

# Best Theratronics Annual Compliance Report - 2016

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**License:** NSPFOL-14.01/2019

**Licensing period:** January 1, 2016 to Dec 31, 2016

**Submitted:** March 31, 2017

## 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 2016 and December 31, 2016.

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 remains 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) Most (Over 95%) monitored employees received an annual dose less than 1 mSv, which is below the public limit. The highest dose was 2.28 mSv.
- 4) No radioactive contamination was found within the facility in 2016.
- 5) Monthly radiation surveys measurements were all well within expected ranges.
- 6) The number of Health and Safety accidents remains low (total of 12 in 2016), consisting primarily of cuts/bruises (75%), twisted/sprained muscle (8%) and other (17%). Four incidents required further, off site medical treatment, one for a broken wrist.

In 2016, 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 2017 as various areas are inspected.

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 2016.

## 2 Summary of Operations

Best Theratronics' operations continued with little change in 2016. 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 slightly lower as a consequence of the order but is starting to increase to normal levels.

The organization has decided to not replace the Director of Compliance and this role has been merged into existing positions, the Radiation Safety Officer and the Quality & Regulatory Manager. The updated organizational chart has been forwarded to the CNSC reflecting this change.

### 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 2016.

Please note there are ongoing changes in 2017 as we update our procedures based on 2016 audits.

Table 2.1: List of procedures changed in 2016.

Document Title	Document Number
Fire Safety Plan	1.08-SC-01
Waste Management Program	5.08-SE-24
Measuring and Test Equipment	5.00-QA-06
Quality Manual	5.00-QA-00

### 3 General Health and Safety

The Best Theratronics Health and Safety Committee meet monthly during 2016. 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 2016 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 2016, Best Theratronics documented a total of 12 medical reports, 4 of which required outside medical attention. The majority were due to minor cuts or scrapes (9), strains (1), one particle in the eye, and one was a broken wrist.

Table 3.1 - Health and Safety Reports Including Lost Time

Year	Lost days	Reports	On site treatment	Off site treatment
2016	3	12	8	4
2015	1	11	9	2
2014	1	18	16	2
2013	7	29	22	7
2012	1	24	23	1

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.

Table 3.2 – Medical Incidents 2016 Requiring Outside Treatment

Injury	Cause	Treatment	Lost Days
Swollen elbow	Hit elbow on fixed post	Following day opted to see doctor for swelling. Reminded to work within limits and be aware of surroundings.	None
Grazed thumb	Tried to lift 16 pound vise and could not support the weight, twisted and scraped thumb	Went to hospital in own vehicle to ensure no break. Put on light duty and reminded to work within limits.	0.5
Swollen finger	Steel part weighing 80 pounds dropped from 2 inches onto finger when operator was not paying close attention.	Went to hospital in own vehicle to ensure no break. Reminded to use caution when handling heavy objects.	0.5
Broken wrist	Placed foot on a mobile cart while reviewing paperwork. Went to move away and lost balance when found shoe was wedged in cart. Fall caused full weight to be put on wrist.	Went to hospital for a cast. Work adjusted to light duty while in cast.	2

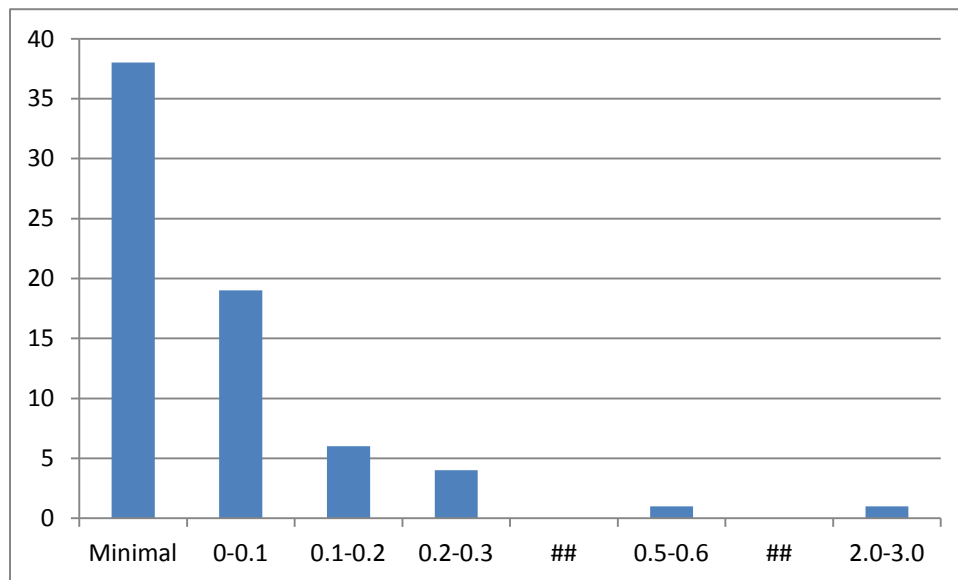
## 4 Radiation Safety

Best Theratronics conducts monthly radiation surveys of its facility. The internal requirements set for radiation fields are 10 uSv/h and 1 uSv/h for Radiation Controlled and Uncontrolled areas respectively. In 2016, 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 2016, 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. No such work found contamination in 2016. Finally, all incoming shipments of radioactive material were wipe tested as part of the receipt of radioactive material into the facility. In 2016, no incoming shipments were found to be contaminated.

A total of 69 Best Theratronics personnel were monitored with personal dosimetry badges. The highest annual dose recorded was 2.28 mSv. The dose distribution is shown in Figure 4.1. As can be seen, the vast majority of personnel received a minimal dose in 2016.

Figure 4. 1: Distribution of annual whole-body dosimetry results for Best Theratronics' employees in 2016.



Twenty-nine (29) employees also received extremity dose monitoring (both left and right hands) in 2016. Of these 29 personnel, 25 recorded a minimal 2016 annual extremity dose. Only four personnel recorded extremity doses: 0.4/M, 0.7/1.1, 21.3/18.0, 29.9/28.9 mSv (left hand/right hand). For the two employees who had significant extremity doses, they performed a larger amount of source loads than normal with the ViewRay system. This involved more hands on positioning of the source container

compared with loading our heads. The whole body dose rates for the individuals were well within limits. Tables 4.1 and 4.2 summarize the dose trends for whole body and extremity reporting respectively.

Table 4.1 – 5 Year Effective Dose Monitoring

Dose data	2011	2012	2013	2014	2015	2016	Regulatory limit
Total persons monitored	80	81	86	74	92	69	n/a
Average effective dose (mSv)	0.13	0.18	0.07	0.09	0.05	0.07	n/a
Maximum individual effective dose (mSv)	0.91	2.01	<b>2.47</b>	0.46	0.85	2.28	<b>50 mSv/year</b>

Table 4.2 – 5 Year Equivalent Dose Monitoring

Dose data	2011	2012	2013	2014	2015	2016	Regulatory limit
Total persons monitored	32	28	30	30	30	28	n/a
Average equivalent dose (mSv)	0.19	0.23	0.36	0.37	0.31	1.85	n/a
Maximum individual equivalent dose (mSv)	0.9	2.9	<b>6.1</b>	3.7	4.2	29.9	<b>500 mSv/year</b>

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

## 5 Environmental

There were no environmental monitoring events in 2016 to report.

A waste audit was performed in November 2016 and found that Best Theratronics continues to decrease landfill waste generated. 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 vs 2016, 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 and 2016.

Description	2015 Amount	2016 Amount
Acetone	820 L	1015 L
Organic Flammable waste	960 L	200 L
Zirconium Alloy scrape	1100 kg	225 kg
PCB ballasts	170 kg	0
Machine Oil	2050 L	940 L
Inorganic Acid Oxidizer	16 L	88 L
Florescent bulbs and HID lamps	306 kg	120 kg
Organic Gas Aerosols	8 L	8 L
Mercury	1 kg	0
Lead acid battery	10 kg	5 kg
Alkaline battery	45 kg	0
Filters with lead dust	0	48 kg
Glycol	0	1025 L

## 5.2 Radioactive Hazardous Materials

In 2016, Best Theratronics received a total of 1727.3 TBq (referenced to Dec 31, 2016) of Co60 and 380 TBq (referenced to Dec 31, 2016) 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 3862.9 TBq (referenced to Dec 31, 2016) of Co60 to international users for recycling purposes. The Co60 sources will be cut open and the Co60 material reused in the manufacturing of new sources for other purposes. 3 Cs-137 devices and 64 sources containing 2006 TBq of Cs 137 (referenced to Dec 31, 2016) have been sent for disposal.

In addition, Best Theratronics diverted a total of 4 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 2016. There were no significant findings from the drill.

Our fire hazard analysis and fire protection program were updated in 2016. As a result of this audit our procedures were updated and submitted to the CNSC in the updated Fire Safety Plan as well as procedures relating to operation and maintenance of our Carpentry Shop and Paint Booth.



## 7 Management Reviews

Best Theratronics held one Management Review Team meetings in 2016. A summary of the outcomes of the meetings are as follows:

- 1) The non-conformance framework at Best Theratronics is still being monitored as a quality objective.
- 2) Require a review of process for self-assessment of management processes.

Best Theratronics had 4 major audits conducted in 2016 by regulatory agencies. These audits and their findings are summarized in Table 3.

Table 7.1. List of major regulatory audits in 2016.

<b>Audit</b>	<b>Description</b>	<b>Findings</b>
bsi	Audit of ISO 9001:2008 and ISO 13485:2003 programs, including CE marking	2 minor non-conformities identified, both administrative in nature.
CNSC	Radiation Protection Program Inspection (June 2016)	4 Action Notices, and 2 Recommendations
CNSC	Export Program Inspection (November 2016)	2 Directives and 1 Recommendation
CNSC	Environmental Protection Inspection (December 2016)	5 Directives, 2 Action Notices, 1 Recommendation
US NRC	Quality Assurance Audit - Transport Packages (September 2016)	4 Notices of Violation relating to records, package design control, failure to document inner bracing inspections, and lack of 3 <sup>rd</sup> party audits for subcontractor (Nordion) performance relating to this program

## 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. This revised guarantee is fully financed and we are currently awaiting commission approval.

## 9 Class II Workload

The R&D Class II prescribed equipment located in Cell 4 (T1000, S/N 4) was operated for a total 81.5 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 30.4 cGy/min at 1 m (referenced to January 1, 2016) was used for the majority of the year, with 55.5 hours and a workload of 1012.3 Gy. Our head survey source, (S/N S6230) was used in new collimator testing for 26 hours. This source has an output of 178.6 cGy/min which gives a workload of 2786. This provides a 2016 workload of 3798 Gy.

## 10 Summary

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2016 did not change significantly from previous years. There were no major events, observations, or non-compliance identified during 2016 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.



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Samantha Mason

Radiation Safety Officer