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**Written submission from
Best Theratronics Limited**

**Mémoire de
Best Theratronics Limited**

In the Matter of the

À l'égard de

Best Theratronics Limited

Best Theratronics Limited

Application for the renewal of the Class IB
Nuclear Substance Processing Facility
Operating Licence

Demande de renouvellement du permis
d'exploitation d'une installation de traitement
de substances nucléaires de catégorie IB

Commission Public Hearing

Audience publique de la Commission

May 16, 2019

Le 16 mai 2019

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Table of Contents

Executive Summary	1
1.0 Introduction.....	4
1.1 Background.....	4
1.2 Highlights.....	6
2.0 Business Plan.....	6
3.0 Safety and Control Areas.....	7
3.1 Management system.....	7
3.2 Human performance management.....	9
3.3 Operating performance	10
3.4 Safety analysis.....	11
3.5 Physical design.....	12
3.6 Fitness for service.....	14
3.7 Radiation protection	14
3.8 Conventional health and safety	17
3.9 Environmental protection	20
3.10 Emergency management and fire protection.....	22
3.11 Waste management.....	24
3.12 Security.....	26
3.13 Safeguards and non-proliferation	27
3.14 Packaging and transport.....	28
4.0 Other Matters of Regulatory Interest	30
4.1 Import/Export activities.....	30
4.2 Cyclotron manufacturing	30
4.3 Financial guarantees.....	31
4.4 Licensee's public information program	31
5.0 Conclusions	32
Addendum A: Supporting details	34
A1: Management system – BTL organizational chart.....	34
A2: Radiation protection – Dose data for BTL employees.....	35
A3: Radiation protection – Updated ALARA dose levels.....	36
A4: Conventional health and safety – Lost time injuries.....	37
A5 – Reportable events	38

Executive Summary

This document is in support of the application to either renew Best Theratronics Ltd.'s Class 1B licence, expiring June 30, 2019, or to continue current operations under a combination of Class II facility license and NSRD licenses, applied for February 15, 2019.

BTL initially sought to consolidate its existing device manufacturing, Class II, and storage licenses into a single Class 1B Nuclear Facility license that would also allow for Class I cyclotron testing (up to 70 MeV) at the facility in Ottawa, ON. However, over the licensing period manufactured cyclotrons were only tested up to 1 MeV, where no nuclear energy was produced, and a review of the original business plan revealed that no cyclotron would require testing above 1 MeV at the BTL facility. Therefore, BTL believes that operations can safely continue under Class II facilities and NSRD licenses, if granted.

Throughout the close to five decades that BTL has been located at 413 March Rd. Ottawa ON, manufacturing medical equipment used throughout the world, including Cobalt-60 (Co60) radiation cancer treatment units and Caesium-137 (Cs137) and x-ray-based blood irradiators. Over the past few years, BTL has been developing a line of cyclotrons for use in health care and research institutions.

The current Class 1B Nuclear Facility license authorizes BTL to conduct the following activities:

- (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 Class II Facility consisting 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).

BTL has made, and will continue to make, adequate provisions for the protection of the environment, the health and safety of both employees and the public, and the maintenance of measures to ensure Canada meets its international obligations to which it has agreed to. The programs BTL has implemented, and the improvements made to these programs, are indicative of the commitment BTL has made to ensure there are adequate provisions in place for the

protection of the environment, our employees, and the public. The program framework BTL has implemented also point to the qualification of BTL to continue licensed activity operations.

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1.0 Introduction

1.1 Background

Best Theratronics Ltd. (BTL) is a medical device manufacturing company located at 413 March Rd in Ottawa. Figure 1 illustrates the location of the facility. The facility was first constructed in approximately 1964 as a part of Atomic Energy of Canada Ltd (AECL). The business was sold to various companies throughout the subsequent years, and in 2008 was purchased by a private investor and became BTL. Directly adjacent to the property is Nordion (Canada) Inc., located at 447 March Rd.

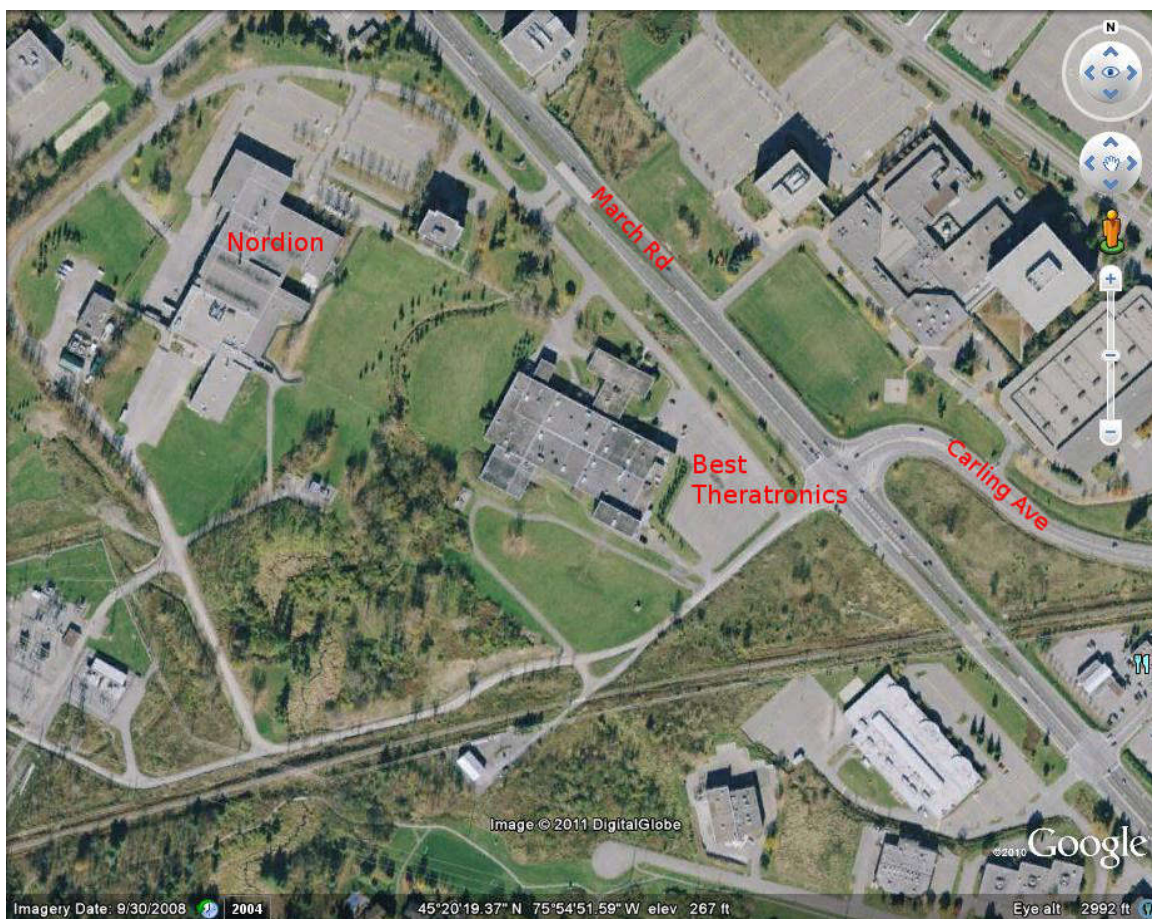


Figure 1 Site Location

Throughout the close to five decades that the facility has been located at 413 March Rd., BTL has been manufacturing medical equipment used throughout the world. BTL manufactures radiation cancer treatment devices that contain Cobalt-60 ($Co60$) radioactive sources. These devices were a Canadian invention that started the radiation therapy paradigm that has helped millions of people world-wide. BTL also manufactures both x-ray and Caesium-137 ($Cs137$)-based blood irradiators used to prevent graft-vs.-host disease. That is, blood used in blood transfusions is sterilized to prevent the donor blood from attacking the immune-comprised host patient. Finally, BTL is working on the

design and manufacture of particle accelerators to be sold for use in health centres to produce the medical isotopes needed for diagnostic imaging.

Our main products (Figure 2) related to current Class 1B licence included:

1. Co60-based external beam radiation therapy units,
2. Cs137-based self-contained irradiators (SCIs) for blood or research irradiation,
3. Cyclotrons with beam energies ranging from 15 to 70 MeV.



Figure 2 BTL products, shown clockwise from upper left: Gammacell blood irradiator; Co60 teletherapy unit; 15 – 70 MeV cyclotrons

BTL's current licensing activities include import, export, use, transfer, manage, dispose, possess, and storage of the nuclear material relating to our manufacturing and research and development activities.

BTL is a major exporter of Category 1 and 2 Co60 and Cs137 sealed sources, used within our radiation devices and Class II prescribed equipment.

1.2 Highlights

Since the purchase of BTL by a private investor in 2008, and until Jun 2014 BTL was operating under Class II facility and NSRD licenses. Around 2009 BTL began the development of cyclotrons and as with all of BTL products, the cyclotrons would be designed, manufactured, and tested at BTL, and then shipped to end-users world-wide. All manufactured cyclotrons are currently tested up to 1MeV.

The necessity for BTL to obtain a Class 1B licence was to only test its first cyclotron at energies up to 70 MeV as was required by the customer. Based on this intention, the CNSC recommended that BTL should move to a Class 1B Nuclear Facility license for all of its activities. The original Class 1B licence was granted on July 25, 2014.

Beside the manufacturing and testing of cyclotrons, other operations at BTL remained the same from 2008 and until now.

On September 10, 2018, BTL submitted an application to renew the Class 1B operating licence, expiring on June 30, 2019. On November 7, 2018, a request to amend the application extending the licensing period to 10 years was submitted. On December 21, 2018, BTL expressed to the CNSC staff the desire to revert back to the same licences prior to Class 1B approval. Further discussions with the CNSC staff were followed by BTL's applications for Class II facility and NSRD licenses submitted on February 15, 2019. Although BTL has implemented and maintained programs to continue with Class 1B regulatory oversight for another licensing period, upon further review BTL concluded that future operations would not require Class 1B licensing. Considering future plans of limiting testing of all manufactured cyclotrons to 1 MeV, BTL believes that operations can adequately be regulated under Nuclear Substance and Radiation Devices (NSRD) and Class II facilities licences as they were from 2008 to 2014 prior to Class 1B License. BTL has submitted applications to the CNSC for these licences, awaiting approval prior to the expiry of the Class 1B licence (June 30, 2019).

The Class 1B renewal application and this CMD have been submitted with documentation supporting BTL's qualification to undertake all licensed activities, where adequate provisions have been made for the protection of the environment, employees, and the public.

2.0 Business Plan

As stated in Section 1.1, BTL has several product lines. To date, the main product lines are:

- 1) Co60 teletherapy units and distributing Co60 replacement sources;

- 2) Cs137 self-shielded irradiators;
- 3) X-ray self-shielded irradiators.
- 4) Cyclotrons (15 – 70 MeV)

BTL is the major world-wide supplier of both Co60 therapy units and self-shielded irradiators. It is estimated that there are approximately 900 BTL Co60 therapy units actively used world-wide, treating tens of thousands of patients a day.

BTL is a significant employer in the Ottawa area, with approximately 150 personnel, from highly skilled tradesmen (welders, machinists, assemblers), to engineers and scientists. BTL sources material and additional services from local vendors where possible. BTL maintains a second, cyclotron design office in Vancouver, consisting of approximately 20 engineers and scientists. The Vancouver office is not included within this Class 1B Nuclear Facility application.

BTL continuously develops its products to meet changing global needs. In addition, BTL has an active R&D program for the development of new products to complement our current product line. One of the newer products is the cyclotron.

Cyclotrons are used to produce the short half-life isotopes commonly used in PET imaging, such as F18. However, as part of the cyclotron development, BTL is also active in the development of targets that can be used for the cyclotron production of Tc99m. The production of Tc99m for a cyclotron would mitigate the need for reactor-based Tc99m.

Our products are sold to and used in hospitals and health-care facilities world-wide. Manufacturing, assembly, and testing of the products occurs at our 413 March Rd facility. BTL plans to continue operations at this site for the long-term.

3.0 Safety and Control Areas

3.1 Management system

3.1.1 Relevance and management

BTL is an ISO 9001:2015 and ISO 13485:2016 certified company and has implemented an extensive quality program. BTL's quality policy states:

BTL is committed to developing, manufacturing, installing and servicing safe, quality products and to continually improving the effectiveness of the quality management system to meet customer and regulatory requirements for health care and research products and services.

The management structure is provided in Addendum A1, the organizational chart for the facility. Oversight for the management system is provided by the Senior Management Team. The Senior Management Team, consisting of five directors reporting directly to Mr. Suthanthiran, regularly holds a Quality Management Review Meeting in order to review the management framework and quality issues. Additionally, these directors are responsible for overseeing the day-to-day operations of the facility.

BTL has implemented an extensive procedures framework that help define roles and responsibilities of various personnel as they relate to the protection of the environment, employees, and the public. Several of the key management documents related to safety include:

- 5.08-QA-00, “Quality Manual”
- 5.08-RP-01, “Radiation Protection Manual”
- 5.08-SE-00, “Best Theratronics EH&S Policy”

Through its management structure, procedures, and Health and Safety (H&S) Committee, BTL has implemented a culture of safety and compliance. Employees are encouraged to provide feedback related to any and all issues of concern to all levels of management.

Internal performance regarding impact on safety, environment and quality is tracked in BTL’s Corrective Action Preventative Action (CAPA) System. CAPAs are raised when employees encounter a condition adverse to quality which cannot be readily resolved through existing channels and which requires the actions of other departments, or a condition that could result in a significant adverse impact on the environment.

3.1.2 Past performance

Several key improvements have been implemented within the licensing period to include:

- A risk based assessment applied to the CAPA system, where an assessment is completed to determine if there is an adverse effect on regulatory, performance or safety.
- Update to the overall quality system to include Best Cyclotron Vancouver operations.
- Develop and implement an “opportunity for improvement” system in order to track and assess instances that may lead to major effects on performance and safety.
- Re-evaluation of all auditor qualifications.

A gap analysis to CSA N286-12 *Management System Requirements for Nuclear Facilities* was completed in 2018. Improvements to the management system are currently underway in order to be compliant with the requirements.

BTL’s document management system was improved following regulatory audit observations. Some of these improvements included:

- Implementing the use of electronic tools to capture notes in order to improve manufacturing processes and aid in controlling access to documentation.
- Digitizing historical documentation to minimize the risk of damage, destruction or loss.
- Incorporating a data backup system between the Ottawa and Vancouver offices.

Annually, a Management Review Team (MRT) meeting was conducted. Three main environmental, health, and safety (EHS) program objectives were realized during the licence period:

- Dispose of or transfer sealed sources at 413 March Road to a licensed facility
- Dispose of or transfer prescribed equipment containing radioactive source to a licensed facility
- Dispose of or transfer depleted uranium at 413 March Road to a licensed facility

Detailed information is provided in Section 3.11.2 *Waste Management – Past Performance*.

3.1.3 Future plans

A method to assess the overall management system is currently being developed. BTL will continue to manage current management systems to maintain compliance to CNSC Class 1B operational requirements.

3.1.4 Challenges

No challenges have been identified.

3.1.5 Requests

No requests are being made.

3.2 Human performance management

3.2.1 Relevance and management

BTL operates a workforce of approximately 150 personnel at its 413 March Road facility. However, only about half of these employees are directly involved in licensed activities.

BTL has implemented a systematic approach to training (SAT), where qualifications and competencies for each job are identified. Minimum requirements for each position are defined by the Director of Human Resources, the Manager or Supervisor for the position, and the Director of the corresponding Department. Potential employees must meet the minimum requirements for the position, including any certifications deemed necessary for the position. Upon a change of an employee's role or responsibilities, a reassessment of their training portfolio is completed.

Training is documented using training records, such as certificates or procedural understanding acknowledgements, which are filed and maintained in the employee's training record file. All BTL employees have a training record file maintained by a designated training coordinator within their department.

3.2.2 Past performance

The continued success of the human performance management program can be attributed to the following improvements:

- Updated procedures within the training program, taking into consideration the principles of SAT.

- Hiring of a qualified Transportation of Dangerous Goods instructor to teach a session on Class 7 transport requirements. This provided an updated perspective of current regulations and acceptable industry practices regarding the safety of employees, the public, and the environment for radioactive shipments.
- The lead control program was reviewed due to operational changes. An updated procedure was implemented to include safety precautions and practices for all other tasks associated with working with lead. A question and answer session is to be scheduled to address any employee concerns.

BTL has been successful in recruiting and training qualified personnel. All personnel have been trained according to the training requirements set out for their position.

3.2.3 Future plans

The use of an electronic training management system is planned to be implemented at BTL within the next licensing period. Continued review of the number of qualified personnel and of the training program will be conducted in accordance with CNSC REGDOC-2.2.2.

3.2.4 Challenges

Although not a requirement, in-house licensing and regulatory training, referred to in the initial Class 1B application, has not been conducted at the mentioned refresher frequency as stated in the initial application. BTL plans to update its training module to clarify current regulations and to increase awareness of licensing and regulatory requirements to applicable employees.

Knowledge transfer between long standing employees and newly hired personnel will continue to be a challenge. BTL's goal is to extend the overlap period between retiring and new employees for it to be adequate enough to provide comprehensive training.

3.2.5 Requests

No requests are being made.

3.3 Operating performance

3.3.1 Relevance and management

BTL has an extensive program to ensure operating performance is maintained. This program includes:

- 1) A Correction Action and Preventative Action (CAPA) mechanism.
- 2) Internal audits.
- 3) Investigations of occupational injuries and near misses.
- 4) Internal procedures (~900) outlining and describing policies and procedures for the various activities undertaken at the facility.

Operating performance is reviewed on a continuous basis as follows:

- 1) Matters relating to health and safety are reviewed at the monthly H&S Committee Meeting.
- 2) Matters relating to the operating performance of the Radiation Protection Program are reviewed monthly at the Radiation Safety & Security Committee (RSSC) Meeting.
- 3) Overall operating performance and the quality system are reviewed by senior management on a regular basis and at the MRT Meeting.

3.3.2 Past performance

BTL operations continued with little change within the licensing period. No licensed operating limits were exceeded within the licensing period.

A gap analysis to the reporting requirements document REGDOC-3.1.2 was conducted. BTL has been satisfactory at providing reports to the CNSC, as necessary, in a timely manner. Updates to current procedures and the creation of the manual were implemented to clearly outline reporting requirements and expected timelines.

In 2018, BTL received a non-compliance regarding a CNSC notification requirement following an international source install. This occurrence was caused by a failure in flagging the unique post-shipment report requirement listed on the export permit within the Import/Export program. A CAPA was issued, procedures updated, and those involved have been retrained to prevent reoccurrence in the future.

3.3.3 Future Plans

BTL will continue to monitor its operating performance through internal audits of its programs and procedures.

3.3.4 Challenges

Staff turn-over within a short period of time poses a challenge in maintaining operating performance at an efficient level.

3.3.5 Requests

No requests are being made.

3.4 Safety analysis

3.4.1 Relevance and management

BTL has implemented a strong and robust safety analysis framework surrounding its activities. The key implementation of this safety analysis framework is the use of safety analysis reports (SARs).

SARs are undertaken as part of the initial design process, or when there are changes to safety critical components. These safety critical components include:

- 1) Radiation Device and Class II Prescribed Equipment,
- 2) Radioactive Material Transport Containers,
- 3) The Facility.

With regards to the facility, SARs are completed to ensure licensed activities are carried out within the facility in a safe manner and that the facility provides adequate provisions for the protection of the environment and the protection of the public.

SARs are covered under BTL's Design Change procedure, which requires extensive review and sign-off on changes to existing SARs or implementation of new safety analysis reports. In depth review of SARs are conducted periodically and when operational changes are planned to occur.

3.4.2 Past performance

Facility hazards were identified and discussed during H&S member meetings following monthly workplace inspections. Radiation safety issues were identified and discussed during RSSC meetings. Safety and security related observations were immediately communicated with the appropriate department head and solutions were implemented within a timely manner.

The Safety Analysis Report for Cyclotron Testing was submitted to the CNSC (IN/SR 6104). During the licensing period, no cyclotrons were tested beyond 1 MeV.

An updated Fire Hazard Analysis was completed by a qualified third party reviewer in 2016. Updates to current emergency response and fire protection procedures were completed to address additional hazards not previously identified.

In 2018, revaluation and review of system components of BTL manufactured transport packages (F431, F430, and F423) was conducted. This was initiated by a USNRC observation related to the requirements of possessing certificates of compliance for these packages.

The SARs related to radiation related operations within the BTL facility and Shielded Room 4 were reviewed to be current and accurate.

3.4.3 Future plans

Manufactured cyclotrons will be tested only up to 1 MeV, where no nuclear energy is produced, at the BTL facility.

3.4.4 Challenges

No challenges have been identified.

3.4.5 Requests

No requests are being made.

3.5 Physical design

3.5.1 Relevance and management

The BTL facility at 413 March Rd. was initially designed by Atomic Energy of Canada Limited (AECL) in approximately 1964-1965. The building was intended for device manufacturing, accelerator development, and sealed source processing and storage.

Management of the facility is the responsibility of Facility Maintenance Specialist, reporting to the Director of Manufacturing and Facility Operations. In general, the state of the facility, as it relates to safety, is reviewed and actioned by the H&S Committee.

All new design work for the facility is undertaken by licensed design engineers. Work is undertaken with applicable City of Ottawa building permits by qualified construction personnel. Electrical work is undertaken by an on-staff electrician or third-party electricians and inspected by the Electrical Safety Authority.

Building changes to areas relating to licensed activities, or those that may affect the health and safety of personnel require the documentation of a safety analysis report prior to work.

BTL has implemented a procedure for the procurement and validation of all new equipment used within the facility. This includes assessment of equipment requirements and the generation and implementation of a validation protocol.

Prototype equipment, designed and manufactured by BTL, is done so according to the procedure set out in BTL's Quality Manual. This includes a hazard risk assessment that is continuously reviewed during the design and manufacturing phases.

3.5.2 Past performance

BTL has maintained a robust facility management framework. All work to the facility has been undertaken by qualified personnel. Modifications/improvements that were initiated within the licensing period included:

- The replacement of an emergency exit door of a controlled access radiation area.
- Roof replacement of the facility.
- Upgrades to several of the facility's air conditioning units.
- Upgrades to several exterior door systems.
- Rerouting of manufacturing equipment wiring to maintain safe work areas.

The plan to design a shielding bunker for cyclotron testing was never initiated. It was mutually decided between BTL and the customer that final acceptance testing of the first 70 MeV cyclotron was to take place at the customer site. Therefore, modifications to the designated cyclotron testing area, as stated in BTL's *INSR 6104 Final Safety Analysis Report for Cyclotron Testing*, was never required.

3.5.3 Future plans

BTL will continue to ensure that the physical design of the facility and equipment is sufficient. Modifications to the designated cyclotron testing area will not be required as tests beyond 1 MeV is not planned for future cyclotron builds.

3.5.4 Challenges

No challenges have been identified.

3.5.5 Requests

No requests are being made.

3.6 Fitness for service

3.6.1 Relevance and management

There are two aspects related to fitness for service:

The first is that of the facility, and more specifically, the areas where licensed activities are undertaken. The fitness for service of the facility is managed by the Facilities Maintenance Specialist. The facility is assessed on an on-going basis by the H&S Committee. Areas where licensed activities occur are also reviewed by the RSSC.

The second aspect of fitness for service is that of equipment. BTL has implemented procedures to ensure all radiation monitoring equipment is calibrated and is in good working order. The equipment is checked on a monthly basis and calibrated by a third-party annually. Instructions are developed and made available to qualified personnel for the safe operation of Class II prescribed equipment contained in shielded rooms. These operating instructions set out the requirements for testing of the radiation safety mechanisms to ensure fitness for service.

3.6.2 Past performance

The preventative maintenance program has proven to be effective during the licensing period as no negative trends of equipment performance was observed. All required equipment were maintained and made available in good working order. In the event that operational deficiencies were discovered, immediate repairs were completed to prevent potential health and safety issues.

3.6.3 Future plans

BTL maintains an exceptional fitness for service program and will implement necessary improvements if opportunities become known in the future.

3.6.4 Challenges

When repair of equipments coincides with other device's calibration due dates, there can cause burden on usage of equipments. BTL has purchased extra devices to overcome this challenge and will continue to monitor this closely in the future.

3.6.5 Requests

No requests are being made.

3.7 Radiation protection

3.7.1 Relevance and management

BTL has an extensive Radiation Protection Program. The program is defined within BTL's Radiation Protection Manual and covers all aspects of the current licensed activities including:

- 1) Radiation safety training,
- 2) Dose monitoring,
- 3) Radiation and contamination monitoring,
- 4) Radioactive material shipments, exporting, and importing,
- 5) Safety analysis developed relating to matters of radiation safety,
- 6) Development of operating procedures and process relating to licensed activities.

The Radiation Protection Program is administered by a team of qualified personnel headed by the Radiation Safety Officer (RSO). RSSC meetings, held monthly, allow for the review of the program on a regular basis.

3.7.2 Past performance

BTL has implemented an ALARA program to control occupational and public exposures to radiation. The ALARA program consists of:

- Planning for special work (Work permits)
- Training
- Monitoring of employee exposure (Dosimetry)

BTL utilizes a work permit system for any special work that falls outside normal, routine work. A work permit for any, non-routine work that may result in a radiation exposure must be approved by the RSO. Work permits may require a safety analysis report or special procedure to be implemented prior to commencement of the work.

Employees that have a reasonable probability of receiving an occupational dose greater than the public limit of 1 mSv per year and require access to designated radiation areas are defined as Nuclear Energy Workers (NEW). All NEWs receives training related to radiation safety and the proper use of radiation measurement instruments.

BTL monitors and tracks radiation exposures for each NEW, where they are classified into one of two groups:

- 1) Building: Device Manufacturing and Class II Research and Development employees
- 2) Service: Class II Servicing employees

Device Manufacturing and Class II Research and Development NEWs strictly conduct radiation related work within the BTL facility. Class II Servicing NEWs are monitored for work completed at the BTL facility in addition to servicing work within Canada (CNSC licenses 14127-3 & 14127-8) and abroad. Annual dose averages and maximums for whole body and extremity exposures for NEWs in both radiation monitoring groups are shown in Table 1. Data for the individual groups can be found in Addendum A2.

Table 1 Whole Body and Extremity Doses for all BTL NEWs
(January 1, 2014 – *September 30, 2018)

Whole Body					
	2014	2015	2016	2017	2018*
Total Monitored	74	76	73	77	77
Average Dose (mSv)	0.03	0.05	0.08	0.11	0.04
Maximum Dose Received (mSv)	0.46	0.85	2.28	5.30	0.77
<i>Regulatory dose limit: 50 mSv per year</i>					

Extremity					
	2014	2015	2016	2017	2018*
Total Monitored	30	32	31	25	27
Average Dose Received (mSv)	0.19	0.16	1.70	0.71	0.35
Maximum Dose Received (mSv)	3.70	2.10	29.90	11.20	3.50
<i>Regulatory dose limit: 500 mSv per year</i>					

Maximum doses for over the licensing years were received by personnel in the servicing monitoring group, with the exception of the 2014 extremity maximum dose. The majority of the employees monitored have received minimal doses (<0.1 mSv), well below the annual NEW limit of 50 mSv. This provides a good indication that worker dose controls are adequate.

As an improvement to the radiation monitoring program, the administrative and action levels were reassessed following CNSC recommendation in 2016 (See table in Addendum A3). Exceeding an administrative level triggers an internal investigation where radiation protection practices can be evaluated. Exceeding of the action levels, reportable to the CNSC, requires in-depth investigation, retraining, and reassessment of radiation work planning.

One exposure incident occurred at the BTL facility within the licensing period. Action levels were exceeded by two Class II service NEWs preparing for the testing of a prototype teletherapy head with a radioactive source. The action level limits and acquired doses are provided in Table 2.

Table 2 Doses for workers exceeding action levels during prototype teletherapy head source loading incident.

	Action Level Exceeded	Measured Dose from Incident
Employee 1	Extremity: 10 mSv/month	13.51 mSv
Employee 2	Whole Body: 4 mSv/month	8.65 mSv

Qualified service personnel are trained to push a drawer containing a radioactive source from a shielded transport container into the teletherapy head, such that a radiation survey may be completed to identify potential shielding flaws caused during the manufacturing process. This exposure incident occurred when hardware (tungsten screws) securing the end plug of the prototype head broke during the drawer push, causing part of the source drawer to exit out of the other end. The source drawer was immediately pulled back into the transport container and into a safe state.

During the incident, the source itself did not exit the therapy head. However, due to the strength of the source, interim source location, and the positioning of the service technicians, doses above BTL's action levels were acquired. As a result of this incident, the design of the prototype head and the source loading procedure were reevaluated. No adverse health effects were observed and work duties were adjusted to minimize radiation work for the two service technicians.

No other incidences were identified regarding other areas of the radiation protection program, determined through area contamination monitoring, radiation surveys of both controlled radiation access areas and uncontrolled access surrounding those areas, and radiation surveys of radioactive shipments.

3.7.3 Future plans

As the development of Class II prescribed equipment and radiation devices continue, review of the radiation program will be frequently conducted to better reflect current operations and manufacturing demand. Action levels will be reviewed periodically and upon operational changes.

BTL continuously seeks improvements on the radiation protection program in order to maintain a safe working environment for its employees.

3.7.4 Challenges

Although licensee commitments were fulfilled, between June 2016 and October 2017 RSSC meetings were not conducted on a regular basis as per internal procedures and practices. This lapse is believed to have been caused by the reorganization of the company at the time. These meetings are currently conducted on a monthly basis to keep all those involved, with licensing activities and radiation protection, informed.

3.7.5 Requests

No requests are being made.

3.8 Conventional health and safety

3.8.1 Relevance and management

BTL maintains a robust health and safety program. In accordance with section 122.2 of the Canada Labour Code, BTL has implemented preventive measures that consist of:

- 1) elimination of hazards,
- 2) reduction of hazards,
- 3) the provision of protective equipment.

The program is monitored by BTL's H&S Committee.

The mandate of the H&S Committee is to evaluate all employee complaints relating to health and safety, to implement and monitor programs related to health and safety, and to perform health and safety audits of the facility and implement corrective actions to any hazard identified. The committee consists of approximately 8 members, equally split between union and management personnel. The committee meets monthly to review all health and safety issues. The minutes of the meeting clearly identify actions required and the committee designated individual for any action. The minutes of the meetings are document and posted for all employees.

3.8.2 Past performance

Regular workplace health and safety inspections have proven to be adequate at identifying hazards and unsafe practices during the licensing period. Health and safety concerns have been forwarded to the committee for discussions on resolutions in a timely manner.

Between 2014 and 2018 the overall number of health and safety events has decreased. These reports include all injuries occurring within the workplace, regardless of how minor the injury may be. The majority of these reports were due to minor cuts/scrapes and strains.

In 2017, an employee received a severe cut through a finger requiring off-site medical treatment resulting in 22 lost work days. Following the leave, the individual was re-trained on correct working procedures and reminded of the necessary safety precautions while working at the saw machine. The individual has not been scheduled to work at machine since their return and are being monitored for safe working practices.

Table 3 Health and safety events between 2014 and 2018

Year	Reports	On-site treatment	Off-site treatment
2014	18	16	2
2015	11	9	2
2016	12	8	4
2017	9	6	3
2018	11	6	5

Near miss reports over the licensing period were a result of five major deficiencies:

- Employees not fully aware of their surroundings while operating shop vehicles
- Improper electrical grounding discovered during product testing
- Slippery conditions leading into the facility during the winter

- Mechanical failure of a securing mechanism during the source loading of a prototype teletherapy head
- Conducting product component testing without the cooling system water outflow valve being open

From these near miss incidences, procedures have been updated, products reevaluated, and the importance of safety awareness expressed to employees. For example, the lock-out tag-out procedure and training was redone due to a near miss incident.

BTL continued its requirement of blood work monitoring for the employees that work in the lead pouring area.

Hearing tests were scheduled and performed for all employees working on the manufacturing floor in 2018.

The following improvements to the conventional health and safety program took place within the licensing period:

- Review of the lead control program: A qualified third party contractor was hired to observe current manufacturing practices working with lead and to provide suggestions on how to improve BTL's lead control program. Area wipe samples and airborne samples were taken to help address employee concerns. Procedures were then updated to include safe practices related to all manufacturing tasks associated to working with lead.
- BTL has ensured that there are an adequate number of First Aiders and supplies available, to tend to workplace injuries. In 2014, a new defibrillator was purchased and installed on-site.
- Lock-out tag-out refresher training was administered.
- The paint handling and disposal procedure was updated to enforce safe practices such as wearing electrostatic discharge straps and air filter maintenance.

3.8.3 Future plans

To further enhance the conventional health and safety program at BTL, several improvements will be initiated in the next licensing period:

- Review of the program to CSA Z1000
- Assessment of employee safety culture perception through company-wide survey
- Introduce company-wide Importance of Safety and Awareness refresher sessions annually, to help ensure safety is kept as a number one priority to all employees.

3.8.4 Challenges

There is a continued challenge in the reporting of near-miss incidences, as these are personnel identified cases. This topic will be covered in the Importance to Safety and Awareness refresher sessions, aiding in preventing future health and safety events.

3.8.5 Requests

No requests are being made.

3.9 Environmental protection

3.9.1 Relevance and management

BTL is committed to the safety and security of not only its personnel and the public, but also to the environment.

BTL's Environmental, Health and Safety Policy states:

Best Theratronics ... ensures protection of the natural environment by using environmentally sound operating practices.

The policy also states,

Best Theratronics commits to ensuring safe working conditions and environmental integrity by using a management system and training designed to prevent pollution and to prevent any unnecessary risks to human health under normal operating conditions and in the event of an emergency.

To this end, BTL has implemented an Environmental Protection Program that deals with:

- 1) Solid emissions that are primarily a result of the manufacturing process
- 2) Liquid effluent that includes normal domestic sewage and wash water and hazardous liquid material effluents such as de-greasers and waste oils
- 3) Chemical spills
- 4) Air emissions

Overall responsibility of the Environmental Protection Program lies with the Director of Quality and Regulatory Affairs. Primary oversight, including environmental hazard assessment, is controlled by the H&S Committee.

With respect to radioactive environmental protection, BTL deals primarily with sealed sources. As such, there have been no releases of radioactive material into the environment, confirmed by area contamination monitoring conducted monthly or as needed.

3.9.2 Past performance

Within the licensing period, a decrease in the amount of solid effluent released was due to improvements within waste management program (Refer to Table 4 in 3.11 *Waste Management* Section). Additionally, BTL complies with the Ministry of the Environment regulation that hazardous waste must be disposed of every 90 days. Hazardous waste is removed by a qualified third party company (Tomlinson) to dispose of the waste properly.

In order to be compliant with ISO 14001:2015, the environmental management system was revised (5.08-SE-35 *Environmental Management System Manual*). The procedure 5.08-SE-36 *Environmental Aspect* was created to identify and evaluate BTL's operations that may have an impact on the environment on an annual basis.

A number of environmental objectives were determined and tracked by the MRT during the licensing period. They include:

- Dispose of or transfer sealed sources at 413 March road to a licensed facility. [Dec 2015]
- Dispose of or transfer prescribed equipment containing radioactive source to a licensed facility.[Dec 2015]
- Dispose of or transfer depleted uranium at 413 March Road to a licensed facility. [Dec 2015]
- Dispose of 128 000 Ci (Co-60) and 30 000 Ci (Cs-137) [Mar 2018]

The environmental objectives currently focus on minimizing the amount of radioactive material stored on-site. The objectives created in December of 2015 have been on-going and will remain environmental objectives. Refer to Section 3.11.2 *Waste Management – Past Performance* for radioactive amounts removed from the facility.

BTL submits a report on lead, and its compounds, to the National Pollutant Release Inventory, maintaining annual compliance with the Toxics Reduction Act. There have not been any abnormal instances within the licensing period. Between 2013 and 2017, there has been a decrease in the amount of lead emissions released into the environment (Figure 3). This can be attributed to improvements in the lead control program over the time period, and to a decrease in manufacturing over the licensing period.

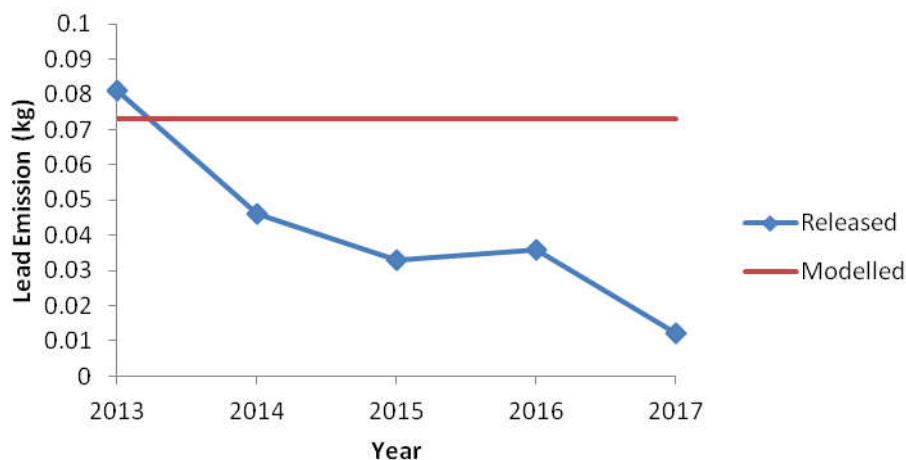


Figure 3 Lead emissions released between 2013 and 2017. The modelled value is a calculated emission estimate based on the amount of lead used annually at BTL.

3.9.3 Future plans

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.

BTL is actively seeking opportunities for safe disposal and transfer of radioactive material to maintain its commitment of protecting the environment through a variety of means.

3.9.4 Challenges

No challenges have been identified.

3.9.5 Requests

No requests are being made.

3.10 Emergency management and fire protection

3.10.1 Relevance and management

BTL has implemented, and continuously maintains, an emergency preparedness program. The purpose of the emergency preparedness program is to:

- 1) Minimize adverse effects to humans and the environment from an emergency or disaster,
- 2) Ensure the earliest possible coordinated response,
- 3) Protect and preserve employees, public health and security,
- 4) Protect and preserve BTL and surrounding community property,
- 5) Restore normal operations with minimal interruption of service to BTL customers

The emergency preparedness program covers all aspects of potential emergency situations. The program is defined by the following BTL procedures:

- 1) Radiation Emergency Response Plan,
- 2) Transportation Emergency Response Plan,
- 3) Fire Safety Plan – Best Theratronics Building,
- 4) Chemical Spill Response Plan.

BTL has defined an Emergency Response Committee (ERC) to manage the emergency preparedness program. The ERC is chaired by the Emergency Response Manager and consists of BTL personnel from various departments.

In addition, BTL maintains and internally posts a list of fire wardens and first-aid responders. Fire wardens are provided training by BTL's Fire Prevention Officer. The first-aid responders are BTL staff that have received certified First-Aid training from an external organization, such as St. Johns Ambulance.

3.10.2 Past performance

A CNSC Fire inspection was conducted in 2015 resulting in six directives and one action notice. The following actions were completed to address these observations:

- Hot work permit procedure implementation and training
- Policy developed on combustibles
- Training completed on the storage and use of flammable and combustible liquids (4.08-SE-45 *Handling and Storage of Flammable and Combustible Materials*)
- Reevaluate the design, operation and maintenance of the spray painting booth
- Training refresher provided on the company fire safety plan and CSA 393.

An updated Fire Hazard Assessment was completed in 2016. From this assessment, it was determined that fire risks to radioactive material associated with the building are appropriately addressed. It was recommended that sprinkler protection in rack storage areas in the building were to comply with NFPA 13. A corrective action plan was created to address the recommendation and increase the sprinkler density. This action plan is to be completed in this licensing period.

In 2016, a qualified consulting firm was hired to conduct a hazardous materials spill response assessment on BTL's chemical spill response team and the capacity to respond to an internal emergency. Improvements to the chemical response plan were made to strengthen BTL's internal chemical spill emergency response.

A CNSC inspection of the emergency management program was completed in 2017. Observations from this inspection resulted in four recommendations, addressing gaps in the availability of resources and command structure.

A review of BTL's Site Emergency Response Plan, following CNSC recommendations, was completed by the ERC in 2017. This meeting focused on the need to consider extreme natural disasters into the response plans. The Site Emergency Response Plan was updated to reflect these discussions and BTL will continue to reevaluate response plans to include natural disasters.

In 2017, the emergency response assistance plan, for transporting depleted uranium (DU) to a disposal site in Ontario required to be updated with the Transport Canada. A table top exercise was conducted including emergency response personnel from BTL, Transport Canada, and contracted support companies. The renewal of this plan is valid until September 2023 and will be reviewed again prior to bulk shipment of DU for disposal.

Fire drills conducted annually during the licensing period were satisfactory. An observation from the 2016 fire drill revealed the need to update the fire warden list as some of the fire wardens and backups were no longer with the company.

A gap analysis to CNSC REGDOC-2.10.1.1 *Nuclear Emergency Preparedness and Response* was performed in 2018. Various updates to procedures and emergency drill planning were implemented.

In 2018, a small fire was extinguished on the roof of the Theratronics building during roof repair. This fire was identified and extinguished immediately by the roofing contractor. Subsequently, smoke from this fire entered the intake system of the Theratronics building, setting off a false alarm. Safe evacuation of the building was completed, with the Fire Department arriving for investigation. Ventilation of the building was recommended, and industrial fans were used to assist the movement of fresh air into the building. There was no breach in security, nor nuclear releases, and the event was immediately reported to the CNSC.

3.10.3 Future plans

A full scale emergency evacuation exercise is scheduled to take place prior to April 30, 2019. This drill will invite participation from local authorities, such as fire and police, the CNSC and surrounding companies.

A smaller scale Klaxon drill was scheduled to occur prior to November 2018, to assess and improve BTL's response to a radiation emergency incident. This drill has been postponed until Spring/Summer of 2019 due to weather conditions.

Re-evaluation of the emergency management and fire protection program will continue and modifications will be made accordingly to ensure all staff are prepared for such events.

3.10.4 Challenges

No challenges have been identified.

3.10.5 Requests

No requests are being made.

3.11 Waste management

3.11.1 Relevance and management

BTL is a manufacturing organization. As a result of its operations, BTL produces the following types of waste:

- 1) Scrap metal resulting from the manufacturing process,
- 2) Hazardous materials used in the manufacturing process,
- 3) Standard waste associated with a typically office environment (i.e. general garbage),
- 4) Radioactive material, including sealed sources and DU typically returned from the field as a result of either service or decommissioning activities.

BTL's priority is to prevent or minimize the generation of wastes as part of an overall integrated cleaner production approach, consistent with the environmentally sound and efficient management of those wastes; and ensuring that environmentally sound waste management options are pursued to the maximum extent possible to meet regulatory requirements.

To this end, BTL has established a waste management program to promote the safe handling and disposal of waste generated from its operations. In general, standard waste is disposed of to the City of Ottawa landfill. Paper and plastic are diverted through an internal recycling program. Scrap metal is diverted from the landfill to scrap metal recycling facilities. Hazardous waste is collected and properly disposed of by a third-party. Finally, radioactive material is managed according to BTL’s end-of-life management program, which includes reuse, recycling, or as a final option, disposal of the radioactive material. BTL’s priority is to reuse or recycling of the radioactive material.

3.11.2 Past performance

Within the licensing period, BTL changed its third party license disposal service to R.W. Tomlinson Ltd. Table 4 shows a summary of the overall non-hazardous waste produced at BTL between 2010 – 2018. The diversion rate has remained consistent prior to the Class 1B license and into current operations. Quantity of non-hazardous landfill waste dropped significantly due to improvements within waste management program. This may also be attributed to a decrease in annual production.

Table 4 Summary of overall non-hazardous waste generation [MT] at BTL from 2010 - 2018

Waste Stream	2010	2013	2015	2016	2017	2018
Waste to Landfill	46	48	44	34	21.6	39.5
Recycled Paper, Cardboard and Shredded Paper	24	24	24	20	20	20
Recycled Glass, Aluminum Cans & Plastics	3.8	3.8	0.9	0.7	0.7	0.7
Recycled Metal	19	52	55	39	7.7	12.13
Other Recovered Material	5.6	5.6	5.6	5.6	5.6	5.6
Totals	98.4	133.4	129.5	99.3	55.6	77.93
Diversion Rate	53%	64%	66%	66%	61%	49%

An initiative was started to reduce the amount of unused chemicals within the facility prior to BTL receiving its Class 1B license. These chemicals were disposed of properly by Tomlinson over the past few years. Procedures have been updated such that chemicals are dispensed on an as-needed basis and training has been administered to ensure chemical waste is kept to a minimum.

BTL has continued to comply with the Ministry of the Environment regulation that hazardous waste must be disposed of every 90 days. BTL has hired third party Tomlinson to dispose of this waste properly.

Through the lead control program, there is a process in place to keep lead contaminated waste separate and to dispose of it with hazardous waste. Scrap lead is also recycled through third party Ottawa Iron and Metal.

Throughout the licensing period (June 2014 – March 2019) BTL's environmental objectives reflected the need to decrease the amount of radioactive material located on-site. To these objectives, BTL has disposed/recycled 493 Co60 sources with a total activity of 10,113 TBq and 67 Cs137 sources with a total activity of 1,882 TBq. Additionally, 34 Cs-137 sealed sources were reused in new products. During licensing period BTL received 1196 kg of DU into safeguarded inventory from decommissioned teletherapy units, where 284.7 kg of the DU was transferred to other licensees for recycling and a returned therapy head, containing 104 kg of DU, was reused.

3.11.3 Future plans

BTL will continue to monitor its waste management program in order to maintain its low impact to the environment.

3.11.4 Challenges

No challenges have been identified.

3.11.5 Requests

No requests are being made.

3.12 Security

3.12.1 Relevance and management

BTL has implemented a robust security program. There are two facets to this program, facility security and security of transportation of hazardous material.

With regard to facility security, BTL has implemented the following:

- Identification access card system for control of facility access,
- A police records check and FBI records check for all employees,
- 24/7 on-site security,
- A network of cameras and other monitoring equipment to monitor the premises.

The other area of security is that of security of the Category I and II sources during transportation. With respect to this, BTL has implemented a strong program, to ensure the radioactive material is safe and secure during transit and meeting the requirements of CNSC document REGDOC-2.12.3 *Security of Nuclear Substances and Sealed Sources*, and it includes:

- Contracting approved and vetted radioactive material carriers
- Conducting annual audits on carrier transport safety plans
- Tracking radioactive material road transport

3.12.2 Past performance

A number of improvements have been employed regarding site security of the BTL facility. Facility and monitoring system upgrades were completed to prevent unauthorized access. An emergency exit protocol was introduced, eliminating false alarms. Upgrades to the corporate network and firewall were completed. The server environment was virtualized and backup solution was redesigned to better protect the corporate IT infrastructure. The frequency for criminal records check renewal was updated to every 5 years. Annual audits of qualified radioactive material transportation carriers were satisfactory within the licensing period.

Concerns regarding the security of radioactive material have become an important topic in recent years. As such, the Radiation Safety Committee (RSC) invited the involvement of security personnel within committee meeting discussions. On a monthly basis, the now called Radiation Safety & Security Committee (RSSC) meet to discuss concerns and identify improvements to the overall safety and security culture at BTL.

BTL has been recently accepted to participate in the Transport Canada Air Cargo Security Program. Shipments leaving the facility for air transportation under this program require additional security measures to ensure packages are not tampered with, leading up to the departing airport in Canada. Within the licensing period, procedures have been created, training conducted, an audit and table top exercise have both been completed and full implementation of the Air Cargo Security Program is the last step to be completed in 2019.

3.12.3 Future plans

The development of a vehicle search program was initiated for all vehicles entering the BTL building in 2018. Full implementation of this program has been targeted to be completed in 2019.

Continued improvements to the security program will remain as one of BTL' priorities within the next licensing period.

3.12.4 Challenges

Security culture requires a collective effort where responsibilities are shared by all BTL employees. Sustaining and promoting an effective security culture is a challenge as security-risk concerns change over time.

3.12.5 Requests

No requests are being made.

3.13 Safeguards and non-proliferation

3.13.1 Relevance and management

BTL is in possession of safeguarded depleted Uranium (DU). As such, BTL has implemented a Safeguards programs as required by the CNSC regulations.

DU was historically used in legacy Co60 teletherapy units as shielding material. However, the DU shielding was replaced in later designs by tungsten. All new teletherapy units manufactured by BTL use tungsten and no longer contain DU.

Decommissioned teletherapy units that contain DU are returned to BTL for end-of-life management or disposal. BTL provides interim storage of the legacy DU until shipped to a supplier for reuse or a licensed disposal facility, such as CNL Chalk River.

3.13.2 Past performance

A gap analysis was conducted to and REGDOC-2.13.1, released in February 2018, and submitted to the CNSC and updates to all safeguards related procedures were made to improve the program.

During an annual Physical Inventory Taking (PIT) in 2017, two discrepancies were observed due to incorrect weight reporting occurring in previous years. These discrepancies were immediately reported to the CNSC and internal inventory records were adjusted to reflect the correct balance.

Within the licensing period, BTL was not chosen by the IAEA for a Physical Inventory Verification (PIV). The IAEA conducted

In October 2018, the CNSC completed a PIT Evaluation and concluded that BTL was adequately prepared for a PIV by the IAEA, if selected for an inspection in the future.

3.13.3 Future plans

BTL maintains an adequate safeguards program and will continue to improve once gaps from REGDOC-2.13.1 are addressed. Reporting through the Nuclear Materials Accountancy Reporting (NMAR) system will be incorporated into BTL's program within the next licensing period.

3.13.4 Challenges

No challenges have been identified.

3.13.5 Requests

No requests are being made.

3.14 Packaging and transport

3.14.1 Relevance and management

BTL ships category 1 and 2 radioactive material worldwide, and as such, has implemented a transport and packaging program that meets the requirements of the CNSC Packaging and Transport of Nuclear Substances Regulations and the IAEA TS-R-1. The category 1 and 2 sealed sources are shipped in certified Type B(U) packages.

BTL's transport and packaging program includes:

- 1) Sealed source manufacture of special form sealed source, certified by competent authorities such as CNSC,

- 2) Manufacture, inspection, and maintenance of Type B(U) containers that have been certified by competent authorities,
- 3) Certification of Radiation Devices,
- 4) Transportation Security Plan,
- 5) Procedures for shipment and receipt of radioactive material.

3.14.2 Past performance

During the licensing period, all transport packages were routinely maintained as per the quality control program. The maintenance program has proven to be adequate within this licensing period.

In 2017, the emergency response assistance plan, for transporting DU to a disposal site in Ontario required to be updated with the Transport Canada. A table top exercise was conducted including emergency response personnel from Best Theratronics, Transport Canada, and contracted support companies. The renewal of this plan is valid until September 2023 and will be reviewed again prior to bulk shipment of DU for disposal.

An unannounced inspection, conducted by Transport Canada, revealed that BTL's 24 hour emergency line, appearing on documentation, was inadequate. To mitigate this, BTL registered with CANUTECH in order to provide immediate specialist assistance in a transport accident scenario.

In 2018, revaluation and review of system components of BTL manufactured transport packages (F431, F430, and F423) was conducted. This was initiated by a USNRC observation related to the requirements of possessing certificates of compliance for these packages.

The following incidents occurred during the licensing period:

- Return of a Co-60 source where no Class 7 placards were visible on the truck and the container was not properly secured on the truck. This incident was reported to the CNSC and further investigation was initiated.
- A second return of a Co-60 source was completed where there were signs of improper bracing of loaded containers on a sea freight container when received. This was reported to the CNSC.
- A shipment was received without the necessary UN labels and with obsolete TI labels. The DU therapy head crate did not have labels on it and was received damaged. This incident was reported to the CNSC and further investigation was initiated.

The security plans of contracted radioactive material carriers were audited within the licensing period. The audits revealed two minor observations regarding refresher training frequency and incorrect contact information following organizational changes. The carriers were notified of these deficiencies and were immediately corrected.

3.14.3 Future plans

BTL will continue to maintain its packaging and transport program in accordance with CNSC regulations and requirements. Continued performance monitoring of radioactive material carriers will be conducted to ensure proper transport practices are performed.

3.14.4 Challenges

No challenges have been identified.

3.14.5 Requests

No requests are being made.

4.0 Other Matters of Regulatory Interest

4.1 Import/Export activities

BTL is a major importer and exporter of category 1 and 2 sealed sources, primarily Cs-137 and Co-60. BTL has implemented a robust import/export program. Due to the high activity of the sources, BTL obtains licenses from the CNSC for the exports. When required, BTL also obtains appropriate permits with DFAIT for exports that may be controlled under Canada's Export Control List or various sanctions.

4.2 Cyclotron manufacturing

BTL manufactures cyclotrons with energies between 15 to 70 MeV. Our present product line comprises of the following models: B15P, B20U, B25P, B30U, B35P and B70P, all of which accelerate negative hydrogen ions and unable to produce nuclear energy.

During factory testing at the Kanata facility, none of these models are tested at energies greater than 1 MeV, where nuclear radiation cannot be produced. All factory testing is performed through injection of the H- beam and acceleration in the center region of the cyclotron up to energies below 1 MeV.

The beam test protocol, below 1 MeV that BTL is presently following, has been initiated at TRIUMF Canada's Particle Accelerator Center, very well-known for its expertise in cyclotron science and engineering. The procedure and typical test setup has become an industry standard.

The theoretical and practical parameters taken into consideration and implemented in order to ensure the safety of the operation are as follows:

- Beam dynamic calculations are performed to determine the first few turns of beam acceleration path hence the location of the 1MeV beam intercepting point (1 MeV radius),
- A mechanical stop, water cooled copper electrode "Pop-up Probe" is positioned in the cyclotron magnet valley in front (ahead) of the 1MeV interception point ensuring that the H- accelerated beam is fully intercepted/stopped in this probe. In addition, the Pop-Up probe design allows for two consecutive beam trajectories to be intercepted, such as if any residual beam is dispersed it will still be intercepted

and fully stopped in the probe. The Pop-Up probe is a normal operational device that is used for beam interception (beam current measurement) and it is actuated in/out of the beam path. During the factory testing this probe is mechanically locked in place to avoid any possibility of accidentally being removed from the beam,

- As a second temporary safety device a large copper block is positioned in the immediate proximity of the Pop-Up probe, fully obstructing the entire magnet gap. This stop device is removed after all tests have been completed and cyclotron de-energized.

Radiation surveys are performed during the cyclotron factory testing, confirming that no nuclear energy is produced.

4.3 Financial guarantees

As of July 2017, BTL has estimated decommissioning costs to be \$1.80 million. This includes a 25% contingency amount. Throughout the licensing period BTL has disposed 493 Co60 sources with a total activity of 10,113 TBq and 67 Cs137 sources with a total activity of 1,882 TBq.

BTL currently has in place the total amount of the financial guarantee with the CNSC in the amount of \$1.8 million. This is in support of BTL's current licenses. This financial guarantee is in the form of a Letter of Credit, issued by Canadian Banks.

The financial guarantee will be maintained on a continuing basis. As the decommissioning plan is revised, due to on-going decommissioning activities or changes to the operational program, the Letter of Credit will also be revised to ensure sufficiency to fund decommissioning activities.

4.4 Licensee's public information program

BTL has implemented a public information and disclosure program to keep the public informed about the nature of our operations.

The primary goal for the public information program is to communicate BTL's operational activities to the surrounding communities and provide an avenue for open, community discussion surrounding BTL's proposed activities, as they related to health, safety, security, and the environment.

The target audience for the public information program includes:

- 1) The local Ottawa community, specifically the Kanata region,
- 2) Local businesses in the direct vicinity of BTL,
- 3) Local, provincial and federal regulators (i.e. CNSC),
- 4) Local aboriginal groups,
- 5) Municipal and provincial politicians.

The primary mechanism for distribution of information to the target audiences is through the BTL website. A Frequently Asked Questions (FAQ) page was added onto the BTL

website. The addition of this page has provided the public with another source to reference in addressing concerns about the environmental, health and safety practices at BTL. Annually, ACRs from each licence are posted to the website for the public to become informed of our yearly operations. In addition, information on major events or incidents, such as fire false alarms are posted onto the website in order to relieve any concern regarding emergency response activities on BTL premises.

A community information session was held in May of 2018. This event was advertised on the BTL and Team Best websites, in the local newspaper (Ottawa Citizen), mailed flyers to surrounding neighborhoods, and through email outreach. The session included a presentation on the operations of BTL, followed by a question and answer period, lead by the president of BTL at the facility. A survey was distributed to audience members following the presentation to help assess the effectiveness of the session.

An invitation to host the Algonquins of Ontario was sent in 2018, offering a tour of the facility and answer any questions or concerns they may have regarding BTL's operations.

No media articles or coverage relating to environmental, health and safety topics occurring at BTL was observed.

5.0 Conclusions

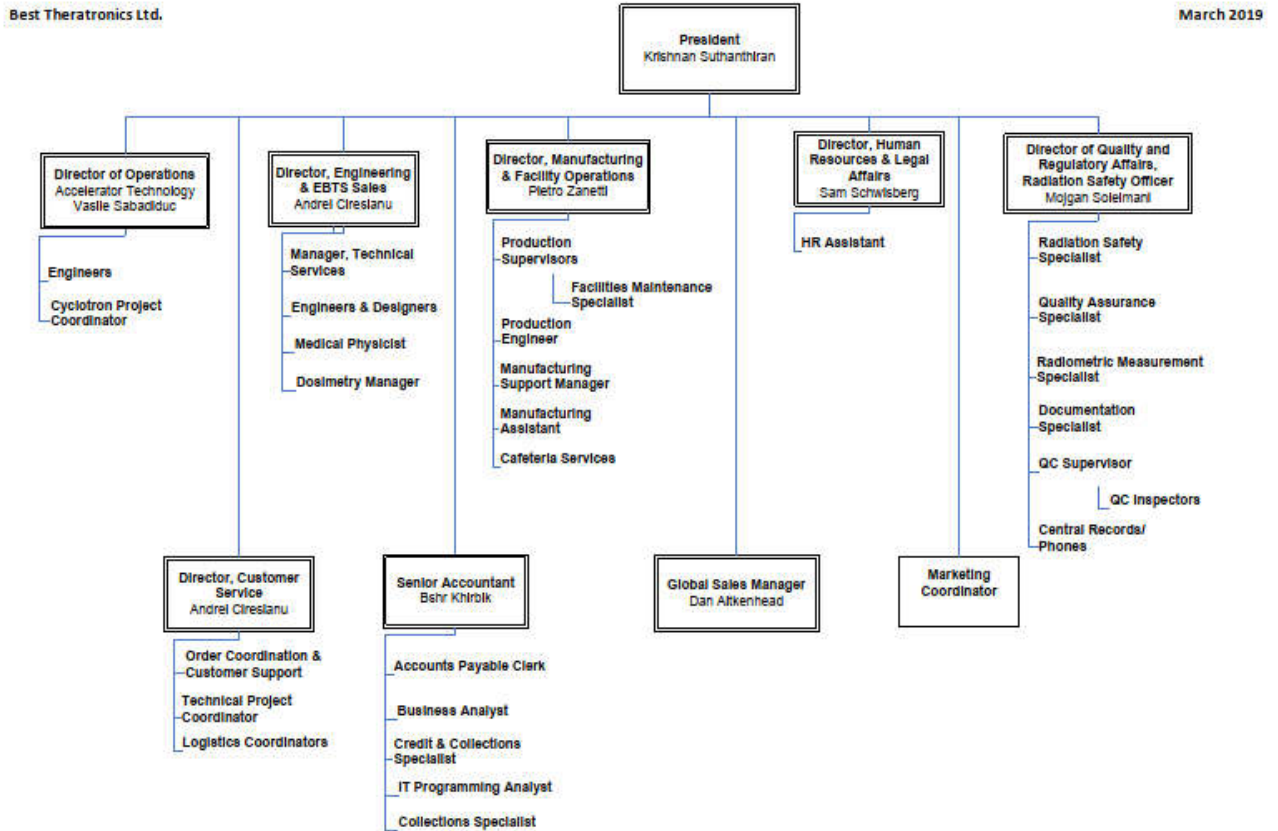
BTL has maintained programs and implemented improvements over the current licensing period ensuring adequate provisions are in place for the protection of the environment, our employees, and the public. The overall satisfactory rating in all safety control areas for BTL's operations provided by the CNSC staff further support BTL's qualifications to conduct operations in a safe manner.

With respect to BTL's licensed activities, no significant changes in operations have occurred over the licensing period nor planned for the near future. BTL believes regulatory oversight by Class II facility and NSRD directorates, as it was prior to Class 1B license, is appropriate for current and future operations. BTL is committed to making improvements in all SCAs, with guidance from CNSC staff, and will continue to do so under any class of license granted by the Commission.

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Addendum A: Supporting details

A1: MANAGEMENT SYSTEM – BTL ORGANIZATIONAL CHART



A2: RADIATION PROTECTION – DOSE DATA FOR BTL EMPLOYEES

*Whole Body and Extremity Doses for BTL building personnel
(January 1, 2014 – *September 30, 2018)*

Whole Body					
	2014	2015	2016	2017	2018*
Total Monitored	61	62	60	68	65
Average Dose (mSv)**	0.00	0.01	0.03	0.02	0.00
Maximum Dose Received (mSv)	0.11	0.20	0.98	0.47	0.02
<i>Regulatory dose limit: 50 mSv per year</i>					

Extremity					
	2014	2015	2016	2017	2018*
Total Monitored	18	16	17	16	15
Average Dose Received (mSv)**	0.21	0.00	0.09	0.07	0.18
Maximum Dose Received (mSv)**	3.70	0.00	1.10	0.50	2.53
<i>Regulatory dose limit: 500 mSv per year</i>					

** Dose values of 0.00 mSv indicate employees received less than measurable radiation exposure level (<0.01mSv). Average dose values of 0.00 mSv indicate that the majority of monitored employees received doses below this measurable threshold.

Whole Body and Extremity Doses for Class II servicing personnel. Doses received while completing servicing work internationally are also included in the acquired doses.

*(January 1, 2014 – *September 30, 2018)*

Whole Body					
	2014	2015	2016	2017	2018*
Total Monitored	13	14	13	9	12
Average Dose (mSv)	0.17	0.26	0.28	1.12	0.24
Maximum Dose Received (mSv)	0.46	0.85	2.28	5.30	0.77
<i>Regulatory dose limit: 50 mSv per year</i>					

Extremity					
	2014	2015	2016	2017	2018*
Total Monitored	12	16	14	9	12
Average Dose Received (mSv)	0.18	0.31	3.66	1.84	0.55
Maximum Dose Received (mSv)	2.10	2.10	29.90	11.20	3.50
<i>Regulatory dose limit: 500 mSv per year</i>					

A3: RADIATION PROTECTION – UPDATED ALARA DOSE LEVELS

	Administrative Level 1		Administrative Level 2		Action Level CNSC Reportable	
Effective Dose	0.5 mSv/mth	0.5 mSv/qtr	1 mSv/mth	1 mSv/qtr	2 mSv/mth	2 mSv/qtr
	1 mSv/year		2 mSv/year		4 mSv/year	
Pregnant NEW	0.3 mSv/mth (if control TLD not used)		0.3 mSv/mth (if control TLD used)		1 mSv/mth (if control TLD used)	
Skin	1 mSv/mth	1 mSv/qtr	2 mSv/mth	2 mSv/qtr	5 mSv/mth	5 mSv/qtr
	2 mSv/year		5 mSv/year		20 mSv/year	
Extremity	1 mSv/mth	1 mSv/qtr	2 mSv/mth	2 mSv/qtr	5 mSv/mth	5 mSv/qtr
	2 mSv/year		10 mSv/year		20 mSv/year	
Non-NEW: Effective Dose	0.3 mSv/qtr		0.4 mSv/qtr		1 mSv/qtr	

A4: CONVENTIONAL HEALTH AND SAFETY – LOST TIME INJURIES

Year	Incident	Result
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. Lost time: 1 day	The incident was reviewed and no further action was taken.
2016	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.
	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.
	Employee placed foot on a mobile cart while reviewing paperwork. Went 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.
2017	An employee cut their thumb on a saw mill when they moved a piece of material from the machine. Lost time: 22 days	The employee was retrained on the procedure and has been reminded of the safety precautions of using the machine. They have not been scheduled to work at the saw machine since their return to work. They are also being monitored to follow safety procedures with all the other tools and machines on the shop floor.
2018	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.
	Another employee hurt their back when applying an upward force to a large pipe wrench.	The LTI was an isolated incident. The work has not been performed since. The individual was put on light duty work when they came back.

A5 – REPORTABLE EVENTS

2014

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 our 447 March Road location unexpectedly, without Best Theratronics' prior acknowledgement, on a truck missing the appropriate placards and incorrect transport container bracing.

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.

Sept 30 – While testing the R&D teletherapy unit in Cell 4, the source failed to return to its fully shielded position, approximately 5cm off its shielded position. The RSO was called in and determined the radiation dose rate was around 5mR/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.

2017

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).

2018

Sept 19 – Cyclist biking through Best Theratronics parking lot was hit by a car, sustained minor injuries.

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.

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.

2019

Feb 18 – The fire alarms at the facility were activated due to a water leak from the roof that had shorted out one of the fire alarms. The building was evacuated safely. Repair and cleanup immediately commenced.