



Annual Compliance and Performance Report

2023

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 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 Device 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 2023. 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 2023.

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

- 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 Management Review Team meeting in 2023 for the operations over 2022. 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 on during 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 June, 2023.

1.4.2.2 Organizational Structure for the Management and Control of Licensed Activities

Minor changes to Best Theratronics' organizational structure occurred in 2023. The position of Radiation Safety Manager was vacated, and a new Radiation Safety Officer was hired. 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 (2)
- Contract Security Supervisor
- Contract Security Officers

1.4.3 Document Changes

Below is a list of the documents that were updated in 2023. 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:

- 5.08-RP-11 Radiation Surveys
- 3.24-AA-33 Shielded Room 3 Operating Instructions
- 5.08-RP-18 Best Theratronics Sealed Source Database
- 50.8-RP-19 Radioactive Material Shipments Tracking

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.

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 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 2023.

Table 2: Number of personnel trained in 2023 for each training program offered at BTL.

Training	# of personnel trained in 2023
Crane	16
First-Aid	14
Fork-lift/Pallet Truck	7
Lead control	19
WHMIS	6
Transportation of Dangerous Goods	14
Nuclear Energy Worker/Radiation Safety Nuclear Energy Worker Service Refresher	32

All personnel trained in 2023 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 two 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 2023 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 radiation safety team, 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 one audit in 2023 on the following topics:

- Type II General Inspection

The Type II General Inspection identified seven non-compliances that were of low safety significance.

As described in section 1.4.2.1, there was an internal audit conducted in 2023

There were no reportable events in 2023.

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 2023, 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 26 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	26	1.06	January 1, 2023	1654
<i>Beam on total [hrs]</i>		26	<i>Total workload [Gy]</i>		1654

1.6.1.2 Cyclotron Operations

The operating limits stated in Best Theratronics License Conditions Handbook are related to cyclotron development and testing. Operational information for the cyclotrons in development is provided in the following table.

Table 4: Operational information for cyclotrons 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 (not operational)	The cyclotron is in manufacturing stage (not operational)	The cyclotron is in manufacturing stage (not operational)

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. There were no changes to the facility in 2023 that had an impact on facility safety analysis reports.

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 at BTL.

In 2023, BTL received license approval for a new Class II Nuclear Facilities and Prescribed Equipment License. The licensed activities associated with the new license include development, testing, and servicing of Class II prescribed equipment including linear accelerators and source containing devices.

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 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 2023, all required equipment was 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 manufacturer recommendations where available. Maintenance schedules are maintained for each piece of equipment and are reviewed quarterly for completeness. In 2023, 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 capabilities at the facility, one new machining device was purchased in 2023. It was not put into service in 2023.

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 2023, 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 Levels exceeded in 2023.

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 2023, there were no incidents where radiation exposure action levels were exceeded.

No other radiation related events occurred in 2023. 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 to ensure compliance with internal procedures and regulations. The program was found to be robust.

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 I 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 (14127-13-28.1/14127-8-24.0). 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 2023:

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

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	71	5	66	0	0	0	0
Class II Servicing	<i>Reported in Class II ACR (14127-13-28.1/14127-8-24.0)</i>						
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	21	35	5	2	0	0	0
Class II Servicing	<i>Reported in Class II ACR (14127-13-28.1/14127-8-24.0)</i>						

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

2023 Class 1B NEW'S	Effective	Extremity
Total workers monitored	71	21
Collective dose (mSv)	3.74	8.36
Average dose with zeros (mSv)	0.06	1.19
Average dose, measured only (mSv)	0.11	1.39
Maximum dose received (mSv)	0.61	4.42

The following table provides Class 1B NEW dose data from 2019 – 2023.

Table 7: Average and maximum values of effective and extremity doses for Class 1B NEW employees at BTL between 2019-2023.

Class 1B NEW Effective Doses						
	2019	2020	2021	2022	2023	Regulatory Limit
Total workers monitored	68	73	64	63	71	--
Average dose , with zeros (mSv)	0.04	0.01	0.01	<0.01	0.06	--
Maximum dose received (mSv)	1.00	0.19	0.13	0.03	0.61	50 mSv
Class 1B NEW Extremity Doses						
	2019	2020	2021	2022	2023	Regulatory Limit
Total workers monitored	19	19	16	17	21	--
Average dose , with zeros (mSv)	0.22	0.15	0.06	0.02	1.19	--
Maximum dose received (mSv)	2.51	2.4	0.47	0.13	4.42	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 <0.01-0.06 mSv while the maximum effective doses received have fluctuated between 0.03 - 1.00 mSv; a maximum dose of 1.00mSv was received by an individual in 2019. For extremity doses, the average extremity dose has fluctuated between 0.02-1.19 mSv, with maximum value of 4.42 recorded in 2023. This single incident resulted in an extremity dose reaching an administrative level for one individual monitored under the Class IB licensed.

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 2023.

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 2023.

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 2023.

1.11 Conventional Health & Safety

The Best Theratronics Health and Safety Program is centered around prevention, first aid, investigations, hazardous substance awareness, an employee 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 2023. Health and safety audits of the facility were also conducted monthly; all findings were made into 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 2023:

- Lead pouring ergonomics
- Operation of a new phone and paging system
- Development of a common machine shop H&S checklist
- Controlled access to first aid items

1.11.1.2 Health & Safety Occurrences

In 2023, Best Theratronics documented a total of 8 medical reports, one of which required outside medical attention. These incidents involved bandaging minor cuts, ice and rest, and an injury to a workers hand. The following graph shows a breakdown of the health and safety reports, including lost time incidences.



Figure 1: Distribution of incurred workplace injuries between 2019-2023. 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 was one occurrence of an injury requiring professional medical treatment and one Lost Time Incident in 2023. Lost time frequency and severity rate are provided in Appendix A for reference between 2019-2023.

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 2023.

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 (<i>as part of First Aid training</i>)	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 30.05 MT in 2023 was comparable with 2022. The following table shows a summary of waste disposal.

Table 10: Waste (in MT) that is disposed of into each waste stream between 2019-2023.

Waste Stream	2019 (MT)	2020 (MT)	2021 (MT)	2022 (MT)	2023 (MT)
Waste to Landfill	38.22	34.75	27.3	27.75	30.05
Recycled Paper, Cardboard and Shredded Paper	25.6*	24	25.7	25.9	22.18
Recycled Glass, Aluminum Cans & Plastics	1.5*	1.3	1.0	1	1.23
Recycled Metal	33.8	24.8	27.3	18.45	15
Other Recovered Material	5.63	5.63	5.98	5.63	5.63
Totals	104.82*	90.48	87.3	78.73	74.09
Diversion Rate	63.5%*	62%	69%	65%	59%

*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 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 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 2019 and 2023.

Table 11: Hazardous waste disposed of between 2019-2023.

Waste Code	Description	2019	2020	2021	2022	2023
114C	Other inorganic acid waste	--	--	10 L	--	--
122	Alkaline batteries	--	--	--	--	--
145	Paint	5 kg	80 L	--	150 L	490 L
146	Non-regulated solid waste (fluorescent bulbs)	185 kg	20 kg	--	300 kg	370 Kg
146	Lead contaminated material	70 kg	460 kg	--	--	705 Kg
146	Zirconium alloy scrap	800 kg	800 kg	--	400 kg	--
148	Corrosive liquid (nitric acid, sodium chloride)	--	48 L	45 L	40 L	205L
212	Acetone	620 L	620 L	--	1200 L	205L
212	Antifreeze	10 L	--	--	--	--
212	Non regulated liquid waste (glycol)	--	140 L	--	20 L	30L
213	Petroleum distillates (varsol)	--	--	--	20 L	--
252L	Watery oil	12900 L	900 L	2000 L	3000 L	1000 L
252	PCB ballasts	--	--	--	--	--
252	Machine oil	--	1220 L	--	--	--
253	Emulsified oil	--	--	--	--	--
263	Organic flammable waste	56 L	60 L	200 L	--	--
331	Organic gas aerosols	16 kg	60 kg	40 kg	30 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 2023, a total source activity of 220 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 sources managed from 2019 to 2023. Values above each year indicate the total activity inclusive of Cesium-137 and Cobalt-60 (reference date set to June 30th each year) managed in the respective year.

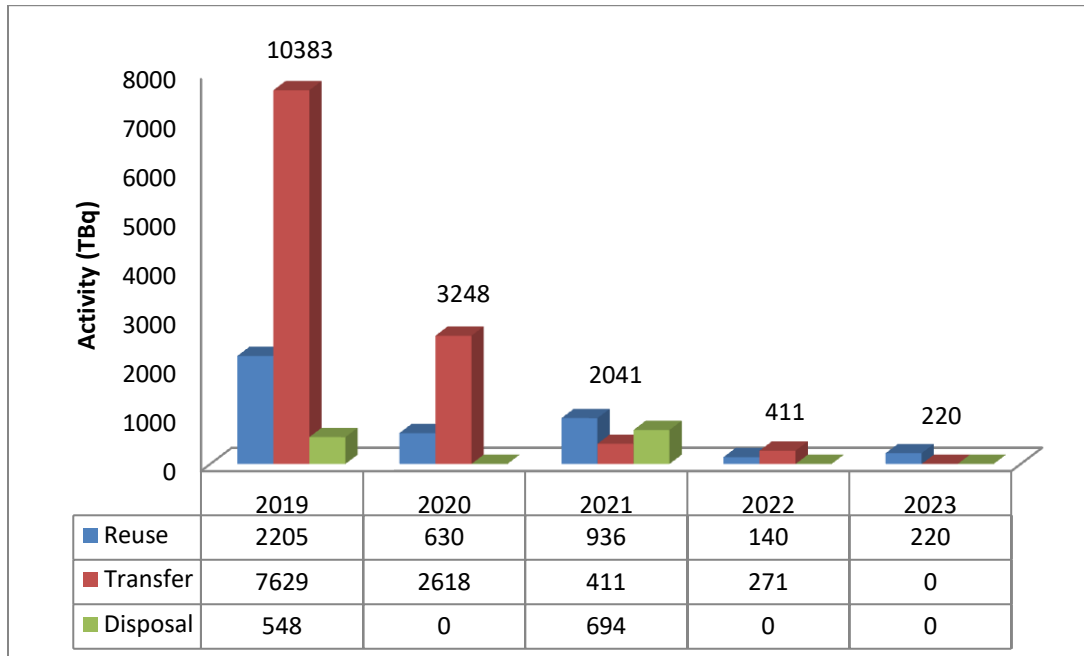


Figure 2: Radioactive waste (TBq) in each of the reuse, transfer, or disposal waste management streams.

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 2023. 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 2023.

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 2023.

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 3, 2023. 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@theratronics.ca email address available on the Best Theratronics website. There were no public inquiries received in 2023. Best Theratronics understands the importance of Indigenous relations, and as such, reached out to the Algonquins of Pikwakanagan First Nation (AOPFN) in January of 2023 by way of their consultation email address. In February of 2023, Best Theratronics met virtually with a representative of AOPFN. At the conclusion of the meeting, AOPFN was invited to come to the Best Theratronics facility, however the invitation was declined. Best Theratronics received no additional inquiries from Indigenous groups in 2023.

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 receive feedback that could be used to improvement to the Public Information and Disclosure program in 2023. 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 2023, Best Theratronics removed 3087 TBq of source activity from its possession. These sources were either reused (220 TBq), transferred (668 TBq) or sold (2199 TBq), in each case, 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 2024.

3 Concluding Remarks

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2023 did not change significantly from previous years. There were no major events, observations, or non-compliances identified during 2023 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 hereby certify that Best Theratronics has been operating in compliance with license NSPFL-14.00/2029, except where otherwise noted.



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2024-02-15

Date

Appendix A – Lost Time Statistics

Table 13: Lost Time and Frequency Rate calculated for 2017-2023.

	2019	2020	2021	2022	2023
# of LTIs	2	0	0	0	1
Frequency Rate	1.37	0.00	0.00	0.00	0.684
Total Missed Days	8	0	0	0	2
Severity Rate	5.47	0.00	0.00	0.00	1.37

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