Directorate of Nuclear Cycle and Facilities Regulation

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Phone: (613) 943-7909
Email: robert.buhr@canada.ca

May 12, 2017

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

Subject: **SRB Technologies (Canada) Inc. Inspection Report No. SRBT-2017-02 conducted on March 20, 2017 to March 21, 2017**

Dear Mr. Levesque,

Please find enclosed Canadian Nuclear Safety Commission's (CNSC) final inspection report SRBT-2017-02 for the Compliance Inspection carried out on March 20, 2017 to March 21, 2017. As a result of this inspection, 1 action notice and 2 recommendations were issued:

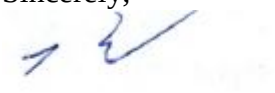
SRBT-2017-02-A01: SRBT shall ensure that all documents are uniquely identified.

SRBT-2017-02-R01: SRBT should remove the burden of manually monitoring, updating and maintaining of registers and logs and consider looking at software based solutions for these processes.

SRBT-2017-02-R02: SRBT should put in place a method for the employees for anonymous submissions of issues or concerns.

SRB Technologies is requested to submit its corrective action for each compliance action 60 business days from the time the report was issued. If you have any questions, or concerns, please do not hesitate to contact me.

Sincerely,



Robert Buhr
Project Officer
Canadian Nuclear Safety Commission
Nuclear Processing Facilities Division

Enclosure: (1)

c.c.: J. MacDonald, SRBT
R. Fitzpatrick, SRBT
K. Murthy, CNSC
K. Sia, CNSC
G. Steedman, CNSC
R. Rashapov, CNSC

Canada's Nuclear Regulator

CNSC COMPLIANCE INSPECTION REPORT

Inspection Identification No.: SRBT-2017-02

Compliance Inspection: Type II Management Systems Inspection

Prepared by: Robert Buhr, Lead Inspector
Nuclear Processing Facilities Division
Directorate of Nuclear Cycle and Facilities Regulation

Report Issuance Date: May 12, 2017

Security Designation: Choose an item.

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Canada

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CANADIAN NUCLEAR SAFETY COMMISSION
COMPLIANCE INSPECTION
Inspection Identification No.: SRBT-2017-02

Licensee:	SRB Technologies (Canada) Inc.
Licence No.:	NSPFOL-13.00/2022
Facility Inspected:	Pembroke Ontario
Inspection Date(s):	March 20, 2017 – March 21, 2017
Report Issuance Date:	May 12, 2017
Prepared by:	Robert Buhr Lead Inspector, NPFD
Approved by:	Kavita Murthy Director NPFD
Safety and Control Area(s):	Management System
Inspector Accompanied by:	
Licensee Staff:	Jamie MacDonald – Manager, Health and Regulatory Affairs Tanya Sennett – Compliance Manager
CNSC Staff:	Kuen Sia – Management System Specialist Gavin Steedman – Management System Officer Rinat Rashapov – Management System Officer

EXECUTIVE SUMMARY

Pursuant to subsection 30(1) of the *Nuclear Safety and Control Act*, Canadian Nuclear Safety Commission (CNSC) staff conducted a Compliance Inspection at SRB Technologies (Canada) Inc. (SRBT) from March 20, 2017 to March 21, 2017. The purpose of this inspection was to verify compliance with regulatory requirements.

The scope of the inspection was to focus on the management system safety and control area, to verify compliance of implementation of SRBT's new revised Management System against the CSA N286-12, "Management system requirements for nuclear facilities"

CNSC inspectors' preliminary inspection facts and findings were discussed with licensee staff. A Preliminary Inspection Facts and Findings Report was tabled during the closing meeting held on March 21, 2017.

The CNSC inspection team found SRBT's revised management system implemented to be in compliance with the CSA N286-12, "Management system requirements for nuclear facilities". However, due to SRBT's inconsistency in the documents control process, 1 Action Notice and 2 Recommendations were raised for SRBT to address. The identified enforcement actions do not pose an immediate or unreasonable risk to the health and safety of persons, but improvements are required to address the identified issues.

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Type II Management System Inspection

1. INTRODUCTION

A Type II Management System Inspection at SRB Technologies (Canada) Inc. (SRBT) was conducted from March 20, 2017 to March 21, 2017.

The licensee was assessed against provisions of the *Nuclear Safety and Control Act* and its associated regulations, the conditions of the SRBT's Licence NSPFOL-13.00/2022 and the CSA N286-12, "Management system requirements for nuclear facilities" as well as applicable facility-specific documentation.

Criteria for this inspection were derived directly from the set of documents described in the notification letter and compiled into a Compliance Matrix, which had been provided to licensee staff prior to the inspection. Observations, interviews and review of records were undertaken to assess compliance with regulatory expectations.

This report documents the findings and conclusions of the inspection, along with any compliance actions and recommendations arising from these findings. The results of this inspection activity will form part of CNSC staff's evaluation of the licensee's performance.

2. PURPOSE AND SCOPE

The purpose of the inspection is being conducted as part of the baseline compliance. The purpose of the inspection is to verify compliance with regulatory requirements.

The scope of the inspection was focused on the management system safety and control area. The inspection focussed only on sampling a number of processes of the SRBT's management system and the following processes were assessed:

- Work Management
- Assessment
- Problem identification and resolution.

3. DESCRIPTION OF INSPECTION METHODS

Three methods of assessment were used during the inspection:

A. Documentation and record review

- Records were verified to be maintained as required by many of the outlined criteria, and a review of selected documents were performed to ensure their accuracy and completeness.

B. Visual assessment and verification

- A physical inspection of the facility with licensee staff was conducted. Observations based on identified compliance criteria were made for verification purposes.

C. Interviews and discussions with licensee staff

- Interviews and discussions with various licensee staff were conducted during the inspection. Questions were posed based on compliance criteria and responses documented for verification purposes.

Selected documentation and records were reviewed during the field verification component of the inspection. These were reviewed to confirm compliance with the CSA N286-12 requirements.

As per CNSC process, at the conclusion of the field verification portion of the inspection, a Preliminary Inspection Facts and Findings report was provided to SRBT representatives. This report was provided for purposes of outlining observations made by the inspection team at an overall level, based on a preliminary review of the criteria set identified in the Compliance Matrix (Appendix D).

Based on criteria identified in the Compliance Matrix, regulatory requirements and compliance expectations were determined to be met or not met, and reported as inspection findings. CNSC staff may identify compliance actions and recommendations in relation to an inspection finding. Appendix A outlines definitions of the respective compliance action categories.

4. INSPECTION RESULTS

The following findings and subsequent compliance actions and recommendations are the result of CNSC staff's inspection at SRBT. This section of the report has been structured to show the link from the initial inspection finding to the resulting compliance action and/or recommendation as shown below:

- Compliance verification criteria used to identify the deficiency;
- A description of the observed deficiency;
- An analysis linking the compliance verification criteria or regulatory requirement to the observed deficiency; and
- Detailed compliance action or recommendation requiring the licensee to address the deficiency.

The order in which findings are presented in the report does not indicate a ranking of their safety significance.

The findings documented in this report were arrived at by assessing the facts and observations gathered by CNSC staff during the inspection activities, with the related compliance criteria and regulatory requirements, as detailed in the Compliance Matrix. Where improvements are necessary, compliance actions and recommendations have been issued as detailed in this section of the inspection report.

Compliance criteria that was met during the inspection is listed in the compliance matrix.

4.1 MANAGEMENT SYSTEM

4.1.1 Work Management Work Control

Criteria

CSA N286-12, Clause 4.8.2, Work control, SRBT is required to ensure that work is controlled. The following are requirements to ensure that work is authorized and carried out using controlled:

A. Documents;
B. Software, including engineering tools and analytical software;
C. Items;
D. Tools, gauges, instruments, and other measuring and testing devices;
E. Processes; and
F. Practices.

Fact(s)

1. Some documents were not uniquely identified (e.g. fume hood maintenance records and test forms).
2. Of the sampled change control packages, some were using an older format while newer forms are using the updated format. As of January 1, 2017, all documentation is created in a format that complies to CSA N286-12.

Analysis/Finding(s)

Staff reviewed documentation provided by SRBT to ensure that it supports work activities. This requires that documentation is properly authorized and controlled. The following documentation was reviewed to verify compliance:

A. Document Matrix
B. Master List – Calibrated Instruments
C. Valve Change Work Package
D. MSP-002 Process Planning and Control
E. Master list of calibrated equipment
F. Calibration record for tritium certification
G. MTC-016-F-01 Preventive maintenance schedule
H. MTC-003 Maintenance procedure for active ventilation maintenance
I. QAS-028 Control of Measuring and Test Equipment
J. RSO-011 Instrument Calibration

CNSC staff observed multiple cases where supporting documentation for the work control lacked unique identification. N286-12, 4.7.3, requires that documents shall have a unique identification but this is not done consistently. For example, documents lacking unique identification include the supporting documentation for work package #2 where a generic form is used to record results from testing of the PUTT bases as part of this research program but with no unique identifier. As part of the transition from N286-05 to N286-12 as of January 1, 2017, some of the work packages and supporting documentation were initiated under the older standard's requirements. This resulted in an observed variation between the applicable requirements for different work packages. As more time passes since the transition, CNSC expects to see all open work packages to be compliant with N286-12.

Several important controlled processes included paper-based records. This includes the audit register, Non-Conformance Report (NCR) log, and calibration log. While all of these records were maintained, CNSC staff express that the burden of manually monitoring, updating and maintaining these registers and logs; the risk of missing important dates and losing these records should be of concern to SRBT. SRBT management shared this concern and stated that they are looking at software-based solutions for these processes.
CNSC staff conclude that the work control requirements for clause 4.8.2 as implemented by SRBT meets the requirements for N286-12 however, it is noted that some of the supporting documentations are not uniquely identified as required by N286-12, Clause 4.7.3, documents.

Compliance Action(s)/Recommendations

Action Notice

SRBT-2017-02-A01: SRBT shall ensure that all documents are uniquely identified.
Recommendation- SRBT-2017-02-R01: SRBT should remove the burden of manually monitoring, updating and maintaining of registers and logs and consider looking at software based solutions for these processes.

Recommendation

SRBT-2017-02-R01: SRBT should remove the burden of manually monitoring, updating and maintaining of registers and logs and consider looking at software based solutions for these processes.

4.1.2 Problem Identification and Resolution

Criteria

As per CSA N286-12, SRBT is required to have a process in place for the identification and resolution of problems. When problems arise, they shall be:

A. Immediately controlled, if required;
B. Documented;
C. Evaluated for significance and for underlying cause if deemed by management to be systemic or having impact on meeting business objectives; and
D. Accepted.
E.

Actions employed to resolve problems shall be reviewed for effectiveness.

Fact(s)

1. The non-conformance process is rigorous and addresses the requirements of N286-12.
2. The effectiveness of corrective actions is reviewed and any ineffective actions implemented were followed up in other non-conformance reports.
3. Tracking of actions related to problem identification and resolution is currently performed manually.

Analysis/Finding(s)

Staff reviewed documentation provided by SRBT to ensure that a rigorous problem identification and resolution process was in place. The following documentation was reviewed to verify compliance:

A. MSP-012 Corrective Action
B. SRBT Quality Manual
C. NCR Register
D. NCR Form
E. NCR reports NCR-464 ,NCR 465, NCR 576, NCR 497 and NCR 577
F. Committee meeting minutes
G. 2016 Management review minutes
H. Root Cause Analysis Training record of Quality Manager

CNSC staff reviewed the NCR register and found that NRCs include all required elements. Evidence showed that arising problems are accepted by the Compliance Manager (CM) and Senior Management who are required to sign off on them. Additionally, all NCRs are reviewed by top management and are discussed in the annual management review. Finally, the CM stated that trending is done at a minimum of once a year for the Management Review. However, this can occur at any time if deem necessary based on the findings frequencies seen in the NCR register. Part of the effectiveness review of the process is to identify if there is a noticeable trend in NCRs that are similar.

CNSC noted that a method for anonymous submissions of issues or concerns is not available to SRBT staff. SRBT staff commented that a similar system was in place many years ago but management received no valuable feedback from the system.

CNSC staff conclude that the problem identification and resolution requirements for clause 4.9 as implemented by SRBT meets the requirements for N286-12, however, CNSC staff recommend that a method should be put in place for anonymous submissions of issues or concerns for those afraid to speak up for fear of repercussion.

Compliance Action(s)/Recommendations

Recommendation

SRBT-2017-02-R02: SRBT should put in place a method for the employees for anonymous submissions of issues or concerns.

5. SUMMARY OF COMPLIANCE ACTIONS AND RECOMMENDATIONS ISSUED

SRBT-2017-02-A01: SRBT shall ensure that all documents are uniquely identified.

SRBT-2017-02-R01: SRBT should remove the burden of manually monitoring, updating and maintaining of registers and logs and consider looking at software based solutions for these processes.

SRBT-2017-02-R02: SRBT should put in place a method for the employees for anonymous submissions of issues or concerns.

6. CONCLUDING STATEMENTS

CNSC staff performed an Inspection of SRBT's Management System against the CSA N286-12 requirements, in order to verify compliance with the new standard requirements.

The scope of the inspection was to focus on the management system safety and control area, to verify compliance of implementation of SRBT's new revised Management System against the CSA N286-12, "Management system requirements for nuclear facilities"

As a result of these findings, and following further analysis of records provided and inspection facts and findings, CNSC staff found items of non-compliance with the criteria assessed from the *Compliance Matrix*, and therefore 1 Action Notice, and 2 Recommendations have been raised. SRBT is requested to submit its corrective action for each compliance action **60** business days from the time the report was issued. The response must include corrective measures and proposed completion dates, including the date by which the corrective measure will be documented (if required), implemented, and verified for adequacy and effectiveness.

APPENDIX A: DEFINITIONS

Compliance Action Categories:

Directive

A written request that the licensee take action to correct a non-compliance with governing regulations, licence conditions, codes, standards or a general or sustained failure to adhere to approved documents, policies, procedures, instructions, programs, or processes that the licensee has established to meet licensing requirements.

Action Notice

A written request that the licensee take action to correct a non-compliance that is not a direct contravention of governing regulations, licence conditions, codes or standards, but that can compromise safety, security, or the environment. Such non-compliances include:

- A failure to satisfy one of the compliance criteria if the criteria are not directly referenced in the governing regulations or licence conditions.

- A significant but non-systemic failure to comply with the licensee's own policies, procedures, or instructions that it has established to meet licensing requirements (including programs and internal processes submitted in support of a licence application).

Recommendations:

Recommendation

A written suggestion to effect an improvement based on good industry practice. A recommendation is not an indication of non-compliance with regulatory requirements, and the recipient is not obliged to accept the recommendation. A recommendation is not subject to enforcement action. Recommendations shall not be issued as a means of suggesting improvements to areas outside the CNSC's mandate.

APPENDIX B: ACRONYMS AND ABBREVIATIONS

CM	Compliance Manager
CNSC	Canadian Nuclear Safety Commission
LCH	Licence Conditions Handbook
NCR	Non-Conformance Report
SRBT	SRB Technologies (Canada) Inc.

APPENDIX C: APPENDIX RECORDS

Canadian Nuclear Safety Commission / Commission canadienne de sûreté nucléaire

Inspection Opening Meeting Attendance Record

Division	NPFD
Title of Inspection	Type II Management Systems Inspection
Inspection Identification Number	SRBT-2017-02

Name of Licensee	SRBT
Licence Number	NSPFOL-13.00/2022

Lead Inspector	Robert Buhr
Date of Inspection	March 20, 2017 to March 21, 2017
Date of Opening Meeting	March 20, 2017

Instructions: Complete the top section of this form prior to the formal Opening Meeting. Have all attendees at the formal Inspection Opening Meeting sign this form, indicating their presence. Use multiple sheets if needed.

Name	Organization / Role	Signature
Tanya Sennett	Compliance Mgr.	T. Sennett
Katie Levesque	Executive Assistant	Katie Levesque
Mary-Ann Demers	Production Control Manager	M Demers
KUEN SIA	CNSC - MS specialist	Kuen Sia
Rinat Rafikov	CNSC - MS Officer	Rafikov
Gavin Steedman	CNSC MS Officer	G. Steedman
JAMIE MACDONALD	MANAGER - HP-RA SRBT	
STEPHANE LEVESQUE	PRESIDENT / SRBT	
ROSS FITZPATRICK	VICE-PRESIDENT/SRBT	

280 Slater Street, Post Office Box 1046, Station B, Ottawa, Ontario K1P 5S9 Canada
nuclearsafety.gc.ca

Canada

280 rue Slater, Case postale 1046, Succursale B, Ottawa (Ontario) K1P 5S9 Canada
suretenucleaire.gc.ca

Canadian Nuclear Safety Commission / Commission canadienne de sûreté nucléaire

Inspection Opening Meeting Attendance Record

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Name	Organization / Role	Signature
Tanya Sennett	Compliance Mgr.	T. Sennett
Katie Levesque	Executive Assistant	Katie Levesque
Mary-Ann Demers	Production Control Manager	M Demers
KUEN SIA	CNSC - MS specialist	
Rinat Rashapov	CNSC - MS Officer	
Gavin Steadman	CNSC MS Officer	G. Steadman
JAMIE MACDONALD	MANAGER - HP-RA SRBT	
STEPHANIE LEVESQUE	PRESIDENT / SRBT	
ROSS FITZPATRICK	VICE-PRESIDENT/SRBT	

APPENDIX D: COMPLIANCE MATRIX

DIRECTORATE OF NUCLEAR CYCLE AND FACILITIES REGULATION
COMPLIANCE MATRIX

Division	NPFD
Title of Inspection	Management Systems Inspection
Inspection Identification Number	SRBT-2017-02

Name of Licensee	SRB Technologies (Canada) Inc.
Location/Site	Pembroke
Licence Number	NSPFOL-13.00/2022

Inspection Team: Robert Buhr (Lead Inspector/ Project Officer)
Kuen Sia (Management System Specialist)
Gavin Steedman (Management System Officer)
Rinat Rashapov (Management System Officer)

Safety and Control Area(s) of Interest:

☒Management System
☐Human Performance Management
☐Operating Performance
☐Safety Analysis
☐Fitness for Service
☐Conventional Health and Safety
☐Environmental Protection
☐Waste Management
☐Security
☐Safeguards and Non-Proliferation
☐Radiation Protection
☐Packaging and Transport
☐Physical Design
☐Emergency Management and Fire Protection
☐ Other: _____

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
1	Source: LCH Details: CSA N286-12 4.8 Work Management 4.8.1 Work planning	Work shall be identified and planned with the following: a. a clear description of the work, including requirements and verification; b. worker requirements, including verification worker; c. supply chain requirements, including lead times; d. resources assignment, including the worker to perform the verification; e. critical characteristics of the work to be verified, verification methods, extent, and acceptance criteria established; f. the sequencing and scheduling of the work, including verification (e.g., inspection and testing requirements); and g. the acceptance criteria for the finished product. **CNSC expectations:** CNSC staff to pick 3-5 samples of completed work packages and have SRBT personnel involved in the work planning walk through the process from initiation of the work request to issuing of the work package to verify that this clause is being implemented. Review Engineering Work Packages (WP) and verify if they include tritium content, parts list, work instructions, product requirements. WP may include the following elements: materials bill, routing,	SRBT provided 2 completed Work Packages and 1 that is currently in progress: Action Level Exceedance/Valve Change, Remote Display Units, PUTT Life Extension. **Observations:** SRBT met a-g for all three Work Packages. **Documents reviewed:** **Valve Change WP** 1. Engineering Change Request (ECR) Form #529 ENG-004 2. Non-Conformance Report (NCR 464) 3. Final Written Report, June 30, 2015 4. Change Control Package: PUTT Manual Valve 5. Mitigation Committee Minutes 6. Good Inward Inspection, Dec 15, 2015 7. Commissioning Test Record 8. Approved Vendors List (AVL) **PUTT Life Extension** 1. Engineering Change Request Form #719 2. Research and Development Plan, January 18, 2017 3. Forms: Data Testing 4. Staff Coaching Records 5. Correspondence to CNSC **RDU** 1. ECR 579, ECR 657 2. NCR 464 3. Final Written Report, June 30, 2015 4. Updated procedures as a result of this change	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		drawing, legend, card gauge, label information sheet. Review permanent work packages elements (BOM, ROUT, etc.) retained as records.		
2	Source: Other Details: QA Manual Rev I, Sect 4.8.1 Work Planning, para (2)	Workers follow clear descriptions of their work activities, either using management system procedures or by following instructions for the manufacture of our products using work packages. The sequence of work, including verification and resource assignment are included in these documents as well as the acceptance criteria for finished product. **CNSC expectations:** • Talk to personnel involved in the work activities on their work practices to ensure that they reflect documented.	**Observations:** 1. Interviewed Health Physics Technician who follows documented procedures (e.g. RSO-011 Instrument Calibration) and receives on-the-job training for new processes. Routine work is part of the worker's roles and responsibilities whereas for non-routine work, work packages are created.	Objectives are met
3	Source: Other Details: QA Manual Rev I, Sect 4.8.1, Work Planning, para (3)	Verification processes are embedded in procedures and work packages in a graded fashion; for example, targeted quality checks at certain points in the manufacturing process may be outlined in a work package, or a second member of the Health Physics Team may be required to independently verify calculations pertaining to the calibration of a radiation protection instrument as per procedure requirements. **CNSC expectations:** • CNSC staff to confirm where graded approach application is used, criteria and processes used for grading are defined by SRBT. Graded approach	**Observation:** SRBT has a graded approach process fully implemented. However, SRBT has not applied graded approach to their internal processes and procedure but rather applies the full process requirements of the management system. SRBT will invoke the graded approach process when deemed necessary **Documents reviewed:** - MSP-006 Graded Approach	Not implemented

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		process described in MSP-006. • Review records of memo to QA Manager on application for using graded approach. Memo must include description of MS element, activity description, grades, recommendations, approval by QM.		
4	Source: Other Details: MSP-002 Rev A, Process Planning and Control, Sect 5, para (3)	All work associated with licensed activities is to be planned with the following as applicable: (a) a clear description of the work, including requirements and verification; (b) worker requirements, including verification worker ; (c) supply chain requirements, including lead times; (d) resources assignment, including the worker to perform the verification; (e) critical characteristics of the work to be verified, verification methods, extent, and acceptance criteria established; (f) the sequencing and scheduling of the work, including verification (e.g., inspection and testing requirements); and (g) the acceptance criteria for the finished product. **CNSC expectations** • Addressed in item 1) above.	**Observations and documents reviewed:** See item #1 for evidence.	Objectives are met
5	Source: LCH Details: CSA N286-12 4.8 Work	Conduct of work shall be authorized and carried out using controlled a) documents; b) software, including engineering tools and analytical software;	**Observations:** 1. Some documents lack unique identifications (e.g. Commissioning Test Form, Internal Audit Schedule, Record of Staff Coaching, Master List –	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	Management 4.8.2 Work control	c) items; d) tools, gauges, instruments, and other measuring and testing devices; e) processes; and f) practices. **CNSC expectations:** • Observe/talk to personnel authorized to do the work to confirm. • Documented records showing work carried out was authorized and carried out using the controlled criteria listed from a) to f).	Calibrated Instruments) 2. Documents and their revisions are tracked in a Document Matrix 3. Calibration on tools and equipment is performed regularly and according to their calibration schedule 4. For processes and practices see item #1 5. Workers working in Zone 1 to Zone 3 areas were observed to be complying with a,c-f. **Documents reviewed:** 1. Document Matrix 2. Master List – Calibrated Instruments	
6	Source: Other Details: MSP-002 Rev A, Process Planning and Control, Sect 6.0	Work is to be controlled to ensure products are made correctly and consistently with a high level of quality and to ensure that the operations of the facility do not result in any risk to the workers, the public or the environment. It is our policy to always ensure that processes are carried out under controlled conditions. **CNSC expectations:** • Talk to management and staff on their responsibilities with regard to safety being the paramount consideration and to demonstrate how this requirement is being met.	**Observations:** 1. Top Management promote safety culture with supervisors and staff by: • encouraging them to report new issues, • having an open door policy, • having various committees to address issues, • having open communications, • addressing Opportunities for Improvement (OFI) • encouraging NCRs to be raised, • indoctrination of training, • encouraging staff to read license and LCH, commission hearing. 2. Interviewed Health Physics and Regulatory Affairs Manager and verification with Health Physics Technician to confirm their responsibilities and safety. Staff is told to be conscious of risk related activities and be involved with coaching. Management asks to be informed of issues. Example of the putts where the decision to increase the number of cycles is now done with safety as the main priority.	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
			SRBT compare themselves to other nuclear facilities of similar size. SRBT are trying to incorporate more OPEX. SRBT also had their first safety stand down following a recent lost time incident. SRBT put the onus on multiple levels to promote the reporting of events related to safety. Open door policy, constant communication, committees, and learn by example. No formal way of submitting anonymized safety concerns. SRBT has a safety culture committee and a process which was developed in 2016. First review will be in 2017. There was a formalized training for safety culture when the new management system was implemented. It was intended to familiarize staff with the concept. The expectation for safety requirements is a key condition for hiring. SRBT staff read the license, the LCH and the licensing transcripts.	
7	Source: Other Details: MSP-002 Rev A, Process Planning and Control, Sect 7.0, Introduction of new process	The introduction of a new process, equipment or document (program, procedure, form, etc.) that may affect licenced activities must be reviewed and approved to ensure that it is aligned with SRBT quality manual, is suitable for the business and does not result in a risk to the workers, the public or the environment. **CNSC expectations:** Staff to verify compliance through sample completed work packages on the review and approval of new process, equipment or document.	**Observations:** 1. Valve Change Work Package resulted in introduction of new equipment that affected licensed activities. SRBT reviewed and approved this change. SRBT issues ECRs for the introduction of new equipment, processes and documents. **Documents reviewed:** 1. Valve Change Work Package 2. MSP-002 Process Planning and Control	Objectives are met
8	Source: Other Details: MSP-002 Rev A,	Change can be implemented for several reasons; problems can require changes to processes or equipment, new regulatory	**Observations:** 1. NCR 464 was generated to address stack	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	Process Planning and Control, Sect 8.0, Changes to approved processes	requirements can be applied, or modified, improvements can be identified, or modern equipment or practices introduced. Where changes to the facility structure, safety- or business-significant systems or components, or the management system are required, MSP-007, Change Control is implemented to ensure that the change is controlled in a fashion that is commensurate with potential risk **CNSC expectations:** • Staff to verify compliance through sample completed work packages on the review and approval of changes made to a process, equipment or document. • Staff to verify that documented changes include: o reason for the change o reason to justify the change o reviewed by relevant stakeholders o reviewed by persons with knowledge of original intent and requirements o approved for implementation o implemented as planned and o change reviewed for effectiveness.	monitoring air emission leakage in a valve and to replace the valve. 2. A Change Control Plan (CCP) was initiated by the Health Physics Manager and Project Engineer for the valve replacement ECR from the Mitigation Committee meeting minutes. 3. From CCP, ECR is initiated for valve change which included reasons and justification for change and circulated for review and approval. 4. All applicable reviewers and approvers signed off on the ECR. 5. Also observed: a. CCP has 8 elements incl. risk assessment, hazards, LLb. Custom made valves in coordination with Swagelock c. Good inward inspection by Engineer upon receipt of new valves d. CM process and supplier evaluation performed, reviewed AVL, checks out e. Procurement, testing + commission plan, turnover, verification of records + docs f. No procedures changes as a result of the change g. Staff coaching record produced h. Changes are signed-off and new processes approved after. i. Checks and balances as per standards are in place. j. SCAs where identified based on the risks that the changed imposes on them. A review of internal events that occurred to see if there are things that SRBT learned in the past that could be applied. k. Other procedures that apply were cited to ensure that they were meeting the requirements. l. There was the review of changes to work procedures and how the change will affect staff. m. A verification of records and documentation was done.	

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
			n. Record of coaching was provided that shows the training done for staff. Finally, a presentation to the mitigation committee to show how the manager felt this was a superior solution. Data of tritium release showed that this was a superior item. (According to SRBT staff, this goes right to the generation of ECR. Once it is completed it goes to a engineering change order. Now it's all part of change control. - Documented work package is done before work is activated. A comprehensive package can be done before.) o. As part of commissioning plan there are hold points where acceptance is documented that the criteria is met. p. All WP include a CCP.	
9	Source: Other Details: QA Manual Rev I, Sect 4.8.2 Work control	Conduct of work shall be authorized and carried out using controlled a) documents; b) software, including engineering tools and analytical software; c) items; d) tools, gauges, instruments, and other measuring and testing devices; e) processes; and f) practices.) **CNSC expectations:** • Addressed in item 5) above.	Addressed in item #5	Objectives are met
10	Source: Other Details: QA Manual Rev I, Sect 4.8.2 Work control para (3)	Where work requires the use of important specific items such as software, engineering tools, and / or measuring and testing devices, these items are also controlled. Serial numbers, calibration records and certificates of conformance	**Observations:** 1. Master List of calibrated equipment includes equipment description, serial number, equipment location, calibration frequency, date calibrated, due date of calibration. 2. Necessary information is included in the list	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	QAS-028 'Control of Measuring and Test Equipment'	are maintained using processes such as QAS-028, Control of Measuring and Test Equipment and QAS-006, Goods Inward Inspection. **CNSC expectations:** • Staff to confirm that the 'Master List – Calibrated Equipment' for all calibrated measuring equipment/tools showing their serial number, calibration date, calibration due date and calibration certificate is available as well as a maintenance schedule for other equipment used that could have an impact on safety. • Verify if any maintenance backlog exists. • Certain equipment must be calibrated against a standard • Instances of equipment removed from use due to unacceptable accuracy? • Equipment out of calibration must be labeled and a NCR issued.	3. No backlogs found 4. Standards used where necessary for calibration of tritium measuring 5. Equipment that is coming up for calibration is manually monitored by Compliance Manager 6. Inconsistent documenting of due dates of calibrations found in the Masters List (month vs. specific date) 7. Master List of calibrated equipment is updated and tracked manually **Documents reviewed**: 1. Reviewed master list of calibrated equipment 2. Calibration record for tritium certification 3. MTC-016-F-01 Preventive maintenance schedule 4. MTC-003 Maintenance procedure for active ventilation maintenance 5. QAS-028 Control of Measuring and Test Equipment 6. RSO-011 instrument Calibration	
11	Source: LCH Details: CSA N286-12 Work Management 4.8 Work Management 4.8.3 Independent verification of work	Work activities throughout the life of the nuclear facility shall be independently verified by workers who did not perform the work to confirm that it meets requirements. The extent and timing of the verification shall be based on the potential impact of the work. **CNSC expectations:** Staff to confirm that verification performed on completed work packages was performed by workers that did not perform the work.	**Observations:** 1. Work Packages are verified independently and signed off by supervisor, technicians and managers 2. Work of Health Physics Technician verified by Health Physics and Regulatory Affairs Manager **Documents reviewed:** 1. Work Packages	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
12	Source: Other Details: QA Manual Rev I, Sect 4.8.3, Independent verification of work, para (3)	Where independent verification is called for, controlled procedures reflect this. For example, operation of the bulk splitter requires no less than two operators to perform the activity, and the calculations and output from this work is independently checked for accuracy. Key maintenance activities include a level of independent verification to ensure that the work is performed correctly, and that systems and components remain fit-for-service, as outlined in procedures. **CNSC expectations:** • What are the key maintenance activities and are they documented? • Staff to verify that procedures for bulk splitter work and key maintenance activities call for independent verification to be performed and confirm that it is reflected on the work verification records.	**Observations:** 1. In the tritium lab that is the bulk splitter where large containers of tritium gas is split into smaller containers. This is to prevent dumping bulk tritium gas out the stack, causing a large spike in emissions. Records are kept for the operation of the bulk splitter. 2. Repair and maintenance of bulk splitter stated as future initiative in Mitigation Committee meeting minutes. **Documents reviewed:** 1. Reviewed Management review minutes from Feb 2016 2. 2017/2017 Committee meeting minutes: Executive, Mitigation, Safety Culture	Objectives are met
13	Source: LCH Details: CSA N286-12 4.11 Assessment 4.11.1 Self-assessment	Management shall conduct self-assessments to identify opportunities for continual improvement and to confirm that work meets the requirements of the management system. **CNSC expectations:** • Staff to verify that this clause is being implemented by each organizational manager in their respective area of responsibilities. • Verify sample of self-assessment conducted on the implementation of the planning and control process	**Observations:** 1. List of individuals who perform self- assessments are included in the management review meeting minutes. This is a list of individuals at the management level. 2. Items listed as actions in some cases go to the OFI process because that suits their resolution better than reoccurring action items in the minutes for the management review meeting. The OFI process is found to be a better driver for action items. **Documents reviewed:** 1. 2016 self-assessments of all organizational managers	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		and/or issues arising from the process.		
14	Source: Other Details: QA Manual Rev I, Sect 4.11.1, Self-Assessment	Routine self-assessments by organizational managers, including Top Management, are undertaken to identify, correct and prevent problems that hinder the achievement of SRBT's vision, mission, goals, values and policy, as well as to assess the adequacy and effectiveness of the management system. Self-assessments can also be performed at any time, depending on the need and justification for conducting the assessment. **CNSC expectations:** • Talk to personnel responsible for self-assessment on their responsibilities and frequencies of their self-assessments. • Confirmation of a schedule in place for routine self-assessment. • Confirmation of self-assessment being carried out by all the various organizational manager via records. • Confirm that poor performance that hinders the organization's objectives is flagged to top management's attention and corrective action plans were developed and implemented.	**Observations:** 1. Organizational management reviews include benchmarks and self-assessments. Each organizational manager completes this review for the management review meeting, which occurs yearly. The minutes of the management review meeting contains a copy of each review. 2. There was no mention of progress from the meeting minutes about a NCR that was issued from the review of the Quality manager (NCR-438). According to the QA Manager, this NCR was not completed hence an effectiveness review has not been invoked. It was originally brought up as a result of an audit and, it is based on reject reporting of non-conforming items produced. 3. Poor performance are captured in the NCR and/or OFI process. These items go to a specific process and are tracked by management. 4. Top management tries to provide a broad perspective to the self-assessment activities. Goal is to empower and push people to give their perspective. **Documents reviewed:** 1. 2016 Management Review Meeting minutes	Objectives are met
15	Source: Other Details: MSP-010 Rev A, Self-Assessment,	The responsibility to ensure that the requirements pertaining to formal, routine Self-Assessment are met, rest with individual Organizational Managers.	**Observations:** 1. Non-routine Self-Assessment (SA) is not required to be formally documented, but can be documented as a memo. However, non-routine SAs may initiate NCRs.	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	Sect 4, Responsibilities	**CNSC expectations:** • Staff to verify if criteria used to determine the frequency for formal, routine self-assessments are the same across all organizations manager. • Staff to verify that self-assessments are also initiated in response to adverse trends in performance, after significant changes and new processes are implemented. • Staff to confirm actual assessments conducted versus assessments planned	2. SA reports leave a blank for topics that are covered by another manager. 3. Each organization manager is required to submit their respective organization management review as a part of the management review meeting that is held yearly. 4. Process gives the opportunity for unplanned assessments. Planned self-assessments occur once a year. Informal assessments have not been formally documented the same as the planned assessments. It is optional and can be used to critically review a process/topic. Items are addressed through NCRs and OFIs. 5. Shipping manager did an informal assessment of the receiving procedure that was documented in a memo, which created an action to update the procedure. This was done before the formalization of MSP-010. An NCR or OFI would indicate that they were created as a result of an informal assessment. **Documents reviewed:** 1. 2016 Management Review Meeting minutes	
16	Source: Other Details: MSP-010 Rev A, Self-Assessment, Sect 5, Frequency	Self-Assessment is performed formally by Organizational Managers on at <u>least an annual</u> basis, in support of the Organizational Management Review activities defined in MSP-008, Management Review. As such, annual Self-Assessment activities shall be targeted for completion by <u>mid-February</u> of each year, unless otherwise directed by Top Management. **CNSC expectations**: • Verify annual self-assessment reports	**Observations:** 1. Meeting occurred prior to mid-February. The reports from all organization managers are present in the report. 2. The management review reports include a list of performance and effectiveness criteria to discuss, a review of the quality policy, the status of actions from the previous management review, a review of changes in external and internal issues that a relevant to the management system, and the results of the self-assessment. **Documents reviewed:**	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		are available from all organizational managers for the management review. • Self-assessments are objective, and results, decisions, and any actions or recommendations are documented. • Management review addresses issues raised in self-assessments reports and action accordingly. • Examples of non-routine self-assessments. Self-assessment as a result of a safety-related event (e.g. fire event in 2015)?	1. 2016 Management Review Meeting minutes	
17	Source: Other Details: MSP-008 Rev A, Management Review	Management review (MR) activities include assessments, use of experience, continual improvement, problem identification and resolution and performance evaluation. Responsibility for MRs is shared by members of the Executive Committee but ultimate decision authority lies with Top Management. All managers who are responsible for the management of facility programs/procedures are required to perform management review activities. **CNSC expectations:** • Following topics considered in MR: action status, review of quality policy, changes to MS, performance and effectiveness of QMS, effectiveness of actions taken, opportunities for improvement, decisions made	**Observations:** 1. Management review lists benchmarking, strengths, improvements, areas needing improvement, overall assessment, problem identification and resolution. **Documents reviewed:** 1. 2016 Management Review Meeting minutes	Objectives are met
18	Source: Other Details: MSP-010 Rev A,	Self-assessments typically consist of: • Generating an appropriately critical comparison between the performance	**Observations:** 1. Opportunities for improvement are identified as OFIs.	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	Self-assessment, Sect 6, Self-assessment - Requirements	in the area, and the requirements, expectations, guidance or other criteria, • Determine if the performance has met, exceeded, or failed to meet the requirements, expectations, guidance or other criteria, • Determine if the performance has met the Quality Policy of SRBT, • Determine if there are opportunities of improvement in performance based on the findings of the Self-Assessment, • Taking action to improve performance based upon the Self-Assessment, • Reviewing the effectiveness of actions previously taken in this area. **CNSC expectations:** • Staff to verify self-assessment reports address the criteria above as a minimum and assessed against set criteria. • Staff to verify formal and informal assessments reports. • Staff to confirm actions are followed up for effectiveness.	2. Not all performance measurements show how it compares to expectations or other criteria. 3. Some completed NCRs are still awaiting effectiveness reviews. This is due to the need for more time before the effectiveness can be determined. 4. The NCR is checked by the Compliance manager as well as the manager responsible for the process where the NCR originated. 5. Managers are required to state in the assessment how the benchmarking of their responsible area meets the Quality Policy of SRBT. 6. 1 exceedance of safety pass-fail contamination (92 vs. 95%). This was discussed with the team and although the challenging target was not met, the team felt comfortable to not issue OFIs but continue to monitor these results in the future. **Documents reviewed:** 1. 2016 Management Review Meeting minutes	
19	Source: Other Details: MSP-010 Rev A, Self-assessment, Sect 7, Records	Any actions to be taken as a result of Self-Assessment should be controlled by generating an 'Opportunity for Improvement (OFI)' record, as described in MSP-011, Continual Improvement. If Self-Assessment uncovers any regulatory or program-related non-compliance, a non-conformance report (NCR) shall be generated in accordance	**Observations:** 1. Many cases where OFIs were raised as well as NCRs. A summary from all organizational review is listed at the back of the management review meeting minutes. 2. There is also evidence that NCRs and OFIs that are generated in the calendar year are assessed, corrective actions implemented and closed out by the end of the assessment period.	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		with MSP-012, Corrective Action, in order to address the issue and ensure that the problem is resolved in a controlled fashion. **CNSC expectations:** • Staff to verify records arising from self-assessment for an OFI and records of NCR and CAR.	**Documents reviewed:** 1. 2016 Management Review Meeting minutes	
20	Source: LCH Details: CSA N286-12 4.11 Assessment 4.11.2 Independent assessment	Independent assessments shall be conducted on behalf of top management to confirm that the documented management system meets requirements and the implementation of the management system is effective. Independent assessors shall (a) have access to the work site, workers, the work, documents, and records; and (b) neither have performed, verified, nor supervised the work being assessed. The results of independent assessments shall be reported to the level of management having sufficient authority to resolve any identified problems **CNSC expectations:** • Confirmation of audit plan and audit schedule for 2016 and 2017. • Verify audits conducted versus audits as planned. • Verify internal auditors and training records. • Audit results are reviewed at the Management Review Meeting and actions accordingly	**Observations:** 1. There was a total of 13 audits performed during 2016 2. In 2016, 13 NCRs and 31 OFIs were issued as a result of internal audits 3. Compliance Manager was responsible for performing all audits except for dosimetry which was a process that the Compliance Manager was responsible for. This audit was performed by the Quality Manager. 4. Both the Compliance manager and the Quality manager are trained for performing audits 5. Audit reports are given to top management directly, and answers only to them 6. All corrective actions are added to the NCR process 7. Audit scheduled for 2017 through 2019 verified 8. 18 of 19 audits planned for 2016 were completed 9. Audits are listed as part of a separate section of the Management Review report. 10. No external audits listed limited access as an issue in their reports **Documents reviewed:** 1. Audit schedule 2017-2019 2. Audit schedule 2012-2016	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		• Independent assessors have adequate access to sites, documents and records. • Corrective actions as a result of independent assessments are followed up with and closed. • Review open corrective actions and check timeline.	3. Audit Criteria document 4. Selected audit reports (e.g. Maintenance report April 2016) 5. Auditor Training records for QA Manager and Compliance Manager	
21	Source: Other Details: QA Manual Rev I, Sect 4.11.2, Independent Assessment	Audits also assess the effectiveness of relevant programs, processes and practices, and demonstrate the adequacy of work performance. **CNSC expectations:** • Staff to verify evidences on assessment of effectiveness of processes, procedures and practices and confirm actions are reported to top management. • Tracking of work performance	**Observation**s: 1. Performance and effectiveness of the QMS is reviewed during annual management review meeting 2. Maintenance audit report March 2016 includes a statement on work performance and effectiveness review. **Documents reviewed:** 1. Management review meeting minutes 2. Report No. 02-16, Maintenance audit report March 2016	Objectives are met
22	Source: Other Details: QA Manual Rev I, Sect 4.11.2, Independent Assessment	The results identified through independent assessment are reported to the level of management having sufficient authority to resolve any identified problems. **CNSC expectations:** • Staff to verify that organizational managers with sufficient authority to resolve identified problems in their organizational area are informed and are taking actions accordingly	**Observations** 1. Results are reviewed by top management, process owner, and executive assistant **Documents reviewed:** 1. Report No. 02-16, Maintenance audit report March 2016	Objectives are met
23	Source: Other Details: QA Manual Rev I, Sect 4.11.2, Independent	For internal audits, the auditor must not have performed, verified or supervised the work. **CNSC expectations:**	**Observations**: 1. Only Quality and Compliance Manager are qualified to perform audits 2. Compliance Manager performs most audits	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	Assessment	• Confirmation of audits conducted in 2016 were audited by auditors not involved in the work or process.		
24	Source: Other Details: QAS-007, Audits, Sect 2 Scope, Sect 3, Responsibilities	**CNSC expectations:** • Audit schedule encompass all licensed activities and processes • Audits assess effectiveness of relevant programs, processes and practices • Audits identify OFIs and areas of NCs • Responsibilities of QM and Compliance Manager are clear	**Observations:** 1. All licensed activities are covered in internal audits and audit schedules 2. 31 OFIs and 13 NCRs were issued as a result of audits in 2016 3. Audits assessed program effectiveness. **Document reviewed:** 1. 2016 Management review meeting minutes 2. Internal Audit Schedule – 2017-2019 3. QAS-007 Audits 4. Report No. 02-16, Maintenance audit report March 2016	Objectives are met
25	Source: Other Details: QAS-007, Audits, Sect 4.1, Types of Audits	Types of audits: internal, supplier, external. **CNSC expectations:** • Review external audit reports (CNSC, BSI, UL). How are corrective actions addressed and tracked? Any OFIs, NRCs as a result? Verify if CAs issued by external organizations are recorded, tracked and followed up with. • Verify if Management Review Meeting minutes include discussions of all types of audits. • Verify approval and acceptance of Supplier audits. Role of Compliance Manager? Does SRBT receive external audit reports of supplier	**Observations:** 1. Management Review cites the audits performed in the different areas. 2. This includes CNSC, BSI, and customer audits. 3. The meeting minutes also include discussion of the internal audits performed. 4. SRBT does not receive supplier audit reports not initiated by SRBT 5. Questionnaire sent out to supplier every 2-3 years. Currently waiting for suppliers to reply. 6. Audit reports are included in questionnaire 7. Approved Vendor List (AVL) included Swagelock, Radiation Monitoring Services. 8. 2016 management review includes discussions of external audit reports such as ISO 9001 and supplier audits. **Document reviewed:**	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		which was not ordered by SRBT?	1. AVL 2. 2016 Management review meeting minutes	
26	Source: Other Details: QAS-007, Audits. Sect 4.2, Auditor	**CNSC expectations:** • Review training, qualifications and selection of SRBT auditors • Independence of audited operations given? How is this determined by SRBT? • Verify access to site, documents and records of auditors	**Observation**s: 1. Both Compliance and Quality manager are trained in ISO 9001-2015 internal audit training through BSI 2. Auditors report directly to executive management. 3. Audit plan lists the month of the scheduled audit and the area to be audited. This plan lists all the relevant documents to be reviewed for this audit. 4. Independence of audited operations verified by CNSC, auditors do not audit their own work **Documents reviewed:** 1. AVL 2. 2016 Management review meeting minutes 3. Training records for ISO certification	Objectives are met
27	Source: Other Details: QAS-007, Audits, Sect 4.3, Audit schedule	Audit schedule shall encompass all licensed activities and processes, and shall be developed with audit frequencies spanning over 1 to 3 years. Schedule takes into consideration the importance of the processes concerned, changes, and results of previous audits. **CNSC expectations:** • Verify if all licensed activities and processes are included in schedule. • Verify audit frequencies. • Verify how significance is determined (grading process) and documented. • Verify if results from previous audits are taken into account.	**Observations**: 1. Audits are carried out every month 2. Audits for 10 departments occur every year. There are seven other areas/department that are audited in a three year cycle. **Documents reviewed:** 1. IA schedule 2017-2019	Objectives are met
28	Source: Other Details: QAS-007, Audits	Each audit shall be uniquely identified, logged in *Audit Register* and include elements such as serial number, date,	**Observations:** 1. Audits logged in Audit Register and include all required elements	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	Sect 4.4, Audit Report	signatures, scope, summary, results and findings. All findings that require CAs are recorded in NCR. NCRs are followed-up with and verified. Refer to QAS-020, Corrective Action. **CNSC expectations:** • Audit reports are complete and logged • NCRs are completed, followed-up with and verified • Manager responsible for the area shall take appropriate CAs to timely address NCs • Verify recorded OFIs and responses/approval from respective area manager	2. Audit reports are signed off by representatives 3. OFIs are generally issued by organizational managers	
29	Source: Other Details: QAS-007, Audits, Sect 5, Records	All completed and reviewed records associated with this procedure are scanned and stored electronically. Hard copies may also be kept on file. All records are maintained by the Compliance Manager as per the retention time stated on the Master Records List held by the Quality Department. **CNSC expectations:** • Verify if audit reports are retained and maintained adequately as per requirements above.	**Observations:** 1. Generally, records are scanned and stored electronically. However, the frequency for filing records electronically is not explicitly defined and is left to the discretion of the respective org. manager. 2. Audit records are maintained in the Audit Register **Documents reviewed:** 1. Audit Register	Objectives are met
30	Source: LCH Details: CSA N286-12	When problems arise, they shall be (a) immediately controlled, if required; (b) documented;	**Observations:** 1. People come to Compliance manager to raise issues who then logs the issues in the register. Currently	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
	4.9 Problem identification and resolution	(c) evaluated for significance and for underlying cause if deemed by management to be systemic or having impact on meeting business objectives; and (d) accepted. Actions employed to resolve problems shall be reviewed for effectiveness. **CNSC expectations:** • Staff to verify process compliance through problems raised from a completed work package.	paper-based. Date, originator, area affected, follow-up and closure date (usually 30 days), how it was actioned/source, review date for effectiveness, and brief description of the issue. 2. This register is reviewed every day. When actions are taken the register is updated. With the new standard, and the Compliance Manager taking full responsibility, it seems to take too long, where a software solution would save a lot of time. Currently it requires diligence to manage. 3. Compliance Manager logs NCR details and then sends a form with a number on it which will either be blank for the initiator to fill out or the Compliance Manager will populate it with their help. It will then be sent out to responsible people to comment and add details for actions. When the 30 day follow-up comes around the Compliance Manager will go back to these people to make sure they have added what is required if they don't get back in time. The Compliance Manager usually stops what she is doing to fill out an NCR form. 4. With the process, the initial problem is logged on the computer. The whole completed nonconformance is kept in the binder. At the end of the year they are taken out of the binder and kept separately. These are then scanned at some point, usually once a year. 5. Internal company network keeps these records. A copy of the network backup is kept in a safe in the bank. 6. NCR log is updated and tracked manually **Documents reviewed:** 1. MSP-012 Corrective Action 2. NCR log 3. NCR Form	

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
31	Source: Other Details: QA Manual Rev I, Sect 4.9, Problem identification and resolution	SRBT implements a process designed to identify, control and document problems that arise as part of our activities. **CNSC expectations:** • See above	See item #30	Objectives are met
32	Source: Other Details: QA Manual Rev I, Sect 4.9, Problem identification and resolution, para (4)	CA process also explicitly notes that safety issues shall always receive top priority and immediate allocation of resources, in alignment with both the principle where safety is the paramount consideration in guiding our actions, and where resources are managed. **CNSC expectations:** • Staff to confirm with personnel that makes these decisions using sample non-conformance and corrective action reports to explain how they apply these two principles to address safety issues non-conformances.	**Observations:** 1. Done at the discretion of the Compliance Manager, but knowledge of serious issues are known through various avenues and many opportunities exist to raise issues to senior management. 2. All NCRs are reviewed by top management and in the annual management review 3. Multiple committees exist where safety issues can be directly brought up by SRBT employees. Examples include Mitigation, Safety Culture, and Executive committees. **Documents reviewed:** 1. Committee meeting minutes 2. 2016 Management review 3. Sample NCRs	Objectives are met
33	Source: Other Details: QA Manual Rev I, Sect 4.9 Problem identification and resolution, para (6)	Identified problems are accepted through the CA process by Compliance Manager and Top Management. Actions are followed up to ensure that they were completed in an expeditious manner, and that they were effective in addressing the identified problem. **CNSC expectations:** • Verify acceptance of problems by Compliance Manager and Top Management. • Staff to verify effectiveness review of	**Observations:** 1. Effectiveness is reviewed based on the Compliance Managers discretion that sufficient time has passed. The status of the NCR is updated to reflect that the effectiveness has been reviewed. 2. Arising problems are accepted by Compliance Manager and Senior Management 3. Senior management is aware of problems early in the process, usually even before an NRC is raised **Documents reviewed:** 1. Sample NCRs 2. NCR log	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		implemented corrective actions (sample from completed work packages and in-process work).		
34	Source: Other Details: MSP-012 Rev A, Corrective Action, Sect 3, para (2)	All staff are responsible to follow the requirements of this procedure and to report problems to their supervisors or directly to the Compliance Manager so that they can be assessed and resolved. In addition, all staff are responsible for ensuring that safety-related issues receive top priority and immediate allocation of resources, depending on the relative risks to workers, the public or the environment. **CNSC expectations:** • Staff to verify SRBT staff understanding of this requirement.	**Observations:** 1. Compliance Manager reviews NCRs within 30 days of being added to the register to verify that the responsible staff have reviewed the NCR. The Compliance Manager will contact the staff to make sure that they address the NCR as soon as possible. 2. All staff responsible, staff encouraged to initiate NCR which is generally written and issued by the section manager instead of staff **Documents reviewed:** 1. NCR log	Objectives are met
35	Source: Other Details: MSP-012 Rev A, Corrective Action, Sect 3, para (3)	Senior management is responsible to review all Non-Conformance Reports (NCRs). **CNSC expectations:** • Staff to talk to senior management regarding their role in the non-conformance process. • Verify sample records to confirm involvement.	**Observations:** 1. Spoke with Compliance Manager and Regulatory Affairs Manager. 2. Senior management reviews all NCRs, there is a signature section in the NCR form for their signature and review. **Documents reviewed:** 1. Sample NCRs	Objectives are met
36	Source: Other Details: MSP-012 Rev A, Corrective Action, Sect 4, para (2)	The root cause needs to be determined to ensure appropriate corrective action is taken. The effectiveness of corrective action taken is reviewed by the individual who raised the Non-Conformance Report (NCR). **CNSC expectations:** • Verify examples of NRCs in which	**Observations**: 1. Person who raised the NCR is consulted with when the effectiveness review is completed and deemed effective. Root cause determination is completed by either the Compliance Manager or Quality Manager, both of whom have training in the determination of root cause. **Documents reviewed:**	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		the root cause was determined. Who determines RCs and are personnel qualified to determine RCs? • Clarification of this requirement from SRBT – who is this individual? Someone that is involved throughout the initiation of the NCR to completion of the CA or just someone that raised the NCR?	1. Root Cause Analysis Training record of Quality Manager	
37	Source: Other Details: MSP-012 Rev A, Corrective Action, Sect 5, para (1)	The Non-Conformance Report (NCR) is used when corrective action is necessary to investigate and address the non-conformance identified, which as part of its function formalizes the conduction of an investigation and document details of the root cause and corrective action taken. **CNSC expectations:** • Clarification of this requirement from SRBT. • When is the conduction of an investigation required?	**Observations:** 1. By completing the root cause and NCR process, it is deemed to be an investigation. This is completed by a trained individual, either the Compliance or Quality Manager.	Objectives are met
38	Source: Other Details: MSP-012 Rev A, Corrective Action, Sect 5.1	The Compliance Manager is responsible for coordinating the reporting and recording system for all the NCR's. Each NCR is issued a serial number from the NCR register. The follow-up/ close-out date and effectiveness of the corrective action taken are also documented on the NCR register. Any employee may raise NCRs however; all requests must go through the Compliance Manager. **CNSC expectations:** • Staff to review NCR register for verification of information	**Observation:** 1. CM and Senior Management accept NCRs and are required to sign off 2. Any SRBT employee can raise an NCR through the CM **Documents reviewed:** 1. Sample NCRs	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
		captured. • Verify the definition of NCR request. • Clarify who accepts NCs, as QAM Rev I, Sect 4.9 states that the CM and Top Management must accept problems when they arise.		
39	Source: Other Details: MSP-0120 Rev A, Corrective Action, Sect 5.3	**CNSC expectations:** • Review sample of NCRs and verify the following is documented: description of the NC, immediate/permanent actions taken, completion date, acceptance signatures, root cause, follow-up/close date, effectiveness review of CA	**Observations:** 1. NRCs include all required elements **Documents reviewed:** 1. Sample NCRs	Objectives are met
40	Source: Other Details: MSP-012 Rev A, Corrective Action, Sect 5.4	All NCR's, including those that affect health and safety or protection of the environment, are reported to Senior Management for acknowledgement of the necessary corrective action needed. **CNSC expectation:** • Staff to confirm senior management involvement in this process and review sample records.	**Observations:** 1. All NCRs require the review and signature of the senior management before they are deemed complete. **Documents reviewed:** 1. Sample NCRs	Objectives are met
41	Source: Other Details: MSP-012 Rev A, Corrective Action, Sect 5.5	Trending analysis of NCRs are conducted periodically by Compliance Manager through graphs. **CNSC expectation:** • Verify conduction of trending analysis of NCRs including trending of causes and problems	**Observations:** 1. Trending is done at a minimum of once a year for the Management Review. However, the Compliance manager is able to trend at any time if the CM deems it necessary based on the findings she sees in the NCR register. Part of the effectiveness review is to identify if there is a noticeable trend in NCRs that are similar.	Objectives are met

Management System				
	SOURCE	**CRITERIA**	**FACTS**	**MET/ NOT MET**
			Documents reviewed: 1. 2016 Management review meeting minutes	