Annual Compliance and Performance Report 2024

Best Theratronics Ltd.

413 March Road
Ottawa, Ontario, Canada
K2K 0E4

Class 1B License

NSPFL-14.00/2029

Reporting Period: January 1st, 2024 to December 31st, 2024

Report Submitted: April 14, 2025

Report Revision History

Revision	Submission Date	Comments
1	2025-Apr-14	• Original submission addressing only license condition 3.2
2	2025-06-16	• Full report

Table of Contents

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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 reflects information related to the NSPFL-14.00/2029 activities. Note that Best Theratronics experienced a strike by UNIFOR and PSAC in 2024, followed by a complete blockade of the above mentioned two unions. During the blockade, no activities were happening within BTL facility. During the strike but before the blockade, highly limited activities were happening within BTL facility.

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 2024. 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 2024.

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 generated one Management Review Team report in 2024 for the operations in 2023, on August 21, 2024. Best Theratronics held one Management Review Team meeting in 2024 for the operations over 2023, on July 30, 2024. The following topics were discussed:

- Quality policy
- Environmental, Health & Safety Policy
- Quality, Environment and Health & Safety Objectives
- Audits
- Customer Feedback
- Post Market Surveillance
- Complaints
- Process Performance and Product Conformity
- Status of Corrective and Preventative Actions and OFI's
- Other Quality Processes
- 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
- Adequacy of Resources
- 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.

1.4.2.1 Annual Quality Management System Audit

Usually, 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). Due to various issues including the strike and blockade, an annual quality management system audit was not completed in 2024.

1.4.2.2 Organizational Structure for the Management and Control of Licensed Activities

Minor changes to Best Theratronics' organizational structure occurred in 2024. A new Radiation Safety Officer was apointed to replace one that left the company. An interim manager of production planning was appointed to replace one that left the company. A new BMC & Sales and Customer Service Manager was appointed.

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
- Medical Physicist
- Compliance Specialist
- Production Supervisors (2)
- Contract Security Supervisor
- Contract Security Officers

The above mentioned roles were filled by their usual personnel from beginning of 2024 to the start of the strike in May 2024.

After the start of the strike until the start of blockade, operations at BTL were significantly reduced. One supervisor position was vacant in June 2024. The QC supervisor position was vacant as of June 2024, but the QA and Regulatory Manager took over.

After the start of blockade, no BTL staff was present within the building.

1.4.3 Document Changes

Below is a list of the documents that were updated in 2024. 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:

- 108 SC 10 Hazardous Material Transportation Security Plan
- 401 SE 21 Transport Package Checklist (at Customer Site)
- 508 RP 06 External Personal Radiation Monitoring

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 2024.

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

Training	# of personnel trained in 2023
Crane	8
First-Aid	0
Fork-lift/Pallet Truck	4
Lead control	0
WHMIS	17
Transportation of Dangerous Goods	8
Nuclear Energy Worker/Radiation Safety Nuclear Energy Worker Service Refresher	29

All personnel trained in 2024 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, twenty nine 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 2024 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. Weekly RAM meetings were not conducted during BTL's blockade due to labor dispute in 2024.

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

Best Theratronics underwent a Type II general inspection from April 8, 2024 to April 10, 2024. The inspection number was BT-BTL-2024-01. Best Theratronics was working on addressing the non-compliances listed in the report at the end of 2024.

Best Theratronics underwent a type II Security System Inspection on June 25, 2024. The Inspection No. was BTL-2024-02. Best Theratronics was working on addressing the non-compliances listed in the report at the end of 2024.

Best Theratronics underwent a compliance inspection on November 4th, 2024, during the blockade. An Inspector's Order was issued as a result of this inspection. The Inspector's Order was ongoing at the end of 2024.

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 2024, 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 29 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	29	0.92	January 1, 2024	1600
Beam on total [hrs]		29	*Total workload [Gy]*		1600

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 2024 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. Before the start of the strike in May, the monthly tours were performed as usual. From the start of strike to start of blockade, one tour was performed. 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.

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 2024, 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. After start of blockade, monthly checks were not performed, since BTL staff were not able to enter the building.

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 2024, 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.

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 2024, quarterly meetings were held to ensure effective communication of radiation-related work and security concerns. On the fourth quarter of 2024, no meeting was held due to a labor dispute and the resulting blockade of BTL facility.

1.10.1.1 ALARA Action Level Reportable Incidences

There were no Class 1B ALARA Action Levels exceeded in 2024.

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 2024, there were no incidents where radiation exposure action levels were exceeded.

No other radiation related events occurred in 2024. 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 2024:

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	60	50	10	0	0	0	0
Class II Servicing	*Reported in Class II ACR (14127-13-28.1/14127-8-29.0)*						
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	14	10	2	0	0	0	0
Class II Servicing	*Reported in Class II ACR (14127-13-28.1/14127-8-24.0)*						

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

2024 Class 1B NEW'S	*Effective*	*Extremity*
Total workers monitored	60	14
Collective dose (mSv)	0.13	0.22
Average dose with zeros (mSv)	0.00	0.02
Average dose, measured only (mSv)	0.01	0.11
Maximum dose received (mSv)	0.03	0.12

The following table provides Class 1B NEW dose data from 2020 – 2024.

Table 7: *Average and maximum values of effective and extremity doses for Class 1B NEW employees at BTL between 2020-2024.*

	Class 1B NEW Effective Doses					
	2020	*2021*	*2022*	*2023*	*2024*	*Regulatory Limit*
Total workers monitored	73	64	63	71	60	--
Average dose , with zeros (mSv)	0.01	0.01	<0.01	0.06	<0.01	--
Maximum dose received (mSv)	0.19	0.13	0.03	0.61	0.03	50 mSv
	Class 1B NEW Extremity Doses					
	2020	*2021*	*2022*	*2023*	*2024*	*Regulatory Limit*
Total workers monitored	19	16	17	21	14	--
Average dose , with zeros (mSv)	0.15	0.06	0.02	1.19	0.02	--
Maximum dose received (mSv)	2.4	0.47	0.13	4.42	0.12	500 mSv

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 – 0.61 mSv. For extremity doses, the average extremity dose has fluctuated between 0.02-1.19 mSv, with maximum value of 4.42 recorded in 2023.

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 2024.

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 2024.

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 2024.

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 7 occasions during 2024. Health and safety audits of the facility were also conducted monthly before start of strike. One health and safety audit was conducted after the start of strike but before the start of blockade. 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 2024:

- Lead pouring ergonomics
- Development of a common manufacturing shop H&S checklist
- Providing general access to SDS
- Outside source for chemical spills/hazardous waste training

1.11.1.2 Health & Safety Occurrences

In 2024, Best Theratronics documented a total of seven workplace injuries, two of which required outside medical attention. These incidents involved cuts and slips. The following graph shows a breakdown of the health and safety reports, including lost time incidences.

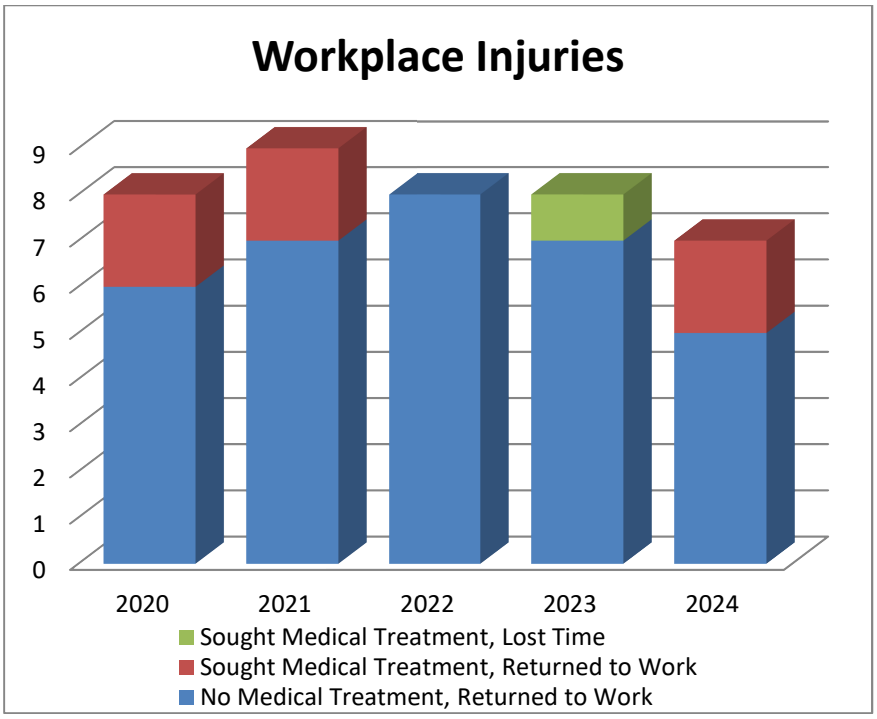

Figure 1: *Distribution of incurred workplace injuries between 2020-2024.*

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. No Lost Time Incident occurred in 2024.

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 2024.

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	Monthly
Radiation Alarms	Quarterly (Klaxon)
Emergency Power	Monthly
Full scale evacuation exercise**	Once every three 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.

*Fire Evacuation Alarm and Drill was not done in 2024, due to the strike and subsequent blockade.

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. ERC meetings usually happen around October of each year. In 2024, ERC meeting did not happen due to the blockade.

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 effectiveness is usually assessed after the annual fire drill. In 2024, due to the blockade, this assessment was not completed.

1.14 Waste Management

Due to disruption caused by strike and blockade, BTL only operated in its normal manufacturing capacity for four months in 2024. Best Theratronics did not have sufficient data to complete the waste management section or provide trend analysis.

1.15 Security

1.15.1 Site Security

Best Theratronics has a 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. Site security was audited by CNSC in June 2024, and the issues of non-compliance were detailed in the report. At the end of 2024, Best Theratronics was working on addressing the non-compliances found during the audit.

After the start of blockade, Best Theratronics had an inspection by CNSC on November 4, 2024. An Inspector's Order was issued as a result of this inspection. At the end of 2024, Best Theratronics was working on addressing the Inspector's Order.

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.

In September 2024, Transport Security Plan was not accepted by CNSC. BTL was working on updating its Transport Security Plan at the end of 2024.

No transport security reportable incidences occurred in 2024.

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) was performed in 2024. It produced no discrepancies between the physical values and the reported values to the CNSC.

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 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. During the strike and subsequent blockade, there was media coverage of BTL. Best Theratronics provided update about the strike and blockade to the general public via its website.

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 improve the Public Information and Disclosure program in 2024. Best Theratronics will continue to monitor its public information program performance.

2.2 Financial Guarantees

The financial guarantee is the subject of a designated officer's order dated November 06, 2024 (e-Doc 7396415). This order remained in effect at the end of 2024.

3 Concluding Remarks

This annual compliance report addresses the licensing conditions set out in license NSPFL-14.00-2029 and the associated Licensing Conditions Handbook.

3.1 Signing Authority Certification

I certify that all statements and representations made in this Annual Compliance Report are true and correct to the best of my knowledge

2025-06-10

Mark Xu **Date**

Radiation Safety Officer

613-591-2100 ext 2762

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