

Best Theratronics Annual Compliance Report - 2014

License: NSPFOL-14.01/2019

Licensing period: January 1, 2014 to Dec 31, 2014

Submitted: March 31, 2015

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. Although license NSPFOL-14.01/2019 was received in July of 2014, this report covers all CNSC related activities between January 1 2014 and December 31, 2014.

Best Theratronics continued operations with little change in 2014. The most significant change was the successful factory acceptance testing (to <1 MeV) of the 70 MeV cyclotron being designed and manufactured. Upon completion of this testing, 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 2014.
- 5) Monthly radiation surveys measurements were all well within expected ranges.
- 6) The number of Health and Safety accidents remains low (total of 16 in 2014), consisting primarily of cuts/bruises (50%), pull/sprained muscle (31%) and other (19%). Only two incidents required further, off site medical treatment, both of which were related to cuts.

In 2014, Best Theratronics also revised the Fire Safety Plan, based on feedback received from the CNSC during the Class 1B application process. This revised Fire Safety Plan was provided to, and accepted by, the City of Ottawa Fire Services. An annual fire drill exercise conducted in the fall of 2014 revealed no significant concerns.

In August of 2014, Best Theratronics revised its preliminary decommissioning plan, to reflect updated inventory and costing estimates. This was submitted to, and accepted by, the CNSC. In late 2014, Best Theratronics also proposed a change to the form of the proposed Financial Guarantee, which will be presented at a Commission Hearing in March 2015.

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. Although the Class 1B license was issued in July of 2014, this ACR covers the entire year (January 1, 2014 to December 31, 2014) and thus includes activities previously conducted under the old licenses.

2 Summary of Operations

Best Theratronics' operations continued with little change in 2014. 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. There were no significant changes in personnel.

2.1 Cyclotron Testing

The major change in 2014 was the completion and successful testing to <1 MeV of the 70P cyclotron. Dismantling of the cyclotron began in late December 2014. 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 2014. Of these, all except 5.00-QA-00, C1B-SD-15C and C1B-SD-15D were performed as part of the Class 1B license application and were implemented prior to receiving the Class 1B license. The Quality Manual, 5.00-QA-00 was updated and provided to the CNSC for review prior to implementation, as required in Best Theratronics' Licensing Conditions Handbook. Documents C1B-SD-15C and C1B-SD-15D were revised to reflect updated estimates for the preliminary decommissioning plan and were reviewed and accepted by the CNSC.

Table 1: List of procedures changed in 2014.

Document Title	Document Number
Best Theratronics Environmental, Health & Safety Responsibilities and Committees	5.08-SE-01
Training	5.00-QA-23
Device Design Risk Management	5.00-QA-29
Best Theratronics EH&S Policy	5.08-SE-00
Keeping Radiation Exposures and Doses ALARA	5.08-RP-12
Fire Safety Plan	1.08-SC-01
Radiation Protection Manual	5.08-RP-01
Preventative Maintenance	3.11-MC-19
Transport of Radioactive Material	5.08-TDG-01
Quality Manual	5.00-QA-00
Preliminary Decommissioning Plan	C1B-SD-15C
Financial Guarantee	C1B-SD-15D

In 2014, Best Theratronics also established a new procedure, 3.24-AA-30, "Cell A, B, and C Operating Procedure". This procedure was implemented to formalize and clearly define the roles and responsibilities of personnel working with Cells A, B, and C.

3 General Health and Safety

The Best Theratronics Health and Safety Committee meet monthly during 2014. 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 2014 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 2014, Best Theratronics documented a total of 16 medical reports, 2 of which required outside medical attention. A breakdown of the medical reports is as follows:

- 1) 9 reports (50%) related to cuts, scrapes, minor burns, and bruises.
- 2) 2 reports related to receiving particulate in the eye.
- 3) 3 reports related to straining or pulling a muscle.
- 4) 2 reports related to falls on ice in the parking lot.

The 2 incidents requiring outside medical attention were both cuts received by employees. In all instances, the medical reports were reviewed and corrective actions taken if appropriate. Corrective actions included use of face shields (verses standard safety glasses), increased salting of the parking lot, and additional precautions to employees to be aware of their surrounding 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 2014, all monthly facility surveys were found to be within these limits.

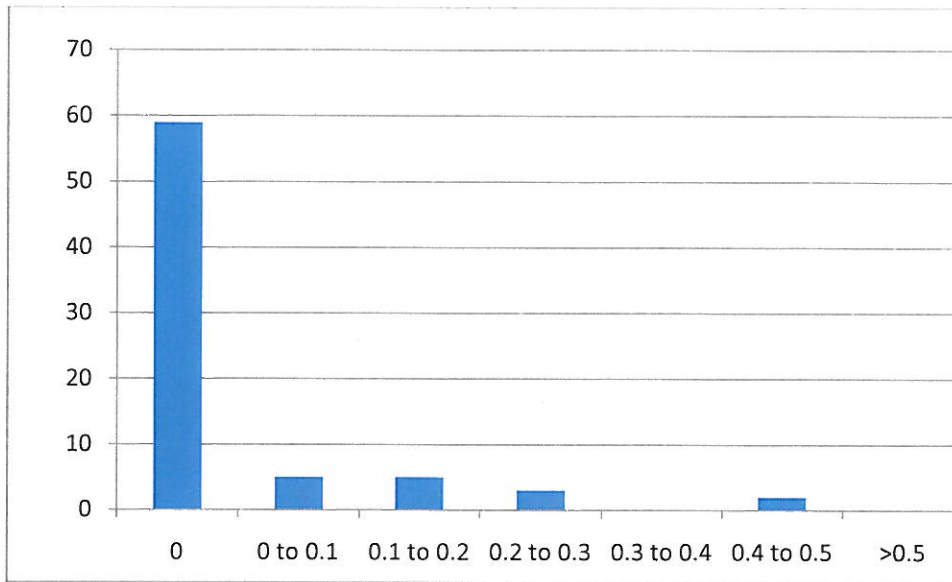
Best Theratronics also conducts monthly contamination checks of the facility. The limits set for determination of contamination is a reading twice background. In 2014, the monthly facility contamination checks were documented to be equal to background, indicating no contamination. Contamination checks are also performed on an as-needed basis, i.e., if work is undertaken that may potentially result in contamination. However, there was no such work performed in 2014. Finally, all incoming shipments of radioactive material were wipe tested as part of the receipt of radioactive material into the facility. In 2014, no incoming shipments were found to be contaminated.

A total of 74 Best Theratronics personnel were monitored with personal dosimetry badges. The highest annual dose recorded was 0.46 mSv. The dose distribution is shown in Figure 1. As can be seen, the vast majority of personnel received a dose of 0 mSv in 2014.

Twenty-eight (28) employees also received extremity dose monitoring (both left and right hands) in 2014. Of these 28 personnel, 26 recorded a 2014 annual extremity dose of 0 mSv. Only two personnel recorded extremity doses: 3.6 mSv and 2.0 mSv (both averaged over the left and right hands).

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 2014.



5 Environmental

There were no environmental monitoring reports in 2014 to report.

In 2014, Best Theratronics submitted a Toxic Reductions Act Plan to the Ontario Ministry of the Environment. This plan outlined the use of lead in manufacturing and potential means of reducing such usage. Lead is a key component of the Best Theratronics manufactured devices for radiation shielding. The plan was posted to the Best Theratronics' website.

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 2014, 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 2014.

Description	Amount
Acetone	615 L
Organic Flammable waste	400 L
Zirconium Alloy scrape	600 kg
PCB ballasts	20 kg
Machine Oil	1205 L
Inorganic Acid Oxidizer	40 L
Inorganic Caustic	80 L
Florescent bulbs and HID lamps	46 kg
Organic Gas Aerosols	8 L
Oily Rags	200 L
Glass	40 kg

5.2 Radioactive Hazardous Materials

In 2014, Best Theratronics received a total of 3341.6 TBq (referenced to Dec 31, 2014) of Co60 and 329.1 TBq (referenced to Dec 31, 2014) 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, Best Theratronics shipped 2106 TBq (referenced to Dec 31, 2014) 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.

In addition, Best Theratronics diverted a total of 19 disused Cs137 sealed source from the end-of-life stream to new inventory for use in new Gammacells.

6 Emergency Procedures

In 2014, Best Theratronics updated its Fire Safety Plan based on CNSC feedback obtained during the Class 1B application process. The updated Fire Safety Plan was provided to and accepted by the City of Ottawa Fire Services. The City of Ottawa Fire Services conducted an inspection of Best Theratronics in 2014 with no findings being reported.

The annual fire drill exercise was executed in fall 2014. There were no significant findings from the drill.

7 Management Reviews

Best Theratronics held two Management Review Team meetings in 2014. 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) Implemented a process to document experiences from external sources.
- 3) Need identified to streamline the non-conformance framework at Best Theratronics, which has begun. This will be monitored as a quality objective.
- 4) Require a review of process for self-assessment of management processes.

Best Theratronics had 4 major audits conducted in 2014 by regulatory agencies. These audits and their findings are summarized in Table 3.

Table 3. List of major regulatory audits in 2014.

Audit	Description	Findings
US FDA	Audit of QA program and process for manufacturing of medical products	2 minor observations. No regulatory follow-up required.
bsi	Audit of ISO 9001:2008 and ISO 13485:2003 programs, including CE marking	2 minor non-conformities identified, both administrative in nature.
CNSC	Export licensing compliance audit	No non-compliances were identified.
CNSC	Audit of 14127-1-14.0* license.	No non-compliances were identified.

*The activities licensed under 14127-1-14.0 were included in the Class 1B license. License 14127-1-14.0 was revoked once the Class 1B license was issued.

8 Financial Guarantee

Best Theratronics updated its Preliminary Decommissioning Plan in August of 2014 to reflect changes in inventory and to update to 2014 costing. This preliminary decommissioning plan was reviewed and accepted by the CNSC. In late 2014, Best Theratronics also proposed a change to the form of the proposed Financial Guarantee. This was submitted to the CNSC in early 2015 and will be presented at a Commission Hearing in March 2015.

9 Class II Workload

The R&D Class II prescribed equipment located in Cell 4 (T1000, S/N 4) was operated for a total 67 hours. All 67 hours were related to research. The Co60 source (S/N S5955) in the device head has an output of 38.6 cGy/min at 1 m (referenced to January 1, 2014). This provides a 2014 workload of 1551.7 Gy.

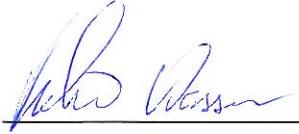
10 Summary

The Class 1B license offers Best Theratronics increased flexibility in its operations. Despite this, Best Theratronics operating status in 2014 did not change significantly from previous years. There were no major events, observations, or non-compliance identified during 2014 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.



Richard Wassenaar, PhD, MCCPM

Director of Compliance and RSO