

Best Theratronics Annual Compliance Report - 2015

License: NSPFOL-14.01/2019

Licensing period: January 1, 2015 to Dec 31, 2015

Submitted: March 30, 2016

Executive Summary

Best Theratronics received a Class 1B license (NSPFOL-14.01/2019) from the Canadian Nuclear Safety Commission (CNSC) in July 2014. This license consolidated several existing licenses and provided increased flexibility in the allowed licensed activities. This Annual Compliance Report is being submitted in compliance with condition 4.2 of the license covering all CNSC related activities between January 1 2015 and December 31, 2015.

After successful factory acceptance testing (to <1 MeV) of the 70 MeV cyclotron, dismantling of the 70 MeV cyclotron began in December of 2014 for shipment to the customer in early 2015. Testing only occurred to <1 MeV, and hence did not require release of the hold points on the Class 1B license, which remain in place.

Best Theratronics continued to operate in manner ensuring the safety of employees, the public, and the environment, as in previous years. Some of the key points highlighting Best Theratronics' continued commitment to health and safety include:

- 1) There were no environmental releases from the facility.
- 2) All non-radiation hazardous waste produced during the manufacturing process was, and continues to be, removed on a continuous basis by a licensed third-party vendor.
- 3) All monitored employees received an annual dose less than 1 mSv, which is below the public limit.
- 4) No radioactive contamination was found within the facility in 2015.
- 5) Monthly radiation surveys measurements were all well within expected ranges.
- 6) The number of Health and Safety accidents remains low (total of 11 in 2014), consisting primarily of cuts/bruises (73%), twisted/sprained muscle (18%) and other (9%). Only two incidents required further, off site medical treatment, one for a cut and one for a twisted knee. A third incident involved the EMS being called to treat low blood sugar in a diabetic. The employee chose to go home and visit his personal physician the following day.

In 2015, Best Theratronics continued to update procedures and policies to meet the requirements of our Class 1 license. This is an ongoing process and will continue in 2016.

In summary, Best Theratronics continues to act in a responsible manner, compliant with the conditions set out in its license, NSPFOL-14.01/2019 and ensuring the safety and security of both the public and the environment.

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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 testing of cyclotrons.

This annual compliance report (ACR) is submitted with respect to license condition 4.2 and contains the information defined in Section 4.2 of Best Theratronics' Licensing Conditions Handbook, covering January to December 2015.

2 Summary of Operations

Best Theratronics' operations continued with little change in 2015. Best Theratronics continued to manufacture and sell both the Cs137 self-contained irradiators (Gammacell 1000, Gammacell 3000, and Gammacell 40) and the Co60 teletherapy product line. Production levels of these products was consistent with previous years.

There were no notable changes in organization or the operating policies. Our former Director of Compliance and RSO, Richard Wassenaar, left the company in September 2015. Samantha Mason has become our new RSO, and a new Director of Compliance is being searched for. Pietro Zanetti, previously the manager of the 70 MeV cyclotron assembly project, was promoted to Director of Manufacturing and Facility Operations.

2.1 Cyclotron Testing

The 70 MeV cyclotron was shipped and installed at INFN, Italy and is undergoing its final FAT testing. Best Theratronics' license allowed for the testing of the cyclotron to 70 MeV, with certain hold points listed on the license. However, in consultation with the purchaser and end-user of the 70 MeV cyclotron, it was decided that full testing would be completed at the end user's site. As such, the hold points relating to testing and decommissioning of cyclotrons remain on the license.

2.2 Document Changes

Table 1 lists the documents referred in the Licensing Conditions Handbook that have had administrative changes in 2015.

Please note there are ongoing changes in 2016 as we update our procedures based on 2015 audits.

Table 1: List of procedures changed in 2015.

Document Title	Document Number
Preventative Maintenance	3.11-MC-19
Waste Management Program	5.08-SE-24
Training	5.00-QA-23
Device Design Risk Management	5.00-QA-29

In late 2015 and early 2016, Best Theratronics established new policies as part of the fire and environmental system review. These procedures are being reviewed by the CNSC and suggested changes will be implemented in an ongoing basis.

3 General Health and Safety

The Best Theratronics Health and Safety Committee meet monthly during 2015. Health and safety audits of the facility were also conducted monthly with all findings actioned in the health and safety meeting minutes. There were no major findings to report.

The Radiation Safety Committee met monthly in 2015 to review radiation safety matters. There were no significant highlights arising from this committee, not otherwise noted elsewhere in this ACR.

There were no changes to any safety significant equipment performance. Best Theratronics continues to ensure adequate equipment (survey meters, area alarms) are present and in working condition through monthly checks of the equipment.

In 2015, Best Theratronics documented a total of 11 medical reports, 2 of which required outside medical attention. A breakdown of the medical reports is as follows:

- 1) 8 reports (73%) related to cuts, scrapes, and bruises.
- 2) 2 reports related to straining or pulling a muscle.
- 3) 1 report related to an existing medical condition.

The 2 incidents requiring outside medical attention was a cut received by an employee and a twisted knee for a second employee. In the case of the existing medical condition, EMS was called to assist with treating an employee with low blood sugar. He received an IV on site and went home with his spouse. The following day he visited his medical practitioner. In all instances, the medical reports were reviewed and corrective actions taken if appropriate. Corrective actions included to be aware of their surroundings and to act in safe manner.

4 Radiation Safety

Best Theratronics conducts monthly radiation surveys of its facility. The internal requirements set for radiation fields are 10 $\mu\text{Sv/h}$ and 1 $\mu\text{Sv/h}$ for Radiation Controlled and Uncontrolled areas respectively. In 2015, all monthly facility surveys were found to be within these limits.

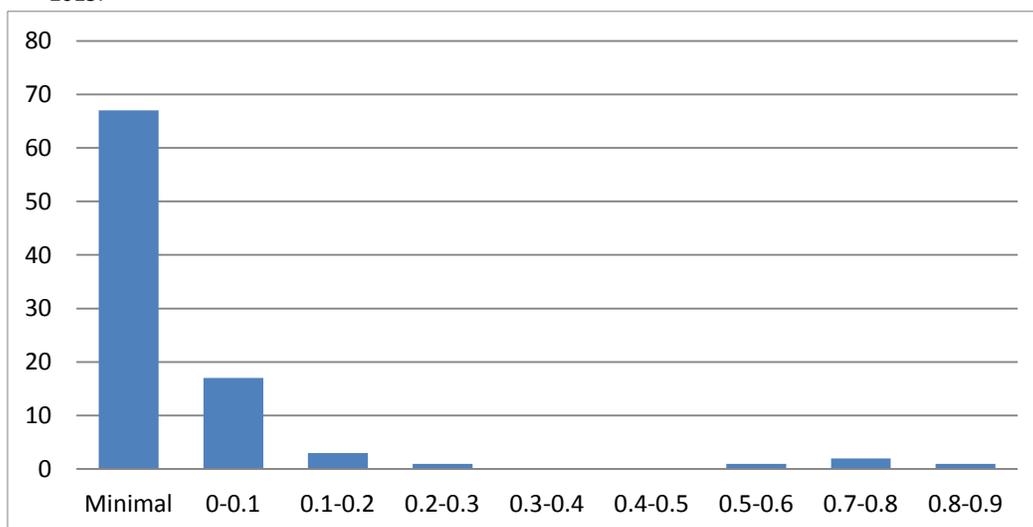
Best Theratronics also conducts monthly contamination checks of the facility. The limit set for determination of contamination is a reading twice background. In 2015, the monthly facility contamination checks were documented to be equal to background, indicating no contamination. Contamination checks are also performed on an as-needed basis, i.e., if work is undertaken that may potentially result in contamination. Several returned heads were cut down to reduce the disposal size in the summer and the saw cutting area was monitored for contamination. Three of the heads were found to have readings above background but less than half of background. These heads are being treated as contaminated waste for disposal purposes. Finally, all incoming shipments of radioactive material were wipe tested as part of the receipt of radioactive material into the facility. In 2015, no incoming shipments were found to be contaminated.

A total of 92 Best Theratronics personnel were monitored with personal dosimetry badges. The highest annual dose recorded was 0.85 mSv. The dose distribution is shown in Figure 1. As can be seen, the vast majority of personnel received a minimal dose in 2015.

Thirty (30) employees also received extremity dose monitoring (both left and right hands) in 2015. Of these 30 personnel, 27 recorded a minimal 2015 annual extremity dose. Only three personnel recorded extremity doses: 0.5/1.0 mSv, 1.7/1.9 and 2.1/2.1 mSv (left hand/right hand).

There were no instances or unusual occurrences that resulted in increased exposure to either employees or the public.

Figure 1: Distribution of annual whole-body dosimetry results for Best Theratronics' employees in 2015.



5 Environmental

There were no environmental monitoring events in 2015 to report.

An external waste audit was performed by Tomlinson Group in November 2015 and found that Best Theratronics continues to decrease landfill waste generated. The majority of this comes from an increase in metal recycling of returned decommissioned therapy heads and machining/prototyping related to the cyclotron project. Recommendations to reduce landfill waste further are under review.

5.1 Non-radioactive Hazardous Materials

Best Theratronics produces non-radioactive hazardous waste as part of the routine manufacturing process. Table 2 provides the amount of hazardous waste removed in 2015, which is approximately equal to the amount annually produced as waste is removed several times over the year.

Table 2: Quantity of waste produced and removed from site in 2015.

Description	Amount
Acetone	820 L
Organic Flammable waste	960 L
Zirconium Alloy scrape	1100 kg
PCB ballasts	170 kg
Machine Oil	2050 L
Inorganic Acid Oxidizer	16 L
Florescent bulbs and HID lamps	306 kg
Organic Gas Aerosols	8 L
Mercury	1 kg
Lead acid battery	10 kg
Alkaline battery	45 kg

5.2 Radioactive Hazardous Materials

In 2015, Best Theratronics received a total of 2847 TBq (referenced to Dec 31, 2015) of Co60 and 487 TBq (referenced to Dec 31, 2015) of Cs137 in the form of returned, disused sealed sources. These sources will be managed according to Best Theratronics' sealed source end-of-life management program.

As part of the sealed source end-of-life management program and the Order issued, Best Theratronics shipped 2428 TBq (referenced to Dec 31, 2015) of Co60 to a user in the USA for recycling purposes. The Co60 sources will be cut open and the Co60 material reused in the manufacturing of new sources for other purposes. 25 Cs-137 devices containing 697 TBq of Cs 137 (referenced to Dec 31, 2015) devices have been sent for unloading and source recovery for reuse or disposal.

In addition, Best Theratronics diverted a total of 21 disused Cs137 sealed source from the end-of-life stream to new inventory for use in new Gammacells.

6 Emergency Procedures

The annual fire drill exercise was executed in fall 2015. There were no significant findings from the drill.

Based on the CNSC inspection in October 2015 and input from the CNSC, our fire hazard analysis and fire protection program are currently being performed by a new company. This information is still being updated and will be sent to the CNSC as soon as it is completed.

7 Management Reviews

Best Theratronics held two Management Review Team meetings in 2015. A summary of the outcomes of these meetings is as follows:

- 1) End-of-life management of disused sources is an on-going issue. New streams for managing this inventory have been identified and implemented.
- 2) The non-conformance framework at Best Theratronics is still being monitored as a quality objective.
- 3) Require a review of process for self-assessment of management processes.

Best Theratronics had 4 major audits conducted in 2015 by regulatory agencies. These audits and their findings are summarized in Table 3.

Table 3. List of major regulatory audits in 2015.

Audit	Description	Findings
bsi	Audit of ISO 9001:2008 and ISO 13485:2003 programs, including CE marking	2 minor non-conformities identified, both administrative in nature.
CNSC	Type II Inspection (May 2015)	2 Directives, 4 Action Notices, and 2 Recommendations
CNSC	Fire Inspection (October 2015)	6 Directives and 1 Action Notice
CNSC	Training Inspection (November 2015)	6 Action Notices

8 Financial Guarantee

Best Theratronics did not meet its required payment plan for the current financial guarantee, and as such remains under an order for not meeting its license obligation. Under this order we are reducing our disposal inventory at an accelerated rate. A revised preliminary decommissioning plan was submitted in January 2016 and an additional guarantee amount was placed with the CNSC. A payment plan will be submitted prior to the completion of the Order.

9 Class II Workload

The R&D Class II prescribed equipment located in Cell 4 (T1000, S/N 4) was operated for a total 138 hours, all hours were related to research. Two sources were used in the device. The Co60 source (S/N S5955) in the device head has an output of 34.7 cGy/min at 1 m (referenced to January 1, 2015) was used for the majority of the year, with 124 hours and a workload of 2582 Gy. Our head survey source, (S/N S6230) was used in new collimator testing for 14 hours. This source has an output of 2 Gy/min which gives a workload of 1680. This provides a 2015 workload of 4262 Gy.

10 Summary

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2015 did not change significantly from previous years. There were no major events, observations, or non-compliance identified during 2015 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-14.01/2019 and the associated Licensing Conditions Handbook.

11 Certification

I hereby certify that Best Theratronics has been operating in compliance with license NSPFOL-14.01/2019, except where otherwise noted.



Samantha Mason

Radiation Safety Officer