



ORIGINAL

CMD: 19-H2

Date signed/Signé le : MARCH 19, 2019

A Licence Renewal

Le renouvellement d'un permis

Best Theratronics Ltd.

Best Theratronics Ltd.

Commission Public Hearing

Audience publique de la Commission

Scheduled for:

Prévue pour :

May 16, 2019

Le 16 mai 2019

Submitted by:

Soumise par :

CNSC Staff

Le personnel de la CCSN

e-Doc 5642579 (WORD)

e-Doc 5830797 (PDF)

Summary

This CMD presents information about the following matter of regulatory interest with respect to Best Theratronics Ltd.:

- Request to renew the Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-14.02/2019 for a period of 10 years commencing on July 1, 2019 and ending on June 30, 2029.

The following actions are requested of the Commission:

- Renew the Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-14.02/2019
- Authorize the delegation of authority as set out in section 4.6 of this CMD

The following items are attached:

- Proposed Class IB Nuclear Substance Processing Facility Licence NSPFL-14.00/2029
- Draft Licence Conditions Handbook
- The current licence NSPFOL-14.02/2019

Résumé

- Le présent CMD présente de l'information sur un ensemble de questions d'ordre réglementaire concernant Best Theratronics Ltd. :
- Demande de renouvellement du permis d'exploitation de l'installation de traitement de substances nucléaires de catégorie IB, NSPFOL-14.02/2019, pour une période de 10 ans allant du 1er juillet 2019 au 30 juin 2029.

On demande à la Commission de prendre les mesures suivantes :

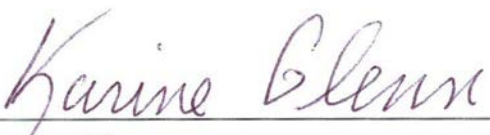
- Renouveler le permis d'exploitation de l'installation de traitement de substances nucléaires de catégorie IB, NSPFOL-14.02/2019
- Autoriser la délégation de pouvoirs, tel que présentée à la section 4.6 de ce CMD

Les pièces suivantes sont jointes :

- Permis proposé pour l'installation de traitement de substances nucléaires de catégorie IB, NSPFL-14.00/2029
- Ébauche du Manuel des conditions de permis
- Permis actuel, NSPFOL-14.02/2019

Signed/signé le

March 19, 2019



For Haidy Tadros

Director General

Directorate of Nuclear Cycle and Facilities Regulation

Directrice générale de la

Direction de la réglementation du cycle et des installations nucléaires

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EXECUTIVE SUMMARY

The current Best Theratronics Limited (BTL) licence NSPFOL-14.02/2019 [1] is valid until June 30, 2019. BTL has applied to renew the licence for a period of 10 years until June 30, 2029 [2] [3].

The current licence authorizes BTL to operate a Class IB facility for the purpose of manufacturing, developing and testing prescribed equipment – such as teletherapy units, self-shielded irradiators and particle accelerators (more specifically, cyclotrons) – and to possess and store nuclear substances.

BTL is requesting to renew the Class IB licence with no modifications or changes to its licensed activities. The purpose of this Commission Member Document (CMD) is to provide the results of CNSC staff's assessment of the BTL application, including conclusions and recommendations to inform the Commission decision on the licence renewal. CNSC staff reviewed all 14 safety and control areas (SCAs) and BTL's past performance. Table 1 presents CNSC staff's ratings of BTL's performance over the last five years.

During the licence period, all SCAs were rated as “satisfactory” except for “emergency management and fire protection” in 2015. The performance rating for emergency management and fire protection was revised from “below expectations” in October 2015 to “satisfactory” in November 2015. This change is a reflection of BTL having fulfilled all terms and conditions of an order issued by the CNSC, with respect to a dust collector, to comply with the *National Fire Code of Canada*.

BTL submitted a revised preliminary decommissioning plan to reflect a significant decrease in the number of sealed sources, prescribed equipment and depleted uranium at its facility, including a revised decommissioning cost estimate of \$1.8 million. On July 14, 2017, the Commission accepted the financial guarantee of \$1.8 million [4].

CNSC staff conclude that BTL has made and will continue to make adequate provision for the protection of the environment and the health and safety of persons, and that there are no anticipated adverse effects on the health and safety of persons or the environment as a result of the operations at BTL and that BTL is qualified to carry on the proposed activities the licence would authorize.

This conclusion is supported by the results of an environmental protection review conducted under the [Nuclear Safety and Control Act \(NSCA\)](#) [5] for the BTL licence application. More information on this review can be found in section 3.8 of the CMD.

The public, Indigenous groups and other stakeholders were invited to participate in the licensing process. To enable participation, up to \$35,000 was made available through the CNSC Participant Funding Program.

This CMD has two parts. Part One presents CNSC staff's review and assessment of BTL's licence application and a summary of BTL's performance since 2014. Part Two presents the CNSC staff proposed licence and licence conditions handbook.

Table 1: Performance Rating for BTL from 2014 to 2018

Safety and control area	2014	2015	2016	2017	2018
Management system	SA	SA	SA	SA	SA
Human performance management	SA	SA	SA	SA	SA
Operating performance	SA	SA	SA	SA	SA
Safety analysis	SA	SA	SA	SA	SA
Physical design	SA	SA	SA	SA	SA
Fitness for service	SA	SA	SA	SA	SA
Radiation protection	SA	SA	SA	SA	SA
Conventional health and safety	SA	SA	SA	SA	SA
Environmental protection	SA	SA	SA	SA	SA
Emergency management and fire protection	SA	BE	SA	SA	SA
Waste management	SA	SA	SA	SA	SA
Security	SA	SA	SA	SA	SA
Safeguards and non-proliferation	SA	SA	SA	SA	SA
Packaging and transport	SA	SA	SA	SA	SA

SA = Satisfactory; BE = Below Expectations

CNSC staff recommend that the Commission renew, pursuant to subsection 24(2) of the NSCA, the BTL licence to authorize BTL to continue to operate for a period of 10 years from July 1, 2019 to June 30, 2029.

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

PART ONE

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

Part One includes:

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

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

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1. OVERVIEW

1.1 Background

Best Theratronics Ltd. (BTL) is located at 413 March Rd, Ottawa, Ontario, in an industrial zone within the Kanata Research Park. The site has been used for industrial purposes since the 1960s. The surrounding area is a mixture of residential, commercial and industrial zoning. A perimeter road surrounds the BTL and the adjacent Nordion (Canada) Ltd.'s buildings. The company is privately owned.

The Commission issued BTL a Class IB nuclear facility licence, valid from July 1, 2014 to June 30, 2019, following a two part hearing. Prior to the Class IB licence being issued, BTL possessed several Class II nuclear facility and nuclear substance and radiation devices licences. BTL submitted its application for the renewal of the Class IB licence for a period of 10 years, until June 30, 2029 [2] [3].

BTL has established programs to support its activities and a management system focused on continuous improvement. CNSC staff conduct regular oversight activities to ensure BTL continues to meet regulatory requirements. BTL has an end-of-life management program for the exhausted and returned sealed sources. These sources are reused, recycled, re-encapsulated, transferred to other manufacturers, or disposed of, as appropriate.

1.2 Highlights

BTL is not requesting any modifications or additions to the activities that they are currently licensed to carry out.

BTL manufactures cobalt-60 radiation therapy units, cesium-137 blood irradiators and cyclotrons with the capability of producing energies ranging between 15 to 70 Megaelectron-Volts (MeV).

Whether a particle accelerator is considered to be a Class IB or a Class II particle accelerator is determined in the Regulations by its capability – the specifications of both are set out in section 1 of the [Class I Nuclear Facilities Regulations](#) and section 1 of the [Class II Nuclear Facilities and Prescribed Equipment Regulations](#). Class II particle accelerators are defined as:

(d) a particle accelerator that is capable of producing nuclear energy and has a beam energy of less than 50 MeV for beams of particles with a mass equal to or less than 4 atomic mass units;

(e) a particle accelerator that is capable of producing nuclear energy and has a beam energy of no more than 15 MeV per atomic mass unit for beams of particles with a mass greater than 4 atomic mass units; (section 1 [Class II Nuclear Facilities and Prescribed Equipment Regulations](#))

All other particle accelerators are defined as Class IB particle accelerators.

On February 15, 2019, BTL submitted an application for a Class II Nuclear Facility and Prescribed Equipment and two Nuclear Substances and Radiation Devices licences with an interest of revoking their Class IB licence. BTL stated that while it is a manufacturer of cyclotrons up to 70 MeV, operations are limited to the development and testing of cyclotrons below 1 MeV. At this beam energy, the cyclotron does not produce nuclear energy.

The BTL facility has several areas designated as radiation controlled areas: seven shielded rooms or “cells”, used for testing equipment, and storing radioactive materials; the “Old Paint Booth”, used to store radioactive materials; and the “High Bay” area, which is used to develop, manufacture and test cyclotrons. Currently, all “hotcell” related work is provided under contract by neighboring Nordion (Canada) Ltd., a CNSC licensed facility.

During the licensing term, BTL constructed one 70 MeV cyclotron and tested it at beam energies less than 1 MeV. Particles accelerated at 1 MeV or less do not produce nuclear energy. Following the testing and dismantling (of the operational systems), the cyclotron was shipped to the customer.

Since BTL’s licensed activities include testing cyclotrons greater than 1 MeV, CNSC staff are recommending deleting the hold points as outlined in current licence conditions (LC) 16.1 and 16.2 and replacing it with a new LC 15.1 (hold point). The new hold point would state that BTL may not operate cyclotrons at greater than 1 MeV without authorization from the Commission or a person authorized by the Commission. BTL is required to submit technical specifications of the cyclotron, operating, testing and dismantling (operational systems) procedures to ensure that the cyclotron is operated and dismantled safely. Further details are given in Part II of this CMD: Proposed Licence Changes.

Figure 1: Aerial view of the BTL facility



In 2015, a CNSC Designated Officer issued an order to BTL [6]. The order was issued following BTL's failure to comply with a condition of the Commission issued licence NSPFOL-14.01/2019 that required BTL to provide an acceptable financial guarantee. BTL submitted a revised preliminary decommissioning plan (PDP) [7] reflecting a significant decrease in the number of sealed sources, prescribed equipment and depleted uranium at its facility, and provided a revised decommissioning cost estimate of \$1.8 million. On July 14, 2017, the Commission accepted the financial guarantee [4]. Additional details are found in section 4.4 of this CMD.

An additional order was issued to BTL in October 2015 [8], to cease operation of the dust collector machine until BTL demonstrate that it complied with the *National Fire Code of Canada* (NFCC). The noncompliance was found by a CNSC Inspector during an on-site inspection. CNSC staff reviewed the corrective measures implemented by BTL and found these corrective actions to be satisfactory. The CNSC inspector confirmed during an inspection in November 2015 that BTL had complied with all the terms and conditions of the order and a new dust collector, satisfactory to the CNSC inspector, was put in place. Additional information on the corrective measures implemented by BTL can be found in section 3.9 of this CMD.

In October 2018, BTL reported that two workers exceeded BTL's radiological monthly action levels while working on the teletherapy device in Shielded Room 4. A report was provided to the CNSC and BTL took appropriate corrective actions [9]. Additional details on the corrective actions taken by BTL can be found in section 3.6 of this CMD.

The purpose of this CMD is to provide the Commission with the results of CNSC staff's assessment of the BTL application to renew its Class IB licence and to provide CNSC staff's conclusions and recommendations to inform the Commission decision on the licence application. CNSC staff's assessment of the application takes into consideration the results of CNSC staff's compliance verification activities, BTL's operational performance history and information submitted in support of the application.

1.3 Overall Conclusions

CNSC staff have concluded the following with respect to paragraphs 24(4)(a) and (b) of the NSCA [5], in that the licensee:

1. is qualified to carry on the activities that the licence will authorize the licensee to carry on; and
2. in carrying on that activity, has made, and will continue to make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

1.4 Overall Recommendations

CNSC staff recommend that the Commission:

1. Renew the Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-14.02/2019
2. Authorize the delegation of authority as set out in subsection 4.6 of this CMD

2. MATTERS FOR CONSIDERATION

2.1 Environmental Protection Review

CNSC staff have determined that the [Canadian Environmental Assessment Act, 2012](#) does not apply. Since the facility has minimal environmental interactions, an Environmental Protection Review under the NSCA was not produced. Instead, the assessment was based on the past EA and the regulatory oversight that has occurred since [10].

CNSC staff conclude that the licensee has made and will continue to make adequate provision for the protection of the environment and human health. More information on CNSC staff's assessment can be found in section 3.8 of the CMD.

2.2 Relevant Safety and Control Areas (SCAs)

CNSC regulatory oversight is performed in accordance with a standard set of 14 SCAs. SCAs are technical topics used across all CNSC regulated facilities and activities to assess, evaluate, review, verify, and report on licensee regulatory requirements and performance. Each SCA is comprised of "specific areas" of regulatory interest; however, the specific areas associated with each SCA vary between facility types. Addendum D provides further information about the SCAs including definitions for each SCA and their specific areas.

2.3 Other Matters of Regulatory Interest

Table 2 identifies other matters relevant to this CMD.

Table 2: Other matters relevant to this CMD

OTHER MATTERS OF REGULATORY INTEREST	
Area	Relevant to this CMD?
Environmental Assessment	Yes
Aboriginal / Indigenous Consultation	Yes
Other Consultation	Yes
Cost Recovery	Yes
Financial Guarantees	Yes
Licensee's Public Information Program	Yes
Nuclear Liability Insurance	No
Non-Proliferation	Yes

The relevant “other matters” of regulatory interest are discussed in section 4.

2.4 Regulatory and Technical Basis

The regulatory and technical basis for the matters discussed in this CMD are provided in Addendum C.

3. GENERAL ASSESSMENT OF SAFETY AND CONTROL AREAS

The CNSC uses a risk-informed regulatory approach in the management and control of regulated facilities and activities. The depth of regulatory reviews of each SCA and the baseline frequency of regulatory compliance activities are established by the risk ranking of that facility. CNSC staff apply a graded approach in conducting regulatory oversight activities. CNSC staff's assessment is presented in the following sections. This assessment was based on the review of BTL's licence application, supporting documentation, and compliance verification activities carried out since 2014.

Table 3 presents the compliance effort of CNSC staff for BTL, in person-days, from July 1, 2014 to September 30, 2018. Additional information on rating levels is provided in Addendum B.

Table 3: Summary of CNSC staff licensing and compliance activities carried out at BTL since July 1, 2014 to September 30, 2018

	2014*	2015	2016	2017	2018
Number of Inspections	0	3	4	4	1
Licensing Activities (Person days)	19.2	43.0	2.6	4.8	20.9
Compliance Activities (Person days)	14.4	85.2	73.0	106.3	49.3

* Note: 2014 are not for the entire year but only for the 6-month licensing period

3.1 Management System

The Management System SCA is 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.

The specific areas that comprise this SCA at BTL include:

- Management system
- Organization
- Performance assessment, improvement and management review
- Operating experience (OPEX)
- Change management
- Safety Culture
- Records management
- Management of contractors

3.1.1 Trends

The following table indicates the overall rating for the Management System SCA over the current licence period:

MANAGEMENT SYSTEM				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the Management System SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.1.2 Discussion

BTL's management system is supported by program documents such as *Quality Manual*, *Best Theratronics Environment Health and Safety Policy*, *Corrective Action and Preventive Action*, *Control of Documents* and *Design Change Procedure*. *Quality Manual* describes BTL's quality management requirements in general, management responsibilities, resource management, including human resources and work environment, and operational expectations.

In 2018, BTL submitted a gap analysis of its management system documentation against the requirements of CSA N286-12 *Management System Requirements for Nuclear Facilities* [11]. CNSC staff's review of this gap analysis found deficiencies such as identifying those workers that need relevant information, ensuring the information is current, correct and timely, and experience is used to initiate improvement under *Generic Requirements and Site Selection* section of N286-12. CNSC staff provided BTL with their review of the gap analysis requiring BTL to address each action item [12]. CNSC staff expect BTL to be fully aligned with N286-12 and complete its implementation in 2019.

In 2017, CNSC staff conducted a management system compliance inspection at BTL where 4 action notices were raised [13]. The actions were related to clear identification of roles and responsibilities, internal audits, availability of information and qualification of BTL contractors. The actions raised as a result of this inspection have since been closed by CNSC staff.

3.1.3 Summary

A summary of the licensee's past performance, proposed improvements and CNSC future regulatory focus are presented in the following subsections.

3.1.3.1 Past Performance

During the current licence period, BTL updated its management system, continued improving its effectiveness and implemented sound management practices and controls.

BTL maintained the practice of documenting operational experience and identifying and correcting problems. Any employee who encounters a condition that could result in a significant adverse impact on safety, environment and quality can raise a Corrective Action and Preventative Action (CAPA). CAPAs are tracked by BTL to resolution.

3.1.3.2 Regulatory Focus

CNSC staff will continue to monitor BTL's performance in this SCA through regulatory oversight activities with focus on the implementation of CSA N286-12. CNSC staff have planned to conduct a management system implementation inspection to verify the alignment of BTL's governing document with CSA N286-12 and its implementation in early 2020.

3.1.3.3 Proposed Improvements

An internal audit of the management system was conducted by BTL in 2017 and several improvement actions were identified: using electronic tools in document control, developing an “opportunity for improvement” system and re-evaluation of all auditor qualifications. BTL is continuing to make improvements in these areas.

3.1.4 Conclusion

During the current licence period, CNSC staff concluded that the Management System SCA at BTL met performance objectives and all applicable regulatory requirements. BTL is performing satisfactorily with respect to this SCA.

3.1.5 Recommendation

Licence Condition 1.1 in the proposed licence pertains to implementing and maintaining a management system.

3.2 Human Performance Management

The Human Performance SCA covers activities that enable effective human performance through the development and implementation of processes ensuring that licensee staff is sufficient in number, in all relevant job areas, and that licensee staff have the necessary knowledge, skills, procedures, and tools in place to safely carry out their duties.

The specific areas that comprise this SCA at BTL include:

- Personnel Training
- Work Organization and Job Design
- Personnel Certification

3.2.1 Trends

The following table indicates the overall rating for Human Performance Management over the current licensing period:

HUMAN PERFORMANCE MANAGEMENT				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the Human Performance Management SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.2.2 Discussion

BTL's Human Performance Management procedure tabulates an overview of qualifications, responsibilities and training requirements for the staff carrying out Class IB activities. An organizational analysis was performed by BTL to identify any positions where the consequence of human error poses a risk to the environment, the health and safety of persons, or to the security of nuclear facilities and nuclear substances. The training programs for these identified positions are subject to the requirements of CNSC [REGDOC-2.2.2, Personnel Training, Version 2](#).

BTL reviews the training needs whenever an employee's roles or responsibilities change. BTL has ensured that there are sufficient number of staff required for the operations and that all staff have the knowledge, skills and training to perform their work safely.

CNSC staff confirm that BTL has a training program that complies with CNSC [REGDOC-2.2.2, Personnel Training, Version 2](#) and the training requirements in the [General Nuclear Safety and Control Regulations](#) and [Class I Nuclear Facilities Regulations](#).

The BTL facility contains within its perimeter a Class II facility, and therefore, BTL must also meet the relevant regulatory requirements for Class II facilities. A regulatory requirement for Class II facilities is to have a certified radiation safety officer, to which BTL has complied.

3.2.3 Summary

A summary of the licensee's past performance, proposed improvements and CNSC staff's future regulatory focus are presented in the following subsections.

3.2.3.1 Past Performance

Training

BTL has implemented a systematic approach to training (SAT) during this licence period to provide assurance that personnel are trained and qualified for the work they perform.

CNSC staff have conducted various compliance verification activities including reviews of annual reports, and an inspection in 2015 focusing on training. Action items from this inspection included requiring BTL to update its training document to maintain a training program in accordance with the principles of SAT, conducting an organizational analysis to define the workers in positions where the consequence of human error poses a risk to safety and the environment, and administrative oversight in ensuring that proper records are kept in the training files. CNSC staff confirmed that the actions taken by BTL to address the above findings were adequate.

3.2.3.2 Regulatory Focus

CNSC staff will continue to verify, through compliance activities, the performance of BTL in the SCA of Human Performance, focusing on training and confirming that BTL training program and activities continue to comply with CNSC [REGDOC-2.2.2, Personnel Training, Version 2](#).

3.2.3.3 Proposed Improvements

BTL plans to develop an electronic training management system in the next licence period and continue to improve their SAT based training program as they implement their new electronic training management system.

3.2.4 Conclusion

Based on CNSC staff assessments of BTL's application, supporting documents and past performance, CNSC staff conclude that BTL has implemented and maintained effective training programs in accordance with regulatory requirements.

3.2.5 Recommendation

Licence Condition 2.1 in the proposed licence pertains to implementing and maintaining a training program.

3.3 Operating Performance

The Operating Performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

The specific areas that comprise this SCA at BTL include:

- Conduct of licensed activity
- Procedures
- Reporting and trending

3.3.1 Trends

The following table indicates the overall rating trends for the Operating Performance over the current licence period:

TRENDS FOR OPERATING PERFORMANCE				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the Operating Performance SCA at BTL as "satisfactory". CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.3.2 Discussion

CNSC staff confirm that BTL has implemented and maintains an effective operational program supported by procedures such as *Operating Performance*, *Shielded Room 4 Operating Instructions*, *Corrective and Preventive Action*, and *Quality Manual* in order to ensure licensed activities are performed safely and in compliance with regulatory requirements. CNSC staff conclude, through on-site inspections, review of licensee's governing documents and submissions, that BTL's Operating Performance program met all applicable regulatory requirements and performance objectives.

Procedures

Since 2014, BTL updated, as needed, its facility-specific procedures relating to operations to support ongoing process improvements. BTL has submitted sealed source tracking, inventory, reporting, accident management and non-conformance reporting procedures. CNSC staff have reviewed these procedures and find that the procedures and supporting documentation are satisfactory and met the regulatory requirements for this SCA.

BTL also submitted operational procedures for the facility, including the testing of the safety systems and training of the operators. CNSC staff have reviewed the procedures and supporting documentation and conclude that the information is satisfactory.

Conduct of Licensed Activities

BTL has applied to have a licence that includes testing cyclotrons greater than 1 MeV [14]; therefore, CNSC staff are recommending a hold point (licence condition) that states:

“The licensee shall not operate a cyclotron/ cyclotrons at beam energy greater than 1 MeV without prior authorization from the Commission or a person authorized by the Commission.”

The hold point is required for CNSC staff to ensure that the *Final Safety Analysis Report* (FSAR) is updated in accordance to existing conditions at the facility, that radiation doses to employees involved in radiological activities at BTL would be below administrative levels, and the activities related to operating, testing and dismantling of the cyclotron will not have an adverse effect on health and safety of the workers, public and environment.

In order to operate a cyclotron at beam energy greater than 1 MeV, BTL will need to provide to the CNSC the technical information regarding the cyclotron and include information on operating, testing and dismantling of the operational systems. Once CNSC staff have reviewed the information, a decision will be required by the Commission or a person authorized by the Commission to operate the cyclotron at greater than 1 MeV.

A new LC (15.1) applicable to cyclotrons operating at beam energies above 1 MeV will replace the current LCs 16.1 and 16.2. Further details are given in Part II of this CMD: Proposed Licence Changes.

Reporting and Trending

The BTL licence conditions handbook (LCH) includes compliance verification activities for reporting unplanned situations or events at BTL to the CNSC. Since 2014, BTL has continued to submit the required reports in accordance with the regulations. Table 4 presents the number of reportable events during the past licence period. All events were minor and did not pose an immediate or unreasonable risk to the health and safety of persons or the environment. Addendum F: *Reportable Events* provides more details.

Table 4: Reportable Events for BTL (2014-2018)

	2014	2015	2016	2017	2018
Total	3	0	0	1	2

3.3.3 Summary

A summary of the licensee's past performance, proposed improvements and CNSC staff's future regulatory focus are presented in the following subsections.

3.3.3.1 Past Performance

Since 2014, CNSC staff have carried out a number of compliance verification activities on BTL's operations, including on-site inspections, review of revised and new governing documents, annual compliance reports and event reports. CNSC staff found that overall BTL has been operating safely over the licence period. BTL continues to provide information regarding the operational performance at its facility in annual reports submitted to the CNSC. There has been little change in operations at BTL over the current licence period.

During the licensing period, BTL completed construction of one 70 MeV cyclotron and shipped it to its client after testing and disassembling of operational systems (2016).

3.3.3.2 Regulatory Focus

CNSC staff will focus on ensuring that BTL's operating limits and conditions for its facilities are as authorized under the licence, including limits and conditions for the possession, use, management, transfer, storage, import, export of nuclear substance and constructing and testing of cyclotrons.

3.3.3.3 Proposed Improvements

BTL has no identified key initiatives to be carried out during the proposed licence period.

3.3.4 Conclusion

Based on CNSC staff assessments of BTL's application, supporting documents and past performance, CNSC staff conclude that BTL continues to implement and maintain effective operational programs in accordance with regulatory requirements.

3.3.5 Recommendation

Operating Performance: Licence Conditions 3.1 to 3.3 in the proposed licence pertain to implementing and maintaining an operating program, implementing and maintaining a program for reporting to the Commission (including sealed source tracking) and implementing and maintaining a program for inventory control.

Site Specific: LC 15.1 applies only to operating a cyclotron/ cyclotrons at beam energy greater than 1 MeV and requires prior authorization from the Commission or a person authorized by the Commission for operation and testing (new).

Site Specific: LC 15.2 prohibits the export of high-risk radioactive sealed sources (new).

3.4 Safety Analysis and Physical Design

The SCAs designated as Safety Analysis and Physical Design will be considered together for this application. These two SCAs are intertwined as the physical design of the facility is described and assessed in BTL's Safety Analysis Reports (SARs). These reports support the overall safety case for the facility or systems.

The specific areas that comprise this SCA at BTL include:

- deterministic safety analysis
- hazard analysis

3.4.1 Trends

SAFETY ANALYSIS				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the Safety Analysis SCA / Physical Design SCA at the BTL facility as "satisfactory". CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.4.2 Discussion

BTL has implemented and maintains safety analyses programs at its facility in accordance with regulatory requirements. The CNSC requires BTL to conduct safety analyses in order to demonstrate that the facility meets relevant safety requirements and the design continues to provide adequate prevention and mitigation to protect against accidents. CNSC staff reviewed the SARs for Shielded Room 4, *Cyclotron Testing* and *Building Radioactive Material Processes* and found that the shielding and design of the systems and their components are adequate for the protection of the health and safety of workers, the public and the environment.

BTL utilizes Shielded Room 4 for beam characterization, collimator, source, and accessory testing of Co-60 teletherapy heads and collimators. Shielded Room 4 is equipped with radiation safety systems which include door interlocks, “last person out” buttons, emergency stop buttons, audible and visual alarms, operation indicators, and area radiation monitors.

The High Bay Area in the south east wing of the BTL building is dedicated for the construction and testing of cyclotrons. There are two modes for cyclotron testing. The first is testing of the beam on a copper probe, internal to the cyclotron. The second testing is the extraction of the beam from the cyclotron. The SAR for the testing of the 70 MeV cyclotron defines the limiting operational design parameters, typically the beam energy, current and shielding.

The SAR *Building Radioactive Material Processes* describes the radiological and industrial hazards associated with the operations conducted at BTL. It assesses safety of radiation work and the transfer of sources in rooms other than the Shielded Room 4 and High Bay area. These rooms are constructed to contain and control the radiation dose to adjacent areas.

3.4.3 Summary

A summary of the licensee’s past performance, proposed improvements and CNSC future regulatory focus are presented in the following subsections.

3.4.3.1 Past Performance

CNSC staff confirm that during the licence period, no cyclotrons were tested beyond 1 MeV and no challenges were identified pertaining to this SCA. BTL continues to review and implement their safety analysis program to meet regulatory requirements.

3.4.3.2 Regulatory Focus

CNSC staff will continue to monitor BTL's performance in this SCA through desktop reviews of relevant program documentation. CNSC staff will focus on confirming that BTL documentation mirrors the actual plant and that the SARs are updated to reflect the physical plant and current operating procedures.

BTL intends on testing linear accelerators during the next licence period and will be required to submit a licence amendment request to the CNSC for consideration.

3.4.3.3 Proposed Improvements

BTL will continue to improve and update the SARs including identifying and evaluating new information or unforeseen risks that were not considered previously.

3.4.4 Conclusion

CNSC staff confirm that the information submitted by BTL is sufficient and that the design and the shielding of the facility will incorporate adequate provisions for the protection of the health and safety of persons and the environment.

3.4.5 Recommendation

Licence Conditions 4.1 and 5.1 in the proposed licence pertain to implementing and maintaining safety analysis and physical design programs.

3.5 Fitness for Service

The Fitness for Service SCA covers activities that have impact on the physical condition of systems, components and structures to ensure that they remain effective over time. This includes programs that ensure all equipment is available to perform its intended design function.

The specific areas that comprise this SCA at BTL include:

- equipment fitness for service/equipment performance
- maintenance
- periodic inspection and testing

3.5.1 Trends

The following table indicates the overall rating for fitness for service over the current licence period:

FITNESS FOR SERVICE				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
<p style="text-align: center;">Comments</p> <p>CNSC staff continue to rate the fitness for service SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirement and performance objectives.</p>				

3.5.2 Discussion

CNSC staff confirm that BTL has a fitness for service program in place to ensure fitness of all machinery equipment, radiation measuring and monitoring equipment, and emergency response systems. The program is supported by detailed procedures on preventive maintenance, measuring and testing of equipment and the new equipment validation.

Since BTL designs, manufactures, and tests radiation devices and cyclotrons, it implements preventative maintenance procedures to ensure all manufacturing equipment is fit for service as per regulatory requirements. CNSC staff have verified that manufacturing equipment is maintained on a regular basis; the maintenance schedule is determined by several factors, including usage, operational history and manufacturer’s recommendations.

CNSC staff confirmed that all measuring and testing equipment (i.e., gauges, meters, etc.) are maintained according to BTL’s *Measurement and Testing Equipment* procedure.

CNSC staff confirmed, during on-site inspection, that BTL keeps an inventory of radiation monitoring equipment, including radiation survey meters, radiation area monitors, and personal digital reading dosimeters. Maintenance of radiation instruments is implemented through BTL’s calibration checks, conducted at required intervals and monthly inspections (*Radiation Survey Meter and Area Monitor Check Procedure*) to ensure that all area radiation alarms and radiation meters are in good working order.

BTL's Class II facility, within the Class IB facility, requires that the interlocks, pre-exposure alarm and emergency stops are in working order before commencement of work with the Class II equipment. CNSC compliance activities verify that BTL has an ongoing maintenance, calibration and testing program to ensure the necessary level of reliability required for these systems.

CNSC staff conduct inspections and review BTL submissions, related procedures and supporting documentation and annual compliance reports to ensure that all equipment and systems are maintained and fit for service.

CNSC staff have reviewed the procedures and supporting documentation and conducted inspections and considers BTL's performance in this SCA satisfactory.

3.5.3 Summary

A summary of the licensee's past performance, proposed improvements and CNSC future regulatory focus are presented in the following subsections.

3.5.3.1 Past Performance

CNSC staff verified through compliance activities that BTL continues to implement its fitness for service program through preventive maintenance, measurement and testing of equipment and new equipment validation; no declining trends of equipment performance was observed. Compliance activities showed monthly equipment and calibration checks were completed in a timely way to ensure the manufacturing equipment, radiation alarm and access control/shutdown systems and radiation instruments are in good working order.

BTL has a design change procedure for engineering changes to safety components to ensure the systems and components perform their intended functions.

3.5.3.2 Regulatory Focus

CNSC staff will continue to verify that *Corrective Action and Preventative Action* items are tracked to completion in a timely way and that BTL carries out the maintenance, inspection and testing activities according to its schedule.

3.5.3.3 Proposed Improvements

BTL has not indicated any specific improvements to its fitness for service program, other than the ones arising from continuous improvements.

3.5.4 Conclusion

Based on CNSC staff assessments of BTL's application, supporting documents and past performance, CNSC staff conclude that BTL continues to implement and maintain an effective fitness for service program.

3.5.5 Recommendations

Licence Condition 6.1 in the proposed licence pertains to implementing and maintaining a fitness for service program.

3.6 Radiation Protection

The Radiation Protection (RP) SCA covers the implementation of a radiation protection program in accordance with the [Radiation Protection Regulations](#). The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained as low as reasonably achievable (ALARA).

The specific areas that comprise this SCA at BTL include:

- Application of ALARA
- Worker dose control
- RP program performance
- Radiological hazard control
- Estimated dose to public

3.6.1 Trends

The following table indicates the overall rating for the RP SCA over the current licence period:

RADIATION PROTECTION				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the Radiation Protection (RP) SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.6.2 Discussion

The [Radiation Protection Regulations](#) require licensees to establish an RP program to keep exposures ALARA, through the implementation of a number of controls, including: management control over work practices; workers qualification and training; control of occupational and public exposures to radiation; and planning for unusual situations. The [Radiation Protection Regulations](#) also prescribe dose limits for workers and members of the public.

3.6.3 Summary

A summary of the licensee's past performance, proposed improvements and CNSC future regulatory focus are presented in the following subsections.

3.6.3.1 Past Performance

Application of ALARA

This specific area reviews BTL's efforts towards maintaining radiation doses to persons ALARA, social and economic factors taken into account. BTL's commitment to the ALARA principle has been demonstrated through the implementation of its RP program, which was developed in line with the CNSC regulatory guide [G-129, Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable \(ALARA\)"](#) [15].

BTL has documented expectations for their ALARA program including a clear substantiation for the existence of the program, clearly delineated management control over work practices, and dose trend analysis.

Worker Dose Control

This specific area reviews BTL's efforts to control occupational exposures to radiation and to report on radiation doses received by workers. During the current licence period, no worker at BTL received an effective or equivalent dose that exceeded the corresponding regulatory dose limits pursuant to the [Radiation Protection Regulations](#).

Radiation exposures are monitored to ensure compliance with the CNSC's regulatory dose limits and to keep radiation doses ALARA. BTL workers are exposed externally to sealed sources of radiation. External whole-body and equivalent doses are ascertained using CNSC licensed dosimetry.

At BTL, employees are classified as nuclear energy workers (NEWs) if they are expected to have a reasonable probability of receiving an occupational dose greater than 1 mSv. NEWs are identified as either building workers (those who work strictly at the Class IB facility), or Class II servicing workers (those who work at the Class IB facility and also under separate CNSC licences authorizing the servicing of radiation devices and Class II prescribed equipment throughout Canada). For completeness, building workers and Class II servicing workers' doses are reported in the figures and tables, below.

Between 2014 and 2018 (by September 30, 2018), the maximum effective dose received by a NEW at BTL was 8.92 mSv, or approximately 18% of the effective dose regulatory limit of 50 mSv in a one-year dosimetry period (Table 5).

Table 5: All NEWs-Effective dose (2018 monitoring data up to October 2, 2018)

Dose data	2014	2015	2016	2017	2018	Regulatory limit
Average effective dose (mSv)	0.03	0.05	0.08	0.11	0.16	N/A
Maximum individual effective dose (mSv)	0.46	0.85	2.28	5.30	8.92	50 mSv/year
Number of NEWs Monitored	74	76	73	77	77	

Tables 6 and 7 provide the average and maximum effective doses for Class II servicing and building NEWs at BTL between 2014 and 2018. Due to the nature of the servicing work, which involves service and source change outs of irradiators and teletherapy machines, doses to Class II servicing workers are higher than those received by building personnel. The dose of 8.92 mSv in 2018 was associated to a service technician, and although higher than previous years, is within the expected range based on historical data.

Table 6: Class II Servicing NEWs – Effective dose (2018 monitoring data up to October 2, 2018)

Dose data	2014	2015	2016	2017	2018	Regulatory limit
Average effective dose (mSv)	0.17	0.26	0.28	1.12	0.97	N/A
Maximum individual effective dose (mSv)	0.46	0.85	2.28	5.30	8.92	50 mSv/year
Number of NEWs Monitored	13	14	13	9	12	

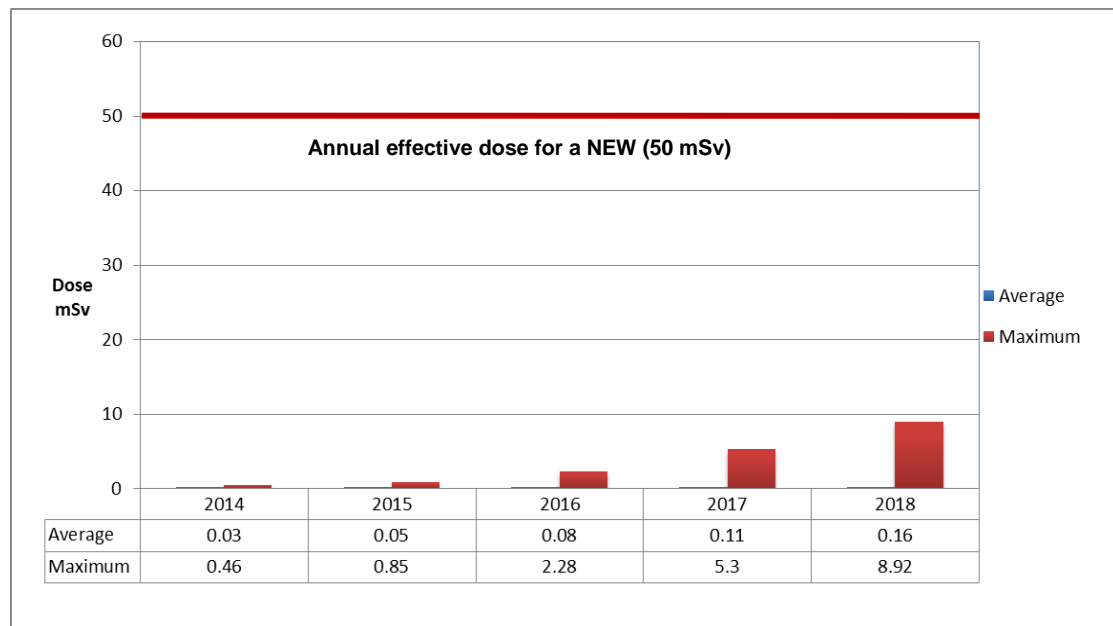
Table 7: Building Personnel NEWs – Effective dose (2018 monitoring data up to October 2, 2018)

Dose data	2014	2015	2016	2017	2018	Regulatory limit
Average effective dose (mSv)	0.00 ¹	0.01	0.03	0.02	0.04	N/A
Maximum individual effective dose (mSv)	0.11	0.20	0.98	0.47	0.74	50 mSv/year
Number of NEWs Monitored	61	62	60	68	65	

¹ Below reportable limit of 0.01 mSv

Figures 2 and 3 below show the average (including zero doses) and maximum individual effective doses for all NEWs at BTL and Building NEWs, between 2014 and 2018 up to September 30, 2018.

Figure 2: Effective dose distribution to NEWs at BTL from 2014 to 2018 (2018 monitoring data up to October 2, 2018)



Annual average and maximum equivalent extremity dose results from 2014 to 2018 are provided in tables 8 and 9. The maximum equivalent extremity dose from 2014 to 2018 was 29.9 mSv, or approximately 6.0% of the equivalent dose regulatory limit to the extremities of 500 mSv in a one-year dosimetry period.

Table 8: Class II Servicing NEWs – Extremities (2018 monitoring data up to October 2, 2018)

Dose data	2014	2015	2016	2017	2018	Regulatory limit
Average extremity dose (mSv)	0.18	0.31	3.66	1.84	2.13	N/A
Maximum individual extremity dose (mSv)	2.10	2.10	29.90	11.20	14.72	500 mSv/year
Number of NEWs Monitored	12	16	14	9	12	

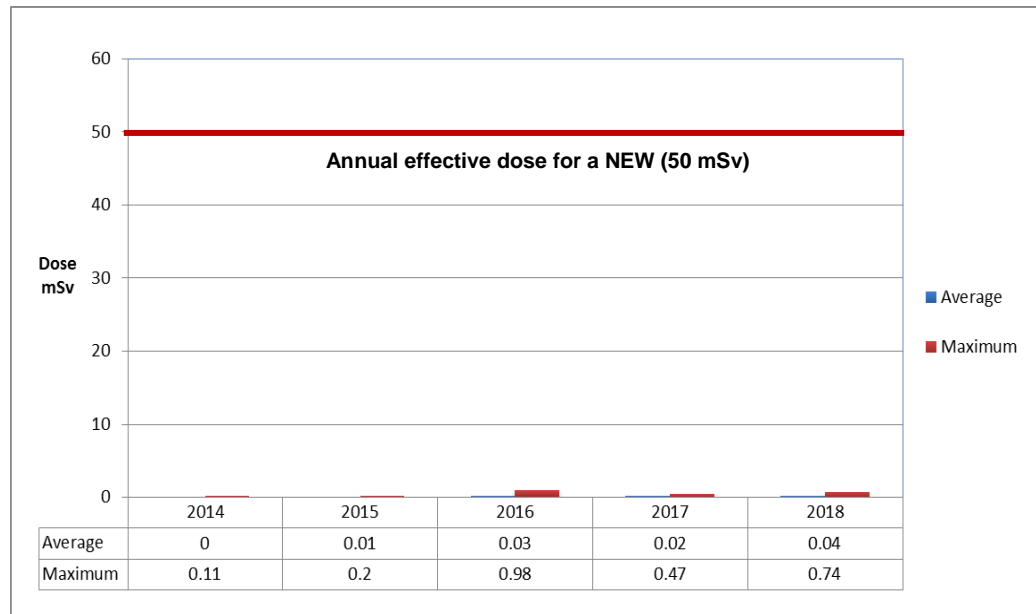
Table 9: Building Personnel NEWs – Extremities (2018 monitoring data up to October 2, 2018)

Dose data	2014	2015	2016	2017	2018	Regulatory limit
Average extremity dose (mSv)	0.21	0.00	0.09	0.07	0.180	N/A
Maximum individual extremity dose (mSv)	3.70	0.00	1.10	0.50	2.53	500 mSv/year
Number of NEWs Monitored	18	16	17	16	15	

Although equivalent skin doses are ascertained, due to the nature of exposure, which is limited to deeply penetrating gamma radiation, they are essentially equal to the whole-body effective dose and are not repeated.

BTL workers identified as non-NEWs, such as administrative staff, are restricted from accessing controlled areas where nuclear substances are stored or areas where there is a potential for the annual public dose limit of 1 mSv to be exceeded.

Figure 3: Effective dose distribution to Building NEWs from 2014 to 2018
(2018 monitoring data up to October 2, 2018)



Radiation Protection Program Performance

This specific area reviews the effectiveness of BTL's RP program in protecting the health and safety of persons.

CNSC Compliance Activities

CNSC staff assessed BTL's RP program performance over the current licence period through various CNSC staff compliance verification activities, including desktop reviews of annual compliance reports and CNSC on-site inspections. CNSC staff performed a focused RP inspection at BTL in 2016 [16]. CNSC staff's assessment of BTL's RP program performance identified areas of strength and also opportunities for improvement: BTL's Action Levels for effective, extremity and skin doses were set relatively high when contrasted to doses reported over the previous five years and correct radiation warning signs were not posted. BTL implemented enhancements to the RP program such as a periodic review of their action levels and setting more realistic limits and posting of correct radiation warning signs. As a result of onsite inspections and desktop reviews, CNSC staff found that BTL's RP program complies with CNSC regulatory requirements.

Radiological Action Levels

In accordance with regulatory requirements, BTL has established Radiological Action Levels for effective dose for various categories of workers in order to alert BTL of a potential loss of control of the RP program. In late 2016, as a result of a Type II inspection, BTL performed a review and updated their RP Action Levels. The new Action Levels were reviewed and approved by CNSC staff. During the licence period, BTL reported one instance where RP action levels were reached. In early October 2018, two Class II servicing personnel, performing work inside the BTL facility under the Class IB licence, exceeded radiation dose action levels during a source loading procedure for the purposes of testing the prototype teletherapy head at the facility. One worker exceeded the monthly extremity action level of 10 mSv, with an equivalent dose to the right extremity of 13.51 mSv. The other worker exceeded the monthly whole body dose action level of 4 mSv with an effective dose of 8.65 mSv. The incident occurred when hardware (a tungsten screw) securing the end plug (Figure 4) of the prototype teletherapy head failed and part of the source drawer exited the other end of the source head. The source was immediately pulled back into the transport container and safely stored. Due to the high activity of the source, very little exposure time was needed to accrue the doses. BTL's corrective actions include replacing the tungsten screws with stainless steel screws along with taking radiation measurements to ensure localized dose rates at screw locations remain acceptably low.

Figure 4: Broken tungsten screw and end plug



Radiological Hazard Control

This specific area reviews BTL's measures to control radiological hazards, preventing unnecessary radioactive releases and radiation exposures through monitoring.

The majority of the nuclear substances in use at BTL are sealed sources; therefore, the potential for contamination is very low. Notwithstanding, the licensee has implemented a thorough surface contamination monitoring procedure to monitor any potential contamination at its facility. Contamination checks are performed monthly in designated areas where nuclear substances may be handled, and following work where the potential for contamination exists. Over the last five years, there has been no indication of the presence of contamination from routine contamination monitoring at the BTL facility.

Monthly dose rate measurements are also performed in all radiation areas. In addition, fixed dose rate monitors are in place with set alarm thresholds in a variety of designated locations within the BTL facility. These measurements and alarm thresholds help to ensure a safe workplace.

Estimated Dose to the Public

There are no activities that occur inside the BTL facility that result in the release of nuclear substances to the environment. In addition, gamma radiation dose rates are kept ALARA to protect staff within the BTL facility. Therefore, due to BTL's licensed activities, there is an insignificant dose impact to members of the public that cannot be distinguished from natural background gamma radiation.

3.6.3.2 Regulatory Focus

CNSC staff will focus on BTL's implementation of its radiation protection program within the next licence period, to ensure that it is effective in keeping radiation exposures and doses to workers ALARA. CNSC staff will also ensure that BTL conducts a documented review of their radiological action levels and, if necessary, revise them at least every five years, as required.

3.6.3.3 Proposed Improvements

BTL will evaluate its processes and practices to ensure that the protection of the workers is optimized, including periodic reviews of radiological action levels and ensuring that radiation exposures and doses to workers remain ALARA.

3.6.4 Conclusion

CNSC staff conclude that the submissions made by BTL in support of the RP SCA are satisfactory and that there is an RP program in place to ensure that all regulatory requirements will be met.

No worker or member of the public received a radiation dose in excess of CNSC regulatory limits as a result of the licensed activities conducted at BTL during the current licence period.

3.6.5. Recommendation

Licence Condition 7.1 in the proposed licence pertains to implementing and maintaining an RP Program.

3.7 Conventional Health and Safety

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

The specific areas that comprise this SCA at BTL include:

- Performance
- Practices

BTL's performance related to conventional health and safety is monitored by CNSC staff using onsite inspections and desktop reviews. BTL is expected to take all reasonable precautions to ensure worker safety, the safety of the other persons at the site, and provide the necessary means to effectively manage, control and minimize health and safety risks. CNSC staff reviewed BTL's procedures related to health and safety and found them adequate. BTL's performance in this SCA is considered satisfactory.

3.7.1 Trends

The following table indicates the overall rating for the Conventional Health and Safety over the current licence period:

CONVENTIONAL HEALTH AND SAFETY				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
<p style="text-align: center;">Comments</p> <p>CNSC staff continue to rate the conventional health and safety SCA at BTL as "satisfactory". CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.</p>				

3.7.2 Discussion

BTL's *Environmental Health & Safety Policy* and *Environmental, Health and Safety Responsibilities* set the frame work for BTL's Conventional Health and Safety program. CNSC staff confirmed that BTL implements the health and safety measures through elimination and reduction of hazards and the provision of protective equipment. Each of these elements are supported by procedures, including hazard prevention, preventive maintenance, training, personal protective equipment and accident reporting.

CNSC staff confirmed that a Health and Safety Committee oversees conventional safety at BTL, implementing, monitoring and auditing programs related to health and safety, and evaluating all relevant employee complaints. The Committee performs monthly inspections of areas with potential hazards (chemical, fire, tripping, etc.) through Designated Inspectors. BTL encourages the employees to raise concerns on health and safety. During the on-site CNSC inspection in September 2018, CNSC staff reviewed the monthly meeting minutes of the Committee and associated corrective actions and observed that the issues related to health and safety were resolved in a timely way.

CNSC staff verified that BTL has a First Aid program with the aim of providing care to their staff in the event of an injury, illness or other first aid emergency and keeps a first aid room, with trained personnel, and first aid stations located throughout the facility.

In addition, CNSC staff confirmed that BTL mitigates any hazards from airborne emissions related to exhaust from the lead pouring area, old paint booth, fire torching areas and sand blasting through engineered and administrative controls. Air sampling, analysis and monitoring are conducted by BTL to ensure the safety of the workers against airborne lead and chemicals in the work area. Personnel are also required to wear appropriate protective equipment (respirators/masks) within the lead pouring area. Blood lead levels in employees who pour lead are regularly monitored to ensure their exposure does not exceed regulatory limits.

BTL's performance related to conventional health and safety is monitored by CNSC staff using on-site inspections and desktop reviews. BTL is expected to take all reasonable precautions to ensure worker safety, the safety of the other persons at the site, and provide the necessary means to effectively manage control and minimize health and safety risks. CNSC staff reviewed BTL's procedures related to health and safety and found them adequate. BTL's performance in this SCA is considered satisfactory.

3.7.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

3.7.3.1 Past Performance

Performance considerations for this SCA include:

- the number of Lost Time Incidents (LTI) that occur per year
- improvements in conventional health and safety practices
- participation of the workers in health and safety matters

An LTI is an injury that takes place at work, and results in the worker being unable to return to work and carry out their duties for a period of time. As indicated in Table 10, LTI numbers show a slight increase in 2016 and 2018.

Addendum E. *Lost Time Injuries* explains the nature of the injuries. Most of these injuries were related to workers hurting themselves while operating machinery such as a saw-mill or a grinder.

BTL is taking steps to improve the conventional safety at its facility. CNSC staff confirmed that during the licence period, BTL has made a number of improvements in its Conventional Health and Safety program:

- implemented additional safety-related administrative procedures, and updated existing procedures like paint handling and disposal
- delivered lock-out tag-out refresher training
- reviewed the lead (Pb) handling program
- updated the procedures to include safe practices related to all manufacturing tasks associated to working with lead

Table 10: Lost Time Incidents, 2014-18

	2014	2015	2016	2017	2018
LTIs	1	1	3	1	2

CNSC staff have confirmed that when issues have been raised through BTL's workplace health and safety inspections and Health and Safety Committee, BTL addresses these issues and takes corrective actions.

3.7.3.2 Regulatory Focus

CNSC staff will focus on the effectiveness of BTL's health and safety improvements and monitor its compliance with the conventional health and safety program. BTL's conventional activities and operations must comply with Part II of the *Canada Labour Code*.

3.7.3.3 Proposed Improvements

BTL has identified further improvements in this SCA including the following activities:

- improving documentation to change over to an electronic filing system
- surveying workers to better understand their perception of safety culture
- introducing company-wide refresher sessions of BTL's *Importance of Safety and Awareness*

3.7.4 Conclusion

CNSC staff conclude that the submissions made by BTL in support of Conventional Health and Safety are satisfactory and that BTL has procedures in place for the protection of the health and safety of persons.

3.7.5 Recommendation

Licence Condition 8.1 in the proposed licence pertains to implementing and maintaining a Conventional Health and Safety program.

3.8 Environmental Protection

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

This CMD covers the following specific areas of Environmental Protection:

- Effluent and emissions control (releases)
- Environmental management system (EMS)
- Assessment and monitoring
- Environmental Risk Assessment

The information provided by BTL in its *Environmental Impact Statement* (EIS) [17], the review of *Environmental Protection C1B-SD-09* [18] by CNSC staff and the mitigation measures proposed during the EA process form the basis for CNSC staff recommendations and conclusions in this SCA.

CNSC staff have determined that the *Canadian Environmental Assessment Act, 2012* does not apply. Since the facility has minimal environmental interactions, an Environmental Protection Review under the NSCA was not produced. Instead, the assessment was based on past EA and regulatory oversight that has occurred since. *Environmental Assessment Report: Best Theratronics Class IB Facility* provides further details [19].

3.8.1 Trends

The following table indicates the overall rating for Environmental Protection over the current licensing period:

ENVIRONMENTAL PROTECTION				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	N/A
Comments				
<p>CNSC staff continue to rate the environmental protection SCA at the Best Theratronics Limited (BTL) facility as “satisfactory”.</p> <p>BTL does not have radioactive releases to the environment. The risk of radiation exposure to members of the public from normal operations is very low. There have been no releases of hazardous substances (non-radiological) to the environment that would pose a risk to the public or the environment.</p> <p>BTL has implemented an Environmental Management System in order to conform to CNSC REGDOC-2.9.1, Environmental Protection: Environmental Protection Policies, Programs and Procedures (2013).</p>				

3.8.2 Discussion

Radioactive material at the BTL facility is limited to sealed sources and depleted uranium which is used as shielding for the sealed sources when manufacturing the prescribed equipment. Since only sealed sources are used, there are no radiological releases (waterborne or airborne) that would require controls or effluent monitoring.

BTL has provided information that hazardous liquid effluents from routine operations would be collected, temporarily stored on-site, and regularly removed for disposal by a certified third party contractor (Tomlinson). Lubricating oil for on-site boring and milling machines would be recovered and re-circulated. Therefore, there would be no hazardous waterborne releases that would require controls or effluent monitoring.

BTL produces substantial quantities of solid waste due to the manufacturing process. Zircaloy, lead and other non-hazardous metals are collected accordingly for recycling and are delivered to off-site recycling vendors.

BTL has provided information that there would be hazardous airborne emissions related to exhausting from the lead pouring area, paint booth, fire torching areas and sand blasting. Engineering controls are in place to reduce or eliminate air pollution generated during operations, including the use of filters, ventilation, and a bag house in the lead pouring area (the latter is an air pollution control device that removes particulates before air is vented outside). Indoor air sampling would be monitored periodically to ensure that chemical levels remain below indoor air quality regulatory limits.

Since there would be a small amount of hazardous airborne emissions from the facility, BTL applied to the Ontario Ministry of the Environment (MOE) for an Environmental Compliance Approval (ECA) for atmospheric emissions. To support this application, BTL conducted modelling of non-radionuclide atmospheric emissions for the site which indicated that under conservative operating scenarios, the facility would not result in changes to local air quality that would impact public or environmental health. BTL received an ECA on October 8, 2015 and CNSC staff determined that environmental monitoring is not warranted at this time.

Since there are no radiological releases from the facility, the risk of radiation exposure to members of the public from normal operation is negligible. The most exposed members of the public are the drivers transporting radioactive material from the site. The radioactive material is contained within a welded stainless steel encapsulation and a Type B transport container or self-shielded irradiator. The average dose to the driver for a typical shipment of radioactive material is 8.35 μSv and is well below the public limit of 1 mSv (1000 μSv).

3.8.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

3.8.3.1 Past Performance

Over the licensing period, BTL continued to operate in a manner that protected the health and safety of the environment.

In 2015, BTL implemented a new Environmental Management System to conform to CNSC [REGDOC-2.9.1, *Environmental Protection: Environmental Protection Policies, Programs and Procedures \(2013\)*](#) [20]. CNSC staff completed a review and are satisfied with the procedures in place to help protect the environment.

Within BTL's licensing period, a decrease in the amount of solid effluent released was due to improvements within the waste management program. Between 2013 and 2017, there has been a decrease in the amount of lead emissions released to the environment. This is directly attributable to the improvements in the lead control program and the decrease in manufacturing over the licensing period.

In order to be in compliance with ISO 14001: 2015, BTL's environmental management system was revised to include an evaluation on BTL's operations that may have an impact on the environment on an annual basis. In addition, a procedure was developed on the implementation of environmental objectives.

From an environmental risk assessment perspective, the last *Environmental Protection Report* (EPR) was done in 2011, when BTL commissioned a Phase I Environmental Site Assessment [21], which was used as both a risk assessment and means for monitoring environmental releases. This report was referenced in BTL's most recent EPR [18] and also helped inform their EIS [17]. The Phase I assessment identified areas within and outside the facility that could be potential environment risks and reported the mitigating measures in place.

3.8.3.2 Regulatory Focus

CNSC staff will continue to monitor BTL's performance in this SCA through regulatory oversight activities. CNSC staff will ensure that BTL continues to comply with CNSC [REGDOC-2.9.1, *Environmental Protection: Environmental Protection Policies, Programs and Procedures \(2013\)*](#) and CNSC [REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures \(2017\)*](#) [22], when implemented by the licensee. This will require the licensee to establish, implement and maintain an Environmental Management System, and BTL's internal governing document *Environmental Protection CIB-SD-09*.

CNSC staff also require BTL to update their environmental risk assessment to be consistent with CSA Standard N288.6-12, *Environmental risk assessments at class I nuclear facilities and uranium mines and mills* in order to be fully compliant with the current version of CNSC [REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures \(2017\)*](#) by the end of 2019.

3.8.3.3 Proposed Improvements

BTL will maintain the environmental protection program, implementing a policy with commitments to pollution prevention. BTL plans on consulting with the City of Ottawa Sewer Use Program in order to identify opportunities to minimize environmental impact based on current operations. In addition, BTL is actively seeking opportunities for safe disposal and transfer of radioactive material to maintain its commitment to protecting the environment.

3.8.4 Conclusion

CNSC staff conclude that, over the licence period, BTL operated in a manner that protects the environment and will continue to make adequate provision for the protection of the environment, and the submissions made by BTL in support of environmental protection are satisfactory.

3.8.5 Recommendation

Licence condition 9.1 in the proposed licence pertains to implementing and maintaining an environmental program.

3.9 Emergency Management and Fire Protection

This SCA covers emergency plans and emergency preparedness programs which exist for emergencies and for non-routine conditions. This also includes any results of exercise participation.

The specific areas that comprise this SCA at BTL include:

- Nuclear Emergency Preparedness and Response
- Fire Emergency Preparedness and Response

3.9.1 Trends

The following table indicates the overall rating for the Emergency Management and Fire Protection over the current licence period:

EMERGENCY MANAGEMENT AND FIRE PROTECTION				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	BE	SA	SA	SA
<p style="text-align: center;">Comments</p> <p>CNSC staff continue to rate the emergency management and fire protection SCA at BTL as satisfactory”. CNSC staff conclude that BTL met applicable CNSC requirements and performance objectives.</p> <p>Performance rating for Emergency Management and Fire Protection system SCA progressed from “Below Expectations” in October 2015 to “Satisfactory” in November 2015 through the fulfillment of all terms and conditions of a CNSC inspector order to comply with the <i>National Fire Code of Canada</i> with respect to a dust collector.</p>				

3.9.2 Discussion

BTL implements Nuclear Emergency and Fire Protection programs as required by CNSC [REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response, Version 2* \[23\]](#) and CSA N393-13, *Fire Protection for Facilities that Process, Handle, or Store Nuclear Substances* [24]. CNSC staff confirm BTL has Fire Hazard Assessment (FHA) and Fire Protection (FPP) programs.

As part of the licence application, BTL submitted a FPP to demonstrate that a defence-in-depth approach has been used in the facilities design and operation with respect to protection from fire.

CNSC staff conclude that BTL’s FPP has adequate fire protection features such as fire prevention, fire detection, fire warning, emergency communication, fire by-product management, fire suppression and fire containment, non-combustible construction and robust design of fire protection systems and structures and components for the protection of persons and the environment.

A CNSC order was given in October 2015 [8] to cease operation of the dust collector machine because it was in noncompliance with the *National Fire Code of Canada* (NFCC). The noncompliance was found by a CNSC inspector during an on-site inspection. CNSC staff reviewed the corrective measures implemented by BTL and found these corrective actions to be satisfactory. CNSC staff confirmed that BTL had complied with all the terms and conditions of the order during an on-site inspection in November 2015. The corrective actions were: establishing a comprehensive housekeeping procedure, removing the existing dust collector and replacing it with a unit having lower capacity and removing excessive waste wood.

CNSC staff confirm that BTL's Emergency Management program includes:

- A Radiation Emergency Response Plan to react to emergency situations involving radioactive material in order to:
 - minimize radiation exposure to employees and the general public,
 - minimize damage to the environment, and
 - restore normal operations as quickly as possible.
- A Transportation Emergency Response Plan which outlines the procedures to be followed in the event of transportation emergency.
- A Chemical Spill Response Plan in the event of an unplanned chemical release in order to minimize risk to personnel, environment, product and property.

3.9.3 Summary

A summary of the licensee's performance, regulatory focus and proposed improvements are presented in the following subsections.

3.9.3.1 Past Performance

Action items identified by CNSC staff during Emergency Program and Fire Response inspections conducted over the current licence period were addressed satisfactorily by BTL:

- BTL took appropriate actions to address Directives, regarding compliance with the NFCC, accumulation of combustibles, storage of flammable and combustible liquids, and one order [8] to cease operation of the Model 81 Donaldson/Torit cabinet dust collector. The Directives and Order resulted from a fire inspection on October 6, 2015 [25].
- Best Theratronic's Site Emergency Response Plan was updated to reflect the action items identified by CNSC staff during an inspection [26] conducted in 2017 focusing on the emergency management program. Actions taken by BTL included establishing a command and control structure in case of emergency, identifying an area for emergency operations center and availability of personal protective equipment.

BTL continued with the improvement of their emergency management and FPP.

3.9.3.2 Regulatory Focus

CNSC staff will continue to evaluate and verify BTL's implementation of CNSC [REGDOC-2.10.1, Nuclear Emergency Preparedness and Response, Version 2](#) [23] and CSA N393-13, *Fire Protection for Facilities that Process, Handle, or Store Nuclear Substances* [24] to ensure that BTL meets all regulatory requirements.

A full scale emergency response drill is scheduled to take place in 2019 with participation from local authorities, such as the Ottawa Fire Department, the Ottawa Police Department, and surrounding companies. CNSC staff will participate in evaluating this drill as part of the CNSC compliance efforts.

CNSC staff will continue to monitor BTL's response to radiation emergency incidents, and BTL's reevaluation of the emergency management and FPP, as part of the CNSC regulatory compliance process.

3.9.3.3 Proposed Improvements

CNSC staff will confirm that BTL continues to improve its emergency procedures and drill planning and that the improvements to be identified during the drill in April 30, 2019 are incorporated in BTL's emergency response program.

3.9.4 Conclusion

Emergency Management

CNSC staff conclude that the submissions made by BTL in support of Emergency Management are satisfactory and that there are emergency plans and emergency preparedness programs in place for emergencies and for non-routine conditions.

Fire Protection

CNSC staff confirmed that during the licence period, BTL has conducted a third party audit of its FPP and implemented the actions recommended by the audit, developed procedures on how combustibles are to be handled and provided training on paint handling and storage to employees involved in painting.

CNSC staff conclude that the submissions made by BTL in support of Fire Protection are satisfactory and that there is a FPP to demonstrate that an adequate defence-in-depth approach has been used in the facilities design and operation with respect to protection from fire.

CNSC staff conclude that BTL continues to implement and maintain effective emergency management and FPP at BTL in accordance with regulatory requirements.

3.9.5 Recommendation

Licence conditions 10.1 and 10.2 in the proposed licence pertain to implementing and maintaining an emergency preparedness program which includes fire response.

3.10 Waste Management

The Waste Management SCA 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 planning for decommissioning.

The specific areas that comprise this SCA at BTL include:

- Waste characterization
- Waste minimization
- Waste management practices
- Decommissioning plans

3.10.1 Trends

The following table indicates the overall rating for the Waste Management SCA over the current licence period:

WASTE MANAGEMENT				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the waste management SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.10.2 Discussion

BTL has a waste management program that meets the requirements of CSA standard N292.3-08, *Management of Low and Intermediate Level Radioactive Waste* [27]. The objectives of this program are to minimize the generation of waste at the facility and dispose of wastes and by-products generated in accordance with CNSC regulatory requirements. BTL’s waste management program describes how waste is managed throughout its lifecycle to the point of disposal. This includes storage, recycling and removal/transfer activities.

CNSC staff confirmed that BTL also maintains a PDP for its facility in accordance with CSA N294-09 (reaffirmed in 2014), *Decommissioning of Facilities Containing Nuclear Substances* [28] and CNSC regulatory guide [G-219, Decommissioning Planning for Licensed Activities](#) [29]. CNSC staff conclude that BTL has established and maintains a waste management program and a PDP to the satisfaction of CNSC staff.

3.10.3 Summary

A summary of the licensee’s performance, regulatory focus and proposed improvements are presented in the following subsections.

3.10.3.1 Past Performance

Details pertaining to the specific areas within this SCA are presented in the following subsections.

Waste Characterization, Waste Minimization, and Waste Management Practices

BTL's licence application included a documented waste management program for the facility. The program involves minimization, storage and disposal of hazardous and non-hazardous substances. BTL has hazardous waste, non-hazardous waste that is recyclable, radioactive sealed sources and depleted uranium. Depleted uranium is used in shielding in transport containers and teletherapy units.

BTL produces substantial quantities of solid waste due to its manufacturing process. Zircaloy, lead and other non-hazardous metals are collected for recycling and are delivered to off-site recycling vendors.

Radioactive waste management is documented in BTL's RP Manual and in the document *Management of Depleted Uranium Radioactive Material*.

CNSC staff assessed BTL's waste management program and found the procedures and supporting documentation satisfactory to support this licence application.

Decommissioning Plans

In accordance with paragraph 3(k) of the [Class I Nuclear Facilities Regulations](#), BTL is required to maintain a PDP throughout the life of the facility. The PDP must be periodically updated to reflect any changes in the facility or operations at a minimum of every five years or when required by the Commission. Decommissioning should be conducted in a manner that ensures that the health, safety, and security of workers, the public, and the environment are protected.

BTL's PDP sets out the strategy and the preliminary plan by which the facility will be decommissioned. Decommissioning involves removing the radioactive and other hazardous materials from the site and restoring it to an agreed end state to obtain a CNSC licence to abandon.

BTL last revised their PDP in 2016 [7] and CNSC staff verified that it meets CSA N294-09 (reaffirmed in 2014), *Decommissioning of Facilities Containing Nuclear Substances* [28].

3.10.3.2 Regulatory Focus

CNSC staff verified that BTL is currently in compliance with CSA standard N292.3-08, *Management of Low and Intermediate Level Radioactive Waste* [27]. CNSC staff requested that BTL perform a gap analysis for its waste program against the updated CSA standards N292.3-14, *Management of low- and intermediate-level radioactive waste* [30] and N292.0-14, *General Principles for the management of radioactive waste and irradiated fuel* [31]. CNSC staff will review all submissions related to the implementation of these standards and monitor program implementation through the conduct of compliance verification activities.

3.10.3.3 Proposed Improvements

BTL is committed to complete a gap analysis for the implementation of CSA standards N292.0-14 and N292.3-14 by 2019 and comply with the requirements of the Canadian standards by 2020, as reflected in the draft LCH. Based on the current waste management program, this timeline is acceptable to CNSC staff.

Best Theratronics has a life-cycle waste management program for the exhausted and returned sealed sources which are reused, recycled, re-encapsulated, transferred to other manufacturers, or disposed of as appropriate. Over the current licensing period, BTL has significantly reduced its resident waste inventory and is currently in talks with licensees for safe disposal and transfer of radioactive material.

3.10.4 Conclusion

CNSC staff conclude that BTL has an acceptable waste management program and that BTL has and will continue to make adequate provision for the protection of workers, the public and the environment.

CNSC staff also conclude that BTL's PDP meets the applicable regulatory requirements of CSA standard CSA N294-09 (reaffirmed in 2014) *Decommissioning of Facilities Containing Nuclear Substances* [28], and conforms to CNSC regulatory guide [G-219, Decommissioning Planning for Licensed Activities](#) [29].

3.10.5 Recommendation

Licence Conditions 11.1 and 11.2 in the proposed licence pertain to implementing and maintaining a waste management program and a decommissioning plan.

3.11 Security

The specific areas that comprise security cover the security and response programs which exist to maintain the security of devices, to ensure that measures are in place to alert the licensee to the illegal use or removal of nuclear substances; and that measures are in place to alert the licensee to sabotage or attempted sabotage anywhere at the site of the licensed activity.

The programs also ensure that all workers are instructed on the facility security program at BTL.

The specific areas that comprise this SCA at BTL include:

- Facilities and equipment
- Response arrangements
- Security practices
- Drills and exercises

3.11.1 Trends

The following table indicates the overall rating for the Security SCA over the current licence period:

SECURITY				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the security SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.11.2 Discussion

A security inspection was conducted in May 2017 as part of the CNSC compliance verification activities. All action notices from these inspections have been subsequently addressed by the licensee in a satisfactory manner. No action items were of significance to impact the security at the facility. Security related action notices are not available in this CMD as they are confidential.

The BTL Security Program was assessed as satisfactory by CNSC staff and is in compliance with the applicable requirements.

CNSC staff have assessed BTL’s implementation of the physical protection program from the access control perspective. Measures for controlling access were assessed as being satisfactory.

3.11.3 Summary

A summary of the licensee’s past performance, challenges and proposed improvements are presented in the following subsections.

3.11.3.1 Past Performance

BTL updated its site security plan in August 2017. This plan was reviewed by CNSC staff and assessed as meeting the necessary requirements.

BTL currently maintains all security systems and devices for the facility. In addition, the licensee has satisfactory processes in place for testing and maintaining the security devices and systems. Equivalent security measures are implemented for the secure transportation of high-risk radioactive sources by road. BTL maintains a satisfactory transport security plan. This transport security plan is reviewed annually by CNSC staff and meets security requirements.

The licensee completed a Threat and Risk Assessment for the activities associated with cyclotrons. There is no indication that these activities have any impact on the security of the facility or the safety of the personnel, the public or the environment.

3.11.3.2 Regulatory Focus

CNSC staff will continue to monitor BTL's performance in this SCA through regulatory oversight activities, including on-site inspections and desktop reviews of relevant program documentation. CNSC staff will review BTLs transport security plan annually to ensure it meets CNSC's security requirements.

3.11.3.3 Proposed Improvements

BTL has not indicated any specific improvements to its Security program, other than the ones arising from continuous improvements such as the development of a vehicle search program for all vehicles entering the BTL site.

3.11.4 Conclusion

CNSC staff conclude that the submissions made by BTL in support of Security are satisfactory. BTL will continue to implement the existing program thereby ensuring adequate provisions for the security of devices, that measures are in place to alert the licensee to the illegal use or removal of nuclear substances; that measures are in place to alert the licensee to sabotage or attempted sabotage anywhere at the site; and that all workers will be instructed on the facility security program.

3.11.5 Recommendation

Licence Condition 12.1 in the proposed licence pertains to implementing and maintaining a security program.

3.12 Safeguards and Non-Proliferation

The Safety and Control Area "Safeguards and Non-Proliferation" covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the [*Treaty on the Non-Proliferation of Nuclear Weapons*](#).

The specific areas that comprise this SCA at BTL:

- Nuclear material accountancy and control
- Access and assistance to the IAEA
- Operational and design information
- Safeguards equipment, containment and surveillance
- Import and export

3.12.1 Trends

The following table indicates the overall rating for the Safeguards and Non-Proliferation SCA over the current licence period:

SAFEGUARDS AND NON-PROLIFERATION				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
<p style="text-align: center;">Comments</p> <p>CNSC staff continue to rate the safeguards and non-proliferation protection SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.</p>				

3.12.2 Discussion

Safeguarded material at BTL consists of less than one effective kilogram of nuclear material, placing BTL in the category “Location Outside Facility (LOF)”. Note that LOFs, as defined for safeguards purposes, are facilities that do not have a reactor or a critical facility, or, a nuclear material conversion, fabrication, reprocessing or isotope separation plant, or, a separate nuclear material storage installation, and the customarily used material is subject to full-scope safeguards in amounts less than 1 effective kilogram. As such, BTL must fulfil the requirements for safeguards implementation for LOFs, as codified in CNSC [REGDOC-2.13.1 Safeguards and Nuclear Material Accountancy](#) [32].

Currently, BTL maintains a safeguards program to comply with licence requirements. The program conforms to measures required by the CNSC to meet Canada’s international safeguards obligations as well as other measures arising from the [Treaty on the Non-Proliferation of Nuclear Weapons](#). Currently, BTL is in compliance with REGDOC-2.13.1’s predecessor, [RD-336, Accounting and Reporting of Nuclear Material](#) [33]. REGDOC-2.13.1 became effective February 14, 2018. BTL has submitted a Gap Analysis for implementation of REGDOC-2.13.1, identifying areas in its safeguards program requiring updates. CNSC staff have reviewed this analysis and found that it is satisfactory to ensure compliance with the updated regulatory requirements. As of January 1, 2019, BTL has updated its procedures and has implemented REGDOC-2.13.1.

The import and export of controlled nuclear substances, equipment and information identified in the [Nuclear Non-proliferation Import and Export Control Regulations](#) require separate authorization from the CNSC, consistent with subsection 3(2) of the [General Nuclear Safety and Control Regulations](#). The guidance to seek such an authorization is provided in CNSC [REGDOC-2.13.2, Import and Export](#).

3.12.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

3.12.3.1 Past Performance

During the licence period, BTL provided the CNSC and IAEA with all reports and information necessary to comply with safeguards regulatory requirements, including those related to nuclear material accounting and reporting, and operational and design information. For IAEA safeguards inspections and CNSC safeguards evaluations, BTL provided the necessary access and assistance to perform activities, and the IAEA was able to utilize safeguards equipment, as necessary. Containment and surveillance were not employed and therefore were not assessed.

During this licence period, the IAEA visited BTL once, in October 2015. This visit included a Physical Inventory Verification combined with a Design Information Verification. A CNSC safeguards assessment was conducted in October 2016. There were no reportable events or action notices issued as a result of these inspections.

As stated above, BTL has submitted a gap analysis for implementation of REGDOC-2.13.1, identifying areas in their safeguards program requiring updates. As of January 1, 2019, BTL has updated its procedures and has implemented REGDOC-2.13.1.

3.12.3.2 Regulatory Focus

CNSC staff will continue to monitor and evaluate BTL's compliance with CNSC [REGDOC-2.13.1 Safeguards and Nuclear Material Accountancy](#) [32] and [Treaty on the Non-Proliferation of Nuclear Weapons](#) and perform regulatory oversight activities including on-site inspections and reviews of compliance reports and revisions to relevant program documentation.

3.12.3.3 Proposed Improvements

BTL updated its program documentation to coincide with its gap analysis conducted against REGDOC-2.13.1. Additional improvements such as reporting through Nuclear Materials Account Reports (NMAR) system will be incorporated into the Safeguards program within the next licence period.

3.12.4 Conclusion

CNSC staff conclude that the submissions made by BTL in support of safeguards and non-proliferation are satisfactory and continued implementation of their safeguards program will ensure that the obligations arising from the Canada/IAEA safeguards agreements, as well as all other measures arising from the [Treaty on the Non-Proliferation of Nuclear Weapons](#) are met.

3.12.5 Recommendation

Licence Condition 13.1 in the proposed licence pertains to implementing and maintaining a safeguards program.

3.13 Packaging and Transport

The Packaging and Transport SCA covers the safe packaging and transport of nuclear substances to and from the licensed facility.

The specific areas that comprise this SCA at BTL include:

- Package design and maintenance
- Packaging and transport
- Registration for use

3.13.1 Trends

The following table indicates the overall rating for Packaging and Transport over the current licence period:

PACKAGING AND TRANSPORT				
Overall Compliance Ratings				
2014	2015	2016	2017	2018
SA	SA	SA	SA	SA
Comments				
CNSC staff continue to rate the packaging and transport SCA at BTL as “satisfactory”. CNSC staff conclude that BTL met applicable regulatory requirements and performance objectives.				

3.13.2 Discussion

BTL currently has a packaging and transport program that ensures compliance with the [Packaging and Transport of Nuclear Substances Regulations, 2015](#) and the [Transportation of Dangerous Goods Regulations](#).

CNSC staff conducted one inspection of BTL’s packaging and transport program over the licensing period, in November 2017 [34], and found it to be acceptable. Areas of improvement were identified in regards to training and shipping documentation, which have been addressed by BTL. Recommendations made by CNSC staff included completeness and clarity when filling out shipping documents as well as the issuance of a TDG certificate for all staff who complete TDG training, not only shippers and logistics staff.

The packaging program at BTL is effectively implemented and maintained, and the transport of nuclear substances to and from the BTL facility is done in a safe manner.

3.13.3 Summary

Details pertaining to the specific areas within this SCA are presented in the following subsections.

3.13.3.1 Past Performance

Package Design and Maintenance

The [*Packaging and Transport of Nuclear Substances Regulations, 2015*](#), apply to the packaging and transport of nuclear substances, including the design, production, use, inspection, maintenance and repair of packages, and the preparation, consigning, handling, loading, carriage and unloading of packages. The BTL package designs and maintenance program meet these requirements. Where necessary, BTL package designs are certified by the CNSC.

Packaging and Transport

Three transport and packaging events were reported during the licence period. All three events concerned incoming shipments for which BTL was not the consignor. The first event involved the return of a Co-60 source with no Class 7 placards while the second one involved receipt of a shipment without the necessary UN labels and obsolete TI labels. The third one was improper bracing of a returned Co-60 package in a sea freight container. None of the events had any safety consequences and these events were reported to the CNSC by BTL and followed by a full event report in accordance with the Regulations.

Registration for Use

BTL's packaging and transport program covers the registration for use of certified packages as required by the Regulations. BTL has demonstrated compliance with CNSC requirements in this area.

3.13.3.2 Regulatory Focus

CNSC staff will continue to monitor and evaluate BTL's performance in this SCA through regulatory oversight activities. These activities include inspections, reviews of compliance reports and other licensee submissions. CNSC staff focus on completeness and clarity of shipping documents, and the issuance of TDG certificates for all staff that complete TDG training, not limited to shippers and logistics staff.

3.13.3.3 Proposed Improvements

BTL has identified no key initiatives to be carried out during the proposed licence period.

3.13.4 Conclusion

CNSC staff conclude that the submissions made by BTL in support of Packaging and Transport are satisfactory and that there are procedures in place for the safe packaging and transport of nuclear substances to and from BTL.

3.13.5 Recommendation

Licence Condition 14.1 in the proposed licence pertains to implementing and maintaining a transport and packaging program.

4 OTHER MATTERS OF REGULATORY INTEREST

4.1 Indigenous Consultation

The common-law duty to consult with Indigenous groups applies when the Crown contemplates actions that may adversely affect potential or established Indigenous and/or treaty rights. The CNSC ensures that all of its licensing decisions under the NSCA [5] uphold the honour of the Crown and consider Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the constitution.

4.1.1 Discussion

CNSC staff have identified First Nation and Métis groups who may have an interest in the proposed licence decision. The Algonquins of Ontario (Algonquins of Pikwàkanagàn), Kitigan Zibi Anishinabeg, the Algonquin Anishinabeg Tribal Council (Algonquins of Quebec), the Anishinabek Nation (Union of Ontario Indians), and the Métis Nation of Ontario were identified because all have previously expressed interest in being kept informed of CNSC licensed activities occurring in their traditional territories.

CNSC staff sent letters of notification in December 2018 to these identified groups, providing information regarding the proposed licence renewal application, the availability of participant funding to facilitate participation in the hearing process, and details on how to participate in the Commission's public hearing process in May 2019. Follow-up phone calls were conducted to ensure they had received the letters and to answer any questions about the regulatory process and how to get involved in the Commission proceedings. To date, none of the identified First Nation and Metis groups have expressed any direct concerns about the licence renewal. CNSC staff will continue to notify and engage with Indigenous groups who express an interest in the BTL facility.

CNSC [REGDOC-3.2.2, *Aboriginal Engagement*](#) [35], published in February 2016, sets out requirements and guidance for licensees whose proposed projects may raise the Crown's duty to consult. While the CNSC cannot delegate its obligation, it can delegate procedural aspects of the consultation process to licensees. The information collected and measures proposed by licensees to avoid, mitigate or offset adverse impacts from the proposed licence renewal may be used by CNSC staff in meeting its consultation obligations.

As BTL's licence application does not propose any new activities, regulatory requirements set out in REGDOC-3.2.2 pertaining to formal engagement do not apply. However, CNSC staff encourage BTL to continue to engage with interested Indigenous communities on the licence application and on-going activities of interest to the communities.

4.1.2 Conclusion

Based on the information received and reviewed, CNSC staff have determined that BTL's operations occur wholly indoors within its facilities, that there is no planned expansion of the facilities footprint, and there is a low probability of emissions or waste being produced which could adversely impact the surrounding environment. BTL's facilities are located in an existing industrial zone within a suburban neighbourhood in close proximity to a large urban center. This licence renewal application will not cause adverse impacts to any potential or established Indigenous and/or treaty rights.

Therefore, CNSC staff are of the opinion that the decision on the licence application for BTL before the Commission does not raise the duty to consult.

4.2 Other Consultation

The CNSC made available up to \$35,000 through its Participant Funding Program to Indigenous peoples, members of the public and stakeholders in providing value-added information to the Commission through informed and topic-specific interventions. This funding was offered to review BTL's application and associated documents and to prepare for and participate in the Commission's public hearing.

The deadline for applications was January 25, 2019 and no applications were received.

4.3 Cost Recovery

Paragraph 24(2)(c) of the NSCA [5] requires that a licence application is accompanied by the prescribed fee. The [CNSC Cost Recovery Fees Regulations \(CRFR\)](#) set out the specific requirements based on the activities to be licensed. An applicant for a Class I facility licence is subject to Part 2 of CRFR, which is based on Regulatory Activity Plan fees.

Through review of CNSC records, CNSC staff conclude that BTL is in good standing with respect to CRFR requirements and has paid their cost recovery fees in full. CNSC staff do not have concerns regarding payment of future cost recovery fees.

4.4 Financial Guarantees

Subsection 24(5) of the [Nuclear Safety and Control Act](#) states “A licence may contain any term or condition that the Commission considers necessary for the purposes of this Act, including a condition that the applicant provide a financial guarantee in a form that is acceptable to the Commission”.

CNSC regulatory guide [G-206, Financial Guarantees for the Decommissioning of Licensed Activities](#) [36], sets out guidance on the development of financial guarantees for licensed facilities and activities. The Financial Guarantee is updated every five years and submitted to the CNSC for review. LC G.3 requires that the licensee shall maintain a financial guarantee for decommissioning acceptable to the Commission.

BTL has established and maintains a FG for decommissioning of its facility that meets condition G.3 of the licence and the acceptance criteria set in the CNSC G-206.

In January 2017, BTL submitted a revised PDP to reflect a significant decrease in the number of sealed sources, prescribed equipment and depleted uranium at its facility. CNSC staff reviewed BTL’s cost estimate for decommissioning and the proposed financial instrument Letter of Credit (LoC) and found that the amount of \$1.8 million is sufficient to cover for all decommissioning activities as described in the PDP.

In July 2017, the Commission accepted the financial guarantee of \$1.8 million dollars [4], in line with CNSC staff’s recommendation. This amount includes a 25% contingency. CNSC staff have received two LoCs for a total amount of \$1,800,000.00 [37], which ensures that the licensee will have sufficient funds for decommissioning to unrestricted general industrial use of the facility.

CNSC staff conclude that BTL has a valid and acceptable FG in place and the draft LCH requires that BTL revise the FG on a five-year cycle along with the PDP.

4.4.1 Recommendation

Licence Condition G.3 in the proposed licence pertains to implementing and maintaining a financial guarantee for decommissioning acceptable to the Commission.

4.5 Licensee Public Information Program

The availability and clarity of information pertaining to nuclear activities is essential to establishing an atmosphere of openness, transparency and trust between the licensee and the public. Since 2012, the CNSC requires major licensees to maintain a Public Information and Disclosure Program (PIDP), supported by a robust disclosure protocol that addresses stakeholders' needs.

CNSC [REGDOC-3.2.1, *Public Information and Disclosure*](#) [38], (formerly known as RD/GD-99.3 [39]) sets out the requirements for public information and disclosure. The primary goal of the program, as it relates to the licensed activities, is to ensure that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of nuclear facilities are effectively communicated to the public. This information promotes transparency and improves the public's understanding of the licensed activities and operations. The program includes a commitment to and protocol for ongoing, timely communication of information related to the licensed facility during the course of the licence period.

CNSC expectations of a licensee's public information program and disclosure protocol are commensurate with the level of risk of the facility, as well as the level of public interest in the licensed activities. The program and protocol may be further influenced by the complexity of the nuclear facility's lifecycle and activities, and the risks to public health and safety and the environment perceived to be associated with the facility and activities.

CNSC staff have reviewed the BTL PIDP and determined that it:

- identifies clear goals and measurable objectives in terms of dissemination of information to targeted audiences
- is available to the public and is posted on the licensee's web site
- provides sufficient information on BTL operations through a variety of communication activities, including: a community information session, facility tours, website updates, and press releases
- targets multiple audiences such as local residents, elected and government representatives, business leaders and local aboriginal groups
- provides contact information for members of the public who want to obtain additional information

CNSC staff will continue to monitor BTL's compliance with public information requirements and ongoing implementation of the PIDP.

4.5.1 Conclusion

CNSC staff conclude that BTL's PIDP meets the regulatory requirements set out in the [Class I Nuclear Facilities Regulations](#). CNSC staff continue to oversee BTL implementation of the PIDP to ensure it meets the obligations regarding dissemination and notifying the public and indigenous communities on their licensed activities. CNSC staff expect BTL to refine and update their PIDP on a regular basis to meet the changing information needs of their target audiences.

4.6 Delegation of Authority

The Commission may include in a licence any condition it considers necessary for the purposes of the NSCA [5]. The Commission may delegate authority to CNSC staff with respect to the administration of licence conditions, or portions thereof.

There are two proposed licence conditions in the proposed licence that contain the phrase "the Commission or a person authorized by the Commission"; licence conditions 3.2, on reporting and 15.1, on operation of a cyclotron.

CNSC staff recommend the Commission delegate its authority for the purposes described in the above licence conditions to the following staff:

- Director, Nuclear Processing Facilities Division
- Director General, Directorate of Nuclear Cycles and Facilities Regulation
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch

5. OVERALL CONCLUSIONS AND RECOMMENDATIONS

CNSC staff have concluded the following with respect to paragraphs 24(4)(a) and (b) of the NSCA [5], in that BTL:

1. is qualified to carry on the activities authorized by the licence; and
2. will in carrying out the licensed activities, has made, and will continue to make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

Therefore, CNSC staff recommend that the Commission:

- Accept CNSC staff's conclusions and renew the Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-14.02/2019 for ten years, from July 1, 2019 to June 30, 2029
- Authorize the delegation of authority as set out in section 4.6 of this CMD

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REFERENCES

- [1] Class IB Nuclear Substance Processing Facility Operating Licence Best Theratronics Ltd., NSPFOL-14.02/2019, July 14, 2017 (e-Doc [5201133](#)).
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- [3] Amendment of NSPFOL-14.02 Class IB Renewal Licence Application - BTL, November 7, 2018 (e-Doc [5698291](#)).
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- [15] G-129, Rev. 1, Keeping Radiation Exposures and Doses “As Low as Reasonably Achievable (ALARA)”, October 2004.
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- [26] CNSC Compliance Inspection Report, *Best Theratronics Limited Inspection Report No. BT-2017-03*, October 30-31, 2017 (e-Doc [5400345](#)).
- [27] CSA N292.3-08, *Management of Low and Intermediate Level Radioactive Waste* (e-Doc [4022079](#)).
- [28] CSA N294-09, *Decommissioning of Facilities Containing Nuclear Substances* (e-Doc [4270738](#)).
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- [30] CSA N292.3-14, *Management of low- and intermediate-level radioactive waste* (e-Doc [4477456](#)).
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- [33] RD-336, *Accounting and Reporting of Nuclear Material*.
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- [37] Financial Guarantees (e-Docs [5694099](#) (BMO) and [5694098](#) (ICICI Ammendment) and [5024457](#) (ICICI Original)).
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- [39] RD/GD-99.3, *Public Information and Disclosure*.

GLOSSARY

ALARA	As low as reasonably achievable, taking into account social and economic factors
AL	Action Level
AOO	Algonquins of Ontario
BE	below expectations
Bq	becquerel
BRP	Building Radioactive Material Processes
BTL	Best Theratronics Limited
CAPA	Corrective Action and Preventative Action
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association (now CSA Group)
CVC	Compliance Verification Criteria
DCR	Document Change Request
DNCFR	Directorate of Nuclear Cycle and Facilities Regulation
EIS	Environmental Impact Statement
EMS	environmental management system
EP	Environmental Protection
ERA	environmental risk assessment
FG	Financial Guarantee
FS	fully satisfactory
FSAR	Final Safety Analysis Report
FPP	Fire Protection Program
g	gram
GBq	gigabecquerel
IAEA	International Atomic Energy Agency
LC	Licence Condition
LCH	Licence Conditions Handbook
LTI	Lost Time Injuries
MeV	megaelectron-volt
MOECP	Ontario Ministry of Environment, Conversation and Parks
mSv	millisievert
NEW	nuclear energy worker
NFCC	National Fire Code of Canada
NSCA	<i>Nuclear Safety and Control Act</i>

OPEX	Operating experience
PDP	Preliminary Decommissioning Plan
PIDP	Public Information and Disclosure Program
RP	Radiation Protection
SAR	Safety Analysis Report
SAT	Systematic Approach to Training
SCA	safety and control area
TBq	terabecquerel

A. RISK RANKING

The CNSC uses a risk-informed regulatory approach in the management and control of regulated facilities and activities. CNSC staff have, therefore, established an approach to identifying appropriate levels of regulatory monitoring and control for specific classes of licensed facilities and types of licensed activities based on risk ranking.

Risk ranking is applied to each SCA, and is determined by considering the probability and consequence of adverse incidents associated with each SCA as it relates to the given facility and activity types.

The methodology used to determine risk ranking is based on Canadian Standards Association guideline CAN/CSA-Q850, Risk Management: Guideline for Decision Makers. This guideline provides a description of the major components of the risk management decision process and their relationship to each other, and describes a process for acquiring, analyzing, evaluating, and communicating information that is necessary for making decisions.

In section 2.2 of the CMD, in the Relevant Safety Control Areas table, the “Risk Ranking” column shows a high (H), moderate (M) or low (L) indicator for each SCA that is relevant to the current facility and activities being addressed in this CMD. The risk rankings are not static and will change over time for a given facility and activities (e.g., facilities age, facilities and equipment are upgraded, activities cease or begin, licensees change, technology and programs mature, knowledge and understanding of impacts and probabilities increase, etc.).

The following matrix provides a high-level overview of risk ranking, and the management and monitoring approach associated with the various degrees of risk.

APPROACH TO ASSESSING AND MANAGING POTENTIAL RISK			
CONSEQUENCE	MANAGEMENT/MONITORING APPROACH		
Significant Impact	Considerable management of risk is required	Must manage and monitor risk with occasional control	Extensive management is essential. Constant monitoring and control
Moderate Impact	Occasional monitoring	Management effort is recommended	Management effort and control is required
Low Impact	Random monitoring	Regular monitoring	Manage and monitor
Probability of Occurrence	Unlikely to Occur	Might Occur	Expected to Occur
RISK RANKING SCALE			
L	Low Risk	M	Moderate Risk
		H	High Risk

On this basis, a high-risk SCA would be subject to increased regulatory scrutiny and control while a low-risk SCA would generally require minor verification and control.

B. RATING LEVELS

Fully Satisfactory (FS)

Safety and control measures implemented by the licensee are highly effective. In addition, compliance with regulatory requirements is fully satisfactory, and compliance within the safety and control area (SCA) or specific area exceeds requirements and CNSC expectations. Overall, compliance is stable or improving, and any problems or issues that arise are promptly addressed.

Satisfactory (SA)

Safety and control measures implemented by the licensee are sufficiently effective. In addition, compliance with regulatory requirements is satisfactory. Compliance within the SCA meets requirements and CNSC expectations. Any deviation is minor and any issues are considered to pose a low risk to the achievement of regulatory objectives and CNSC expectations. Appropriate improvements are planned.

Below Expectations (BE)

Safety and control measures implemented by the licensee are marginally ineffective. In addition, compliance with regulatory requirements falls below expectations. Compliance within the SCA deviates from requirements or CNSC expectations to the extent that there is a moderate risk of ultimate failure to comply. Improvements are required to address identified weaknesses. The licensee is taking appropriate corrective action.

Unacceptable (UA)

Safety and control measures implemented by the licensee are significantly ineffective. In addition, compliance with regulatory requirements is unacceptable and is seriously compromised. Compliance within the SCA is significantly below requirements or CNSC expectations, or there is evidence of overall noncompliance. Without corrective action, there is a high probability that the deficiencies will lead to unreasonable risk. Issues are not being addressed effectively, no appropriate corrective measures have been taken and no alternative plan of action has been provided. Immediate action is required.

C. BASIS FOR THE RECOMMENDATION(S)

C.1 Regulatory Basis

The recommendations presented in this CMD are based on compliance objectives and expectations associated with the relevant SCAs and other matters. The regulatory bases for the matters that are relevant to this CMD are as follows.

Management System

It is a requirement of the *Class I Nuclear Facilities Regulations* under paragraph 3(d) that an application for a licence for a Class I nuclear facility shall contain the proposed management system for the activity to be licensed, including measures to promote and support safety culture.

The *General Nuclear Safety and Control Regulations* require that an application for a licence shall contain, under the following paragraph:

- 3(1)(k), the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the NSCA and the Regulations made under the NSCA, including the internal allocation of functions, responsibilities and authority.
- 15(a), the persons who have the authority to act for them (the applicant/licensee) in their dealings with the Commission.
- 15(b), the names and position titles of the persons who are responsible for the management and control of the licensed activity and the nuclear substance, nuclear facility, prescribed equipment or prescribed information encompassed by the licence.

Human Performance Management

- It is a requirement of the *General Nuclear Safety and Control Regulations* under section 12, that the licensee shall:
 - 12(1)(a), ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the NSCA, the Regulations made under the NSCA, and the licence.
 - 12(1)(b), train the workers to carry on the licensed activity in accordance with the NSCA, the Regulations made under the NSCA, and the licence.
 - 12(1)(e), require that every person at the site of the licensed activity to use equipment, devices, clothing, and procedures in accordance with the NSCA, the Regulations made under the NSCA, and the licence.

It is a requirement of the [Class I Nuclear Facilities Regulations](#) under paragraph 6(m) that a licence application contain information on the proposed responsibilities, qualification requirements, and training program for workers including the procedures for the requalification of workers.

It is a requirement of the [Class I Nuclear Facilities Regulations](#) under paragraph 6(n) that a licence application contain information on the results that have been achieved in implementing the program for recruiting, training, and qualifying workers in respect of the operation and maintenance of the nuclear facility.

Operating Performance

Paragraph 6(d) of the [Class I Nuclear Facilities Regulations](#) requires that an application for a licence to operate a Class I nuclear facility contains the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

Subsection 24(5) of the NSCA states that the licence may contain any term or condition that the Commission considers necessary for the purpose of the NSCA.

Safety Analysis and Physical Design

3(1)(d) of the [General Nuclear Safety and Control Regulations](#) requires that an application for a licence shall contain a description of any nuclear facility, prescribed equipment, or prescribed information to be encompassed by the licence.

- 3(1)(i) of the [General Nuclear Safety and Control Regulations](#) requires that an application for a licence shall contain a description and the results of any test, analysis, or calculation performed to substantiate the information included in the application.
- It is a requirement of the [Class I Nuclear Facilities Regulations](#) that an application for a licence to operate a Class I nuclear facility shall contain the following information under paragraph:
 - 6(c), a final safety analysis report demonstrating the adequacy of the design of the nuclear facility.
 - 6(h), the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects.

Other requirements set out in paragraphs 3(a), 3(b), 6(a) and 6(b) of the [Class I Nuclear Facilities Regulations](#) require more specific information to be submitted in the licence application related to the site and design of the facility and the final safety analysis report.

Paragraphs 6(c) and 6(d) of the [Class I Nuclear Facilities Regulations](#) require that an application for a licence contain a final safety analysis report demonstrating the adequacy of the design of the facility and proposed measures, policies, methods, and procedures for operating and maintaining the facility.

Fitness for Service

It is a requirement of the [Class I Nuclear Facilities Regulations](#) under paragraph 6(d) that an application for a licence to operate a Class I nuclear facility contain the proposed measures, policies, methods, and procedures for operating and maintaining the nuclear facility.

Radiation Protection

- The [General Nuclear Safety and Control Regulations](#) require, under subsection 3(1), that a licence application contain the following information under paragraph:
 - 3(1)(e), the proposed measures to ensure compliance with the [Radiation Protection Regulations](#).
 - 3(1)(f), any proposed action level for the purpose of section 6 of the [Radiation Protection Regulations](#).

The [Radiation Protection Regulations](#) require, under sections 4 to 6, that the licensee implements a radiation protection program, ascertain and record doses, and take the required actions in the case that an action level has been reached.

- The [Class I Nuclear Facilities Regulations](#) require that an application for a licence to operate a Class I nuclear facility contain the following information under paragraph:
 - 6(e), the proposed procedures for handling, storing, loading, and transporting nuclear substances and hazardous substances.
 - 6(h), the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measure that will be taken to prevent or mitigate those effects.

Conventional Health and Safety

It is a requirement of the [Class I Nuclear Facilities Regulations](#) under paragraph 3(f) that an application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the proposed worker health and safety policies and procedures.

The BTL's activities and operations must comply with the *Canada Labour Code, Part II: Occupational Health and Safety*.

Environmental Protection

The [General Nuclear Safety and Control Regulations](#), under paragraphs 12(1)(c) and (f) require that each licensee take all reasonable precautions to protect the environment and the health and safety of persons, and to control the release of radioactive nuclear substances and hazardous substances within the site of the licensed activity and into the environment.

The [Radiation Protection Regulations](#) prescribe the dose limit for the general public, which under subsection 1(3) is 1 mSv per calendar year.

- In addition, sections 3 and 6 of the [Class I Nuclear Facilities Regulations](#) must be met by the applicant. The application for a licence shall contain under paragraph:
 - 3(e), the name, form, characteristics, and quantity of any hazardous substances that may be on the site while the activity to be licensed is carried on.
 - 3(g), the proposed environmental protection policies and procedures.
 - 3(h), the proposed effluent and environmental monitoring programs.
 - 6(e), the proposed procedures for handling, storing, loading, and transporting nuclear substances and hazardous substances.
 - 6(h), the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects.
 - 6(i), the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical, and radiological characteristics.
 - 6(j), the proposed measures to control releases of nuclear substances and hazardous substances into the environment.

Emergency Management and Fire Protection

12(1)(c) of the [General Nuclear Safety and Control Regulations](#) states that every licensee shall “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”.

12(1)(f) of the [General Nuclear Safety and Control Regulations](#) states that every licensee shall “take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances within the site of the licensed activity and into the environment of the licensed activity...”.

- It is a requirement of the [Class I Nuclear Facilities Regulations](#) under paragraph 6(k) that a licence application contain information on the licensee’s proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including measures to:
 - Assist off-site authorities in planning and preparing to limit the effects of an accidental release.
 - Notify off-site authorities of an accidental release or the imminence of an accidental release.
 - Report information to off-site authorities during and after an accidental release.

- Assist off-site authorities in dealing with the effects of an accidental release.
- Test the implementation of the measures to prevent or mitigate the effects of an accidental release.

Waste Management

It is a requirement of the [General Nuclear Safety and Control Regulations](#) under paragraph 3(1)(j) that an application for a licence include the name, origin, quantity, form, and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including waste that may be stored, managed, processed, or disposed of at the site of the activity to be licensed, and the proposed method for managing and disposing of that waste.

Security

Paragraph 3(1)(e) of the [General Nuclear Safety and Control Regulations](#) requires that an application for a licence contains the proposed measures to ensure compliance with the [Radiation Protection Regulations](#), the [Nuclear Security Regulations](#) and the [Packaging and Transport of Nuclear Substances Regulations, 2015](#).

Paragraph 12(1)(c) of the [General Nuclear Safety and Control Regulations](#) requires the licensee to 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.

Paragraph 6(k) of the [Class I Nuclear Facilities Regulations](#) requires that an application for a licence to operate a Class I nuclear facility contains the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances to the environment, the health and safety of persons and the maintenance of national security.

Paragraph 2(a) of Part 1 of [Nuclear Security Regulations](#) states that Part 1 applies to Category I, II or III nuclear material.

Subsection 24(5) of the NSCA states that the licence may contain any term or condition that the Commission considers necessary for the purpose of the NSCA.

Safeguards and Non-Proliferation

Subsection 24(5) of the NSCA states that the licence may contain any term or condition that the Commission considers necessary for the purpose of the NSCA.

Paragraph 12(1)(i) of the [General Nuclear Safety and Control Regulations](#) requires the licensee to take all necessary measures to facilitate Canada's compliance with any applicable safeguard agreement.

Paragraph 6(f) of the [Class I Nuclear Facilities Regulations](#) requires that an application for a licence to operate a Class I nuclear facility contains the proposed measures to facilitate Canada's compliance with any applicable safeguards agreement. The applicable safeguards agreements are:

- Agreement Between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons (INFCIRC/164); and
- Protocol Additional to the Agreement Between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons (INFCIRC/164/Add. 1).

Packaging and Transport

BTL is required to comply with the [Packaging and Transport of Nuclear Substances Regulations, 2015](#), and *Transport Canada's* [Transportation of Dangerous Goods Regulations](#).

Cost Recovery

Paragraph 24(2)(c) of the NSCA requires that a licence application is accompanied by the prescribed fee.

The [CNSC Cost Recovery Fees Regulations \(CRFR\)](#) set out the specific requirements based on the activities to be licensed.

Financial Guarantee

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

Licensee Public Information Program

It is a requirement of the [Class I Nuclear Facilities Regulations](#) under paragraph 3(j) that an application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain information on the licensee's public information program.

C.2 Technical Basis

The technical bases for the recommendations presented in this CMD are as follows. The following CNSC regulatory documents and CSA standards are relevant to BTL:	
Management System	<ul style="list-style-type: none"> • CSA N286-12 – <i>Management System Requirements for Nuclear Facilities</i> (2012)
Human Performance Management	<ul style="list-style-type: none"> • CNSC REGDOC-2.2.2, v. 2, <i>Personnel Training</i> (December 2016)
Operating Performance	<ul style="list-style-type: none"> • CNSC REGDOC-3.1.2, <i>Reporting Requirements for Non-Power Reactor Class I Facilities and Uranium Mines and Mills, January 2018</i>
Safety Analysis	N/A
Physical Design	<ul style="list-style-type: none"> • CSA B51-14, <i>Boiler Pressure Vessel and Pressure Piping Code (2014) *</i>
Fitness for Service	N/A
Radiation Protection	<ul style="list-style-type: none"> • CNSC G-129, rev.1, <i>Keeping Radiation Exposures and Doses “As Low As Reasonably Achievable (ALARA)”</i> (Oct 2004)* • CNSC G-228, <i>Developing and Using Action Levels</i> (March 2001)*
Conventional Health and Safety	<ul style="list-style-type: none"> • CSA Standard Z94.4 <i>Selection, Use and Care of Respirators 2011*</i> • CSA Z1000 <i>Occupational health and safety management 2014*</i>
Environmental Protection	<ul style="list-style-type: none"> • CNSC REGDOC-2.9.1, <i>Environmental Protection : Environmental Principles, Assessments and Protection Measures</i> (April 2017) v1.1
Emergency Management and Fire Protection	<ul style="list-style-type: none"> • CNSC REGDOC 2.10.1, <i>Nuclear Emergency Preparedness and Response v2</i> (Feb 2016) • CSA N393-13, <i>Fire protection for facilities that process, handle, or store nuclear substances</i> (2013) • <i>National Building Code of Canada, 2015</i> • <i>National Fire Code of Canada, 2015</i>
Waste Management	<ul style="list-style-type: none"> • CSA N294-09, <i>Decommissioning of Facilities Containing Nuclear Substances</i> • CNSC G-219, <i>Decommissioning Planning for Licensed Facilities, June 2000 *</i> • CNSC Policy P-290, <i>Managing Radioactive Waste</i> (July 2004)* • CSA N292.0-14, <i>General Principles for the Management of Radioactive Waste and Irradiated Fuel *</i> • CSA N292.3-14, <i>Management of Low- and Intermediate-level radioactive waste</i>
Security	<ul style="list-style-type: none"> • CNSC REGDOC 2.12.3, <i>Security of Nuclear Substances: Sealed Sources</i> (May 2013)
Safeguards and Non- proliferation	<ul style="list-style-type: none"> • CNSC REGDOC 2.13.1, <i>Safeguards and Nuclear Material Accountancy</i> February 2018** • CNSC REGDOC 2.13.2, <i>Import and Export</i> September 2016**

Packaging and Transport	<ul style="list-style-type: none">• CNSC G-208 <i>Transportation Security Plans for Category I, II or III Nuclear Material 2003*</i>• CNSC G-274 <i>Security Programs for Category I or II Nuclear Material or Certain Nuclear Facilities 2003*</i>
Aboriginal Consultation	<ul style="list-style-type: none">• CNSC REGDOC -3.2.2, <i>Aboriginal Engagement</i>
Financial Guarantee	<ul style="list-style-type: none">• CNSC G-206, <i>Financial Guarantee for the Decommissioning of Licensed Activities</i>
Public Information Program	<ul style="list-style-type: none">• CNSC REGDOC-3.2.1, <i>Public Information and Disclosure</i>

D. SAFETY AND CONTROL AREA FRAMEWORK

D.1 Safety and Control Areas Defined

The safety and control areas identified in section 2.2, and discussed in summary in sections 3.1 through 3.14 are comprised of specific areas of regulatory interest which vary between facility types.

The following table provides a high-level definition of each SCA.

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	Safety and Control Area	Definition
Management	Management System	Covers the framework which establishes the processes and programs required to ensure an organization achieves its safety objectives and continuously monitors its performance against these objectives and fostering a healthy safety culture.
	Human Performance Management	Covers activities that enable effective human performance through the development and implementation of processes that ensure that licensee staff is sufficient in number in all relevant job areas and that licensee staff have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.
	Operating Performance	This includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.
Facility and Equipment	Safety Analysis	Maintenance of the safety analysis that supports that 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.
	Physical Design	Relates to activities that impact on the ability of systems, components and structures to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	Safety and Control Area	Definition
	Fitness for Service	Covers activities that impact on the physical condition of systems, components and structures to ensure that they remain effective over time. This includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.
Core Control Processes	Radiation Protection	Covers the implementation of a radiation protection program in accordance with the RP Regulations. This program must ensure that contamination and radiation doses received are monitored and controlled.
	Conventional Health and Safety	Covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.
	Environmental Protection	Covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.
	Emergency Management and Fire Protection	Covers emergency plans and emergency preparedness programs which exist for emergencies and for non-routine conditions. This also includes any results of exercise participation.
	Waste Management	Covers internal waste-related programs which 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. Also covers the planning for decommissioning.
	Security	Covers the programs required to implement and support the security requirements stipulated in the regulations, in their licence, in orders, or in expectations for their facility or activity.
	Safeguards and Non-Proliferation	Covers the programs and activities required for the successful implementation of the obligations arising from the Canada/IAEA safeguards agreements as well as all other measures arising from the <i>Treaty on the Non-Proliferation of Nuclear Weapons</i> .
	Packaging and Transport	Programs that cover the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility.

D.2 Specific Areas for this Facility Type

The following table identifies the specific areas that comprise each SCA for BTL.

SPECIFIC AREAS FOR THIS FACILITY TYPE	
Safety and Control Area	Specific Areas
Management System	<ul style="list-style-type: none"> • Management System • Organization • Performance Assessment, Improvement and Management Review • Operating Experience (OPEX) • Change Management • Safety Culture • Records Management • Management of Contractors
Human Performance Management	<ul style="list-style-type: none"> • Personnel Training • Personnel Certification • Work Organization and Job Design
Operating Performance	<ul style="list-style-type: none"> • Conduct of Licensed Activity • Procedures • Reporting and Trending
Safety Analysis and Physical Design	<ul style="list-style-type: none"> • Deterministic Safety Analysis • Hazard Analysis
Fitness for Service	<ul style="list-style-type: none"> • Equipment Fitness for Service/Equipment Performance • Maintenance • Periodic Inspection and Testing
Radiation Protection	<ul style="list-style-type: none"> • Application of ALARA • Worker Dose Control • Radiation Protection Program Performance • Radiological Hazard Control • Estimated Dose to Public
Conventional Health and Safety	<ul style="list-style-type: none"> • Performance • Practices
Environmental Protection	<ul style="list-style-type: none"> • Effluent and Emissions Control (releases) • Environmental Management System (EMS) • Assessment and Monitoring

SPECIFIC AREAS FOR THIS FACILITY TYPE	
Safety and Control Area	Specific Areas
	<ul style="list-style-type: none"> • Environmental Risk Assessment
Emergency Management and Fire Protection	<ul style="list-style-type: none"> • Nuclear Emergency Preparedness and Response • Fire Emergency Preparedness and Response
Waste Management	<ul style="list-style-type: none"> • Waste Characterization • Waste Minimization • Waste Management Practices • Decommissioning Plans
Security	<ul style="list-style-type: none"> • Facilities and Equipment • Response Arrangements • Security Practices • Drills and Exercises
Safeguards and Non-Proliferation	<ul style="list-style-type: none"> • Nuclear Material Accountancy and Control • Access and Assistance to the IAEA • Operational and Design Information • Safeguards Equipment, Containment and Surveillance • Import and Export
Packaging and Transport	<ul style="list-style-type: none"> • Package Design and Maintenance • Packaging and Transport • Registration for Use

E. LOST-TIME INJURIES

Year	BTL's Description
2014	An employee cut his left hand thumb while using a cut off wheel which slipped. The employee was reminded to have both hands on power tools when using them.
2015	An employee twisted his knee when walking in the kitchen and supply area. This resulted in one day of lost time. The incident was reviewed and no further action was taken.
2016	<p>Employee tried to lift 16 pound vise and could not support the weight, twisted and scraped thumb. This individual was reminded to work within their limits.</p> <p>Steel part weighing 80 pounds dropped from 2 inches onto finger when operator was not paying close attention. This employee was reminded to use caution when handling heavy objects.</p> <p>Employee placed foot on a mobile cart while reviewing paperwork. Want to move away and lost balance when found shoe was wedged in cart. Fall caused full weight to be put on wrist. This was an accident. This employee was reminded to be aware of their surroundings and to act in a safe manner. They were also reminded that the cart is not a footstool.</p>
2017	An employee cut their thumb on a saw mill when they moved a piece of material from the machine resulting in 22 days lost time. The employee was retrained on the procedure and has been reminded of the safety precautions of using the machine. He has not been scheduled to work at the saw machine since his return to work and he is also being monitored to follow safety procedures with all the other tools and machines on the shop floor.
2018	<p>An employee had a cut and abrasion to the stomach area when the grinder used caught coveralls and pulled them in. The individual was reminded to use the proper guard when performing the work.</p> <p>The employee hurt their back when applying an upward force to a large pipe wrench. The second LTI was an isolated incident. The work has not been performed since. The individual was put on light duty work when they came back.</p>

F. REPORTABLE EVENTS

Year	BTL's Description
2014	<p>Apr 1 – A Co-60 source was returned from Nepal at the end of March, awaiting customs clearance at Montreal Airport. The loaded container arrived at location unexpectedly, without Best Theratronics' prior acknowledgement, on a truck missing the appropriate placards and incorrect transport container bracing.</p> <p>Sept 11 – A Co-60 source was returned from Johannesburg. BTL reported of a concern that the transport container was not properly braced or secured to the sea freight container that it arrived in (as required by paragraph 564 of SSR-6). This bracing was not done by Best Theratronics or its forwarder, but by the consignor or their shipper.</p> <p>Sept 30 – While testing the R&D teletherapy unit in Cell 4, the source failed to return to its fully shielded position, approximately 5 cm off its shielded position. The RSO was called in and determined the radiation dose rate was around 5 mR/h on the surface of the head. The source was manually pushed back into the fully shielded position by a qualified technician and locked into place. The technician's DRD read 0.0 mR from this emergency procedure. The investigation concluded that this event was caused by a component failure and the unit was put under quarantine until the matter was fully corrected and tested.</p>
2015	Non reported
2016	Non reported
2017	<p>Nov 27 – A return shipment from Trinidad and Tobago included an F147 (with two sources), one crate with DU head and one crate with DU collimator. Although these packages were prepared by BTL's qualified and trained technicians, they arrived at Best Theratronics without the UN labels originally affixed. Both the F147 and DU collimator crate's TI labels were replaced with obsolete TI labels, and the DU head crate did not have any UN labels and was damaged (hole on top).</p>
2018	<p>Sept 19 – Cyclist biking through Best Theratronics parking lot was hit by a car, sustained minor injuries.</p> <p>Oct 2 – During the source loading process of a prototype teletherapy head in Cell 4, the hardware securing the end plug failed. As a result, part of the source drawer had exited the other end of the head and source loaders were exposed to radiation higher than our internal action levels. The source was immediately pulled back into the F147 transport container and safely stored. The work was stopped and the RSO was called in to assess the situation. The F147 container was safely detached from the prototype head and placed in storage while the prototype head was quarantined pending investigations.</p>

Year	BTL's Description
	Nov 29 – During the installing of heating units on the roof of the Best Theratronics facility, a sprinkler water pipe was hit and snapped off causing a loss in water pressure, setting off the fire alarms. Employees evacuated the building and the fire department responded. The building was deemed safe for employees to re-enter the building shortly after. The office area below the pipe break became flooded. Areas containing radioactive material were checked and no contamination was detected.

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PART TWO

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

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

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PROPOSED LICENCE CHANGES

Overview

Best Theratronics Limited (BTL) has a Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-14.02/2019, issued by the Commission, effective July 1, 2014 for a five-year period. This was the first Class I licence issued to BTL, consolidating several nuclear substances and Class II licences that BTL held previously. The licence issued in 2014 was accompanied by a licence conditions handbook (LCH).

Licence Conditions

Previous and proposed licence conditions are given in the table below.

PROPOSED LICENCE CHANGES		
Previous Licence Conditions	Proposed Licence Condition	Reasons
<p>11.1</p> <p>The licensee shall implement and maintain an emergency preparedness program, which includes fire response.</p>	<p>10.1</p> <p>The licensee shall implement and maintain an emergency preparedness program.</p> <p>10.2</p> <p>The licensee shall implement and maintain a fire protection program.</p>	<p>Use of standardized licence conditions.</p>
<p>8.1</p> <p>The licensee shall implement and maintain a radiation protection program, which includes a set of action levels.</p>	<p>7.1</p> <p>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 7 days.</p>	<p>Use of standardized licence conditions.</p>

PROPOSED LICENCE CHANGES		
<p>16.1 Any Class I particle accelerator shall be operated only in accordance with the commissioning plan approved by the Commission or a person authorized by the Commission.</p> <p>16.2 Any Class I particle accelerator shall be dismantled only in accordance with the dismantling plan that the Commission or a person authorized by the Commission has approved.</p>	<p>15. 1 The licensee shall not operate a cyclotron/cyclotrons at beam energy greater than 1 MeV without prior authorization from the Commission or a person authorized by the Commission.</p>	<p>BTL states that they do not have plans to test the cyclotron greater than 1 MeV [14]. However, as BTL has applied to have a licence that includes testing cyclotrons greater than 1 MeV, a hold point in the licence is being proposed.</p> <p>Activities under operating cyclotrons are covered in the LCH.</p> <p>No hold point is required for disassembling cyclotrons. Once tested, BTL shall not disassemble the cyclotrons. Only the operational systems (vacuum, cooling, high voltage, RF, etc.) could be disconnected for transportation of the cyclotron to the customer.</p>
<p>IV) LICENSED ACTIVITIES: This licence authorizes the licensee to:</p> <p>a) operate a Class IB Facility, comprising of:</p> <p>(i) a particle accelerator(s)/cyclotron;</p> <p>(ii) a nuclear substance processing facility for the purposes of manufacturing radiation devices;</p> <p>(iii) a radioactive source teletherapy machine, for the purposes of developing and testing of Class II Prescribed Equipment;</p>	<p>IV) LICENSED ACTIVITIES: This licence authorizes the licensee to:</p> <p>a) operate a Class I nuclear facility located at 413 March Road, Ottawa, Ontario, including activities related to:</p> <p>(i) operating a cyclotron/cyclotrons;</p> <p>(ii) possessing nuclear substances for the purposes of manufacturing radiation devices and radioactive source teletherapy machines,</p> <p>(iii) possessing a radioactive source teletherapy machine, for the purposes of developing and testing of radioactive source teletherapy machines;</p>	<p>Location of the BTL defined in order to avoid the confusion of BTL with other Best facilities.</p> <p>The word “particle accelerator” removed to avoid understanding of any equipment other than cyclotrons,</p> <p>“using prescribed equipment” changed to “producing prescribed equipment” to bring clarity and align with the wording in the Regulations.</p>

PROPOSED LICENCE CHANGES		
<p>b) possess, transfer, manage, store, and dispose of nuclear substances arising from the activities regarding the cyclotrons; possess, transfer, use, import, export, manage, store, and dispose within the processing facility any nuclear substances that are required for, associated with, or arise from the activities of manufacturing radiation devices, and development and testing of Class II Prescribed Equipment;</p> <p>c) possess, transfer, use, import, export, store, and dispose prescribed equipment that is required for, associated with, or arise from the activities related to the manufacturing of radiation devices and development and testing of Class II Prescribed Equipment;</p> <p>d) possess and use prescribed information that is required for, associated with, or arise from the activities described in a).</p>	<p>b) possess, transfer, manage, store, and dispose of nuclear substances arising from the activities regarding the cyclotrons;</p> <p>c) produce prescribed equipment;</p> <p>d) possess, transfer, use, import, export, manage, store, and dispose within the facility any nuclear substances that are required for, associated with, or related to manufacturing radiation devices, and development and testing of radioactive source teletherapy machines;</p> <p>e) possess, transfer, use, import, export, store, and dispose prescribed equipment that is required for, associated with, or related to manufacturing of radiation devices and development and testing of radioactive source teletherapy machines, and manufacturing radioactive source teletherapy machines;</p> <p>f) possess and use prescribed information that is required for, associated with, or arise from operating the Class I nuclear facility.</p>	
N/A.	<p>15. 2</p> <p>The current licence does not authorize the licensee to export, for the valid period, of nuclear substance, a radioactive sealed source, whose corresponding activity is equal to or greater than the value set out in column 2 of Table 1(in the proposed licence).</p>	<p>To ensure that the licence prohibits the export of high risk radioactive sources, as separate licences are required for their export.</p>

Licence Format

The proposed licence uses the standard format and incorporates the standard licence conditions applicable to BTL.

Licence Period

BTL has requested extending the licence period from five years (NSPFOL-14.02/2019) to 10 years in the renewed licence.

Based on CNSC staff review of the BTL's application, performance history, and supporting information, CNSC staff support BTL's request for a licence period of 10 years. Over the proposed 10-year period, CNSC staff would provide reporting on regulatory oversight conducted at BTL in public Commission proceedings.

CNSC staff note that operation of linear accelerators are not included within the proposed renewed licence. An amendment to the licence will be required to operate a linear accelerator.

BTL has expressed desire to transfer to a Class II/Nuclear Substance and Radiation Devices licence.

Licence Conditions Handbook

The LCH associated with the licence provides CVC used by CNSC staff to determine whether the conditions of the licence have been met.

Additionally, the LCH includes information such as applicable standards and/or regulatory documents, regulatory interpretation, references to relevant licensee documents and guidance. This structure allows more freedom for the operation to improve and update its documentation within the licensing basis.

PROPOSED LICENCE

e-Doc 5763736 (Word)

e-Doc 5837569 (PDF)

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PROPOSED LICENCE

PDF Ref: e-Doc 5837569
Word Ref: e-Doc 5763736
File / Dossier: 2.02

CLASS IB NUCLEAR SUBSTANCE PROCESSING FACILITY LICENCE

BEST THERATRONICS LTD.

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

I) LICENCE NUMBER: NSPFL-14.00/2029

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

Best Theratronics Limited
413 March Road
Ottawa, Ontario
K2K 0E4

III) LICENCE PERIOD: This licence is valid from **July 1, 2019**, to **June 30, 2029**, unless otherwise suspended, amended, revoked, or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

- (a) operate a Class IB nuclear facility located at 413 March Road, Ottawa, Ontario, including activities related to:
 - (i) operating a cyclotron/cyclotrons;
 - (ii) possessing nuclear substances for the purposes of manufacturing radiation devices and radioactive source teletherapy machines;
 - (iii) possessing a radioactive source teletherapy machine, for the purposes of developing and testing of radioactive source teletherapy machines;

- b) possess, transfer, manage, and store nuclear substances arising from the activities regarding the cyclotrons;
- c) produce prescribed equipment;
- d) possess, transfer, use, import, export, manage, and store within the facility any nuclear substances that are required for, associated with, or related to manufacturing radiation devices, and development and testing of radioactive source teletherapy machines;
- e) possess, transfer, use, import, export, and store prescribed equipment that is required for, associated with, or related to manufacturing of radiation devices and development and testing of radioactive source teletherapy machines, and manufacturing radioactive source teletherapy machines; and
- f) possess and use prescribed information that is required for, associated with, or arise from operating the Class IB nuclear facility.

V) EXPLANATORY NOTES:

- a) The “Best Theratronics Ltd. Licence Conditions Handbook (LCH)” provides:
 - (i) compliance verification criteria in order to meet the conditions listed in the licence;
 - (ii) information regarding delegation of authority to CNSC staff; and
 - (iii) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

VI) CONDITIONS:

1. GENERAL

G.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 this licence and the documents directly referenced in this 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”).

G.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.

- G.3 The licensee shall maintain a financial guarantee for decommissioning acceptable to the Commission.
- G.4 The licensee shall implement and maintain a public information and disclosure program.

1. MANAGEMENT SYSTEM

- 1.1 The licensee shall implement and maintain a management system.

2. HUMAN PERFORMANCE MANAGEMENT

- 2.1 The licensee shall implement and maintain a training program.

3. OPERATING PERFORMANCE

- 3.1 The licensee shall implement and maintain an operating program, which includes a set of operating limits.
- 3.2 The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.
- 3.3 The licensee shall implement and maintain a program for inventory control of all nuclear substances and prescribed equipment including radiation devices.

4. SAFETY ANALYSIS

- 4.1 The licensee shall implement and maintain a safety analysis program.

5. PHYSICAL DESIGN

- 5.1 The licensee shall implement and maintain a design program.

6. FITNESS FOR SERVICE

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

7. RADIATION PROTECTION

- 7.1 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 7 days.

8. CONVENTIONAL HEALTH AND SAFETY

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

9. ENVIRONMENTAL PROTECTION

9.1 The licensee shall implement and maintain an environmental protection program.

10. EMERGENCY MANAGEMENT AND FIRE PROTECTION

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

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

11. WASTE MANAGEMENT

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

11.2 The licensee shall implement and maintain a decommissioning plan.

12. SECURITY

12.1 The licensee shall implement and maintain a security program.

13. SAFEGUARDS AND NON-PROLIFERATION

13.1 The licensee shall implement and maintain a safeguards program.

14. PACKAGING AND TRANSPORT

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

15. SITE SPECIFIC

15.1 Class IB Facility: Cyclotron

The licensee shall not operate a cyclotron/cyclotrons at beam energy greater than 1 MeV without prior authorization from the Commission or a person authorized by the Commission.

15.2 Export Restrictions

This licence does not authorize the licensee to export, for the valid period of this licence in respect of a nuclear substance, a radioactive sealed source whose corresponding activity is equal to or greater than the value set out in column 2 of Table 1:

Table 1: Activity Limits for Exporting Sealed Sources

Column 1 Nuclear Substance	Column 2 (TBq)
Americium 241	0.6
Americium 241/Beryllium	0.6
Californium 252	0.2
Curium 244	0.5
Cobalt 60	0.3
Cesium 137	1
Gadolinium 153	10
Iridium 192	0.8
Promethium 147	400
Plutonium 238	0.6
Plutonium 239/Berilium	0.6
Radium 226	0.4
Selenium 75	2
Strontium 90 (Yttrium 90)	10
Thulium 170	200
Ytterbium 169	3

SIGNED at OTTAWA, this _____ day of _____, 2019

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

DRAFT LICENCE CONDITIONS HANDBOOK

e-Doc 5729112 (Word)

e-Doc 5837602 (PDF)

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e-Doc 5729112 (WORD)
e.Doc 5837602 (PDF)
File no. 2.02

LICENCE CONDITIONS HANDBOOK

BEST THERATRONICS LTD.

Nuclear Substance Processing

Facility Licence

Revision 0



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DRAFT

Licence Conditions Handbook
(NSPFOL-14.00/2029)

Effective: Month Day Year

Nuclear Substance Processing
Facility Licence

SIGNED at OTTAWA this _____ day of _____, 2019

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

REVISION HISTORY:

Effective Date m/d/y	Rev. #	LCH e-Doc #	Description	Document Change Record e-Doc #
xxxxxxx	0	5729112	New document	

DRAFT

Revision History

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INTRODUCTION

The general purpose of the Licence Conditions Handbook (LCH) is to identify and clarify the relevant parts of the licensing basis for each licence condition (LC). This will 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 should be read in conjunction with the licence.

The LCH typically has three parts under each LC: the Preamble, Compliance Verification Criteria (CVC), and Guidance. The Preamble explains, as needed, the regulatory context, background, and/or history related to the LC. CVC are criteria used by CNSC staff to verify and oversee compliance with the LC. Guidance is non-mandatory information, including direction, on how to comply with the LC.

Throughout the licence, the statement “or a person authorized by the Commission” reflects to whom the Commission may delegate certain authority to CNSC staff. The delegation of authority by the Commission to act as a “person authorized by the Commission” is only applied to the incumbents of the following positions (source: Record of Decision for licence renewal issued Month 2019):

- Director, Nuclear Processing Facilities Division
- Director General, Directorate of Nuclear Cycle and Facilities Regulation
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch

The links provided in the LCH are references to the internal CNSC electronic filing system, and those documents cannot be opened from outside of the CNSC network.

Current versions of the licensing basis publications, licensee documents that require notification of change, and guidance documents referenced in the LCH are tracked in the document *Licensing Documents for Best Theratronics* (e-Doc 5685000), which is controlled by the Nuclear Processing and Facilities Division and are available to the licensee upon request.

Most CNSC documents referenced in the LCH are available through the CNSC public website. Documents listed on the CNSC website may contain prescribed information as defined by the *General Nuclear Safety and Control Regulations*. Information in these documents will be made available only to stakeholders with appropriate security clearance on a valid need to know.

Domestic and international standards (in particular consensus standards produced by the CSA Group) are an important component of the CNSC's regulatory framework. Standards support the regulatory requirements established through the *Nuclear Safety and Control Act* (NSCA), its Regulations and licences by setting out the necessary elements for acceptable design and performance at a regulated facility or a regulated activity. Standards are one of the tools used by the CNSC to evaluate whether licensees are qualified to carry out licensed activities.

The CNSC offers complimentary access to the CSA Group [suite of nuclear standards](#) through the CNSC website. This access platform allows interested stakeholders to view these standards online.

This LCH has the following appendices:

Appendix A: Provides definitions of terms and a list of acronyms used throughout it.

Introduction

GENERAL

Licence Condition G.1: Licensing Basis

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

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

Preamble:

The licensing basis is discussed in CNSC INFO-0795.

Facility Location: The location of the Best Theratronics Facility, is at 413 March Rd, Ottawa, Ontario, is provided in document PEAE-21000 (Issue 5).

For operational purposes Best Theratronics Ltd. may store radioactive sealed sources at 447 March Rd (See e-Doc [4418518](#)).

Compliance Verification Criteria:

Licencee Documents

Document Number	Document Title	e-Doc #
na	CNSC Class IB Licence Application Renewal of Licence NSPFOL-14.02/2019	5631853

Part (i) of the Licensing Basis

Part (i) of the licensing basis, includes, but is not limited to, the following:

- [Nuclear Safety and Control Act](#) (NSCA) and its Regulations;
- [Canadian Environment Protection Act](#)
- [Canadian Environmental Assessment Act, 2012](#) (CEAA, 2012) and its Regulations;
- [Transportation of Dangerous Goods Act](#) and its Regulations;
- [Canada Labour Code, Part II](#)
- [Fisheries Act](#) (CNSC responsibilities are defined in the *Memorandum of Understanding between the CNSC and Fisheries and Oceans Canada*); and
- [Canada/IAEA safeguards agreements](#).

The safety and control measures mentioned in the LC under Parts (ii) and (iii) of the licensing basis include important aspects of analysis, design, operation, etc. They may be found in high-level, programmatic licensee documents but might also be found in lower-level, supporting documentation. They also include safety and control measures in licensing basis publications (e.g., CNSC REGDOCs or CSA standards) that are cited in the licence, the application, or any documents needed to support that licence application.

Licensing basis publications are listed in tables in this LCH under the most relevant LC. All “shall” or normative statements in licensing basis publications are considered CVC unless stated otherwise.

The licensee documents in question, as well as the relevant licensing basis publications, may cite other documents that also contain safety and control measures (i.e., there may be safety and control measures in “nested” references). There is no predetermined limit to the degree of nesting at which relevant safety and control measures may be found.

The licensing basis is established when the Commission renders its decision regarding the licence application.

LC G.1 requires the licensee to implement all the safety and control measures. Note, however, that not all details in referenced documents are necessarily considered to be safety and control measures.

- Details that are not directly relevant to safety and control measures for facilities or activities authorized by the licence are excluded from the licensing basis.
- Details that are relevant to a different safety and control area (i.e., not the one associated with the main document), are only part of the licensing basis to the extent they are consistent with the main requirements for both safety and control areas.

In the event of any perceived or real conflict or inconsistency between two elements of the licensing basis, the licensee shall consult CNSC staff to determine the approach to resolve the issue.

In the event of any perceived or real conflict or inconsistency between two elements of the licensing basis, the licensee shall consult CNSC staff to determine the approach to resolve the issue.

This LC 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, in accordance with its management system. Where the licensing basis refers to specific configurations, methods, solutions, designs, etc. the licensee is free to propose alternate approaches as long as they remain, overall, in accordance with the licensing basis and have a neutral or positive impact on health, safety, the environment, security, and safeguards. However, the licensee shall assess changes to confirm that operations remain in accordance with the licensing basis.

Changes to certain licensee documents require written notification to the CNSC, even if they are in accordance with the licensing basis. Further information on this topic is provided under LC G.2.

For unapproved operation that is not in accordance with the licensing basis, the licensee shall take action as soon as practicable to return to a state consistent with the licensing basis, taking into account the risk significance of the situation.

Guidance:

When the licensee becomes aware that a proposed change or activity might not be in accordance with the licensing basis, it should first seek direction from CNSC staff regarding the potential acceptability of this change or activity. The licensee should take into account that certain types of proposed changes might require significant lead times before CNSC staff can make recommendations and/or the Commission can properly consider them. Guidance for notifications to CNSC related to licensee changes are discussed under LC G.2.

Licence Condition G.2: Notification of Changes

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

Preamble:

CNSC staff tracks, in e-Doc 5685000, the version history of licensee documents that require notification of change (with the exception of security-related documents).

Compliance Verification Criteria:

The licensee shall, as a minimum, notify CNSC staff in writing of changes to licensee's documents identified in the LCH. The written notification of change shall include a copy of the revised document and a description of the change.

In general, the changes for which the licensee shall notify the CNSC are captured as changes to specific licensee documents. The LCH identifies them under the most relevant LC. However, the licensee documents identified in the LCH only represent the minimum subset of documents that require notification of change. For any change that is not captured as a change to a document identified in the LCH, if it negatively impacts designs, operating conditions, policies, programs, methods, or other elements that are integral to the licensing basis, the licensee shall provide written notification of the change. For example, if a licensee document in the CVC refers to another document, including a third-party document, without citing the revision # of that document, if that document changes and the licensee uses the revised version, the licensee shall determine if it is necessary to notify the CNSC of the change.

The documents needed to support the licence application may include documents produced by third parties (e.g., reports prepared by third party contractors). Changes to these documents require written notification to the CNSC only if the new version continues to form part of the licensing basis. That is, if the licensee implements a new version of a document prepared by a third party, it shall inform the CNSC of the change(s), per LC G.2. On the other hand, if a third party has updated a certain document, but the licensee has not adopted the new version as part of its safety and control measures, the licensee is not required to inform the CNSC that the third party has changed the document.

Licensee documents tabulated in the CVC of the LCH are subdivided into groups having different requirements for notification of change – ones that require prior written notification of changes and those that require written notification only. For the former type, the licensee shall submit the document to the CNSC prior to implementing the change. Typically, the requirement is to submit the proposed changes 30 days prior to planned implementation; however, the licensee shall allow sufficient time for the CNSC to review the change proportionate to its complexity and the importance of the safety and control measures being affected. For the latter type, the licensee need only submit the document at the time of implementing the change.

Written notifications shall include a summary description of the change, the rationale for the change, expected duration (if not a permanent change), and a summary explanation of how the licensee has concluded that the change remains in accordance with the licensing basis (e.g., an evaluation of the impact on health, safety, security, the environment and Canada’s international obligations). A copy of the revised document shall accompany the notification.

Changes that are not clearly in the safe direction require further assessment of impact to determine if Commission approval is required in accordance with LC G.1.

The licensee shall notify the CNSC in writing when it plans to implement a new licensing basis publication, including the date by which implementation of the publication will be complete. The notice shall indicate the corresponding changes to licensee documents listed in CVC of the LCH.

Definition	Description
“N”	written notification is required as the revised document comes into effect.
“P”	written notification prior to implementation and CNSC staff acceptance at least 30 days before the revised document comes into effect.

Changes that may affect the licensing basis, including any change that is not captured as a change to a document listed in the LCH requires written notification to the CNSC to verify they are in accordance with the licensing basis.

For any change that is outside the licensing basis defined in subsection G.1 of the LCH, the licensee shall obtain Commission approval before proceeding with the change.

Guidance:

For proposed changes that would not be in accordance with the licensing basis, the guidance for licence condition G.1 applies.

Licence Condition G.3: Financial Guarantee

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)(1) that a licence application contain a description of any proposed financial guarantee relating to the activity to be licensed.

This condition 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, the expectation is that the financial guarantee is revised and submitted to the Commission for acceptance.

As part of the application, Best Theratronics provided a *Preliminary Decommissioning Plan* and an associated cost estimate which was reviewed by CNSC staff and deemed satisfactory.

The Commission accepted the financial guarantee of \$1.8 million in the form of two letters of credit for \$1,564,000.00 and \$236,000.00 on July 17, 2017.

Compliance Verification Criteria:

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-15d	Financial Guarantee	5631951	P

The financial guarantee for decommissioning the nuclear facility shall be reviewed and revised by the licensee every five years or when the Commission requires or following a revision of the preliminary decommissioning plan that significantly impacts the financial guarantee.

The next full review to the five (5) year reference plan for financial guarantee purposes is expected in 2022.

The licensee shall submit annually to the Commission a written report confirming that the financial guarantees for decommissioning costs remain valid and in effect and sufficient to meet the decommissioning needs. The licensee shall submit this report by the end of March of each year, or at any time as the Commission may request.

Guidance:

Document Number	Document Title	Version
G-206	Financial Guarantee for the Decommissioning of Licensed Activities	2000
<u>G-219</u>	Decommissioning Planning for Licensed Activities	2000

Licence Condition G.4: Public Information and Disclosure Program

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

Preamble:

The primary goal of a 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. A 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.

Paragraph 3(j) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the activity to be licensed.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
RD/GD-99.3	Public Information and Disclosure	2012	March 31 2013

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-15B	Public Information and Disclosure Program	5632267	N

Guidance:

None provided.

SCA – MANAGEMENT SYSTEM

Licence Condition 1.1: Management System

The licensee shall implement and maintain a management system.

Preamble:

Safe and reliable operation of nuclear facilities requires a commitment and adherence to a set of management system principles and, consistent with those principles, the implementation of planned and systematic processes that achieve expected results.

Paragraph 3(k) of the [General Nuclear Safety and Control Regulations](#) requires that a licence application contain “the applicant’s organization management structure insofar as it may bear the applicant’s compliance with the NSCA and the regulation made under the Act, including the internal allocation of functions, responsibilities and authority.”

Paragraph 3(d) the [Class I Nuclear Facilities Regulations](#) requires that a licence application contain “the proposed management system for the activity to be licenses, including measures to promote and support safety culture”

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.

The management system is in place to satisfy the requirements set out in the NSCA, Regulations made pursuant to the Act, the licence and the measures necessary to ensure that safety is of paramount consideration in the implementation of the management system. The management system promotes and supports a healthy safety culture by integrating the characteristics of a healthy safety culture:

- Safety is a clearly recognized value;
- Accountability for safety is clear;
- Safety is integrated into all activities;
- A safety leadership process exists; and
- Safety culture is learning driven

CSA standard N286 contains the requirements for a management system throughout the lifecycle of a nuclear facility and extends to all safety and control areas.

CSA standard N286.0.1 provides background information concerning certain clauses and requirements in CSA N286. This background information can help the user clarify the context of the CSA N286 requirements.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
CSA N286	Management system requirements for nuclear facilities	2012	July 01, 2014

Licensee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-01	Management Systems	5631871	P
5.00-QA-00	Quality Manual	5631860	N
5.00-QA-23	Training	See LC 2.1	

Guidance:

The management system should be used to promote and support a healthy safety culture. The CNSC recognizes the following characteristics that form the framework for a healthy safety culture: safety is a clearly recognized value, accountability for safety is clear, safety is integrated into all activities, a safety leadership process exists, and safety culture is learning-driven.

The licensee should perform ongoing monitoring of its safety culture program.

Guidance Documents

Document Number	Document Title	Version
CSA N286.0.1	Commentary on N286-12, Management system requirements for nuclear facilities	2014
REGDOC 2.1.2	Safety Culture	2018

SCA – HUMAN PERFORMANCE MANAGEMENT

Licence Condition 2.1: Training Program

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 completed in accordance with the licence

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
REGDOC-2.2.2	Personnel Training	2014	July 01, 2015

The licensee shall implement and maintain training programs for workers in accordance with the requirements set out in REGDOC 2.2.2, *Personnel Training*

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-02	Human performance Management	5631958	N
5.00-QA-23	Training	5631955	N

Guidance:

Guidance Documents

Document Number	Document Title	Version
REGDOC 2.2.2	Personnel Training	2016

SCA – OPERATING PERFORMANCE

Licence Condition 3.1: Operations Program

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

Preamble:

Paragraph 3(1)(c) of the [General Nuclear Safety and Control Regulations](#) requires that a licence application contain the name, maximum quantity and form of any nuclear substance to be encompassed by the licence.

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 operations program is to include an up to date set of operating limits for the facilities and activities authorized under the licence, including limits for the possession, use, management, transfer, storage, import and export of nuclear substances, and operational limits/specifications for nuclear facilities.

Compliance Verification Criteria:

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-03	Operating Performance	5631972	N
5.00-QA-00	Quality Manual	See LC 1.1	
3.24-AA-16	Shielded Room 4 Operation Instructions	5631995	P
IN/SR 6104	Final Safety Analysis Report for Cyclotron Testing	See LC 4.1	
C1B-SD-15	Import/Export	5631935	N

Commissioning plans must be submitted to the CNSC and accepted by a person authorized by the Commission before the cyclotron is operated at greater than 1 MeV and the beam is extracted. See licence conditions 15.1 for more information.

Guidance:

None provided.

Licence Condition 3.2: Reporting Requirements

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

Preamble:

None provided.

Compliance Verification Criteria:

The licensee shall submit to the Commission or a person authorized by the Commission, 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 summary of the workload of the Class II prescribed equipment in various modes of operation during the reporting period as shown below:

Make and model	Serial number	room	Workload per year, Gy at 1m			
			operation	Maintenance/servicing	research	total

Workload= air kerma rate of source(s) x exposure duration summed over all exposures during the reporting period

- The total number of hours of various operating modes during the year, including the energies and beam currents used in conjunction with the cyclotron.

Unless otherwise permitted by the prior approval of the Commission or a person authorized by the Commission, the licensee shall, in respect of a radioactive nuclear substance set out in column 1 of table 1, report in writing to the CNSC staff any transfer, receipt, export or import of a sealed source whose corresponding activity is equal to or greater than the value set out in column 2 of the table:

- at least seven business days (or not less than 24 hours for transfers within Canada) before any transfer or export, and
- within two business days of any receipt of a transfer or import.

Table 1: Activity Limits for Reporting the Transfer of Sealed Sources

Column 1	Column 2
Nuclear Substance	(TBq)
Americium 241	0.6
Americium 241/Beryllium	0.6
Californium 252	0.2
Curium 244	0.5
Cobalt 60	0.3
Cesium 137	1
Gadolinium 153	10
Iridium 192	0.8
Promethium 147	400
Plutonium 238	0.6
Plutonium 239/Beryllium	0.6
Radium 226	0.4
Selenium 75	2
Strontium 90 (Yttrium 90)	10
Thulium 170	200
Ytterbium 169	3

The written report shall be in a form acceptable to the CNSC staff and shall include:

1. on transfer of a sealed source(s),
 - (a) the date of transfer,
 - (b) the name of the recipient and licence number,
 - (c) the address of the recipient's authorized location,
 - (d) the nuclear substance (radionuclide),
 - (e) activity (radioactivity) (Bq) per sealed source on the reference date,
 - (f) the reference date,
 - (g) the number of sealed source(s),
 - (h) the aggregate activity (Bq),
 - (i) the sealed source unique identifiers (if available), and
 - (j) where the sealed source is incorporated in prescribed equipment,
 - (i) the name and model number of the equipment, and
 - (ii) the equipment serial number (if available);
2. on receipt of a sealed source(s),
 - (a) the date of receipt of a transfer,
 - (b) the name of the shipper and licence number,
 - (c) the address of the shipper's authorized location,
 - (d) the nuclear substance (radionuclide),
 - (e) activity (radioactivity) (Bq) per sealed source on the reference date,
 - (f) the reference date,
 - (g) the number of sealed source(s),
 - (h) the aggregate activity (Bq),
 - (i) the sealed source unique identifiers (if available), and
 - (j) where the sealed source is incorporated in prescribed equipment,
 - (i) the name and model number of the equipment, and
 - (ii) the equipment serial number (if available).

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
REGDOC-3.1.2	Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills	2018	January 1, 2019

Licensee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
5.08-RP-18	Best Theratronics Sealed Source Database	5631970	N
5.08-RP-19	Radioactive Material Shipments Tracking	5631971	N

Guidance:

None provided.

Licence Condition 3.3: Inventory Control

The licensee shall implement and maintain a program for inventory control of all nuclear substances and prescribed equipment including radiation devices.

Preamble

This condition requires the licensee to implement and maintain a program for inventory control.

Compliance Verification Criteria

Full and accurate records shall be maintained including:

- The acquisition of nuclear substances, radiation devices and Class II prescribed equipment, including the quantity received, the form of the substance, and the name of the vendor,
- The inventory of all nuclear substances, radiation devices and Class II prescribed equipment, at the facility,
- The disposition of all nuclear substances, radiation devices and Class II prescribed equipment used or stored by the facility, including the name and address of the recipient, a copy of the recipient's licence (if applicable), the quantity of the nuclear substance, and the date of shipment.

For compliance with licence condition 3.3, the following documents require written notification of changes made:

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
5.08-RP-18	Best Theratronics Sealed Source Database	5631970	N
5.08-RP-19	Radioactive Material Shipments Tracking	5631971	N
5.08-RP-04	Management of Depleted Uranium Radioactive Material	5631915	N

Guidance:

None provided.

DRAFT

SCA – SAFETY ANALYSIS

Licence Condition 4.1: Safety Analysis Program

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) and 6(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.

Compliance Verification Criteria:

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-04	Safety Analysis	5631975	N
IN/SR 6104	Final Safety Analysis Report for Cyclotron Testing	5631980 To be updated	P
IN/SR 1765	Final Safety Analysis Report for Shielded Room 4	5631977	P
IN/SR 1818	Final Safety Analysis Report for Best Theratronics Building Radioactive Material Processes	5631979	P

Guidance:

Guidance Documents

Document Number	Document Title	Version
IAEA GSR Part 4 Rev 1	Safety Assessment for Facilities and Activities	2016

SCA – PHYSICAL DESIGN

Licence Condition 5.1: Design Program

The licensee shall implement and maintain a design program.

Preamble:

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

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.

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.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
NA	National Building Code of Canada	2015	xxxx

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-05	Physical Design	5631991	N
3.24-AA-01	Design Change Procedure	5631961	N
PEAE-21000	Blueprint of facility	5631854	P

Guidance:

None provided.

SCA – FITNESS FOR SERVICE

Licence Condition 6.1: Fitness for Service Program

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

Preamble:

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

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:

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-06	Fitness for Service	5629694	N
3.11-MC-19	Preventative Maintenance	5631993	N

Guidance:

None provided.

SCA – RADIATION PROTECTION

Licence Condition 7.1: Radiation Protection Program

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

Preamble:

The [Radiation Protection Regulations](#) requires that the licensee implement a radiation protection program and also ascertain and record doses for each person who performs any duties in connection with any activity that is authorized by the NSCA or is present at a place where that activity is carried out. This program must ensure that doses to workers do not exceed prescribed dose limits and are kept as low as reasonably achievable (ALARA), social and economic factors being taken into account. Also, the program ensures that occupational exposures are ascertained and recorded in accordance with the [Radiation Protection Regulations](#) through the establishment of dosimetry requirements.

The regulatory dose limits to workers and the public are explicitly provided in the [Radiation Protection Regulations](#). The [Radiation Protection Regulations](#) also specify the requirements related to action levels (ALs) and indicate that the licence will be used to identify their notification timeframes. ALs relate to the parameters of dose to workers.

Action levels (ALs) 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](#) and the licence. ALs are not intended to be static and are to reflect operating conditions at the BTL facility.

Compliance Verification Criteria:

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-07	Radiation Protection	5632095	N
5.08-RP-01	Radiation Protection Manual	5632084	P
5.08-RP-08	Contamination Monitoring Program Sampling and Measurement	5632089	N
5.08-RP-09	Leak Test Sampling and Measurement	5632090	N
5.08-RP-11	Radiation Surveys	5632091	N
5.08-RP-12	Keeping Radiation Exposures and Doses ALARA	5632092	P
5.08-RP-02	Radiation Emergency Response Plan	5631880	P

ALs for radiation protection are included in table 7-1. In the event of a discrepancy between the table and the licensee documentation upon which they are based, the licensee documentation shall be considered the authoritative source considering that the licensee has followed its own change control process.

Table 7-1: Effective Doses for Servicing and Manufacturing Personnel

Type of Dose	NEW	Non-NEW
Technical Services	4 mSv/month, 4 mSv/qtr, 8 mSv/year	1 mSv/qtr
Building Personnel	2 mSv/month, 2 mSv/qtr, 4 mSv/year	1 mSv/qtr

Guidance:

Guidance Documents

Document Number	Document Title	Version
CNSC G-129, Rev. 1	Keeping Radiation Exposures and Doses “As Low as Reasonably Achievable (ALARA)”	2004
CNSC G-228	Developing and Using Action Levels	2001
CNSC G-91	Ascertaining and Recording Radiation Doses to Individuals	2003

The licensee should conduct a documented review and, if necessary, revise the ALs at least once every five years in order to validate their effectiveness. The results of such reviews should be provided to CNSC staff. Best Theratronics reviewed the ALs in 2016 and is expected to complete the next full review in 2021.

SCA – CONVENTIONAL HEALTH AND SAFETY

Licence Condition 8.1: Conventional Health and Safety Program

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

Preamble:

The [Class I Nuclear Facilities Regulations](#) requires that a licence application contain the proposed worker health and safety policies and procedures.

The regulation of non-radiological health and safety at BTL is governed by the [Canada Labour Code, Part II](#). As a federal regulated site, BTL is also subject to the requirement of [Canada Occupational Health and Safety Regulations](#).

Compliance Verification Criteria:

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-08	Conventional Health and Safety	5632199	N

The Ministry of Labour is mandated with overseeing and enforcing compliance with the *Canada Labour Code* and its Regulations. CNSC staff monitor licensee compliance with its conventional health and safety program, and will take regulatory actions for any potential unsafe work practice situations.

Guidance:

None provided.

SCA – ENVIRONMENTAL PROTECTION

Licence Condition 9.1: Environmental Protection Program

The licensee shall implement and maintain an environmental protection program.

Preamble:

The [Class I Nuclear Facilities Regulations](#) requires that a licence application contain information related to environmental protection. The [General Nuclear Safety and Control Regulations](#) requires every licensee to take all reasonable precautions to protect the environment. The [Radiation Protection Regulations](#) prescribe the radiation dose limits for the general public of 1 mSv/calendar year.

CNSC regulatory document REGDOC-2.9.1: *Environmental Protection: Environmental Principles, Assessments and Protection Measures*, 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: 2015, *Environmental Management Systems – Requirements with Guidance for Use*.

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, and Management Review.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
REGDOC-2.9.1	Environmental Protection: Environmental Principles, Assessments and Protection Measures (2017)	1.1	August 09 2018
CSA N288.6-12	Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills	1	June 30 2012

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-09	Environmental Protection	5632223	N
5.08-SE-00	Best Theratronics EH&S Policy	5632207	N
5.08-SE-01	Best Theratronics EH&S Responsibilities and Committees	5632208	N

Guidance:

Guidance Documents

Document Number	Document Title	Version
CSA N288.1	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	2014 (Update 1)
CSA N288.2	Guidelines for calculating the radiological consequences to the public of a release of airborne radioactive material for nuclear reactor accidents	2014

SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION

Licence Condition 10.1: Emergency Preparedness Program

The licensee shall implement and maintain an emergency preparedness program.

Preamble:

This licence condition requires the licensee to establish an emergency preparedness program to prepare for, to respond to, and to recover from the effects of accidental radiological/nuclear and/or hazardous substance release. As part of the emergency preparedness program, the licensee establishes an onsite emergency response plan and an emergency response organization and makes arrangements for coordinating off-site activities and cooperating with external response organizations throughout all phases of an emergency.

The [Class I Nuclear Facilities Regulations](#) requires measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including measures to assist, notify, report to offsite authorities including the testing of the implementation of these measures.

Expectations for this program include adequate inter-relation with off-site emergency preparedness and response organizations to ensure adequate protection at the Best Theratronics facilities, and offsite if, and as, required.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
REGDOC-2.10.1	Nuclear Emergency Preparedness and Response, Version 2	2016	April 1, 2018

Licencee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-10	Emergency Management and Fire Protection	5631883	N
5.08-ERP-01	Site Emergency Response Plan	5631877	N

Guidance:

None provided.

Licence Condition 10.2: Fire Protection Program

The licensee shall implement and maintain a fire protection program.

Preamble:

Licenses require a comprehensive fire protection program (the set of planned, coordinated, controlled and documented activities) to ensure the licensed activities do not result in 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.

Fire protection provisions, including response, are required for the design, construction, commissioning, operation, and decommissioning of nuclear facilities, including structures, systems, and components (SSCs) that directly support the plant and the protected area. External events such as an aircraft crash or security threats are addressed in LCH section 12.1.

CSA standard N393 *Fire Protection for Facilities that Process, Handle, or Store Nuclear Substances* provides the minimum fire protection requirements for the design, construction, commissioning, operation, and decommissioning of facilities which process, handle, or store nuclear substances, and other hazardous substances that directly relate to the nuclear substances being regulated.

The *National Fire Code of Canada* sets out technical provisions regulating (a) activities related to the construction, use or demolition of buildings and facilities; (b) the condition of specific elements of buildings and facilities; (c) the design or construction of specific elements of facilities related to certain hazards; and (d) protection measures for the current or intended use of buildings.

The *National Building Code of Canada* sets out technical provisions for the design and construction of new buildings. It also applies to the alteration, change of use and demolition of existing buildings.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
CSA N393	Fire Protection For Facilities That Process, Handle, or Store Nuclear Substances	2013 (R2016)	Nov 15 2015

Licencee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-10	Emergency Management and Fire Protection		See LC 10.1
1.08-SC-01 (D)	Fire Safety Plan	5631874	

Guidance:

None provided.

Licence Conditions: SCA EMERGENCY MANAGEMENT AND FIRE PROTECTION

SCA – WASTE MANAGEMENT

Licence Condition 11.1: Waste Management Program

The licensee shall implement and maintain a waste management program.

Preamble:

The [General Nuclear Safety and Control Regulations](#) require that a licence application contain information related to the 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.

CSA standard N292.3-14 provides criteria associated with the management of low and intermediate-level radioactive waste.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
CNSC Policy P - 290	Managing Radioactive Waste	2004	
CSA N292.0-14	General Principles for the Management of Radioactive Waste and Irradiated Fuel	2014	
CSA N292.3-14	Management of low- and intermediate-level radioactive waste	2014	April 1, 2018

Licencee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-11	Waste Management	5631895	N

BTL shall characterize its waste streams and minimize the production of all wastes taking into consideration the health and safety of workers and the environment, integrate waste management programs as a key element of the facility's safety culture, and regularly audit its program to maximize its efficiency.

Guidance

Guidance Documents

Document Number	Document Title	Version
REGDOC 2.11.1	Assessing the Long term Safety of Radioactive Waste Management	2018

Licence Condition 11.2: Decommissioning Plan

The licensee shall implement and maintain a decommissioning plan.

Preamble:

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

CSA standard N294 specifies requirements for the decommissioning of licensed facilities and other locations where nuclear substances are managed, possessed, or stored.

This LC requires that the licensee maintain a preliminary decommissioning plan (PDP) for the licensed site. A preliminary decommissioning plan (PDP) 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 PDP defines areas to be decommissioned and the general structure and sequence of the principle work packages. The PDP forms the basis for establishing and maintaining a financial arrangement (financial guarantee) that will assure adequate funding of the decommissioning plan.

It is expected that the PDP will be revised as the conditions at the facility change. When the PDP is revised the cost of decommissioning must be reviewed. At a minimum, the PDP must be reassessed every five years.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
CSA N294	Decommissioning of facilities containing nuclear substances	2009 (R2014)	April 1, 2018

The PDP shall be kept current to reflect any changes in the site or nuclear facility. The PDP shall be revised at a minimum every five years or when required by the Commission.

The PDP was last revised and submitted to CNSC staff in 2017. BTL's next submission of the PDP is due to be submitted to CNSC staff in 2022.

Licencee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-15c	Preliminary Decommissioning Plan	5631944	NT
3.24-AA-24	Class II Decommissioning Plan for Class II Facility Shielded Room 4	5631939	PN

Guidance:

Guidance Documents

Document Number	Document Title	Version
G-219	Decommissioning Planning for Licensed Activities	2000

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 G.3).

SCA – SECURITY

Licence Condition 12.1: Security Program

The licensee shall implement and maintain a security program.

Preamble:

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

Paragraphs 3(1)(h) of the [General Nuclear Safety and Control Regulations](#) require that a licence application shall contain “the proposed measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information”.

Paragraph 6(1) of the [Class I Nuclear Facilities Regulations](#) requires that a licence application shall contain “the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility; including measures to alert the licensee to such acts”.

Paragraphs 12(1) (c), (g), (h) and (j) of the [General Nuclear Safety and Control Regulations](#) requires that the licensee shall 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, implement measures for alerting the licensee to acts of sabotage or attempted sabotage anywhere at the site of the licensed facility and instruct the workers on the physical security program at the site of the licensed activity and on their obligations under that program

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

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
REGDOC 2.12.3	Security of Nuclear Substances: Sealed Sources	2013	May 31 2015

Licence Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-12	Security	5631908	N
1.08-SC-02	Security Plan – Best Theratronics Ltd. Prescribed Information	5631899	

Guidance:

None provided.

SCA – SAFEGUARDS AND NON-PROLIFERATION

Licence Condition 13.1: Safeguards Program

The licensee shall implement and maintain a safeguards program.

Preamble:

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

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

Paragraph 12(i) of the [General Nuclear Safety and Control Regulations](#) requires the licensee to take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement.

This licence condition requires the licensee to take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement. Safeguards is a system of inspection and other verification activities undertaken by the International Atomic Energy Agency (IAEA) in order to evaluate a Member State's compliance with its obligations pursuant to its safeguards agreements with the IAEA. The requirements for reporting to the CNSC staff on the inventory and transfer of sealed sources are included in licence condition 3.2 of this LCH.

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

- [Treaty on the Non-Proliferation of Nuclear Weapons](#);
- [Agreement Between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons](#); and
- [Protocol Additional to the Agreement Between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons](#).

These are reproduced in information circulars INFCIRC/140, INFCIRC/164, and INFCIRC/164/Add. 1.

The import and export of controlled nuclear substances, equipment and information identified in the [Nuclear Non-proliferation Import and Export Control Regulations](#) require separate authorization from the CNSC, consistent with subsection 3(2) of the [General Nuclear Safety and Control Regulations](#). The guidance to seek such an authorization is provided in REGDOC-2.13.2 – *Import and Export*.

Compliance Verification Criteria:

Licensing Basis Publications

Document Number	Document Title	Version	Effective Date
REGDOC-2.13.1	Safeguards and Nuclear Material Accountancy	2018	January 1 2019
CNSC REGDOC 2.12.2	Import and Export	2016	

Licensee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-13	Safeguard	5631918	N

Guidance:

The licensee shall obtain prior written approval of the CNSC, for any changes to operation, equipment or procedures requested by the licensee that would affect the implementation of safeguards measures.

SCA – PACKAGING AND TRANSPORT

Licence Condition 14.1: Packaging and Transport Program

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

Preamble:

The [Class I Nuclear Facilities Regulations](#) require that a licence application contain information on the proposed procedures for transporting nuclear substances and hazardous substances.

The transport of nuclear substances or hazardous substances shall be done in accordance with the requirements of the *Packaging and Transport of Nuclear Substances Regulations, 2015*, (PTNSR) and *Transportation of Dangerous Goods Regulations* (TDGR) set out by Transport Canada.

IAEA document SSR-6, *Regulations for the Safe Transport of Radioactive Material (2012 Edition)* is incorporated by reference in PTNSR. These regulations establish standards of safety which provide an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the transport of radioactive material.

Compliance Verification Criteria:

Licencee Documents that Require Notification of Change

Document Number	Document Title	e-Doc	Notification
C1B-SD-14	Packaging and Transport	5631928	
5.08-TDG-02 (D)	Transportation Emergency Response Plan	5631882	
1.08-SC-10 (G)	Hazardous Material Transportation Security Plan – Prescribed Information	5631904	

Guidance:

Guidance Documents

Document Number	Document Title	Version
REGDOC-2.14.1	Information Incorporated by Reference in Canada’s <i>Packaging and Transport of Nuclear Substances Regulations, 2015</i>	2016

SCA – SITE SPECIFIC

Licence Condition 15.1 Class IB Facility: Cyclotron

The licensee shall not operate a cyclotron/ cyclotrons at beam energy greater than 1 MeV without prior authorization from the Commission or a person authorized by the Commission.

Preamble

Cyclotron(s) will be assembled at the Best Theratronics Ltd. Facility in Ottawa to be solely operated for testing purposes and not for routine operation.

In order to operate any cyclotron at energies greater than 1 MeV, prior authorization from the Commission or a person authorized by the Commission is required.

To operate a Class I cyclotron at beam energy greater than 1 MeV the licensee must demonstrate to the CNSC that there is a clearly defined and appropriate plan to carry out the operation including commissioning. The plan should include measures to ensure that the operation of the cyclotron will be done safely and measures will be taken to mitigate against hazards.

Guidance

The cyclotron shall not be operated at beam energies greater than 1 MeV unless the Commission or a person authorization by the Commission authorizes it. To receive authorization to operate at beam energies than 1 MeV, BTL should provide documentation to include:

Updated Final Safety Analysis Report (FSAR) that radiation doses to employees involved in radiological activities at Best Theratronics would be below the administrative level outlined in the Radiation Protection Manual, and there would be no release of radioactive material to the environment and detail the radiological activities conducted in the facility, to analyze the risks and the procedures to minimize those risks.

Any additional information relating to a cyclotron including detailed commissioning test plans to demonstrate that hazards have been analyzed and that risks have been sufficiently mitigated.

Licence Condition 15.2 Export Restrictions

This licence does not authorize the licensee to export, for the valid period of this licence in respect of a nuclear substance, a radioactive sealed source whose corresponding activity is equal to or greater than the value set out in column 2 of table 15.1:

Table 15.1: Activity Limits for Exporting Sealed Sources

Column 1 Nuclear Substance	Column 2 (TBq)
Americium 241	0.6
Americium 241/Beryllium	0.6
Californium 252	0.2
Curium 244	0.5
Cobalt 60	0.3
Cesium 137	1
Gadolinium 153	10
Iridium 192	0.8
Promethium 147	400
Plutonium 238	0.6
Plutonium 239/Beryllium	0.6
Radium 226	0.4
Selenium 75	2
Strontium 90 (Yttrium 90)	10
Thulium 170	200
Ytterbium 169	3

Preamble:

None provided

Compliance Verification Criteria:

Best Theratronics Ltd. shall not export any of the nuclear substances listed in LC 15.2 without a valid export licence issued by the CNSC. Licence No. NSPFOL-14.00/2029 issued to Best Theratronics Ltd. does not authorize the export of the listed nuclear substances equal to or greater than the value set in column 2 of table 15.1 and therefore additional export licences shall be obtained from the CNSC. CNSC inspectors can verify compliance by reviewing shipping documents pertaining to exports.

Guidance:

None provided

DRAFT

APPENDIX A: DEFINITIONS AND ACRONYMS

1. DEFINITIONS

The following is a list of definitions of words or expressions used in the LCH that may need clarification; they are defined for the purpose of the LCH only. All other terms and expressions used in the LCH are consistent with the definitions provided in the NSCA, the regulations made pursuant to the Act, or in the CNSC regulatory document REGDOC-3.6 *Glossary of CNSC Terminology*.

Approval – Commission’s permission to proceed, for situations or changes where the licensee would be:

- not compliant with a regulatory requirements set out in applicable laws and regulations;
- not compliant with a licence condition; and
- not in the safe direction but the objective of the licensing basis is met.

Boundary Conditions – procedural, administrative rules and operating limits for ensuring safe operation of the facility based on safety analyses and any applicable regulatory requirements.

Certified Staff – trained licensee staff, certified by the Commission as qualified to perform the duties of their respective roles.

Compliance Verification Criteria – regulatory criteria used by CNSC staff to verify compliance with the licence conditions.

Design Basis – the entire range of conditions for which the nuclear facility is designed, in accordance with established design criteria, and for which damage to the fuel and/or the release of radioactive material is kept within authorized limits.

Effective Date – the date that a given document becomes effective within the licensing period. The effective date is either set to the licence issue date or to a future date when the given document becomes effective.

Guidance – guidance in the LCH is non-mandatory information, including direction, on how to comply with the licence condition.

Important to Safety – items important to safety include, but are not limited to:

- (a) SSCs whose malfunction or failure could lead to undue radiation exposure of the facility/site personnel, or members of the public;
- (b) SSCs that prevent anticipated operational occurrences from leading to accident conditions;
- (c) those features that are provided to mitigate the consequences of malfunctions or failures of SSCs; and
- (d) tasks, duties, activities, aging mechanisms, findings, or any work that improperly performed could lead to radiation exposure of the facility/site personnel, or members of the public.

APPENDIX A: DEFINITIONS AND ACRONYMS

Program(s) – a documented group of planned activities, procedures, processes, standards and instructions coordinated to meet a specific purpose.

Qualified Staff – trained licensee staff, deemed competent and qualified to carry out tasks associated with their respective positions.

Safe Direction – changes in facility safety levels that would not result in:

- (a) a reduction in safety margins;
- (b) a breakdown of barrier;
- (c) an increase (in certain parameters) above accepted limits;
- (d) an increase in risk;
- (e) impairment(s) of safety systems;
- (f) an increase in the risk of radioactive releases or spills of hazardous substances;
- (g) injuries to workers or members of the public;
- (h) introduction of a new hazard;
- (i) reduction of the defence-in-depth provisions;
- (j) reducing the capability to control, cool and contain the reactor while retaining the adequacy thereof; or
- (k) causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility.

Safety and Control Measures – measures or provisions which demonstrate that the applicant:

- (i) is qualified to carry on the licensed activities; and
- (ii) has made adequate provision for the protection of the environment, the health and safety of persons, the maintenance of national security and any measures required to implement international obligations to which Canada has agreed.

Written Notification – a physical or electronic communication between CNSC staff and a person authorized to act on behalf of the licensee.

2. ACRONYMS LIST

Acronym Definition

AL	Action Levels
ALARA	As Low As Reasonably Achievable
CAF	Change Approval Form
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association
CVC	Compliance Verification Criteria
DG-DNCFR	Director General, Directorate of Nuclear Cycle and Facilities Regulations
EMS	Environmental Management System
EOP	Emergency Operating Procedures
FG	Financial Guarantee
GNSCR	<i>General Nuclear Safety and Control Regulations</i>
IAEA	International Atomic Energy Agency
LC	Licence Condition
LCH	Licence Conditions Handbook
NSCA	<i>Nuclear Safety and Control Act</i>
N	Notification at time of making the change
P	Prior Notification
PDP	Preliminary Decommissioning Plan
PTNSR	<i>Packaging and Transport of Nuclear Substances Regulations, 2015</i>
SSC	Structures, Systems, Components
TDGR	<i>Transportation of Dangerous Goods Regulations</i>

CURRENT LICENCE

e-Doc 5194913 (Word)
e-Doc 5201133 (PDF)

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CLASS 1B NUCLEAR SUBSTANCE PROCESSING FACILITY OPERATING LICENCE

BEST THERATRONICS LTD.

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

I) LICENCE NUMBER: NSPFOL-14.02/2019

II) LICENSEE: Pursuant to section 25 of the *Nuclear Safety and Control Act*, this licence is issued to:

**Best Theratronics Ltd.
413 March Road
Ottawa, Ontario
K2K 0E4**

III) LICENCE PERIOD: This licence is valid from **July 1, 2014**, to **June 30, 2019**, unless otherwise suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

- (a) operate a Class 1B Facility, comprising of:
 - (i) a particle accelerator(s)/cyclotron;
 - (ii) a nuclear substance processing facility for the purposes of manufacturing radiation devices;
 - (iii) a radioactive source teletherapy machine, for the purposes of developing and testing of Class II Prescribed Equipment;
- b) possess, transfer, manage, store and dispose of nuclear substances arising from the activities regarding the cyclotrons;

- c) possess, transfer, use, import, export, manage, store and dispose within the processing facility any nuclear substances that are required for, associated with, or arise from the activities of manufacturing radiation devices, and development and testing of Class II Prescribed Equipment;
- d) possess, transfer, use, import, export, store and dispose prescribed equipment that is required for, associated with, or arise from the activities related to the manufacturing of radiation devices and development and testing of Class II Prescribed Equipment;
- e) possess and use prescribed information that is required for, associated with, or arise from the activities described in a).

V) EXPLANATORY NOTES:

- (a) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the NSCA and associated Regulations.
- (b) The “*Best Theratronics Ltd. Licence Conditions Handbook (LCH)*” provides:
 - (i) compliance verification criteria in order to meet the conditions listed in the licence;
 - (ii) information regarding delegation of authority to CNSC staff; and
 - (iii) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

VI) CONDITIONS:

1. GENERAL

- 1.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:
- (i) the regulatory requirements set out in the applicable laws and regulations
 - (ii) the conditions and safety and control measures described in the facility’s or activity’s licence and the documents directly referenced in that licence
 - (iii) the safety and control measures described in the licence application and the documents needed to support that licence application
- unless otherwise approved in writing by the CNSC (hereinafter “the Commission”).

- 1.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design operating conditions, policies, programs and methods referred to in the licensing basis.
- 1.3 The licensee shall maintain a financial guarantee for decommissioning acceptable to the Commission.
- 1.4 The licensee shall implement and maintain a public information and disclosure program

2. MANAGEMENT SYSTEM

- 2.1 The licensee shall implement and maintain a management system.

3. HUMAN PERFORMANCE MANAGEMENT

- 3.1 The licensee shall implement and maintain a training program.

4. OPERATING PERFORMANCE

- 4.1 The licensee shall implement and maintain an operating program, which includes a set of operating limits.
- 4.2 The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.
- 4.3 The licensee shall implement and maintain a program for inventory control of all nuclear substances and prescribed equipment including radiation devices.

5. SAFETY ANALYSIS

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

6. PHYSICAL DESIGN

- 6.1 The licensee shall implement and maintain a design program.

7. FITNESS FOR SERVICE

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

8. RADIATION PROTECTION

8.1 The licensee shall implement and maintain a radiation protection program, which includes action levels

9. CONVENTIONAL HEALTH AND SAFETY

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

10. ENVIRONMENTAL PROTECTION

10.1 The licensee shall implement and maintain an environmental protection program.

11. EMERGENCY MANAGEMENT AND FIRE PROTECTION

11.1 The licensee shall implement and maintain an emergency preparedness program, which includes fire response.

12. WASTE MANAGEMENT

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

12.2 The licensee shall maintain a preliminary decommissioning plan.

13. SECURITY

13.1 The licensee shall implement and maintain a security program.

14. SAFEGUARDS AND NON-PROLIFERATION

14.1 The licensee shall implement and maintain a safeguards program.

15. PACKAGING AND TRANSPORT

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

16. SITE SPECIFIC

16.1 Any Class I particle accelerator shall be operated only in accordance with the commissioning plan approved by the Commission or a person authorized by the Commission.

16.2 Any Class I particle accelerator shall be dismantled only in accordance with the dismantling plan that the Commission or a person authorized by the Commission has approved

SIGNED at OTTAWA, this 14th day of July, 2017



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