



Annual Compliance and Performance Report

2017

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

Class 1B License

NSPFOL-14.02/2019

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3	August 15, 2018	<ul style="list-style-type: none">• Update to Section 2.7.3 (<i>ref: July 27, 2018 email</i>)<ul style="list-style-type: none">○ Page 14: Table – 2017 Building Personnel Doses○ Page 15: Table – Whole Body & Extremity Doses

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1 Introduction

Best Theratronics was granted a Class 1B license, number NSPFOL-14.01/2019, 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-14.01/2019 consolidated the previous licensing activities at Best Theratronics' facility and extended the allowable activities to including 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, 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 Audit 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.

An annual internal audit was completed by a third-party auditor, regarding the overall quality management system at Best Theratronics, to help determine the suitability and effectiveness of the implemented quality system. The internal audit completed in 2017 revealed that the quality management system is functioning efficiently and effectively, verifying Best Theratronics' compliance with applicable Canadian medical device regulations.

Three external party audits were also conducted in 2017. These audits included two international audits, assessing the quality system and manufacturing practices against regulations for medical devices in Brazil and the United States. The third external audit evaluated the effectiveness of the management system at Best Theratronics for ISO certification. The third audit reviewed Best Theratronics' practices in accordance with the company objectives, policies and procedures, the management standard, requirements of ISO 13485:2003, requirements of ISO13485:2016, and requirements of ISO 9001:2015. Ten minor non-conformities were observed from this audit resulting in the following actions:

- Document changes reflecting additional requirements and clarification of definitions
- Implementation of a scaling system based on risk into CAPA system
- Design change implementations are verified prior to closure
- Decision tree application towards management of customer complaints stemming from service records

- Establishing a new procedure to address the communication requirements for internal and external communications relevant to the quality management system

All mentioned actions were addressed within the following few months after the 2017 audit. The effectiveness of actions conducted as a result of the CAPAs are assessed six months following the closure date.

2.1.1.1 CNSC Management Inspection

The CNSC conducted an inspection on the Management Systems in June 2017, resulting in 4 action notices and 6 recommendations. The closure of all observations is expected to be completed by April 30, 2018. The following points relate to the outstanding action notice and recommendations stemming from this inspection:

- Cyclotron development and design activities, occurring at Best Theratronics' Vancouver office, are required to follow the same management system requirements as the Kanata office. It was found that an internal audit of the Vancouver office was to be conducted to fulfill this requirement. This has been scheduled to take place in 2018.
- Uncontrolled, handwritten aids were discovered on a manufacturing workstation during this inspection. In an effort to ensure work is carried out using controlled, approved and current instructions a network scanner and tablet system was to be implemented to capture the information and make it readily available to workers.
- In order to measure the performance and effectiveness of management processes and the promotion of improvement, it was recommended to track and analyze "opportunities for improvement" suggestions. A mechanism to track and analyze these suggestions, to look for similar and occurring trends, is being developed.
- Inspected training records of internal auditors were non-current and required updating. A review on auditor qualifications and training has been added to the annual audit schedule.

Management Review 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 2017. 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:

Quality Objectives

1. Reduce product rejected at incoming inspection
2. Reduce product returned from field
3. Reduce deviation reports waiting for disposition
4. Reduce design changes waiting for implementation

Environmental Objectives

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

Objectives	Target	2017 Results
Reduce product rejected at incoming inspection	Average, less than 10 per month	MET - Average: 5.33/month
Reduce product returned from field	Average, less than 4 per month	MET - Average: 1.0/month
Reduce deviation reports waiting for disposition	Less than 100	MET - 37
Reduce design change waiting for implementation	Less than 50	MET - 47
Dispose of or transfer inventory at 413 March Road to a licensed facility: <ul style="list-style-type: none">• sealed sources• depleted uranium• prescribed equipment containing radioactive		<i>Refer to Section 2.11.2</i>

2.1.2 Organizational Structure

In 2017, key EH&S roles were established due to changes in the compliance department. The Compliance Coordinator position was replaced by a Quality Assurance Specialist. The Radiation Safety Officer (RSO) position was taken over interim by the Isotope Supply & Production Specialist until RSO designation was granted by the CNSC. A Radiation Safety Specialist was also hired into the department to assist in managing the radiation protection program. Currently, the responsibilities of the preexisting Compliance Director role, vacated in 2015, are shared amongst the RSO and Quality & Regulatory Manager. The organizational chart is provided in Appendix A.

2.1.3 Manager Self-Assessments on Management System

No results self- assessments on the management system were provided for 2017. Evaluations will be discussed in the MRT 2017 yearly review meeting in March 2018. Results will be reported in the 2018 review year report.

2.1.4 Document Changes

Below is a list of the documents references in Best Theratronics License Conditions Handbook that were updated in 2017. Updates to such documents reflect changes in regulation, audit observations, and corrective action implementation.

Document Number	Document Title
5.00-QA-00	Quality Manual
5.00-QA-23	Training
5.08-RP-04	Management of Depleted Uranium Radioactive Matter
5.08-RP-12	Keeping Radiation Exposures and Doses ALARA
5.08-RP-15	Radiation Survey Meter and Area Monitor Check Procedure
5.08-RP-19	Radioactive Material Shipments Tracking
5.08-SE-02	First Aid Program
5.08-SE-06	Control of Hazardous Energy – Lockout and Tagout Systems
5.08-SE-11	Lead Control Program
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. Reanalysis of roles and implementation of this training program is expected to occur in 2018.

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

Radiation safety refresher training for the service technicians are conducted yearly to ensure safe practices are applied at Best Theratronics customer’s sites.

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
- Conclusions of audit results, where inadequate training was determined to be the root cause of occurrence
- 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 required training and the number of graduated participants.

Training	# of personnel trained in 2017	# of personnel who completed the course
Chemical Spill	0	N/A
Crane	13	13
Emergency Response	15	15
First-Aid	8	8
Fork-lift	18	18
Lead control	29	29
WHMIS	110	110
Transportation of Dangerous Goods	10	10

Based on the completion rates, it is apparent that for the aforementioned training programs are adequately delivered to produce graduated participants.

2.2.3.1 Radiation Safety Training

During the reporting year, twenty-five employees required radiation-related training. All required participants completed the training. The table below shows the average results from the course tests between the 2016 and 2017 training years.

The majority of Best Theratronics employees trained as Nuclear Energy Workers will be completing their refresher training in 2018. The goal for 2018 is to reevaluate the course content to reflect current practices and examples. The course evaluations and assessments will be used as guidance in determining the training effectiveness of the updated course material.

Training Year		NEW Initialization	NEW Refresher	NEW Service Refresher
2017	Average	92.9%	90.3%	85.5%
	Participants	12	16	17
	Passed	12	16	17
2016	Average	86.5%	90.4%	91.2%
	Participants	2	21	15
	Passed	2	21	15

2.2.4 Certified Personnel

In 2017, the role of the Radiation Safety Officer was awarded to an existing employee within the radiation safety department at Best Theratronics. Mojgan Soleimani was awarded with an RSO certification by the CNSC in October 2017.

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 Committee meetings occurring monthly. Weekly meetings regarding customer supply 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.

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*.

2.3.1 Licensed Activities Audits Overview

Entering into 2017, all observations from three previous year CNSC inspections were still in progress. As of the submission of this report, all outstanding inspection responses have been closed.

Four CNSC audits took place in 2017 regarding Best Theratronics' Security, Management System, Emergency Management, and Transport & Packaging. All observations were addressed with the opening of CAPAs. The following table identifies the audit observations and status.

Inspection	Observations	Status
Security (May 2017)	Actions 6 Recommendations 1	Open – Initial response provided to the CNSC with Corrective Action plans addressing all observations. Completion for final action item is targeted for May 31, 2018. <i>See Section 2.12.3 for details.</i>
Management System (June 2017)	Actions 4 Recommendations 6	Open – Initial response provided to the CNSC with Corrective Action plans addressing all observations. Completion for final action item is targeted for Apr 30, 2018. <i>See Section 2.1.1.1 for details.</i>
Emergency Management (October 2017)	Recommendations 4	Closed – February 8, 2018 Gap Analysis Required by Apr 30, 2018
Transport and Packaging (October 2017)	Directive 1 Actions 1 Recommendations 1	Open – Initial response provided to the CNSC and all Corrective Actions have been addressed. <i>Awaiting CNSC closure confirmation.</i>

An internal evaluation of the Radiation Protection Program at Best Theratronics was conducted in 2017. Refer to Section 2.7.5 for a summary of the findings.

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 2017, Best Theratronics operated within the limits outlined in the Class 1B license.

2.3.3 Reportable Events

On November 26, 2017 a discrepancy regarding packages received in Canada following a unit removal from a customer site overseas was observed. A Best Theratronics service technician prepared the return packages for shipment back to Best Theratronics. Pictures taken by the service technician, following package preparations prior to leaving the customer site, displayed the appropriate TI and UN labels for radioactive transport. Upon receipt TI labels appeared to have been replaced, required UN number labels were removed, and one package showed signs of damage. Both the customer and the CNSC were notified. An investigation was initiated by the CNSC and the competent authorities of the customer's country. No further actions were required by Best Theratronics.

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 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. One of the monthly workplace inspections revealed the need to replace a deteriorating fire escape wooden door from an active area. This door was replaced in August with the installation of a luminous exit sign, allowing for quick exit if the main entrance was locked from the exterior.

Several areas around the facility where repairs of the roof are required, deflectors have been installed to minimize damage to manufacturing equipment, electrical components, and workplace environmental hazards. These have been installed as a temporary solution while roof repair solutions are discussed.

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.

There were no modifications to the overall physical design of Best Theratronics' building or property in the year of 2017.

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. In 2017, 131 items of radiation monitoring equipment were sent for calibration to a certified third-party calibration facility, of which 11 items required both repair and calibration. Thirteen Deviation Reports were created for radiation monitoring equipment past their calibration due date. All instances were caused by delays in returning service equipment from customer sites overseas.

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 2017, 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, repairs are anticipated to commence 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 Committee (RSC) is to meet regularly to review radiation-related safety matters at Best Theratronics. An observation stemming from an internal audit of the radiation protection program conducted in late 2017 revealed an inconsistency between the meeting frequency stated in Class 1B

supporting documentation and the practiced frequency in 2017. This was immediately addressed and monthly meetings resumed since November 2017. The target for 2018 is to hold monthly meetings to ensure effective communication of radiation-related work and 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. The decrease in these administrative limits will be reevaluated in 2018 to determine the effectiveness of the current radiation protection program.

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

Only 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).

Extremity monitoring is implemented for NEWs who requires working with their hands in close proximity to a contained source. 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 whole body and extremity doses.

Work Group	Total Monitored	Dose Range (mSv)					
		<0.01	0.01-1.00	1.01-5.00	5.01-10.00	10.01-20.00	>20.01
Effective Whole Body		<0.01	0.01-1.00	1.01-5.00	5.01-10.00	10.01-20.00	>20.01
Building Personnel	68	55	13	0	0	0	0
Class II Servicing	9	<i>Reported in Class II servicing licenses ACRs (14127-3-18/14127-8-19)</i>					
Extremity (Maximum)		<0.01	0.01-1.00	1.01-5.00	5.01-10.00	10.01-20.00	>20.01
Building Personnel	16	13	3	0	0	0	0
Class II Servicing	9	<i>Reported in Class II servicing licenses ACRs (14127-3-18/14127-8-19)</i>					

Based on the dose distribution, Best Theratronics operates with occupational doses below the maximum allowable NEW whole body dose of 50 mSv in one dosimetry year and 500 mSv per year for extremities. Furthermore, the occupational doses received by building personnel have not exceeded the public annual dose limit of 1 mSv. The following table displays the calculated statistics associated with the building personnel doses:

2017 Building Personnel	Whole Body	Extremity
Total workers monitored	68	16
Collective dose (mSv)	1.29	1.10
Average dose , with zeros (mSv)	0.02	0.07
Average dose, measured only (mSv)	0.10	0.37
Maximum dose received (mSv)	0.47	0.50

Doses reported within previous ACRs, dated 2013 to 2016 inclusive, 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 the service technician doses are a combination of both Canadian and international service work.

Company Wide Whole Body Doses

	2013	2014	2015	2016	2017
Total workers monitored	72	74	76	73	77
Collective dose (mSv)	2.78	2.36	4.12	5.7	11.35
Average dose , with zeros (mSv)	0.04	0.03	0.05	0.08	0.11
Average dose, measured only (mSv)	0.10	0.16	0.16	0.18	0.52
Maximum dose received (mSv)	0.65	0.46	0.85	2.28	5.3

Company Wide Extremity Doses

	2013	2014	2015	2016	2017
Total workers monitored	32	30	32	31	25
Collective dose (mSv)	16.6	5.8	5	52.7	17.7
Average dose , with zeros (mSv)	0.52	0.19	0.16	1.70	0.71
Average dose, measured only (mSv)	2.77	2.90	1.67	13.18	2.21
Maximum dose received (mSv)	6.1	3.7	2.1	29.9	11.2

In the extremity doses table above, the collective and average doses are reported for all extremity dosimeters, ie. not based on the maximum dose between the left and right hands.

The trends apparent from the presented data indicate that service work contributes to a large fraction of the acquired dose, companywide. Doses recorded for building personnel are minimal, indicating that radiation protection practices at Best Theratronics are adequate.

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. All monthly facility contamination checks were also found to be within acceptable limits.

Contamination checks are also performed on an as-needed basis; from incoming radioactive shipments to movement of depleted uranium inventory around the facility. In December of 2017 a shielded storage room, previously used to cut and store depleted uranium (DU) from legacy teletherapy units, was cleared out for sealed source inventory storage. Two-thirds of this room was checked for contamination, in preparation for the sealed source shipment, and no contamination was found. The remainder of this room will be checked in 2018.

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. In 2017, there were no incidences exceeding the regulatory limits.

Additionally, all receipts that contain radioactive sources are wiped for surface contamination to ensure contamination events are isolated prior to unloading. There were no incidences of surface contamination in the year 2017.

2.7.5 **Radiation Protection Program Effectiveness**

Dedicated internal audits on the Radiation Protection Program and DRD control were completed in 2017. The audits produced 3 CAPAs with minor procedural changes, verifying Best Theratronics' compliance to the CNSC Nuclear Safety and Control Act and General Nuclear Safety and Control Regulations.

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 10 occasions during 2017. 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 2017, there were 12 action items left open to be completed in 2018.

2.8.2 **Conventional Health & Safety Program Improvements**

Following workplace observations and concerns discussed within the Health & Safety Committee meetings, the following improvements to the program were initiated in 2017:

- New chemical spill response team established and relevant training administered
- Design and implement a lifting jig for proper handling of main frame bases
- On-going discussions on long term solutions for incidences for oil spills on the shop floor and clearing of electrical panel obstructions
- Administrative controls over workplace cleanliness, such as ensuring daily logs are completed
- A reevaluation of the lead control program was initiated to reflect changes in manufacturing operations.

A few opportunities on employee refresher training were made apparent following monthly observations from Health & Safety Committee members:

- Lock-out tag-out training
- Correct placement of radioactive devices when stored
- Necessity to wear harnesses when working at heights
- Using designated equipment to minimize airborne contamination

2.8.3 Health & Safety Occurrences

In 2017, Best Theratronics documented a total of 9 medical reports, 3 of which required outside medical attention. These incidents were due to minor cuts or scrapes (3), rashes(2), heat burn, a twisted ankle, slip and pinched finger. 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
2017	9	6	3	22
2016	12	8	4	3
2015	11	9	2	1
2014	18	16	2	1
2013	29	22	7	7

In all instances, medical reports were reviewed and corrective actions were introduced if appropriate. A summary of the medical incidents in 2017 requiring outside treatment is shown below.

Injury	Cause	Treatment	Lost Days
Rashes	Allergic reaction	Instructed to use barrier hand cream and latex gloves.	0
Twisted ankle	Stepped onto uneven surface	Work adjusted to light duty until ankle became better.	0
Finger pinch	Finger caught on machine belt and into pulley during machine repair	Reminded to use caution when repairing machinery with moving parts.	0
Cut through thumbnail	Cut thumb on saw when blade still moving while removing cut material. Saw blade cut through thumbnail. (Non-NEW worker)	Driven to hospital for medical attention. Reminded to use caution when repairing machinery with moving parts.	22

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. Regarding the 22 lost days in 2017, the individual was retrained on working procedures and reminded of the necessary safety precautions while working around the machine. The individual has not been scheduled to work at the saw machine since their return and are being monitored for safe working practices.

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 transport container or self-shielded irradiator is stored within a radiation designated area within the facility. The source material cannot be released and therefore does not pose 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 monitoring events in 2017 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 once a year to oversee emergency response planning at Best Theratronics Ltd. The last meeting took place on October 19, 2017. The following action items were discussed:

- 1) Emergency personnel call list update
- 2) *Industrial accident* scenarios and response plan
- 3) Security guard fire warden duties outside of normal business hours
- 4) Security measures related to current shipping and receiving procedures

Action items 1 and 2 were discussed and completed within the 2017 report year. Discussions and results of Action items 3 and 4 are in progress with a completion target by the end of 2018.

In October of 2017, the BTL’s Emergency Preparedness Program was inspected by the CNSC. This inspection resulted in 4 recommendations that were addressed and closed within the following months.

As of 2017, a new chemical response spill team was established for the facility following a CNSC inspection observation on training. Chosen individuals were trained at the beginning of 2018.

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

A full scale evacuation exercise will be planned to take place in 2018. This full scale exercise will involve the participation of BTL employees, Ottawa Fire and Ottawa Police Services.

2.10.2.1 Emergency Response Assistance Plan – Depleted Uranium Disposal

Best Theratronics has an inventory of depleted uranium originating from returned legacy teletherapy units and components. As part of Best Theratronics’ radioactive material end-of-life management program and Transport Canada requirements, an emergency response assistance plan (ERAP) has been implemented. In 2017, a table top exercise was successfully conducted with Transport Canada in support of BTL’s ERAP renewal application for future depleted uranium disposals.

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 2017, the Fire Protection Program and equipment was proven to be satisfactory.

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.

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 21.6 MT in 2017 decreased from 2016 by 12.4 MT, likely due to a downturn in production in the reporting year. Overall diverted material is largely the result of recycled scrap metal. The decreased amount of prototyping, related to the cyclotron and other new products, as well as a reduction in old therapy head decommissioning is the most probable cause of the scrap metal waste reduction seen in 2017.

2.11.1 Non-Radioactive Hazardous Materials

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. Table 2 provides the amount of hazardous waste removed between 2015 and 2017, which is approximately equal to the amount annually produced as waste is removed several times over the year.

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

2.11.2 Radioactive Hazardous Materials

2.11.2.1 Medical Device Sources

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 2017, a total source activity of 3272.6 TBq was managed according to Best Theratronics' end-of-life management program. The table below indicates the activity breakdown of how these sources were managed in 2017.

Management	Co-60	Cs-137	Notes
Reuse	362.8 TBq	686.8 TBq	Source capsules were reused in Best Theratronics self-contained irradiators and teletherapy machines.
Transfer	599.8 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	181.9 TBq	1441.3 TBq	Sources were transferred to Canadian Nuclear Laboratories in Chalk River, ON for long-term storage and disposal.
<i>Total Activity</i>	1144.5 TBq	2128.1 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. A total amount of 8115.13 kg of depleted uranium was accounted for in 2017. 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 accepted Security program in place, where the site-security plan is reviewed on a regular basis. No security-related events have occurred in the year 2017.

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. At the end of 2017, an internal audit revealed that the security plans and measures of the contracted carrier companies were sufficient.

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. Resulting from a CNSC security inspection observation, conducted in May of 2017, Best Theratronics has implemented a criminal record check renewal policy every five years. This policy implementation is currently underway with the target completion date of March 31, 2018.

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 as per RD-336 annually. During the 2017 Physical Inventory Taking (PIT) in September, a minor inventory discrepancy was found and was immediately reported and reconciled with the CNSC.

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.

In Nov 2017, a CNSC inspection on BTL's packaging and transport program was completed. Two non-conformances were observed resulting in one action notice, directive, and recommendation each, all administrative related. All observations were addressed and successfully closed with the CNSC.

3 Other Matters of Regulatory Interest

3.1 Licensee's Public Information and Disclosure Program

3.1.1 Public Inquiries and Media Coverage

There were no public inquiries received in 2017. The public is encouraged to contact Best Theratronics for more information regarding concerns through the info@theratronincs.ca email address available on the Best Theratronics website.

Two press releases were posted to the Best Theratronics website informing the public of our progress into the cyclotron and synchrotron markets. This information was posted to the *Press Releases* webpage of the Best Theratronics website.

Facility tours are periodically provided to visitors to inform participants of the company's history, manufacturing capabilities, regulatory compliance and future endeavors. During 2017, Best Theratronics hosted tours for several regulatory agencies and students of Carleton University's Mechanical and Aerospace Engineering department.

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

- An annual report on lead (and its compounds) was posted in May
- The Annual Compliance Report for 2016 was posted in June
- A public information FAQ page (*Appendix B – Website FAQ Update*). This page was created to address potential questions the public may have on radiation and the activities within the Best Theratronics facility.

3.1.2 Future Public Information Program Plans

Best Theratronics is planning on hosting a public outreach information session in 2018 to continue with efforts of informing the community of the business and regulatory compliance. Invitations will be sent out to surrounding neighbourhoods, local community groups, community officials, and emergency services.

3.2 Financial Guarantees

A revision of BTL's Preliminary Decommissioning Plan (PDP) was accepted by the Commission on July 14, 2017. A financial guarantee totaling in the amount of \$1.8 million was accepted by the Commission as sufficient funds for the decommissioning of the BTL facility. BTL's financial guarantee will be reviewed and revised by BTL every five years or when the Commission so requires, or following a revision of the PDP.

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. In 2017, the production of one 15 MeV and one 70 MeV cyclotron was initiated. Acceleration and endurance tests were performed on one 15 MeV cyclotron at an energy of 0.8MeV. The accelerated beam current was maintained at 400µA, with peak current at 450µA.

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 107 hours, where all hours were related to research. Operational information is provided in the table below.

Source Serial Number	Source Type	2017 Beam On Time (hrs)	Output at 1m (Gy/min)	Output date reference	Total work load (Gy)
S-5595	Co-60	43	0.251	Jan 2017	647.58
S-5298	Co-60	64	1.87	Mar 2017	7180.8
<i>Total work load in 2017</i>					<i>7828.38</i>

4 Summary

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2017 did not change significantly from previous years. There were no major events, observations, or non-compliance identified during 2017 that would affect the safety and security of personnel, the public, or the environment.

Best Theratronics continues to make adequate provisions for the protection of the environment and the safety of both employees and the public. Best Theratronics acts in compliance with the licensing conditions set out in license NSPFOL-14.02/2019 and the associated Licensing Conditions Handbook.

5 Signing Authority Certification

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

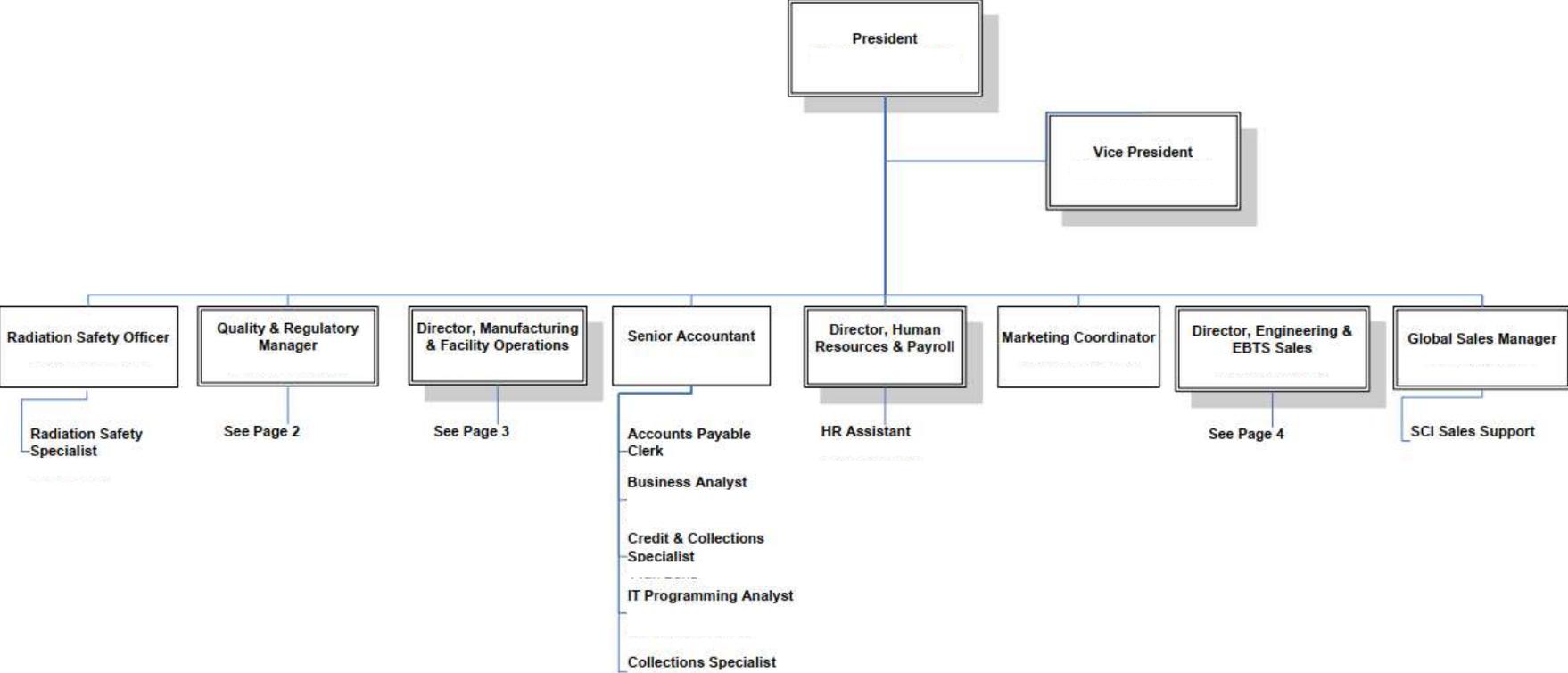
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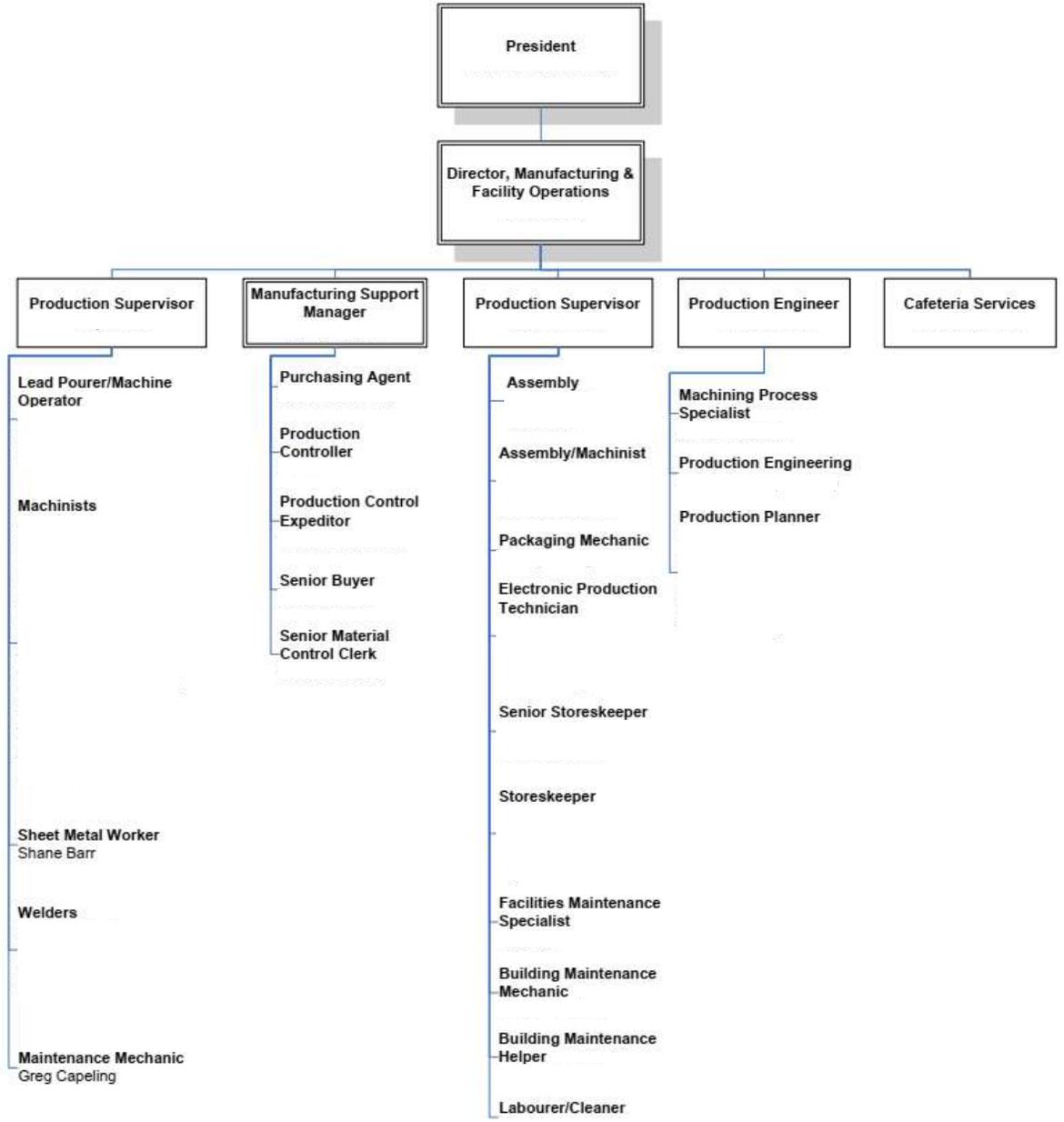
Radiation Safety Officer

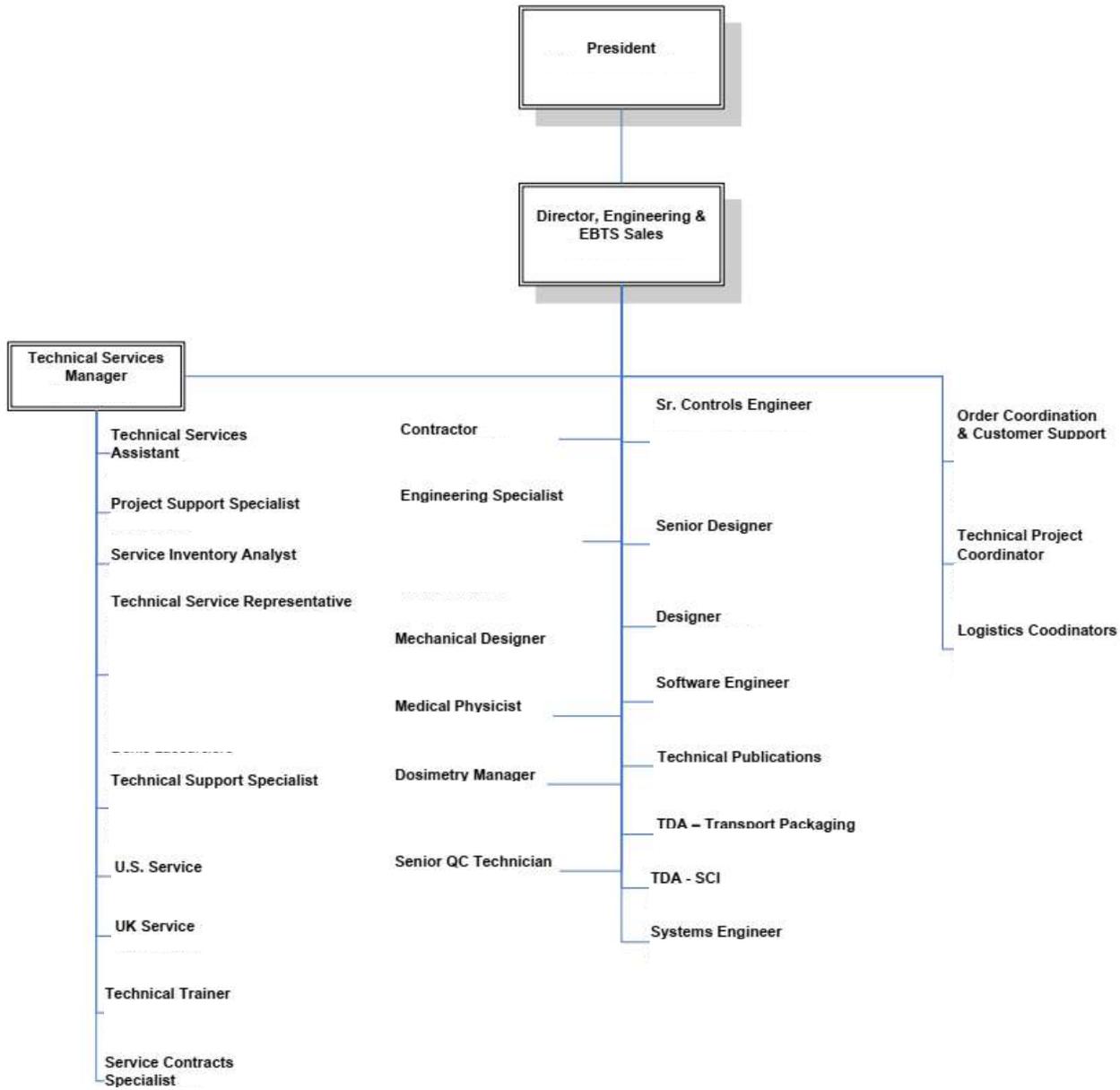
613-591-2100 ext 2766

Appendix A – Organizational Structure

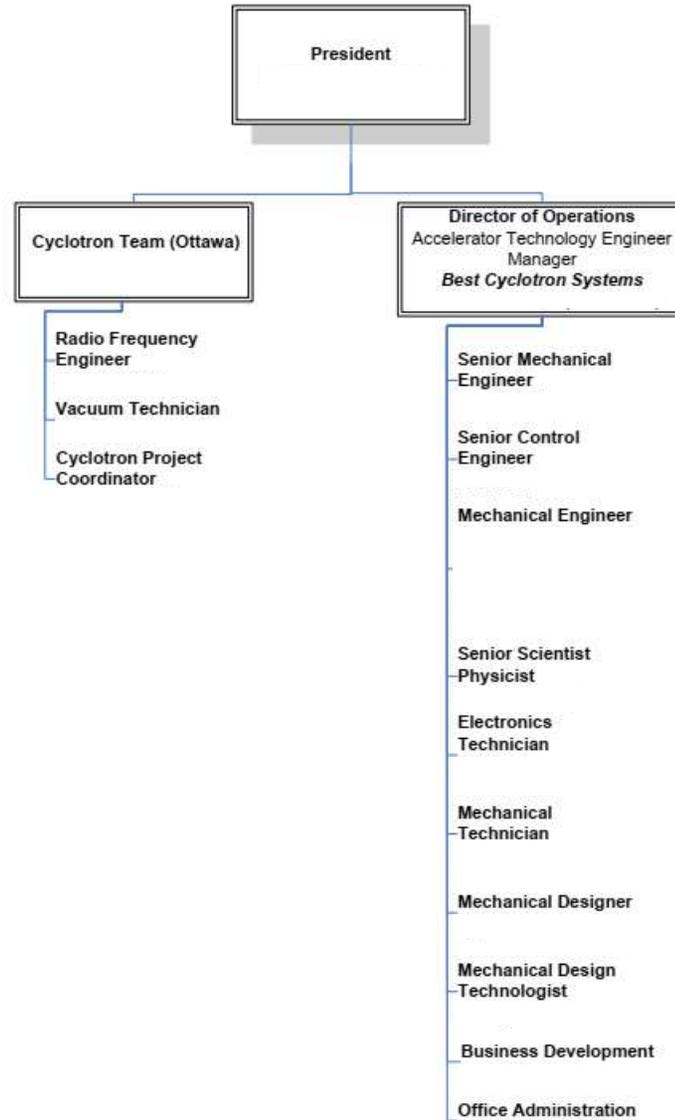








Best Cyclotron Systems



Appendix B – Website FAQ Update

BestTM Theratronics

frequently asked questions (FAQs)

Environment, Health & Safety

SEARCH

- ▶ HOME
- ▶ OUR PRODUCTS
- ▶ ABOUT US
- ▶ CAREERS
- ▶ NEWS
- ▶ TESTIMONIALS
- ▶ FAQs
- ▶ CONTACT US

Q: What is Radiation?

Radiation is all around us. Radiation is the emission of energy in the form of electromagnetic waves or subatomic particles. Some examples of the different types of radiation include radiowaves, microwaves, visible light, and x-rays. Based on how energetic these emissions are, they can be classified as either non-ionizing and ionizing radiation. The classification most people are familiar with is ionizing radiation. This type of radiation possesses enough energy to knock out orbiting electrons surrounding an atom. Examples of ionization radiation are x-rays and gamma rays.

Q: How do your products at Best Theratronics utilize radiation?

Hospitals and transfusion services irradiate stored blood inventory at low radiation doses in order to prevent Transfusion-Associated Graft-Versus-Host Disease, or TA-GVHD for short. TA-GVHD causes an immune response of a blood transfusion recipient, attacking the transfused blood and creating medical complications. Our blood irradiation products use either x-rays or gamma radiation.

Our external beam therapy units incorporate radioactive sources that produce gamma radiation for the treatment of variety of cancers. These radioactive sources are heavily shielded in the treatment head of the therapy machine. When a treatment starts, the source is moved to an exposure position. The radiation field is then shaped to localize the treatment to a specific area, such as a tumor, and minimizing unnecessary damage to other parts of the body.

Cyclotrons are used by health care facilities to produce medical radioisotopes for diagnosis and treatment of diseases. Particles are accelerated to bombard a variety of elemental targets, resulting in radioactive substances that can be used for nuclear medicine or imaging.

One World • One Source
healthcare for everyone
Team Best
Your True Partner
The Best!

Q: Does the manufacturing of your products produce nuclear waste or radiological release into the environment?

The radioactive sources incorporated into our devices are contained within a double-encapsulated casing. These capsules are very robust and are welded shut in designated shielded rooms called hot cells. As per international regulations, the source capsules are tested for any leaks prior to shipment to and from our facility. These sources are loaded into heavily shielded transportation containers within hot cells and then checked for external contaminations prior to shipment.

The release of any airborne contamination created at our Kanata, ON manufacturing facility is extremely unlikely. As a precaution, and as part of our radioactive materials licence, we have implemented in our radiation protection program continuous monitoring for indications of the release of radioactive contamination.

In addition, we have developed a program for our customers where we accept their legacy blood irradiator and external beam therapy radioactive sources for proper disposal at licensed facilities.

Q: How do you ensure radiological protection of the environment and to your employees?

We have a radiation protection program in place to monitor radiation exposure to our employees and the surrounding environment. Our program includes internal investigation trigger levels well below regulatory limits to ensure that unnecessary exposures are kept at a minimum. A few components included in our program are:

- Continuous training of employees on radiation safety and their working environment.
- Radiation area monitoring around the facility.
- Contamination monitoring of temporary radioactive source storage locations.
- Dose monitoring of employee radiation exposures through dosimeter reading.
- 24/7 on-site security.

Continuous Improvement

At Best Theratronics, we actively seek opportunities for improvement to our monitoring programs, protecting our employees and the environment. We accomplish this by:

- Ensuring employees are aware of regulatory changes by offering refresher courses.
- Conducting monthly Environment, Health & Safety Committee meetings to discuss employee concerns.
- Implementing corrective actions/preventative actions framework to recognize and ensure deficiencies do not occur in the future.
- Conduct annual audits to find deficiencies in our environmental, health & safety programs.
- Hire specialists to guide us on the development of such programs and address employee and community concerns regarding their safety and the environment.

For more information, please email us at info@theratronics.ca.

[Click here to learn about our Public Information Program.](#)