Annual Compliance and Performance Report

2018

Best Theratronics Ltd.

413 March Road
Ottawa, Ontario, Canada
K2K 0E4

Class 1B License

NSPFOL-14.02/2019

Reporting Period: January 2018 to December 2018

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Report Revision History

Revision	Submission Date	Comments
0	March 28, 2018	• Original submission
1	January 23, 2020	• Update to Section 2.7.3 ○ Class 1B NEW dose information

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1 Introduction

Best Theratronics was granted a Class 1B license, number NSPFOL-14.02/2019, on July 1, 2014. Prior to this, Best Theratronics held 3 licenses from both the Class II Directorate and the Nuclear Substance and Radiation Device Directorate. License NSPFOL-14.02/2019 consolidated the previous lessened activities at Best Theratronics' facility and extended the activities to include the testing of cyclotrons.

This annual compliance report (ACR) is submitted with respect to license condition 4.2, containing the following information (Section 4.2 of Best Theratronics' Licensing Conditions Handbook):

- *A brief summary of operation during the year, including changes in organization and operating policies.*
- *A list of documents which are referred into the LCH that have had administrative changes, during the year.*
- *A summary of any safety significant equipment performance.*
- *A summary for the year of any changes to the facility or operating procedures which might affect safety.*
- *A summary and analysis of results of radiation safety measurements performed in the year (both routine and special measurements).*
- *The distribution of annual radiation exposures to personnel at the facility.*
- *A summary of unusual occurrences in which personnel or the public were, or might have been, exposed to radiological or other hazards. This should include a description of action taken as a result of the occurrences.*
- *The activity, volume and composition of hazardous and radioactive waste generated during the year and the method employed for their disposal.*
- *Changes to the emergency procedures or other changes that affected or may affect the facility's emergency response arrangements, training activities, drill and exercise activities, and unplanned events in which the facility's emergency response organization has been tested.*
- *A summary of the outcomes from the management reviews performed at the facility according to the Best Theratronics Quality Manual.*
- *A brief report on the status of the financial guarantee.*
- *The name and signature of the signing authority, certifying that the facility has been operated in compliance with the license except where noted. Include the signatory's function, address and telephone number.*
- *A summary of the workload of the Class II prescribed equipment in various modes of operation during the reporting period.*
- *The total number of hours of various operating modes during the year, including the energies and beam currents used in conjunction with the cyclotron.*

2 Safety and Control Areas

2.1 Management System

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.

Best Theratronics has established several management systems to help guarantee this commitment. These management systems include:

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

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

2.1.1 Management System Overview

Compliance to Best Theratronics' CNSC licence conditions were assessed in-house regarding 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.

2.1.1.1 Annual Internal Audit

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

2.1.1.2 Management Review Team Meeting

Management review team (MRT) meetings are conducted annually to analyze and discuss general trends of the organization. This meeting involves the Quality Management Representative, the Radiation Safety Officer, and management representatives or their delegates from the following departments: compliance, finance, technical services, customer service, engineering, and manufacturing.

Best Theratronics held one Management Review Team meeting in 2018. The following topics were discussed:

- Post-market surveillance

- Self-assessments of management processes must be implemented
- On-going concerns from the Health & Safety committee regarding roof leaks and chemical spill program

The overall quality system and objectives were discussed, reviewing the quality system to ensure that each objective remains applicable and effective. Below are the objectives discussed during the meeting and a summary of the year-end results:

Objectives	Target	2018 Results
Reduce product rejected at incoming inspection	Average, less than 10 per month	MET – Average: 6.5/month
Reduce product returned from field	Average, less than 4 per month	MET – Average: 2.3/month
Reduce deviation reports waiting for disposition	Less than 100	MET – 74
Reduce design change waiting for implementation	Less than 50	MET – 26

Several environmental objectives were also discussed in this meeting and are provided in Section 2.11.2.

2.1.1.3 CNSC Management Inspection Update

The CNSC conducted an inspection on the Management Systems in June 2017, resulting in 4 action notices and 6 recommendations. BTL opened 8 CAPAs in response to these observations, where only 1 CAPA was left to close at the end of 2018. The last CAPA relates to implementing a system to control, approve, and ensure current production documentation in addition to providing easy access to those referencing the material. Implementation of this system is in progress, where implementation verification in the future is required to successfully close the CAPA.

2.1.2 Organizational Structure

In 2018, minor changes in BTL's organizational structure occurred. The original position of Director of Human Resources and Payroll became vacant in September of 2018. Shortly after, the new role of Director of Human Resources & Legal Affairs was filled. The notification of retirement plans of the Radiometric Measurement Specialist, a position part of the radiation safety team, was provided in 2018. This individual has remained on contract, ensuring proper overlap training has been provided to the internal hire taking on those responsibilities within the company.

2.1.3 Self-Assessments on Management System

Implementation of a procedure for self-assessment of management process is currently ongoing.

2.1.4 Document Changes

Below is a list of the documents references in Best Theratronics License Conditions Handbook that were updated in 2018. Updates to such documents reflect changes in regulation, audit observations, and corrective action implementation. Updated versions of documents supporting the Class 1B licence submitted to the CNSC as per requirement in the Licence Conditions Handbook.

Document Number	Document Title
5.00-QA-00	Quality Manual
5.00-QA-29	Device Design Risk Management
5.08-ERP-01	Site Emergency Response Plan
5.08-RP-01	Radiation Emergency Response Plan
5.08-RP-04	Management of Depleted Uranium Radioactive Material
5.08-SE-00	Environmental Health & Safety Policy
5.08-SE-01	Environmental, Health Safety Responsibilities
5.08-TDG-01	Transport of Radioactive Material

2.2 Human Performance Management

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

2.2.1 Systematic Approach to Training Program

A CNSC inspection at the end of 2015 revealed the necessity to implement a Systematic Approach to Training (SAT) for positions where *the "consequence of human error poses a risk to the environment, the health and safety of persons, or to the security of the nuclear facilities and of nuclear substances".* This type of training involves identifying qualifications and competencies related to each job in order to provide the worker with a comprehensive training program. If ever an employee's roles or responsibilities change, the training program is reviewed.

2.2.2 Training Programs

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

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

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

In 2018, two major training updates were imposed:

1) Lead control program – Following an assessment of internal procedures and current operations, changes were made to the lead control program. Updates to internal procedures were required and training administered.
2) Class 7 TDG Training – A third-party company was hired to provide a refresher and updated training on Class 7 transportation of dangerous goods.

2.2.3 Training Effectiveness Evaluation

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

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

For training courses that have a graded learning assessment in order for completion, a grade of at least 70% must be achieved to pass the course. The following table identifies the number of employees trained in 2018.

Training	# of personnel trained in 2018
Chemical Spill	4
Crane	16
Emergency Response	2
First-Aid	1
Fork-lift	3
Lead control	43
WHMIS	8
Transportation of Dangerous Goods	16
Nuclear Energy Worker/Radiation Safety Nuclear Energy Worker Service Refresher	25

All personnel trained in 2018 successfully passed the end of course evaluations. Training adaptations are made to ensure all training material and its delivery can accommodate varying learning styles when necessary.

2.2.3.1 Lead Control Update Training

Updated lead control procedures, as observed by supervisors and Health & Safety Committee members, have determined training was adequately delivered and practiced. It is expected that the lead control update will be fully implemented following the scheduled employee information session in 2019.

2.2.3.2 Transportation of Dangerous Goods

All individuals who attended the training session successfully passed the evaluation. Training effectiveness will be continuously monitored such that class 7 transportation incidences do not occur.

2.2.3.3 Radiation Safety Training

During the reporting year, twenty-five employees successfully completed Nuclear Energy Worker radiation safety training. This grouping includes facility personnel who required initial NEW training and refresher training, in addition to Best Theratronics' service personnel, who complete radiation safety refresher training annually. In 2018, no radiation related incidences occurred where the root cause was determined to be due to lack of training.

2.3 Operating Performance

As an ISO 9001:2008 certified facility, Best Theratronics operating performance program integrates operating experience, adequacy of procedures, and the conduct of licensed activities.

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

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

2.3.1 Licensed Activities Audits Overview

The CNSC conducted audits in 2018 regarding:

1) Fitness for Service
2) Radiation Protection
3) Operating Performance
4) Conventional Health and Safety
5) Human Performance Management
6) Physical Design
7) Physical Inventory Taking of Safeguarded Material

All observations were addressed with the opening of CAPAs. The following table provides a summary of the audit observations and status as of December 2018.

Inspection	Observations	Status
• Fitness for Service • Radiation Protection • Operating Performance • Conventional Health and Safety • Human Performance Management • Physical Design	Directives 3 Action Notice 1	Closed – All observations regarding this inspection have been closed.
• Physical Inventory Taking Evaluation of Safeguarded Material	Actions 4	Closed – All actions arising from follow-up items have been completed.

2.3.2 Operating Limits

The basis of obtaining the Class 1B License for the Best Theratronics facility was to manufacture and test cyclotrons for the medical and research industries. In 2018, Best Theratronics operated within the limits outlined in the Class 1B license.

2.3.3 Reportable Events

In 2018, the following incidences were reported to the CNSC. Proper notification to CNSC was made and follow-up investigations were conducted when necessary:

May 24 - During roof repairs of the Best Theratronics building a small, localized fire was extinguished. Smoke entered the ventilation system of the building and set off the fire alarm. The building was immediately evacuated, while the Best Theratronics emergency response team and the local fire department responded. The event was resolved quickly. There was no impact to the health and safety of the employees, public, or to the environment from this event.

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

October 2 – During the source loading process of a prototype teletherapy head in Cell 4, the hardware securing the end plug failed. As a result, part of the source drawer had exited the other end of the head and source loaders were exposed to radiation higher than our internal action levels. The source was immediately pulled back into the F147 transport container and safely stored. The work was stopped and the RSO was called in to assess the situation. The F147 container was safely detached from the prototype head and placed in storage while the prototype head was quarantined pending investigations.

October 29 – A loaded transport container returning from a source removal in Pakistan was discovered to have incorrect Transport Index (TI) labels prior to its arrival in Canada. The Pakistani forwarder was

notified of the error and was instructed to stop the shipment until the labels were corrected. However, the shipment continued and was received in Montreal. The labels were corrected prior to transport within Canada, CNSC was notified immediately of the incident, and communication of the issue and concern sent to those in Pakistan involved.

November 29 – During the installing of heating units on the roof of the Best Theratronics facility, a sprinkler water pipe was hit and snapped off causing a loss in water pressure, setting off the fire alarms. Employees evacuated the building and the fire department responded. The building was deemed safe for employees to re-enter the building shortly after. The office area below the pipe break became flooded. Areas containing radioactive material were checked and no contamination was detected.

2.4 Safety Analysis

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

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

2.4.1 Facility Safety Improvements

The facility is toured and inspected by two members of the Health & Safety Committee on a monthly basis. Health & Safety Committee observations and employee concerns were mainly related to the roof of the facility. In 2018, roof replacement commenced and have been planned to be continued into 2019.

2.5 Physical Design

A design change process for the control, management, evaluation, release, completion and implementation of changes to Best Theratronics drawings and documents is implemented.

Two modifications to the physical design of Best Theratronics' building or property occurred in 2018:

1) Replacement of the Best Theratronics roof
2) Upgraded replacement to several building cooling units on the roof of the facility

Due to a break in one of the fire sprinkler pipes in November of 2018, remediation and renovation of the affected office area was initiated at the end of 2018.

2.6 Fitness for Service

In accordance with Best Theratronics Class 1B license, a fitness for service program is implemented and maintained.

2.6.1 Radiation Monitoring Equipment

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. 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.

In 2018, there were instances where equipment repairs were required, but coincided with other device's calibration due dates. This coincidence can cause burden on usage of equipments. To overcome this challenge, BTL has purchased extra devices and will continue to monitor this closely in the future.

2.6.2 Manufacturing Equipment

Preventative maintenance on production equipment is performed at regularly scheduled intervals determined by the usage, operation history, and manufactures' recommendations where available. Maintenance schedules are maintained for each piece of equipment and are reviewed quarterly for completeness. In 2018, there were no issues related to the operation of any of the manufacturing equipment.

2.6.3 Facility

Best Theratronics assess its facility on an on-going basis through monthly Health & Safety audits, general review of the facility and as concerns are presented from employees. Due to employee concerns raised about the state of the facility's leaking roof, roof replacement initiated in 2018.

2.7 Radiation Protection

2.7.1 ALARA Principle Application

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

The Radiation Safety & Security Committee (RSSC) meets regularly to review radiation-related safety matters at Best Theratronics. In 2018, security personnel involvement within committee meeting discussions was initiated and the original name, Radiation Safety Committee (RSC), was changed to include Security. On a monthly basis, the now called Radiation Safety & Security Committee (RSSC) meet to discuss concerns and identify improvements to the overall safety and security culture at BTL. In 2018 monthly meetings were held to ensure effective communication of radiation-related work and security concerns.

2.7.2 Radiation Protection Program Performance

Following an audit on the Radiation Protection Program in 2016, administrative levels of effective and equivalent doses were decreased to provide a better indication of the application of the program. In addition, in-house wipe test and surface contamination trigger levels were reduced. These levels were decreased to better reflect current operations. In 2018, there were two incidents where radiation exposure action levels were exceeded (See Section 2.7.3.1).

2.7.3 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 BTL's 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 *(14127-3-18/14127-8-19).* On rare occasions, qualified Class II Servicing employees conduct Class 1B Licensed tasks. All NEW doses associated with any Class 1B work is reported in this section as Class 1B NEWs.

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

Work Group	**Total Monitored**	**Dose Range (mSv)**					
Effective Dose		**<0.01**	**0.01-1.00**	**1.01-5.00**	**5.01-10.00**	**10.01-20.00**	**>20.01**
Class 1B NEWs	68	54	12	1	1	0	0
Class II Servicing	12	*Reported in Class II servicing licenses ACRs (14127-3-18/14127-8-19)*					
Extremity (Maximum between hands)		**<0.01**	**0.01-1.00**	**1.01-5.00**	**5.01-10.00**	**10.01-20.00**	**>20.01**
Class 1B NEWs	18	11	3	2	1	1	0
Class II Servicing	12	*Reported in Class II servicing licenses ACRs (14127-3-18/14127-8-19)*					

Based on the dose distribution, Best Theratronics operates with occupational doses below the maximum allowable NEW effective dose of 50 mSv in one dosimetry year and 500 mSv per year for extremities. The following table provides the dose data for 2018:

2018 Class 1B NEWS	*Effective*	*Extremity*
Total workers monitored	68	18
Collective dose (mSv)	11.06	25.36
Average dose , with zeros (mSv)	0.16	1.41
Average dose, measured only (mSv)	0.79	3.62
Maximum dose received (mSv)	8.65	13.51

The following table provides Class 1B NEW dose data from 2014 – 2018.

Class 1B NEW Effective Doses

	2014	*2015*	*2016*	*2017*	*2018*
Total workers monitored	61	62	60	68	68
Average dose , with zeros (mSv)	0.00	0.01	0.03	0.02	0.16
Maximum dose received (mSv)	0.11	0.20	0.98	0.47	8.65

Class 1B NEW Extremity Doses

	2014	*2015*	*2016*	*2017*	*2018*
Total workers monitored	18	16	17	16	18
Average dose , with zeros (mSv)	0.21	0.00	0.09	0.07	1.41
Maximum dose received (mSv)	3.70	0.00	1.10	0.50	13.51

Doses reported in previous ACRs, between 2014 and 2016, presented dose data which included service technicians monitored under a separate BTL Class II servicing license. For comparison, the following tables show the comprehensive data, including doses received by the service technicians under the Class II servicing license, over the past 5 years. It should be noted that doses received by service technician are a combination of both Canadian and international service work.

Company Wide Effective Doses

	2014	*2015*	*2016*	*2017*	*2018*
Total workers monitored	74	76	73	77	77
Average dose , with zeros (mSv)	0.03	0.05	0.08	0.11	0.20
Maximum dose received (mSv)	0.46	0.85	2.28	5.30	8.92

Company Wide Extremity Doses

	2014	*2015*	*2016*	*2017*	*2018*
Total workers monitored	30	32	31	25	27
Average dose , with zeros (mSv)	0.19	0.16	1.70	0.71	1.34
Maximum dose received (mSv)	3.70	2.10	29.90	11.20	14.94

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

2.7.3.1 ALARA Action Level Reportable Incident

An exposure incident occurred at the BTL facility where reportable action levels were exceeded by two Class II service personnel conducting tasks covered under the Class 1B licence. Doses were acquired while preparing the test of a prototype teletherapy head with a radioactive source. The action level limits and acquired doses are provided in the table below. As a precaution the service technicians conducting this work were provided with spare TLDs, in addition to their assigned TLDs, which has allowed for this dose information to become available.

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

These service personnel were trained and qualified to push a drawer containing a radioactive source from a shielded transport container into the teletherapy head. This work is conducted in order to complete a radiation survey to help identify potential shielding flaws caused during the manufacturing process of the prototype head. This exposure incident occurred when hardware (tungsten screws) securing the end plug of the head broke during the drawer push, causing part of the source drawer to exit out of the other end. The source drawer was immediately pulled back into the transport container and into a safe state.

During the incident, the source itself did not exit the therapy head. However, due to the strength of the source, interim source location, and the positioning of the service technicians, doses above BTL's action levels were acquired. Work was stopped and a CAPA was raised to fully investigate the root cause of the incident. As a result the design of the prototype head and the source loading procedure were revaluated and training was administered. No adverse health effects were observed and work duties were adjusted to minimize radiation work for the two service technicians.

2.7.4 Routine Radiation Protection Assessments

2.7.4.1 Facility Monitoring

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.

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

2.7.4.2 Receipt of Radioactive Material

When radioactive shipments are received at Best Theratronics, the radiation field is measured to ensure the packages are within the Transport of Dangerous Good Regulations. Additionally, all receipts that contain radioactive sources are wiped for surface contamination to ensure contamination events are isolated prior to unloading.

In 2018, no incidences where transport package radiation surveys exceeded regulatory limits were observed or package surface contamination were detected.

2.7.5 Radiation Protection Program Effectiveness

Annually, an internal audit of the radiation protection program is conducted. The internal audit for 2018 reveals that minor procedural updates were required (OFI#190102) in order to reflect current operations.

Considering no radiation related events were linked to insufficient radiation protection procedures, the training program has proven to be adequate. Best Theratronics continues to improve training material and presentations to better suit varying learning methods.

2.8 Conventional Health & Safety

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

2.8.1 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 9 occasions during 2018. Health and safety audits of the facility were also conducted monthly with all findings actioned and recorded in the meeting minutes. At the end of 2018, there were 3 action items left open to be completed in 2019.

2.8.2 Conventional Health & Safety Program Improvements

As a result of workplace observations and concerns discussed within the Health & Safety Committee meetings, the following items were actioned on in 2018:

- Chemical spill team response training and spill kit inventory identified
- Replacement of the facility roof initiated
- Hearing tests conducted
- Fixture designed and manufactured to assist with lifting heavy items
- Notifications distributed reminding workers to maintain safe and clear work spaces
- Lead control program updated to include the purchasing of dedicated lead cleaning tools purchased for machine shop, procedural updates and training. Follow-up surface wipe testing and analysis was conducted by a third party to confirm lead control practice improvements. An employee information session is scheduled to take place in 2019.
- Design and manufactured a platform for safer pouring of oil
- Effectiveness review of winter salting of the Best Theratronics parking lot
- A third-party contractor was hired for the safe removal of asbestos containing material in the affected area. This renovation was caused by a flood in an office area due to a break in the fire sprinkler pipe

2.8.3 Health & Safety Occurrences

In 2018, Best Theratronics documented a total of 11 medical reports, 5 of which required outside medical attention. These incidents caused cuts or scrapes, pinches, heat burn, slips on ice and strains. The following table shows a breakdown of the health and safety reports, including lost time.

Year	Reports	On-site treatment	Off-site treatment	Lost days
2018	11	6	5	12
2017	9	6	3	22
2016	12	8	4	3
2015	11	9	2	1
2014	18	16	2	1

In all instances, medical reports were reviewed and corrective actions were introduced if appropriate. A summary of 2018 job related injuries requiring outside treatment is shown below. The fifth report requiring off-site treatment was a slip in the parking lot due to winter icy conditions.

Injury	Cause	Treatment	Lost Days
Neck pain	Roll up trailer door of contracted transport carrier's truck fell down onto driver	Driven to hospital for a neck scan	N/A
Cut to top of nail	Drill twisted when it broke through the material and finger was caught between the frill & the material	Ice pack, disinfect, bandage	0
Cuts & abrasion to right side of stomach area	Grinder caught coverall and was pulled	Sterilized & cleaned, gauze applied	1
Lower back strain	Applied upward force to a large pipe wrench	Chiropractor visit	11

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.

2.9 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.

BTL 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 BTL's manufactured medical devices is contained within a welded stainless steel encapsulation. The loaded transport container or loaded self-shielded irradiators are stored within a radiation designated area within the facility. All radioactive material are double encapsulated sealed sources or depleted uranium, therefore there are no releases into the environment and do not pose as an exposure hazard to the public.

All aspects of BTL's operations that may have an impact on the environment are identified, evaluated, recorded and reviewed periodically. There were no environmental release incidences in 2018 to report.

2.10 Emergency Management and Fire Protection

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

2.10.1 Emergency Preparedness 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 November 29, 2018. The following action items were discussed:

1) Emergency response procedural updates
2) Preparation of full-scale evacuation
3) Fire prevention officer designation
4) Security response regarding unauthorized access scenarios

2.10.2 Emergency Preparedness Program Performance

Elements of the BTL's Emergency Response Program are tested periodically as indicated below:

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

A full scale evacuation exercise was planned originally to take place in November 2018. Due to weather conditions his full scale evacuation has been postponed to April 2019 and will include participation of BTL employees with Ottawa fire, paramedic, and police services.

2.10.3 Fire Protection Program Performance

Following a fire inspection audit from the CNSC in 2015, BTL has completely updated its fire hazard analysis and fire protection program. Since then, Best Theratronics has implemented various measures to improve fire safety at the workplace. Elements of the fire protection program at BTL include:

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

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

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

2.10.4 Fire Protection Program Effectiveness

During BTL's annual fire drill exercise in Oct 2017, it was realized that the Fire Warden list was non-current. The list has since been updated and fire warden training was administered earlier in 2018. Fire warden training and the list review of designated individuals are conducted periodically.

Overall in 2018, the Fire Protection Program and equipment was proven to be satisfactory. Due to the retirement of the Fire Prevention Officer, the Fire Marshall took over their position and a new Fire Marshall was appointed.

2.11 Waste Management

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

2.11.1 Non-Radioactive Hazardous Materials

An internal waste audit was performed in December 2017 and revealed the continued decrease in land fill generation from Best Theratronics operations. The landfill waste stream of 39.5 MT in 2018 increased from 2017 by 17.9 MT. This is likely due to the construction project to redo 55% of the roof in the year 2018.

Overall diverted material is largely the result of recycled scrap metal. The increase from 2017 is likely due to a combination of slight increase in the external beam therapy system production and the fabrication of parts for a 70 MeV cyclotron.

Waste Stream	2015	2016	2017	2018
Waste to Landfill	44	34	21.6	39.5
Recycled Paper, Cardboard and Shredded Paper	24	20	20	20
Recycled Glass, Aluminum Cans & Plastics	0.9	0.7	0.7	0.7
Recycled Metal	55	39	7.7	12.13
Other Recovered Material	5.6	5.6	5.6	5.6

Totals	129.5	99.3	55.6	77.93
Diversion Rate	66%	66%	61%	49%

BTL's hazardous waste management program is responsible for the proper disposal wastes such as chemical waste, electronics, paint, batteries, construction/demolition waste, and PCB containing light ballasts and fluorescent light bulbs. The following table provides the amounts of hazardous waste removed between 2015 and 2018.

Waste Code	Description	2015	2016	2017	2018
112	Lead acid batteries	10 kg	5 kg	--	--
122	Alkaline batteries	45 kg	--	--	70 kg
146	Filters with lead dust	--	48 kg	--	--
146	Florescent bulbs and HID lamps	306 kg	150 kg	140 kg	65 kg
146	Zirconium alloy scrap	1300 kg	225 kg	--	--
148	Inorganic Acid Oxidizer	16 L	88 L	--	16 L
212	Acetone	820 L	1015 L	600 L	530 L
252	PCB ballasts	170 kg	--	40 kg	10 kg
252	Machine Oil	2050 L	1965 L	1980 L	1920 L
263	Organic Flammable waste	960 L	200 L	245 L	340 L
331	Organic Gas Aerosols	48 L	8 L	20 kg	73 Kg
253	Emulsified oil	--	--	--	1000 L
	Mercury	1 kg	--	--	--

2.11.2 Radioactive Hazardous Materials

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

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

In the 2018 MRT another environmental objective was added:

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

The contract for cobalt disposal was finalized in 2018.

2.11.2.1 End-of-Life Management Program

Best Theratronics has an end-of-life management program for the exhausted and returned sealed sources. These sources are reused, recycled, re-encapsulated, transferred to other manufacturers, or disposed of as appropriate. In 2018, a total source activity of 2548.4 TBq was disposed of or recycled according to Best Theratronics' end-of-life management program. The table below indicates the activity breakdown of how these sources were managed in 2018.

Management	Co-60	Cs-137	Notes
Reuse	768.8 TBq	267.2 TBq	Source capsules were reused in Best Theratronics self-contained irradiators and teletherapy machines.
Transfer	2548.1 TBq	--	Sources were shipped to another source supplier and manufacturer for recycling purposes. Co-60 sources will be cut open and the radioactive material reused in the manufacturing of new sources for other purposes.
Disposal	--	0.3 TBq	Sources were transferred to Canadian Nuclear Laboratories in Chalk River, ON for long-term storage and disposal.
Total Activity	3316.9 TBq	267.5 TBq	

2.11.2.2 Depleted Uranium Inventory

The depleted uranium inventory at BTL originates from returned components of legacy teletherapy units and other legacy items. This inventory is temporarily stored at BTL awaiting proper disposal through the end of life management program. No disposal or recycling of depleted uranium occurred in 2018.

BTL is actively seeking opportunities to recycle/dispose the depleted uranium in the next reporting period.

2.12 Security

2.12.1 Site Security

Best Theratronics has an adequate security program in place, where the site-security plan is reviewed on a regular basis. No security-related events have occurred in the year 2018.

Concerns regarding the security of radioactive material have become an important topic in recent years. As such, the Radiation Safety Committee (RSC) invited the involvement of security personnel within committee meeting discussions in 2018. On a monthly basis, the now called Radiation Safety & Security Committee (RSSC) meet to discuss concerns and identify improvements to the overall safety and security culture at BTL.

2.12.2 Transport Security

To further ensure the security of devices or components containing radioactive material during transit, limited and approved carriers of radioactive material are contracted. These carriers are audited annually to ensure their procedures comply with current regulations and Best Theratronics' security policies. Transportation security plans of contracted radioactive material carriers have been audited to be adequate. No transport security related incidences occurred in 2018.

2.12.3 Personnel Security

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

2.13 Safeguards and Non-proliferation

Best Theratronics possess and temporarily stores depleted uranium from legacy teletherapy units destined for disposal. Accounting and reporting of BTL's inventory of depleted uranium and other materials containing depleted uranium are completed annually as per REGDOC-2.13.1 *Safeguards and Nuclear Material Accountancy*, published in February 2018. BTL conducted a gap analysis and successfully implemented changes to its program to be compliant by the end of 2018.

2.13.1 Physical Inventory Taking

During the 2018 Physical Inventory Taking (PIT) in September, a minor inventory discrepancy was found and was immediately reported and reconciled with the CNSC.

Furthermore, the CNSC completed a Physical Inventory Taking Evaluation (PIT-E) at BTL. A PIT-E is an evaluation by the CNSC of a licensee's readiness for a Physical Inventory Verification (PIV) conducted by the International Atomic Energy Agency (IAEA). Four items were observed regarding report documentation and corrections were submitted immediately. As such, CNSC confirmed that BTL was adequately prepared for a PIV by the IAEA, if chosen.

2.14 Packaging and Transport

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

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

3 Other Matters of Regulatory Interest

3.1 Licensee's Public Information and Disclosure Program

3.1.1 Public Inquiries and Media Coverage

The public is encouraged to contact Best Theratronics for more information regarding concerns through the info@theraronincs.ca email address available on the Best Theratronics website. There were no public inquiries received in 2018.

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 BTL's CNSC licences (servicing and Class 1B)
- Notifications of licence renewals
- Annual reports on lead (and its compounds)

- Notification of false alarms and building evacuations
- Incidents occurred where any reporting or action level was exceeded

3.1.2 Community Information Session

On May 12th, BTL hosted a community information session. With the hope of addressing any public concerns about BTL, this event provided a brief overview of our operation, business direction, and internal practices to ensure public safety. Invitations were mailed to surrounding neighbourhoods, posted in the newspaper and on the company website, and through direct contact. A copy of the flyer/newspaper ad is provided in Appendix B. Following the presentation and question period, attendees were asked to fill out a survey (See Appendix C) on what was learnt by attending the session. A summary of the finding from the survey are provided below:

- Direct email resulted in a higher attendance than any other invitation method
- The majority attended to better understand what Best Theratronics does and learn about the products that Best Theratronics manufactures
- The level of understanding of Best Theratronics operations increased following the presentation
- The majority of attendees ranked Best Theratronics' safety processes to protect its employees, the community and the environment 4 out of 5.
- The majority of attendees were residents of Kanata

3.1.3 Future Public Information Program Plans

Best Theratronics will continue to monitor its public information program performance. BTL plans to continue hosting public information sessions and facility tours.

3.2 Financial Guarantees

As of July 2017, BTL has estimated decommissioning costs to be $1.80 million. This includes a 25% contingency amount. Since the beginning of the licensing period until December 2018, BTL has disposed 96 Co60 sources with a total activity of 6,338 TBq and 67 Cs137 sources with a total activity of 1,882 TBq.

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

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

3.3 Other Facility-Specific Matters of Regulatory Interest

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

3.4 Class II Workload

The R&D Class II prescribed equipment located in Cell 4 (T1000, S/N 4) was operated for a total 111 hours, where all hours were related to research. Operational information is provided in the table below.

Source Serial Number	Source Type	Beam On Time [hrs]	Output at 1m [Gy/min]	Output date reference	Total work load (Gy)
S-6298	Co-60	64	1.87	March 2017	7180.8
S-5984	Co-60	47	0.94	June 2018	2650.8
			Total work load in 2018		*9831.6*

4 Summary

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2018 did not change significantly from previous years. There were no major events, observations, or non-compliance identified during 2018 that would affect the safety and security of personnel, the public, or the environment.

On September 10, 2018, BTL submitted an application to renew the Class 1B operating licence, expiring on June 30, 2019. On November 7, 2018, a request to amend the application extending the licensing period to 10 years was submitted. On December 21, 2018, BTL expressed to the CNSC staff the desire to revert back to the same licences prior to Class 1B approval. Further discussions with the CNSC staff were followed by BTL's applications for Class II facility and NSRD licenses submitted on February 15, 2019. Although BTL has implemented and maintained programs to continue with Class 1B regulatory oversight for another licensing period, upon further review BTL concluded that future operations would not require Class 1B licensing. Considering future plans of limiting testing of all manufactured cyclotrons to 1 MeV, BTL believes that operations can adequately be regulated under Nuclear Substance and Radiation Devices (NSRD) and Class II facilities licences as they were from 2008 to 2014 prior to Class IB License. BTL has submitted applications to the CNSC for these licences, awaiting approval prior to the expiry of the Class 1B licence (June 30, 2019). 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 NSPFOL-14.02/2019 and the associated Licensing Conditions Handbook.

5 Signing Authority Certification

I herby certify that Best Theratronics has been operating in compliance with license NSPFOL-14.02/2019, except where otherwise noted.

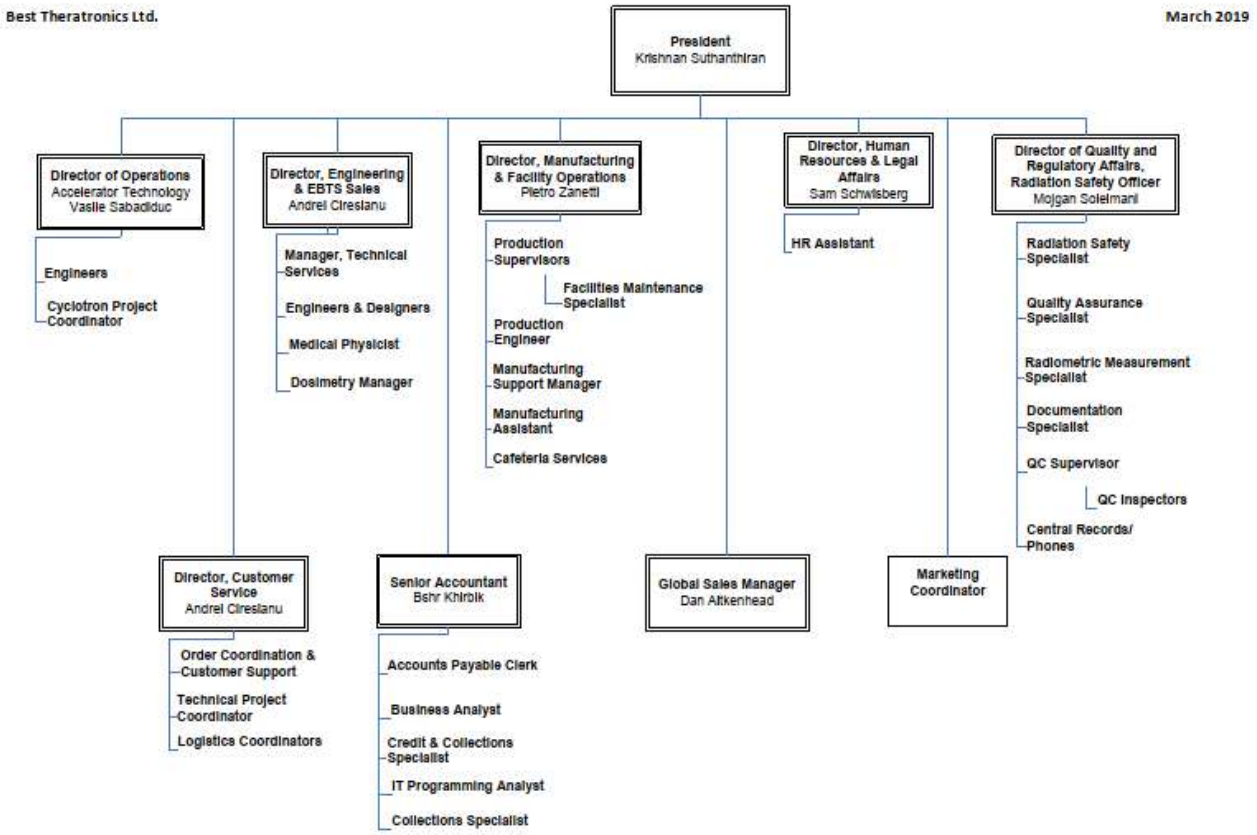
<Signature on file>

Mojgan Soleimani

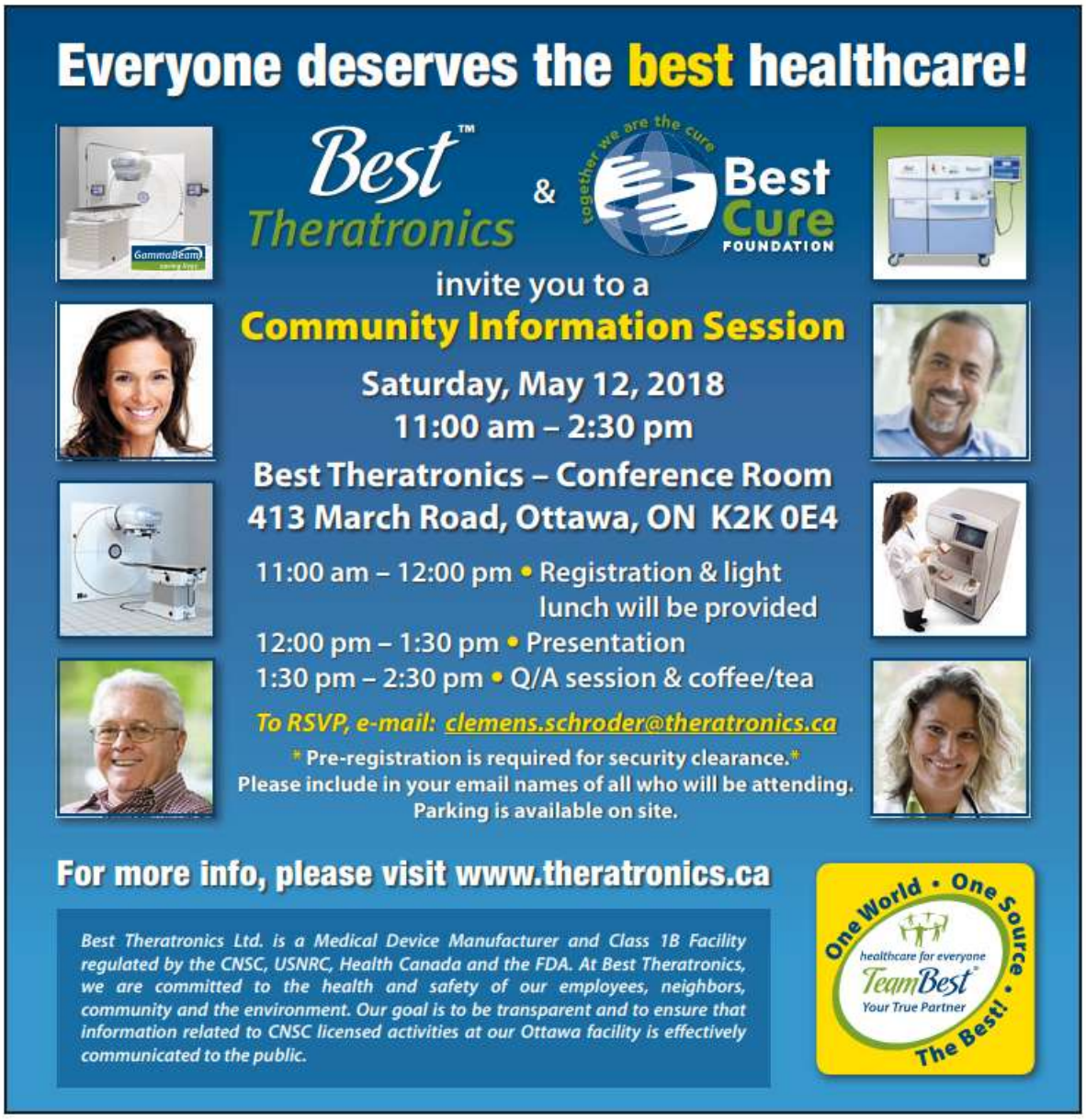
Director of Quality and Regulatory Affairs, RSO

613-591-2100 ext 2766

Appendix A – Organizational Chart



Appendix B – Community Information Session Flyer/Ad



Appendix C – Community Information Session Survey

Community Information Session

- May 12, 2018 -

1) **How did you hear about the Community Information Session?**

   a. Mailed flyer (Canada Post)
   b. Newspaper (Ottawa Citizen)
   c. Company website (www.theratronics.ca)
   d. Email outreach
   e. **Other (Please specify):** _____

2) **Why did you decide to attend the Community Information Session?**

   a. Understand what Best Theratronics does
   b. Learn about products that Best Theratronics manufactures
   c. I had concerns about Best Theratronics operations
   d. **Other (Please specify):** _____

3) **Were your questions answered?**

   a. Yes
   b. No
   c. N/A

4) **Rank your understanding of Best Theratronics before the information session.**

   1 – low 2 3 4 5 – high

5) **Rank your understanding of Best Theratronics following the information session.**

   1 – low 2 3 4 5 – high

6) **How would you rank Best Theratronics' safety processes to protect its employees, the community and the environment?**

   1 – low 2 3 4 5 – high

7) **Did you find this information session useful?**

   Yes No

8) **How would you classify yourself?**

   a. Resident of Kanata
   b. Work in Kanata
   c. Representative of the City of Ottawa
   d. Community association representative: _____
   e. Other **(Please specify):** _____