



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Summary Record of Decision

In the Matter of

Applicant **Best Theratronics Limited**

Subject **Application to Renew the Best Theratronics
Limited Class IB Nuclear Substance Processing
Facility Licence**

**Public Hearing
Date** **May 16, 2019**

SUMMARY RECORD OF DECISION

Applicant: Best Theratronics Limited

Address/Location: 413 March Road, Kanata, Ontario, K2K 0E4

Purpose: Application to Renew the Best Theratronics Limited Class IB Nuclear Substance Processing Facility Licence

Application received: September 10, 2018

Amendment to application received: November 11, 2018

Date of public hearing: May 16, 2019

Location: Canadian Nuclear Safety Commission (CNSC) Public Hearing Room, 280 Slater St., 14th Floor, Ottawa, Ontario

Members present: R. Velshi, Chair
S. Demeter
M. Lacroix
K. Penney
T. Berube

Assistant Secretary: K. McGee
Recording Secretary: M. Hornof
Senior General Counsel: L. Thiele

Applicant Represented By	Document Number
K. Suthanthiran, President M. Soleimani, Director of Quality & Regulatory Affairs, RSO V. Sabaiduc, Director of Cyclotron Operations S. Schwisberg, Director of Human Resources & Legal Affairs	CMD 19-H2.1 CMD 19-H2.1A CMD 19-H2.1B CMD 19-H2.1C
CNSC staff	Document Number
R. Jammal, Executive Vice-President and Chief Regulatory Operations Office, Regulatory Operations Branch H. Tadros, Director General, Directorate of Nuclear Cycle and Facilities Regulation C. Moses, Director General, Directorate of Nuclear Substance Regulation C. Ducros, Director, Nuclear Processing Facilities Division M. Broeders, Director, Accelerators and Class II Facilities Division C. Purvis, Director, Radiation Protection Division K. Glenn, Director, Wastes and Decommissioning Division	CMD 19-H2 CMD 19-H2.A CMD 19-H2.B

I. Erdebil, Senior Project Officer, Nuclear Processing Facilities Division	
A. Erdman, Senior Project Officer, Nuclear Processing Facilities Division	
W. Khan, Project Officer, Nuclear Processing Facilities Division	
D. Estan, Radiation Protection Officer, Radiation Protection Division	

Licence: Renewed

Table of Contents

1.0 INTRODUCTION..... 1
2.0 DECISION..... 3
3.0 ISSUES AND COMMISSION FINDINGS 5

1.0 INTRODUCTION

1. Best Theratronics Limited (BTL) has applied to the Canadian Nuclear Safety Commission¹ for the renewal of its Class IB Nuclear Substance Processing Facility Licence (Class IB licence) for its facility located in the west end of Ottawa, Ontario. The current operating licence, NSPFOL-14.02/2019, expires on June 30, 2019. BTL requested a renewal of the licence for a period of 10 years.
2. Following a public Commission hearing in May 2014,² the Commission issued BTL its current licence, a Class IB licence. This licence authorizes BTL to manufacture and operate particle accelerators (specifically cyclotrons) that are capable of producing nuclear energy and have a beam energy up to 70 MeV, which are Class IB nuclear facilities pursuant to the *Class I Nuclear Facilities Regulations*³ (Class I Regulations). BTL's Class IB licence also authorizes BTL to possess and store nuclear substances, including waste containing radioactive nuclear substances at which the resident inventory of radioactive nuclear substances contained in the waste is $1\text{E}10^{15}$ Bq or more.⁴
3. Additionally, BTL's licence authorizes BTL to produce, possess and use prescribed equipment and radiation devices – such as teletherapy units and self-shielded irradiators. Prior to the issuance of the Class IB licence, BTL held four Class II nuclear facility and prescribed equipment licences (Class II licences) and nuclear substance and radiation devices licences (NSRD licences). These licences were consolidated into the Class IB licence in June 2014.
4. Although up to \$35,000 in funding to participate in this licensing process was made available to Indigenous groups, members of the public and other stakeholders through the CNSC's Participant Funding Program (PFP) in November 2018, no applications for funding were received. At the time of the PFP offering, interventions were invited from persons who have an interest or expertise in this matter, or information that may be useful to the Commission in coming to a decision on BTL's application; none were submitted.
5. This *Summary Record of Decision* reflects the substance of the Commission's decision with respect to the licence renewal and applicable licence conditions. It is issued now, in light of the pending expiry of the current licence. The detailed reasons for the Commission's decision and its assessment of the submissions made in respect of the application will be provided in a detailed *Record of Decision*, to be published at a later date.

¹ The *Canadian Nuclear Safety Commission* is referred to as the "CNSC" when referring to the organization and its staff in general, and as the "Commission" when referring to the tribunal component.

² CNSC Record of Decision, Including Reasons for Decision – Best Theratronics Limited, *Application for a Class IB Nuclear Substance Processing Facility Operating Licence*, decision issued on June 27, 2014.

³ Statutory Orders and Regulations (SOR)/2000-204

⁴ SOR/2000-202, paragraph 19(a).

Issues

6. In considering the application, the Commission was required to decide:
 - a) what environmental assessment review process to apply in relation to this application
 - b) whether BTL is qualified to carry on the activity that the licence would authorize; and
 - c) whether, in carrying on that activity, BTL will make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.
7. The Commission also assessed the assertion by BTL that a Class IB licence was not required for it to carry out its licensed activities. The Commission considered the issue of whether a Class II licence and two NSRD licences would apply to the licensed activities carried out at BTL's facility.

Requirement for Class IB Licence in Respect of BTL's Activities

8. On February 15, 2019, BTL submitted an application for a Class II licence and two applications for NSRD licence. These applications were submitted in addition to the Class IB licence renewal application but were intended to cover the same licensed activities as the Class IB renewal application. The Commission notes that BTL did not withdraw its Class IB licence renewal application following the submission of the applications for the one Class II licence and two NSRD licences. The Commission also notes that such licence applications are usually treated by designated officers (DO).
9. The Commission has authorized DOs within the Directorate of Nuclear Substance Regulation to carry out licensing authorities in respect of Class II licences and NSRD licences.⁵ However, the Commission has retained all licensing authorities in respect of Class I licences, including the Class IB licence application that is being considered by the Commission during this hearing.
10. In its submission for this proceeding, BTL expressed the view that its licensed activities, as defined by section 26 of the NSCA, did not fall within the scope of the Class I Regulations. Rather, BTL argued that its licensed activities fell within the scope of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*⁶ (Class II

⁵ CNSC Record of Decision, *Establishing Classes of Licences under Subsection 24(1) for the Designated Officer Authorization under Section 37 of the NSCA, and Authorizing Designated Officer Powers pursuant to Subsection 37(2) and Section 65.01 of the NSCA*, February 26, 2019.

⁶ SOR/2000-205

Regulations) and the *Nuclear Substances and Radiation Devices Regulations*⁷ (NSRDR), and could therefore be licensed through the DO-issued Class II and two NSRD licences, rather than a consolidated Commission-issued Class IB licence.

11. The result of the foregoing is that the Commission had to consider the renewal application for the Class IB licence and determine whether the activities BTL wishes to be authorized to carry out require a Class IB licence. CNSC staff submitted that the activities did require a Class IB licence, and therefore no DO decisions were to be made on BTL's other applications until the Commission decided this renewal application.

Public Hearing

12. The Commission, in making its decision, considered information in respect of BTL's Class IB licence renewal application presented for a one-part public hearing held on May 16, 2019 in Ottawa, Ontario. The public hearing was conducted in accordance with the *Canadian Nuclear Safety Commission Rules of Procedure*.⁸ During the public hearing, the Commission considered written submissions and heard oral presentations from BTL (CMDs 19-H2.1, 19-H2.1A, 19-H2.1B and 19-H2.1C) and CNSC staff (CMDs 19-H2, 19-H2.A, and 19-H2.B). The Commission invited oral interventions for this hearing, but none were received. The hearing was webcast live via the CNSC website, and video archives are available on the CNSC's website.

2.0 DECISION

13. Based on its consideration of the matter, the Commission concludes that BTL is qualified to carry on the activity that the licence will authorize. The Commission is of the opinion that BTL, in carrying on that activity, will make adequate provision for the protection of the environment, the health and safety of persons, and the maintenance of national security and measures required to implement international obligations to which Canada has agreed. Therefore,

the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, renews the Class IB Nuclear Substance Processing Facility Licence issued to Best Theratronics Limited for its facility located in Ottawa, Ontario. The renewed licence, NSPFL-14.00/2029, is valid from July 1, 2019 until June 30, 2029.

14. The Commission concludes that the licensed activities carried out by BTL in respect of both particle accelerators (cyclotrons) and waste containing radioactive nuclear

⁷ SOR/2000-207

⁸ SOR/2000-211

substances meet the definitions of a Class IB facility as set out in the GNSCR and the Class I Regulations.

15. In making its decision to renew the Class IB licence for BTL's facility and licensed activities, the Commission considered BTL's alternate interpretations of the Class I and Class II Regulations, and their applicability to its licensed activities. The Commission concludes that the operation of a particle accelerator *capable* of producing nuclear energy and with a beam energy of 70 MeV is defined as a Class IB nuclear facility, pursuant to paragraph 26(e) of the NSCA, even in instances where the particle accelerator is solely operated for the purposes of testing at 1 MeV.
16. The Commission considered BTL's interpretation of the GNSCR in respect of the management of waste radioactive nuclear substances and the International Atomic Energy Agency's (IAEA) definition of waste. The Commission notes that waste containing a resident inventory of more than $1\text{E}10^{15}$ Bq of radioactive nuclear substances meets the definition of a Class IB nuclear facility under paragraph 19(a) of the GNSCR and section 1 of the Class I Regulations.⁹ The Commission further notes that, during CNSC staff's April 2019 inspection at BTL's facility, the inventory of nuclear substances accepted for management, storage or disposal, that had reached the end of operational life, and for which there was unknown use was $1.56\text{E}10^{15}$ Bq. Since BTL had not identified the sources as having a use beyond the original intent and no future use was clearly foreseen at the time of their acceptance, these sources were appropriately classified as waste containing radioactive nuclear substances. Based on this information, the Commission concludes that BTL's licensed activities in this regard are therefore properly classified as the operation of a Class IB nuclear facility pursuant to paragraph 26(e) of the NSCA.
17. The Commission does not include licence condition 15.1 in the licence as proposed by CNSC staff in CMD 19-H2.A and does not delegate authority for the purposes of licence condition 15.1 to "a person authorized by the Commission." The Commission includes licence condition 15.1 in the licence that shall read:

"The licensee shall not operate a particle accelerator/particle accelerators (cyclotron/cyclotrons) with a capability of producing nuclear energy above 50 MeV at beam energy greater than 1 MeV without prior authorization from the Commission."
18. With the exception of licence condition 15.1 as detailed above, the Commission includes in the licence the conditions as recommended by CNSC staff. Specifically, the Commission includes in the licence Part IV) as detailed in CMD 19-H2.A and all other licence conditions as detailed in CMD 19-H2. The Commission delegates authority for the purposes of licence condition 3.2, as recommended by CNSC staff.

⁹ "Class IB nuclear facility means any of the following nuclear facilities:... (f) a facility prescribed by paragraph 19(a) or (b) of the *General Nuclear Safety and Control Regulations*.", section 1, SOR/2000-204.

19. The Commission is satisfied that an environmental assessment (EA) under the *Canadian Environmental Assessment Act, 2012*¹⁰ was not required in this matter. The Commission notes that a licence renewal is not a designated project under the CEAA 2012. The Commission is also satisfied that, based on the minimal interactions that BTL's facility has with the environment, a CNSC environmental protection review was not required for this matter.
20. With this decision, the Commission directs CNSC staff to report regularly on the performance of BTL as part of a *Regulatory Oversight Report*. CNSC staff shall present this report at a public proceeding of the Commission, where members of the public will be able to participate.
21. The Commission notes that CNSC staff can bring any matter to the Commission that merits its attention. The Commission directs CNSC staff to inform the Commission on an regular basis of any changes made to the Licence Conditions Handbook (LCH).

3.0 ISSUES AND COMMISSION FINDINGS

22. In making its licensing decision, the Commission considered a number of issues and submissions relating to BTL's qualification to carry out the licensed activities. The Commission also considered the adequacy of the proposed measures for protecting the environment, the health and safety of persons, national security and international obligations to which Canada has agreed.
23. BTL submitted a Class IB licence renewal application for its Ottawa, Ontario facility on September 10, 2018, with an amendment to the application filed on November 11, 2018. In its consideration of this matter, the Commission examined the completeness of the application and the adequacy of the information submitted by BTL, as required by the NSCA, the GNSCR and other applicable regulations made under the NSCA. The Commission also examined CNSC staff's assessment of BTL's performance in all 14 safety and control areas (SCAs) and in relation to several other matters of regulatory interest over the current licence period.
24. The Commission is satisfied that, based on the minimal interactions that BTL's facility has with the environment, a CNSC environmental protection review was not required for this matter in order to ensure that BTL's licensed activities do not pose unreasonable risk to the environment. The Commission is satisfied that the NSCA provides a strong regulatory framework for environmental protection in respect of the impact of BTL's facility on the environment.

¹⁰ S.C. 2012, c. 19, s. 52

25. Details of the Commission's rationale, and its consideration of the information submitted by BTL in support of its licence renewal application and of CNSC staff assessments in relation to this matter will be presented in a detailed *Record of Decision*, to be published at a later date.



June 25, 2019

Rumina Velshi
President,
Canadian Nuclear Safety Commission

Date