

Directorate of Nuclear Cycle and Facilities Regulation

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December 22, 2015

Mr. Stephane Levesque President SRB Technologies (Canada) Inc. 320-140 Boundary Road Pembroke, Ontario K8A 6W5

Subject:

SRB Technologies (Canada) INC. Licence Conditions Handbook (LCH) Rev

1, to accompany NSPFOL-13.00/2022.

Dear Mr. Levesque:

Please find enclosed SRB Technologies (Canada) INC. LCH Revision 1. It has been revised to include changes that reflect compliance with CSA N393 Fire protection for Facilities that Process, Handle or Store Nuclear Substances and REGDOC 2.10.1. *Nuclear Emergency Preparedness and Response*.

If you have any comments or questions on this letter please do not hesitate to contact me.

Yours truly,

Jennifer Campbell

Project Officer

Nuclear Processing Facilities Division

c.c.: M. Rinker, J. MacDonald, R. Fitzpatrick

Reference:

1. Licence Conditions Handbook, SRB Technologies Inc. Nuclear Substance Processing Facility Operating Licence, Revision 0 (e-Doc 4540023).





e-Doc 4869492 (Word) e-Doc 4899130 (PDF)

Licence Conditions Handbook

SRB TECHNOLOGIES (CANADA) INC. Nuclear Substance Processing Facility Operating Licence (NSPFOL)

NSPFOL-13.00/2022

(Effective: December 22, 2015)

Revision 1





Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	Prepared by: Jennifer Campbell, NPFD	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 1	Page 2 of 62

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Project Officer

Nuclear Processing Facilities

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Date

Approved by:

M. Rinker

Director,

Nuclear Processing Facilities

Division

Date

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	Prepared by: Jennifer Campbell, NPFD	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 1	Page 3 of 62

Revision History:

Effective Date	Revit	ECH E-BOCS 4	Section(s)	Description of the Changes	DCR Eist E-DOCS #
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		4024021 (FDI')		NSPFOL-13.00/2022	
2015-12-22	1	4869492	Section	Added CSA N393 to section 4.1	4852322
		(Word)	4.1	CVC numbers 5 and 6.	
		4899130 (PDF)			
2015-12-22	1	4869492	Section	Removed Transition plan	4852322
		(Word)	11.2	provisions for transition to	
		4899130 (PDF)		compliance with CSA N393	
2015-12-22	1	4869492	Section	Removed transitional provisions for	4872504
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		4899130 (PDF)		Nuclear Emergency Preparedness	
				and Response	
2015-12-22	1	4869492	Section	Text updated, replaced	
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		4899130 (PDF)		"Recommendations and Guidance"	

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	•	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 4 of 62

Table of Contents

PA	RT I: INTRODUCTION7
1.	DESCRIPTION OF THE SECTIONS IN THE LICENCE7
1.1	Section I: Licence Number
1.2	Section II: Licensee
1.3	Section III: Licence Period8
1.4	Section IV: Licensed Activities8
1.5	Section V: Explanatory Notes9
1.6	Section VI: Conditions9
PA	RT II: FRAMEWORK FOR EACH CONDITION10
1.	GENERAL LICENCE CONDITIONS11
1.1	Licensing Basis for Licensed Activities
1.2	Notification of Change12
1.3	Financial Guarantee
1.4	Public Information and Disclosure 15
2.	SCA-MANAGEMENT SYSTEM16
2.1	Management System
3.	SCA- HUMAN PERFORMANCE MANAGEMENT23
3.1	Human Performance Management23
4.	SCA-OPERATING PERFORMANCE24
4.1	Operations Program24
4.2	Reporting Requirements27
5.	SCA – SAFETY ANALYSIS28
5.1	Safety Analysis Program29

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	Prepared by: Jennifer Campbell, NPFD	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 5 of 62

6. SCA - PHYSICAL DESIGN	30
6.1 Design Program	30
7. SCA-FITNESS FOR SERVICE	31
7.1 Fitness for Service Program	31
8. SCA-RADIATION PROTECTION	33
8.1 Radiation Protection Program	33
9. SCA - CONVENTIONAL HEALTH AND SAFETY	36
9.1 Conventional Health and Safety Program	36
10. SCA - ENVIRONMENTAL PROTECTION	37
10.1 Environmental Protection Program	37
11. SCA-EMERGENCY MANAGEMENT AND FIRE PROTECTION	43
11.1 Emergency Preparedness Program	
12. SCA - WASTE MANAGEMENT	45
12.1 Waste Management Program 12.2 Decommissioning Strategy	45
13. SCA- SECURITY	48
13.1 Security Program	48
14. SCA-PACKAGING AND TRANSPORT	
	49

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	9492 Word Jennifer Cam	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 6 of 62

A.1	LCH Change Control Process	52
A.2	Document Control and Approval/Consent	54
A.3	Dispute Resolution	56
A.4	Records Management	56
A.5	Distribution	56
A.6	Reporting to the Commission	56
	PENDIX B - Glossary of Terms PENDIX C – Documents in support of Licence Application	
7 1 1	ETVENTA C Documents in support of Electice reprince to the support of Electic reprince to the support of E	
APP	ENDIX D - List of Documents used as Guidance or Criteria	60
APP	PENDIX E – Environmental Release Limits	62

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	Prepared by: Jennifer Campbell, NPFD	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 7 of 62

PART I: INTRODUCTION

The general purpose of the Licence Conditions Handbook (LCH) is identify and clarify the regulatory requirements and other relevant parts of the licensing basis for each licence condition. This is to help ensure that the licensee maintains facility operation in accordance with the licensing basis for the facility and the intent of the licence.

The LCH is structured in two parts:

- Part I provides an overview, which introduces the LCH and describes the sections of the operating licence
- Part II provides the compliance framework for each licence condition (LC) set out in the operating licence

The LCH is intended for use by both the licensee and CNSC staff and should be read in conjunction with licence NSPFOL-13.00/2022. The LCH does not introduce new requirements but provides explanation on how to meet licence conditions and regulatory requirements. The compliance framework (Part II) identifies the compliance verification criteria (CVC) the Canadian Nuclear Safety Commission (CNSC) staff use to verify licensee compliance with each LC listed in the operating licence. The LCH contains operational limits and applicable versions of documents. Furthermore, the LCH provides non-mandatory recommendations and guidance on how to achieve compliance with the conditions and criteria. The LCH also establishes provisions for dispute resolution found in the appendix.

1. DESCRIPTION OF THE SECTIONS IN THE LICENCE

1.1 Section I: Licence Number

The alpha numeric expression NSPFOL-13.00/2022 stems from the CNSC standard convention for identifying licences. The following table provides a description of each identifier used in the expression.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	Prepared by: Jennifer Campbell, NPFD	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 8 of 62

Identifier	Description
NSPFOL	Nuclear Substance Processing Facility Operating Licence
13	Refers to facility name (13 = SRB Technologies (Canada) Inc.)
00	Licence version number (00 = Initial licence, 01 = Amendment No. 1, etc.)
2022	Expiration year

1.2 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:

SRB Technologies (Canada) Incorporated 320-140 Boundary Road Pembroke, Ontario K8A 6W5

1.3 Section III: Licence Period

The duration for which the licence is valid, which in this case, the licence period for NSPFOL-13.00/2022 is from July 1, 2015 to June 30, 2022, unless otherwise suspended, amended, revoked, or replaced.

1.4 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).

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	1	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 9 of 62

This licence authorizes the licensee to:

- (a) operate a Class 1B Facility, comprising of a tritium processing facility, at the location referred to in Section II of this licence (hereinafter "the facility") for the purposes of manufacturing radiation devices;
- (b) produce, possess, transfer, service and use, radiation devices arising from the activities described in (a);
- (c) possess, transfer, use, process, manage, store and dispose nuclear substances that are required for, associated with, or arise from the activities described in (a);
- (d) the possession of tritium up to a limit of 6000 terabecquerels of tritium in any form;
- (e) possess, and use prescribed information that is required for, associated with, or arise from the activities described in (a).

<u>Facility Location</u>: The SRB facility is located at, 320 Boundary Road, Suite 140, Pembroke, Ontario, further defined in drawing "SRB Technologies (Canada) Inc. Building Floor Plan September 18, 2014 (e-Doc 4522521).

1.5 Section V: Explanatory Notes

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

For licence NSPFOL-13.00/2022 there are no hold points in the licence therefore delegation of authority is not required.

1.6 Section VI: Conditions

This section of the licence lists the LCs.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 10 of 62

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 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.

<u>Preamble:</u> Contains background history and/or the regulatory context related to the LC and provides, where applicable, the related regulatory requirements contained in the NSCA and associated regulations.

<u>Compliance Verification Criteria:</u> This section identifies the 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 written notification documents referenced within this LCH. Current versions of written notification documents are tracked and can be accessed through the document "SRB Written Notification Tracking Sheet" e-Doc 4472953. This document is controlled by the Nuclear Processing Facilities Division (NPFD).

Recommendations and Guidance: While recommendations and guidance are non-mandatory, this section refers to industry best practices, CNSC documents and other documents that provide recommendations and guidance associated with protection of the environment, health and safety, and other conditions of the NSCA and its associated Regulations. Recommendations and guidance provide acceptable means to meet requirements; however, licensees may propose alternate ways to meet the licence condition.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 11 of 62

1. GENERAL LICENCE CONDITIONS

1.1 Licensing Basis for Licensed Activities

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 CNSC (hereinafter "the Commission").

Preamble

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity, thus establishing the basis for the CNSC compliance program with respect to that regulated facility or activity.

One part 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. Safety and control measures 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 conform to, and/or implement, all these safety and control measures.

Relevant documents that require version control.

Nomes	Document Title	Lawmment #	Revision#
CNSC	Licensing Basis Objective and Definition	INFO-0795	January 2010

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 12 of 62

This licence condition 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 licence condition does not explicitly prohibit changes (such as in management or operation) with a neutral or positive impact on safety. This means that changes shall be within 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 do not impact the licensing basis; see licence condition 1.2. If the licensing basis is proposed to be changed the Commission would be the authority for approval.

Appendix C of the LCH lists the key documents which are deemed to contain the safety and control measures that are considered to form item (iii) of the licensing basis.

In the event of any conflict or inconsistency between LCs or any documents referenced in the LCH, SRB shall direct the conflict or inconsistency to the CNSC for resolution (see Appendix A, section A.3).

The licensee and CNSC staff will discuss any identified conflicts and inconsistencies to ensure a common understanding of CNSC expectations. The resolution of these conflicts and inconsistencies will be documented by CNSC staff and acknowledged by the licensee.

Compliance Verification Criteria

Compliance verification criteria are identified throughout the LCH.

Recommendations and Guidance

There are no recommendations or guidance.

1.2 Notification of Change

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.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 13 of 62

Preamble

The licensee documents that require written notification are primarily selected from the set of documents supporting the application and which describe the licensee's safety and control measures. If the licensee identifies that changes made to documents not listed in the LCH and may require written notification; the licensee is to follow the written notification process.

Tables under each LC in the LCH identify the documents (if any) requiring written notification of change. Appendix A describes some of the general criteria that CNSC staff will use to assess changes to documents subject to the written notification requirement.

CNSC staff will track the version history of all revisions cited in the LCH. A spreadsheet list controlled by the Nuclear Processing Facilities Division entitled "SRB Written Notification Tracking Sheet", (e-Doc 4472953) has been created for this purpose.

Compliance Verification Criteria

- 1. The licensee shall ensure that adequate oversight of document changes is taking place such that it is clear that requirements of this licence condition are being met. Documents that require written notification of change are identified in this LCH under the most relevant LC.
- 2. When the licensee makes any changes to the documents identified in each SCA, CNSC written notification is required as follows.

Definition	Description
"N"	written notification is required as the revised document comes into effect.
"Y"	written notification prior to planned implementation.

3. For documents identified as requiring prior written notification, the licensee is to submit the proposed changes 30 days prior to planned implementation. However there are provisions for using judgment and basing the timing of the advance notice on the extent or significance of the changes being made. The written notification shall include a description of the change and a summary explanation of how the changed document remains within the licensing basis.

Recommendations and Guidance

There are no recommendations and guidance associated with this licence condition.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 14 of 62

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.

This LC 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. If the preliminary decommissioning plan is revised and significantly impacts the FG, the expectation is that the FG is revised and submitted to the Commission for acceptance.

SRB has provided a *Preliminary Decommissioning Plan* and an associated cost estimate. From its assessment, CNSC staff deemed both documents to be satisfactory. As a FG Instrument SRB Technologies continue to use an Escrow Account and proposed an additional payment schedule (e-Doc 4657138). The Commission has accepted the cost estimate for decommissioning, the financial instrument and the additional payment schedule.

Compliance Verification Criteria

- 1. The licensee shall maintain in effect a financial guarantee for decommissioning acceptable to the Commission or a person authorized by the Commission which shall remain valid and in effect and adequate to fund the activities described in the preliminary decommissioning plan.
- 2. The licensee shall make payments to the escrow account in accordance with the payment schedule that the Commission has approved and is given in the Table below.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 15 of 6

Financial Guarantee Payment Schedules

Payment Due date	Decommissioning Escrow Account Deposits
October 31, 2015	17,002.00
April 30, 2016	17,002.00
October 31, 2016	17,002.00
April 30, 2017	17,002.00
October 31, 2017	17,002.00
April 30, 2018	17,002.00

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

Recommendations and Guidance

CNSC Regulatory Document G-206, Financial Guarantees for the Decommissioning of Licensed Activities, sets out guidance on the development of financial guarantees for licensed facilities and activities.

CNSC regulatory document G-219 *Decommissioning Planning for Licensed Activities* provides guidance regarding the preparation of decommissioning plans for activities licensed by the CNSC. It also provides the basis for calculating the financial guarantees discussed in the regulatory document G-206.

CSA standard N294-09 *Decommissioning of Facilities Containing Nuclear Substances* provides direction on the decommissioning of licensed facilities and specifies requirements for the planning, preparation, execution and completion of decommissioning.

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 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.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 16 of 62

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 include 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

Relevant documents that require version control.

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

 The licensee shall implement and maintain a public information and disclosure program in accordance with CNSC regulatory document RD/GD-99.3 Public Information and Disclosure.

In accordance with licence condition 1.2, the following document requires written notification of changes made.

Fource	Document Title	Print Notification?
SRB	Public Information Program	N

Recommendations and Guidance

There are no recommendations or guidance

2. SCA-MANAGEMENT SYSTEM

The Safety and Control Area "Management System" covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives and fosters a healthy safety culture.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 17 of 6

2.1 Management System

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 related to the applicant's organizational management structure including the internal allocation of functions, responsibilities and authority.

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

A quality assurance program 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 quality regardless of the delegation of any work or responsibilities to other organizations

Compliance Verification Criteria

Relevant documents that require version control.

Samer	Document Litte	Programment #	Revition =
CSA	Management systems requirements for nuclear facilities	N286	2012

Transition plan

The licensee shall be in compliance with CSA standard N286-12, "Management systems requirements for nuclear facilities" by December 31, 2016.

The following compliance verification criteria will be used during the transition period. These requirements apply to safety related activities, components, systems, structures associated with the nuclear facility, procurement, design, and operations.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		ared by: umpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 18 of 62

Quality Assurance Program - General

- 1. The applicant/licensee identifies clearly in the quality assurance program documentation for the facility, the safety-related systems, structures, and activities to which the program is to be applied.
- 2. Although the applicant/licensee may delegate work or responsibilities to other organizations, the responsibility for assuring quality remains with the applicant/licensee.
- 3. The applicant/licensee hereinafter referred to as *the organization* has a quality assurance program that controls work activities from the planning stages on to completion. The quality assurance program covers both the control of activities at the working level, and at the management level. The latter provides the oversight needed to provide corporate direction and maintain overall accountability, and to ensure that communication between individuals and organizations is effective and in the interest of quality and safety.
- 4. The extent of application of the quality assurance program takes full account of the safety significance of the activity, system, component, or structure. The rationale or the method for determining the extent is covered in *the organization's* quality assurance documentation.

Program Requirements

- 1. Program Definition; The required quality and the means of achieving it will be defined.
 - The quality assurance program is a major part of *the organization's* management system. It provides the means of controlling those activities that affect quality and safety. The scope of the program and what it applies to are clearly defined. The program documentation describes policies and consequent systematic processes that are issued by *the organization's* senior management. These enable the requirements that are stated below to be met.
- 2. Policy; A policy statement will be issued committing all units of the organization to the program.
 - A written policy statement certifying the authority of the program, and *the organization's* commitment to its implementation and effectiveness, is issued by senior management who is accountable for ensuring compliance.
- 3. Organization and Responsibilities; Organizational responsibilities will be defined and understood.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	1	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 19 of 62

The organizational structure, responsibilities, levels of authority, and interfaces are specified and communicated. Organizational and unit responsibilities are clear so that communication is effective within *the organization* and between organizations, and can sustain the achievement of good results.

To ensure that personnel understand their individual responsibilities, training and instructional methods and reviews are provided. The responsibilities of contributing organizations are established and reflected in pertinent documentation or contractual agreements.

Personnel engaged in performing work, verifying that it is correct, and in auditing the effectiveness of the program have appropriate independence from each other. Senior management's accountability for the effectiveness of the program is defined. The individual assigned responsibility for monitoring and assessing the effectiveness of the program reports to a management level such that the required authority and organizational freedom are provided, and cost and schedule considerations do not override adherence to requirements. This authority permits such individuals to identify problems, initiate or recommend solutions, and confirm their implementation and effectiveness.

Organizational units, managers and employees understand that they are responsible and accountable for the work they perform and the decisions they make. The results expected of individuals are defined and communicated to them. Actual results are measured and compared against expected results.

4. Personnel Capability; Personnel will be competent at the work they do.

Qualifications and training requirements are identified, personnel are given appropriate training and instruction, and tasks are assigned to personnel that have been properly trained. Training programs are monitored and assessed regularly, and the competency of personnel is reviewed to maintain their effectiveness and skill levels. Records of training, qualification, and experience are maintained.

5. Use of Experience; Relevant experience will be sought and used.

The organization has an information-gathering and review process to identify, obtain, and evaluate in-house and external experience gained during the term of the licence and the facility life-cycle. The analysis of this information is used, and action is taken to improve safety, quality and the management processes.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	•	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 20 of 62

6. Work Planning and Control; Work will be planned and controlled.

Work is planned and controlled so that it will be performed precisely and systematically. Work activities are identified, sequenced, and defined in approved plans, procedures, instructions, and drawings. The work unit and, where appropriate, the identity of the performer is also specified. Supervisor acceptance is scheduled.

Requirements are identified for avoiding damage, contamination, and foreign material ingress, for maintaining clean and protective conditions, and for proper handling, storing, shipping and preservation. Independent verifications are identified and scheduled to verify that specified requirements are met. Procedures, instructions, drawings, programs and tools are identified, prepared and approved for use.

7. Work Process Control Practices; the right items, processes and practices will be used.

Work is assigned to qualified personnel and is carried out according to the requirements that are specified in up-to-date approved instructions, procedures, drawings, or other appropriate media that define e.g. the identification of the specific item or activity, conditions, methods, characteristics, acceptance criteria, and reporting and recording requirements. The preparation, issue, and revision of these requirements is controlled to ensure that it is correct, and that the correct information is available for use. Obsolete information is not used. The prescribed precautions are taken to avoid damage and contamination.

Self-checks and Supervisor checks are performed routinely. In-process and final verifications are done as planned. When deficiencies are found, they are recorded and reported, and items, processes and practices that are deficient or are found to be unacceptable are excluded from use.

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 and calibrations. The method and interval of calibrations are defined, and records of calibrations are kept. Methods are used to show the current acceptance and operating status, and to prevent the use of systems, equipment or devices that are inaccurate or not in working order. When deviations beyond accuracy limits are found or suspected, their consequence on past results, and on present performance is evaluated.

8. Verification; Work will be verified to confirm that it is correct. Those who verify work will do so independently from those who do the work.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	_	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 21 of 62

Verification is additional to self-checks and to the checks carried out by supervisors. Verification is carried out by personnel who have not performed the work and who have appropriate independence from those who did perform the work. Intermediate and final verifications (reviews, inspections, tests, evaluations, witnessing) are carried out as planned to determine that results are satisfactory, and that the specified requirements are being met. The method of verification is documented. The extent of the verification, its timing, the results and the identification of the verifier are recorded. The results are accepted before further work proceeds.

9. Nonconformance; Deficiencies will be identified and remedied.

When nonconformances are found, they are identified, recorded, and reported. Further work, processing or use is not permitted without authorization. The nonconformance is reviewed to determine its significance, and to decide on usage as-is, after correction, or rejection. The person(s) who make(s) this determination are competent and have been given this responsibility. Nonconformances that affect or can affect safety and operability are reported to the appropriate levels of management to initiate the process of correcting their cause.

Note: The term deficiency is sometimes used to describe a nonconformance. Other terms such as snags, failures, malfunctions, errors, defects, noncompliances, are also used.

10. Corrective Action; The root cause of deficiencies will be identified and corrected.

Nonconformances that can affect safety or operability are identified, reported to management and analyzed to determine the (root) cause. Management initiates action to prevent recurrence. Those responsible for the analyses, for initiating and implementing the correction of the cause, and for taking follow-up action are identified.

11. Change Control; Changes to accept items, processes and practices will be controlled.

Before a change can be made it is justified and subjected to the same level of review and approval as was originally obtained. Persons reviewing and approving a proposed change understand the original intent and the associated requirements, and are able to assess the effect the proposed change will have on both. When a change is proposed, its effect on existing conditions is determined. This includes e.g. design documentation, analyses, computer programs, training, maintenance and operating documents, and other supporting documentation. Work is scheduled to make the corresponding revisions and updates, and alignment is obtained before the change is used, or put into service.

12. Document Control and Records; The preparation and use of documents will be controlled. Essential records will be maintained.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	-	pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 22 of 62

Documents and records are considered to be important and necessary to manage, perform and assess work effectively, and to demonstrate that requirements are being satisfied on a continuing basis. The documents that are to be produced and controlled and the records that will be generated and retained are identified ahead of time by planning. Systems are established to ensure that only approved and current documents are issued and used, that obsolete documents are withdrawn, that documents and records are available when they are needed, and that appropriate records are produced, are acceptable, and are retained and protected. The resources needed to manage these systems are planned for and allocated.

13. Audits; Periodic assessment of program effectiveness will be conducted.

Internal audits are planned and carried out on behalf of management to measure performance, the effectiveness of the management processes and to promote improvement. The organizational unit responsible for conducting audits has sufficient authority and organizational freedom to carry out its responsibilities. Persons conducting audits have no direct responsibility for the activities being audited. Results are reported and assessed by management, and action is taken to correct unsatisfactory conditions or to implement improvements. Follow-up action is scheduled to confirm the accomplishment of corrective measures. Audits of external organizations follow these same requirements.

14. Management Self-Assessment; Managers at all levels will regularly assess the management process for which they are responsible.

Managers at all levels regularly assess the management processes for which they are responsible. Managers determine how effective they are in establishing, promoting and achieving quality and safety objectives. Weaknesses in the management processes, and barriers that hinder the achievement of these objectives are identified and corrected.

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prog Solffication?
SRB	SRB Technologies (Canada) Inc. Quality Manual	Y

Recommendations and Guidance

There are no recommendations or guidance

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 23 of 6

3. SCA- HUMAN PERFORMANCE MANAGEMENT

The Safety and Control Area "Human Performance Management" Covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

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 licensees ensure that there are a sufficient number of properly trained and qualified workers to safely conduct the licensed activities.

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 and requalification program for workers; along with the results that have been achieved in implementing the program for recruiting, training and qualifying workers. Paragraph 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.

Compliance Verification Criteria

Relevant documents that require version control.

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

 The licensee shall implement and maintain training programs for workers in accordance with REGDOC 2.2.2 Personnel Training, which defines the requirements regarding the development and implementation of a training system.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		oared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 24 of 62

In Accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification?
SRB	SRBT Training Program Manual	N

Recommendations and Guidance

CNSC Document TPED-01 "Objectives and Criteria for Regulatory Evaluation of Nuclear Facility Training Programs" sets out the compliance criteria to evaluate all training programs.

4. SCA-OPERATING PERFORMANCE

The Safety and Control Area 'Operating Performance' includes an overall review of the conduct of the licensed activities and the activities that enable effective 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 proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

An operating program is to include 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, and an inventory of nuclear substances possessed under the licensee's operating licence.

The operating program is to ensure that any modifications are made in accordance with the National Building Code, the National Fire Code, and CSA 393-13 Fire protection for Facilities that process, Handle or Store Nuclear Substances.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	1	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 25 of 62

CSA N393-13 Fire protection for Facilities that process, Handle or Store Nuclear Substances, includes specific requirements for reporting and follow-up of fire incidents and fire protection program audits.

Compliance Verification Criteria

Criteria for Facility Operation

- 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. The licensee shall maintain an accurate inventory of their nuclear substances, both in use and in storage, and provide details of this inventory to show:
 - a) the acquisition of nuclear substances including the quantity received, the form of the substance, and the name of the vendor;
 - b) the disposition of all nuclear substances acquired for use or processed by the facility, including the name and address of the recipient, a copy of the recipient's licence (if applicable), the quantity of radioactive nuclear substance, and the date of shipment.
 - c) the authorized tritium possession limit is met.
- 3. The licensee shall not operate the reclamation unit that is currently found in the facility.
- 4. The licensee shall continue its practice of not processing tritium when there is precipitation.

Criteria for Fire Protection

Relevant documents that require version control.

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

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	Contract of the Contract of th	pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 26 of 62

- 5. 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 CSA N393 Fire protection for Facilities that process, Handle or Store Nuclear Substances, and the *National Building Code of Canada* and the *National Fire Code of Canada*.
- The licensee shall operate, maintain, test, and inspect the facility in accordance with CSA N393 Fire protection for Facilities that process, Handle or Store Nuclear Substances, and the National Fire Code.
- 7. 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.

In Accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification?
SRB	SRBT Quality Manual	Y
SRB	SRBT Radiation Safety Program	Y
SRB	Tritium Inventory Management, RSO-029	N
SRB	Safety Analysis Report	Y
SRB	Environmental Management System	Y

Recommendations and Guidance

The 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. The operations program establishes safe, uniform, and efficient operating practices within the nuclear facility.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 27 of 62

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 CNSC. This includes compliance monitoring and operational performance, occurrence and response to unusual events.

Compliance Verification Criteria

Criteria for Compliance Reporting

- 1. The licensee shall submit 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 that includes at a minimum:
 - a. Operational review including equipment and facility performance and changes, significant events/highlights that occurred during the year.
 - b. Information on production including verification that limits specified in the licence was complied with.
 - Modifications including changes in organization, administration and/or procedures that may affect licensed activities.
 - d. Health physics information including operating staff radiation exposures including distributions, maxima and collective doses; review of action level or regulatory exceedence(s), if any, historical trending where appropriate.
 - e. Environmental and radiological compliance including results from environmental and radiological monitoring, assessment of compliance with licence limits, historical trending where appropriate, and quality assurance/quality control results for the monitoring.
 - f. Facility effluents including gaseous and liquid effluent releases of nuclear substances from the facility, including unplanned releases of radioactive materials and any releases of hazardous substances.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		nred by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 28 of 62

- g. Waste management including types, volumes and activities of solid wastes produced, and the handling and storage or disposal of those wastes.
- h. Updates regarding activities pertaining to safety, fire protection, security, quality assurance, emergency preparedness, research and development, waste management, tritium mitigation and training (as applicable).
- i. Compliance with other federal and/or provincial Regulations.
- j. A summary of non-radiological health and safety activities, including information on minor incidents and lost time incidents.
- k. A summary of stakeholder engagement activities, public opinion and information products, as committed to in the Public Information Program.
- 1. Forecast for coming year(s).
- 2. The licensee shall provide, to the CNSC, the results of the tritium concentration in well water, within 30 days of monitoring the wells.

Criteria for Event Reporting

3. The licensee shall report all incidents in accordance with the NSCA and its regulations. Inclusion of a summary of these incidents in the *Annual Compliance Monitoring and Operational Report* does not release the licensee from any other reporting requirements specified in NSCA or its *Regulations*.

Recommendations and Guidance

The annual report for each calendar year should provide information as found in CNSC document entitled *Annual Compliance Monitoring and Operational Performance Reporting Requirements for Class 1A and 1B Nuclear Facilities* (e-Doc 3471152).

5. SCA – SAFETY ANALYSIS

The SCA entitled "Safety Analysis" covers maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 29 of 62

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 contain a description and the results of any test, analysis or calculation performed to substantiate the information included in the application.

Paragraphs 6(c)(d) of the Class I Nuclear Facilities Regulations require that a licence application contain: "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".

This condition 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

- The licensee shall maintain the safety analysis report described below to ensure it adequately
 considers the hazards associated with the facility. The Safety analysis shall be a systematic
 evaluation of the potential hazards associated with the conduct of a proposed activity or
 facility and consider the effectiveness of preventative measures and strategies in reducing the
 effects of such hazards.
- 2. A component of CSA N286-12 standard requires the licensee to develop a safety analysis process. As such, SRB it to revise its current safety analysis to align with the new safety analysis process by December 1, 2015.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 30 of 62

In accordance with licence condition 1.2, the following documents require written notification of changes made.

'Source	Document True	Prior Northeatton?
SRB	Safety Analysis Report	Y

Recommendations and Guidance

There are no recommendations or guidance.

6. SCA - PHYSICAL DESIGN

The Safety and Control Area "Physical Design" relates to activities that impact the ability of systems, structures and components to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

6.1 Design Program

Licence Condition 6.1

The licensee shall implement and maintain a design program.

Preamble

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.

The design basis is the range of conditions and events taken into account in the design of structures, systems and components of a facility according to established criteria, such that the facility can withstand them without exceeding authorized limits for the planned operation of safety systems.

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.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 31 of 6.

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

CSA N286-12 Management system requirements for nuclear facilities, includes specific requirements related to design that apply to isotope processing facilities. As such, the licensee's design program is to follow the design requirements found in CSA N286-12.

Compliance Verification Criteria

- 1. The licensee shall maintain a design program that will be evaluated against activities that impact on the ability of systems, components and structures to meet and maintain their design basis taking into consideration changes in the external environment, the effect of aging and new information arising over time.
- 2. The licensee shall ensure that all designs, including changes to the designs, meet all relevant safety, code, standard and regulatory requirements.

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Samos	Document Title	Prior Natification?
SRB	Quality Manual	Y

Recommendations and Guidance

There are no recommendations or guidance.

7. SCA-FITNESS FOR SERVICE

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

7.1 Fitness for Service Program

Licence Condition 7.1

The licensee shall implement and maintain a fitness for service program

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	•	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 32 of 62

Preamble

Paragraph 6(d) of the Class I Nuclear Facilities Regulations requires that a licence application contain 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 its function reliably. Accuracy is maintained by planning and carrying out periodic adjustments, calibrations, repairs and replacement.

Compliance Verification Criteria

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

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 33 of 62

- 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.
- The licensee shall properly identify all equipment in the calibration records, and shall regularly verify the validity of the calibration in accordance with the quality management system.

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification?
SRB	Maintenance Program	Y
SRB	Quality Manual	Y

Recommendations and Guidance

There are no recommendations or guidance.

8. SCA-RADIATION PROTECTION

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

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.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 34 of 62

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 As Low As Reasonably Achievable (the ALARA principle), 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*.

The *Radiation Protection Regulations* specifies the requirements related to action levels and requirements for when a licensee becomes aware that an action level referred to in the licence has been reached.

Compliance Verification Criteria

- 1. The licensee shall implement and maintain a radiation protection program that is in accordance with the requirements set out in the *Radiation Protection Regulations*.
- 2. When the licensee becomes aware that a radiation protection action level has been reached, it shall notify the Commission, within seven days.
- 3. Following the exceedance of an action level the licensee shall file a final report to the Commission as found in the licensee's document "Licence Limits, Action Levels and Administrative Limits".

The licensee action levels are found in the *Licence Limits, Action Levels And Administrative Limits* document. They are:

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 35 of 62

Effective Dose

Application	Action Level	
	1.0 mSv / quarter	
Effective Dose to Worker	3.0 mSv / year	
	15 mSv / 5 year period	
Effective Dose to Pregnant Worker	2.0 mSv for balance of pregnancy	
Bioassay Result	1,000 Bq/ml for any sampling period	

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

In Accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification?
SRB	Radiation Safety Program	Y
SRB	Licence Limits, Action Levels And Administrative Limits	Y

Recommendations and Guidance

Guidance on aspects of radiation protection is provided in the following documents.

- CNSC Regulatory Guide G-129, Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable" (ALARA)
- CNSC Regulatory Guide G-228, Developing and Using Action Levels
- CNSC Regulatory Guide G-91, Ascertaining and Recording Radiation Doses to Individuals
- CNSC Regulatory Standard S-260, Making Changes to Dose-Related Information Filed with the NDR

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 36 of 62

9. SCA - CONVENTIONAL HEALTH AND SAFETY

The Safety and Control Area "Conventional Health and Safety" covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.

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 a conventional health and safety program with the proposed worker health and safety policies and procedures.

For conventional health and safety the Canada Labour Code Part II applies to all federally regulated facilities.

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

Compliance Verification Criteria

Relevant documents that require version control.

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

- 1. The licensee shall comply with the Canada Labour Code Part II.
- The licensee shall implement and maintain a respirator program for workers in accordance with CSA Z94.4 Selection, Use and Care of Respirators, which defines the requirements regarding the Selection, Use and Care of Respirators.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 37 of 62

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification?
SRB	Health and Safety Policies and Procedures	Y
SRB	Hazard Prevention Program	Y

Recommendations and Guidance

There are no recommendations or guidance.

10. SCA - ENVIRONMENTAL PROTECTION

The Safety and Control Area "Environmental Protection" covers programs that identify, control, and monitor all releases of radioactive and hazardous substances and the effects on the environment from facilities or as the result of licensed activities.

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.

<u>Preamble</u>

Paragraph 3(g) of the Class I Nuclear Facilities Regulations requires that a licence application contain the proposed environmental protection policies and procedures.

Paragraph 3(h) of the Class I Nuclear Facilities Regulations requires that a licence application contain the proposed effluent and environmental monitoring programs.

Paragraph 12(1)(c) of the General Nuclear Safety and Control Regulations requires that every licensee take all reasonable precautions to protect the environment and the health and safety of persons and to maintain the security of nuclear facilities and of nuclear substances

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 38 of 62

CNSC Regulatory Document REGDOC-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.

SRB's derived release limit (DRL) report "Derived Release Limits for the SRB Pembroke Facility", was submitted with SRB's licence renewal application. Any new or revised DRL report is to be submitted for CNSC staff review and acceptance before the report is finalized.

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

Relevant documents that require version control.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 39 of 62

Source	Document Title	Document#	Revision#
CNSC	Environmental Protection Policies, Programs and Procedures.	REGDOC-2.9.1	September 2013
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

Transition plan

The licensee is expected to conduct a gap analysis of its current environmental monitoring program against the regulatory document and three CSA standards listed above by December 31, 2015. Following the gap analysis, SRB expects to have addressed the gaps for each document as follows.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 40 of 62

Document Title	Expected Completion Date
REGDOC-2.9.1 - Environmental Protection Policies, Programs and Procedures, September 2013.	December 30, 2016
N288.4-10 Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills	June 30, 2016
N288.5-11 Effluent Monitoring Programs at Class 1 Nuclear Facilities and Uranium Mines and Mills	December 30, 2016
N288.6-12 Environmental Risk Assessments at Class 1 Nuclear Facilities and Uranium Mines and Mills	June 30, 2017

The following compliance verification criteria will be used during the transition period. These requirements identify, control, and monitor all releases of radioactive and hazardous substances and the effects on the environment from facilities or as the result of licensed activities.

- 1. The licensee shall have a documented environmental protection program for the facility. This program should cover control of all radioactive and hazardous releases to the environment and the assessment of those releases on the environment.
- 2. The licensee's environmental protection program shall include an environmental management system that conforms to CNSC Regulatory Document REGDOC-2.9.1: Environmental Protection Policies, Programs and Procedures
- 3. The licensee's environmental protection program shall include an effluent monitoring program.
- 4. The licensee environmental protection program shall have action levels for effluent monitoring of tritium water soluble to the sewer system found in the *Licence Limits*, *Action Levels And Administrative Limits* document. They are:

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 41 of 62

NUCLEAR SUBSTANCE AND FORM	DAILY ACTION LEVEL (GBq)
Tritium water soluble	0.15

- 5. The licensee's environmental protection program shall have an environmental monitoring program.
- 6. The licensee's environmental protection program shall ensure the control, monitoring and recording of releases of tritium to the environment from the nuclear facility such that the releases do not exceed the release limits specified in Appendix E of this LCH.
- 7. The licensee environmental protection program shall have action levels for atmospheric releases of tritium to the environment are found in the *Licence Limits*, *Action Levels And Administrative Limits* document. They are:

NUCLEAR SUBSTANCE AND FORM	WEEKLY ACTION LEVEL (GBq)
Tritium as tritium oxide (HTO)	840
Total tritium as tritium oxide (HTO) and tritium gas (HT)	7,753

CHART RECORDER MEASUREMENT	
10,000 μCi/m³ for a duration of one hour	

- 8. When the licensee becomes aware that an environmental action level has been reached, it shall notify the Commission within seven days.
- 9. Following the exceedance of an action level the licensee shall file a final report to the Commission as found in the licensee's document "Licence Limits, Action Levels and Administrative Limits".
- 10. The licensee shall review and if necessary, revise the action levels at a frequency of once per five years to validate their effectiveness.
- 11. The licensee's environmental protection program shall include a groundwater monitoring program or procedures that include the sampling of groundwater at the wells at the following locations at the frequency specified below.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 42 of 62

Location	Frequency
MW series wells	Monthly
CN wells	The months of March, July and November
Residential wells	The months of March, July and November

- 12. The licensee's environmental protection program shall control and monitor the releases of hazardous substances.
- 13. The licensee's environmental protection program shall conform with the requirements of federal and provincial environmental regulations.

In Accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification?
SRB	Environmental Management System	Y
SRB	EH&S Manual Environmental Monitoring Program	Y
SRB	Licence Limits, Action Levels and Administrative Limits	Y

Recommendations and Guidance

There are no recommendations or guidance.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 43 of 6

11. SCA-EMERGENCY MANAGEMENT AND FIRE PROTECTION

The Safety and Control Area "Emergency Management and Fire Protection" covers emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.

11.1 Emergency Preparedness Program

Licence Condition 11.1

The licensee shall implement and maintain an emergency preparedness program.

Preamble

As part of the emergency preparedness 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 on-site activities and cooperating with external response organizations throughout all phases of an emergency.

Compliance Verification Criteria

Relevant Documents that Require Version Control.

Source	Document Title	Document #	Revision#
CNSC	Nuclear Emergency Preparedness and Response	REGDOC 2.10.1	2014

In Accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification	
SRB	Emergency Plan	Y	

Recommendations and Guidance

There are no recommendations or guidance.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	diam'r.	pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 44 of 62

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

Relevant documents that require version control.

1-miree	Document Title	Document #	Revision#
CSA	Fire protection for Facilities that Process, Handle or Store Nuclear Substances.	N393	2013

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Gonnment Title	Programming
SRB	Fire Protection Program	Y

Recommendations and Guidance

There are no recommendations or guidance.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF	1	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 45 of 62

12. SCA - WASTE MANAGEMENT

The Safety and Control Area "Waste Management" covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.

12.1 Waste Management Program

Licence Condition 12.1

The licensee shall implement and maintain a waste management program.

Preamble

Paragraph 3(1)(j) of the General Nuclear Safety and Control Regulations requires that a licence application contain information related to the in-plant management of radioactive waste or hazardous waste resulting from the licensed activities.

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

Clause 5.7.3 of CSA standard N292.3-08 "Management of low and intermediate-level radioactive waste," defines the requirements for a waste management program that includes strategies for waste minimization.

Compliance Verification Criteria

- 1. The licensee shall
 - a. ensure that the production, in terms of both rate and volume, of radioactive waste is minimized;
 - 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

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 46 of 6

- 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.

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification
SRB	Waste Management Program	Y

Recommendations and Guidance

Guidance on elements that should be included in the Waste Management Program is provided in the following documents:

- a. CNSC Policy P-290, Managing Radioactive Waste
- General principles for the management of radioactive waste and irradiated fuel, CSA N292.0-14
- c. Management of Low and Intermediate-Level Radioactive Waste, CSA N292.3-14

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 a proposed plan for decommissioning of the nuclear facility.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		oared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 47 of 6

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 guarantee that will assure adequate funding of the decommissioning plan.

The decommissioning strategy and the cost estimate for decommissioning were finalized in the "Preliminary Decommissioning Plan - November 13, 2014", (e-Doc 4628632) and the Financial Guarantee, (e-Doc 4657138).

Compliance Verification Criteria

Relevant documents that require version control.

Source	Document Title	Document =	Revision #
CSA	Decommissioning of Facilities Containing Nuclear Substances, issued July 2009	N294	2009

- 1. The decommissioning strategy for the facility shall comply with CSA standard N294-09 Decommissioning of Facilities Containing Nuclear Substances.
- 2. The licensee shall maintain a decommissioning plan to reflect any changes in the site or nuclear facility. The decommissioning plan shall be revised at a minimum every five years, unless specified otherwise by the Commission.

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Sittree	Document Title	Hylor Notification?		
SRB	Preliminary Decommissioning Plan	Y		

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 48 of 62

Recommendations and Guidance

CNSC regulatory document G-219 *Decommissioning Planning for Licensed Activities* provides guidance regarding the preparation of decommissioning plans for activities licensed by the CNSC. It also provides the basis for calculating the financial guarantees discussed in the regulatory document G-206 *Financial Guarantees for the Decommissioning of Licensed Activities* (further discussed under licence condition 1.3).

13. SCA-SECURITY

The Safety and Control Area "Security" covers the programs required to implement and support the security requirements stipulated in the regulations, in its licence, or in expectations for the facility or activity.

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 related to site access control and measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information.

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

Paragraphs 12 (1) (c), (g), (h) and (j) of the General Nuclear Safety and Control Regulations, requires that the licensee shall demonstrate that measures will be in place to maintain the security of nuclear facilities and of nuclear substances, implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, prescribed equipment or prescribed information, or the illegal use of a nuclear facility, and instruct the workers on the physical security program at the site of the licensed activity and on their obligations under that program.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 49 of 6

Compliance Verification Criteria

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Sumpe	Disament Title	Price Notification
SRB	Facility Security	Y

- 1. The licensee shall implement and maintain security measures to prevent persons from carrying out actions capable of affecting the safe and secure operation of the facility. These provisions shall include physical protection, and emergency preparedness.
- 2. The licensee shall implement and maintain a facility security plan, and ensure it is designated as prescribed information. The facility security plan shall be reviewed by the licensee at least once a year and be updated based on any changes to the facility operational security measures or to address any changes within the licensed facility that may impact on facility security.

Recommendations and Guidance

International Atomic Energy Agency, 2008, Nuclear Security Series # 9, Security in Transport of Radioactive Material.

International Atomic Energy Agency, 2009, Nuclear Security Series # 11, Security of Radioactive Material and Associated Facilities.

International Atomic Energy Agency, 2011, Nuclear Security Series # 14, Nuclear Security Recommendation on Radioactive Material and Associated Facilities.

International Atomic Energy Agency, 2011, Nuclear Security Series # 15, Nuclear Security Recommendations on Nuclear and Other Radioactive Material out of Regulatory Control.

14. SCA-PACKAGING AND TRANSPORT

The Safety and Control Area "Packaging and Transport" covers the safe packaging and transport of nuclear substances to and from the licensed facility.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 50 of 62

14.1 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 transporting nuclear 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*.

The Packaging and Transport of Nuclear Substances Regulations 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

1. The licensee shall implement and maintain a packaging and transport program that is in accordance with the requirements set out in the *Transportation of Dangerous Goods Regulations* and in the *Packaging and Transport of Nuclear Substances Regulations*.

In accordance with licence condition 1.2, the following documents require written notification of changes made.

Source	Document Title	Prior Notification?
SRB	Packaging and Shipping General Requirements, SHP-001	N
SRB ·	Document – Dangerous Goods Document, SHP-005	N
SRB	Radiation Safety Program	Y

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	•	ared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 51 of 62

Recommendations and Guidance

Not applicable.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	•	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 52 of 62

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 Director of the Nuclear Processing Facilities Division has the authority to make changes to the LCH.

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 of the Nuclear Processing Facilities Division may consent to the requested change only once it has been 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 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.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 53 of 62

4. Changes to recommendations and 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 Request Form (provided below).
- 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) ad send the updated document to the parties identified on the distribution list (see section A.5).

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	Prepared by: Jennifer Campbell, NPFD	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 54 of 62

LCH CHANGE REQUEST FORM

· N	SPFOL- 130.00/2015Lice	logies (Canada) nce Conditions I Request Form	
Document Title	Current Rev No.		Document's E-Docs No.
	REVISION REC	QUEST INFORMA	ATION
Requestor	Division		Date of Request: MM / DD / YY
Line Manager	☐ Concur wit	th request Do Not	Concur
Description of Proble	m to be Resolved: (additional space	on reverse of form)	Take Take
Proposed Changes: (additional space on reverse of form)	
Other Documents Pot	entially Affected by Proposed Char	nges	
	SUBJECT MATTER E	XPERT (SME) AS	SSESSMENT
SME	☐ Concur with request	☐ Do Not Concur	Date: MM / DD / YY
Assessment Commen	nts:		
	Revisions to be Reviewed	by: (Check off all applica	able divisions)
	Director - Nuclear	Processing Facilities Div	vision
Name	Change Request Approved	Date: MM / DD / YY	Signature

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	1	ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 55 of 62

CNSC review criteria related to written notification document changes

For the acceptance of document changes described above, CNSC staff verifies 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 licensee's quality assurance and change control processes, applicable design guides, design requirements, standards, operating documentation, regulatory documents, applicable safety principles and applicable safeguards agreement.
- The proposed change or action is in a safety neutral or safety positive direction.
- Following the proposed change or action:
 - the licensee remains qualified to carry out the licensed activity;
 - the licensee remains in compliance with the requirements set out in the applicable laws, regulations and licence;
 - 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.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	· .	ared by: umpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 56 of 62

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, 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
- SRB Technologies (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.

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 57 of 62

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

DCR Document Change Request

DNCFR Directorate of Nuclear Cycle and Facilities Regulation

EP Environmental Protection

HRSDC Human Resources and Skills Development Canada

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

WN Written Notification

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF	Prepared by: Jennifer Campbell, NPFD	
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 58 of 62

APPENDIX C – Documents in support of Licence Application

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

Notes:

Y = Notification Required, as described in LC 1.2.

N = Prior Notification and Acceptance Required, as described in LC 1.2.

e-Doc 4472953 maintains document version control of the documents referenced below.

Document Title	Prior Notification	Licence Conditions
Financial Guarantee	Y	1.3
Public Information Program	N	1.4
Quality Manual	Y	2.1
SRBT Training Program Manual	N	3.1
Tritium Inventory Management	N	4.1
Safety Analysis Report	Y	5.1
Maintenance Program	Y	7.1
Radiation Safety Program	Y	8.1
Licence Limits, Action Levels and Administrative limits	Y	8.1
Health and Safety Policies and Procedures	Y	9.1
Hazard Prevention Program	Y	9.1
Environmental Management System	Y	10.1

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 59 of 62

Document Title	Heroe Notification	Caralitans
Environmental Monitoring Program	Y	10.1
Derived Release Limits	Y	10.1
Emergency Plan	Y	11.1
Fire Protection Program	Y	11.2
Waste Management Program	Y	12.1
Preliminary Decommissioning Plan	Y	12.2
Facility Security Program	Y	13.1
Packing and Shipping General Requirements SHP-001	N	14.1
Document - Dangerous Goods SHP-005	N	14.1

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No.: 4869492 Word 4899130 PDF		pared by: ampbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 60 of 62

APPENDIX D - List of Documents used as Guidance or Criteria

Document #	Document Title	L.C.
INFO-0795	Licensing Basis Objective and Definition	1.1
G-206	Financial Guarantees for the Decommissioning of Licensed Activities, issued June 2000	1.3, 12.2
RD/GD-99.3	Public Information and Disclosure	1.4
TPED-01	Objectives and Criteria for Regulatory Evaluation of Nuclear Facility Training Programs	3.1
e-Doc 3471152	Annual Compliance Monitoring and Operational Performance Reporting Requirements for Class 1A and 1B Nuclear Facilities.	4.2
G-129	Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)", issued October 2004.	8.1
G-228	Regulatory Guide, "Developing and Using Action Levels", March 2001	8.1
G-91	Ascertaining and Recording Radiation Doses to Individuals	8.1
S-260	Making Changes to Dose-Related Information Filed with the NDR	8.1
REGDOC 2.9.1	Environmental Protection Policies, Programs and Procedures	10.1
CSA Standard N393	Fire protection for Facilities that Process, Handle or Store Nuclear Substances	11.1
G-225	Emergency Planning at Class I Nuclear Facilities and Uranium Mines, issued August 2001	11.1

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 13.00/2022	E-doc No. : 4869492 Word 4899130 PDF		ared by: mpbell, NPFD
Approved by: Director, Nuclear Processing Facilities Division	Subject: Nuclear Substance Processing Facility Operating Licence	December 22, 2015	Rev.: 0	Page 61 of 6

Doorment#	Document Title	6
P-299	Regulatory Fundamentals	Appendix A
CNSC Policy P-290	Managing Radioactive Waste	12.1
GD-320	Assessing the Long Term Safety of Radioactive Waste Management	12.1
CSA N292.3, 2008	Management of Low and Intermediate-Level Radioactive Waste	12.1
CSA N294	Decommissioning of Facilities Containing Nuclear Substances, issued July 2009	12.2
G-219	Decommissioning Planning for Licensed Activities, issued June 2000	12.2

Directorate of Nuclear Cycle and Facilities Regulation	SRB Technologies (Canada) Inc. NSPFOL- 130.00/2015	e-Doc No.: 4473427 Word 4624621 PDF	Prepared by: Robert Buhr, NPFD	
Approved by: DNCFR Director General	Subject: Nuclear Substance Processing Facility Operating Licence	Effective Date: December 22, 2015	Rev.: 0	Page 62 of 62

APPENDIX E – Environmental Release Limits

To Atmosphere

Nuclear Substances and Form	Limits (Bq/year)		
Tritium as Tritium Oxide	6.72 E + 13		
Total Tritium as Tritium Oxide and Tritium Gas	4.48E+14		

To Sewer

Nuclear Substance and Form	Limits (Bq/year)
Tritium-Water Soluble	2.0E+11