



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Record of Decision

DEC 19-H2

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 Date June 25, 2019

Detailed
Record of
Decision Date August 21, 2019

RECORD OF DECISION – DEC 19-H2

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

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Licence: Renewed

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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 Ottawa, Ontario. BTL requested a renewal of the licence for a period of 10 years. On June 25, 2019, the Commission renewed BTL's Class IB licence for the facility, in advance of its expiry on June 30, 2019.² This *Record of Decision* provides the detailed reasons for that decision.
2. Following a public Commission hearing in May 2014,³ the Commission issued BTL its previous licence, a Class IB licence. This licence authorized 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*⁴ (Class I Regulations). BTL's Class IB licence also authorized 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 10^{15} Bq or more.⁵
3. Additionally, BTL was authorized 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 in 2014, BTL held two Class II nuclear facility and prescribed equipment licences (Class II licences)⁶ and two nuclear substance and radiation device licences (NSRD licences).⁷ These licences were consolidated into the Class IB licence in June 2014.
4. Although up to \$35,000 in funding to participate in this licence renewal 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.

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 Summary Record of Decision – Best Theratronics Limited, *Application to Renew the Best Theratronics Limited Class IB Nuclear Substance Processing Facility Licence*, decision issued June 25, 2019.

³ 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.

⁴ Statutory Orders and Regulations (SOR)/2000-204

⁵ *General Nuclear Safety and Control Regulations*, SOR/2000-202, paragraph 19(a)

⁶ *Class II Nuclear Facilities and Prescribed Equipment Regulations*, SOR/2000-205

⁷ *Nuclear Substances and Radiation Devices Regulations*, SOR/2000-207

Issues

5. 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.
6. The Commission also assessed the assertion by BTL that a Class IB licence was not required for it to carry out the activities for which it seeks authorization. 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, instead of a single Class IB licence.

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

7. On February 15, 2019, BTL submitted an application for a Class II licence and two applications for NSRD licences. These applications were submitted in addition to the Class IB licence renewal application that was submitted to the CNSC on September 10, 2018, but were intended to cover the same 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 its applications for the Class II licence and NSRD licences.
8. The Commission has authorized designated officers (DO) within the Directorate of Nuclear Substance Regulation to carry out licensing authorities in respect of Class II licences and NSRD licences.⁸ However, the Commission has retained all licensing authorities in respect of Class I licences, including the Class IB licence application that was being considered by the Commission during this hearing.
9. 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*⁹ (Class II

⁸ 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.

⁹ SOR/2000-205

Regulations) and the *Nuclear Substances and Radiation Devices Regulations*¹⁰ (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.

10. 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 on 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 rendered a decision on this licence renewal application.
11. In its consideration of the requirement of a Class IB licence for BTL's requested activities, the Commission's analysis of these issues included, but was not limited to, the interpretation of the following definitions in the NSCA and its regulations:
 - i. The definition of a "Class IB nuclear facility" under section 1 of the Class I Regulations includes

*"a) a facility that includes a particle accelerator, other than a particle accelerator described in paragraphs (d) and (e) of the definition **Class II prescribed equipment** in section 1 of the Class II Nuclear Facilities and Prescribed Equipment Regulations;"*

"d) a plant, other than a Class II nuclear facility as defined in section 1 of the Class II Nuclear Facilities and Prescribed Equipment Regulations, for the processing or use, in a quantity greater than 10^{15} Bq per calendar year, of nuclear substances other than uranium, thorium or plutonium;"

and

"f) a facility prescribed by paragraph 19(a) or (b) of the General Nuclear Safety and Control Regulations."
 - ii. Paragraph 19(a) of the *General Nuclear Safety and Control Regulations*¹¹ (GNSCR) prescribes as a nuclear facility for the purposes of paragraph (i) of the definition "nuclear facility" in section 2 of the NSCA as

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

¹⁰ SOR/2000-207

¹¹ SOR/2000-202.

- iii. Section 1 of the Class II Regulations defines a “Class II nuclear facility” as “*a facility that includes Class II prescribed equipment.*”
- iv. The definition of “Class II prescribed equipment” under section 1 of the Class II Regulations includes
 - “*d) a particle accelerator that is capable of producing nuclear energy and has a beam energy of less than 50 MeV for beams of particles with a mass equal to or less than 4 atomic mass units;*”

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 hearing was conducted in accordance with the *Canadian Nuclear Safety Commission Rules of Procedure*.¹² During the 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 interventions 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. The hearing was webcast live via the CNSC website, and video archives are available on the CNSC’s website. A *Summary Record of Decision* was issued on June 25, 2019.

2.0 DECISION

- 13. Based on its consideration of the matter, as described in more detail in the following sections of this *Record of Decision*, 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.

¹² SOR/2000-211

14. The Commission concludes that the licensed activities carried out by BTL in respect of both particle accelerators (cyclotrons) and the resident inventory of waste containing radioactive nuclear 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 interpretations of the GNSCR, the Class I Regulations and the Class II Regulations, as they relate to BTL's licensed activities. Specifically, the Commission considered these submissions in regard to the management of waste containing radioactive nuclear substances and the operation of a particle accelerator (cyclotron) capable of producing nuclear energy with a beam energy of 70 MeV. As detailed in the following sections of this *Record of Decision*, the Commission concludes that BTL's activities in this regard are appropriately classified as the operation of a Class IB nuclear facility.
16. With the exception of licence condition 15.1 as detailed in paragraph 17 below, 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.
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. The Commission is satisfied that an environmental assessment (EA) under the *Canadian Environmental Assessment Act, 2012*¹³ (CEAA 2012) 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, based on the minimal interactions that BTL's facility has with the environment, that the CNSC environmental protection review for this matter was not required to entail an in-depth analysis to adequately assess environmental protection.
19. With this decision, the Commission directs CNSC staff to report regularly on the performance of BTL as part of a *Regulatory Oversight Report* (ROR). CNSC staff shall present this report at a public proceeding of the Commission, where members of the public will be able to participate.

¹³ S.C. 2012, c. 19, s. 52

20. 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 a regular basis via an ROR or other means, as practicable, of any changes made to the Licence Conditions Handbook (LCH).

3.0 ENVIRONMENTAL ASSESSMENT

21. In coming to its decision, the Commission was first required to determine whether an EA under CEAA 2012 was required.
22. The application submitted by BTL is for a Class IB facility licence renewal and BTL is not requesting authorization for new projects or physical activities.¹⁴ The Commission notes that a licence renewal is not a designated project under CEAA 2012.
23. CNSC staff submitted that BTL's facility has minimal environmental interactions and that its operations did not change during the previous licence period. For these reasons, and based on the EA that was carried out in November 2013¹⁵ and regulatory oversight that had been carried out during the previous licence period, CNSC staff reported that an EA was not required for this licence renewal.
24. Based on the information provided for this hearing, the Commission concludes that this licence renewal is not a designated project under CEAA 2012 and that an EA under CEAA 2012 is not required prior to its approval. Further, the Commission is satisfied that BTL has made, and will continue to make, adequate provision for the protection of the environment throughout the renewed licence period.
25. The Commission is satisfied that CNSC's staff's review of BTL's performance in the environmental protection SCA, based on regulatory oversight results and the 2013 EA (as detailed in section 4.8), is adequate for this licence renewal.

4.0 ISSUES AND COMMISSION FINDINGS

26. 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.
27. 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

¹⁴ "Projects" as defined in section 66 of CEAA 2012.

¹⁵ CNSC, *Environmental Assessment Report: BEST Theratronics Class IB Licence Application*, November 2013.

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 previous licence period.

28. In response to BTL's submission of the Class II and NSRD licence applications – in addition to the Class IB licence application for the same licensed activities – the Commission was required to determine whether the activities BTL wishes to be authorized to carry on require a Class IB licence or whether they could be appropriately regulated under Class II and NSRD licences. The Commission considered the interpretations submitted by BTL of the NSCA and its regulations in respect of cyclotron capability and its operation, and the management and definition of radioactive waste. The following sections of this *Record of Decision* provide the rationale for which the Commission concluded that a Class IB licence is the appropriate regulatory instrument in respect of the activities that BTL requested to carry out at its facility.

4.1 Management System

29. The Commission examined BTL's management system which covers the framework that establishes the processes and programs required to ensure that BTL achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture. Throughout the previous licence period, CNSC staff rated BTL's performance in this SCA as "satisfactory."
30. The Commission assessed BTL's quality management program, noting that BTL had achieved ISO 9001:2015, *Quality management systems – Requirements*¹⁶ and ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*¹⁷ certification. BTL submitted that its management system was supported by key documents including its Quality Manual, Radiation Protection Manual and Environmental Health and Safety (EH&S) Policy.¹⁸
31. BTL reported that it had carried out a gap analysis in respect to the implementation of CSA N286-12, *Management System Requirements for Nuclear Facilities*¹⁹ and that BTL would continue to implement the identified improvements to its management system during the renewed licence period. CNSC staff reported that its review of the CSA N286-12 gap analysis revealed several deficiencies in respect to the "generic requirements and site selection" specifications of the standard, and that CNSC staff had provided BTL with action items to address the deficiencies. CNSC staff reported that

¹⁶ International Organization for Standardization, International Standard ISO 9001:2015, *Quality management systems – Requirements*, Fifth edition, 2015.

¹⁷ International Organization for Standardization, International Standard ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*, Third edition, 2016.

¹⁸ EH&S: Environmental health and safety.

¹⁹ CSA N286-12: *Management System Requirements for Nuclear Facilities*, CSA Group, 2012.

BTL was expected to be fully aligned with CSA N286-12 by the end of 2019 and that CNSC was planning an inspection to verify the implementation of the standard in early 2020.

32. BTL reported that a 2017 internal audit of its facility identified improvement actions in respect of BTL's document management system, including the increased use of electronic tools for documentation, digitizing historical documentation, and improving digital backup systems. CNSC staff submitted that the audit also identified improvement actions in regard to the development of an "opportunity for improvement" system and the re-evaluation of all auditor qualifications, and that CNSC staff would verify that BTL continued to make improvements in these areas during the renewed licence period.
33. The Commission assessed the safety culture at BTL's facility, with BTL submitting that it had implemented a culture of safety and compliance through its management structure, procedures and health and safety committee. BTL also reported that its corrective action preventative action (CAPA) system tracked internal performance in relation to safety, environment and quality assurance and that risk-based assessment was applied to the CAPA system during the previous licence period.
34. On the basis of the information provided on the record for this hearing, the Commission concluded that BTL has appropriate management and organizational structures in place, and that the operating performance at its facility in the previous licence period provides a positive indication of BTL's ability to adequately carry on the activities under the renewed licence. The Commission is also satisfied that BTL has maintained and will continue to maintain a strong safety culture during the renewed licence period.
35. The Commission fully expects BTL to continue the implementation of CSA N286-12 during the renewed licence period, as detailed in the materials that it submitted for this hearing.

4.2 Human Performance Management

36. The Commission assessed BTL's human performance management programs. These programs encompass activities that enable effective human performance through the development and implementation of processes that ensure that BTL staff are sufficient in number in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties. During the previous licence period, CNSC staff rated BTL's performance in this SCA as "satisfactory."
37. The Commission examined the information submitted by BTL regarding its personnel training program. In its written materials, BTL provided information about the systematic approach to training (SAT) based program that was implemented at BTL during the previous licence period. BTL also reported that all BTL employees had a

training record file to ensure that they maintained the necessary knowledge and skills required for their position. CNSC staff informed the Commission that compliance verification activities during the previous licence period showed that BTL's human performance programs ensured that BTL had a sufficient number of staff required to carry out its operations.

38. CNSC staff submitted that BTL's training program met the specifications of REGDOC-2.2.2, *Personnel Training*, Version 2.²⁰ CNSC staff also submitted that BTL's training program met the requirements of the GNSCR and the Class I Regulations, and that BTL had a certified radiation safety officer (RSO), in accordance with the CNSC regulations. CNSC staff reported that, during the renewed licence period, BTL's compliance with REGDOC-2.2.2 and applicable regulations would continue to be verified through regular compliance activities.
39. BTL reported to the Commission that, during the renewed licence period, an electronic training management system would be implemented at its facility. BTL also reported that its training programs would be updated to provide employees with clarification about licensing and regulatory requirements in respect of BTL's operations. CNSC staff submitted that, although BTL's SAT-based training program met CNSC expectations, the electronic training management system would improve the implementation of that program.
40. In regard to knowledge management, BTL informed the Commission that its goal during the renewed licence period would be to increase the time overlap between retiring employees and new employees to allow for more comprehensive training of new hires. The Commission asked CNSC staff about whether the higher staff turnover identified by BTL was considered as a potential risk to BTL's operation. CNSC staff responded that BTL's programs were reviewed during inspections to ensure that all staff maintained adequate levels of training for the work being carried out. CNSC staff also stated that BTL's programs and performance in this regard were assessed by CNSC staff as being satisfactory during the previous licence period. The Commission is satisfied on this point.
41. Having examined all of the information provided on the record for this hearing, the Commission is satisfied that BTL's training programs meet the objectives of REGDOC-2.2.2. The Commission concludes that BTL has appropriate programs in place and that current efforts related to human performance management provide a positive indication of BTL's ability to adequately carry on the activities under the renewed licence.
42. The Commission notes the planned improvements identified by BTL in respect of its human performance program, such as electronic training management and knowledge management, and anticipates that these improvements will be carried out during the renewed licence period as detailed in the materials submitted for this hearing.

²⁰ CNSC Regulatory Document REGDOC-2.2.2, *Personnel Training*, Version 2, 2016.

4.3 Operating Performance

43. The Commission examined BTL's operating performance, which includes an overall review of the conduct of the licensed activities and the activities that enable effective performance, as well as improvement plans and significant future activities at the facility. Throughout the previous licence period, CNSC staff rated BTL's performance in the operating performance SCA as "satisfactory."
44. The Commission assessed BTL's operating procedures. BTL reported that it had an extensive program in place to ensure that operating performance was maintained and that this program included approximately 900 internal procedures. BTL submitted that its operational performance would be monitored throughout the renewed licence period via internal audits of its programs and procedures.
45. CNSC staff reported that BTL's procedures and supporting documentation met CNSC expectations. CNSC staff also submitted that BTL had updated its operational procedures during the previous licence period and that compliance verification activities showed that the BTL facility was operated safely, with BTL implementing CNSC-approved programs in accordance with its licensing requirements.
46. CNSC staff submitted that, during the previous licence period, BTL had constructed one cyclotron capable of producing nuclear energy with a beam energy of 70 MeV. However, since BTL had not operated a cyclotron beyond 1 MeV, BTL had not requested for authorization in that regard, as required by licence condition 16.1 of the previous operating licence.
47. The Commission assessed the information submitted by BTL regarding its adherence to the specifications of REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*.²¹ BTL submitted that, throughout the previous licence period, reports were provided to the CNSC in a timely manner and in accordance with REGDOC-3.1.2. CNSC staff submitted information about reportable events at the BTL facility during the previous licence period, noting that reports were submitted in accordance with regulatory requirements and that reportable events were minor and did not pose an unreasonable risk to the health and safety of persons or the environment.
48. Based on the information submitted for this hearing, the Commission concludes that the operating performance at BTL's facility during the previous licence period provides a positive indication of BTL's ability to carry out the activities authorized under the renewed licence. The Commission is also satisfied that BTL met, and will continue to meet, reporting requirements as set out in REGDOC-3.1.2.

²¹ CNSC Regulatory Document REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*, 2018.

4.4 Safety Analysis and Physical Design

49. Due to the intertwined nature of safety analysis and physical design at BTL's facility, CNSC staff considered the safety analysis and physical design SCAs together during its assessment of this licence renewal application, with the Commission considering these SCAs together as well.
50. Safety analysis includes a systematic evaluation of the potential hazards associated with the conduct of the licensed activity or the operation of a facility, and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards. Safety analysis supports the overall safety case for BTL's facility. Physical design includes the activities to design the systems, structures and components to meet and maintain the design basis of the facility. CNSC staff reported that, throughout the previous licence period, BTL's facility was operated safely, and within BTL's licence limits and design basis, with BTL's performance in the safety analysis and physical design SCAs being rated as "satisfactory" by CNSC staff.
51. In its written materials, BTL informed the Commission that a key component of its safety analysis framework was the use of safety analysis reports (SAR), which were implemented to ensure that BTL's licensed activities were carried out safely. BTL submitted that SARs were undertaken as part of the initial design process or when there were changes to safety critical components, including radiation devices and Class II prescribed equipment, radioactive material transport containers and the facility itself. BTL also submitted that changes to SARs were considered in BTL's design change procedure, and that any changes to existing SARs or the implementation of new SARs required extensive review and sign-off. BTL also reported that SARs for its radiation-related operations were reviewed internally during the previous licence period and were found to be current and accurate.
52. CNSC staff submitted that, during the previous licence period, a review of BTL's SARs for the Shielded Room 4 (used for beam characterization and the testing of cobalt-60 teletherapy heads and collimators), for cyclotron testing and building, and for radioactive material processes showed that the shielding and design of BTL's systems and components were adequate and met CNSC staff's expectations.
53. BTL reported that, during the previous licence period, facility hazards were discussed at health and safety meetings, and addressed through approved procedures. BTL also reported that an updated fire hazard analysis for its facility was completed by a qualified third-party reviewer in 2016, resulting in updates to emergency response and fire protection procedures.
54. The Commission assessed the information provided by BTL regarding its facility management framework. BTL submitted that all modifications and improvements at its facility had been carried out by qualified personnel, noting that all building changes to areas relating to licensed activities or that may affect health and safety required a SAR prior to work being started. BTL also submitted that all of the design work for its

facility was undertaken by licensed engineers.

4.4.1 Operation of a Cyclotron Capable of Producing a Beam Energy Greater than 50 MeV

55. In making its decision regarding the regulatory requirements that applied to BTL's licensed activities in respect of the operation of cyclotrons, the Commission considered BTL's interpretations of the Class I and Class II Regulations, and their applicability to BTL's licensed activities. Specifically, BTL argued that the particle accelerator (cyclotron) manufactured at BTL's facility was not able to produce over 50 MeV of energy until this functionality was enabled by the end user through the removal of the physical barrier that BTL put in place during manufacturing. As such, BTL submitted that the cyclotrons produced by BTL did not fall within the scope of the definition of a Class IB facility, as provided for by the Class I Regulations, and need not be licensed as such.
56. BTL reported to the Commission that, during the previous licence period, no cyclotrons were operated beyond a beam energy of 1 MeV. BTL further submitted that, for this reason, the plan to design a shielding bunker for operating cyclotrons at those beam energies was not initiated and that modifications to the High Bay Area of the BTL facility – which is dedicated for the construction and testing of cyclotrons, as detailed in BTL's *Final Safety Analysis Report for Cyclotron Testing* (FSAR) – were not required. BTL also submitted that it did not intend to operate cyclotrons above 1 MeV during the renewed licence period and that, for this reason, modifications to the designated cyclotron testing area to allow for testing at higher beam energies would not be required.
57. CNSC staff provided additional information about the cyclotron testing SAR, explaining that the SAR defined the limiting operational design parameters, typical beam energy and current, and shielding. CNSC staff submitted that, prior to its issuance of authorization for the operation of a cyclotron above 1 MeV, BTL would be required to submit to the CNSC an updated FSAR that would analyze radiological risks and specify the procedures that would be implemented to minimize those risks.
58. In regard to the assertion by BTL that its licensed activities in respect of the operation of cyclotrons should not be regulated under the Class I Regulations, namely the operation of a cyclotron capable of producing nuclear energy with a beam energy of 70 MeV, the Commission asked about how CNSC staff assessed the regulatory requirements for a licensed activity. CNSC staff responded that its assessments of a licensee's activities focussed on limiting the risk to persons and the environment, and the capability of nuclear energy being produced – in this case a beam energy of 70 MeV – rather than the various contexts – such as limiting the operation to below 1 MeV – that may, or may not, lead to the production of nuclear energy.

59. The Commission enquired about how particle accelerators were regulated internationally. CNSC staff responded that, in regard to international regulation of particle accelerators, IAEA safety standards had well-established requirements for such activities and facilities, including the operation of accelerators. CNSC staff further stated that IAEA safety standards were founded on having regulatory control based on the maximum design capability, recognizing that it is the licensee's responsibility to ensure that it is working within its established safety limits. CNSC staff acknowledged that BTL may have contractual agreements under which they may only test cyclotrons up to 1 MeV, but stated that the IAEA safety standards and CNSC regulations were based on the maximum design capability of the cyclotron and the barriers in place to ensure the safety of workers and the public, and not on the licensee's contractual agreements. CNSC staff noted that these IAEA safety standards also recognized that the regulator would not be carrying out daily monitoring of licensees to ensure that they were only operating at specified limits, such as a 1 MeV in the case of BTL's cyclotron, that may not match its design capability.
60. In response, the BTL representative submitted the view that IAEA safety standards did not apply to cyclotrons producing a beam energy below 1 MeV and at which nuclear energy is not produced. The BTL representative also argued that IAEA standards only applied to facilities operating cyclotrons, not to their manufacturers.
61. The Commission requested additional information regarding the barriers – whether physical or administrative – that are in place to prevent BTL's 70 MeV cyclotrons from operating above 1 MeV. CNSC staff provided the Commission with general information about the operation of a cyclotron and noted that, although physical beam control mechanisms to control a cyclotron's operation could be implemented, inappropriate handling of such mechanisms remained a risk. In regard to BTL's cyclotron specifically, CNSC staff explained that the cyclotron as constructed had a panel to prevent its operation above 1 MeV which clearly stated "do not remove," but that this was by no means a permanent barrier. As such, CNSC staff stated the cyclotron was still *capable* of producing nuclear energy with a beam energy of 70 MeV, whether this temporary barrier was in place or not.
62. In regard to administrative barriers, CNSC staff informed the Commission that, in order to operate the cyclotron at 70 MeV, procedures dealing with requirements for dedicated shielding in the facility that would have to be in place and adequate regulatory oversight of those operations would have to be implemented. CNSC staff further explained that these administrative barriers would be covered in the FSAR.
63. Asked to provide information on this topic of operational barriers, the BTL representative explained that the barrier used by BTL to prevent a cyclotron's operation above 1 MeV had been designed by TRIUMF²² and was akin to an industry standard. The BTL representative also explained that BTL's practice, as well as international

²² TRIUMF, a CNSC Class IB licensee, was established in 1968 in Vancouver, British Columbia and hosts the largest cyclotron in the world. TRIUMF is considered as a leading Canadian physics laboratory and an internationally-recognized subatomic physics research centre. (source: www.triumf.ca).

practice, was to not test cyclotrons above 1 MeV. Additionally, the BTL representative stated that, since BTL was ISO 9001 and ISO 13485 certified, BTL was required to have detailed documentation for all of its activities in respect of these cyclotrons, including their operation. The Commission is satisfied with the information provided by BTL and CNSC staff on this topic.

64. Further on the issue of operating a cyclotron above 1 MeV, the BTL representative informed the Commission that cyclotron components could become radioactive if a cyclotron was operated above 1 MeV, making it nearly impossible to ship to customers. The BTL representative noted that this was one of the reasons the 70 MeV cyclotron BTL constructed in 2014 for a European client had not been tested at 70 MeV at BTL's facility, as was originally planned. The BTL representative stated that, for all of these reasons, BTL has not tested and does not intend to test cyclotrons over 1 MeV.
65. Considering the information provided by BTL regarding the testing of cyclotrons, the Commission enquired about how a cyclotron could be fully tested prior to delivery to a customer without operating it at its full design capability. The BTL representative provided information about how the final trajectory of particles inside cyclotrons operating at low energy could be ascertained, and about other design criteria and parameters that could be assessed at low energy. The BTL representative submitted that operating experience has shown this to be an acceptable and effective practice for particle accelerator manufacturers. The Commission was satisfied with the information provided on this topic.
66. The Commission requested information about how beam current was considered in the regulation of particle accelerators. CNSC staff responded that, although the Class I and Class II Regulations used beam energy as a demarcation to differentiate between low- and high-risk accelerators, when a licensee was establishing a safety case it was required to consider both the beam current and beam energy together for the proposed design of its facility. The Commission was satisfied with the information provided on this point.
67. Based on the information provided during this hearing, the Commission disagrees with BTL's interpretation of the applicability of IAEA safety standards and of the applicable CNSC regulations. The Commission notes that IAEA safety standards are clear in their application to accelerators (radiation generators), as well as to both manufacturers and operators of the accelerators. The Commission further notes that the IAEA safety standards provide for the safe use once an accelerator is assembled since accelerators do not pose a radiation hazard until power is applied to the units. In considering this information as a whole, the Commission is of the view that the operation of an accelerator, even at a beam energy below 1 MeV, is defined as the use of an accelerator as per the IAEA safety standards and agrees with CNSC staff's interpretation of the international standards in this regard.

68. Based on the information considered during this hearing, the Commission is satisfied that BTL's SAR for the operation of cyclotrons is adequate. The Commission is also satisfied that CNSC staff had adequately assessed BTL's licensed activities as they relate to the operation of cyclotrons.

4.4.2 Conclusion on Safety Analysis and Physical Design

69. On the basis of the information presented, the Commission concludes that the systematic evaluation of the potential hazards and the preparedness for reducing the effects of such hazards is adequate for the operation of the BTL's facility and the activities under the renewed licence. The Commission finds that BTL's safety analysis program meets regulatory requirements and that BTL has adequate preventive measures and strategies in place to ensure the protection of workers, members of the public and the environment, and that its facility meets safety requirements.
70. On the basis of the information presented, the Commission also concludes that BTL continues to implement and maintain an effective design program and that the design of BTL's facility is adequate for the renewed licence period.
71. The Commission notes that, during this hearing, BTL submitted that it operated the cyclotrons that it manufactured at a maximum beam energy of 1 MeV. Upon consideration of the evidence on the record for this hearing, the Commission concludes that the operation of a particle accelerator *capable* of producing a beam energy greater than 50 MeV at any beam energy is a licensed activity under the NSCA, with the particle accelerator meeting the definition of a Class IB nuclear facility under the Class I Regulations and therefore requiring licensing under these regulations. Furthermore, the Commission finds that the operation of a particle accelerator *capable* of producing nuclear energy with a beam energy of 70 MeV is the operation of a Class IB nuclear facility. The Commission finds that this definition is applicable even when particle accelerators are solely operated for the purposes of testing them at 1 MeV, and that a Class IB licence is appropriate in respect of the regulation of this licensed activity. The Commission is also of the view that the temporary physical barrier put in place to limit the beam energy of the cyclotron does not amount to a reduction in the cyclotron's capability.
72. The Commission considered the site-specific licence condition 15.1 and the recommended delegation of authority to CNSC staff, as detailed in CMD 15-H2.A:

“The licensee shall not operate a particle accelerator/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 or a person authorized by the Commission.”

73. The Commission notes that, although BTL submitted that it did not intend to operate manufactured cyclotrons above 1 MeV, BTL does not have in place controls and measures to ensure that the operation of a cyclotron above 50 MeV would not have an adverse impact on the health and safety of workers, the public and the environment. Due to the risks represented by the operation of a cyclotron above 50 MeV, the Commission does not delegate the authority to CNSC staff to consider the provision of authorization to BTL to carry on this activity. Therefore, Commission includes in the renewed licence the facility-specific licence condition 15.1 which reads

“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.”

74. Should BTL request to carry out this licensed activity during the renewed licence period, an application for authorization with adequate technical information supporting BTL’s carrying out of this activity shall be submitted to the Commission for its decision. With its application, BTL shall include an updated *Final Safety Analysis Report* with details about the proposed cyclotron operation and the radiation protection measures that will be taken by BTL. BTL shall also submit information about how it would ensure the health and safety of workers and the public, as well as the protection of the environment.

4.5 Fitness for Service

75. Fitness for service covers activities that are performed to ensure that BTL’s systems, structures and components (SSCs) continue to effectively fulfill their intended purpose. CNSC staff rated the BTL’s performance in this SCA as “satisfactory” throughout the previous licence period.
76. The Commission considered the information provided by the BTL and CNSC staff regarding the fitness for service of BTL’s facility and the equipment within the facility. BTL reported that the fitness for service of its facility was managed by its Facilities Maintenance Specialist, with the facility assessed on an on-going basis by BTL’s H&S Committee. BTL also reported that the areas where licensed activities were carried out were reviewed by the Radiation Safety & Security Committee. BTL further informed the Commission that BTL implemented improvements to its facility, as required, through its fitness for service program.
77. In its written materials, BTL provided the Commission with information about its procedures for the facility, which ensured that radiation monitoring equipment was calibrated and in good working order. BTL noted that the equipment was checked monthly and calibrated by a third-party annually. BTL also submitted that the fitness for service of Class II prescribed equipment was maintained through operating instructions which ensured their safe operation and also set out the requirements for the

testing of the radiation safety mechanisms of the equipment.

78. The Commission considered BTL's preventive maintenance program, with BTL reporting that no negative trends of equipment performance were observed during the previous licence period and all required equipment was maintained in good working order, with repairs completed immediately when required in order to prevent potential health and safety issues. BTL also submitted that, to resolve issues relating to equipment unavailability due to repairs or expired calibration dates, BTL purchased additional equipment and confirmed to the Commission that this situation would be closely monitored during the renewed licence period.
79. CNSC staff submitted that compliance verification activities during the previous licence period showed that BTL implemented an adequate fitness for service program through preventive maintenance, measurement and testing of equipment, and new equipment validation, and that the program was supported by adequate detailed procedures. CNSC staff also submitted that BTL had ongoing maintenance, calibration and testing programs to ensure continued reliability of the safety systems which were required for its Class IB nuclear facility and the Class II nuclear facility located within the Class IB facility.
80. Based on the information provided on the record for this hearing, the Commission concludes that the equipment as installed at BTL's facility is fit for service and that appropriate programs are in place to ensure that the equipment remains fit for service throughout the renewed licence period.
81. The Commission is satisfied with the measures put in place by BTL to resolve issues related to equipment unavailability and expects BTL to continue to monitor and address this situation during the renewed licence period as proposed in the information submitted on the record for this hearing.

4.6 Radiation Protection

82. As part of its evaluation of the adequacy of the measures for protecting the health and safety of persons, the Commission considered the past performance of BTL in the area of radiation protection. The Commission also considered how BTL's radiation protection program ensured that radiation doses to persons were monitored, controlled and kept as low as reasonably achievable (ALARA), with social and economic factors taken into consideration. Throughout the previous licence period, CNSC staff rated BTL's performance in this SCA as "satisfactory."
83. The Commission considered the information provided by BTL and CNSC staff to assess whether BTL's radiation protection program satisfied the requirements of the *Radiation Protection Regulations*²³ (RPR). CNSC staff submitted that compliance verification activities carried out during the previous licence period, including desktop

²³ SOR/2000-203

reviews of annual compliance reports and on-site inspections, showed that BTL had implemented an appropriate and effective radiation protection program at its facility that met regulatory requirements.

84. The Commission enquired about the radiation protection measures that would be required if BTL were to operate a cyclotron above 1 MeV. CNSC staff responded that measures such as additional shielding, interlocks and safety systems would be required in BTL's facility. CNSC staff added that this was the reason for the 1 MeV hold point that CNSC staff recommended in licence condition 15.1 of the renewed licence, noting that below 1 MeV these additional measures were not required. The BTL representative confirmed that BTL currently had the infrastructure in place to safely operate cyclotrons below 1 MeV, but confirmed that additional radiation protection measures for operation above 1 MeV were not put into place during the previous licence period since BTL had not carried out that activity. The Commission is satisfied with the information provided on this topic and notes that BTL does not currently have appropriate shielding or safety systems in place at its facility to operate cyclotrons above 1 MeV.

4.6.1 Application of ALARA

85. The Commission assessed the information submitted by BTL and CNSC staff regarding the application of ALARA at BTL's facility. BTL submitted that its ALARA program consisted of planning for special work (work permits), training, and dosimetry. In its written materials, BTL explained that a work permit system for any work that fell outside of normal and routine work was used at the BTL facility. BTL further noted that any non-routine work that could result in a radiation exposure had to be approved by the BTL RSO, and that a work permit had to be issued prior to this work being undertaken. BTL submitted that, during the renewed licence period, BTL would continue to improve its radiation protection program to ensure that doses to workers remained ALARA.
86. In regard to nuclear energy workers (NEW) at its facility, BTL reported that all employees who had a reasonable probability of receiving an occupational dose greater than the public regulatory dose limit of 1 mSv/year and required access to designated radiation areas were defined as NEWs. BTL also reported that all NEWs received radiation safety training and training on the use of radiation measurement instrumentation.
87. CNSC staff reported that BTL had adequately implemented the ALARA principle through its radiation protection program, which met the specifications of G-129, *Keeping Radiation Exposures and Doses "As Low As Reasonable Achievable" (ALARA)*.²⁴ CNSC staff informed the Commission that its regulatory focus during the renewed licence period would include ensuring that BTL evaluated its processes and

²⁴ CNSC Regulatory Guide G-129, *Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable" (ALARA)*, 2004.

practices, including reviews of radiological action levels, to maintain radiation doses to workers ALARA.

88. CNSC staff reported that, since BTL did not carry out activities that may result in the release of nuclear substances to the environment and BTL maintained gamma radiation dose rates ALARA, the dose impact of BTL's licensed activities to members of the public could not be distinguished from natural background gamma radiation. CNSC staff also noted that drivers transporting radioactive materials in appropriate packaging were the most likely members of the public to receive a dose, with the average dose to the driver for a typical shipment being 0.00835 mSv (8.35 µSv), resulting in a yearly dose well below the public limit of 1 mSv/year.
89. Based on the information considered for this hearing, the Commission is satisfied that the ALARA concept is adequately applied to all of BTL's activities. The Commission is also satisfied that BTL is adequately controlling radiological doses to the public.

4.6.2 Worker Dose Control

90. In regard to radiological hazards, BTL reported that the primary radiological risk to workers at its facility was from sealed radiation sources. CNSC staff submitted that, although the potential for radiological contamination at the BTL facility was low, BTL had implemented a thorough surface contamination monitoring procedure at its facility and that no contamination had been detected during the previous licence period.
91. BTL reported that its NEWs were classified into two categories: device manufacturing and Class II research and development employees (R&D NEWs), and Class II servicing employees (Class II servicing NEWs). BTL submitted that the R&D NEWs conducted radiation-related work solely in BTL's Class IB facility.
92. In regard to its Class II servicing activities, BTL submitted that this licensed activity was regulated under a Class II licence and not included in the Class IB licence. As such, BTL reported that the Class II servicing NEWs were monitored for both work completed at the BTL facility under the Class IB licence, as well as licensed servicing work carried out across Canada under the Class II service licence, to ensure that their dosimetry record took into account all radiation-related work that they carried out.
93. The Commission considered the information submitted by BTL regarding the average and maximum whole body and extremity doses to BTL workers. BTL reported that, during the previous licence period, the Class II servicing NEWs received the highest whole body and extremity doses, with the exception of a 2014 maximum extremity dose of 3.7 mSv received by an R&D NEW. BTL also reported that the majority of its NEWs – both R&D and Class II servicing – received doses smaller than 0.1 mSv/year, well below the annual whole-body regulatory dose limit of 50 mSv/year, as prescribed by the RPR.²⁵ BTL further submitted noted that the highest extremity dose of 29.90

²⁵ SOR/2000-203, subsection 13(1)

mSv was received by a BTL Class II servicing NEW in 2016, well below the annual extremity regulatory dose limit of 500 mSv/year.²⁶

94. In its written submission, CNSC staff informed the Commission that, due to the nature of the servicing work carried out by BTL, the Class II servicing NEWs were expected to have higher doses than the R&D NEWs. CNSC staff also reported that that all doses to NEWs during the previous licence period remained well below regulatory limits and were within expected range. CNSC staff noted that, in order to ensure a radiologically safe workplace, BTL had fixed dose rate monitors with set alarm thresholds installed throughout its facility.
95. The Commission also considered action level²⁷ exceedances at BTL's facility during the previous licence period. BTL reported that, following a 2016 CNSC inspection and subsequent finding that BTL's action levels were set high in contrast to doses reported over five years, action levels at BTL's facility were reassessed and decreased. CNSC staff submitted that it was satisfied with the actions taken by BTL to set more meaningful actions levels, noting that BTL implemented periodic reviews of its action levels and that the periodic reviews were an enhancement to its radiation protection program. The Commission is satisfied with the actions taken by BTL in this regard.
96. BTL submitted information about an October 2018 exposure incident which led to action level exceedances by two Class II servicing NEWs during preparatory activities for the testing of a prototype teletherapy head with a radioactive source. As a result of the incident, BTL reported that one NEW exceeded the whole body dose action level of 4 mSv/month, with a dose of 8.65 Sv, and that the second NEW exceeded the extremity dose action level of 10 mSv/month, with a measured dose of 13.51 mSv.
97. Asked about why the doses reported by BTL differed from those reported by CNSC staff, the BTL representative provided information about its NEWs that had doses reported for both their work under the Class IB licence as well as the Class II servicing licence, noting that CNSC staff had only reported on doses in respect of BTL's activities related to the Class IB licence. The BTL representative further explained that, in terms of radiation protection of its workers, BTL did not separate its report on doses between the two licences to ensure that a single dose-profile for each worker was available. The Commission is satisfied with BTL's explanation on this point but requests that, in future submissions to the Commission, BTL and CNSC report worker dose data in a clearer, more consistent manner.
98. The Commission enquired about the maximum dose to BTL's workers during the previous licence period, noting that, although it remained below the

²⁶ SOR/2000-203, subsection 14(1)

²⁷ The *Radiation Protection Regulations* define an "action level" as a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program and triggers a requirement for specific action to be taken.

50 mSv/year dose limit,²⁸ the maximum effective dose had increased from 0.46 mSv/year in 2014 up to 8.92 mSv/year in 2018. The BTL representative stated that the average annual dose to workers remained below 1 mSv/year throughout the licence period and explained that the increased maximum effective doses were due to understaffing of in-house trained source loaders. BTL further stated that, as a result of the understaffing, source loading work was carried out by BTL workers whose doses were also tracked under BTL's Class II servicing licence and whose doses were typically higher than those of the Class IB manufacturing workers. The BTL representative also noted that the 8.92 mSv maximum effective dose in 2018 was a direct result of the October 2018 exposure event.

99. When asked for comment on this issue, CNSC staff stated that, although there did appear to be a trend of increasing maximum dose during the previous licence period, this increased dose was accounted for by the 2018 exposure event and BTL's utilization of its Class II servicing workforce, whose doses were generally higher than those of the R&D NEWs due to the nature of their work. CNSC staff stated that, based on these factors and on its assessment of BTL's radiation protection program over the previous licence period, BTL's workers were adequately protected from radiological hazards and that BTL's operations remained stable throughout the previous licence period. The Commission is satisfied with the explanation on this point.
100. Based on the information provided for this hearing, the Commission is satisfied that BTL adequately controls, and has measures in place to adequately control, doses to workers. As detailed in the materials submitted during this hearing, the Commission expects BTL to continue enhancing its radiation protection program during the renewed licence period to ensure that doses to its workers remain ALARA.

4.6.3 Conclusion on Radiation Protection

101. Based on the information provided on the record for this hearing, the Commission concludes that, given the mitigation measures and safety programs that are in place and will be in place to control radiation hazards, BTL provides for, and will continue to provide for, the adequate protection of the health and safety of persons and the environment throughout the renewed licence period.
102. The Commission is satisfied that BTL's radiation protection program meets the requirements of the RPR.

²⁸ Under subsection 13(1) of the *Radiation Protection Regulations*, the maximum effective dose limit for a new is 50 mSv over a one-year dosimetry period and 100 mSv over a five-year dosimetry period.

4.7 Conventional Health and Safety

103. The Commission examined the implementation of a conventional health and safety (H&S) program at BTL, which covers the management of workplace safety hazards. The conventional health and safety program is mandated by provincial statutes for all employers and employees to minimize risk to the health and safety of workers posed by conventional (non-radiological) hazards in the workplace. This program includes compliance with applicable labour codes and conventional safety training. Throughout the previous licence period, CNSC staff rated BTL's performance in this SCA as "satisfactory."
104. BTL provided the Commission with information regarding its conventional H&S program, reporting that, in accordance with Part II, section 122.2 of the *Canada Labour Code*²⁹ (CLC), BTL had implemented measures for the reduction and elimination of hazards, and the provision of protective equipment to its workers. BTL also submitted that the H&S Committee met monthly and that the committee's meeting minutes had clearly identified actions and were posted for all employees to review.
105. CNSC staff reported that BTL had implemented an adequate conventional H&S framework at its facility and that the CNSC monitored BTL's performance in this SCA throughout the previous licence period by way of on-site inspections and desktop reviews. CNSC staff further reported that reviews of BTL's H&S procedures had found them to be adequate and that a September 2018 on-site inspection showed that, through its H&S framework, BTL had resolved H&S issues in a timely manner with adequate corrective actions.
106. In its written materials, BTL reported that its procedures required employees to report all injuries occurring within the workplace, regardless of how minor. BTL also informed the Commission that, although the number of incidents requiring off-site treatment had increased between 2014 and 2018, the overall number of H&S events had decreased, from 18 reported H&S events in 2014 to 11 events in 2018. BTL reported that blood work monitoring of employees in the lead pouring area and hearing tests for employees in the manufacturing area continued to be carried out throughout the previous licence period, and that these will continue to be carried out in the renewed licence period.
107. BTL submitted information about H&S improvements that were implemented during the previous licence period, including a third-party review of BTL's lead control program, ensuring an adequate number of first aiders at the facility, and lock-out tag-out refresher training. CNSC staff reported that, although the number of lost-time injuries (LTIs) at BTL's facility had increased from 2016 to 2018, CNSC staff was satisfied with the measures and improvements that BTL had implemented during the previous licence period.

²⁹ R.S.C., 1985, c. L-2

108. BTL reported that, during the renewed licence period, its H&S program would be assessed against CSA Z1000, *Occupational health and safety management*³⁰ and that an assessment of employee safety culture perception would be carried out through a company-wide survey.
109. Based on the information presented, the Commission concludes that BTL's conventional H&S program satisfies CNSC requirements. The Commission also concludes that the health and safety of workers and the public was adequately protected during the previous licence period and that the health and safety of persons will continue to be adequately protected during throughout the renewed licence period.
110. The Commission expects BTL to assess its conventional H&S program against CSA Z1000, as submitted by BTL in the materials for this hearing, and anticipates an update in this regard during the presentation of an ROR or by other means, as appropriate.

4.8 Environmental Protection

111. The Commission examined BTL's environmental protection programs, which are intended to identify, control and monitor all releases of radioactive and hazardous substances, and aim to minimize the effects on the environment which may result from the licensed activities. These programs include effluent and emissions control, environmental monitoring and estimated doses to the public. CNSC staff rated BTL's performance in this SCA as "satisfactory" throughout the previous licence period.
112. The Commission considered whether BTL's environmental protection programs adequately met the specifications of REGDOC-2.9.1, *Environmental Protection Policies, Programs and Procedures*.³¹ The Commission also considered BTL's implementation of REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*, version 1.1.³²
113. The Commission reviewed BTL's programs to control the release of effluent and emissions to the environment. BTL submitted that it complied with provincial regulations requiring that hazardous waste be disposed of every 90 days, and that a third-party company had been contracted to remove and properly dispose of the waste. BTL also reported that, during the renewed licence period, it would consult with the City of Ottawa in respect of its Sewer Use Program with the aim of minimizing the environmental impact of its operations. CNSC staff reported that its reviews showed that BTL did not have any hazardous waterborne releases that would require controls or effluent monitoring.

³⁰ CSA Z1000:14, *Occupational health and safety management*, CSA Group, 2014.

³¹ CNSC Regulatory Document REGDOC-2.9.1, *Environmental Protection Policies, Programs and Procedures*, 2013.

³² CNSC Regulatory Document REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*, version 1.1, 2017.

114. In regard to lead emissions from its facility, BTL reported that an annual report was submitted in this regard to the National Pollutant Release Inventory in accordance with the Ontario *Toxics Reduction Act*.³³ BTL also submitted that, through improvements in its lead control program, as well as a decrease in manufacturing, BTL had decreased lead emissions to the environment during the previous licence period.
115. CNSC staff reported that BTL had been issued an Environmental Compliance Approval (ECA) from the Ontario Ministry of Environment, Conservation and Parks in regard to its hazardous airborne emissions relating to the lead pouring area, the paint booth, the fire torching areas and the sand blasting activities. CNSC staff further reported that it had determined that BTL did not have to carry out environmental monitoring at its facility, based on the resulting findings that emissions from the facility would not impact public or environmental health.
116. CNSC staff reported that compliance verification activities showed that BTL continued to operate in a manner that protected the environment. During the renewed licence period, CNSC staff submitted that BTL would be required to update its environmental risk assessment (ERA) to meet the specifications of CSA N288.6-12, *Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*,³⁴ thus meeting the specifications of REGDOC-2.9.1, Version 1.1, with BTL committing to implement this REGDOC by the end of 2019.
117. The Commission assessed the information provided by BTL and CNSC staff about its Environmental Management System (EMS). BTL submitted that, during the previous licence period, the EMS for its facility was revised in order to meet the specifications of ISO 14001:2015, *Environmental management systems – Requirements with guidance for use*.³⁵ BTL also reported that it had developed a new procedure which provided for the annual identification and evaluation of BTL's operations that may have an impact on the environment. CNSC staff submitted that BTL's EMS met licensing expectations.
118. Based on the assessment of the application and the information provided for this hearing, the Commission is satisfied that, given the mitigation measures and safety programs that are in place to control hazards, BTL has provided and will continue to provide adequate protection to the health and safety of persons and the environment throughout the renewed licence period.
119. The Commission is satisfied that BTL's environmental protection programs adequately meet the specifications of REGDOC-2.9.1.

³³ *Toxics Reduction Act*, 2009, Statutes of Ontario 2009, c.19.

³⁴ N288.6-12, *Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*, CSA Group, 2012.

³⁵ International Organization for Standardization, International Standard ISO 14001:2015, *Environmental management systems – Requirements with guidance for use*, Third Edition, 2015.

120. The Commission anticipates that BTL will implement REGDOC-2.9.1, Version 1.1 and CSA N288.6-12 during the renewed licence period as detailed in the licence renewal application. The Commission expects updates in this regard via an ROR or other means, as appropriate.

4.9 Emergency Management and Fire Protection

121. The Commission considered BTL's emergency management and fire protection programs which cover the measures for preparedness and response capabilities implemented by BTL in the event of emergencies and non-routine conditions. This includes nuclear emergency management, conventional emergency response, and fire protection and response. CNSC staff rated BTL performance in this SCA as "below expectations" in 2015, and as "satisfactory" during 2014 and 2016 to 2018.
122. In its written materials, BTL submitted that its emergency preparedness program included plans in respect of radiation emergencies, transport emergencies, fire safety and chemical spill response, with a defined Emergency Response Committee managing this program. CNSC staff submitted that BTL's emergency preparedness program met the specifications of REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*, Version 2³⁶ and CSA N393-13, *Fire protection for facilities that process, handle or store nuclear substances*.³⁷
123. BTL reported to the Commission that CNSC staff's recommendations to consider extreme natural disasters in its response plans informed a review of BTL's Site Emergency Response Plan in 2017. BTL further reported that its response plans were updated to reflect these recommendations and that BTL would continue to re-evaluate its response plans to include natural disasters in the renewed licence period.
124. BTL submitted that, in 2016, a qualified consulting firm carried out a hazardous materials spill response assessment in respect of BTL's chemical response team and its capacity to respond to an internal emergency, resulting in the implementation of measures to strengthen BTL's chemical spill response program.
125. BTL informed the Commission that a successful full-scale emergency evacuation exercise was carried out at its facility in April 2019 and that the exercise included Ottawa first responders and surrounding businesses. BTL also submitted that fire drills were conducted at its facility annually.
126. CNSC staff submitted that BTL's fire protection program met licensing requirements at the time of this hearing. However, CNSC staff reported that, during a fire prevention inspection in 2015, a CNSC inspector issued an order to BTL in October 2015 because

³⁶ CNSC Regulatory Documents, REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*, Version 2, 2017.

³⁷ N393-13, *Fire protection for facilities that process, handle or store nuclear substances*, CSA Group, reaffirmed 2016.

its dust collector machine was not in compliance with the *National Fire Code of Canada 2010*.³⁸ CNSC staff submitted that, following this inspection, BTL's rating in this SCA decreased to "below expectations" but returned to "satisfactory" when the terms and conditions of the order were complied with, as verified by CNSC staff in a follow-up November 2015 inspection. BTL reported that corrective actions, such as procedure development and implementation, training, and re-evaluation of facility design, were implemented to address the inspection findings.

127. BTL submitted that an updated fire hazard assessment (FHA) was carried out at its facility in 2016, with the FHA showing that fire risks in respect of radioactive material associated with the facility were appropriately addressed. BTL further submitted that the FHA recommended a corrective action in respect of the building's sprinkler system and that this action was addressed during the previous licence period.
128. Based on the above information provided on the record for this hearing, the Commission concludes that BTL's nuclear and conventional emergency management preparedness programs and the fire protection measures that are in place, and that will be in place during the renewed licence period, are adequate to protect the health and safety of persons and the environment.
129. The Commission is satisfied with the actions taken by BTL in respect of the updating of its Emergency Site Response Plan and expects BTL to continue improvements to this plan as detailed during this hearing.
130. During the renewed licence period, the Commission expects BTL to continue its improvement of emergency procedures and the implementation of lessons learned from the April 2019 full-scale emergency exercise in its emergency planning, as detailed during this hearing. The Commission anticipates updates in regard to these lessons learned via an ROR or other means, as appropriate.

4.10 Waste Management

131. The Commission assessed BTL's waste management program. Throughout the previous licence period, CNSC staff assessed BTL's performance in this SCA, including waste minimization, segregation, characterization and storage programs, as "satisfactory."
132. The Commission reviewed the information submitted by BTL about the generation and diversion rates of wastes at its facility from 2010 to 2018. In its written submission, BTL reported that it aimed to prevent or minimize the generation of all types of wastes from its operations, including scrap metal, hazardous materials, standard waste associated with an office environment, and waste containing radioactive nuclear substances. In regard to non-hazardous waste, BTL also reported that, during the previous licence period, the quantity of non-hazardous landfill waste produced at

³⁸ IRC-10NBF, *National Fire Code of Canada 2010*, National Research Council 2010.

BTL's facility dropped significantly – from 133.4 MT in 2015 to 77.93 MT in 2018 – due to improvements to its waste management program.

133. CNSC staff informed the Commission that compliance verification activities showed that BTL maintained a waste management program that met the specifications of CSA N292.3-08, *Management of low and intermediate-level radioactive waste*³⁹ and that BTL's documentation for the program met CNSC staff's expectations.
134. BTL submitted that its waste containing radioactive nuclear substances included sealed sources and depleted uranium (DU) that were returned from the field as a result of either service or decommissioning activities. During the previous licence period, BTL reported that it had reduced the number of cesium-137 and cobalt-60 sources, with a total activity of 11,995 TBq, at its facility through disposal and recycling. BTL also reported that it had received 1,196 kg of DU into its safeguarded inventory, with 284.7 kg of DU having since been transferred to other licensees for recycling and 104 kg of DU having since been reused.
135. The Commission requested information about BTL's use of DU and about the legacy sources stored at its facility. The BTL representative informed the Commission that BTL no longer used DU as shielding materials for its products. The Commission was satisfied on this point.
136. CNSC staff informed the Commission that BTL was carrying out gap analyses for the implementation of the updated CSA N292.3-14, *Management of low- and intermediate-level radioactive waste*⁴⁰ and CSA N292.0-14, *General principles for the management of radioactive waste and irradiated fuel*,⁴¹ with BTL committing to completing the gap analyses by the end of 2019. CNSC staff further reported that BTL would implement the updated standards by 2020 and that compliance verification activities to confirm implementation would be carried out.

4.10.1 BTL's Activities in Respect of the Management of Waste Containing Radioactive Nuclear Substances

137. The Commission considered BTL's interpretation of the GNSCR in respect of the management of waste containing radioactive nuclear substances. In its supplementary submission and oral presentation, BTL argued that the IAEA's definition of waste – "*material in gaseous, liquid or solid form for which no further use is foreseen*"⁴² – excluded much of BTL's inventory of double-encapsulated sources because, although the inventory at times exceeded 10^{15} Bq, those sources were intended for future resale, use, recycling or disposal. The Commission notes that CNSC staff did not agree with

³⁹ N292.3-08, *Management of low and intermediate-level radioactive waste*, CSA Group, 2008.

⁴⁰ N292.3-14, *Management of low- and intermediate-level radioactive waste*, CSA Group, 2014.

⁴¹ N292.0-14, *General principles for the management of radioactive waste and irradiated fuel*, CSA Group, 2014.

⁴² International Atomic Energy Agency, *IAEA Safety Glossary Terminology Used in Nuclear Safety and Radiation Protection*, 2016.

BTL's interpretation of the definition of waste. The Commission also notes that, per IAEA guidance, radioactive waste storage includes the holding of radioactive waste in a facility that provides for its containment, with the intention of retrieval, whereas waste disposal indicates that there is no intent to retrieve the material.⁴³

138. Answering the Commission's questions about the alternate interpretations of the definitions of waste as submitted by BTL and CNSC staff, CNSC staff explained that, internationally, "disused sources" referred to sources that were no longer capable of being used for their designed intent.⁴⁴ CNSC staff further stated that, since some countries did not allow the return of sources categorized as "waste," IAEA Member States categorized such sources as "disused sources," rather than as radioactive waste, to allow for their return to their originating countries, thus greatly reducing the likelihood of loss of control of the sources. CNSC staff noted that BTL's inventory of disused and returned sources for recycling or disposal, but for which no further use was foreseen, included high-risk Category 1 and 2 sources.⁴⁵ CNSC staff further explained that, based on these internationally-accepted definitions, any sources managed and stored by a licensee that did not have an identified use beyond the original intent are considered as waste.
139. CNSC staff provided the Commission with information on the internationally-accepted waste management hierarchy principle, which includes waste minimization, reuse, recycling and the final path of disposal. CNSC staff noted that, in its guidance, the IAEA referred to the recycling or potential alternate uses of waste radioactive materials inline with the waste management hierarchy principle. CNSC staff further explained that, also in accordance with international practice, when a disused source was returned to BTL, there was no way of knowing ahead of time which sources would be recycled, reused or disposed of and that, until such time this decision was made, the sources were considered to be radioactive waste.
140. Further on this topic, CNSC staff explained that Canada reported on disused sources in its national reports to the *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management*⁴⁶ (Joint Convention). CNSC staff also reported that, in its 2017 National Report to the Joint Convention, BTL itself reported its disused sources as part of its waste inventory⁴⁷ and that these sources included those intended for reuse, transfer and disposal.

⁴³ *Ibid.*

⁴⁴ The Commission notes that the IAEA defines disused sources as: "...sources that are no longer used and there is no intention of using them again in the practices they were authorized for. Spent sources, which can no longer be used for their intended purposes as a result of radioactive decay, are a sub-set of disused sources." <https://www.iaea.org/topics/disused-sources> (accessed 16 May 2019).

⁴⁵ As defined in IAEA-TECDOC-1344, *Categorization of radioactive sources*, International Atomic Energy Agency, 2003.

⁴⁶ *Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management* (1997), IAEA Doc. INFCIRC/546, 2153 UNTS 357, entered into force 18 June 2001.

⁴⁷ CNSC, *Canadian National Report for the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management*, Sixth Report, October 2017, page 28, nuclearsafety.gc.ca/pubs_catalogue/uploads/joint-convention-sixth-national-report-oct-2017-eng.pdf (accessed 17 May 2019); also as detailed in Table 1 of CMD 19-H2.A.

141. CNSC staff confirmed that, prior to the issuance of a Class IB licence in 2014, BTL's resident inventory of waste containing radioactive nuclear substances remained below 10^{15} Bq, but after the issuance of the Class IB licence, this limit on waste resident inventory no longer existed. CNSC staff further noted that, most recently in 2018, waste with a total activity of $3.584E10^{15}$ Bq of was managed by BTL (either reused, transferred or disposed of) and that an April 16, 2019 inspection at BTL showed a waste resident inventory of $1.56E10^{15}$ Bq, noting that this included disused sources returned to BTL for which the future use was unknown.
142. In response to CNSC staff's assertions, the BTL representative submitted BTL's view that the only actual radioactive waste at its site that should be considered as part of its waste resident inventory included the sources specifically earmarked for disposal at the Chalk River Laboratories (CRL), of which BTL had an annual total inventory of $0.0003E10^{15}$ Bq in 2018, well below the 10^{15} Bq threshold for resident inventory. BTL stated that the other sources which may be recycled or reused did not, in BTL's view, constitute radioactive waste.
143. The BTL representative informed the Commission that, in any given year, BTL received approximately $3E10^{15}$ Bq in disused sources throughout the year, noting that this represented the total annual inventory and did not represent the fluctuating waste resident inventory at BTL's facility. Asked to comment on its actual waste resident inventory at the time of this hearing, BTL submitted the argument that, although the waste resident inventory at the BTL facility on April 16, 2019 was nearly $1.56E10^{15}$ Bq, BTL was exporting $0.8E10^{15}$ Bq of that inventory for recycling in the US within two weeks of this hearing. The BTL representative stated that, as such, BTL would be below the 10^{15} Bq when those sources left the facility. The Commission notes that, at the time of this hearing, the resident inventory of disused sources at BTL's facility was over 10^{15} Bq.
144. In its rebuttal to BTL's arguments on this issue, CNSC staff stated that its recommendations to the Commission were not based on hypothetical conditions. Rather, CNSC staff's recommendations were based on international best practices, actual conditions, the licensed activities carried out during the previous licence period and the licensee's annual compliance reports. CNSC staff further noted that, based on reporting from the previous licence period, BTL's waste resident inventory was not below 10^{15} Bq, with its operations therefore defined as a Class IB facility. CNSC staff also explained that BTL's operations were such that, at any time, additional disused sources could be shipped to the facility, increasing the resident inventory. CNSC staff further stated that the resident inventory was intended to represent a 'snapshot in time,' which was precisely what the April 16, 2019 CNSC inspection showed.
145. The Commission considered the submission from the BTL representative during the hearing which argued that BTL's disused sources presented much lower risks than the new sources stored at BTL's facility, and that regulating BTL as a Class IB facility amounted to overregulation. In response, the BTL representative submitted that BTL

did not handle open sources and that all sources were returned to BTL in Type B(U) packages,⁴⁸ as required. In regard to the regulation of the high activity sources, CNSC staff submitted the view that its proposed regulation of BTL's activities was appropriate and provided the Commission with information about the regulation of BTL's Category 1, 2 and 3 sources, noting the high level of regulatory oversight required, especially in regard to radiation protection and security.

146. Based on the information provided regarding the internationally-accepted definitions of radioactive waste and the waste management hierarchy principle, the Commission is of the view that radioactive sources that are identified as not having a use beyond the original intent and for which no future use is foreseen are appropriately characterized as radioactive waste.
147. The Commission is satisfied that evidence during this hearing shows that, during the previous licence period, the inventory of nuclear substances accepted by BTL for management, storage or disposal, that had reached the end of operational life, and for which there was unknown use exceeded 10^{15} Bq. The Commission notes that, pursuant to the Class I Regulations, a nuclear facility which has waste containing a resident inventory of more than 10^{15} Bq of radioactive nuclear substances meets the definition of a Class IB nuclear facility under paragraph 19(a) of the GNSCR and must be licensed under the Class I Regulations. The Commission notes that the Class I Regulations do not specify a minimum time period for having this resident waste inventory of 10^{15} Bq and is of the view that *any* exceedance of this threshold triggers regulation under the Class I Regulations.
148. The Commission is of the view that the 10^{15} Bq threshold that is set out in the regulations for waste containing a resident inventory of radioactive nuclear substances is intended to reflect the relative risk of the licensed activity. Therefore, based on a purposive interpretation of the regulations, the Commission concludes that a higher resident waste inventory – which surpasses the 10^{15} Bq threshold at any given time – represents a higher relative risk and needs to be regulated as such.

4.10.2 Conclusion on Waste Management

149. Based on the above information and consideration of the hearing materials, the Commission is satisfied that BTL has appropriate programs in place to safely manage waste at its facility.
150. The Commission expects BTL to implement updated standards during the renewed licence period as detailed in its submission for licence renewal.
151. In considering the various definitions of waste submitted for this hearing, the Commission concludes that, since BTL had not identified the disused sources as having a use beyond the original intent and no future use was clearly foreseen at the time of

⁴⁸ Type B(U) package as defined by the SOR/2015-145.

their acceptance, these sources were appropriately qualified as waste containing radioactive nuclear substances. The Commission does not accept BTL's interpretation of the definition of waste, specifically that it does not include sources that may be re-used, recycled or sold. Furthermore, the Commission agrees that, in its assessments, CNSC staff appropriately used the internationally-accepted definitions of waste adopted by the IAEA and its Member States.

152. Based on the information submitted during this hearing, the Commission concludes that BTL is managing, storing or disposing of waste containing radioactive nuclear substances with a resident inventory exceeding 10^{15} Bq, thus defining BTL's facility as a Class IB nuclear facility in accordance with paragraph 19(a) of the GNSCR and the definitions in section 1 of the Class I Regulations.⁴⁹ As such, BTL's licensed activities in this regard are properly classified as the operation of a Class IB nuclear facility.

4.11 Security

153. The Commission examined BTL's security program, which is required to implement and support the security requirements stipulated in the relevant regulations and the licence. This includes compliance with the applicable provisions of the GNSCR and the Class I Regulations. During the previous licence period, CNSC staff rated BTL's performance in this SCA as "satisfactory."
154. In its written materials, BTL informed the Commission that its security program was made up of two main components, facility security and the security of transportation of hazardous materials. BTL provided the Commission with details on its facility security measures and the upgrades to these measures that were carried out during the previous licence period. These upgrades included 24/7 on-site security and upgraded access control; background checks for all employees every five years; facility monitoring cameras; upgrades to the corporate network and firewalls; and the participation of security personnel in the newly-established Radiation Safety & Security Committee (previously the Radiation Safety Committee). BTL also informed the Commission that a vehicle search program had been initiated for all vehicles entering the BTL facility, with full implementation of this program to be completed in 2019.
155. In regard to the security of Category 1 and 2 sources during transport, BTL submitted that its program met the specifications of REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*.⁵⁰ BTL added that its transport security program included the contracting of approved radioactive material carriers; conducting annual audits of carrier transport safety plans; and the tracking of radioactive material in transport. BTL also submitted that it had recently been accepted into the Transport Canada Air Cargo Security Program which helps ensure that packages leaving Canada are not tampered with.

⁴⁹ "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.

⁵⁰ CNSC Regulatory Document REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*, 2013.

156. CNSC staff submitted that compliance verification activities at BTL showed that its security program met applicable regulatory requirements, with satisfactory processes in place for the testing and maintenance of security devices and a satisfactory transport security plan. CNSC staff added that BTL completed a threat and risk assessment in respect of its activities associated with cyclotrons which showed that there was no indication that these activities would impact the security of the facility, the safety of workers, the public or the environment.
157. On the basis of the information provided on the record for this hearing, the Commission is satisfied that BTL's performance with respect to maintaining security at its facility and the transport of Category 1 and 2 has been acceptable. The Commission concludes that BTL has made adequate provision for the physical security at its facility and for the transport of Category 1 and 2 sources, and is of the opinion that BTL will continue to make adequate provision for security during the renewed licence period.

4.12 Safeguards and Non-Proliferation

158. The Commission examined the adequacy of BTLs' safeguards program. The CNSC's regulatory mandate includes ensuring conformity with measures required to implement Canada's international obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons*⁵¹ (NPT). Pursuant to the NPT, Canada has entered into a Comprehensive Safeguards Agreement and an Additional Protocol (safeguards agreements) with the IAEA. The objective of these agreements is for the IAEA to provide credible assurance on an annual basis to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there is no undeclared nuclear material or activities in this country. CNSC staff rated BTL's performance in this SCA as "satisfactory" throughout the previous licence period.
159. BTL submitted that its safeguards program covered BTL's possession of safeguarded DU which was used in legacy cobalt-60 teletherapy units as a shielding material, with the DU being returned to BTL for end-of-life management or disposal. CNSC staff reported that the safeguarded material at BTL's facility consisted of less than one effective kilogram of nuclear material which categorized BTL as a "location outside facility (LOF)."⁵²

⁵¹*Treaty on the Non-Proliferation of Nuclear Weapons* (1968), IAEA Doc. INFCIRC/140, 729 UNTS 169, entered into force 5 March 1970 (NPT).

⁵² For safeguards purposes, the IAEA defines a locations outside facilities as "facilities that do not have a reactor or a critical facility, or, a nuclear material conversion, fabrication, reprocessing or isotope separation plant, or, a separate nuclear material storage installation, and the customarily used material is subject to full-scope safeguards in amounts less than 1 effective kilogram." (Source: *Model Protocol Additional to the Agreement(s) Between State(s) and the International Atomic Energy Agency for the Application of Safeguards* (1997), IAEA Doc. INFCIRC/540, articles 18(i) and (j).

160. CNSC staff reported that BTL provided the CNSC and the IAEA with all required reports and information to comply with safeguards requirements, and that CNSC compliance verification activities showed that BTL maintained a satisfactory safeguards program during the previous licence period. CNSC staff also reported that BTL met the specifications of RD-336, *Accounting and Reporting of Nuclear Material*⁵³ and that, following a CNSC staff-reviewed gap analysis, BTL successfully implemented REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*⁵⁴ on January 1, 2019.
161. BTL informed the Commission that, during the renewed licence period, BTL's safeguards reporting would be improved through the incorporation of the Nuclear Materials Accountancy Reporting (NMAR) system into its safeguards program.
162. The Commission enquired about the proposed licence condition 15.2, relating to the export of nuclear substances. CNSC staff explained that BTL was an exporter of high-risk sources and had an appropriate program in place for these export activities. However, separate CNSC export licences were required for these export activities. CNSC staff further explained that the intent of this licence condition was to clarify which exports were authorized by the Class IB licence and which exports required a separate CNSC export licence. The Commission was satisfied with the information provided on this point.
163. Based on the above information, the Commission is satisfied that BTL has provided, and will continue to provide, adequate measures in the areas of safeguards and non-proliferation that are necessary for maintaining national security and measures necessary for implementing international agreements to which Canada has agreed.
164. The Commission expects BTL to incorporate the NMAR system into its safeguards program during the renewed licence period as detailed during this hearing and anticipates updates in this regard during the presentation of an ROR or by other means, as appropriate.
165. Following its consideration of the information provided for this hearing, the Commission includes licence condition 15.2 in the renewed licence, as proposed in CMD 19-H2.

4.13 Packaging and Transport

166. The Commission examined BTL's packaging and transport program. Packaging and transport covers the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility. The licensee must adhere to the *Packaging and Transport of Nuclear Substances Regulations, 2015*⁵⁵ (PTNSR, 2015) and

⁵³ CNSC Regulatory Document RD-336, *Accounting and Reporting of Nuclear Material*, 2010.

⁵⁴ CNSC Regulatory Document REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*, 2018.

⁵⁵ SOR/2015-145

Transport Canada's *Transportation of Dangerous Goods Regulations*⁵⁶ (TDG Regulations) for all shipments. During the previous licence period, CNSC staff rated BTL's performance in this SCA as "satisfactory."

167. In its written submission, BTL provided the Commission with information about the components of its transport and packaging program. BTL reported that it ships Category 1 and 2 nuclear materials worldwide and that these materials were shipped in certified Type B(U) packages.⁵⁷ BTL also reported that all transport packages were routinely maintained as per its quality control program.
168. CNSC staff submitted that BTL's packaging and transport program met the requirements of the PTNSR, 2015 and of IAEA No. SSR-6 (Rev. 1), *Regulations for the Safe Transport of Radioactive Material*.⁵⁸ CNSC staff also reported that that BTL's package designs and maintenance programs met requirements and that packages were certified by the CNSC when necessary.
169. Based on the information presented on the record for this hearing, the Commission is satisfied that BTL is meeting, and will continue to meet, regulatory requirements regarding packaging and transport.

4.14 Indigenous Engagement and Public Information

4.14.1 Participant Funding Program

170. The Commission assessed the information provided by CNSC staff regarding public engagement in the licensing process as enhanced by the CNSC's Participant Funding Program (PFP). CNSC staff submitted that, in November 2018, 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 to review BTL's licence renewal application and associated documents, and to provide the Commission with value-added information through topic-specific interventions. 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. No applications for funding were received and no interventions were submitted.
171. The Commission notes that Indigenous groups, members of the public and other stakeholders did not avail themselves of the opportunity to participate in this licence renewal process.

⁵⁶ SOR/2001-286

⁵⁷ Type B(U) package as defined by the SOR/2015-145.

⁵⁸ Specific Safety Requirements No. SSR-6 (Rev.1), *Regulations for the Safe Transport of Radioactive Material*, IAEA, 2018 Edition.

4.14.2 Indigenous Engagement

172. The common law duty to consult with Indigenous peoples applies when the Crown contemplates action that may adversely affect established or potential Indigenous and/or treaty rights. The CNSC, as an agent of the Crown and as Canada's nuclear regulator, recognizes and understands the importance of building relationships and engaging with Canada's Indigenous peoples. The CNSC ensures that its licensing decisions under the NSCA uphold the honour of the Crown and consider Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the *Constitution Act, 1982*.⁵⁹
173. The Commission examined the information submitted by BTL regarding its ongoing engagement with Indigenous groups near the facility. In its written submission, BTL informed the Commission that the Algonquins of Ontario had been invited for a facility and site tour in 2018 and that BTL ensured that Indigenous groups near its facility remained informed about BTL's operations throughout the previous licence period. BTL reported that its Indigenous engagement efforts would continue during the renewed licence period.
174. CNSC staff submitted that BTL's licence renewal application did not propose any new licensed activities or a change in the footprint of the facility. CNSC staff further submitted that its assessment of the application showed that the renewal would not cause adverse impacts to any potential or established Indigenous and/or treaty rights, and therefore it did not raise the duty to consult.
175. CNSC staff provided the Commission with information about five First Nation and Métis groups that were identified as having a potential interest in the BTL's licence renewal and that had previously expressed interest in being kept informed about CNSC-licensed activities occurring in their traditional territories. These groups included the Algonquins of Ontario (Algonquins of Pikwàkanagàn), Kitigan Zibi Anishinabeg, the Algonquin Anishinabeg Tribal Council (Algonquins of Quebec), the Anishinabek Nation (Union of Ontario Indians), and the Métis Nation of Ontario.
176. CNSC staff reported that, in December 2018, these First Nations and Métis groups were contacted regarding BTL's licence renewal application, the PFP opportunity and the opportunity to participate in the public hearing. CNSC staff submitted that none of the groups contacted had expressed concerns with BTL's operations or its facility. CNSC staff confirmed to the Commission that it would continue communication with interested Indigenous groups throughout the renewed licence period to ensure that the groups received all information requested and to establish, maintain and enhance relationships with the groups.
177. Based on the information provided for this hearing, the Commission is satisfied that Indigenous engagement activities carried out for this licence renewal were adequate. The Commission expects Indigenous engagement activities by BTL and CNSC staff to

⁵⁹ *Constitution Act, 1982*, Schedule B to the *Canada Act 1982*, 1982, c. 11 (U.K.).

continue throughout the renewed licence period, as detailed in the materials submitted for this hearing.

4.14.3 Public Information

178. The Commission assessed BTL's public information and disclosure program (PIDP). A public information program is a regulatory requirement for licence applicants and licensed operators of Class I nuclear facilities. Paragraph 3(j) of the Class I Regulations requires that licence applications include:

“the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the activity to be licensed.”

179. The Commission also assessed whether BTL's PIDP met the specifications of REGDOC-3.2.1, *Public Information and Disclosure*.⁶⁰ BTL submitted to the Commission that it had implemented a PIDP that communicated BTL's operational activities to the public and provided an avenue for open and community-based discussions about its facility. BTL also reported that the primary mechanism used to disseminate information to the public was its corporate website. BTL submitted that its annual CNSC compliance reports were posted on its website for public review, that information on incidents or false alarms was also posted on BTL's website to ensure that the public remained informed about events at its facility and noted that a “Frequently Asked Questions” section was added to its website during the previous licence period.
180. Recognizing that its facility was near a residential area in the Ottawa suburb of Kanata, BTL informed the Commission that a community information session was held at its facility in May 2018. BTL submitted information about the extensive advertising that it had done in respect of this event and reported that a survey was carried out after the event in order to assess its effectiveness.
181. CNSC staff submitted that its assessment of BTL's PIDP showed that it met the expectations of REGDOC-3.2.1 and the requirements of the Class I Regulations. CNSC staff submitted that, during the renewed licence period, CNSC staff would continue to monitor BTL's PIDP to ensure that it continued to be relevant to the public as influenced by public interest, risk of the facility and BTL's licensed activities.
182. Based on the information presented for this hearing, the Commission is satisfied that BTL's PIDP has and will continue to communicate information to the public about the health, safety and security of persons and the environment, and other issues related to its facility.

⁶⁰ CNSC Regulatory Document REGDOC-3.2.1, *Public Information and Disclosure*, 2018.

4.14.4 Conclusion on Indigenous Engagement and Public Information

183. Based on the information presented, the Commission is satisfied that, overall, BTL's PIDP meets regulatory requirements and is effective in keeping Indigenous groups and the public informed of BTL's operations. The Commission acknowledges the many best practices already implemented by BTL and encourages its efforts in creating, maintaining and improving its dialogue with the neighbouring communities.
184. The Commission acknowledges the current efforts and commitments made by BTL in relation to Indigenous engagement and CNSC staff's efforts in this regard on behalf of the Commission. Based on the information presented on the record for this hearing, the Commission is satisfied that this licence renewal will not result in changes to BTL's facility or operations that would cause adverse impacts to any potential or established Indigenous and/or treaty rights and that no formal duty to consult was engaged in this matter. The Commission is also of the opinion that the engagement activities taken for the review of BTL's licence renewal application are adequate.⁶¹
185. The Commission is satisfied that the public was provided with adequate opportunity to participate in this hearing through interventions and funding provided through the CNSC's PFP.

4.15 Decommissioning Plans and Financial Guarantee

186. The Commission requires that BTL has operational plans for the decommissioning and long-term management of waste produced during the lifespan of its facility. In order to ensure that adequate resources are available for safe and secure future decommissioning, the Commission requires that an adequate financial guarantee for realization of the planned activities is put in place and maintained in a form acceptable to the Commission throughout the licence period. The Commission notes that, in July 2017, it accepted a financial guarantee for the decommissioning of BTL's facility in the amount of \$1.8 million and in the form of two letters of credit.⁶²
187. CNSC staff submitted that BTL last revised its preliminary decommissioning plans (PDP) in 2016 and that CNSC staff had verified that the PDP met the specifications of N294-09 (R2014), *Decommissioning of facilities containing nuclear substances*.⁶³ CNSC staff also submitted that BTL's PDP met the expectations of G-219, *Decommissioning Planning for Licensed Activities*. CNSC staff further reported that BTL would revise its financial guarantee every five years, with the next update expected by 2022.

⁶¹ *Rio Tinto Alcan v. Carrier Sekani Tribal Council*, 2010 SCC 43[2010] 2 S.C.R. 650 at paras 45 and 49.

⁶² CNSC *Record of Decision – Best Theratronics Limited, Amendment under Section 25 of the Nuclear Safety and Control Act and Request for Acceptance of the Financial Guarantee*, issued on July 14, 2017.

⁶³ N294-09 (R2014), *Decommissioning of facilities containing nuclear substances*, CSA Group, reaffirmed in 2014.

188. The Commission enquired about whether the amount of the financial guarantee was dependant on whether BTL was licensed under a Class IB licence or NRSD/Class II licences. CNSC staff informed the Commission that a financial guarantee was based on a licensee's inventory of nuclear substances and the licensed activities being carried out, not the licence under which the licensee carried out these activities. The Commission was satisfied with the information provided on this point.
189. Based on the information considered at this hearing, the Commission concludes that BTL's PDP and related financial guarantee for its facility remain acceptable.
190. The Commission anticipates that BTL's updated PDP will be submitted to the CNSC by 2022, with the updated financial guarantee submitted for Commission acceptance in 2022, in accordance with licence requirements.

4.16 Cost Recovery

191. The Commission examined BTL's standing under the *Cost Recovery Fees Regulations*⁶⁴ (CRFR) requirements for its facility. Paragraph 24(2)(c) of the NSCA requires that a licence application is accompanied by the prescribed fee, as set out by the CRFR and based on the activities to be licensed.
192. CNSC staff submitted that, throughout the previous licence period, BTL had remained in good standing in respect of CRFR requirements and had paid its cost recovery fees in full. CNSC staff further submitted that, based on its assessments, it did not have any concerns about BTL continuing to fulfill CRFR requirements during the renewed licence period.
193. Based on the information submitted by CNSC staff, the Commission is satisfied that BTL has satisfied the requirements of the CRFR for the purpose of this licence renewal.

4.17 Licence Length and Conditions

194. The Commission considered BTL's application for the renewal of its Class IB licence for a period of 10 years. CNSC staff recommended the renewal of the licence for a period of 10 years, until June 30, 2029, submitting that BTL is qualified to carry on the licensed activities authorized by the licence.
195. In order to provide adequate regulatory oversight of changes that are administrative in nature or less significant and do not require a licence amendment nor Commission approval, CNSC staff recommended that the Commission delegate authority for certain approval or consent, as contemplated in licence conditions 3.2 and 15.1, that contain the phrase "a person authorized by the Commission," to the following CNSC staff:

⁶⁴ SOR/2003-212

- 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

196. The Commission requested comments from BTL in regard to its reasons for submitting applications for a Class IB licence, as well as two NSRD licences and one Class II licence, in respect of the same licensed activities. The BTL representative responded that, while reviewing its information in preparation for the Class IB licence renewal, BTL had realized that its operations had not amounted to what was intended in 2014 when BTL first applied for the Class IB licence, namely the operation of a cyclotron up to 70 MeV. The BTL representative further noted that, prior to the 2014 issuance of the Class IB licence, BTL had successfully operated under NSRD and Class II licences.
197. The Commission enquired about why BTL had not withdrawn its Class IB licence application when it submitted the NSRD and Class II licence applications in February 2019. The BTL representative informed the Commission that it had not withdrawn the Class IB application in order to avoid the possibility of being unlicensed should the NSRD and Class II licence applications be denied.
198. In regard to the licensing of 70 MeV cyclotron, CNSC staff stated that, prior to 2014, BTL did not construct and operate a cyclotron capable of producing a beam energy above 50 MeV and these lower energy cyclotrons were therefore not categorized as a Class IB facility. However, after the 2014 hearing, BTL started carrying out this licensed activity and, as such, required a Class IB licence for the construction and operation of the cyclotrons capable of producing a beam energy above 50 MeV.
199. Acknowledging that comprehensive and appropriate regulation was preferable to excessive regulation, the Commission asked BTL for additional views on this licensing issue. The BTL representative submitted that BTL's regulatory performance was "satisfactory" in all 14 SCAs throughout most of the previous licence period and that its programs would remain the same whether licensed under the Class IB or the NSRD/Class II licences. The BTL representative noted that the regulatory costs were also five to 10 times higher and that regulatory oversight was much more burdensome for a Class IB licensee. The BTL representative further submitted that BTL was of the view that, for the scope of its operations, being a Class IB licensee amounted to overregulation.
200. Asked for comment on these licensing issues, CNSC staff reported that it had discussed the regulatory issues related to BTL's multiple and overlapping licence applications, and the licensed activities in depth with the licensee. CNSC staff informed the Commission that, in assessing an application and the regulatory oversight that would be required, CNSC staff reviewed the licensed activities that a licensee had applied for with the aim of ensuring that the activities would be carried out safely and that licensing was in accordance with the NSCA and its regulations. CNSC staff added that

it had followed this process in respect of BTL's application.

201. Further in respect of the licensing issues raised during this hearing, CNSC staff reported that, prior to the 2014 Class IB licence issuance, BTL's waste resident inventory remained below 10^{15} Bq, therefore not triggering the regulation of BTL's licensed activities in respect of radioactive waste management under the Class I Regulations. CNSC staff further explained that, since the issuance of BTL's Class IB licence, BTL's waste resident inventory exceeded this 10^{15} Bq threshold, as was demonstrated during the April 16, 2019 CNSC inspection at BTL's facility. CNSC staff submitted that, for these reasons, it was of the view that the regulation of BTL's licensed activities in respect of the operation of a cyclotron capable of producing a beam energy above 50 MeV and the management of radioactive waste under the Class I Regulations was appropriate.
202. Based on the information examined by the Commission during the course of this hearing, the Commission concludes that the licensed activities carried out by BTL in respect of both particle accelerators (cyclotrons) and waste containing radioactive nuclear substances meet the definitions of a Class IB facility as set out in the GNSCR and the Class I Regulations. The Commission acknowledges BTL's regulatory performance but, nevertheless, the Commission's licensing decisions in respect of licensed activities are based on the definitions in the NSCA and its regulations, and not on arbitrarily selected factors. Further, the Commission's regulation of nuclear activities in Canada is risk informed and its decision in this matter, as well as the Commission's interpretation of the relevant statutory instruments, reflect a purposive interpretation of the regulations.
203. For these reasons and those detailed in this *Record of Decision*, the Commission is satisfied that a 10-year Class IB licence is appropriate for BTL's facility. However, 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."
204. 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 also accepts CNSC staff's recommendation regarding the delegation of authority for the purposes of licence condition 3.2.

5.0 CONCLUSION

205. The Commission has considered the Class IB licence renewal application submitted by BTL. Based on its consideration of the information submitted, the Commission is satisfied that the application submitted by BTL meets the requirements of the NSCA, the GNSCR and other applicable regulations made under the NSCA.
206. The Commission has also considered the information and submissions of the applicant, CNSC staff and all participants as set out in the material available for reference on the record.
207. The Commission is satisfied that BTL meets the test set out in subsection 24(4) of the *Nuclear Safety and Control Act*. That is, the Commission is of the opinion that BTL is qualified to carry on the activity that the proposed Class IB licence will authorize and that it 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.
208. Therefore, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, renews the 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.
209. The Commission considered BTL's alternate interpretations of the GNSCR, the Class I Regulations and the Class II Regulations as they relate to BTL's activities. As detailed in the above sections of this *Record of Decision*, the Commission concludes that a particle accelerator *capable* of producing nuclear energy with a beam energy greater than 50 MeV is defined as a Class IB nuclear facility, pursuant to section 1 of the Class I Regulations. Furthermore, pursuant to paragraph 26(e) of the NSCA, its operation constitutes the operation of a Class IB facility, even in instances where the particle accelerator is solely operated for the purposes of testing at 1 MeV.
210. The Commission also 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 radioactive nuclear substances of more than 10^{15} Bq meets the definition of a Class IB nuclear facility under paragraph 19(a) of the GNSCR and section 1 of the Class I Regulations. 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 $1.56E10^{15}$ Bq and that BTL did not dispute that its inventory remained at this activity at the time of this hearing. 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.

211. The Commission notes that its decision in this matter determines that the Class II and NSRD licence applications will not be further considered by a CNSC DO, as BTL is authorized to carry on the requested licensed activities by the Commission-issued Class IB licence.
212. With the exception of licence condition 15.1, 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.
213. 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.”
214. The Commission is satisfied that an EA under CEAA 2012 was not required for this licence renewal application and notes that the NSCA provides a strong regulatory framework for environmental protection in respect of the impact of BTL’s facility on the environment. Further, the Commission is satisfied that BTL has made, and will continue to make, adequate provision for the protection of the environment and the health and safety of persons throughout the renewed licence period.
215. 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 a regular basis of any changes made to the Licence Conditions Handbook (LCH).
216. 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.



Rumina Velshi
President,
Canadian Nuclear Safety Commission

Aug 21, 2019

Date