporated's Class IB Nuclear Substance Processing Facility Operating Licence for its nuclear substance processing facility located in Ottawa, Ontario. The renewed licence NSPFOL-11A.00/2025 will be valid from November 1, 2015 until October 31, 2025.
203. The Commission includes in the licence the conditions as recommended by CNSC staff in CMD 15-H7. The Commission also accepts the following modification to the draft licence as presented in CMD 15-H7:
 - The current "Licence Condition 14: Packaging and Transport" will be replaced with "Licence Condition 14: Safeguards and Non-Proliferation" and will read "The licensee shall implement and maintain a safeguards program."
 - "Licence Condition 15: Packaging and Transport" will be added to the licence and will read "The licensee shall implement and maintain a packaging and transport program."
204. The Commission notes that CNSC staff can bring any matter to the Commission as applicable. The Commission directs CNSC staff to inform the Commission on an annual basis of any changes made to the LCH.
205. The Commission accepts the revised financial guarantee amount and instruments as presented in CMD 15-H7.1 and CMD 15-H7.1A.
206. The Commission expresses concern about the downgrading of Nordion's performance in the conventional health and safety SCA. The Commission emphasizes the importance of a strong conventional health and safety program and encourages Nordion to continuously improve its performance in this area. The Commission recommends that CNSC staff maintains a high level of oversight in this SCA.
207. With this decision, the Commission directs CNSC staff to provide an annual report on the performance of the Nordion facility as part of the Directorate of Nuclear Cycle and Facilities Regulation *Annual Regulatory Oversight Report on Uranium and Nuclear Substance Processing Facilities in Canada*. CNSC staff shall present these reports at public proceedings of the Commission, where requests to intervene from members of the public can be filed.

208. With this decision, the Commission also directs CNSC staff to present information on Nordion's performance in radiation protection and contamination of the Medical Isotopes and Gamma Technologies businesses separately to ensure that any safety issues in either business, should they arise, are identified. Furthermore, the Commission requests to be updated on the disposal of Nordion's neutron sources when a way-ahead for their disposal has been determined.



SEP 28 2015

Michael Binder
President,
Canadian Nuclear Safety Commission

Date

Appendix A – Intervenors

Bruce Power Inc.	CMD 15-H7.2
Ontario Power Generation Inc.	CMD 15-H7.3
Queensway Carleton Hospital	CMD 15-H7.4
Kanata North Business Improvement Area	CMD 15-H7.5
The Ottawa Hospital	CMD 15-H7.6
Sterigenics International LLC	CMD 15-H7.7
Canadian Nuclear Laboratories	CMD 15-H7.8
TRIUMF	CMD 15-H7.9
Jim Watson, Mayor, City of Ottawa	CMD 15-H7.10
The Canadian Association of Nuclear Medicine	CMD 15-H7.11
The University of Missouri Research Reactor Center (MURR)	CMD 15-H7.12
Lantheus Medical Imaging, represented by C. Villeneuve and I. Goldman	CMD 15-H7.13
Marianne Wilkinson, Councillor Ward 4, Kanata North, City of Ottawa	CMD 15-H7.14
Women in Nuclear (WiN) Canada	CMD 15-H7.15