



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Record of Proceedings, Including Reasons for Decision

In the Matter of

Applicant **Best Theratronics Ltd.**

Subject **Application for a Class 1B Nuclear Substance
Processing Facility Operating Licence**

**Public Hearing
Date** **May 8, 2014**

RECORD OF PROCEEDINGS

Applicant: Best Theratronics Ltd.

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

Purpose: Application for a Class 1B Nuclear Substance Processing Facility Operating Licence

Application received: January 31, 2014

Date of public hearing: May 8, 2014

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

Members present: M. Binder, Chair
 A. Harvey D. D. Tolgyesi
 S. McEwan R. Velshi

Secretary: M.A. Leblanc
 Recording Secretary: S. Dimitrijevic
 General Counsel: L. Thiele

Applicant Represented By			Document Number
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Licence: Issued

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1.0 INTRODUCTION

1. Best Theratronics Ltd. (BTL) has applied to the Canadian Nuclear Safety Commission¹ for the issuance of a Class 1B Nuclear Substance Processing Facility Operating Licence for its medical device manufacturing company located in Ottawa, Ontario, in an industrial zone within the Kanata Research Park.
2. BTL is a medical device manufacturing company that was initially a part of Atomic Energy of Canada Ltd. (AECL), which then became a crown corporation “Theratronics”. In the 1990-s the company was purchased by MDS Nordion Inc. In 2008, the company was purchased by a private investor and became Best Theratronics Ltd. BTL manufactures medical equipment including Cobalt-60 (Co60) radiation cancer treatment units, as well as Caesium-137 (Cs137) and x-ray-based blood irradiators. BTL has been developing a line of cyclotrons for use in health care and research institutions.
3. BTL currently holds four licences issued by the CNSC. These licences cover device manufacturing, research and development, and possession and storage of sealed sources and depleted uranium. BTL is a major importer and exporter of Category I sealed sources. BTL is also requesting to consolidate three of its existing CNSC licences into the aforementioned Class 1B licence.
4. The existing licences restrict BTL’s research and development activities to manufacturing and testing of cyclotrons with energies lower than 1 MeV (Mega-electron volts). The requested Class 1B licence would authorize BTL to continue its existing activities and to manufacture and test cyclotrons with energies up to 70 MeV.

Issue

5. In considering the application, the Commission was required to decide, pursuant to subsection 24(4) of the *Nuclear Safety and Control Act*² (NSCA):
 - a) if BTL is qualified to carry on the activity that the licence would authorize; and
 - b) if, in carrying on that activity, BTL would 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.

Public Hearing

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 Statutes of Canada (S.C.) 1997, chapter (c.) 9.

6. The Commission, in making its decision, considered information presented for a public hearing held on May 8, 2014 in Ottawa, Ontario. The public hearing was conducted in accordance with the *Canadian Nuclear Safety Commission Rules of Procedure*³. During the public hearing, the Commission considered written submissions and heard oral presentations from CNSC staff (CMD 14-H3 and CMD 14-H3A) and BTL (CMD 14-H3.1 and CMD 14-H3.1A). The Commission also considered a written submission from one intervenor (Nordion (Canada) Inc.). The hearing was webcasted live via the CNSC website, and video archives are available for a three-month period following this decision.

2.0 DECISION

7. Based on its consideration of the matter, as described in more detail in the following sections of this *Record of Proceedings*, 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*, issues to Best Theratronics Ltd. a Class 1B Nuclear Substance Processing Facility Operating Licence for its facility located in Ottawa, Ontario. The new licence, NSPFOL-14.00/2019, is valid from July 1, 2014 to June 30, 2019.

8. The Commission includes in the licence the conditions as recommended by CNSC staff and set out in the draft licence attached to CMD 14-H3 with the following change: the part of section IV(b) reading “prepare a site for, and construct a Class1B Particle Accelerator/Cyclotron” shall be deleted.
9. The Commission accepts CNSC staff’s recommendations regarding operating and dismantling of Class I particle accelerator, as set out in the licence conditions 16.1 and 16.2 of the operating licence NSPFOL - 14.00/2019 and in the Licence Conditions Handbook (LCH).
10. The Commission also accepts CNSC staff’s recommendation regarding the delegation of authority in the LCH. The Commission notes that CNSC staff can bring any matter to the Commission as applicable. The Commission directs CNSC staff to inform the Commission on an annual basis of any changes made to the LCH.
11. The Commission requests that BTL identifies and respect due dates for its

³ Statutory Orders and Regulations (SOR)/2000-211.

commitments to close the gaps and implement its safety programs, as identified in CMD 14-H3 and set out in the operating licence and LCH. An update to the Commission on this issue will be included in annual reports on the performance of BTL.

12. With this decision, the Commission directs CNSC staff to provide annual reports on the performance of BTL, as part of the Directorate of Nuclear Cycle and Facilities Regulation (DNCFR) annual safety performance reports. CNSC staff shall present these reports at public proceedings of the Commission.

3.0 ISSUES AND COMMISSION FINDINGS

13. In making its licensing decision, the Commission considered a number of issues relating to BTL's qualification to carry out the proposed activities and 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.

3.1 Management System

14. 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 and continuously monitors its performance against these objectives and fosters a healthy safety culture.
15. BTL presented its organisational chart and procedural framework that defines the roles and responsibilities of personnel regarding the protection of the employees, environment, and the public. BTL informed the Commission about its management structure and the key management documents. BTL stated that it has implemented a culture of safety and compliance through its Senior Management team that regularly holds a Quality Management Review Meeting and through its Health and Safety Committee.
16. BTL added that, in order to meet its regulatory and compliance obligations in the domain of export and shipment of Category 1 sealed sources, BTL has restructured its Logistic Department to report to the Radiation Safety Officer (RSO), as a result of a management structure review conducted in 2012.
17. CNSC staff reported that it had reviewed the procedures and supporting documentation related to the organization, records management, change management, operating experience, and management of contractors, and concluded that they were satisfactory. There were no outstanding issues. CNSC staff rated this safety and control area (SCA) as satisfactory.
18. Based on its consideration of the presented information, the Commission concludes

that BTL has appropriate organization and management structures in place and that the operating performance at the BTL facility provides a positive indication of the applicant's ability to adequately carry out the activities under the proposed licence.

3.2 Human Performance Management

19. Human performance management encompasses activities that enable effective human performance through the development and implementation of processes that ensure licensee staff is 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.
20. BTL informed the Commission that it had implemented a systematic approach to training (SAT) with identified qualifications, competencies and minimum requirements for each position. The training program was revised following the request by CNSC staff. Each BTL department has designated a training coordinator to maintain and keep the training records for employees. To ensure a sufficient number of qualified personnel for the implementation of the Radiation Protection Program, a Radiation Safety Specialist and a Technical Assistant were added to the Compliance department to assist the RSO in matters relating to radiation safety.
21. BTL added that the company will continuously assess the adequacy of its training program and the number of qualified personnel, and intends to continue to fill all key positions related to the licensed activities.
22. CNSC staff informed the Commission that BTL had submitted its revised program and schedule for recruiting, training and qualifying workers needed for the operation and maintenance of the facility, as well as documentation related to work organization and qualification requirements. CNSC staff stated that the updated procedures and supporting documentation are satisfactory for this SCA.
23. CNSC staff recommends that BTL implement the requirements set out in CNSC document TPED-01, "*Objectives and Criteria for Regulatory Evaluation of Nuclear Facility Training Programs*" by July 2015, as specified in the draft Licence Conditions Handbook (LCH).
24. The Commission asked for clarification regarding an apparent discrepancy between the number of employees involved in licensed activities and number of hired qualified personnel. The representative from BTL responded that the company has a satellite office where a substantial number of employees is involved in cyclotron design and engineering tasks, and is not involved in the licensed activities that include work with radioactive sources.
25. The Commission enquired about the turnover rate and how it affects training of employees. The BTL representative responded that a large number of employees remain with the company for long periods of times, 20, 30 or more years, so that

replacements do not occur abruptly, which allows sufficient time for training of recruited workers. CNSC staff stated that their reviews were focused on training program related to the radiation protection and added that, at BTL, each job description clearly defines what sort of training workers need for those type of jobs.

Conclusion on Human Performance Management

26. Based on its consideration of the presented information, the Commission concludes that BTL has appropriate programs in place and that the current efforts related to human performance management provide a positive indication of BTL's ability to adequately carry out the activities under the proposed licence.

3.3 Operating Performance

27. Operating performance 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 BTL.
28. BTL informed the Commission that it has an extensive program that describes policies and procedures for the various activities undertaken at the facility, and encompasses internal audits, a Corrective Action and Preventative Action (CAPA) mechanism, as well as investigations of occupational injuries and near misses. BTL stated that the operating performance is reviewed monthly at the Health and Safety Committee Meeting, and at the Radiation Safety Committee Meeting. Overall operating performance and quality system are reviewed by senior management on a bi-annual basis at the Management Review Meeting.
29. BTL further informed the Commission that the program had been reviewed and improved in 2012, when changes were made to include two new procedures relating to radioactive material shipments and sealed source tracking. An unannounced CNSC inspection in 2013 and follow-up audits in 2013 and 2014 had not resulted in any non-compliance findings.
30. CNSC staff proposed licence conditions and made specific recommendations regarding implementation of an operating program, a program for reporting to the Commission, which includes sealed source tracking, and a program for inventory control. CNSC staff also proposed conditions requiring BTL to operate the cyclotron only in accordance with the commissioning test plan and to dismantle the cyclotron only in accordance with an approved dismantling plan.
31. The Commission asked about the relationship between BTL and Noridon (Canada) Inc. (Nordion). A BTL representative responded that the two companies act independently and provide contracted services to each other. Since the BTL facility does not have a hot-cell storage capability, those services include storage of some of BTL's sources at

the Nordion facility. The liability for the sources stored at the Nordion facility remains with BTL. The stored sources are shifted from one facility to the other only when needed. CNSC staff stated that moving the sources, including transfer between facilities, has to meet requirements related to transport of radioactive material. CNSC staff noted that the shunting of sources is covered under the existing licence, and will be also regulated under the proposed licence. CNSC staff had reviewed sealed source tracking procedures, inventory, reporting and trending, accident management and recovery and non-conformance reporting procedures submitted by BTL, and reported that the procedures and supporting documentation were satisfactory for this SCA.

32. CNSC staff added that current storage of the majority of BTL sealed sources and all hot cell related work is provided under contract to Nordion at Nordion's adjacent facility.
33. CNSC staff reported that BTL had submitted operational instructions describing standard operating procedures for the cyclotron, testing of the safety systems and training of the operators. CNSC staff reviewed these documents and found them to be satisfactory.
34. CNSC staff informed the Commission that, before commissioning the 70 MeV cyclotron, BTL must submit information that verifies the design and procedures for safe operation and dismantling of the cyclotron. Once BTL has completed the testing of the cyclotron, it will be dismantled and shipped to the customer. BTL will not be authorized to operate or dismantle the cyclotron without prior CNSC approval, since these operations are significant events. Consequently, CNSC staff had proposed specific license conditions (16.1 and 16.2) that require BTL to submit detailed procedures prior to conducting these activities. The conditions act as hold points so that CNSC staff can confirm that the health and safety of workers is protected. The verification criteria for these hold points are included in the LCH.
35. The Commission pointed out that the cyclotron testing at the facility at full power represents a new aspect of BTL's operation, compared to its business related to sealed sources and irradiation units, and asked whether each of these business branches could be monitored effectively and appropriately without impacting the other. CNSC staff responded that this was the reason for including specific licence conditions with hold points for the hazards related to new operation. CNSC staff added that, in terms of inspections, there will be joint inspections from CNSC specialists on accelerators with the specialists on nuclear processing facilities.
36. Based on the above information, the Commission concludes that BTL has adequate measures in place to support satisfactory operating performance at the facility and provides an indication of BTL's ability to carry out the activities under the proposed licence.

3.4 Safety Analysis

37. The Commission examined issues related to the program areas of Safety Analysis in order to assess the adequacy of the safety margins provided by the design of the facility.
38. Safety analysis includes the systematic evaluation of the potential hazards associated with the proposed activity or facility and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards.
39. BTL informed the Commission that it has implemented the safety analysis framework, the key element of which is the use of safety analysis reports (SARs). These reports are undertaken as part of the initial design process, or when there are changes to safety critical components (such as radiation devices and Class II prescribed equipment) to radioactive material transport containers, and to the facility itself. SARs are covered under BTL's Design Change procedure.
40. BTL further informed the Commission that the implemented SARs include the Class II research and development area of the facility, testing of cyclotrons up to 70 MeV, as well as reports relating to the radiation devices, Class II prescribed equipment, and transport packages. As requested by CNSC staff, BTL had included in the analysis a threat and risk assessment for the 70 MeV cyclotron.
41. CNSC staff informed the Commission that it had reviewed the SAR for cyclotron testing and found that the proposed shielding and design are adequate for the protection of the health and safety of persons and the environment. This SAR defines the limiting operational design parameters, which had been included in the LCH for the proposed licence.
42. In addition, CNSC staff had reviewed the SAR for the whole facility, as well as the SAR for shielding room designed for the operation of a linear accelerator, and found that the shielding and design of the facility and its components are adequate for the protection of the health and safety of persons and the environment. CNSC staff recommended that the SARs for the Class 1B Facility be updated within one year of the licence being issued.
43. 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 facility and the activities under the proposed licence.

3.5 Physical Design

44. Physical design includes activities to design the systems, structures and components to meet and maintain their design basis. The design basis is the range of conditions and

events taken into account in the design of structures, systems and components of a facility according to established criteria.

45. BTL informed the Commission that the facility had been initially designed by Atomic Energy of Canada Limited (AECL) for device manufacturing, accelerator development, and sealed source processing and storage. All new design work and changes to areas relating to licensed activities were undertaken with applicable City of Ottawa building permits by qualified construction personnel. Prototype equipment was designed and would be manufactured according to the procedure set out in BTL's Quality Manual, which includes a hazard risk assessment that is continuously reviewed during the design and manufacturing phases.
46. CNSC staff stated that the proposed shielding and design were reviewed through the Safety Analysis SCA, and were found to be adequate for the protection of the health and safety of persons and the environment.
47. The Commission sought more information about the bunker for testing of the cyclotron. The BTL representative responded that the bunker is modular for easy construction and dismantling. The bunker provides full protection during the testing of the cyclotron, after which it is disassembled, entirely or in part, to enable packaging and shipment of the cyclotron. The bunker could be either removed and stored or used for another testing if required. The BTL representative added that cyclotron testing at the construction site at high power is done only if required by a customer, and is not a common practice. CNSC staff stated that, if properly done, the use of this modular bunker provides adequate protection. After the bunker is re-assembled, BTL would have to seek CNSC staff's approval for its use.
48. BTL representatives noted that the bunker had been designed by an engineering consulting firm that had followed requested shielding input parameters. The bunker was designed to stand up and preserve shielding characteristics under different conditions, including earthquakes.
49. The Commission asked for the types of analysis required for the bunker use. CNSC staff responded that a complete independent analysis of the shielding requirements and shielding documents submitted by BTL had been done to ensure that CNSC estimations matched BTL's. After the estimated worst case scenario, if the cyclotron run at 70 MeV for 100 hours, the dose at the control console would be 77 μSv . BTL representatives added that the design basis, used for shielding calculations and the dose estimation, included operation at 70 MeV on a specific target material listed in the LCH at given currents. The currents were chosen to represent testing needs, worst case scenario, and the hours required for testing. The change in basic parameters, such as applied current, would affect radiation parameters and would impose a reassessment of the shielding efficiency and bunker design base. Such change could also affect the activation level of the material present in the bunker.

50. On the basis of the information presented, the Commission concludes that the design of the BTL facility is adequate for the operation period included in the proposed licence.

3.6 Fitness for Service

51. Fitness for Service covers activities that are carried out to ensure the physical condition of systems, components and structures remain effective over time and continue to effectively fulfill their intended purpose. This specific area includes equipment fitness for service / equipment performance, maintenance and periodic inspections and testing.
52. The licensee is required to manage maintenance activities to comply with regulatory requirements and accepted industry practice to minimize potential impacts to workers, the public and the environment. In addition, maintenance activities must provide assurance to achieve desired results, provide effective management of inventory of maintenance materials, and provide systematic management of maintenance change control.
53. BTL informed the Commission that the fitness for service of the facility is managed by the Facilities Maintenance Specialist and is assessed on an on-going basis by the Health and Safety Committee. Areas dedicated to licensed activities are also reviewed by the Radiation Safety Committee.
54. BTL further informed the Commission that, in accordance with implemented procedures, the equipment is checked on a monthly basis and calibrated yearly by a third party. The Quality Control department is responsible for the electronic calibration database, which includes data on the radiation monitoring equipment.
55. CNSC staff reported that it had reviewed all procedures and supporting documentation to ensure that all equipment and systems will be maintained and fit for service. CNSC staff found BTL's performance regarding this SCA to be satisfactory. CNSC staff further reported that the manufacturing equipment is maintained on a regular basis and that BTL was already implementing preventive maintenance procedures to ensure that all manufacturing equipment is fit for service. CNSC staff concluded that BTL has an ongoing maintenance, calibration and testing program to ensure the necessary level of reliability required for radiation monitoring systems, pre-exposure alarm, emergency stops and access control interlocks.
56. The Commission is satisfied with BTL's programs for the inspection and life-cycle management of key safety systems. Based on the above information, the Commission concludes that the equipment as installed at the BTL facility is fit for service.

3.7 Radiation Protection

57. Radiation Protection (RP) covers the implementation of a RP program in accordance

with the *Radiation Protection Regulations*⁴ to ensure that contamination and radiation doses received are monitored and controlled.

58. The *Radiation Protection Regulations* require licensees to establish a RP program to keep exposures as low as reasonable achievable (ALARA), through the implementation of a number of controls, including management control over work practices, personnel qualification and training, control of occupational and public exposures to radiation, and planning for unusual situations. The *Radiation Protection Regulations* also prescribe dose limits for workers and members of the public.
59. BTL informed the Commission about its Radiation Protection Program that covers the current and proposed licensed activities, including the following:
- Radiation safety training;
 - Dose monitoring;
 - Radiation and contamination monitoring;
 - Radioactive material shipments, exporting, and importing;
 - Safety analysis developed relating to matters of radiation safety; and
 - Development of operating procedures and process relating to licensed activities.

This program is defined within BTL's Radiation Protection Manual and is administered by the Radiation Safety Team headed by the Radiation Safety Officer. The program is reviewed on a regular basis by the Radiation Safety Committee. BTL added that the key members of the Radiation Safety Team have received outside training provided by third-party consultants.

60. CNSC staff reported that the review of BTL's performance in this SCA included the following specific areas:
- Application of ALARA;
 - Radiation Protection Program Performance;
 - Worker Dose Control; and
 - Radiological Hazard Control.

CNSC staff evaluated BTL's RP program and found it complete and appropriate for this licence application. CNSC staff rated this SCA as satisfactory.

61. BTL further informed the Commission that the company had implemented an ALARA program, and provided the data that illustrate the program effectiveness in maintaining low doses to BTL employees and the public. BTL emphasized that they had never reached any of their administrative or internal action levels.
62. CNSC staff stated that BTL had applied ALARA through the implementation of a number of controls, including: management control over work practices, personnel

⁴ SOR/2000-203

qualification and training, control of occupational and public exposures to radiation, and planning for unusual situations. CNSC staff confirmed that BTL had established appropriate action levels and currently utilizes dosimeters provided by a licensed dosimetry service provider to ascertain whole-body dose and extremity beta/gamma dose. CNSC staff expressed its satisfaction regarding the measures put in place to monitor and control radiological hazards.

63. The Commission is of the opinion that, given the mitigation measures and safety programs that are in place or will be in place to control hazards, BTL will provide adequate protection to the health and safety of persons, the environment and national security.

3.8 Conventional Health and Safety

64. Conventional health and safety covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment. This program is mandatory for all employers and employees in order to reduce the risks associated with conventional (non-radiological) hazards in the workplace. This program includes compliance with Part II of the *Canada Labour Code*⁵ and conventional safety training.
65. BTL provided information about its health and safety program and implemented preventive measures that include reduction and elimination of hazards, as well as the provision of protective equipment. The program is monitored by BTL's Health and Safety Committee, and preventive measures had been implemented in accordance with the *Canada Labour Code*.
66. CNSC staff reported that it had reviewed the procedures and supporting documentation for BTL's conventional health and safety program and considers it to be satisfactory. CNSC staff confirmed that BTL has an investigation procedure for occupational injuries, hazardous occurrences and near misses, and added that BTL's employees receive specialized Health and Safety training according to their job description and duties.
67. BTL further provided a summary of the reported occupational injuries and hazards over the past 3 years, and noted that the increase in the total number of first aid injuries over that period reflects an increased efficiency in reporting of all injuries, including the minor ones.
68. The Commission asked about reporting of the frequency, severity and lost time injuries. CNSC staff responded that, under the Class 1 licence, this information would be required and will be part of the annual compliance report. CNSC staff noted that it had collected information about injuries and that their number does not give rise to concern. Most accidents were not related to handling of radioactive sources.

⁵ R.S.C. 1985, c. L-2

69. The Commission is of the opinion that the health and safety of workers and the public will be adequately protected during the operation of the facility for the proposed licence period.

3.9 Environmental Protection

70. Environmental Protection covers BTL's programs that identify, control and monitor all releases of radioactive and hazardous substances from facilities or as the result of licensed activities and their effects on the environment. It includes effluent and emissions control, environmental monitoring and estimated doses to the public.
71. BTL informed the Commission that they had implemented an Environmental Protection Program that deals with solid emissions, liquid effluents, chemical spills and air emissions. The Director of Compliance is responsible for this program, and primary oversight, including environmental hazard assessment, is conducted by BTL's Health and Safety Committee.
72. CNSC staff stated that BTL, as all Class 1 facilities, is expected to comply with REGDOC-2.9.1, *Environmental Protection: Policies, Programs and Procedures* and the Canadian Standards Association (CSA) ISO 14001. CNSC staff had reviewed BTL's environmental protection program and is satisfied with procedures in place to protect the environment. CNSC staff rated this SCA as satisfactory.
73. BTL stated that, since only sealed sources are used at the site, there have been no releases of radioactive material into the environment. Hazardous airborne emissions are related to non-radioactive sources and result from combustion and manufacturing processes. These emissions are reduced or eliminated by filtering, capture and ventilation. Indoor air quality would be monitored periodically to ensure that it remains within regulatory limits. Hazardous liquid effluents from routine operations would be collected, temporarily stored on-site, and regularly removed for disposal by a certified third party contractor.
74. CNSC staff informed the Commission that BTL had submitted an Emission Summary and Dispersion Modeling (ESDM) Report which compared results of atmospheric emissions modeling for the facility to the applicable criteria established by the Ontario Ministry of the Environment. The submitted information confirms that the design and the proposed shielding of the facility incorporate adequate provisions for the protection of the health and safety of persons and the environment.
75. CNSC staff noted that, since there are no radiological releases from the facility, the risk of radiation exposure to members of the public from normal operation is negligible. The most exposed members of the public are the drivers transporting radioactive material from the site. The dose for a typical shipment is estimated to be less than 10 µSv (microSievert), which is 1% of the regulatory limit of 1 mSv/y (milliSievert per year).

76. In addition, BTL informed the Commission that, at the time the application was submitted (in September 2012), an EA was initiated under the requirements of the *Canadian Environmental Assessment Act, 2012* (CEAA 2012), and an Environmental Impact Statement (EIS) had been submitted to the CNSC. After reviewing the EIS, CNSC staff prepared a draft EA Report which underwent a public review period in February 2013. Thereafter, CNSC staff concluded that, in light of the fact that the BTL project was not a designated project, the environmental review would be completed as part of the assessment of the application under NSCA. The EA was completed for this project in October 2013. The EA determined that the proposed licensed activities would not have significant adverse environmental effects.
77. CNSC staff confirmed that an EA under the NSCA and its Regulations was completed for this application and that CNSC staff had used the information in the EA report to make the recommendations and conclusions under the NSCA. These conclusions and recommendations are included in licence conditions and in the LCH.
78. The Commission enquired whether the current EIS includes, apart from the activities related to the cyclotron testing that would be included in the Class 1B licence, some other activities such as loading of the sources that Nordion is doing currently. CNSC staff responded that this application considered all current BTL activities and only new activities proposed in the CMD. If any other activity is proposed in the future, CNSC staff would do an assessment to see if those activities were within the bounds of that environmental assessment.
79. Based on the above information, the Commission is satisfied that, given the mitigation measures and safety programs that are in place to control hazards, BTL will provide adequate protection to the health and safety of persons and the environment.
80. The Commission is satisfied that no federal EA is required in this case. The Commission accepts the recommendation by CNSC staff as set in the LCH, and expects that BTL's environmental management system is in place by July 1, 2015. The Commission notes that the NSCA provides a strong regulatory framework for environmental protection, and that the CNSC regulatory system ensures that adequate measures are in place to protect the environment and human health in accordance with the NSCA and its Regulations.

3.10 Emergency Management and Fire Protection

81. Emergency Management and Fire Protection covers BTL's provisions for preparedness and response capability to mitigate the effects of accidental releases of nuclear and hazardous substances to the environment during emergency and non-routine conditions.

3.10.1 Emergency Management

82. BTL informed the Commission that it had implemented and maintained the emergency preparedness program that includes the following procedures:
- Radiation Emergency Response Plan;
 - Transportation Emergency Response Plan;
 - Fire Safety Plan – Best Theratronics Building; and
 - Chemical Spill Response Plan.

The emergency preparedness program is managed by an Emergency Response Team consisting of BTL personnel from various departments and chaired by the Radiation Safety Officer. The first-aid responders are members of BTL staff that have received certified first-aid training from an external organization. BTL added that it conducts exercises that include testing of emergency equipment to ensure the adequacy of its emergency preparedness program.

83. CNSC staff reported that BTL had demonstrated that it has an established emergency management and preparedness program, plans and procedures. The programs and supporting documentation are considered to be satisfactory.

3.10.2 Fire Protection

84. BTL informed the Commission that the company was developing a Fire Hazard Assessment (FHA) and Fire Prevention Plan (FPP) using a qualified third-party consultant, as part of the Class 1B application. A number of areas of improvement related to BTL's facility and fire protection equipment and alarms have been identified, and BTL is currently developing a plan to implement the recommended improvements.
85. BTL has also conducted a review and significant rewrite of its Fire Safety Plan, based on CNSC feedback. The revised plan was submitted to the City of Ottawa Fire Services for review.
86. CNSC staff confirmed that BTL had provided an FHA that includes a code compliance review for compliance of the existing operational activities, the building and fire protection systems, structures and components with building and fire codes. CNSC staff reviewed the FHA and considers the submission to be adequate for the licence application.
87. CNSC staff further reported that BTL had provided a gap assessment for its current procedures that relate to fire protection and CNSC staff's expectations for the FPP. CNSC staff added that a transition period will allow BTL to comply with CSA standard N393 *Fire Protection for Facilities that Process, Handle or Store Nuclear Substances*, by July 1, 2015. Timelines for the completion of the related actions will be included in the LCH to ensure clarity of CNSC staff's expectations.

88. BTL noted that it conducts exercises that include testing of emergency equipment and fire systems, as well as annual fire drills.

3.10.3 Conclusion on Emergency Management and Fire Protection

89. Based on the above information, the Commission concludes that the fire protection measures and emergency management preparedness programs in place, and that will be in place, at the facility are adequate to protect the health and safety of persons and the environment.

3.11 Waste Management

90. Waste management covers the licensee's site-wide waste management program and the planning for decommissioning of the facility. CNSC staff evaluated BTL's performance with regards to waste minimization, segregation, characterization, and storage.
91. BTL informed the Commission that they had established a waste management program, and stated that BTL's priority was to prevent or minimize the generation of wastes as part of an overall integrated cleaner production approach. The waste produced as a result of the company's operation consists mainly of scrap metal, general waste associated with an office environment and hazardous material used in the manufacturing process. Radioactive waste consists of sealed sources and depleted uranium typically returned from the field as a result of service or decommissioning activities.
92. CNSC staff reported that BTL has a documented waste management program that involves minimizing, storage and disposal of hazardous and non-hazardous substances. Radioactive waste management is documented in BTL's Radiation Protection Manual and in the document for Management of Depleted Uranium Radioactive Material. After reviewing BTL's waste management program, CNSC staff concluded that the procedures and supporting documentation for this SCA are satisfactory.
93. BTL added that standard waste is disposed of to the City of Ottawa landfill, while paper is recycled internally and scrap metal is diverted to scrap metal recycling facilities. Hazardous waste is collected and properly disposed of by a third-party. Radioactive material is managed according to BTL's end-of-life management program, which includes reuse, recycling or disposal of the radioactive material. BTL further informed the Commission about a campaign to reduce legacy non-radioactive waste, and a campaign to reduce its disused sealed source inventory and recycle sealed sources.
94. The Commission enquired about the storage of radioactive sources and asked about

potential reduction of the volume of the stored material. The BTL representative responded that there are two storage regimes: one for new sources to be used in new units, and the second one for the sources returned from the field. All sources are sealed and meet the requirements of the IAEA. Storage of these sources, at either Nordion or BTL facilities, is an interim storage solution. BTL has an end of life management program to deal with returned sources. Some of them are still viable and are reused, while others could be disposed at a disposal facility, such as Chalk River. The BTL representative noted that the company is working on reducing the number of stored sources. CNSC staff noted that BTL is required to maintain its sources inventory under the waste management program and to submit reports on this inventory to CNSC staff.

95. Based on the above information and considerations, the Commission is satisfied that BTL will be safely managing waste at its facility.

3.12 Security

96. Security covers the programs required to implement and support the security requirements stipulated in the relevant regulations, the licence, and in the expectations for the facility or activity. This includes compliance with the applicable provisions of the *General Nuclear Safety and Control Regulations*⁶ and the *Nuclear Security Regulations*⁷.
97. BTL informed the Commission that it had implemented a robust security program that includes an access card system, a police records check for all employees, on-site security at all times, and a network of cameras and other monitoring equipment on the premises. The security monitoring system was upgraded in 2013 and additional security cameras were installed to ensure full coverage of the facility. BTL added that, in 2013, the Ottawa Police Services had upgraded the facility designation, providing an improved police response time.
98. CNSC staff informed the Commission that BTL's updated site security plan had been reviewed and found to meet CNSC regulatory requirements. BTL's measures for controlling access were assessed and considered satisfactory. BTL had completed a Threat and Risk Assessment for the new activities associated with the 70 MeV cyclotron. There is no indication that these new proposed activities would have any impact on the security of the facility or the safety of the personnel, the public or the environment.
99. BTL had also implemented a strong program to ensure the security of the Category I and II sources during transportation, which meets the CNSC requirements. To ensure that security systems are in place and continue to meet these requirements, BTL performs annual audits of its ground carriers.

⁶ SOR/2000-202

⁷ SOR/2000-209

100. CNSC staff stated that BTL has satisfactory processes in place for testing and maintaining the security devices and systems, as well as the measures implemented for the secure transportation of high risk radioactive sources by road.
101. CNSC staff reported that it had performed a security inspection in March 2013 as part of the compliance activity under the current licences. This inspection resulted in the issuance of three action notices that were subsequently addressed by the licensee in a satisfactory manner.
102. The Commission sought more details regarding site access control. The BTL representative responded that there is permanent on-site security personnel that signs people in, monitors the front door and surveillance cameras. All exterior doors are locked and a few are accessible to personnel with badges. The radiation controlled areas are further secured by various mechanisms, such as cages or large doors with security access and cameras.
103. The Commission is satisfied that BTL's performance with respect to maintaining security at the facility is satisfactory. The Commission concludes that BTL has made adequate provision for ensuring the physical security of the facility, and is of the opinion that BTL will make adequate provision during the proposed licence period.

3.13 Safeguards

104. Safeguards and Non-Proliferation covers the programs and activities required for the successful implementation of the obligations arising from the Canada/IAEA Safeguards agreements as well as all other measures arising from the *Treaty on Non-Proliferation of Nuclear Weapons*.
105. BTL informed the Commission that the company possesses depleted uranium (DU), used earlier in legacy Co60 teletherapy units. Legacy devices containing DU were decommissioned and returned to BTL for disposal. BTL provides short-term storage of this legacy DU until it can be shipped to a licensed disposal facility. BTL has implemented a Safeguards program and performs yearly Physical Inventory Takings, as required by CNSC regulations.
106. CNSC staff informed the Commission that the scope of the non-proliferation program for BTL is limited to the tracking and reporting of foreign obligations and origins of nuclear material. CNSC staff stated that BTL maintains a safeguards program in compliance with all licence requirements. CNSC staff also stated that BTL had submitted acceptable procedures to export Risk-Significant Radioactive Sources, to train staff involved in export and to report on Sealed Source Tracking and export.
107. BTL further informed the Commission that a Physical Inventory Verification, performed by the IAEA in 2013, had found that all material was accounted for and the documentation related to transfers was in order. CNSC staff concurred with BTL.

108. CNSC staff confirmed that BTL had provided the CNSC and IAEA with all reports and information necessary to comply with safeguards regulatory requirements. The IAEA performed two inspections during the period 2009 - 2013. There were no reportable events or action notices issued as a result of these IAEA inspections.
109. Based on the above information the Commission is satisfied that BTL has made, and will continue to make, adequate provision in the areas of safeguards and non-proliferation at the facility for maintaining national security and measures necessary for implementing international agreements to which Canada has agreed.

3.14 Packaging and Transport

110. Packaging and transport covers the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility. BTL must adhere to the *Packaging and Transport of Nuclear Substances Regulations*⁸ and Transport Canada's *Transportation of Dangerous Goods Regulations*⁹ for all shipments leaving and coming to the facility.
111. The *Packaging and Transport of Nuclear Substances Regulations* apply to the packaging and transport of nuclear substances, including the design, production, use, inspection, maintenance and repair of packages, and the preparation, consigning, handling, loading, carriage and unloading of packages containing nuclear substances.
112. BTL informed the Commission that it had implemented a transport and packaging program that meets the requirements of the *Packaging and Transport of Nuclear Substances Regulations* and the IAEA document TS-R-1, and includes the following:
 - Sealed source manufacture of special form sealed source certified by the CNSC;
 - Manufacture, inspection, and maintenance of Type B(U) containers that have been certified by the CNSC;
 - Certification of radiation devices;
 - Transportation Security Plan; and
 - Procedures for shipment and receipt of radioactive material.

BTL added that there have been no releases of radioactive material resulting from a transport incident to date.

113. CNSC staff reported that BTL's packaging and transport program is effectively implemented and maintained. The transport of nuclear substances to and from the facility is done in a safe manner. CNSC staff has reviewed BTL's procedures

⁸ SOR/2000-208

⁹ SOR/2001-286

submitted as part of the licence application for radioactive shipments and is satisfied that the procedures ensure compliance with the regulations.

114. CNSC staff added that potential exposure to radiation during manipulation and shipment is conservatively assumed, for a hypothetical single driver responsible for all export shipments, to the annual effective dose of 0.58 mSv, which is 58% of the regulatory limit for general public (1 mSv/y).
115. The Commission enquired about the safety of transfer of radioactive sources between BTL and Nordion facilities. CNSC staff responded that, for a transfer from one facility to the other, both companies have to meet the requirement for packaging of that source and transport it to its destination. In addition to the inventory control, both companies are required to track the transfer of sources.
116. The Commission further enquired whether this transfer includes transport of sources on public roads. The BTL representative responded that the sources are properly packed and that this transfer takes place on the property shared between BTL and Nordion. CNSC staff added that it reviews transfer packages, and that both companies follow the procedure approved by CNSC staff.
117. The Commission asked about problems BTL might have with exported material regarding abandonment, lack of clear ownership, etc. The BTL representative explained their corporate responsibility to bring their sources back to Canada and under which conditions, taking into account that some of those sources are still in good condition and in use after 30 years. Besides these legacy issues, new cobalt sources are usually replaced every five to seven years, as part of a servicing contract, and brought back to the BTL facility. BTL representatives added that it is up to the regulatory authorities to require licensed users to provide financial means to return used sources. CNSC staff stated that the IAEA member states that have agreed to adhere to the Code of Conduct on the Safety and Security of Radioactive Sources¹⁰ (the Code) have to ensure that the regulatory authority of the importing state has an authorized end user that has in place a licence for a long-term management of the imported source. The Code is thus the instrument that is currently driving the international harmonization with respect to authorization of importation and exportation.
118. Based on the above information, the Commission is satisfied that BTL is meeting regulatory requirements regarding packaging and transport.

3.15 Aboriginal Engagement

119. The common law Duty to Consult with Aboriginal communities and organizations applies when the Crown contemplates actions that may adversely affect established or potential Aboriginal or treaty rights.

¹⁰ CODEOC/2004, International Atomic Energy Agency, Vienna, 2004.

120. BTL informed the Commission that Aboriginal groups with potential interests had been identified and contacted to participate in consultations relating to the Environmental Impact Statement (EIS). These groups had also been included in BTL's public outreach program. BTL added that none of the Aboriginal groups contacted had shown interest in the activities related to this licence application.
121. CNSC staff confirmed that the Algonquins of Ontario, Métis Nation of Ontario, Algonquins of Quebec and Union of Ontario Indians had been identified as potentially having an interest in this project. These First Nation and Métis groups were notified of the opportunity to participate in the environmental assessment and in the Commission's public hearing. The letter of notification and the draft EIS were also provided to Kitigan Zibi Anishinabeg First Nation and Eagle Village First Nation. The opportunity to participate in the EA included the review of the draft EA Report and the draft EIS. No comments have been received or issues raised regarding the EA or licence application.
122. Based on this information, the Commission acknowledges BTL's efforts made in relation to Aboriginal engagement.

3.16 Public Information

123. 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 Nuclear Facilities Regulations*¹¹ 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.*"
124. BTL informed the Commission that it had implemented a public information and disclosure program. BTL noted that the primary mechanism for distribution of information to the target audiences is through BTL's website. BTL intends to further improve its public information and disclosure program through an evaluation of the program at the senior management level. CNSC staff confirmed that it had reviewed BTL's public information program and found that it meets the requirements of RD/GD-99.3.
125. CNSC staff informed the Commission that the draft EA Report was made available for review and comment for a period of 32 days. The notice was posted on the CNSC website and the Canadian Environmental Assessment Registry (CEAR) and emailed to the CNSC subscription list. The draft EA Report was also made available at the Hazeldean public library and the CNSC Library. The South March Highlands – Carp River Conservation Incorporated, submitted comments on the draft EA Report. All comments and responses to the comments have been attached to the EA Report and

¹¹ SOR/2000-204

changes were made to the draft EA Report as appropriate.

126. Based on this information, the Commission is satisfied that BTL's public information program meets regulatory requirements.

3.17 Decommissioning Plans and Financial Guarantee

127. The Commission requires that the licensee has operational plans for decommissioning and long-term management of waste produced during the life-span of the facility. In order to ensure that adequate resources are available for a safe and secure future decommissioning of the BTL site, the Commission requires that an adequate financial guarantee (FG) for realization of the planned decommissioning activities is put in place and maintained in a form acceptable to the Commission throughout the licence period.
128. CNSC staff reported that it had reviewed BTL's Preliminary Decommissioning Plan (PDP) and found it to be satisfactory. The decommissioning cost was estimated at \$ 3.75 million. The decommissioning activities will involve removal of all radioactive material and hazardous material from the facility, including all sealed sources stored at the neighbouring Nordion facility located at 447 March Rd. CNSC staff concluded that the cost estimate of \$3.75 million was acceptable
129. CNSC staff further reported that BTL had proposed a surety bond as FG instrument, which is included in CNSC Regulatory Document G-206, *Financial Guarantees for the Decommissioning of Licensed Activities*. Surety bonds have not been proposed as a FG instrument so far. CNSC staff concluded that surety bonds could be acceptable to form part of a financial guarantee with the appropriate commitments and monitoring, such as reporting that the financial guarantee remains valid, in effect and adequate to fund the decommissioning of the facility. CNSC staff stated that the wording of the surety bond would be subjected to a legal review in order to minimize risk.
130. CNSC staff proposed a two-phase approach: a financial guarantee such as a letter of credit that would be an amount sufficient to place the facility in safe storage, and a remainder in the form of a surety bond. The proposed licence requires BTL to have a financial guarantee in place by January 31st, 2015. An update on the progress of the financial guarantee will be presented to the Commission in October 2014.
131. Based on this information, the Commission considers that the preliminary decommissioning plan is acceptable for the purpose of the current application for licence issuance. The Commission awaits the reporting of an update on the financial guarantee in October 2014. At that time the Commission will determine acceptability of the financial guarantee.

3.18 Cost Recovery

132. Class I licensees are subject to Part 2 of the provisions of the *Cost Recovery Fees Regulations*¹² under the terms of the regulatory activity plan fees.

3.19 Licence Length and Conditions

133. BTL requested the issuance of the operating licence for a period of 5 years. With this request, BTL asked for consolidation of three of its licences covering the company's operation at the site into a new Class 1B operating licence. BTL's licence authorizing the company to perform servicing activities at the premises of clients would not be included in the new Class 1B licence.
134. CNSC staff supported this request stating that BTL is qualified to carry on the licensed activities authorized by the licence.
135. CNSC staff recommends that the Commission endorse the delegation of authority to act as "a person authorized by the Commission" under the proposed licence, including approval of the commissioning and dismantling activities. The criteria for these approvals are listed in the LCH.
136. The Commission enquired about a transition time required for BTL to achieve full compliance with CNSC regulatory documents and requirements in all SCAs. CNSC staff responded that, while reviewing BTL's programs for different SCAs, it had been recognized that some areas could be enhanced or improved; however, the programs that BTL already has in place were acceptable from a safety point of view and meet CNSC requirements. CNSC staff added that it will ensure that all elements of these programs are improved and fully implemented.
137. The Commission asked CNSC staff to explain the licensing implications of constructing a cyclotron. CNSC staff responded that, since there is no radioactivity involved in construction, the construction itself does not require a licence. A Class 1 B facility licence is required for beam energies over 50 MeV. In this case, an appropriate shielding is required to protect workers when the cyclotron is in use. CNSC staff noted that another company in Canada manufactures cyclotrons and does not need a licence since there are no radioactive sources in them.
138. The Commission sought more information regarding activities that are not covered by the three licences to be consolidated. The BTL representative responded that the three licences to be consolidated cover activities at the Ottawa site. The satellite office, which is dealing with cyclotron design and does not use any radioactive devices, is not licensed. The fourth licence covering BTL's activities on the premises of their clients will remain as a standalone licence. The BTL representative added that the company is applying for a fifth licence for servicing of their gamma cells. CNSC staff explained that the licences that are not included in the consolidation are the licences that allow BTL to do work anywhere in Canada to service particular pieces of equipment that they

¹²Statutes of Regulations, S.O.R./2003-212.

had sold. The consolidated licence would cover only activities taking place at the BTL's Ottawa facility.

139. Based on the above information received during the course of this hearing, the Commission is satisfied that a five-year licence is appropriate. The Commission accepts the licence conditions as recommended by CNSC staff. The Commission also accepts CNSC staff's recommendation regarding the delegation of authority, and notes that it can bring any matter to the Commission as applicable.

4.0 CONCLUSION

140. The Commission has 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, as well as the oral and written submissions provided or made by the participants at the hearing.
141. The Commission is satisfied that the applicant meets the requirements of subsection 24(4) of the *Nuclear Safety and Control Act*. That is, the Commission is of the opinion that the applicant is qualified to carry on the activity that the proposed licence will authorize and that the applicant 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.
142. Therefore, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, issues to Best Theratronics Ltd. a Class 1B Nuclear Substance Processing Facility Operating Licence for its facility located in Ottawa, Ontario. The new licence, NSPFOL - 14.00/2019, is valid from July 1, 2014 to June 30, 2019.
143. The Commission includes in the licence the conditions as recommended by CNSC staff and set out in the draft licence attached to CMD 14-H3.
144. The Commission accepts CNSC staff's recommendations regarding operation and dismantling of Class I particle accelerator, as set out in the licence conditions 16.1 and 16.2 of the operating licence NSPFOL - 14.00/2019 and in the Licence Conditions Handbook (LCH).
145. The Commission accepts CNSC staff's recommendation regarding the delegation of authority in the LCH.
146. The Commission requests that BTL identifies and respect due dates for its commitments to close the gaps and implement its safety programs, as identified in CMD 14-H3 and set out in operating licence and LCH. An update to the Commission on this issue will be included in annual reports on the performance of BTL.

147. The Commission directs CNSC staff to provide at public proceedings of the Commission annual reports on the performance of BTL, as part of the Directorate of Nuclear Cycle and Facilities Regulation (DNCFR) annual safety performance reports.



Michael Binder

JUN 27 2014

Michael Binder
President,
Canadian Nuclear Safety Commission

Date