



Annual Compliance and Performance Report

2019

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

Class 1B License

NSPFL-14.00/2029

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1 Introduction

Best Theratronics Ltd. (BTL) is a medical device manufacturing company, located at 413 March Rd, of medical equipment used throughout the world. The main products that require the possession of a Class 1B licence include:

- Cobalt 60-based external beam radiation therapy units,
- Cs137-based self-contained irradiators (SCIs) for blood or research irradiation,
- Cyclotrons with beam energies ranging from 15 to 70 MeV.

In September of 2018, a renewal application was submitted to the CNSC for a period of 10 years, until June 30, 2029. Best Theratronics was granted a renewed Class 1B license on July 1, 2019.

Licence NSPFL-14.00/2029 authorizes Best Theratronics to:

- a) operate a Class 1B nuclear facility located at 413 March Road, Ottawa, Ontario, including activities related to:
 - i. operating a particle accelerator/accelerators (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
- b) possess, transfer, manage, and store nuclear substances arising from the activities regarding the particle accelerators;
- 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 1B nuclear facility.

In addition to the Class 1B nuclear substance and processing facility license, Best Theratronics possesses two licenses (Class II Nuclear Facilities and Prescribed Equipment Licence & Nuclear Substances and Radiation Devices Licence) in order to conduct service work on prescribed equipment sold to customers within Canada. Information related to these activities are reported in their respective Annual Compliance Reports (ACRs).

This ACR is submitted with respect to license condition 3.2 and reflect information related to the NSPFL-14.00/2029 activities.

1.1 Compliance with Other Regulatory Agencies

In manufacturing medical devices that are sold internationally, Best Theratronics is required to comply with many standards and regulatory agencies. Compliance is required by agencies such as:

- International Organization for Standardization (ISO 13485, ISO 9001)
- Health Canada
- United States Nuclear Regulatory Commission (US NRC)
- Federal Drug Administration (FDA)
- United States Department of Transportation (US DOT)
- Medical Directive of Europe
- Other international regulatory agencies where Best Theratronics devices are sold

Within Canada, Best Theratronics complies with all federal, provincial, and municipal regulations in order to operate. Oversight agencies include:

- Transport Canada – Transportation of Dangerous Goods (TDG) Regulations
- Canada Occupational Health and Safety Regulations
- Ministry of Environment (National Pollutant Release Inventory)
- Ministry of the Environment and Climate change (Hazardous Waste Information Network)

In 2019, the US NRC conducted an audit on Best Theratronics' radiation safety and compliance with NRC rules and regulations on licensed activities within the United States. No violations were identified.

1.2 New Licensed Activities

No operational changes have occurred in 2019. There have been no new licensed activities since the last compliance monitoring period.

1.3 Significant Modifications or Changes to Site or Facility

There were no significant modifications and repairs that were carried out since the last compliance monitoring period.

2 Safety and Control Areas

2.1 Management System

2.1.1 Applicable Activities

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

The quality management system is applicable to all Best Theratronics CNSC licensed activities. Best Theratronics has established several management systems to help guarantee this commitment. These management systems include:

- Training, Personnel Examination and Certification
- Work Organization
- Fitness for Duty of Personnel and Facilities
- Procedure Documentation
- Culture of Safety and Compliance

The implementations of these management systems are discussed in the following safety and control areas sections in this report. As a manufacturing facility of medical devices, the overall management system implemented follows current ISO standards.

2.1.2 Management System Effectiveness

Compliance to Best Theratronics' CNSC licence conditions are assessed in-house in the areas of security, emergency management and fire response, waste management, environmental protection, and radiation protection. Refer to the following SCA sections for more information.

Management review team (MRT) meetings are conducted annually to analyze and discuss general trends of the organization. Best Theratronics held one Management Review Team meeting in 2019 for the operations over 2018. The following topics were discussed:

- Quality policy
- Environmental, Health & Safety Policy
- Quality, Environment and Health & Safety Objectives
- Audits
- Post Market Surveillance
- Process Performance and Product Conformity
- Status of Corrective and Preventative Actions and OFI's
- Follow-up Actions from Previous Management Reviews
- Changes that could affect the quality management system or the organization structure
- Effectiveness of Actions Taken to address Risks and Opportunities
- Recommendations for Improvement
- New or Revised Regulatory Requirements
- Review of Risk Methodology
- Self-Assessments of Management Processes
- Safety culture
- Radiation Control Program
- Trend Analysis
- Best Theratronics Training Plan

The overall quality system and objectives were discussed, reviewing the quality system to ensure that each objective remains applicable and effective. Some action items were created to improve the evaluation of the quality system, which will be followed in the next MRT meeting.

In 2019, Best Theratronics conducted a gap analysis of current processes to CSA N299. The transition from applying CSA Z299 Quality program requirements to CSA N299 was initiated by a customer supplying components to nuclear reactors within Canada, in order to comply with industry standards.

2.1.2.1 Annual Internal Audit

Annually, Best Theratronics completes an internal audit of the overall quality management system. This scope of the audit covers the review of company objectives, policies and procedures, the management standard, requirements of ISO13485:2016, and requirements of ISO 9001:2015. In 2019, this audit revealed that the quality management system is functioning efficiently and effectively, thus verifying Best Theratronics' compliance with applicable Canadian medical device regulations. In 2018, Best Theratronics was successfully audited to be in compliance with the Medical Device Single Audit Program (MDSAP). This program allows for a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

2.1.2.2 CNSC Management Inspection Update

The CNSC conducted an inspection on the Management Systems in June 2017, where a CAPA was opened to address the implementation of a system to control, approve, and ensure production documentation was current for employees to reference. A portable electronic device was provided to employees to assist in capturing informal instructions to be incorporated into controlled documentations and for workers to have immediate access to controlled documents in the Quality System.

2.1.3 Organizational Structure for the Management and Control of Licensed Activities

Best Theratronics' organizational structure related the implementation of a safe working culture includes:

- Director of Quality & Regulatory Affairs
- Director of Engineering
- Director of Cyclotron Operations
- Technical Services Manager
- Manufacturing & Facility Operations Manager
- Radiation Safety Officer
- Radiation Safety Specialist
- Radiometric Measurement Specialist
- Medical Physicist
- Quality Assurance Specialist
- Quality Control Supervisor
- Production Supervisors (2)
- Contract Security Supervisor
- Contract Security Officers

2.1.4 Document Changes

Below is a list of the documents references in Best Theratronics License Conditions Handbook that were updated in 2019. Updates to such documents reflect changes in regulation, audit observations, and corrective action implementation. Updated versions of documents supporting the Class 1B licence submitted to the CNSC as per requirement in the Licence Conditions Handbook:

- 1.08-SC-10 *Hazardous Material Transport Security Plan*
Revised to clarify requirements and instructions for regulatory security notifications and update referenced regulations
- 5.00-QA-00 *Quality Manual*
Revised to reflect transition from CSA Z299 to CSA N299
- 5.08-TDG-01 *Transport of Radioactive Material*
Revised to update transport certificates, regulatory requirements, and references regulations
- 5.08-TDG-02 *Transportation Emergency Response Plan*
Revised to clarify instructions regarding emergency personnel contact list

2.2 Human Performance Management

Best Theratronics has implemented a robust human performance management system that ensures that staff is sufficient in numbers and have the required knowledge, skills and training to safely carry out their duties. Staff levels are monitored by supervisors and managers to ensure there is sufficient personnel. Regular meetings between the Directors and the President are also used to assess staffing levels.

A Systematic Approach to Training (SAT) was implemented for positions where *the “consequence of human error poses a risk to the environment, the health and safety of persons, or to the security of the nuclear facilities and of nuclear substances”*. This type of training involves identifying qualifications and competencies related to each job in order to provide the worker with a comprehensive training program. If ever an employee’s roles or responsibilities change, their training requirements are reviewed.

2.2.1 Training Programs

At Best Theratronics various environmental health and safety training programs have been implemented to ensure safe working environments for all employees. Upon employment, employees are trained on Best Theratronics’ policies regarding compliance, security, environmental impacts and the quality system expectations. The following environmental health and safety training programs are conducted at Best Theratronics:

Training Program	Refresher Frequency
Chemical Spill	3 years
Crane	3 years
Emergency Response	2 years
First-Aid	3 years
Fork-lift/Pallet Truck	3 years
Lead Control	3 years
WHMIS	3 years
Nuclear Energy Worker/Radiation Safety	3 years
Nuclear Energy Worker Service Refresher	1 years
Transportation of Dangerous Goods	2 years

On an annual basis, radiation safety refresher training are required for service technicians to ensure safe practices are applied at customer's sites.

In 2019, an in-house Quality System training was developed. This Quality System training was implemented to emphasize the importance of the Quality Management System, reminding all employees of their roles and contributions with ensuring the quality system is functioning adequately.

2.2.2 Training Effectiveness Evaluation

The training program at Best Theratronics is evaluated through several means:

- On-the-job training assessment by the trainer
- Review of CAPAs that indicate a root cause linked to inadequate training
- Regular trend analysis on key indicator quality systems processes
- Training evaluation forms following in-class instructor training

For training courses that have a graded learning assessment in order for completion, a grade of at least 70% must be achieved to pass the course. The following table identifies the number of employees trained in 2019.

Training	# of personnel trained in 2019
Crane	32
Emergency Response	0
First-Aid	2
Fork-lift	5
Lead control	40
WHMIS	7
Transportation of Dangerous Goods	15
Nuclear Energy Worker/Radiation Safety Nuclear Energy Worker Service Refresher	37

All personnel trained in 2019 successfully passed the end of course evaluations. Training adaptations are made to ensure all training material and its delivery can accommodate varying learning styles when necessary.

2.2.2.1 Lead Control Update Training

As part of Best Theratronics' action plan to ensure the health and safety risks from lead contamination of surfaces (work benches, tables, etc.) are minimized, a Question & Answer presentation on Lead Awareness was provided on August 14, 2019 to applicable employees.

2.2.2.2 Radiation Safety Training

During the reporting year, twenty-five employees successfully completed Nuclear Energy Worker radiation safety training. This grouping includes facility personnel who required initial NEW training and refresher training, in addition to Best Theratronics' service personnel, who complete radiation safety refresher training annually. In 2019, no radiation related incidences occurred where the root cause was determined to be due to lack of training.

In 2019, the in-house source loading was reviewed and formally included additional dry run source loading practice, using empty transport containers. Applying the As Low As Reasonably Achievable (ALARA) principles, this addition was implemented to ensure correct preplanning and enough confidence was gained by the workers for the task with the highest licensed activity risk at the Best Theratronics facility.

2.2.3 Sufficient Number of Qualified Workers

Management Review Team discussions are conducted to ensure that there are an appropriate amount of qualified personnel to continue operations in a safe manner. Best Theratronics has security personnel on-site at all times. An emergency contact list is available and tested twice annually, ensuring upper management and appropriate response personnel are reachable. In 2019, the full-scale evacuation exercise provided confirmation to having an appropriate number of emergency response personnel in the emergency response management structure.

2.3 Operating Performance

As an ISO 9001:2015 certified facility, Best Theratronics operating performance program integrates operating experience, adequacy of procedures, and the conduct of licensed activities.

Operating Experience is evaluated using a Corrective Action Preventative Action (CAPA) system which captures non-conformances and improvement opportunities discovered through audits. Reporting and trending of operational experiences are discussed at the annual MRT meeting and monthly Health & Safety meetings. Concerns regarding licensed activities are discussed within Radiation Safety & Security Committee meetings occurring monthly. Weekly meetings regarding shipping and receiving of radioactive material are conducted with members of the radioactive materials supply & production team, logistics, and customer service. Email notifications of daily updates are sent out to key members in order to keep all those involved informed and to track notifications sent to the CNSC.

Procedures are updated and implemented on a regular basis to align with revised regulations. Training on updated procedures takes the form of *Self-Study and Acknowledgement* where all training is overseen and coordinated by their training coordinators.

2.3.1 Licensed Activities Audits Overview

The CNSC conducted one audit in 2019 focusing on the safety control areas of:

- Operating Performance
- Radiation Protection
- Conventional Health and Safety
- Waste Management
- Environmental Protection

All observations were addressed with the opening of CAPAs. The following table provides a summary of the audit observations and status as of December 2019.

Inspection	Observations	Status
<ul style="list-style-type: none"> • Operating Performance • Radiation Protection • Conventional Health and Safety • Waste Management • Environmental Protection 	Action Notice	1
		Closed – Initiation of the action plan to reduce the health and safety risks form lead contamination on surfaces was completed.

2.3.2 Reportable Events

In 2019, two incidences were reported to the CNSC. Notifications to the CNSC were made and follow-up investigations were conducted when necessary.

- February 18, 2019 – A fire alarm was activated due to an electrical short in the fire safety system by a water leak. Emergency fire personnel responded to the alarm and confirmed the false alarm. The electrical short was caused by water entering the building in an area that was to undergo roof repair at a later date.
- February 27, 2019 – Best Theratronics voluntarily disclosed to the CNSC of a non-compliant Pre-shipment Notification to an incorrect importing authority. The correct importing authority was advised, Corrective Action issued, and procedure retraining was administered.

2.3.1 Operational Limits

The basis of obtaining the Class 1B License for the Best Theratronics facility was to manufacture and test cyclotrons for the medical and research industries. In 2019, Best Theratronics operated within the limits outlined in the Class 1B license.

2.3.1.1 Class II Workload

The R&D Class II prescribed equipment located in Cell 4 (T1000, S/N 4) was operated for a total 217 hours, where all hours were related to research. Operational information is provided in the table below.

Source Serial Number	Source Type	Beam On Time [hrs]	Output at 1m [Gy/min]	Output date reference	Output at 1m used for analysis [Gy/min]	Total work load (Gy)
S-5984	Co-60	214	0.76	January 3, 2019	1	12840
S-6431	Co-60	2	2.3	January 14, 2019	2.5	300
S-6033	Co-60	1	0.33	April 11, 2019	0.5	30
<i>Beam on total [hrs]</i>		217	<i>Total work load [Gy]</i>			13170

2.3.1.2 Cyclotron Operations

The operating limits stated in Best Theratronics License Conditions Handbook are related to cyclotron development and testing. No cyclotron testing beyond 1 MeV has occurred within the licensing period. Implemented procedures have limited in-house testing to 1 MeV, where no nuclear radiation is produced. In 2019, one cyclotron was operated. Operational information is provided in the table below.

Model	Serial Number	Nominal beam energy [MeV]	Operating/Test Beam Energy [MeV]	Max beam current at 1 MeV beam stop [μ A]
B15P	B15P01	15	<1	440

2.4 Safety Analysis

Safety analysis reports are undertaken prior to design and implementation of changes to critical safety components, including devices, transport containers, and facilities. Safety analysis reports are reviewed by the management review team.

Overall workplace safety is monitored by two committees in order to maintain the safe and healthy occupational working environments. The Workplace Health & Safety Committee is responsible for monitoring operations and recommends improvements to management. Radiation-related safety concerns are discussed in meetings held by the Radiation Safety & Security Committee.

2.4.1 Facility Safety Improvements

The facility is toured and inspected by two members of the Health & Safety Committee on a monthly basis. Health & Safety Committee observations and employee concerns were mainly related to the roof of the facility. The roof upgrade of the facility has been ongoing since 2018, with the aim for completion in 2020.

2.5 Physical Design

A design change process for the control, management, evaluation, release, completion and implementation of changes to Best Theratronics drawings and documents is implemented. No physical design changes were completed in 2019.

2.6 Fitness for Service

2.6.1 Effectiveness of Maintenance and Testing Programs

Best Theratronics maintains an inventory of radiation survey meters, radiation area monitors, and personal digital reading dosimeters. Monthly checks of these instruments are completed to ensure all radiation monitoring equipment are in good working condition and not past their calibration due dates. In 2019, 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.

Preventative maintenance on production equipment is performed at regularly scheduled intervals determined by the usage, operation history, and manufactures' recommendations where available. Maintenance schedules are maintained for each piece of equipment and are reviewed quarterly for completeness. In 2019, there were no issues related to the operation of any of the manufacturing equipment.

Best Theratronics assess its facility on an on-going basis through monthly Health & Safety audits, general review of the facility and as concerns are presented from employees. Due to employee concerns raised about the state of the facility's leaking roof, roof replacement initiated in 2018 and will continue into 2020. No other modifications to the facility were made in 2019.

2.6.2 Effectiveness of Aging Management Strategies

Best Theratronics Facilities & Maintenance team assesses the requirement for upgrades to existing machinery and improvements required around the facility. A representative from the Facilities & Maintenance team is a member of the Health & Safety Committee and is actively involved in aging management discussions, providing first hand information to management.

2.7 Radiation Protection

2.7.1 ALARA Principle Application

Adherence to the application of the *As Low As Reasonably Achievable* (ALARA) principle within Best Theratronics is supported by the main tenants of training, monitoring employee radiation exposure, and planning for special work. Initial Nuclear Energy Worker (NEW) training is provided and a refresher course is mandatory every 3 years to maintain the NEW status and radiological awareness. NEWs are designated based on their work tasks, required controlled area access, and the likelihood of receiving a higher dose than the public annual effective dose limit of 1 mSv. Personal doses of NEWs are monitored, on either monthly or quarterly basis, with the use of personal dosimeters alongside recorded doses from electronic personal dosimeters (EPDs). In addition, area monitors are installed throughout the facility to alarm if radiation fields exceed normal levels. A special work permit system, requiring authorization by the RSO, is implemented. This system identifies any special work that falls outside of normal, routine work to ensure it is properly planned to minimize unnecessary radiation exposures. Radiation protection assessments, consisting of monitoring for contamination and radiation surveys, are completed monthly to ensure ALARA doses in both controlled and accessible areas.

The Radiation Safety & Security Committee (RSSC) meets regularly to review radiation-related safety matters at Best Theratronics. In 2018, security personnel involvement within committee meeting discussions was initiated and the original name, Radiation Safety Committee (RSC), was changed to include Security. 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 Best Theratronics. In 2019 monthly meetings were held to ensure effective communication of radiation-related work and security concerns.

2.7.2 Radiation Protection Program Performance

Following an audit on the Radiation Protection Program in 2016, administrative levels of effective and equivalent doses were decreased to provide a better indication of the application of the program. In addition, in-house wipe test and surface contamination trigger levels were reduced. These levels were decreased to better reflect current operations. In 2019, there were no incidents where radiation exposure action levels were exceeded.

No other radiation related events occurred in 2019. The radiation protection training program has proven to be adequate.

2.7.3 Radiation Protection Program Improvements

Annually, an internal audit of the radiation protection program is conducted. The internal audit for 2019 revealed minor administrative updates were required (OFI#200201) in order to reflect current operations and procedure clarification. These will be implemented in 2020. Other improvements to the radiation protection program include:

- In-house training improvements completed on an on-going basis in order to consider different learning methods and understanding
- Encouraging open communication between concerned employees, their supervisors, and the radiation safety team to assist with identifying gaps in training related to radioactive licensed activity tasks
- Additional dose monitoring badges and personal alarming dosimeters are provided to workers conducting infrequent radiation related work, allowing for specific task dose information to be made available for future reference
- Movement of transport containers to minimize radiation fields in uncontrolled areas surrounding controlled areas

Future improvements to the radiation protection program include:

- Review of the Nuclear Energy Worker training to incorporate more of a hands-on-learning component by 2021
- Discussion of industry operational experience within the Radiation Safety and Security Meeting

2.7.4 Dose Monitoring Data

All individuals requiring access to controlled areas where radioactive material is stored, in addition to completing work where they may exceed the public annual dose limit of 1 mSv, are classified as a NEW.

Only NEWs are allowed in such areas and are monitored with the use of personal dosimeters as part of the Radiation Protection Program. Doses are monitored for two groups of NEWs at Best Theratronics:

- 1) Device Manufacturing and Class II Research and Development Employees (Building Personnel)
- 2) Class II Servicing Employees

Group 1 employees are reported under the Class 1B License. Class II Servicing Employee doses are reported with the respective Class II Servicing Licenses (14127-3-28/14127-8-24). On rare occasions, qualified Class II Servicing employees participate in Class 1B licensed activities. All NEW doses associated with Class 1B work is reported in this section as Class 1B NEWs.

Extremity monitoring is implemented for NEWs who requires working with their hands in close proximity to radioactive material. Workers are required to wear two extremity TLDs, one on each hand. The distribution of occupationally obtained doses is listed in the following table for both effective and extremity doses.

Work Group	Total Monitored	Dose Range (mSv)					
		<0.01	0.01-1.00	1.01-5.00	5.01-10.00	10.01-20.00	>20.01
Effective Dose		<0.01	0.01-1.00	1.01-5.00	5.01-10.00	10.01-20.00	>20.01
Class 1B NEWs	68	40	28	0	0	0	0
Class II Servicing	13	<i>Reported in Class II servicing licenses ACRs (14127-3-28/14127-8-24)</i>					
Extremity (Maximum between hands)		<0.01	0.01-1.00	1.01-5.00	5.01-10.00	10.01-20.00	>20.01
Class 1B NEWs	19	16	1	2	0	0	0
Class II Servicing	11	<i>Reported in Class II servicing licenses ACRs (14127-3-28/14127-8-24)</i>					

Based on the dose distribution, Best Theratronics operates with occupational doses below the maximum allowable NEW effective dose of 50 mSv in one dosimetry year and 500 mSv per year for extremities.

The following table provides the dose data for 2018:

2019 Class 1B NEWS	Effective	Extremity
Total workers monitored	68	19
Collective dose (mSv)	2.41	4.26
Average dose , with zeros (mSv)	0.04	0.22
Average dose, measured only (mSv)	0.09	1.42
Maximum dose received (mSv)	1.00	2.51

The following table provides Class 1B NEW dose data from 2015 – 2019.

Class 1B NEW Effective Doses

	2015	2016	2017	2018	2019	Regulatory Limit
Total workers monitored	62	60	68	68	68	--
Average dose , with zeros (mSv)	0.01	0.03	0.02	0.16	0.04	--
Maximum dose received (mSv)	0.20	0.98	0.47	8.65	1.00	50 mSv

Class 1B NEW Extremity Doses

	2015	2016	2017	2018	2019	Regulatory Limit
Total workers monitored	16	17	16	18	19	--
Average dose , with zeros (mSv)	0.00	0.09	0.07	1.41	0.22	--
Maximum dose received (mSv)	0.00	1.10	0.50	13.51	2.51	500 mSv

The number of NEWs monitored over the past five years have remained consistent. The average effective dose over this period, with the exception of 2018, increased. The maximum effective doses receive have fluctuated between 0.2 - 1.00 mSv. For extremity doses, the same increase and maximum value in 2018 appears. This single incident resulted in an effective dose and an extremity dose action level exceedence for two personnel conducting Class IB licensed tasks. Aside from the 2018 incident, the general trends are due to the increase in production at Best Theratronics requiring radiation related work. Maximum doses received conducting Class IB licenced activities at Best Theratronics over the past five years account for 17 % and 3% of the regulatory limits, for effective dose and extremity dose respectively.

Doses reported in previous ACRs, between 2014 and 2016, presented dose data which included service technicians, monitored under a separate Best Theratronics Class II servicing license. Company-wide dose information is provided for reference in Appendix A.

2.7.5 ALARA Action Level Reportable Incident

There were no ALARA Action Level exceedences in 2019.

2.7.6 Routine Radiation Protection Assessments

Best Theratronics conducts monthly checks in areas of the facility likely to show signs of radiological contamination or increased radiation fields for both controlled and uncontrolled areas. Internal monitoring limits for radiation fields are 1 mR/h for controlled areas and 0.1 mR/h in uncontrolled areas. All monthly facility surveys were found to be within these limits throughout the monitoring period. No abnormal readings were found in 2019.

Areas within the facility where radioactive material is stored or transported are checked for signs of contamination on a monthly basis. Contamination checks are also performed on an as-needed basis; from incoming radioactive shipments to movement of depleted uranium inventory around the facility. All facility contamination checks were within acceptable limits and no incidences were found where radioactive contamination was of concern. No contamination events occurred in 2019.

When radioactive shipments are received at Best Theratronics, the radiation field is measured to ensure the packages are within the Transport of Dangerous Good Regulations. Additionally, all receipts that contain radioactive sources are wiped for surface contamination to ensure contamination events are isolated prior to unloading. No incidences where transport package radiation surveys exceeded regulatory limits were observed or package surface contamination were detected in 2019.

2.8 Conventional Health & Safety

Best Theratronics Health and Safety Program is centered around prevention, first aid, investigations, hazardous substance awareness, an employee's right to refuse dangerous work acknowledgement, and workplace inspections.

2.8.1 Conventional Health & Safety Program Effectiveness

The CNSC conducted in April 2019, resulted in an action notice requiring Best Theratronics to provide an action plan to ensure the health and safety risks from lead contamination of surfaces are minimized. Best Theratronics began the lead control program improvement initiative in December of 2017. As a result of the CNSC observation, Best Theratronics has implemented periodic in-house lead contamination monitoring, resurfacing work bench tops, and replacing seating within lead work areas to be made of wipeable material.

2.8.2 Conventional Health & Safety Committee

The Health & Safety Committee members are responsible for reviewing reports on the investigations of occupational injuries, hazardous occurrences and near misses. The Best Theratronics Health and Safety Committee met on 10 occasions during 2019. Health and safety audits of the facility were also conducted monthly with all findings actioned and recorded in the meeting minutes. At the end of 2019, there were 5 action items left open to be completed in 2020.

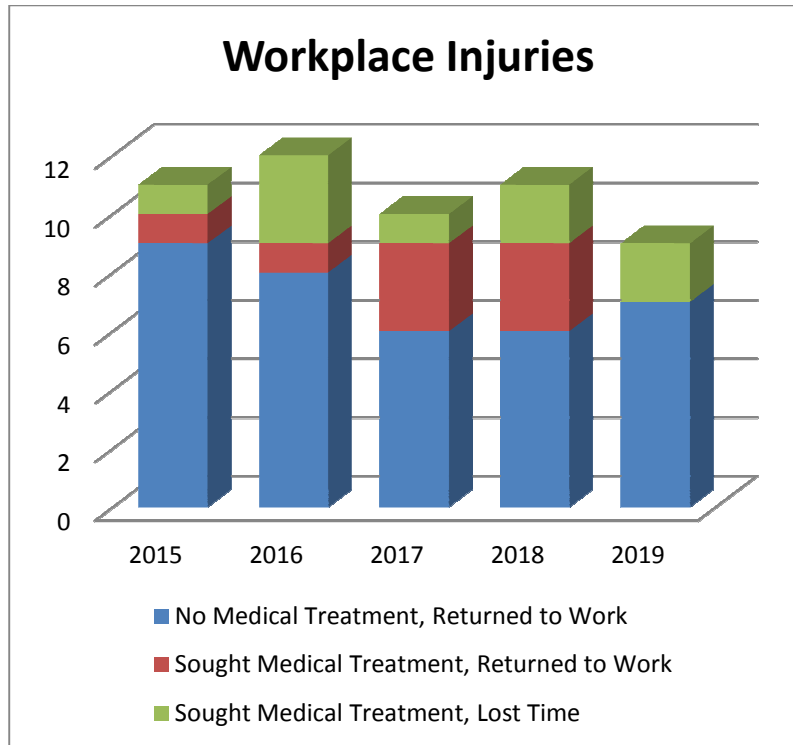
2.8.2.1 Conventional Health & Safety Program Improvements

As a result of workplace observations and concerns discussed within the Health & Safety Committee meetings, the following areas of improvement were actioned on in 2019:

- Chemical spill response
- Continuation of roof replacement of the facility
- Lead control program
- Increased salting of walkways and parking lot
- Hazardous waste storage process
- Ensuring emergency exits are cleared
- Lead pouring ergonomics
- Safety needs communication
- Safety glass hygiene
- Tripping hazards
- Forklift safety

2.8.2.2 Health & Safety Occurrences

In 2019, Best Theratronics documented a total of 8 medical reports, 1 of which required outside medical attention. These incidents caused cuts or scrapes, pinches, heat burn, slips on ice and strains. The following graph shows a breakdown of the health and safety reports, including lost time incidences.



In all instances, medical reports were reviewed and corrective actions were introduced if appropriate. Workplace injuries and lost time incidences are reviewed on a monthly basis by the Health and Safety Committee to ensure effort is put forth to prevent future occurrences. There were two incidences in 2019 where workers sought medical treatment, for workplace-related injuries, resulting in Lost Time:

June 17, 2019 – Worker strained back when physically moving wooden ramps to loading dock.

July 17, 2019 – Worker cut hand while working on product that was not deburred.

Lost time frequency and severity rate are provided in Appendix B for reference between 2015-2019.

2.9 Environmental Protection

2.9.1 Effluent Monitoring

An emissions analysis was completed in 2013 in support of an Environmental Compliance Approval (Air) application. This analysis assumed all significant emission sources were operating simultaneously at their individual maximum rates of production. The results indicated that manufacturing operation emission concentrations are below regulatory limits, demonstrating Best Theratronics' compliance with O. Reg. 419/05: Air Pollution – Local Air Quality.

Best Theratronics manufacturing operations do not produce airborne or liquid radiological releases to the environment as on-site sources are double encapsulated by a third party. The radioactive material used in Best Theratronics manufactured medical devices is contained within a welded stainless steel encapsulation. The loaded transport container or loaded self-shielded irradiators are stored within a radiation designated area within the facility. All radioactive material are double encapsulated sealed

sources or depleted uranium, therefore there are no releases into the environment and do not pose as an exposure hazard to the public.

All aspects of Best Theratronics' operations that may have an impact on the environment are identified, evaluated, recorded and reviewed periodically.

There were no environmental release exceeding regulatory limits or action levels in 2019.

2.9.2 Environmental Protection Program Performance

A Phase I and II Environmental Site Assessment (ESA) was carried out in 2019 to research the past and current use of the Best Theratronics site and adjacent properties in order to identify any environmental concerns with the potential to have impacted the subject property. Boreholes were placed on the property where soil (boreholes) and ground water samples were obtained. No concerns were identified in the resulting report.

2.10 Emergency Management and Fire Protection

As a manufacturing facility for medical devices, where radioactive sources are stored on site, fire and radiological emergency programs are required to ensure the safety of Best Theratronics.

2.10.1 Emergency Preparedness

Aspects of Best Theratronics' Emergency Response Program are tested periodically as indicated below:

Emergency Test/Drill	Minimum Testing Frequency
Emergency Personnel Call List	Semi-Annually
Fire Evacuation Alarm and Drill	Annually
Fire Alarms	Annually
Radiation Alarms	Monthly, Quarterly (Klaxon)
Emergency Power	Monthly
Full scale evacuation exercise	Once every five years
First aid casualty (<i>as part of First Aid training</i>)	Every three years
Chemical Spill	Periodically
Communication test for equipment and effectiveness	Periodically (everyday use)

A full scale evacuation exercise was conducted on April 23, 2019. This exercise included the participation of Best Theratronics employees, Ottawa Fire, Paramedic, and Police services. CNSC representatives attended to observe.

In preparation for, and a result of, the exercise emergency response teams were invited to the Best Theratronics facility for familiarization tours. During these tours, discussions were held between the Emergency Response Committee and the emergency personnel on improvements to Best Theratronics' procedures.

2.10.2 Program Effectiveness

The Emergency Response Committee (ERC) meets at least once a year to oversee emergency response planning at Best Theratronics Ltd. The last meeting took place on August 8, 2019 to review observations from the full scale evacuation exercise in April 2019. The following action items were discussed:

- 1) Emergency response procedural updates – review methods of incorporating an attendance system for building evacuations
- 2) Improvements to emergency response training – five training opportunities were found to increase safety awareness
- 3) Hosting facility tours for emergency responders – invite and rotate through emergency response personnel on a two year frequency, if scheduling permits
- 4) Emergency preparedness resource inventory – introduce reference resources to communicate emergency procedures for all personnel on the premises
- 5) Results of a voluntary survey following the exercise

A total of 30 surveys were completed for the voluntary survey following the full scale evacuation exercise. Comments provided in the survey responses revealed gaps between procedure and practice in a high stress emergency situation. Review of procedures and additional training will be administered to ensure Best Theratronics is adequately prepared to respond in an emergency situation.

2.10.3 Fire Protection Program Performance

Best Theratronics has implemented various measures to improve fire safety at the workplace. Elements of the fire protection program at Best Theratronics include:

- a hot work program
- developed combustibles policy
- refresher training of flammables and combustible liquids
- fire warden training
- training on the correct use of electrical cords

Routine checks of all fire protection related equipment are conducted, at a frequency listed below, to ensure functionality when required.

Equipment	Testing Frequency
Fire Alarm System	Monthly
Emergency Lighting	Monthly
Fire Extinguishers	Monthly
Sprinklers	Quarterly

2.10.4 Fire Protection Program Effectiveness

In 2019, the fire protection program effectiveness was assessed during the full scale evacuation on April 23, 2019.

A false fire alarm on February 18, 2019 provided another assessment opportunity for fire response preparedness at Best Theratronics. As a result, all Security Guards were retrained on their expected actions and responsibilities during all types of emergencies.

2.11 Waste Management

To reduce the impact on the environment, Best Theratronics has established a waste management program to promote the safe handling and disposal of waste generated from its operations.

2.11.1 Non-Radioactive Hazardous Materials

The landfill waste stream of 38.2 MT in 2019 held steady with the values from 2018 (39.5MT). This finding is attributed to the construction project in the Engineering offices after a flood had occurred.

Overall diverted material is largely the result of recycled scrap metal. The 21.74MT increase from 2018 is likely due to a combination of increase in the External beam therapy system production, production of the new Raycell MK1 and the fabrication of parts for the Cyclotrons.

The recycling of paper, cardboard, and shredded paper has not shown a reduction. The remaining 6.5 tons consists mostly of other recoverable materials (5.6 MT) and cans/plastics containers (0.7 MT).

Waste Stream	2015	2016	2017	2018	2019
Waste to Landfill	44	34	21.6	39.5	38.22
Recycled Paper, Cardboard and Shredded Paper	24	20	20	20	20
Recycled Glass, Aluminum Cans & Plastics	0.9	0.7	0.7	0.7	0.7
Recycled Metal	55	39	7.7	12.13	33.8
Other Recovered Material	5.6	5.6	5.6	5.6	5.63
Totals	129.5	99.3	55.6	77.93	98.39
Diversion Rate	66%	66%	61%	49%	61%

The following recommendations are keyed to the largest components of the landfill waste stream:

- Continue to search out options to divert wood waste from landfill.
- Implement a program to collect food waste and paper towels from and send them to a composting facility rather than landfill. Collectively, food waste and paper towels account for about 13 MT annually.
- Review the materials entering the 20 yd³ construction waste bin and assess if any of these materials can be diverted from landfill.
- Continue to support and strengthen the use of existing recycling programs through communications and review of bin placement to optimize employee participation.

Best Theratronics' hazardous waste management program is responsible for the proper disposal wastes such as chemical waste, electronics, paint, batteries, construction/demolition waste, and PCB containing light ballasts and fluorescent light bulbs. The following table provides the amounts of hazardous waste removed between 2015 and 2019.

Waste Code	Description	2015	2016	2017	2018	2019
112	Lead acid batteries	10 kg	5 kg	--	--	--
122	Alkaline batteries	45 kg	--	--	70 kg	--
145	Paint	--	--	--	--	5 kg
146	Filters with lead dust	--	48 kg	--	--	--
146	Florescent bulbs and HID lamps	306 kg	150 kg	140 kg	65 kg	185 kg
146	Lead contaminated material	--	--	--	--	70 kg
146	Zirconium alloy scrap	1300 kg	225 kg	--	--	800 kg
148	Inorganic acid oxidizer	16 L	88 L	--	16 L	--
212	Acetone	820 L	1015 L	600 L	530 L	620 L
212	Antifreeze	--	--	--	--	10 L
251	Watery oil	--	--	--	--	12900 L
252	PCB ballasts	170 kg	--	40 kg	10 kg	--
252	Machine oil	2050 L	1965 L	1980 L	1920 L	--
263	Organic flammable waste	960 L	200 L	245 L	340 L	56 L
331	Organic gas aerosols	48 L	8 L	20 kg	73 Kg	16 kg
253	Emulsified oil	--	--	--	1000 L	--
	Mercury	1 kg	--	--	--	--

2.11.2 Radioactive Hazardous Materials

In order to be compliant with ISO 14001:2015, Best Theratronics revised its environmental management system to include the identification and evaluation of operations that may have an impact on the environment on an annual basis. A number of environmental objectives have previously been determined and tracked by the MRT throughout the licensing period. They include:

- 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.

In the 2018 MRT an environmental objective was added:

- Dispose of 128 000 Ci (Co-60) and 30 000 Ci (Cs-137)

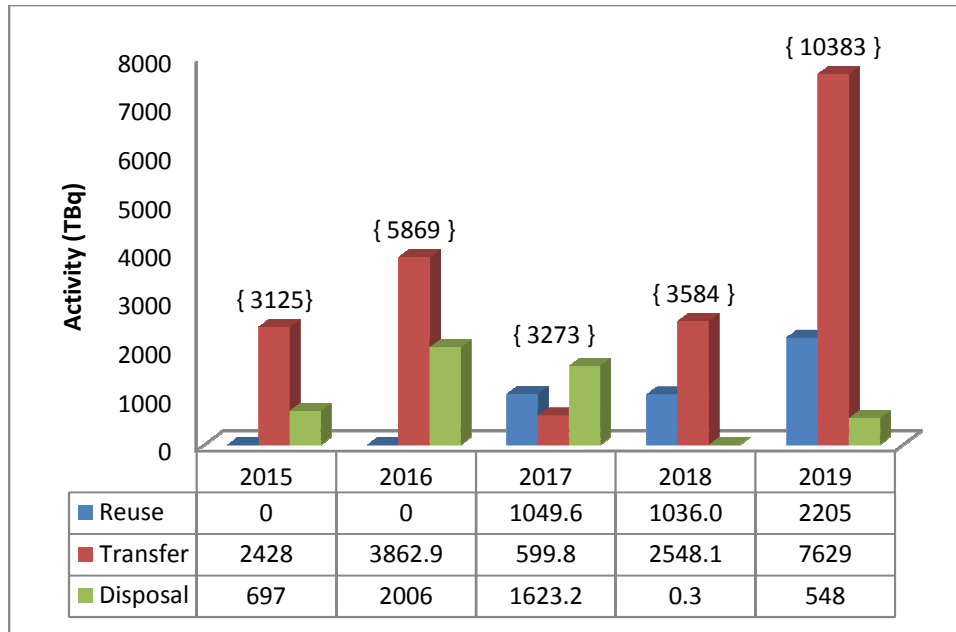
This objective was successfully completed in 2019. Waste disposal will always be part of the environmental objectives of Best Theratronics.

Best Theratronics has an end-of-life management program for the exhausted and returned sealed sources. These sources are sorted into three categories upon return: for reuse, for transfer, or for disposal.

- Sources that are destined for reuse, include sources for re-encapsulation, to be incorporated into Best Theratronics self-contained irradiators or teletherapy machines.
- Sources that are transferred to other manufacturers for recycling. These sources are shipped to other suppliers or manufacturers of Co-60 sources, where the capsules will be cut open and the radioactive material reused in the manufacturing of new sources for other purposes.

- Sources that are destined for disposal are transferred to licensed disposal facilities, such as Canadian Nuclear Laboratories in Chalk River, ON for long-term storage and disposal.

In 2019, a total source activity of 9838 TBq was diverted from the disposal stream and reused or recycled according to Best Theratronics’ end-of-life management program. Legacy sources, with a total activity of 548 TBq, were transferred to Canadian Nuclear Laboratories (CNL) for disposal. The graph below indicates the activity breakdown of the managed sources between 2015-2019. Values above each year indicate the total activity managed in the respective year.



The depleted uranium inventory at Best Theratronics originates from returned components of legacy teletherapy units and other legacy items. This inventory is temporarily stored at Best Theratronics awaiting proper disposal through the end of life management program. No disposal or recycling of depleted uranium occurred in 2019.

Best Theratronics is actively seeking opportunities to recycle/dispose the depleted uranium.

2.12 Security

2.12.1 Site Security

Best Theratronics has an adequate security program in place, where the site-security plan is reviewed on a regular basis. Concerns regarding the security of radioactive material are discussed on a regular basis, during Radiation Safety & Security Committee (RSSC) meetings.

No security-related events have occurred in the year 2019.

2.12.2 Transport Security

Limited and approved carriers of radioactive material are contracted to further ensure the security of devices or components containing radioactive material during transit. These carriers are audited

annually to ensure their procedures comply with current regulations and Best Theratronics' security policies. Transportation security plans of the radioactive material carriers were found to be adequate.

No transport security related reportable incidences occurred in 2019.

2.12.3 Personnel Security

As part of Best Theratronics' employment process, all employees are required to supply a criminal's records check at the start of their employment. Best Theratronics has implemented a criminal record check renewal policy every five years. This policy has been fully implemented.

2.13 Safeguards and Non-proliferation

2.13.1 Safeguards and Non-proliferation Program Performance

Best Theratronics possess and temporarily stores depleted uranium from legacy teletherapy units destined for disposal. Accounting and reporting of Best Theratronics' inventory of depleted uranium and other materials containing depleted uranium are completed annually as per REGDOC-2.13.1 *Safeguards and Nuclear Material Accountancy*.

The annual Physical Inventory Taking (PIT), produced no discrepancies between the physical values and the reported values to the CNSC. Best Theratronics was not selected for either the CNSC Physical Inventory Taking – Evaluation (PIT-E) or the IAEA Physical Inventory Verification (PIV) in 2019.

2.14 Packaging and Transport

Best Theratronics prepares, packages and ships medical devices containing sealed Category 1 and 2 radioactive materials worldwide. The Packing and Transport program at Best Theratronics meets the requirements of the CNSC *Packaging and Transport of Nuclear Substances Regulations* (2015), IAEA *SSR-6* (2012), Transport Canada *Transportation of Dangerous Goods*, USDOT 49 CFR and US NRC 10 CFR.

Radioactive sealed source shipments are transported in Type A or certified Type B containers. Best Theratronics implements a transport container maintenance and inspection program in accordance with IAEA *SSR-6* 2012. In addition to annual inspections, containers undergo a routine inspection each time they are returned from the field.

3 Other Matters of Regulatory Interest

3.1 Licensee's Public Information and Disclosure Program

3.1.1 Public Inquiries and Media Coverage

The public is encouraged to contact Best Theratronics for more information regarding concerns through the info@theraronincs.ca email address available on the Best Theratronics website. There were no public inquiries received in 2019.

As per Best Theratronics' obligation to keep the public informed, the Best Theratronics website is updated with information for public inquiry. The updates to the website include:

- Annual compliance reports (ACRs) for all of Best Theratronics' CNSC licences (servicing and Class 1B)
- Notifications of licence renewals
- Annual reports on lead (and its compounds)
- Notification of false alarms and building evacuations
- Incidents occurred where any reporting or action level was exceeded

There were a total of 12 updates to the public information program pages in 2019.

3.1.2 Facility Tours

In 2019, Best Theratronics held tours for regulators, both international and domestic, in addition to several emergency response personnel in preparation for the full scale evacuation exercise.

3.1.3 Future Public Information Program Plans

There were no changes made to the public information and disclosure program in 2019. Best Theratronics will continue to monitor its public information program performance. Best Theratronics plans to continue hosting public information sessions and facility tours.

3.2 Financial Guarantees

As of July 2017, Best Theratronics has estimated decommissioning costs to be \$1.80 million. This includes a 25% contingency amount. In 2019, Best Theratronics removed 10383 TBq of source activity from its possession. These sources were reused (2205 TBq), transferred to be recycled (7629 TBq), or disposed of at a licensed facility (548 TBq).

Best Theratronics 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 Best Theratronics' 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 Concluding Remarks

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2019 did not change significantly from previous years. There were no major events, observations, or non-compliance identified during 2019 that would affect the safety and security of personnel, the public, or the environment.

Best Theratronics continues to make adequate provisions for the protection of the environment and the safety of both employees and the public. Best Theratronics acts in compliance with the licensing conditions set out in license NSPFL-14.00-2029 and the associated Licensing Conditions Handbook.

4.1 Signing Authority Certification

I hereby certify that Best Theratronics has been operating in compliance with license NSPFL-14.00/2029, except where otherwise noted.

<Signature on file>

Mojgan Soleimani

Director of Quality and Regulatory Affairs, RSO

613-591-2100 ext 2766

Appendix A – Company-wide Dose Information

The following tables show the comprehensive data, including doses received by the service technicians under the Class II servicing license, over the past 5 years. It should be noted that doses received by service technician are a combination of both Canadian and international service work.

Company Wide Effective Doses

	2015	2016	2017	2018	2019
Total workers monitored	76	73	77	77	79
Average dose, with zeros (mSv)	0.05	0.08	0.11	0.20	0.16
Maximum dose received (mSv)	0.85	2.28	5.30	8.92	5.33 ^A

A – Dose adjustment requests have submitted to the CNSC for approval. Calculated values of company-wide maximum effective dose would change to 1.00 mSv.

Company Wide Extremity Doses

	2015	2016	2017	2018	2019
Total workers monitored	32	31	25	27	28
Average dose, with zeros (mSv)	0.16	1.70	0.71	1.34	0.97 ^B
Maximum dose received (mSv)	2.10	29.90	11.20	14.94	10.16

B – Dose adjustment requests have submitted to the CNSC for approval. Calculated values of company-wide average extremity dose would change to 0.78 mSv.

The trends apparent from the presented data indicate that service work contributes to a large fraction of the acquired dose, companywide. This is due to the nature and volume of radioactive work when servicing teletherapy units and radiation devices. Doses recorded for building personnel are minimal, indicating that radiation protection practices at Best Theratronics are adequate.

Appendix B – Lost Time Statistics

	2015	2016	2017	2018	2019
# of LTIs	1	3	1	2	2
Frequency Rate	0.684	2.05	0.684	1.37	1.37
Total Missed Days	1	55	22	12	0
Severity Rate	0.684	37.6	15.0	8.21	6.84

*Assumption is 150 employees working 37.5 hrs/week for 52 weeks.