Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

UNPROTECTED/NON PROTÉGÉ

ORIGINAL/ORIGINAL

CMD: 19-H102

Date signed/Signé le : FEBRUARY 14, 2019

A Licence Transfer

Nordion (Canada) Inc.

Nuclear Substance Processing Facility

Hearing in writing based solely on written submissions

Scheduled for:

February 2019

Submitted by:

CNSC Staff

Un transfert de permis

Nordion (Canada) Inc.

Installation de traitement des substances nucléaires

Audience fondée uniquement sur des mémoires

Prévue pour :

Février 2019

Soumise par :

Le personnel de la CCSN

e-Doc 5710844 (WORD)
e-Doc 5784059 (PDF)

Summary

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

- Request to transfer Nordion's Nuclear Substance Processing Facility licence from Nordion (Canada) Inc. as identified by corporate number 891613-6 to Nordion (Canada) Inc. as identified by a new corporate number, 1115250-5.

CNSC staff recommend the Commission take the following action:

- Accept CNSC staff recommendation to transfer the Nuclear Substance Processing Facility Operating Licence NSPFOL-11A.00/2025 from Nordion (Canada) Inc. to its new corporate number.

The following items are attached:

- Proposed licence
- Proposed licence conditions handbook
- Current licence

Résumé

Le présent CMD comprend de l'information sur un ensemble de questions qui présentent un intérêt réglementaire concernant Nordion (Canada) Inc. :

- Demande de transfert du permis d'une installation de traitement des substances nucléaires de Nordion (Canada) Inc. identifié par le numéro d'entreprise 891613-6 à Nordion (Canada) Inc. identifié par le nouveau numéro d'entreprise 1115250-5.

Le personnel de la CCSN recommande à la Commission de prendre les mesures suivantes :

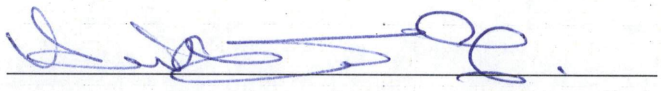
- Accepter la recommandation du personnel de transférer le permis d'une installation de traitement des substances nucléaires, NSPFOL-11A.00/2025, de Nordion (Canada) Inc. à son nouveau numéro d'entreprise.

Les pièces suivantes sont jointes :

- Permis proposé
- Manuel des conditions de permis proposé
- Permis actuel

Signed/signé le

February 14, 2019



Haidy Tadros

Director General

Directorate of Nuclear Cycle and Facilities Regulation

Directrice générale de la

Direction de la réglementation du cycle et des installations nucléaires

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EXECUTIVE SUMMARY

Nordion (Canada) Inc. operates a nuclear substance processing facility under a Class IB Nuclear Substance Processing Facility Operating Licence, NSPFOL-11A.00/2025. Nordion is applying to the Canadian Nuclear Safety Commission (CNSC) under subsection 24(2) of the *Nuclear Safety and Control Act* (NSCA) to request a transfer of its nuclear substance processing facility operating licence from Nordion (Canada) Inc. to a new corporate identity with the same name but identified with a new corporate number.

The purpose of the requested licence transfer is to reflect the amalgamation of Nordion with its direct parent company and two other non-licensee-affiliated companies. The requested licence transfer would not impact Nordion's operational structure or its management structure. Nordion's management system, management system documents, safety-related documents and obligations to the Commission regarding compliance with the NSCA would remain unchanged by the proposed licence transfer.

CNSC staff consider this request to be administrative and recommend that the Commission authorize the licence transfer of NSPFOL-11A.00/2025 from Nordion (Canada) Inc. to its new corporate identity.

Referenced documents in this CMD are available to the public upon request.

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PART ONE

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

Part One includes:

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

Part Two provides all available information pertaining directly to the current and proposed licence.

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1. OVERVIEW

1.1 Background

Nordion (Canada) Inc. operates a nuclear substance processing facility under a Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-11A.00/2025. This licence is valid from November 1, 2015 to October 31, 2025, unless otherwise suspended, amended, revoked, replaced, or transferred.

Figure 1-1: Location of Nordion (Canada) Inc.

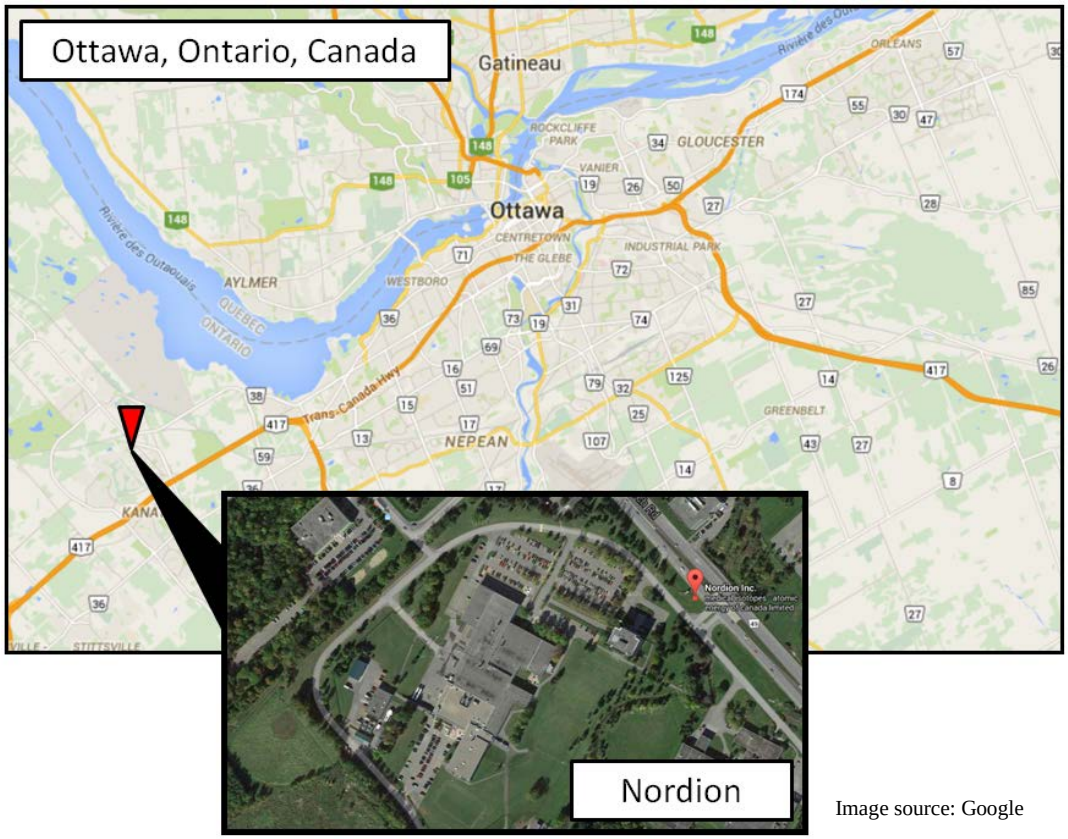

Image source: Google

The Nordion facility is located adjacent to industrial and residential property in Kanata, which is a suburb of Ottawa, Ontario. At this facility, Nordion processes unsealed radioisotopes, such as yttrium-90, for health and life sciences applications, and manufactures sealed cobalt-60 radiation sources for industrial applications.

1.2 Highlights

On November 8, 2018, the Canadian Nuclear Safety Commission (CNSC) received a request [1] from Nordion regarding its Nuclear Substance Processing Facility Operating Licence, NSPFOL-11A.00/2025. Nordion applied under subsection 24(2) of the *Nuclear Safety and Control Act* (NSCA) to request a transfer of the Nordion NSPFOL from Nordion (Canada) Inc. identified by corporate number 891613-6 to a new corporate identity with the same name but a new corporate number, 1115250-5. Nordion stated in its submission that this change is to reflect the amalgamation of Nordion with its direct parent company and two other non-licensee-affiliated companies: Lakeshore Health Centre Inc. (Canada) and Nordion Sterilization Inc. (Canada). The request included an overview of the current organizational structure together with the changes to the organizational structure following the amalgamation.

In its application, Nordion stated that the proposed amalgamation would not impact its operational and management structure. Nordion confirmed that its obligations made to the Commission remained unchanged, and that there were no changes to the financial guarantee or all other information submitted for the existing licence. The requested transfer would not change any operational management system documents, nor would it change documents related to safety management. Moreover, all equipment, facilities, procedures, nuclear substances and personnel required for the licensed activities would remain the same.

2. MATTERS FOR CONSIDERATION

2.1 Environmental Assessment

CNSC staff have reviewed the application under the NSCA and have concluded that, given the administrative nature of the proposed licence transfer, there are no impacts to the environment.

2.2 Relevant Safety and Control Areas

Safety and Control Areas are not relevant to this CMD because the only change for the proposed licence transfer is Nordion (Canada) Inc.'s corporate number. There are no changes to Nordion's authorizations and licensed activities. CNSC staff confirm that findings from Nordion's previous licence renewal in 2015 remain valid.

2.3 Regulatory and Technical Basis

The regulatory and technical bases for the matters discussed in this CMD are provided in Addendum A to this document. For this type of facility, the key requirements come directly from the *Class I Nuclear Facilities Regulations* and the *General Nuclear Safety and Control Regulations* as well as other applicable requirements from the NSCA.

CNSC staff have reviewed Nordion's request for a licence transfer and conclude that the request for the licence transfer is acceptable and meets regulatory requirements. CNSC staff are satisfied that there are no changes to any Nordion operational management system documents or documents related to safety management. CNSC staff are satisfied that all equipment, facilities, procedures, nuclear substances and personnel required for the licensed activities remain the same.

CNSC staff verified that Nordion's financial guarantee remains in effect. Nordion has a financial guarantee in place, in the form of a surety bond and a letter of credit that was approved by the Commission in 2015. The amalgamation did not result in any changes to the licensed activities and therefore, the amount of the financial guarantee remains valid. Nordion provided documentation to demonstrate that the letter of credit [2] and surety bond [3] remain valid and in effect following the corporate amalgamation.

CNSC staff also confirmed Nordion's new legal identity. Nordion submitted a Certificate of Amalgamation that was issued to Nordion by Innovation, Science and Economic Development Canada on January 1, 2019 [4].

2.4 Aboriginal Consultation

The common law duty to consult with Indigenous peoples applies when the Crown contemplates actions that may adversely affect potential or established and/or treaty rights. Based on the information provided in the application, CNSC staff have determined that the requested licence transfer is an administrative change and, as such, is not likely to cause adverse impacts to any Indigenous and/or treaty rights. Therefore, the duty to consult does not arise in relation to the proposed licence transfer.

3. OVERALL CONCLUSIONS AND RECOMMENDATIONS

3.1 Overall Conclusions

With respect to the request for a licence transfer, and pursuant to paragraphs 24(4)(a) and (b) of the NSCA, CNSC staff conclude that Nordion (Canada) Inc.:

1. Is qualified to carry on the activity authorized by the licence.
2. Will, in carrying out that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

3.2 Overall Recommendations

Pursuant to section 24 of the NSCA, CNSC staff recommend that the Commission:

1. Authorize the transfer of licence NSPFOL-11A.00/2025 from Nordion (Canada) Inc., corporate number 891613-6, to Nordion (Canada) Inc., corporate number 1115250-5.

REFERENCES

1. Nordion (Canada) Inc., *Licence Transfer Application for Nordion (Canada) Inc.*, November 8, 2018 (e-Doc 5707075).
2. J.P. Morgan, *Confirmation of Letter of Credit Validity*, December 17, 2018 (e-Doc 5739554).
3. Intact Insurance, *Confirmation of Surety Bond Validity*, December 18, 2018 (e-Doc 5740648).
4. Nordion (Canada) Inc., *Certificate of Amalgamation*, January 1, 2019 (e-Doc 5752362).

A. BASIS FOR THE RECOMMENDATION(S)

A.1 Regulatory Basis

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

Nuclear Safety and Control Act subsection 24(2)

- The *Nuclear Safety and Control Act* under subsection 24(2) states that the Commission may issue, renew, suspend in whole or in part, amend, revoke, or replace a licence, or authorize its transfer, on receipt of an application; in the prescribed form; containing the prescribed information and undertakings and accompanied by the prescribed documents; and accompanied by the prescribed fee.

Financial Guarantee

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

PART TWO

Part Two provides all relevant information pertaining directly to the licence, including:

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

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PROPOSED LICENCE CHANGES

Overview

The proposed changes to the licence are to Nordion's corporate number and to the licence period to reflect the proposed transfer of the licence.

Licensee

PROPOSED CHANGES TO THE LICENSEE	
Current Licensee	**Proposed Licensee**
Nordion (Canada) Incorporated 891613-6 447 March Road Ottawa, Ontario K2K 1X8	Nordion (Canada) Incorporated 1115250-5 447 March Road Ottawa, Ontario K2K 1X8

Licence Conditions

There are no proposed changes to the licence conditions.

Licence Format

There are no proposed changes to the licence format.

Licence Period

The beginning of the proposed licence period is recommended to be the date the licence is transferred.

PROPOSED CHANGES TO THE LICENCE PERIOD	
Current Licence Period	**Proposed Licence Period**
This licence is valid from November 1, 2015 to October 31, 2025	This licence is valid from the date signed and remains in effect until October 31, 2025

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PROPOSED LICENCE

e-doc 5743436 (Word)

e-doc 5784149 (PDF)

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

CLASS IB NUCLEAR SUBSTANCE PROCESSING FACILITY OPERATING LICENCE

NORDION (CANADA) INC.

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

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

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

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

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

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

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

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

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

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

V) EXPLANATORY NOTES:

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

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

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

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

VI) CONDITIONS:

1. GENERAL

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

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

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

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

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

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

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

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

2. MANAGEMENT SYSTEM

2.1 The licensee shall implement and maintain a management system.

3. HUMAN PERFORMANCE MANAGEMENT

3.1 The licensee shall implement and maintain a training program.

4. OPERATING PERFORMANCE

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

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

5. SAFETY ANALYSIS

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

6. PHYSICAL DESIGN

6.1 The licensee shall implement and maintain a design program.

7. FITNESS FOR SERVICE

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

8. RADIATION PROTECTION

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

9. CONVENTIONAL HEALTH AND SAFETY

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

10. ENVIRONMENTAL PROTECTION

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

11. EMERGENCY MANAGEMENT AND FIRE PROTECTION

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

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

12. WASTE MANAGEMENT

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

12.2 The licensee shall implement and maintain a decommissioning strategy.

13. SECURITY

13.1 The licensee shall implement and maintain a security program.

14. SAFEGUARDS AND NON-PROLIFERATION

14.1 The licensee shall implement and maintain a safeguards program.

15. PACKAGING AND TRANSPORT

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

SIGNED at OTTAWA, this _____ day of _____, 2019

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

PROPOSED LICENCE CONDITIONS HANDBOOK

e-doc 5780110 (Word)

e-doc 5784160 (PDF)

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Canada's Nuclear Regulator

e-Doc 5780110 (Word)
e-Doc 5784160 (PDF)

LICENCE CONDITIONS HANDBOOK

LCH-NSPF-11A.01/2025

NORDION (CANADA) INC.

Nuclear Substance Processing Facility Operating Licence (NSPFOL)

NSPFOL-11A.01/2025

Revision 2

DRAFT

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire
Canada

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Licence Conditions Handbook **Effective: Month XX, 2019**

LCH-NSPF-11A.01/2025

Nordion (Canada) Inc.

Nuclear Substance Processing Facility Operating Licence (NSPFOL)

NSPFOL-11A.01/2025

SIGNED at OTTAWA this _____ day of _____, 2019

_____

Caroline Ducros, Director
Nuclear Processing Facilities Division
Directorate of Nuclear Cycle and Facilities Regulation
CANADIAN NUCLEAR SAFETY COMMISSION

Revision History:

Effective Date	Rev. #	LCH e-Doc #	Section(s) changed	Description of the Changes	Document Change Record
2015-12-23	0	4540023 (Word) 4741294 (PDF)		Original document	N/A
2019-01-25	1			Updated Derived Release Limits; updated Licensing Basis Publications and Licensee Documents that Require Notification of Change; removed completed CSA and REGDOC transitions; revised formatting	5447067
2019-XX-XX	2			Updated Nordion corporate number; updated the licence number; updated the licence period	5767479

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PART I: INTRODUCTION

The purpose of the licence conditions handbook (LCH) is to identify the regulatory requirements and other relevant parts of the licensing basis to help ensure that the licensee maintains facility operation in accordance with the licensing basis for the facility and the Nordion Nuclear Substance Processing Facility Operating Licence, NSPFOL-11A.01/2025. The LCH provides compliance verification criteria for conditions set out in the licence. The criteria are written in mandatory language.

1. BACKGROUND

1.1 Objective

This LCH identifies criteria that will be used by Canadian Nuclear Safety Commission (CNSC) staff to assess licensee compliance with the licence conditions (LCs) listed in licence NSPFOL-11A.01/2025. The LCH does not introduce new requirements but provides explanation on how to meet licence conditions and regulatory requirements. The LCH should be read in conjunction with the licence. The LCH contains applicable versions of documents referenced in the licence. It also provides dispute resolution.

The compliance framework for each licence condition consists of:

- a statement of the safety and control area, where applicable;
- a statement of the corresponding licence condition;
- a preamble; and
- compliance verification criteria for that licence condition.

In addition, a section for guidance is also provided for each licence condition.

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

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

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

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

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

2. DESCRIPTION OF THE SECTIONS IN THE NSPFOL

2.1 Section I: Licence Number

The alpha numeric expression NSPFOL-11A.01/2025 stems from the CNSC standard convention for identifying licences. The following table provides a description of each identifier used in the expression:

Identifier	Description
NSPFOL	Nuclear Substance Processing Facility Operating Licence
11A	Refers to facility name (11A = Nordion (Canada) Inc.)
01	Licence version number (00 = Initial licence, 01 = Amendment No. 1, etc.)
2025	Expiration year

2.2 Section II: Licensee

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

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

2.3 Section III: Licence Period

Identifies the duration for which the licence is valid, which in this case, for NSPFOL-11A.01/2025, is from Month XX, 2019 to October 31, 2025 unless suspended, amended, revoked, replaced, or transferred during the licensing period.

2.4 Section IV: Licensed Activities

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

Licensed Activities

This licence authorizes the licensee to:

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

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

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

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

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

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

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

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

2.5 Section V: Explanatory Notes

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

2.6 Section VI: Conditions

This section of the licence lists the LCs.

PART II: FRAMEWORK FOR EACH CONDITION

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

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

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

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

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

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

1 GENERAL LICENCE CONDITIONS

1.1 Licensing Basis

Licence Condition 1.1

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

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

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

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

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

Preamble

The licensing basis is discussed in CNSC INFO-0795.

Compliance Verification Criteria

Part (i) of the licensing basis includes the NSCA and its associated Regulations, and the Canada/International Atomic Energy Agency (IAEA) Safeguards Agreement. The other applicable laws and regulations include but are not limited to:

- *Canadian Environmental Assessment Act, 2012*
- *Canadian Environment Protection Act, 1999*
- *Transportation of Dangerous Goods Act*
- *Radiation Emitting Devices Act*
- *Access to Information Act*
- *National Building Code of Canada*
- *National Fire Code of Canada*
- *Canada Labour Code Part II*

Part ii) of the licensing basis includes the conditions and safety and control measures described in the licence and the documents directly referenced in the licence.

Part iii) of the licensing basis consists of the safety and control measures described in the licence application and the documents needed to support that licence application. This does not mean that all details in those documents are part of the licensing basis; some of these documents may contain administrative elements, which are excluded from the licensing basis.

The safety and control measures include important aspects of analysis, design, operation, etc. They may be found in high-level, programmatic licensee documents but might also be found in lower-level, supporting licensee documentation. LC 1.1 requires the licensee to conduct the activities described in Part IV of its licence, in accordance with the safety and control measures.

The licensing basis is established by the Commission at the time the licence is issued. Per LC 1.1, operation during the licence period that is not in accordance with the licensing basis is only allowed based on the written approval of the Commission. Similarly, only the Commission can change the licensing basis during the licence period, and this would also be expected to be recorded in writing.

Where the licensing basis refers to specific configurations, methods, solutions, designs, etc., the licensee is free to propose alternate approaches that differ from those in the CVC, as long as they remain in accordance with the licensing basis for the facility.

LC 1.1 is not intended to unduly inhibit the ongoing management and operation of the facility or the licensee's ability to adapt to changing circumstances and continuously improve. This LC does not explicitly prohibit changes (such as in management or operation) with a neutral or positive impact on safety. Changes shall be in accordance with the licensing basis and shall be made in accordance with the licensee's management system (see LC 2.1). Changes to licensee documents may require written notification to the CNSC; even if they are in accordance with the licensing basis (see LC 1.2).

In the event of any conflict or inconsistency between two elements of the licensing basis, the licensee shall direct the conflict or inconsistency to CNSC staff for resolution. Any such conflict or inconsistency identified would be discussed between the licensee and CNSC staff; the outcome of such discussions will be documented to ensure a common understanding.

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

Date	Document Title	e-Doc #
November 6, 2014	Application for Renewal of Nordion Operating Licence NSPFOL-11A.05/2015	4575627
March 18, 2015	Amendment to Nordion's Application for Renewal of Nordion Operating Licence NSPFOL-11A.05/2015	4700599

Guidance

When the licensee becomes aware that a proposed change or activity might be outside the licensing basis, it should first seek direction from CNSC staff regarding the potential acceptability of this change or activity. The licensee should take into account that certain types of proposed changes might require significant lead times before CNSC staff can make recommendations and/or the Commission can properly consider them.

1.2 Changes to the Documents in Support of the Licence Application

Licence Condition 1.2

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

Preamble

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity, and thus establishes the basis for the CNSC's compliance program in respect of that regulated facility or activity. Licensees are required to operate nuclear facilities in accordance with the licensing basis; however, as changes to the programs and documents included or referenced in the licence application are to be expected during the licensing period, licensees are expected to assess changes for impact on the licensing basis. Any changes to the licensing basis require evaluation to determine impact, as related to the 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.

In general, it is expected that changes for which the licensee shall notify the CNSC will be captured as changes to specific licensee documents. This LCH identifies licensee documents that require written notification of changes to the CNSC. They are primarily selected from the set of documents supporting the application and which describe the licensee's safety and control measures (part (iii) of the licensing basis, as defined in LC 1.1). In identifying the written notification documents for each LC, CNSC staff select licensee's documents that provide reasonable assurance that adequate safety and control measures are in place to satisfy the LC. See LC 1.1 for additional discussion of the licensing basis.

Tables under each LC in the LCH identify the documents (if any) requiring written notification of change. Appendix A.2 describes some of the general criteria that CNSC staff will use to assess changes to documents subject to the written notification requirement. Written notification documents are subdivided into those that require prior written notification of changes and those that require written notification only.

CNSC staff will track the version history of all written notification documents cited in the LCH with the exception of security-related documents. A spreadsheet list controlled by the CNSC's Nuclear Processing Facilities Division entitled "Nordion LCH Written Notification Tracking Sheet" (e-Doc 4768292) has been created for this purpose.

Compliance Verification Criteria

Licensee documents that require written notification of change are identified in this LCH under the most relevant LC. These documents represent the minimum subset of documents. For any change that is not captured as a change to a document listed in the LCH, if the change impacts designs, operating conditions, policies, programs, methods, or other elements that are integral to the licensing basis and the change is not clearly in the safe direction, the licensee shall provide written notification of the change.

Written notification is defined as a physical or electronic communication from a person authorized to act on behalf of the licensee to a CNSC staff member. For documents requiring prior written notification, the licensee shall submit the written notification to the CNSC prior to implementing the change. Typically, the requirement is to submit the proposed changes 30 days prior to planned implementation. However, the licensee shall allow sufficient time for the CNSC to review the change proportionate to its complexity and the importance of the safety and control measures being affected. For documents requiring notification only, the licensee needs only to submit the written notification at the time of implementing the change. All written notifications shall include a summary description of the change, the rationale for the change, and a summary explanation of how the licensee has concluded that the changed document remains in accordance with the licensing basis. A copy of the revised written notification document shall accompany the notification.

Changes to the licensing basis that are not clearly in the safe direction require further assessment of impact to determine if prior Commission approval is required in accordance with LC 1.1.

Guidance

None provided.

1.3 Financial Guarantee

Licence Condition 1.3

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

Preamble

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

LC 1.3 requires the licensee to maintain a financial guarantee (FG) for decommissioning that is acceptable to the Commission. The FG shall remain valid and in effect and adequate to fund the activities described in the preliminary decommissioning plan or decommissioning strategy. If the preliminary decommissioning plan is revised and significantly impacts the cost estimate for the FG, the expectation is that the FG is revised and submitted to the Commission for acceptance. In addition, the financial guarantee for decommissioning is to be reviewed and revised by Nordion every five years, and when the Commission requires.

Nordion has provided a *Preliminary Decommissioning Plan* and an associated cost estimate. CNSC staff deemed these to be satisfactory and the Commission accepted the financial guarantee with the associated cost estimate. The current cost estimate for decommissioning is $45,124,748. Nordion will use a letter of credit to cover the estimated cost ($12,252,343) for placing the facility in a safe state of storage (i.e., transfer of nuclear substances to a licensee authorized to possess them and removal of hazardous material). The remainder of the financial guarantee ($32,872,405) will be covered by a letter of credit for $12,872,405 and a surety bond for $20,000,000.

Compliance Verification Criteria

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

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

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

4. The licensee shall develop its financial guarantee based on the guidance in the following regulatory guidance document.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Financial Guarantees for the Decommissioning of Licensed Activities	G-206	June 2000
CNSC	Decommissioning Planning for Licensed Activities	G-219	June 2000
CSA	Decommissioning of Facilities Containing Nuclear Substances	N294	2009

1.4 Public Information and Disclosure

Licence Condition 1.4

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

Preamble

The primary goal of the Public Information and Disclosure Program is to ensure that information related to the health and safety of persons and the environment and other issues associated with the lifecycle of the nuclear facility is effectively communicated to the public.

In addition, the program shall include a commitment to a disclosure protocol in regard to information and reports of interest to the public. The disclosure program shall include timely communication of items of interest to the public such as routine and non-routine situations, unplanned events and other incidents and activities related to the licensed facility that may be of interest to the public.

Compliance Verification Criteria

Licensee Document that Requires Notification of Change

Document Title	Document #	Prior Notification
Nordion Public Information Program	SE-LIC-010	No

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Public Information and Disclosure	RD/GD-99.3	2012

Guidance

Guidance Publications

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

2. SCA – MANAGEMENT SYSTEM

2.1 Management System Requirements

Licence Condition 2.1

The licensee shall implement and maintain a management system.

Preamble

Paragraph 3(k) of the *General Nuclear Safety and Control Regulations* requires that a licence application contain information on the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the *Nuclear Safety and Control Act* and the Regulations made under the Act, including the internal allocation of functions, responsibilities and authority.

Paragraph 3(d) the *Class I Nuclear Facilities Regulations* requires that a licence application contain information that includes the proposed quality assurance program for the activity to be licensed.

A management system for safety shall control activities at both the working level and at the corporate level from planning stages to completion, provide corporate direction and maintains overall accountability, and ensures effective quality and safety-related communications between individuals and organizations.

A licensee shall retain overall responsibility for assuring safety regardless of the delegation of any work or responsibilities to other organizations.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

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

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Management Systems Requirements for Nuclear Facilities	N286	2012

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Commentary on N286-12, *Management system requirements for nuclear facilities*	N286.0.1	2014

3. SCA – HUMAN PERFORMANCE MANAGEMENT

3.1 Human Performance Management

Licence Condition 3.1

The licensee shall implement and maintain a training program.

Preamble

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

Paragraphs 6(m) and 6(n) of the *Class I Nuclear Facilities Regulations* require that licence applications include the proposed responsibilities, qualification requirements, training program, including the procedures for the requalification of workers, and the results that have been achieved in implementing the program for recruiting, training and qualifying workers.

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

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Radiation Surveyors and Monitors On-the-Job Training Program	SE-TRN-001	No
Compliance Environment Health and Radiation Safety Training	SE-TRN-003	No
Systematic Approach to Training System	SE-TRN-006	No
Cobalt Monitor On-the-Job Training Program	CO-MD OP-0028	No

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Personnel Training	REGDOC-2.2.2	2014

Guidance

None provided.

4. SCA – OPERATING PERFORMANCE

4.1 Operations Program

Licence Condition 4.1

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

Preamble

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain the following information: the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

An operating program defines the operating rules consistent with the safety analyses and other licensing support documentation within which the facilities will be operated, maintained and modified, all of which should ensure safety. An operations program establishes safe, uniform, and efficient operating practices within a nuclear facility.

An operations program includes an up-to-date set of operating limits for the facility and activities authorized under the licence, including: limits for the possession, use, management, transfer, storage of nuclear substances; an inventory of nuclear substances and prescribed equipment; and a process to track high-risk sealed sources and operational limits/specifications for the nuclear facility.

In addition, the operations program is to ensure that any building modifications are made in accordance with the *National Building Code*, the *National Fire Code*, and CSA N393 *Fire Protection for Facilities that Process, Handle or Store Nuclear Substances*. CSA N393 *Fire Protection for Facilities that Process, Handle or Store Nuclear Substances*, includes specific reporting requirements for reporting and follow-up of fire incidents and fire protection program audits.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
EHS Committee Approved Activity Limits for Facilities	SE-LIC-007	No
Sealed Source Reporting	SE-OP-079	No
Radioactive Material Inventory	SE-LIC-015	No
Management System for Safety	See LC 2.1	

Criteria for Facility Operation:

1. The licensee shall operate its facility using up-to-date procedures that have been through a formal development process which includes validation before the procedure is approved for use. In addition, such procedures shall be reviewed (and revised, as appropriate) on a regular basis.
2. As part of the operating program, the licensee shall implement and maintain a sealed source tracking program.
3. The licensee shall maintain a record of the nuclear substances and radiation devices in its possession, and provide details to show:
   a. the name, quantity, form and location of the nuclear substance;
   b. where the nuclear substance is a sealed source, the model and serial number of the sources;
   c. where the nuclear substance is contained in a radiation device, the model and serial number of the device, the quantity of the nuclear substance used, and the manner in which the nuclear substance is used; and
   d. any transfer, receipt including acquisition, and disposal of a nuclear substance including
      - the date of transfer, receipt, disposal
      - the name and address of the supplier or the recipient
      - the number of the licence of the recipient
      - the name, quantity and form of the nuclear substance transferred, received, disposed of
      - where the nuclear substance is a sealed source, the model and serial number of the source
      - where the nuclear substance is contained in a radiation device, the model and serial number of the device.

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

Criteria for Fire Protection

1. The licensee shall design, build, modify and otherwise carry out work related to the facility with potential to impact protection from fire in accordance with the *National Building Code of Canada, the National Fire Code of Canada* and CSA N393.

2. The licensee shall operate, maintain, test, and inspect the facility in accordance with the *National Fire Code of Canada* and CSA N393.

3. The licensee shall implement the defence-in-depth principle to fire protection, providing measures to prevent fires from starting, to detect and extinguish quickly any fires that do start and to prevent the spread of fires and their effects in or to any area that may affect safety.

Licensing Basis Publications

Source	Document Title	Document #	Revision #
NRC	National Fire Code of Canada	IRC-10NFC	2010
NRC	National Building Code of Canada	IRC-10NBC	2010
CSA	Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2013

Guidance

None provided.

4.2 Reporting Requirements

Licence Condition 4.2

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

Preamble

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

The NSCA and applicable regulations describe reporting to the Commission or a person authorized by the Commission. Some reporting requirements are found in sections 29 - 32 of the *General Nuclear Safety and Control Regulations* and section 27 of the NSCA. Information regarding notification of action level exceedances is found in this LCH under LCs 8 and 10. A licensee is required to have a program that includes all reporting.

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

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Sealed Source Reporting	SE-OP-079	No
Investigations	SE-RP-003	No
EHS Regulatory Reporting and Notifications	SE-EHS-009	No

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

Activity Limits for Sealed Source Tracking

Column 1	Column 2	Column 3
Nuclear Substance	**Reporting Schedule**	**(TBq)**
Americium 241	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Americium 241/Beryllium	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Californium 252	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.2
Curium 244	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.5
Cobalt 60	(a) prior to any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.3
Cesium 137	(a) prior to any transfer, and (b) at least 7 days before any export, and (c) within 48 hours of any receipt of a transfer or import.	1
Gadolinium 153	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	10
Iridium 192	(a) prior to any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.8
Promethium 147	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	400
Plutonium 238	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Plutonium 239/ Beryllium	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.6
Radium 226	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	0.4
Selenium 75	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	2
Strontium 90 (Yttrium 90)	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	10
Thulium 170	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	200
Ytterbium 169	(a) at least 7 days before any transfer or export, and (b) within 48 hours of any receipt of a transfer or import.	3

The written report shall be in a form that includes:

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

(i) the date of transfer, or for export, the date the sealed source(s) leaves the facility,
(ii) the export licence number (where applicable),
(iii) the name of the recipient and licence number,
(iv) the name of the importer,
(v) the address of the recipient's or importer's authorized location,
(vi) the nuclear substance (radionuclide),
(vii) activity (radioactivity) (Bq) per sealed source on the reference date,
(viii) the reference date,
(ix) the sealed source unique identifiers, and
(x) where the sealed source is incorporated in a prescribed equipment:

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

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

(i) the date of receipt of a transfer or import,
(ii) the name of the shipper and licence number,
(iii) the name of the exporter,
(iv) the address of the shipper's or exporter's authorized location,
(v) the nuclear substance (radionuclide),
(vi) activity (radioactivity) (Bq) per sealed source on the reference date,
(vii) the reference date,
(viii) sealed source unique identifiers, and
(ix) where the sealed source is incorporated in a prescribed equipment:

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

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

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills	REGDOC-3.1.2	January 2018

Guidance

None provided.

5. SCA – SAFETY ANALYSIS

5.1 Safety Analysis Program

Licence Condition 5.1

The licensee shall implement and maintain a safety analysis program.

Preamble

Paragraph 3(1)(i) of the *General Nuclear Safety and Control Regulations* requires that a licence application contains information that includes a description and the results of any test, analysis or calculation performed to substantiate the information included in the application.

Paragraphs 6(c) and (d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contains information that includes a final safety analysis report demonstrating the adequacy of the design of the nuclear facility, and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

LC 5.1 requires that the licensee implement and maintain a process to identify and assess hazards and risks on an ongoing basis. This would include identifying and evaluating new or unforeseen risks that were not considered at the planning and design stages and updating previous risk assessments by replacing important assumptions with performance data. The results of this process will be used to set objectives and targets and to develop preventative and protective measures.

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

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Safety Analysis Reports	CPM-6-20	No
Final Safety Analysis report for the Nuclear Medicine Production Facility	IS/SR 1070 Z000	Yes
Final Safety Analysis Report for Cobalt Operations	IS/SR 1057 Z000	Yes
Final Safety Analysis Report for the Cobalt Pools	IN/SR 2638 Co60	Yes

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Management Systems Requirements for Nuclear Facilities	See LC 2.1	

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

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Wet storage of irradiated fuel and other radioactive materials	N292.1	2016
IAEA	Safety of Nuclear Fuel Cycle Facilities	NS-R-5	2014

6. SCA – PHYSICAL DESIGN

6.1 Design Program

Licence Condition 6.1

The licensee shall implement and maintain a design program.

Preamble

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

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

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

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

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

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

Compliance Verification Criteria

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

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

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	See LC 2.1	
Facility Description	SE-LIC-018	Yes

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Management Systems Requirements for Nuclear Facilities	See LC 2.1	

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Boiler, pressure vessel, and pressure piping code	B-51	2014

7. SCA – FITNESS FOR SERVICE

7.1 Fitness for Service Program

Licence Condition 7.1

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

Preamble

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

It is expected that the licensee will conduct routine maintenance, inspection and testing to ensure that the availability, reliability and effectiveness of facilities and equipment that may impact the health, safety and protection of the environment.

This condition requires that the licensee implement and maintain a maintenance program to ensure that the operating condition of systems, equipment and devices is preserved so that they can perform their function reliably. Accuracy is maintained by planning and carrying out periodic adjustments, calibrations, repairs and replacement.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	See LC 2.1	
Facilities Maintenance Master Plan	R-Master	No
Nordion Ottawa Site Instrument Maintenance and Calibration	CP-Master	No

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Fire Protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2013

1. The licensee shall carry out testing and maintenance sufficient to ensure the reliability and effectiveness of all structures, systems and components, and safety-related equipment.

2. The licensee shall determine the extent and frequency of preventive maintenance, testing, surveillance, and inspection of structures, systems and components through a systematic approach, following operating experience and best industry practices, taking into account :

   a) their importance to safety;
   b) their inherent reliability;
   c) their potential for degradation (based on operational and other relevant experience, research and vendor recommendations);
   d) the consequences of failure;
   e) results of condition monitoring; and
   f) the safety analysis.

3. The licensee shall establish, review and validate procedures for maintenance, testing, surveillance, and inspections.

4. Before any structure, system, equipment or component is removed from or returned to service, the licensee shall ensure full consideration and approval of the proposed reconfiguration, followed by a documented confirmation of its correct configuration and, where appropriate, functional testing.

5. Following any abnormal event due to which the safety functions and functional integrity of any structure, system or component may have been challenged, the licensee shall identify and revalidate the safety functions and carry out any necessary remedial actions, including inspection, testing, maintenance, and repair, as appropriate.

6. The licensee shall ensure that all items of equipment used for examinations and tests, together with their accessories, are qualified and calibrated before they are used.

7. The licensee shall properly identify all equipment in the calibration records, and shall establish a calibration program to ensure all equipment remains in calibrated state.

Guidance

None provided.

8. SCA – RADIATION PROTECTION

8.1 Radiation Protection Program

Licence Condition 8.1

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

Preamble

The *Radiation Protection Regulations* require that the licensee implement a radiation protection program for any activity that is authorized by the *Nuclear Safety and Control Act* or is present at a place where that activity is carried on. This program must ensure that doses to workers do not exceed prescribed dose limits and are kept ALARA, social and economic factors being taken into account.

Note that the regulatory dose limits to workers and the general public are explicitly provided in sections 13, 14 and 15 of the *Radiation Protection Regulations*.

Action levels are designed to alert licensees before regulatory dose limits are reached. By definition, if an action level is reached, a loss of control of some part of the associated radiation protection program may have occurred, and specific action is required, as defined in the *Radiation Protection Regulations*.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Radiation Protection Manual - Ottawa Site	SE-RP-001	Yes
Keeping Radiation Exposures and Doses as Low as Reasonably Achievable	SE-RP-002	Yes

1. When the licensee becomes aware that an action level has been reached, it shall notify the CNSC within seven days.

2. If an action level has been reached, the licensee shall file a final report with the CNSC within 21 days of becoming aware of the matter.

The licensee action levels are as follows:

Application	Action Level
Effective Dose	2 mSv/Report 15 mSv/year
Pregnant NEW	1 mSv/balance of pregnancy
Skin	30 mSv/Report 200 mSv/year
Extremity	50 mSv/Report 200 mSv/year
Non-NEW: Effective Dose	0.75 mSv/year

3. The licensee shall review and if necessary, revise the action levels at a frequency of once per five years to validate their effectiveness.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable" (ALARA)	G-129	October 2004
CNSC	Developing and Using Action Levels	G-228	March 2001
CNSC	Ascertaining and Recording Radiation Doses to Individuals	G-91	June 2003
CNSC	Making Changes to Dose-Related Information Filed with the National Dose Registry	S-260	October 2004

9. SCA – CONVENTIONAL HEALTH AND SAFETY

9.1 Conventional Health and Safety Program

Licence Condition 9.1

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

Preamble

Paragraph 3(f) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed worker health and safety policies and procedures.

The regulation of conventional health and safety is governed by the *Canada Labour Code Part II.*

The CNSC also has regulatory responsibilities for the oversight of the protection of the health and safety of workers.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management System for Safety	See LC 2.1	

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Selection, Use and Care of Respirators	Z94.4	2011

Guidance

None provided.

10. SCA – ENVIRONMENTAL PROTECTION

10.1 Environmental Protection Program

Licence Condition 10.1

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

Preamble

CNSC Regulatory Document 2.9.1: *Environmental Protection Policies, Programs and Procedures*, requires licensees to establish, implement and maintain an Environmental Management System that satisfies the requirements set by the Canadian Standards Association's (CSA) ISO 14001: 2004, *Environmental Management Systems – Requirements with Guidance for Use*.

Canadian Standards Association N288.1-14 *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities* provides guidelines and a methodology for calculating the upper limits (the Derived Release Limits) for the rate of release of radionuclides discharged into the atmosphere and surface waters, based on limiting radiation exposures to members of the public.

The releases of nuclear substances to the environment from the Nordion Class IB nuclear facility shall not exceed the Derived Release Limits (DRLs) and the sum of all fractional DRL releases must remain less than unity. Any exceedance indicates that the licensee is in non-compliance with the public dose limit of 1 mSv per year as per the *Radiation Protection Regulations*.

The Environmental Management System (EMS) captures the environmental protection policies, programs, and procedures of the licensed activity, and ensures that environmental protection is managed via an integrated set of documented activities that have the support and commitment of all levels of management within the licensee's organization. It shall be designed in a way that is appropriate to the nature, scale and environmental impacts of its activities with a commitment to pollution prevention and continuous improvement, such that environmental issues are identified, monitored, interpreted and acted upon in a manner that demonstrates "adequate precaution" to protect the environment and the health and safety of persons. Components of an EMS include Environmental Policy, Planning, Implementation and Operation, Checking, and Management Review.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Environmental Management System	SE-ENV-001	Yes
Environmental Protection Program	SE-ENV-015	Yes
Radiation Protection Manual – Ottawa site	See LC 8.1	

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Environmental Protection Policies, Programs and Procedures	REGDOC-2.9.1	1
CSA	Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	N288.4	2010
CSA	Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills	N288.5	2011
CSA	Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills	N288.6	2012

1. The licensee's environmental protection program shall ensure the control, monitoring and recording of releases of radionuclides to the environment from the nuclear facility such that the releases do not exceed the release limits specified in the table below:

Release Limits		
Radionuclide	DRL for Air Effluent at the Nordion Kanata Site (GBq/year)	DRL for Liquid Releases at the Nordion Kanata Site GBq/year
C-14	1.58E+06	1.10E+05
Co-60	2.50E+02	3.54E+01
Cs-137	3.02E+02	2.48E+01
I-123	4.59E+06	2.23E+08
I-125	9.52E+02	1.19E+03
I-131	6.86E+02	3.89E+02
In-111	8.38E+05	1.01E+04
Ir-192	1.66E+04	1.56E+03
Mo-99	5.17E+05	1.02E+04
Nb-95	3.88E+04	3.25E+03
Ni-63	2.37E+05	7.63E+02
Sr-82	9.35E+03	3.46E+02
Sr-85	3.34E+04	2.22E+03
Xe-131m	3.72E+09	n/a
Xe-133	6.77E+08	n/a
Xe-135	1.02E+08	n/a
Xe-135m	6.90E+07	n/a
Y-90	7.31E+05	3.50E+04
Zr-95	6.81E+03	2.06E+03
$\beta < 1$ MeV*		7.63E+02
$\beta > 1$ MeV*		3.50E+04

*The Ni-63 and Y-90 DRLs are used for $\beta < 1$ MeV and $\beta > 1$ MeV respectively since they are conservative among the pure beta-emitting radionuclides expected to be present in liquid releases.

2. The licensee environmental protection program shall have action levels for releases of radionuclides to the environment. The environmental action levels are :

Environmental Action Levels	
Process	**Air Effluent**
Mo-99	N/A
Co-60	1 MBq/ week
I-125	0.1 GBq/week
I-131	0.2 GBq/week
Xe-133	3000 GBq/week

3. When the licensee becomes aware that an action level has been reached, it shall notify the CNSC within seven days. If an action level has been reached, Nordion shall file a final report with the CNSC within 21 days of becoming aware of the matter.

4. The licensee shall review and, if necessary, revise the Action Levels at least once every five years to validate their effectiveness. The results of such reviews should be provided to CNSC staff.

5. The licensee's environmental protection program shall control and monitor the releases of hazardous substances.

6. The licensee's environmental protection program shall conform with the requirements of federal and provincial environmental regulations.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	N288.7	2015
CSA	Establishing and implementing action levels for releases to the environment from nuclear facilities	N288.8	2017

11. SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION

11.1 Emergency Management Program

Licence Condition 11.1

The licensee shall implement and maintain an emergency management program.

Preamble

As part of the emergency management program, the licensee shall prepare an onsite emergency plan and establish the necessary organizational structure for clear allocation of responsibilities, authorities, and arrangements for coordinating onsite activities and cooperating with external response organizations throughout all phases of an emergency.

An effective Emergency Preparedness (EP) program is based on the following four components:

1. Planning basis: an analysis of the risks and hazards that the EP program will address.

2. Emergency response plan and procedures: a comprehensive description of how a response will be executed, with accompanying support material.

3. Preparedness: the processes to ensure that people, equipment and infrastructure will be ready to execute a response according to the emergency response plan and procedures.

4. Program management: the management system aspects that assure the effectiveness of the EP program.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Emergency Response Plan	SE-ERP-002	Yes

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Nuclear Emergency Preparedness and Response	REGDOC-2.10.1	2017

1. The licensee will run a full-scale exercise at least once every three years that includes activation of the Emergency Response Plan.

Guidance

The licensee should test emergency measures listed in its emergency plan over a five-year period. The licensee's full-scale exercise, conducted at least once every three years, should involve any mutual aid partners identified in the emergency plan.

11.2 Fire Protection Program

Licence Condition 11.2

The licensee shall implement and maintain a fire protection program.

Preamble

Licensees shall prepare and implement a fire protection program (a set of planned, coordinated, controlled and documented activities) to ensure that the licensed activities do not result in an unreasonable risk to the health and safety of persons and to the environment due to fire and to ensure that the licensee is able to efficiently and effectively respond to emergency fire situations.

This SCA also includes the requirement for the licensee to have a fire protection program to minimize the risk to the health and safety of persons and to the environment from fire, through appropriate fire protection system design, fire safety analysis, fire safe operation and fire prevention.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Fire Safety Plan	SE-ERP-001	No
Fire Protection Program	SE-EHS-007	No

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Fire protection for Facilities that Process, Handle or Store Nuclear Substances	N393	2013

Guidance

None provided.

12. SCA – WASTE MANAGEMENT

12.1 Waste Management Program

Licence Condition 12.1

The licensee shall implement and maintain a waste management program.

Preamble

CNSC Regulatory Document REGDOC-2.11.1, *Waste Management, Volume III: Assessing the Long-Term Safety of Radioactive Waste Management* defines radioactive waste as any material (liquid, gaseous or solid) that contains a radioactive "nuclear substance," as defined in section 2 of the NSCA, and which the owner has declared to be waste. In addition to containing nuclear substances, radioactive waste may also contain non-radioactive "hazardous substances," as defined in section 1 of the *General Nuclear Safety and Control Regulations*.

Compliance Verification Criteria

1. The licensee shall
   a. ensure that the production, in terms of both rate and volume, of radioactive waste is minimized; and
   b. maintain adequate records of inventory and throughput of radioactive wastes produced.
2. The licensee shall ensure, to the extent reasonably practicable, that
   a. radioactive waste produced is accumulated in a controlled and contained manner such that it cannot escape from such control or containment; and
   b. no leak or escape of nuclear substances or radioactive wastes can occur without being detected.
3. The licensee shall identify the characteristics of all radioactive and hazardous wastes that are produced in the course of the licensed activities.
4. The licensee shall not produce, in the course of the licensed activities, waste for which there is no identified and approved treatment, or storage, or disposal facility.

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Radiation Protection Manual	See LC 8.1	

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CSA	General principles for the management of radioactive waste and irradiated fuel	N292.0	2014
CSA	Management of Low and Intermediate-Level Radioactive Waste	N292.3	2014
CNSC	Waste Management, Volume III: Assessing the Long-Term Safety of Radioactive Waste Management	REGDOC-2.11.1	2018

12.2 Decommissioning Strategy

Licence Condition 12.2

The licensee shall implement and maintain a decommissioning strategy.

Preamble

Paragraph 3(k) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including the proposed plan for the decommissioning of the nuclear facility or of the site.

This licence condition requires that the licensee maintain a decommissioning strategy.

A decommissioning strategy provides an overview of the proposed decommissioning approach that is sufficiently detailed to assure that the proposed approach is, in the light of existing knowledge, technically and financially feasible and appropriate in the interests of health, safety, security and the protection of the environment. The decommissioning strategy defines areas to be decommissioned and the general structure and sequence of the principle work packages. The decommissioning strategy forms the basis for establishing and maintaining a financial arrangement (financial guarantee) that will assure adequate funding of the decommissioning plan.

The decommissioning strategy and estimation of the cost of decommissioning were finalized in the document titled: “Nordion Preliminary Decommissioning Plan for Class IB Facility (KOB), April 2015”.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

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

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CSA	Decommissioning of Facilities Containing Nuclear Substances	N294	2009

1. The licensee shall maintain a decommissioning plan that reflects any changes in the site or nuclear facility. The decommissioning plan shall be revised at a minimum every five years or when required by the Commission.

2. The decommissioning plan was last revised and submitted to the CNSC in 2015. The licensee's next scheduled submission of the decommissioning plan is due to the CNSC in 2020.

Guidance

Guidance Publications

Source	Document Title	Document #	Effective Date
CNSC	Financial Guarantees for the Decommissioning of Licensed Activities	G-206	June 2000
CNSC	Decommissioning Planning for Licensed Activities	G-219	June 2000

13. SCA – SECURITY

13.1 Security Program

Licence Condition 13.1

The licensee shall implement and maintain a security program.

Preamble

Paragraphs 3(1)(g) and (h) of the *General Nuclear Safety and Control Regulations* require that a licence application contain information including the proposed measures to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information.

Paragraph 6(l) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information including he proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts.

Paragraphs 12(1)(c), (g), (h) and (j) of the *General Nuclear Safety and Control Regulations*, requires that the licensee take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security, implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, implement measures for alerting the licensee to acts of sabotage anywhere at the site of the licensed activity and instruct the workers on the physical security program at the site of the licensed activity and on their obligations under that program.

For a licensee that possesses or transfers sealed sources, a security program includes implementation and maintenance security measures for sealed sources.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Nordion Security Plan (PROTECTED)	n/a	No
Nordion General Canadian Transportation Security Plan (PROTECTED)	n/a	Yes

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Security of Nuclear Substances: Sealed Sources	REGDOC-2.12.3	2013

1. The licensee shall maintain the operation, design and analysis provisions specified in the security plan, including that they ensure adequate engineered safety barriers are in place for protection against malevolent acts.

2. Technical and administrative security measures shall be documented by the licensee in a site security plan.

3. The licensee shall implement and maintain a facility security plan, and ensure it is designated as prescribed information. The site security plan must be reviewed by the licensee when changes occur within the licensed facility and/or to address an increased threat level and updated if required.

4. The licensee shall implement satisfactory security measures to prevent the loss, sabotage, illegal use, illegal possession, or illegal removal of sealed sources while under licensee's control, including while the sources are in storage, transport or being stored during transportation.

Guidance

CNSC Regulatory Document 2.12.3, *Security of Nuclear Substances: Sealed Sources* sets out the minimum security measures that licensees must implement to prevent the loss, sabotage, illegal use, illegal possession, or illegal removal of sealed sources during their entire lifecycle, including while the sources are in storage, transport or being stored during transportation.

This document also provides information and guidance on how to meet the minimum security measures, including measures related to transport vehicles, containers and security plans. This document applies only to the transport by road within Canada (there are other instruments and technical instructions that regulate the safe transport of dangerous goods by sea, air and rail).

Guidance Publications

Source	Document Title	Document #	Effective Date
IAEA	Security in Transport of Radioactive Material	Nuclear Security Series # 9	2008
IAEA	Security of Radioactive Material and Associated Facilities	Nuclear Security Series # 11	2009
IAEA	Nuclear Security Recommendation on Radioactive Material and Associated Facilities	Nuclear Security Series # 14	2011
IAEA	Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control	Nuclear Security Series # 15	2011

14. SCA – SAFEGUARDS AND NON-PROLIFERATION

14.1 Safeguards and Non-Proliferation

Licence Condition 14.1

The licensee shall implement and maintain a safeguards program.

Preamble

The *General Nuclear Safety and Control Regulations* (GNSCR) require the licensee to take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement, and GNSCR subsections 30(1) and 30(2) defines reporting requirements for safeguards events.

Paragraph 6 (f) of the *Class I Nuclear Facilities Regulations* require that a licence application contain information on the licensee's proposed measures to facilitate Canada's compliance with any applicable safeguards agreement.

This LC requires that the licensee implement and maintain a safeguards program. Safeguards is a system of inspection and other verification activities undertaken by the International Atomic Energy Agency (IAEA) in order to evaluate a Member State's compliance with its obligations pursuant to its safeguards agreements with the IAEA.

Canada has entered into a Safeguards Agreement and an Additional Protocol (hereafter referred to as "safeguards agreements") with the IAEA pursuant to its obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons* (INFCIRC/140). The objective of the Canada-IAEA safeguards agreements is for the IAEA to provide assurance on an annual basis to Canada and to the international community that all declared nuclear materials are in peaceful, non-explosive uses and that there is no indication of undeclared nuclear materials or activities. This conclusion confirms that Canada is in compliance with its obligations under the following Canada-IAEA safeguards agreements:

- *Agreement between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons*; and

- *Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons.*

These are reproduced in information circulars INFCIRC/164, and INFCIRC/164/Add. 1.

In addition, the import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations*, require separate authorization from the CNSC, consistent with subsection 3(2) of the GNSCR.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Management of Safeguarded Material	SE-LIC-016	No

Licensing Basis Publications

Source	Document Title	Document #	Revision #
CNSC	Safeguards and Nuclear Material Accountancy	REGDOC-2.13.1	2018

The licensee shall implement and maintain a safeguards program in accordance with the requirements set out in REGDOC-2.13.1, *Safeguards and Nuclear Materials Accountancy*. According to the criteria set out in that document, Nordion is currently classified as a Location Outside Facility and must comply with the appropriate requirements in REGDOC-2.13.1. Should changes to conditions on the licensed site necessitate a change in safeguards classification, changes to Nordion's safeguards program may be required.

Guidance

None provided.

15. SCA – PACKAGING AND TRANSPORT

15.1 Packaging and Transport Program

Licence Condition 15.1

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

Preamble

Paragraph 6(e) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information on the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.

Every person who transports radioactive material, or requires it to be transported, shall act in accordance with the requirements of the *Transportation of Dangerous Goods Regulations* and the *Packaging and Transport of Nuclear Substances Regulations, 2015*.

The *Packaging and Transport of Nuclear Substances Regulations, 2015* and the *Transportation of Dangerous Goods Regulations* provide specific requirements for the design of transport packages, the packaging, marking and labeling of packages and the handling and transport of nuclear substances.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Document Title	Document #	Prior Notification
Transport of Radioactive Material	SE-OP-036	No
Receiving Radioactive Material	SE-OP-015	No
Shipping Radioactive Material	SE-OP-014	No

Guidance

None provided.

APPENDIX A – Control of the LCH

This appendix describes the administrative processes used to control the LCH, including LCH change control procedure, change review criteria, dispute resolution, records management and reporting to the Commission.

A.1 LCH Change Control Process

Only the following individual has the authority to make changes to the LCH.

- the Director, Nuclear Processing Facilities Division

A change control process is applied to the LCH to ensure that:

1. Preparation and use of the LCH are properly controlled.

2. All referenced documents are correctly identified and maintained.

3. Changes are conducted in accordance with CNSC Regulatory Policy P-299, *Regulatory Fundamentals.*

4. Procedures for modifying the LCH are followed.

The licensing basis is defined at licence issuance/renewal. A request to change this LCH can be initiated by either CNSC staff or the licensee. The licensee will be consulted on any changes to the LCH that are proposed by CNSC staff.

The Director, Nuclear Processing Facilities Division, may consent to the requested change only once they have determined that the proposed change will not change the objective of the licensing basis.

The following are examples of proposed changes that require a change to the LCH or a document referenced in the LCH:

1. Changes to the design and/or operation of facilities, processes and equipment.

2. Clarification of the compliance verification criteria (CVC) text to achieve a common understanding between the licensee and CNSC staff.

3. Changes to the codes, standards and regulatory documents which are identified as compliance verification criteria

4. Changes to guidance such as inclusion or amendment of CNSC regulatory guidance documents or recommendations

CNSC staff will take the following steps to update the LCH:

1. The CNSC receives or initiates a notification of proposed change.
2. Initiate a change request using the LCH Change Assessment Form (e-Doc 5009501).
3. Complete a technical review of the proposed change, if required.
4. Consult the licensee. In case of disagreement on the proposed change, the dispute resolution process outlined in section A.3 will apply.
5. Obtain consent for changes from both parties.
6. Update the LCH in accordance with the agreed amendment(s) and send the updated document to the parties identified on the distribution list (see section A.5).

If the change involves the revision of a Written Notification (WN) document, NPFD will also update the registry it uses to track the version history of the WN documents.

A.2 Document Control and Approval/Consent

Document Control and Oversight

Following CNSC staff's acceptance of version control documents, the CVC found in the LCH may require updates. The Director, Nuclear Processing Facilities Division, has the authority to make the changes to the CVC as long as the changes remain within the licensing basis.

The CNSC uses a risk-informed process to determine the type of regulatory oversight that is appropriate for each licensee document in the licensing basis.

CNSC Review Criteria Related to Document Changes and Approvals/Consent

For the acceptance of document changes described above, CNSC staff verify if the licensee submission includes the appropriate level of information with regards to the proposed changes or action, to the extent relevant:

- a summary description;
- an indication of the duration (temporary or permanent);
- a justification;
- any relevant supporting documentation;
- an evaluation of the impact on health, safety, security, the environment and Canada's international obligations; and
- an evaluation to determine if the resultant effects remain within the scope of the licensing basis.

The CNSC then assesses whether the following general criteria would be met for the proposed change/action:

- the proposed change or action will be made or done in accordance with the licensee's management system and change control processes, applicable design guides, design requirements, standards, operating documentation, regulatory documents, applicable safety principles and applicable safeguards agreement;
- following the proposed change or action, the licensee remains in compliance with the requirements set out in the applicable laws, regulations and LCs, including appendices of the licence;
- the proposed change or action will provide the equivalent level of safety or is in the safe direction.

- following the proposed change or action:
  - the licensee remains qualified to carry out the licensed activity;
  - the licensee has adequate provision for the protection of the health and safety of persons, protection of the environment, maintenance of national security and measures required to implement international obligations to which Canada has agreed; and
  - the licensed activity remains within the limits defined by the licensing basis.

(The above criteria can also apply when CNSC staff review a notification of a licensee change that was already made.)

A.3 Dispute Resolution

In case of a dispute between the licensee and CNSC staff regarding changes to the LCH, both parties will meet to discuss the dispute and reach a decision on the path forward. The decision, including its rationale will be documented. If any party is not satisfied with the decision, the resolution process will proceed up to the Director General or Executive Vice-President and Chief Regulatory Operations Officer level. If any party is still not satisfied with the decision, the issue will be brought to the attention of the Commission at a Commission meeting or hearing. The decision made by the Commission will be final.

A.4 Records Management

In order to track changes to the LCH, the document change request and accompanying documentation will be archived in records and referenced in the revision history of the LCH. Electronic communication related to the change, such as comments from reviewers will be stored in the CNSC Information Management System.

A.5 Distribution

NPFD staff will distribute a copy of the updated version of the LCH to the following parties:

- Project Officer, Nuclear Processing and Facilities Division
- Nordion (Canada) Inc.

A.6 Reporting to the Commission

CNSC staff will report on the changes made to the LCH during the previous year in their annual report to the Commission.

APPENDIX B – Glossary of Terms

Acronyms

The following is the list of acronyms used in this document:

AL	Action Level
ALARA	As Low As Reasonably Achievable, social and economic factors taken into consideration
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association
CVC	Compliance Verification Criteria
DNCFR	Directorate of Nuclear Cycle and Facilities Regulation
DRL	Derived Release Limits
EP	Environmental Protection
EMS	Environmental Management System
FG	Financial Guarantee
GNSCR	*General Nuclear Safety and Control Regulations*
IAEA	International Atomic Energy Agency
LC	Licence Condition
LCH	Licence Conditions Handbook
NPFD	Nuclear Processing and Facilities Division
NSCA	*Nuclear Safety and Control Act*
RP	Radiation Protection
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SSC	Structures, systems and components
WN	Written Notification

APPENDIX C – Documents in support of Licence Application Referenced in LCH

Documents submitted by the licensee in support of the licence application and ongoing licensing requirements that are referenced within the LCH.

Notes:

No = Notification Required, as described in LC 1.2.

Yes = Prior Notification, as described in LC 1.2.

e-Doc 4768292 maintains document version control of the documents referenced below.

Document Title	Document #	Notification Requirement	Licence Conditions
Facility Description	SE-LIC-018	Yes	1.2, 6.1
Public Information and Disclosure Program	SE-LIC-010	No	1.4
Management System for Safety	SE-LIC-001	Yes	2.1, 4.1, 6.1, 7.1, 9.1
Radiation Surveyors and Monitors On-the-Job Training Program	SE-TRN-001	No	3.1
Compliance Environment Health and Radiation Safety Training	SE-TRN-003	No	3.1
Systematic Approach to Training System	SE-TRN-006	No	3.1
Cobalt Monitor On-the-Job Training Program	CO-MD OP-0028	No	3.1
EHS Committee Approved Activity Limits for Facilities	SE-LIC-007	No	4.1
Sealed Source Reporting	SE-OP-079	No	4.1, 4.2
Radioactive Material Inventory	SE-LIC-015	No	4.1
Investigations	SE-RP-003	No	4.2

Document Title	Document #	Notification Requirement	Licence Conditions
EHS Regulatory Reporting and Notifications	SE-EHS-009	No	4.2
Safety Analysis Reports	CPM-6-20	No	5.1
Final Safety Analysis report for the Nuclear Medicine Production Facility	IS/SR 1070 Z000	Yes	5.1
Final Safety Analysis Report for Cobalt Operations	IS/SR 1057 Z000	Yes	5.1
Cobalt Pools Safety Analysis Report	IN/SR 2638 Co60	Yes	5.1
Facilities Maintenance Master Plan	R-Master	No	7.1
Nordion Ottawa Site Instrument Maintenance and Calibration	CP-Master	No	7.1
Radiation Protection Manual	SE-RP-001	Yes	8.1, 10.1, 12.1
Keeping Radiation Exposures and Doses as Low as reasonably Achievable	SE-RP-002	Yes	8.1
Environmental Management System	SE-ENV-001	Yes	10.1
Nordion Environmental Protection Program	SE-ENV-015	Yes	10.1
Emergency Response Plan	SE-ERP-002	Yes	11.1
Fire Safety Plan	SE-ERP-001	No	11.2
Fire Protection Program	SE-EHS-007	No	11.2
Preliminary Decommissioning Plan	SE-LIC-009	Yes	12.2
Nordion Security Plan (PROTECTED)	N/A	Yes	13.1
Nordion General Canadian Transportation Security Plan (PROTECTED)	N/A	Yes	13.1

Document Title	Document #	Notification Requirement	Licence Conditions
Management of Safeguarded Material	SE-LIC-016	No	14.1
Transport of Radioactive Material	SE-OP-036	No	15.1
Receiving Radioactive Material	SE-OP-015	No	15.1
Shipping Radioactive Material	SE-OP-014	No	15.1

APPENDIX D – List of Documents used as Guidance or Criteria

Document #	Document Title	L.C.
G-206	Financial Guarantees for the Decommissioning of Licensed Activities	1.3, 12.2
G-219	Decommissioning Planning for Licensed Activities	1.3, 12.2
CSA N294	Decommissioning of Facilities Containing Nuclear Substances	1.3, 12.2
RD/GD-99.3	Public Information and Disclosure	1.4
REGDOC 3.2.1	Public Information and Disclosure	1.4
CSA N286-12	Management systems requirements for nuclear facilities	2.1, 5.1, 6.1
REGDOC 2.2.2	Personnel Training	3.1
CSA N393	Fire protection for Facilities that Process, Handle or Store Nuclear Substances	4.1, 7.1, 11.2
IRC-10NFC	National Fire Code of Canada	4.1
IRC-10NBC	National Building Code of Canada	4.1
REGDOC-3.1.2	Reporting Requirements for Non-Power Reactor: Class I Facilities and Uranium Mines and Mills	4.2
CSA N292.1	Wet storage of irradiated fuel and other radioactive materials	5.1
IAEA NS-R-5	Safety of Nuclear Fuel Cycle Facilities	5.1
CSA B-51	Boiler, pressure vessel, and pressure piping code	6.1

Document #	Document Title	L.C.
G-129	Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA	8.1
G-228	Regulatory Guide, "Developing and Using Action Levels"	8.1
G-91	Ascertaining and Recording Radiation Doses to Individuals	8.1
S-260	Making Changes to Dose-Related Information Filed with the National Dose Registry	8.1
CSA Z94.4	Selection and Use of Respirators	9.1
REGDOC 2.9.1	Environmental Protection Policies, Programs and Procedures	10.1
CSA N288.4	Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	10.1
CSA N288.5	Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills	10.1
CSA N288.6	Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills	10.1
CSA N288.7	Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	10.1
CSA N288.8	Establishing and implementing action levels for releases to the environment from nuclear facilities	10.1
REGDOC 2.10.1	Nuclear Emergency Preparedness and Response	11.1
REGDOC-2.11.1	Waste Management, Volume II: Assessing the Long-Term Safety of Radioactive Waste Management	12.1

Document #	Document Title	L.C.
CSA N292.0	General principles for the management of radioactive waste and irradiated fuel	12.1
CSA N292.3	Management of Low and Intermediate-Level Radioactive Waste	12.1
REGDOC 2.12.3	Security of Nuclear Substances Sealed Sources	13.1
IAEA Nuclear Security Series # 9	Security in Transport of Radioactive Material	13.1
IAEA Nuclear Security Series # 11	Security of Radioactive Material and Associated Facilities	13.1
IAEA Nuclear Security Series # 14	Nuclear Security Recommendation on Radioactive Material and Associated Facilities	13.1
IAEA Nuclear Security Series # 15	Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control	13.1
REGDOC-2.13.1	Safeguards and Nuclear Material Accountancy	14.1
P-299	Regulatory Fundamentals	Appendix A

CURRENT LICENCE

e-doc 4180903 (Word)

e-doc 4741253 (PDF)

PDF Ref: e-Doc 4741253
Word Ref: e-Doc 4180903
File / Dossier: 2.02

CLASS 1B NUCLEAR SUBSTANCE PROCESSING FACILITY OPERATING LICENCE

NORDION (CANADA) INC.

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I) LICENCE NUMBER: NSPFOL-11A.00/2025

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

Nordion (Canada) Incorporated
891613-6
447 March Road
Ottawa, Ontario
K2K 1X8

III) LICENCE PERIOD: This licence is valid from **November 1, 2015** to **October 31, 2025,** unless otherwise suspended, amended, revoked, replaced or transferred.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

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

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

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

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

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

V) EXPLANATORY NOTES:

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

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

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

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

VI) CONDITIONS:

1. GENERAL

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

(i) the regulatory requirements set out in the applicable laws and regulations;
(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence;
(iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

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

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

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

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

2. MANAGEMENT SYSTEM

2.1 The licensee shall implement and maintain a management system.

3. HUMAN PERFORMANCE MANAGEMENT

3.1 The licensee shall implement and maintain a training program.

4. OPERATING PERFORMANCE

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

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

5. SAFETY ANALYSIS

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

6. PHYSICAL DESIGN

6.1 The licensee shall implement and maintain a design program.

7. FITNESS FOR SERVICE

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

8. RADIATION PROTECTION

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

9. CONVENTIONAL HEALTH AND SAFETY

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

10. ENVIRONMENTAL PROTECTION

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

11. EMERGENCY MANAGEMENT AND FIRE PROTECTION

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

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

12. WASTE MANAGEMENT

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

12.2 The licensee shall implement and maintain a decommissioning strategy.

13. SECURITY

13.1 The licensee shall implement and maintain a security program.

14. SAFEGUARDS AND NON-PROLIFERATION

14.1 The licensee shall implement and maintain a safeguards program.

15. PACKAGING AND TRANSPORT

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

SIGNED at OTTAWA, this 28 day of September, 2015

M. Binder

Michael Binder, President
on behalf of the Canadian Nuclear Safety Commission