



UNPROTECTED/NON PROTÉGÉ

SUPPLEMENTAL/COMPLÉMENTAIRE

CMD: 19-H2.A

Date signed/signé le : MAY 8, 2019

Reference CMD/CMD de référence : 19-H2

Required Approvals

Des approbations requises

**Best Theratronics
Limited**

**Best Theratronics
Limited**

Commission Public Hearing

Audience publique de la Commission

Scheduled for:
May 16, 2019

Prévue pour :
Le 16 mai 2019

Submitted by:
CNSC Staff

Soumise par :
Le personnel de la CCSN

Summary

This supplemental CMD presents information about the following matters of regulatory interest with respect to Best Theratronics Limited (BTL):

- Additional applications submitted to the CNSC by BTL; and
- CNSC staff's justification for why a Class IB licence is the most appropriate licence for the activities carried on at BTL.

CNSC staff recommend the Commission take the following actions:

- Renew BTL's Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-14.02/2019 in accordance with CMD 19-H2 and CMD 19-H2.A.

Résumé

Le présent CMD complémentaire présente de l'information sur les questions d'ordre réglementaire qui suivent concernant Best Theratronics Limited (BTL) :

- des demandes supplémentaires soumises par BTL à la CCSN
- la justification du personnel de la CCSN expliquant pourquoi un permis de catégorie IB est le permis le plus approprié pour les activités exercées par BTL

La Commission pourrait considérer prendre les mesures suivantes :

- Renouveler le permis d'exploitation d'une installation de traitement de substances nucléaires, NSPFOL-14.02/2019, délivré à BTL, conformément au CMD 19-H2 et CMD 19-H2.A.

Signed/signé le

May 8, 2019

A handwritten signature in blue ink, consisting of several loops and flourishes, positioned above a horizontal line.

Haidy Tadros

Director General

Directorate of Nuclear Cycle and Facilities Regulation

Directrice générale de la

Direction de la réglementation du cycle et des installations nucléaires

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EXECUTIVE SUMMARY

This Commission Member Document (CMD) supplements CMD 19-H2 submitted to the Commission by CNSC staff in support of the renewal of BTL's Class IB Nuclear Substance Processing Facility Operating Licence, NSPFOL-14.02/2019.

The Commission issued BTL a Class IB nuclear facility licence, valid from July 1, 2014 to June 30, 2019. In September 2018, BTL submitted an application for the renewal of its Class IB licence, for a period of 10 years, until June 30, 2029.

On February 15, 2019, BTL submitted to the CNSC the following additional applications:

- A Class II Prescribed Equipment licence for the development and testing of Class II prescribed equipment;
- A Nuclear Substances and Radiation Devices licence for Storage; and
- A Nuclear Substances and Radiation Devices licence for Device Manufacturing.

These additional applications were submitted to the CNSC on the premise that BTL's current activities could be licensed under these three licences in place of the Class IB licence. For reasons that are elaborated throughout this supplemental CMD, CNSC staff conclude that BTL requires a Class IB licence and disagree with BTL's opinion that these additional licences are sufficient. The three applications for licences are not appropriate or sufficient to ensure full regulatory conformity with the *Nuclear Safety and Control Act* (NSCA) and regulations made under the NSCA. It is important to note that BTL did not withdraw its Class IB licence renewal application, and therefore the matter before the Commission for decision remains the renewal of BTL's Class IB Licence NSPFOL-14.02/2019.

The proposed licence found in CMD 19-H2 has been modified and is attached to this supplemental CMD.

CNSC staff conclude that, after assessing BTL's Class IB licence renewal application, historical annual compliance performance reports and compliance verification, including inspections, BTL's operations require a Class IB nuclear facility licence, in accordance with the NSCA and regulations made under the NSCA for the following three reasons:

- BTL's waste inventory at site is greater than 10^{15} Bq;
- BTL manufactures and operates a particle accelerator (cyclotron) with a capability greater than 50 MeV; and
- BTL maintains a large and changing inventory including high-risk sealed sources.

1. OVERVIEW

This supplemental CMD includes CNSC staff's response to the BTL CMD 19-H2.1. The information contained supplements CNSC staff CMD 19-H2, and supports CNSC staff's recommendation for the renewal of BTL's Class IB Nuclear Substance Processing Facility Operating Licence NSPFOL-14.02/2019. The contents will provide the rationale and justification for CNSC staff's conclusion that BTL's operations require a Class IB licence.

1.1 Background

BTL is located at 413 March Road, Ottawa, Ontario, in an industrial zone within the Kanata Research Park. The site has been used for industrial purposes since the 1960s. BTL manufactures cobalt-60 radiation therapy units, cesium-137 blood irradiators and particle accelerators (cyclotrons) with the capability of producing energies ranging between 15 and 70 Megaelectron-Volts (MeV).

Following a two-part public hearing, the Commission issued BTL a Class IB Nuclear Substance Processing Facility Operating Licence, NSPFOL-14.02/2019, valid from July 1, 2014 to June 30, 2019.

On September 7, 2018, BTL applied for the renewal of its Class IB Nuclear Substance Processing Facility Operating Licence, NSPFOL-14.02/2019, for a period of five years [1]. Subsequently, on October 7, 2018, BTL amended this renewal application, by requesting a licensing term of 10 years.

BTL's existing Class IB licence authorizes it to test particle accelerators (cyclotrons). During its licensing term, BTL manufactured one 70 MeV particle accelerator (cyclotron) and tested it at beam energies less than 1 MeV. BTL's current licence contains hold points prohibiting the operation of particle accelerators (cyclotrons) above 1 MeV without prior approval by the Commission or a person authorized by the Commission.

On November 13, 2018, CNSC staff asked BTL if it wanted to keep a regulatory hold point as part of its application. BTL informed CNSC staff that, while it does not currently have plans to test new particle accelerators (cyclotrons) over 1 MeV, BTL wants to keep a regulatory hold point in its licence in the event that it may want to test these above 1 MeV [2].

On December 21, 2018, BTL expressed an interest in withdrawing its Class IB licence application and applying for Class II licences. In a teleconference that took place in January 2019, CNSC staff discussed this approach with BTL. CNSC staff informed BTL that, upon review of its application and supporting documentation, BTL requires a Class IB licence because of its resident waste nuclear substances and the capability of its particle accelerators (cyclotrons). Additionally, because BTL was close to the expiration of its licence at the time, CNSC staff explained that it would not be prudent to change directions at that stage in its application. BTL agreed in principle that it would proceed with the renewal hearing for its Class IB licence and mentioned the possibility of

submitting subsequent applications for the Class II and NSRD licences. CNSC staff sent a letter to BTL on January 31, 2019, summarizing these conclusions [3].

On February 15, 2018, BTL submitted to the CNSC the following additional applications:

- A Class II Prescribed Equipment licence for the development and testing of Class II prescribed equipment;
- A Nuclear Substances and Radiation Devices licence for Storage; and
- A Nuclear Substances and Radiation Devices licence for Device Manufacturing.

BTL submitted these applications with the intention of revoking its Class IB licence, as it maintains that these three licences would authorize the activities currently being authorized by BTL's Class IB licence. Concerning the particle accelerators (cyclotrons), it is BTL's opinion that because it does not intend to test these particle accelerators above 1 MeV, there is no requirement for a licence from the CNSC for that activity [4].

CNSC staff assessed BTL's Class IB licence renewal in conjunction with other relevant information, including the BTL annual compliance report [5] and the results and findings of compliance verification data, against the relevant clauses of the NSCA and regulations made under the NSCA applicable to operations at BTL.

CNSC staff's conclusion is summarized in the following section of this supplemental CMD.

1.2 Overall Conclusions

CNSC staff have concluded that, with respect to the NSCA and regulations made under the NSCA, BTL requires a Class IB nuclear facility licence (as is currently the case) and is qualified to carry on activity authorized by a Class IB licence.

1.3 Overall Recommendations

CNSC staff recommend that the activities in BTL's current Class IB licence not be split into individual licences. A consolidated Class IB licence for all the activities that are carried on at BTL, including the manufacturing of cobalt-60 radiation therapy units, cesium-137 blood irradiators and particle accelerators (cyclotrons) with the capability of producing energies ranging between 15 and 70 Megaelectron-Volts (MeV), provides various regulatory and compliance verification advantages.

It is not effective regulatory oversight to regulate a facility's operations based on the facility's daily activities, nor to regulate each activity independently of one another under various licences. Therefore, CNSC staff recommend that all proposed activities be consolidated under a Class IB licence, as is the case with

BTL's current licence. It is the responsibility of licensees to control the authorized licensed activities within the limits of their licences.

CNSC staff recommend that the Commission renew the Class IB Nuclear Substance Facility Operating Licence, NSPFOL-14.02/2019, in accordance with CMD 19-H2 and CMD 19-H2.A.

2. MATTERS FOR CONSIDERATION

2.1 CNSC Staff's Assessment of BTL's Request

CNSC staff considered the NSCA and regulations made under the NSCA to determine how the activities carried on at BTL, namely the storage of radioactive waste, use of nuclear substances, and manufacturing and testing of particle accelerators (cyclotrons), should be licensed. CNSC staff also considered the regulatory efficiencies to be gained by having multiple activities captured under one Class IB licence, especially concerning compliance oversight.

Storage of Radioactive Waste

According to the *Class I Nuclear Facilities Regulations*¹, 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 is a Class IB nuclear facility. CNSC staff considered the waste management operations, including the inventory of waste stored and managed at BTL's facility, to determine whether BTL requires a Class IB nuclear facility licence.

BTL imports radioactive sealed sources²; these may be new sealed sources for use in new units or sources returned to BTL, that have reached the end of operational life. In its application, BTL defines waste as material that no longer has a use as it was initially intended (it includes materials that may be recycled or sent to a licensed long-term waste management facility). BTL reports two types of radioactive waste:

- Medical device sealed sources; and
- Depleted uranium.

CNSC staff assessed these disused sources (i.e., sources that are no longer useful for their intended design) using the IAEA³ definition of waste and the CSA N292.0-19⁴ definition of waste. The IAEA defines waste as "material in gaseous, liquid or solid form for which no further use is foreseen". The CSA N292.0-19 defines waste as "material in gaseous, liquid or solid form for which no further

¹ *Class I Nuclear Facilities Regulations* (SOR/2000-204), section 1 definition of "Class IB nuclear facility", paragraph (f).

² IAEA: Sealed source, a *radioactive source* in which the *radioactive material* is (a) permanently sealed in a capsule or (b) closely bonded and in a solid form.

³ IAEA Safety Glossary Terminology Used in Nuclear Safety and Radiation Protection 2016 Revision

⁴ CSA N292.0-19: General principles for the management of radioactive waste and irradiated fuel

use is foreseen". In accordance with these definitions, BTL requires a Class IB nuclear facility licence because it possesses or uses a resident inventory of waste greater than 10^{15} Bq.

BTL has an end-of-life waste management program for the disused and returned medical device sealed sources. These sources are stored for reuse, recycling or disposal, as appropriate.

Discussions and review of the reports from BTL indicate that the inventory of disused and returned sealed sources for recycling or disposal at BTL is higher than 10^{15} Bq/year, and includes sources of IAEA⁵ high-risk category I & II risk significance. During the current licensing period, approximately 3.6×10^{15} Bq of returned and disused sources were recycled or disposed and approximately 3.3×10^{15} Bq/year were returned to BTL from its clients (Table 1).

Table 1: Management of waste at BTL during the licence period (extracted from BTL's Annual Compliance Reports) [5]

Management of Waste* in 10^{15} Bq	2014	2015	2016	2017	2018
Reuse - Source capsules were reused in BTL's self-contained irradiators and teletherapy machines				1.050 $\times 10^{15}$ Bq	1.036 $\times 10^{15}$ Bq
Transfer - Sources were shipped to another source supplier and manufacturer for recycling purposes. Cobalt-60 sources may be cut open and the radioactive material reused in the manufacturing of new sources for other purposes	2.106 $\times 10^{15}$ Bq	2.428 $\times 10^{15}$ Bq	3.863 $\times 10^{15}$ Bq	0.600 $\times 10^{15}$ Bq	2.548 $\times 10^{15}$ Bq
Disposal - Sources were transferred to Canadian Nuclear Laboratories in Chalk River, Ontario for long-term storage and disposal		0.697 $\times 10^{15}$ Bq	2.006 $\times 10^{15}$ Bq	1.623 $\times 10^{15}$ Bq	0.0003 $\times 10^{15}$ Bq
TOTAL	2.106 $\times 10^{15}$ Bq	3.125 $\times 10^{15}$ Bq	5.869 $\times 10^{15}$ Bq	3.273 $\times 10^{15}$ Bq	3.584 $\times 10^{15}$ Bq

* Waste includes used sources that BTL has identified as not having a use beyond its original intent, and destined to be composted, recycled or sent to long-term waste management.

* A Nuclear Energy Worker would receive the regulatory limit of 50 mSv, at 1 meter, in less than a second from unshielded 10^{15} Bq of cobalt-60.

The quantities of waste that reside at BTL vary throughout a calendar year since BTL sends waste to be recycled or disposed of by licenced facilities. However, at any given time during the year, in terms of throughput in a calendar year and/or in

⁵ IAEA-TECDOC-1344, *Categorization of radioactive source*. Retrieved from https://www-pub.iaea.org/MTCD/publications/pdf/te_1344_web.pdf

terms of resident waste, BTL may have quantities in its possession of waste above 10^{15} Bq, including high-risk Category I & II sources. CNSC staff verified this finding during an inspection that took place on April 16, 2019. The preliminary findings of this inspection indicate that the resident waste on site that day was approximately 1.6×10^{15} Bq. In addition, a review of the waste inventory at BTL over the course of 2014 through 2018 indicates that the resident inventory of waste at BTL remained over 1.6×10^{15} Bq. The nature of the operations at BTL concerning waste volume that it may be requested to receive or that may be returned to the site are not always foreseeable. Therefore, there is a high likelihood that the inventory of waste exceeds the threshold level of 10^{15} Bq.

CNSC staff conclude that, given this waste inventory, BTL meets the definition of a Class IB nuclear facility and should be licensed as such.

BTL also possesses depleted uranium inventory at BTL that originates from returned components of legacy teletherapy units and other legacy items. This inventory is temporarily stored at BTL for proper disposal at a licensed facility, as part of the BTL end-of-life waste management program. This waste is not considered in the waste inventory.

Manufacturing and Testing Particle Accelerators (cyclotrons)

BTL manufactures and operates particle accelerators (cyclotrons) with design capabilities ranging from 15 to above 70 MeV. These particle accelerators are tested at BTL prior to dismantling and shipment to BTL's customers. BTL's current licence includes the operation of cyclotrons designed to operate at a maximum energy above 50 MeV. In BTL's licence application, it indicated that it plans to continue to manufacture particle accelerators (cyclotrons) above 50 MeV and to test them at approximately 1 MeV. Therefore, for the following reasons, CNSC staff are proposing that the Commission renew the Class IB licence with authorization to operate Class IB particle accelerators.

According to the *Class I Nuclear Facilities Regulations*⁶, a facility with a particle accelerator other than a Class II particle accelerator, is a Class IB nuclear facility. Class II particle accelerators are prescribed equipment with the capability producing nuclear energy 50 MeV or lower. In other words, a Class IB licence is required to operate (i.e. to test) a particle accelerator with the capability of producing over 50 MeV, regardless of whether the testing is below 1 MeV or not. Therefore, if BTL continues to manufacture and test particle accelerators (cyclotrons) with design capabilities above 50 MeV, it is required to have a Class IB licence. CNSC staff do not recommend that BTL be permitted to operate

⁶ *Class I Nuclear Facilities Regulations* (SOR/2000-204), section 1 definition of "Class IB nuclear facility" paragraph (a).

USNRC: *Cyclotron* means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

MeV: mega electron volt

eV, electron volt is the amount of energy gained by the charge of a single **electron** moved across an electric potential difference of one **volt**.

particle accelerators (cyclotrons) with the capability of producing nuclear energy above 50 MeV, without a licence. A Class IB licence is required for this activity, in accordance with the NSCA and regulations made under the NSCA, and affords the appropriate regulatory oversight.

Manufacturers of particle accelerators can mitigate the risk associated with testing these accelerators by temporarily limiting the operating energy for testing purposes. This testing is typically done at a much lower energy than the maximum energy capability. The role of the CNSC in this context is to ensure the measures implemented to limit the operating energy (for testing) are effective and all other regulatory expectations are met at a level commensurate with the risk. During inspections, CNSC staff verify the manufacturer acceptance test results for each particle accelerator, to confirm they are tested at 1 MeV or less. CNSC inspectors verify these records during inspections or desktop reviews.

Use or Processing of Nuclear Substances

BTL maintains a large and changing inventory, that includes high-risk sealed sources. BTL's teletherapy machine used for research and development uses a cobalt-60 source (IAEA Category I) for the generation of the required radiation. The shielding housing for the source in the machine (the machine "head") is tested with a source at BTL facilities to validate the integrity of the head shielding prior to being shipped to the customer.

BTL also manufactures irradiators typically used for the sterilization of blood products. These irradiators use a caesium-137 source (IAEA Category I) that is loaded at an external facility and returned to BTL for final quality assurance prior to shipment to the customer.

In support of its operations, BTL imports sealed sources. During the current licence period, BTL sold sources for the teletherapy machines and blood irradiators in a quantity significantly greater than 10^{15} Bq per calendar year.

CNSC staff recommend that BTL continues to be licensed under a Class IB licence.

Regulating Under a Consolidated Class IB Licence

CNSC staff recommend the renewal of BTL's Class IB NSPFOL-14.02/2019 licence to:

- (a) Operate a Class IB nuclear facility located at 413 March Road, Ottawa, Ontario, including activities related to:
 - i. operating a particle accelerator/accelerators (cyclotron/cyclotrons);
 - ii. possessing nuclear substances for the purposes of manufacturing radiation devices and radioactive source teletherapy machines; and
 - iii. possessing a radioactive source teletherapy machine, for the purposes of developing and testing of radioactive source teletherapy machines;

- (b) Possess, transfer, manage, and store nuclear substances arising from the activities regarding the cyclotrons;
- (c) Produce prescribed equipment;
- (d) Possess, transfer, use, import, export, manage, and store within the facility any nuclear substances that are required for, associated with, or related to manufacturing radiation devices, and development and testing of radioactive source teletherapy machines;
- (e) Possess, transfer, use, import, export, and store prescribed equipment that is required for, associated with, or related to manufacturing of radiation devices and development and testing of radioactive source teletherapy machines, and manufacturing radioactive source teletherapy machines; and
- (f) Possess and use prescribed information that is required for, associated with, or arise from operating the Class IB nuclear facility.

This licence would consolidate all activities for which BTL submitted the following additional licence applications on February 15, 2019:

- A Class II Prescribed Equipment licence for the development and testing of Class II prescribed equipment;
- A Nuclear Substances and Radiation Devices licence for Storage; and
- A Nuclear Substances and Radiation Devices licence for Device Manufacturing.

It is the conclusion of CNSC staff that BTL requires a Class IB licence for the following reasons that have been discussed throughout this supplemental CMD:

1. BTL possesses on site, at times within a calendar year, a resident waste inventory in the form of sealed sources destined for recycling or disposal at levels that exceed 10^{15} Bq. This inventory can include IAEA high-risk Category I and II sources. In accordance with the *Class I Nuclear Facilities Regulations*⁷, 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 is a Class IB nuclear facility.
2. BTL manufactures particle accelerators (cyclotrons) capable of producing above 50 MeV of energy and operate these for testing at 1 MeV. In accordance with the *Class I Nuclear Facilities Regulations*⁸, Class IB particle accelerators with design capabilities of 50 MeV⁴ or higher are nuclear facilities. Therefore, if BTL continues to manufacture particle accelerators (cyclotrons) with capabilities above 50 MeV and to test them, it is required to have a Class IB licence. CNSC staff do not recommend that BTL be permitted

⁷ *Class I Nuclear Facilities Regulations* (SOR/2000-204), section 1 definition of “Class IB nuclear facility”, paragraph (f).

⁸ *Class I Nuclear Facilities Regulations* (SOR/2000-204), section 1 definition of “Class IB nuclear facility” paragraph (a).

to operate particle accelerators (cyclotrons), with the capability of producing nuclear energy above 50 MeV, without a licence.

3. In a typical year, the total activity handled at BTL is far greater than 10^{15} Bq. Therefore, because of the large and changing inventory, including some high-risk sources (IAEA Categories I & II), CNSC staff recommend that these activities continue to be consolidated under the proposed Class IB licence.

A consolidated Class IB licence for all the activities that are carried on at BTL, including the manufacturing of cobalt-60 radiation therapy units, cesium-137 blood irradiators and particle accelerators (cyclotrons) with the capability of producing energies ranging between 15 and 70 Megaelectron-Volts (MeV), provides various regulatory and compliance verification advantages. Firstly, a consolidated licence reduces duplication in submissions including reporting requirements, licence renewals, amendments, and responses to requests for additional information from the regulator. This streamlines regulatory effort and provides additional assurance of consistency in compliance activities carried out by CNSC staff. Secondly, CNSC staff are better able to assess potential aggregate effects of multiple and diverse activities at a licensed facility when all activities are included under one single licence. Lastly, consolidated licences reduce administrative duplication of effort, enable a broader understanding of proposed decommissioning strategies and provide for a more appropriate, risk informed, financial guarantee for all activities at a single facility.

If the Commission is not in agreement that BTL requires a Class IB licence to carry on its activities, the Class IB licence can be left to expire and CNSC staff will proceed to assess and issue, where possible, the licences requested for the Class II facility and the NSRD licences for storage and device manufacturing. The Class IB particle accelerator/accelerators will be unlicensed and therefore unregulated.

3. OVERALL CONCLUSIONS AND RECOMMENDATIONS

CNSC staff have concluded that, with respect to the NSCA and regulations made under the NSCA, BTL requires a Class IB nuclear facility licence (as is currently the case) and is qualified to carry on activities authorized by the licence.

CNSC staff recommend that the activities in BTL's current Class IB licence not be split into individual licences. A consolidated Class IB licence for all the activities that are carried on at BTL, including the manufacturing of cobalt-60 radiation therapy units, cesium-137 blood irradiators and particle accelerators (cyclotrons) with the capability of producing energies ranging between 15 and 70 Megaelectron-Volts (MeV), provides various regulatory and compliance verification advantages.

It is not effective regulatory oversight to regulate a facility's operations based on the facility's daily activities, nor to regulate each activity independently of one another under various licences. Therefore, CNSC staff recommend that all proposed activities be consolidated under a Class IB licence, as is the case with

BTL's current licence. It is the responsibility of licensees to control the authorized licensed activities within the limits of their licences.

CNSC staff recommend that the Commission renews the Class IB Nuclear Substance Facility Operating Licence NSPFOL-14.02/2019 in accordance with CMD 19-H2 and CMD 19-H2.A.

REFERENCES

- [1] NSPFOL-14.02 Class IB Licence Renewal Application Submissions, September 10, 2018, e-Doc 5631824.
- [2] Correspondence, M. Soleimani (BTL) to A. McLay (CNSC), *Question on Operation of Cyclotron*, November 14, 2018, e-Doc 5780253.
- [3] Correspondence, C. Ducros (CNSC) to M. Soleimani (BTL), *RE: Best Theratronics Licencing, Class Revision*, January 31, 2019, e-Doc 5772076.
- [4] Correspondence, E. Sacay (BTL) to CNSC, *Class II Licence Application Submissions – Best Theratronics*, February 15, 2019, e-Doc 5794691.
- [5] Submission by Best Theratronics Limited, *Annual Compliance Report Calendar Year 2018*, e-Doc 5894575.
- [6] CMD for the Renewal of Best Theratronics Limited, March 19, 2019, e-Doc 5642579.
- [7] Current Best Theratronics Limited Licence, July 14, 2017, e-Doc 5201133.

PROPOSED LICENCE CHANGES

CNSC staff recommend that the Commission renew BTL's Class IB licence, NSPFOL-14.02/2019, as per CMD 19-H2 for a period of 10 years, with the following proposed modifications to Part IV (a) and (b) and Part VI 15.1 of the proposed licence found in CMD 19-H2:

PROPOSED LICENCE CHANGES	
Proposed Licence	Proposed Modified Licence
<p>IV) LICENSED ACTIVITIES:</p> <p>This licence authorizes the licensee to:</p> <p>(a) operate a Class IB nuclear facility located at 413 March Road, Ottawa, Ontario, including activities related to:</p> <p style="padding-left: 40px;">i. operating a cyclotron/cyclotrons</p> <p>(b) possess, transfer, manage, and store nuclear substances arising from the activities</p>	<p>IV) LICENSED ACTIVITIES:</p> <p>This licence authorizes the licensee to:</p> <p>(a) operate a Class IB nuclear facility located at 413 March Road, Ottawa, Ontario, including activities related to:</p> <p style="padding-left: 40px;">i. operating a particle accelerator/accelerators (cyclotron/cyclotrons)</p> <p>(b) possess, transfer, manage, and store nuclear substances arising from the activities regarding the particle accelerators;</p>
<p>VI) CONDITIONS:</p> <p>15.1 Class IB Facility: Particle Accelerator (cyclotron)</p> <p>The licensee shall not operate a particle 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.</p>	<p>VI) CONDITIONS:</p> <p>15.1 Class IB Facility: Particle Accelerator (cyclotron)</p> <p>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.</p>

A copy of the proposed modified licence is attached to this CMD.

PROPOSED MODIFIED LICENCE

e-Doc [5896762](#) (WORD)

e-Doc 5896961 (PDF)



PROPOSED LICENCE

PDF Ref: e-Doc 5896961
Word Ref: e-Doc 5896762
File / Dossier: 2.02

CLASS IB NUCLEAR SUBSTANCE PROCESSING FACILITY LICENCE

BEST THERATRONICS LTD.

Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* (NSCA) and its associated Regulations.

I) LICENCE NUMBER: NSPFL-14.00/2029

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act*, this licence is issued to:

**Best Theratronics Limited
413 March Road
Ottawa, Ontario
K2K 0E4**

III) LICENCE PERIOD: This licence is valid from **July 1, 2019**, to **June 30, 2029**, unless otherwise suspended, amended, revoked, or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

- (a) operate a Class IB nuclear facility located at 413 March Road, Ottawa, Ontario, including activities related to:
 - (i) operating a particle accelerator/accelerators (cyclotron/cyclotrons);
 - (ii) possessing nuclear substances for the purposes of manufacturing radiation devices and radioactive source teletherapy machines;
 - (iii) possessing a radioactive source teletherapy machine, for the purposes of developing and testing of radioactive

- b) possess, transfer, manage, and store nuclear substances arising from the activities regarding the particle accelerators;
- c) produce prescribed equipment;
- d) possess, transfer, use, import, export, manage, and store within the facility any nuclear substances that are required for, associated with, or related to manufacturing radiation devices, and development and testing of radioactive source teletherapy machines;
- e) possess, transfer, use, import, export, and store prescribed equipment that is required for, associated with, or related to manufacturing of radiation devices and development and testing of radioactive source teletherapy machines, and manufacturing radioactive source teletherapy machines; and
- f) possess and use prescribed information that is required for, associated with, or arise from operating the Class IB nuclear facility.

V) EXPLANATORY NOTES:

- a) The “Best Theratronics Ltd. Licence Conditions Handbook (LCH)” provides:
 - (i) compliance verification criteria in order to meet the conditions listed in the licence;
 - (ii) information regarding delegation of authority to CNSC staff; and
 - (iii) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

VI) CONDITIONS:

1. GENERAL

G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

- (i) the regulatory requirements set out in the applicable laws and regulations;
- (ii) the conditions and safety and control measures described in this licence and the documents directly referenced in this licence;
- (iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the CNSC (hereinafter “the Commission”).

G.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design operating conditions, policies, programs and methods referred to in the licensing basis.

G.3 The licensee shall maintain a financial guarantee for decommissioning acceptable to the Commission.

G.4 The licensee shall implement and maintain a public information and disclosure program.

1. MANAGEMENT SYSTEM

1.1 The licensee shall implement and maintain a management system.

2. HUMAN PERFORMANCE MANAGEMENT

2.1 The licensee shall implement and maintain a training program.

3. OPERATING PERFORMANCE

3.1 The licensee shall implement and maintain an operating program, which includes a set of operating limits.

3.2 The licensee shall implement and maintain a program for reporting to the Commission or a person authorized by the Commission.

3.3 The licensee shall implement and maintain a program for inventory control of all nuclear substances and prescribed equipment including radiation devices.

4. SAFETY ANALYSIS

4.1 The licensee shall implement and maintain a safety analysis program.

5. PHYSICAL DESIGN

5.1 The licensee shall implement and maintain a design program.

6. FITNESS FOR SERVICE

6.1 The licensee shall implement and maintain a fitness for service program.

7. RADIATION PROTECTION

7.1 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within 7 days.

8. CONVENTIONAL HEALTH AND SAFETY

8.1 The licensee shall implement and maintain a conventional health and safety program.

9. ENVIRONMENTAL PROTECTION

9.1 The licensee shall implement and maintain an environmental protection program.

10. EMERGENCY MANAGEMENT AND FIRE PROTECTION

10.1 The licensee shall implement and maintain an emergency preparedness program.

10.2 The licensee shall implement and maintain a fire protection program.

11. WASTE MANAGEMENT

11.1 The licensee shall implement and maintain a waste management program.

11.2 The licensee shall implement and maintain a decommissioning plan.

12. SECURITY

12.1 The licensee shall implement and maintain a security program.

13. SAFEGUARDS AND NON-PROLIFERATION

13.1 The licensee shall implement and maintain a safeguards program.

14. PACKAGING AND TRANSPORT

14.1 The licensee shall implement and maintain a packaging and transport program.

15. SITE SPECIFIC

15.1 Class IB Facility: Particle Accelerator (cyclotron)

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.

15.2 Export Restrictions

This licence does not authorize the licensee to export, for the valid period of this licence in respect of a nuclear substance, a radioactive sealed source whose corresponding activity is equal to or greater than the value set out in column 2 of Table 1:

Table 1: Activity Limits for Exporting Sealed Sources

Column 1 Nuclear Substance	Column 2 (TBq)
Americium 241	0.6
Americium 241/Beryllium	0.6
Californium 252	0.2
Curium 244	0.5
Cobalt 60	0.3
Cesium 137	1
Gadolinium 153	10
Iridium 192	0.8
Promethium 147	400
Plutonium 238	0.6
Plutonium 239/Berilium	0.6
Radium 226	0.4
Selenium 75	2
Strontium 90 (Yttrium 90)	10
Thulium 170	200
Ytterbium 169	3

SIGNED at OTTAWA, this _____ day of _____, 2019

 Rumina Velshi, President
 on behalf of the Canadian Nuclear Safety Commission