Annual Compliance and Performance Report

2022

Best Theratronics Ltd.

413 March Road
Ottawa, Ontario, Canada
K2K 0E4

Class 1B License

NSPFL-14.00/2029

Reporting Period: January 1st, 2022 to December 31st, 2022

Report Submitted, Rev 0: March 8, 2023

Report Revision History

Revision	Submission Date	Comments
0	March 8, 2023	• Original submission

Table of Contents

This page has been left blank intentionally.

1 Introduction

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

- Cobalt 60-based external beam radiation therapy units,
- Cesium 137-based self-contained irradiators (SCIs) for blood or research irradiation,
- Cyclotrons with beam energies ranging from 6 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.

License NSPFL-14.00/2029 authorizes Best Theratronics to:

a) operate a Class IB 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
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 IB nuclear facility.

In addition to the Class 1B nuclear substance and processing facility license, Best Theratronics possesses two other CNSC licenses (Class II Nuclear Facilities and Prescribed Equipment License & Nuclear Substances and Radiation Devices License) in order to conduct service work on prescribed equipment sold to customers within Canada. Information related to these activities is 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 and shipped 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)

1.2 New Licensed Activities

No operational changes occurred in 2022. There were no new Class 1B licensed activities since the last compliance monitoring period.

1.3 Significant Modifications or Changes to Site or Facility

There were no significant modifications, or changes, to the site/facility in 2022.

Safety and Control Areas

1.4 Management System

1.4.1 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 (cont.)

- Procedure Documentation
- Culture of Safety and Compliance

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

1.4.2 Management System Effectiveness

Compliance to Best Theratronics' CNSC license 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 large Management Review Team meeting in 2022 for the operations over 2021. Throughout the year many small, informal meetings were held. 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 up onin the next MRT meeting.

1.4.2.1 Annual Quality Management System Audit

Best Theratronics completes an annual internal audit of the overall quality management system. The scope of the audit covers the review of company objectives, policies and procedures, the management

standard, requirements of ISO13485:2016, ISO 9001:2015, and the Medical Device Single Audit Program (MDSAP). An annual internal audit was completed in September, 2022.

1.4.2.2 Organizational Structure for the Management and Control of Licensed Activities

Minor changes to Best Theratronics' organizational structure occurred in 2022. The position of Radiation Safety Manager was filled, who also fulfills the role of Radiation Safety Officer. The following roles outline the personnel employed to ensure licensed activities are properly managed at Best Theratronics:

- Quality & Regulatory Manager
- Director of Engineering
- Director of Cyclotron Operations
- Technical Services Manager
- Production Planning Manager
- Supply Chain Manager
- Radiation Safety Officer
- Radiation Safety Specialist
- Radiometric Measurement Specialist
- Medical Physicist
- Compliance Specialist
- Quality Control Supervisor
- Production Supervisors (3)
- Contract Security Supervisor
- Contract Security Officers

1.4.3 Document Changes

Below is a list of the documents that were updated in 2022. Updates to such documents reflect changes in regulation, audit observations, and corrective action implementation. Updated versions of documents supporting the Class 1B license were submitted to the CNSC as per requirement in the License Conditions Handbook:

- 1.08-SC-10 Hazardous Material Transportation Security Plan
- 3.24-AA-01 Design Change Procedure
- 3.24-AA-16 Shielded Room 4 Operating Instructions
- 5.00-QA-00 Quality Manual
- 5.00-QA-23 Training
- 5.08-ERP-01 Site Emergency Response Plan
- 5.08-RP-01 Radiation Protection Manual
- 5.08-RP-02 Radiation Emergency Response Plan
- 5.08-RP-08 Contamination Monitoring Program Sampling and Measurement
- 5.08-RP-09 Leak Test Sampling and Measurement
- 5.08-RP-11 Radiation Surveys

1.5 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.

Elements of a Systematic Approach to Training (SAT) have been 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''.* If ever an employee's roles or responsibilities change, their training requirements are reviewed.

1.5.1 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 table lists the environmental health and safety training programs that are conducted at Best Theratronics.

On an annual basis, radiation safety refresher training is required for Class II service technicians to ensure safe practices are applied at customer's sites within Canada and internationally.

Table 1: *Training programs offered at BTL and frequency that refresher training is mandated.*

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

1.5.2 Training Effectiveness Evaluation

The training program at Best Theratronics is evaluated through:

- 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 2021.

Table 2: *Number of personnel trained in 2022 for each training program offered at BTL.*

Training	# of personnel trained in 2021
Crane	8
First-Aid	1
Fork-lift/Pallet Truck	6
Lead control	26
WHMIS	7
Transportation of Dangerous Goods	10
Nuclear Energy Worker/Radiation Safety Nuclear Energy Worker Service Refresher	35

All personnel trained in 2022 successfully passed the end of course evaluations. Implementation of SAT-based training programs is fully underway, which re-analyzed training requirements, training techniques, and assessed the incorporation of additional training modules.

1.5.2.1 Radiation Safety Training

During the reporting year, thirty 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. No radiation related incidences occurred in 2022 where the root cause was determined to be due to lack of training.

1.5.3 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 per year, ensuring upper management and appropriate response personnel are reachable.

1.6 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, capturing 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 quarterly. Weekly meetings regarding radioactive material shipments are conducted with members of the radioactive production team, regulatory compliance, logistics, and customer service. Email notification updates are sent out to key operational members of the organization to keep all those involved informed and to track notifications sent to the CNSC.

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

1.6.1 Licensed Activities Audits Overview

The CNSC conducted two audits in 2022 on the following topics:

- Radiation Protection
- Emergency Management and Fire Protection

The Radiation Protection audit identified three areas of non-compliance that were of low safety significance and one recommendation. The Emergency Management and Fire Protection audit identified three areas of non-compliance that did not pose an immediate or unreasonable risk to the health and safety of persons or to the environment and were of low safety significance.

1.6.2 Reportable Events

There were no reportable events in 2022.

1.6.1 Operational Limits

The basis of obtaining the Class 1B License for the Best Theratronics facility was to manufacture and test Class II prescribed equipment and cyclotrons for the medical and research industries. In 2022, Best Theratronics operated within the limits outlined in the Class 1B license.

1.6.1.1 Class II Workload

The R&D Class II prescribed equipment located in Cell 4 (T1000, S/N 4) was operated for a total 59 hours, where all hours were related to research. Operational information is provided in the following table.

Table 3: *Operational information for Class II prescribed equipment located in Cell 4.*

Source Serial Number	Source Type	Beam On Time [hrs]	Output at 1m [Gy/min]	Output date reference	Total work load (Gy)
S-6306	Co-60	59	1.2	January 1, 2022	4248
Beam on total [hrs]		59	*Total workload [Gy]*		4248

1.6.1.2 Cyclotron Operations

The operating limits stated in Best Theratronics License Conditions Handbook are related to cyclotron development and testing. The 6 MeV cyclotron in development and testing in 2021 was completed and shipped to the client in 2022. Operational information for the remaining cyclotrons in development is provided in the following table.

Table 4: *Operational information for Class 1B prescribed equipment located in High Bay.*

Model/Serial number	B15P02	B35P01	B70P02
Nominal Beam energy	15MeV	35MeV	70MeV
Operating beam energy	<1MeV in factory	<1MeV in factory	<1MeV in factory
Beam current (nominal)	500µA nominal	1200µA nominal	1000µA nominal
Beam-on times	The cyclotron is in manufacturing stage	The cyclotron is in manufacturing stage	The cyclotron is in manufacturing stage

1.7 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.

1.7.1 Facility Safety Improvements

The facility is toured and inspected by two members of the Health & Safety Committee on a monthly basis. There were no significant Health & Safety concerns brought up from these inspections.

1.8 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. In 2020, Best Theratronics applied for a CNSC Class II Facility construction license to prepare a pre-existing bunker for development and testing of Class II equipment. Modification plans were submitted to the CNSC for review in April 2020, and a pre-construction inspection was completed in November 2020. The development and testing work associated with this project progresses under the design change process.

An application was started in 2022 to change the construction license over to an operations license. The application will be submitted to the CNSC in 2023.

1.9 Fitness for Service

1.9.1 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 2022, 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, or units were retired if repairs were deemed to not be cost effective.

Preventative maintenance on production equipment is performed at regularly scheduled intervals determined by the usage, operation history, and manufacturers' recommendations where available. Maintenance schedules are maintained for each piece of equipment and are reviewed quarterly for completeness. In 2022, there were no issues related to the operation of any of the manufacturing equipment.

In addition, Best Theratronics assesses its facility on an on-going basis through monthly Health & Safety inspections, general review of the facility and as concerns are presented from employees.

1.9.2 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.

To improve the versatility of the manufacturing shop machining capabilities at the facility, a new sandblasting booth was purchased in 2021 and installed to replace an aging unit. It was put into service in 2022, but the old sandblasting unit has not been retired yet.

1.10 Radiation Protection

1.10.1 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. The meetings take place to discuss concerns and identify improvements to the overall safety and security culture at Best Theratronics. In 2022, quarterly meetings were held to ensure effective communication of radiation-related work and security concerns.

1.10.1.1 ALARA Action Level Reportable Incidences

There were no Class 1B ALARA Action Level exceedances in 2022.

1.10.2 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 2022, there were no incidents where radiation exposure action levels were exceeded.

No other radiation related events occurred in 2022. The radiation protection training program has proven to be robust.

1.10.3 Radiation Protection Program Improvements

On an annual basis, an internal audit of the radiation protection program is conducted. The internal audit for 2022 was not conducted due to the CNSC's Radiation Protection audit and inspection.

1.10.4 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 occasion, 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 applied to NEWs whose job tasks require working with their hands in close proximity to radioactive material, such as service technicians or radiation device welders. Workers are required to wear two extremity Optically Stimulated Luminescent Dosimeters (OSLD), one on each hand. The distribution of occupationally obtained doses is listed in table 5 for both effective and extremity doses.

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. Table 6 provides the dose data for 2022:

Table 5: *Effective and extremity radiation dose distribution for Class 1B NEW employees at BTL.*

Work Group	Total Monitored	Dose Range (mSv)					
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	63	59	4	0	0	0	0
Class II Servicing	*Reported in Class II servicing licenses ACRs (14127-3-28/14127-8-24)*						
Extremity (left and right)		**<0.01**	**0.01-1.00**	**1.01-5.00**	**5.01-10.00**	**10.01-20.00**	**>20.01**
Class 1B NEWs	17	31	3	0	0	0	0
Class II Servicing	*Reported in Class II servicing licenses ACRs (14127-3-28/14127-8-24)*						

Table 6: *Dose statistics for Class 1B NEW employees at BTL.*

2021 Class 1B NEWS	*Effective*	*Extremity*
Total workers monitored	63	17
Collective dose (mSv)	0.19	0.35
Average dose with zeros (mSv)	< 0.01	0.02
Average dose, measured only (mSv)	0.01	0.12
Maximum dose received (mSv)	0.03	0.13

The following table provides Class 1B NEW dose data from 2017 – 2022.

Table 7: *Average and maximum values of effective and extremity doses for Class 1B NEW employees at BTL between 2017-2022.*

Class 1B NEW Effective Doses							
	2017	*2018*	*2019*	*2020*	*2021*	*2022*	*Regulatory Limit*
Total workers monitored	68	68	68	73	64	63	--
Average dose , with zeros (mSv)	0.02	0.16	0.04	0.01	0.01	<0.01	--
Maximum dose received (mSv)	0.47	8.65	1.00	0.19	0.13	0.03	50 mSv
Class 1B NEW Extremity Doses							
	2017	*2018*	*2019*	*2020*	*2021*	*2022*	*Regulatory Limit*
Total workers monitored	16	18	19	19	16	17	--
Average dose , with zeros (mSv)	0.07	1.41	0.22	0.15	0.06	0.02	--
Maximum dose received (mSv)	0.50	13.51	2.51	2.4	0.47	0.13	500 mSv

The number of NEWs monitored over the past six years has remained consistent. The average effective dose over this period has fluctuated between <0.01-0.04 mSv while the maximum effective doses received have fluctuated between 0.03 - 1.00 mSv, with the exception of 2018.. For extremity doses, the average extremity dose has fluctuated between 0.06-0.15 mSv, with the exception of the maximum value in 2018. This single incident resulted in an effective dose and an extremity dose action level exceedance for two personnel conducting Class IB licensed tasks. Maximum doses received conducting

Class IB licensed activities at Best Theratronics over the past six years account for 17% and 3% of the regulatory limits, for effective dose and extremity dose respectively.

1.10.5 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 2022.

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 the 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 2022.

When radioactive shipments are received at Best Theratronics, the radiation field is measured to ensure the packages are within the Transport of Dangerous Goods Regulations. Additionally, all receipts that are intended to 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 2022.

1.11 Conventional Health & Safety

The 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.

1.11.1 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 2022. Health and safety audits of the facility were also conducted monthly; all findings were made action items, and recorded in the meeting minutes.

1.11.1.1 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 tracked in 2022:

- Lead pouring ergonomics
- Operation of a new phone and paging system
- Development of a common machine shop H&S checklist
- Need for lowering catch basins in the parking lot
- PPE in the paint booth
- Audio earbud usage on the shop floor

1.11.1.2 Health & Safety Occurrences

In 2022, Best Theratronics documented a total of 8 medical reports, none of which required outside medical attention. These incidents involved bandaging minor cuts, ice and rest, and a slip on ice. The following graph shows a breakdown of the health and safety reports, including lost time incidences.

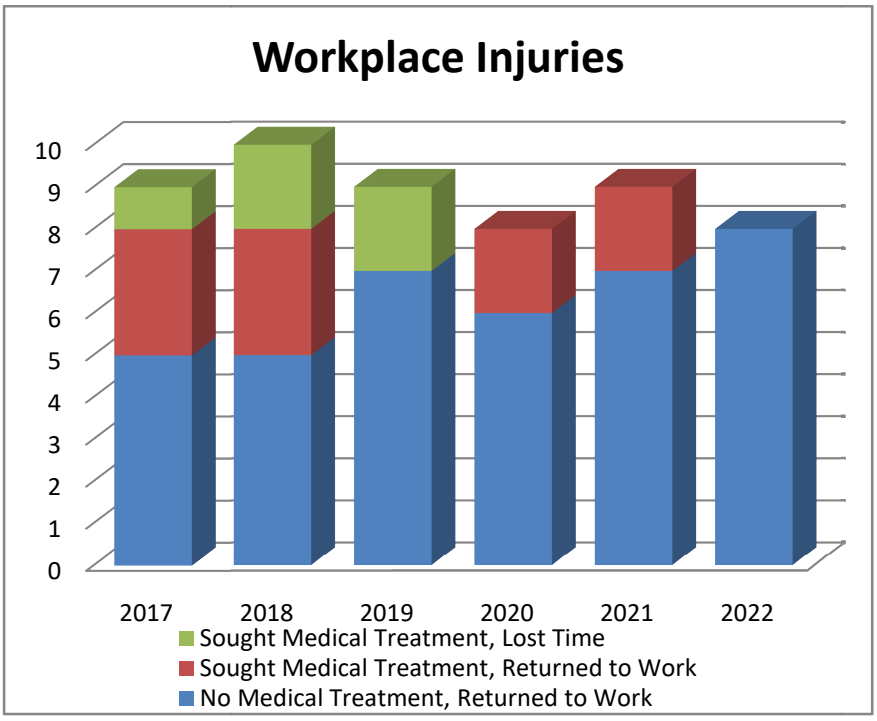


Figure 1: *Distribution of significance of incurred workplace injuries between 2017-2022. Medical Treatment is defined as requiring a trip to the doctor or hospital. `No Medical Treatment' may have required the use of the Best Theratronics' first aid kit.*

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.

A Lost Time Incident (LTI) occurs if an employee suffers a workplace injury resulting in an absence from work past the day of the incident, loss of wages, or a permanent disability/impairment. There were zero occurrences of an injury requiring professional medical treatment and zero Lost Time Incidences in 2022. Lost time frequency and severity rate are provided in Appendix A for reference between 2017-2022.

1.12 Environmental Protection

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. As manufacturing processes have not changed since 2013 this study is considered valid.

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. Loaded transport containers, or loaded self-shielded irradiators, are stored within a radiation designated area within the facility. All radioactive materials are double encapsulated sealed sources or depleted uranium; they have no releases into the environment and do not pose 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.

Operations of the facility do not produce airborne or liquid radiological emissions. No environmental releases occurred in 2022.

1.13 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.

1.13.1 Emergency Preparedness

Aspects of Best Theratronics' Emergency Response Program are tested periodically, as indicated in the following table.

Table 8: *Emergency Preparedness Test/Drills*

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 *(as part of First Aid training*)	Every three years
Chemical Spill	Periodically
Communication test for equipment and effectiveness	Periodically (everyday use)

*Full scale evacuation last occurred in March 2022.

1.13.2 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 March 23, 2022 following the planned full scale evacuation training session. The following action items were discussed:

1) Emergency response procedural updates – Improve methods of the attendance system (head counting) for building evacuations
2) Improvements to access – provide access to controlled areas with a badge for first responders
3) Communication and identification resources – Upgrade Emergency Response Committee and first aiders identification armbands to vests and increase communication devices

Emergency Response procedures are reviewed yearly, as well as periodic worker refresher training regarding ER, to ensure Best Theratronics is adequately prepared to respond in an emergency situation.

1.13.3 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 in the following table, to ensure functionality when required.

Table 9: *Life safety equipment testing frequency.*

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

1.13.4 Fire Protection Program Effectiveness

The fire protection program's effectiveness was assessed during the full scale evacuation and fire drill in March 2022. See section 1.13.2.

1.14 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.

1.14.1 Non-Radioactive Hazardous Materials

The landfill waste stream of 27.75 MT in 2022 was comparable with 2021. The following table shows a summary of waste disposal.

Table 10: *Waste (in MT) that is disposed of into each waste stream between 2017-2022.*

Waste Stream	2017 (MT)	2018 (MT)	2019 (MT)	2020 (MT)	2021 (MT)	2022 (MT)
Waste to Landfill	21.6	39.5	38.22	34.75	27.3	27.75
Recycled Paper, Cardboard and Shredded Paper	20	18*	25.6*	24	25.7	25.9
Recycled Glass, Aluminum Cans & Plastics	0.7	0.3*	1.5*	1.3	1.0	1
Recycled Metal	7.7	12.13	33.8	24.8	27.3	18.45
Other Recovered Material	5.6	5.6	5.63	5.63	5.98	5.63
Totals	55.6	75.53*	104.82*	90.48	87.3	78.73
Diversion Rate	61%	48%*	63.5%*	62%	69%	65%

*Upon review of 2018 and 2019 data for the 2020 Waste Audit Report, these values have been corrected.

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 yd^3 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 of 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 2017 and 2022.

Table 11: *Hazardous waste (in kg) that was disposed of between 2017-2022.*

Waste Code	Description	2017	2018	2019	2020	2021	2022
114C	Other inorganic acid waste	--	--	--	--	10 L	--
122	Alkaline batteries	--	70 kg	--	--	--	--
145	Paint	--	--	5 kg	80 L	--	150 L
146	Non-regulated solid waste (fluorescent bulbs)	140 kg	65 kg	185 kg	20 kg	--	300 kg
146	Lead contaminated material	--	--	70 kg	460 kg	--	--
146	Zirconium alloy scrap	--	--	800 kg	800 kg	--	400 kg
148	Corrosive liquid (nitric acid, sodium chloride)	--	16 L	--	48 L	45 L	40 L
212	Acetone	600 L	530 L	620 L	620 L	--	1200 L
212	Antifreeze	--	--	10 L	--	--	--
212	Non regulated liquid waste (glycol)	--	--	--	140 L	--	20 L
213	Petroleum distillates (varsol)	--	--	--	--	--	20 L
252L	Watery oil	--	--	12900 L	900 L	2000 L	3000 L
252	PCB ballasts	40 kg	10 kg	--	--	--	--
252	Machine oil	1980 L	1920 L	--	1220 L	--	--
253	Emulsified oil	--	1000 L	--	--	--	--
263	Organic flammable waste	245 L	340 L	56 L	60 L	200 L	--
331	Organic gas aerosols	20 kg	73 Kg	16 kg	60 kg	40 kg	30 kg

1.14.2 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:

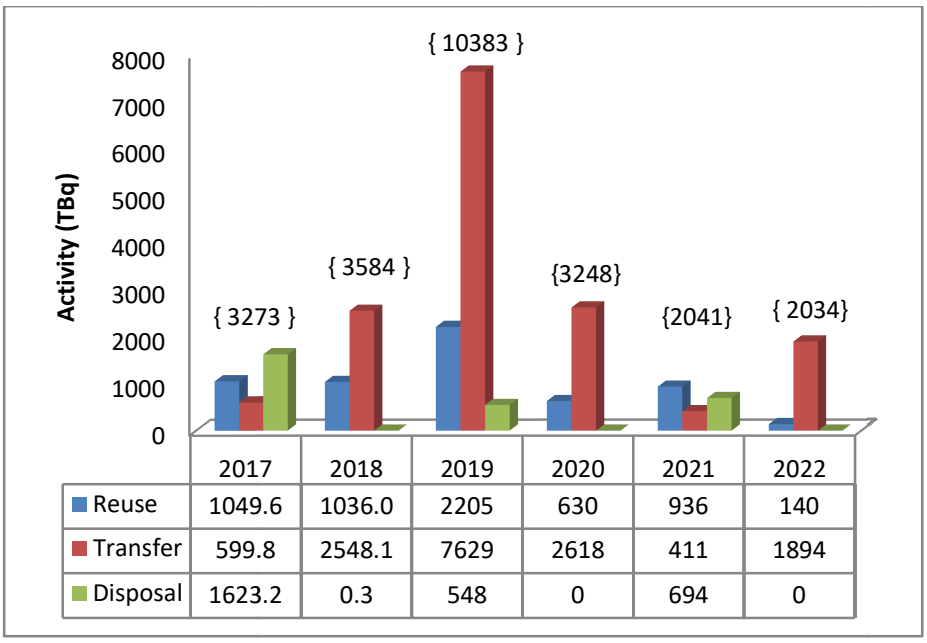
- Dispose of, or transfer, sealed sources at 413 March road to a licensed facility.
- Dispose of, or transfer, prescribed equipment containing radioactive source to a licensed facility.
- Dispose of, or transfer, depleted uranium at 413 March Road to a licensed facility.

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, including 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, for long-term storage and eventual disposal

In 2022, a total source activity of 140 TBq was diverted from the disposal stream and reused or recycled according to Best Theratronics' end-of-life management program. The graph below indicates the activity

breakdown of the managed sources between 2017-2022. Values above each year indicate the total activity managed in the respective year.



	2017	2018	2019	2020	2021	2022
Reuse	1049.6	1036.0	2205	630	936	140
Transfer	599.8	2548.1	7629	2618	411	1894
Disposal	1623.2	0.3	548	0	694	0

Figure 2: **Radioactive waste (TBq) in each of the reuse, transfer, or disposal waste management streams.**

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 2022. Best Theratronics is actively seeking opportunities to recycle the depleted uranium.

1.15 Security

1.15.1 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 can be discussed on a regular basis, during Radiation Safety & Security Committee (RSSC) meetings.

No security-related events occurred in 2022.

1.15.2 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 reportable incidences occurred in 2022.

1.15.3 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.

1.16 Safeguards and Non-proliferation

1.16.1 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 selected for the IAEA Physical Inventory Verification (PIV) and had an inspection on October 19, 2022. A CNSC safeguards inspector accompanied the IAEA team. No issues were found or reported.

1.17 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* Rev. 1 (2018), 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 (Rev. 1) 2018. In addition to annual inspections, containers undergo a routine inspection each time they are returned from the field.

2 Other Matters of Regulatory Interest

2.1 Licensee's Public Information and Disclosure Program

2.1.1 Public Inquiries and Media Coverage

The public is encouraged to contact Best Theratronics for more information regarding concerns through the info@theraronics.ca email address available on the Best Theratronics website. There were no public inquiries received in 2022. Best Theratronics understands the importance of Indigenous relations, and as such, reached out to the Algonquins of Pikwakanagan First Nation (AOPFN) in November of 2022 by way of their consultation email address. No response was received in 2022. Best Theratronics received no direct inquiries from Indigenous groups in 2022.

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 licenses (servicing and Class 1B)
- Notifications of license 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 Facility Tours

2.1.2 Future Public Information Program Plans

Best Theratronics did not review its Public Information and Disclosure program in 2022. Best Theratronics will continue to monitor its public information program performance.

2.2 Financial Guarantees

As of July 2017, Best Theratronics has estimated decommissioning costs to be $1.80 million. This includes a 25% contingency amount. In 2022, Best Theratronics removed 2034 TBq of source activity from its possession. These sources were either reused (140 TBq) or sold (1894 TBq), in both cases the sources went to another licensed facility .

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. The next full review of the financial guarantee will take place in 2023.

3 Concluding Remarks

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2022 did not change significantly from previous years. There were no major events, observations, or non-compliances identified during 2022 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.

3.1 Signing Authority Certification

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

2023-03-08

Matthew Efseaff, PhD, MSc
Radiation Safety Manager
613-591-2100 ext 2762
matthew.efseaff@theratronics.ca

Date

Appendix A – Lost Time Statistics

Table 13: *Lost Time and Frequency Rate calculated for 2017-2022.*

	2017	*2018*	*2019*	*2020*	*2021*	*2022*
# of LTIs	1	2	2	0	0	0
Frequency Rate	0.684	1.37	1.37	0.00	0.00	0.00
Total Missed Days	22	12	8	0	0	0
Severity Rate	15.0	8.21	5.470	0.00	0.00	0.00

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