Best Theratronics Ltd.
Request for Class IB Renewal

CMD 19-H2.B

May 16, 2019

Staff Presentation

Errata in CMD 19-H2

1. Page 12, Section 3.1.3.3, should say,
   'There are currently no proposed improvements related to this SCA.'
2. Page 73, Appendix E, title should say
   'Lost Time Incidents'

Outline

- Introduction
- Current Operations
- Evaluation of Licence Application
- Compliance History
- Other Matters of Regulatory Interest
- CNSC Staff's Recommendations

Introduction

On September 7, 2018, BTL submitted an application for the renewal of its **Class IB Nuclear Substance Processing Facility Operating Licence** to:

- Operate particle accelerators (cyclotrons)
- Manufacture and test radiation devices
- Develop and test Class II prescribed equipment (teletherapy machines)
- Store sealed sources

Additional Applications from BTL

On February 15, 2019, BTL submitted three additional licence applications:

- Radiation Device Manufacturing
- Storage of Nuclear Substances
- Development and Testing of Class II Prescribed Equipment

Cyclotron parts photographed during a CNSC inspection of BTL

Timeline

Between 2008 and 2014, BTL operated under **four licences**: Two **Class II licences** and two **NSRD licences**

On September 7, 2018, BTL applied for renewal of its **Class IB** licence

On February 15, 2019, BTL applied for three additional licences with the intention of reverting back to: **Class II licences and Nuclear Substances and Radiation Devices licences**

2008 — **2014** — **2018** — **2019**

In 2014, BTL applied for a **Class IB** licence to consolidate its existing **Class II** licence and two **NSRD** licences with the addition of operating **Class IB** cyclotrons. One Class II servicing licence was kept separate. **Licence was issued on July 1, 2014.**

June 30, 2019 is the expiration of BTL's **Class IB licence**

Class I Nuclear Facilities Regulations

The definition of ***Class IB nuclear facility*** in the *Class I Nuclear Facilities Regulations* includes:

(a) particle accelerators that are **capable** of producing nuclear energy and have a beam energy **≥ 50 MeV**

Cyclotrons are licensed based on **capabilities**

General Nuclear Safety and Control Regulations

The definition of a **nuclear facility** in the *General Nuclear Safety and Control Regulations* includes:

> "A facility for the management, storage or disposal of waste containing nuclear substances at which the resident inventory of radioactive nuclear substances contained in the waste is 10^{15} Bq or more."

Activities at BTL require a Class IB licence in accordance with the NSCA and regulations made under the NSCA

Activity and Licence Type

ACTIVITY	LICENCE TYPE
Resident waste inventory >10^{15}	Class I
Operate particle accelerators ($\geq$ 50 MeV)	Class I
Manufacture and test radiation devices	Nuclear Substance and Radiation Devices
Development and testing of teletherapy machines	Accelerators and Class II Facilities

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CURRENT OPERATIONS

Current Operations

Photo source: Google Maps

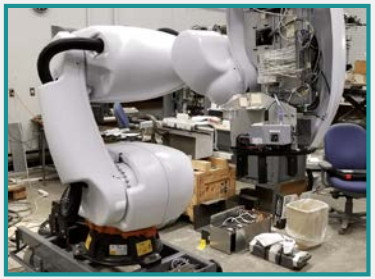
Highlighted in red is BTL's facility located in Ottawa, Ontario.

It is within an industrial zone adjacent to the Nordion facility, shown in blue.

Operations

Operations at BTL consist of:

- Manufacturing Co-60 teletherapy machines
- Manufacturing self-shielded irradiators
- Manufacturing cyclotrons ranging from 15MeV – 70MeV
- Developing and testing Class II prescribed equipment (teletheraphy machines)



Cobalt Teletherapy

Cyclotron

Gammacell 3000

Operations

- Prescribed equipment and radiation devices are manufactured at BTL
- Once manufactured, equipment is sent to Nordion, where the sources are loaded and equipment is returnedto BTL for testing and then shipped to customers
- Sources are stored at Nordion under its care and control
- Cyclotrons are currently tested below 1 MeV

Transport packages photographed during a CNSC inspection of BTL

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LICENCE APPLICATION

Ratings and Performance

- Safety and control areas (SCAs) are used to assess and evaluate licensee performance
- CNSC staff rate performance as:
  - Fully satisfactory (FS)
  - Satisfactory (SA)
  - Below expectations (BE)
  - Unacceptable (UA)
- Ratings are derived from results of regulatory oversight activities

CNSC staff rated all SCAs as satisfactory in 2018

Safety and Control Areas
Management System
Human Performance Management
Operating Performance
Safety Analysis
Physical Design
Fitness for Service
Radiation Protection
Conventional Health and Safety
Environmental Protection
Emergency Management and Fire Protection
Waste Management
Security
Safeguards and Non-Proliferation
Packaging and Transport

Environmental Protection

CNSC staff assessed BTL's environmental protection SCA against REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*

- There are no radiological releases from the facility
- There are hazardous releases due to lead pouring (below regulatory limits)

The environment has been and continues to be protected

Radiation Protection (1/2)

Radiation doses were well below regulatory limits

- Maximum effective dose to NEW: 0.98 mSv (2016)
- Maximum extremity dose to NEW: 3.70 mSv (2014)
- Revised action levels in 2016
- One event occurrence in 2018 (Class II servicing personnel)

An effective Radiation Protection program is in place

Radiation Protection (2/2)

Dose data	2014	2015	2016	2017	2018	Regulatory limit
Average effective dose (mSv)	0.00[1]	0.01	0.03	0.02	0.04	N/A
Maximum individual effective dose (mSv)	0.11	0.20	0.98	0.47	0.74	50 mSv/year
Number of NEWs Monitored	61	62	60	68	65	

[1] Below reportable limit of 0.01 mSv

Conventional Health and Safety (1/2)

BTL's Conventional Health and Safety program consists of:

- Hazard Prevention
- Health & Safety Committee and Inspections
- Provision of personal protective equipment and first aid

Effective Conventional Health and Safety program

Conventional Health and Safety (2/2)

Year	Incident Reports	On-site Treatment	Off-site Treatment	LTIs
2014	18	16	2	1
2015	11	9	2	1
2016	12	8	4	3
2017	9	6	3	1
2018	11	6	5	2

Compliance History

- 12 inspections and several desktop reviews were conducted during the licence period
- Order issued by CNSC Designated Officer related to financial guarantee in August 2015 – Closed
- Order issued by CNSC Inspector in October 2015 related to non-compliances with the National Fire Code of Canada – Closed

No outstanding enforcement actions

Future Regulatory Focus

- Risk Informed 10-year Baseline Inspection Plan for increased efficiency and effectiveness
  - 10 baseline inspections planned
- Reactive Inspections

Compliance Verification Criteria found in Licence Conditions Handbook

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OTHER MATTERS OF REGULATORY INTEREST

Financial Guarantee

- CNSC staff reviewed BTL's current preliminary decommissioning plan (PDP) and cost estimate which was found to be acceptable
- BTL submitted a financial guarantee (FG) for $1.8 million to reflect the preliminary decommissioning plan (CMD 17-H103)
- CNSC staff are satisfied that BTL has a valid financial guarantee
- Next review of PDP and FG to take place in 2022

Accepted by the Commission in July 2017

Delegation of Authority (1/2)

- Two proposed licence conditions for the Delegation of Authority from the Commission:
  - Licence Condition 3.2 – Reporting Requirements
  - Licence Condition 15.1 – Class IB Facility: Cyclotron
- Compliance verification criteria provided in licence condition handbook

Delegation of Authority (2/2)

Delegation of Authority proposed to:

- Director, Nuclear Processing Facilities Division
- Director General, Directorate of Nuclear Cycle and Facilities Regulation
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch

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RECOMMENDATIONS

Recommendations

CNSC staff recommend that the Commission:

1. Renew BTL's Class IB Nuclear Substance Processing Facility Operating Licence for 10 years
2. Authorize the Delegation of Authority to act as a person authorized by the Commission

Questions

Thank You!

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