Record of Decision

DEC 25-H102

In the Matter of

Persons named in or subject to order

Best Theratronics Ltd.

Purpose Review of Designated Officer

Order 7396415, dated November 6, 2024

Date of

Commission's

review

January 23, 2025

Record of Decision Date

February 14, 2025

RECORD OF DECISION – DEC 25-H102

Persons named in or subject to order:

Best Theratronics Ltd.

Address/Location:

413 March Road, Kanata, Ontario, K2K 0E4

Purpose:

Review of Designated Officer Order 7396415,

dated November 6, 2024

Order issued:

November 6, 2024

Date of Commission's

review:

January 23, 2025

Hearing Location:

Virtual via MS Teams

Record of Decision Date:

February 14, 2025

Panel of Commission:

P. Tremblay, President

Registrar:

C. Salmon

Recording Secretary:

C. Moreau/M. Young

Senior General Counsel:

L. Thiele

Person Named in and Subject to the Order Represented By		Document Number
R. Stellick	Counsel	CMD 25-H102.1
CNSC staff		Document Number
L. Sigouin	Designated Officer Director General, Directorate of Nuclear Cycle and Facilities Regulation	CMD 25-H102

Designated Officer Order: Amended

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1.0 INTRODUCTION

1. Pursuant to paragraph 37(2)(f) of the <u>Nuclear Safety and Control Act</u>¹ (NSCA), a designated officer (DO) of the Canadian Nuclear Safety Commission² (CNSC) issued order 7396415³ ("the order"), to <u>Best Theratronics Ltd</u>. (Best Theratronics or "the licensee") on November 6, 2024. Best Theratronics is located in Ottawa, Ontario, and holds a Class IB nuclear substance processing facility operating licence, NSPFL-14.00/2029. Best Theratronics manufactures cyclotrons and medical equipment, including cobalt-60-based external beam radiation therapy units and cesium-137 self-contained irradiators for blood irradiation.

2. The order stipulates 3 actions, that:

- 1. Effective immediately, Best Theratronics Ltd. must not undertake the activities named in part IV (a)-(e) of licence NSPFL-14.00/2029, reproduced below, other than the possession and storage of nuclear substances and prescribed equipment. For clarity, this order does not impact Best Theratronics Ltd.'s authority to possess nuclear substances and prescribed equipment, or to possess and use prescribed information. Best Theratronics Ltd. must continue to maintain its inventory of nuclear substances and prescribed equipment in a safe and secure manner, in accordance with its licensing basis.
 - (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 source teletherapy machines;
 - (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;

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¹ Statutes of Canada (S.C.) 1997, c. 9.

² 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.

³ Order by a Designated Officer Under Paragraph 37(2)(f) and Subsection 35(2) of the *Nuclear Safety and Control Act*, issued November 6, 2024.

- 2. Best Theratronics Ltd. submit for Commission acceptance a financial guarantee that is in alignment with the Commission's <u>decision</u> on this matter from 2017⁴ and in accordance with <u>REGDOC-3.3.1</u>, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*.⁵
- 3. Best Theratronics Ltd. provide a plan, acceptable to the Designated Officer, that describes the measures it will take to ensure that resumption of operations can be done in a safe and secure manner, protective of the environment and the public.
- 3. The order is stated to remain in effect until all of the information required by the order has been provided, actions required by this order have been completed, and the DO is satisfied that Best Theratronics can operate in accordance and in compliance with the licence issued by the CNSC.
- 4. Pursuant to subsection 37(6) of the NSCA, the order was referred to the Commission for review. In accordance with the NSCA, upon review, the Commission must confirm, amend, revoke or replace the order. This *Record of Decision* describes the Commission's review of the order and the reasons for its decision in this matter.

Issue

5. In its review of the order, the Commission is required to confirm, amend, revoke or replace the order, pursuant to subsection 37(6) of the NSCA.

Review of Order and Opportunity to be Heard

6. Pursuant to section 22 of the NSCA, the President of the Commission established himself as a Panel of the Commission to review the order. Pursuant to paragraph 40(1)(d) of the NSCA, the Commission provided an opportunity to be heard in respect of the review of the order to Best Theratronics, as the entity that is subject to and named in the order. The Commission held a virtual oral hearing on January 23, 2025, via MS Teams. The Commission, in making its decision, considered the order and the information referred to in the order, as well as submissions from the CNSC DO (CMD 25-H102) and Best Theratronics (CMD 25-H102.1).

2.0 DECISION

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

the Commission, pursuant to subsection 37(6) of the *Nuclear Safety and Control Act*, amends designated officer order 7396415, issued to Best Theratronics Ltd. on November 6, 2024.

⁴ CNSC Record of Decision in the Matter of Best Theratronics Limited, "Amendment under Section 25 of the *Nuclear Safety and Control Act* and Request for Acceptance of the Financial Guarantee", July 14, 2017.

⁵ CNSC REGDOC-3.3.1, Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities, January 2021.

- 8. The Commission confirms conditions 1 and 3 of the order. The Commission amends the wording of the second condition of the order to clarify the language respecting what is required of Best Theratronics in terms of the financial guarantee. The full text of the amended order is as follows:
 - 1. Effective immediately, Best Theratronics Ltd. must not undertake the activities named in part IV (a)-(e) of licence NSPFL-14.00/2029, reproduced below, other than the possession and storage of nuclear substances and prescribed equipment. For clarity, this order does not impact Best Theratronics Ltd.'s authority to possess nuclear substances and prescribed equipment, or to possess and use prescribed information. Best Theratronics Ltd. must continue to maintain its inventory of nuclear substances and prescribed equipment in a safe and secure manner, in accordance with its licensing basis.
 - (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 source teletherapy machines;
 - (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;
 - 2. Best Theratronics Ltd. shall reestablish a financial guarantee acceptable to the Commission in the amount of \$1.8 million, and in accordance with REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*.
 - 3. Best Theratronics Ltd. provide a plan, acceptable to the Designated Officer, that describes the measures it will take to ensure that resumption of operations can be done in a safe and secure manner, protective of the environment and the public.
- 9. The Commission notes that it is also a condition of the licence held by Best Theratronics that it maintain the financial guarantee. Once Best Theratronics reestablishes its financial guarantee in accordance with the order, the Commission fully expects that under licence condition G.3 and its accompanying compliance verification criteria set out in the Licence Conditions Handbook (LCH), Best Theratronics will submit a revised Preliminary Decommissioning Plan (PDP) and decommissioning cost

estimate to the CNSC, and submit for Commission acceptance an updated financial guarantee, in accordance with REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*.

3.0 ISSUES AND COMMISSION FINDINGS

3.1 Circumstances Leading to the Making of the Order

- 10. The DO reported that, in 2014, the Commission issued Best Theratronics' Class IB licence with no financial guarantee in place; the financial guarantee was to be put in place by January 2015. The establishment of an acceptable financial guarantee ensures that there are sufficient funds available for decommissioning of the facility and the safe disposal of all high-risk sealed sources and licensed material. Best Theratronics failed to establish the financial guarantee, which led to an order being issued in 2015. Best Theratronics subsequently revised its PDP and proposed a financial guarantee of \$1.8 million.⁶
- 11. In July 2017, the Commission accepted Best Theratronics' financial guarantee of \$1.8 million in the form of two letters of credit, one for \$236,000 from BMO and one for \$1,564,000 from ICICI. In its 2019 decision⁷ to renew Best Theratronics' licence, the Commission noted that Best Theratronics was to submit an updated PDP to the CNSC in 2022, with an updated financial guarantee to be submitted to the Commission for acceptance.
- 12. Licence Condition G.3: Financial Guarantee of NSPFL-14.00/2029 requires that

The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.

Licence Conditions Handbook NSPFL-14.00/2029⁸, states that:

The financial guarantee for decommissioning the nuclear facility shall be reviewed and revised by the licensee every five years; when required by the Commission; or following a revision of the preliminary decommissioning plan that significantly impacts the financial guarantee. The next full review of financial guarantee is to take place in 2022.

And

The licensee shall submit annually to the Commission, a written report confirming that the financial guarantees for decommissioning costs remain valid and in effect and sufficient to meet the decommissioning needs. The licensee shall submit this report by the end of March of each year, or at any time as the Commission may request.

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⁶ Transcript, page 5.

⁷ CNSC Record of Decision in the Matter of Best Theratronics Limited, "Amendment under Section 25 of the *Nuclear Safety and Control Act* and Request for Acceptance of the Financial Guarantee", July 14, 2017.

⁸ Licence Conditions Handbook NSPFL-14.00/2029, Revision 0, October 11, 2019.

- 13. The DO submitted that, in October 2024, CNSC staff received confirmation from ICICI that the letter of credit for \$1,564,000 had expired in 2021. CNSC staff did not receive any notification from Best Theratronics regarding changes to its financial guarantee instruments. In section 1.1 of CMD 25-H102, the DO also reported that Best Theratronics had submitted neither an updated PDP, nor an updated financial guarantee, as required. The DO further submitted that Best Theratronics Ltd. had reported in 2022 and 2023 that the financial guarantee of \$1.8 million was active and in place. Best Theratronics had therefore failed to meet the requirements of licence condition G.3. The failure by Best Theratronics to meet the requirement in its licence to maintain an acceptable financial guarantee in order to decommission and provide safe disposal of high-risk sealed sources and licensed material is of significant concern.
- 14. On November 6, 2024, the CNSC DO issued the order.

3.2 Actions and Measures of the Order

15. The order stipulates 3 actions, set out in paragraph 2 of this *Record of Decision*. The order is stated to remain in effect until all of the information required by the order has been provided, actions required by this order have been completed, and the DO is satisfied that Best Theratronics can operate in accordance and in compliance with the licence issued by the CNSC.

3.3 Actions since the Making of the Order

16. The DO reported that, to the best of the CNSC's knowledge, Best Theratronics had not made any progress in reestablishing its financial guarantee since the order was made.⁹

3.4 Opportunity to be Heard

- 17. Best Theratronics filed a written submission (CMD 25-H102.1) in exercise of its opportunity to be heard in regard to the review of the order. Best Theratronics submitted that:
 - Best Theratronics is of the view that the financial guarantee accepted in 2017 was excessive to serve the purposes of the REGDOC-3.3.1, and that the remaining guarantee currently in place was sufficient to achieve that result
 - Best Theratronics recognizes that it is not in compliance with its licence, and is required to update its PDP, including decommissioning cost estimates
 - the restrictions under condition 1 of the order would significantly and unduly impact its business
 - the restriction with respect to the transfer of Best Theratronics' products is punitive, as it is not directly connected to the concerns identified in the order, and would not affect the safety of the facility

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⁹ Transcript, page 7.

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- 18. In its submission, Best Theratronics requested that the Commission amend the order. The proposed amendments would:
 - 1. remove the restrictions on its operations in condition 1 of the order, at the very least to allow Best Theratronics to continue to transfer its products
 - 2. require Best Theratronics to submit for Commission acceptance a financial guarantee that is in alignment with the requirements prescribed in REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*. This guarantee would be in the amount of \$1,564,000 (in addition to BTL's already existing guarantee from BMO) or an amount sufficient to meet BTL's obligations under REGDOC-3.3.1, as established by the Commission on review.
- 19. During the hearing, the representative for the licensee noted that Best Theratronics had been communicating with CNSC staff in July 2024 regarding Best Theratronics' position that the 2017 financial guarantee was excessive. ¹⁰ The Best Theratronics representative added that, restrictions to Best Theratronics' operations could affect its ability to secure financing for the financial guarantee. ¹¹
- 20. In response to the points raised by Best Theratronics, the DO agreed that CNSC staff had had ongoing communication with Best Theratronics in the summer of 2024 concerning the status of Best Theratronics' required review of the PDP and financial guarantee. With respect to the impact of the order on Best Theratronics' operations, the DO noted that Best Theratronics' ability to carry out licensed activities was already limited due to an ongoing work disruption. 12
- 21. With respect to the proposed amendment to the order, the DO submitted that there is a process in place for licensees to request a review of the financial guarantee amount, and that Best Theratronics had not followed this process. ¹³ The DO further submitted that, based on CNSC inspectors' observations of Best Theratronics' current inventory of radioactive sources, it would not be unexpected if the resulting review of the PDP would lead to a higher financial guarantee being required. ¹⁴
- 22. To the points raised by the DO, the Best Theratronics representative submitted that Best Theratronics was working to resolve the labour disruption, and that Best Theratronics was seeking to revise its PDP and financial guarantee for Commission acceptance. The Best Theratronics representative stated that Best Theratronics "wants the opportunity to present a revised preliminary decommissioning plan and to have the financial guarantee be tethered to that revised plan."¹⁵
- 23. Asked about the status of the labour disruption, the Best Theratronics representative reported that work at Best Theratronics was limited, as two groups of unionized workers were on strike, and that Best Theratronics was pursuing its legal options to resolve the disruption.

¹⁰ Transcript, page 10.

¹¹ Transcript, page 13.

¹² Transcript, page 15.

¹³ Ibid.

¹⁴ Transcript, page 15-16.

¹⁵ Transcript, page 17.

- 24. The Commission asked whether Best Theratronics contested the facts leading to the making of the order. The Best Theratronics representative responded that Best Theratronics did not. The Best Theratronics representative added that the expiry of the ICICI letter of credit had been unexpected, and that Best Theratronics had been unable to reinstate it with ICICI. The Best Theratronics representative acknowledged that Best Theratronics had reported in 2022 and 2023 that the financial guarantee was in place, when in fact it was not. The section of the place o
- 25. The Commission asked why Best Theratronics had not followed the CNSC process to review and update financial guarantees, particularly if Best Theratronics was of the view that the value accepted in 2017 was too high. The Best Theratronics representative acknowledged that Best Theratronics should have followed this process but could not explain why it had not. The DO expressed the view that once the licensee had reinstated its existing financial guarantee obligation under the order, it could undertake the formal review process in parallel. 19
- 26. The Commission asked about CNSC staff's regulatory oversight of Best Theratronics' PDP and financial guarantee. The DO responded that CNSC staff was aware that Best Theratronics had not submitted a PDP in 2022 as required, and that it had been having ongoing communications with Best Theratronics on this matter. The DO noted that the review of the PDP was considered to be a lower risk matter, since Best Theratronics had reported that the financial guarantee remained in place. CNSC staff acknowledged that it was not aware that the ICICI letter of credit had a clause that would allow it to expire without the CNSC's awareness. The DO reiterated that the issue remains that Best Theratronics is not in compliance with its licence, and that the order was issued to ensure that Best Theratronics returns to compliance.²⁰

3.5 Commission Findings

27. Based on the information submitted on record and summarized above, the Commission finds that Best Theratronics is in non-compliance with condition G.3 of its licence. From the hearing conducted to review the order, the Commission also heard evidence of inaccurate reporting by Best Theratronics regarding the validity of its financial guarantee and a failure on the part of the licensee to follow up on the review and updating of its decommissioning plans and costing, something it now says it wishes to do. The Commission underscores the seriousness of these matters. As indicated in the order, the purpose of the financial guarantee is to provide for the safe disposal of high-risk sealed sources and licensed material, and this requirement cannot be taken lightly.

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¹⁶ Transcript, page 20.

¹⁷ Transcript, page 21.

¹⁸ Transcript, page 22.

¹⁹ Transcript, page 23.

²⁰ Transcript, pages 25-26.

- 28. The Commission notes that Best Theratronics did not contest the facts leading to the order, nor has it requested that the order be revoked. The Commission therefore considered whether to confirm or amend the order, pursuant to subsection 37(6) of the NSCA. As further described below, the Commission:
 - confirms action 1 of the order
 - amends action 2 of the order
 - confirms action 3 of the order

Action 1

- 29. The Commission considered Best Theratronics' request to amend the first action of the order, to allow it to conduct certain operational activities, in a limited capacity, without an adequate financial guarantee in place. The Commission was provided with no persuasive rationale on which to accede to this request and finds the DO's reasoning for this restriction on operation, given the importance to overall safety of having an acceptable financial guarantee in place, to be sound.
- 30. The Commission does not accept Best Theratronics' position that the restriction to its licensed activities is unreasonably punitive. It is not punitive at all. Best Theratronics has violated condition G.3 of its licence, failed to update its PDP and financial guarantee as required, and its reports to the CNSC regarding the validity of its existing financial guarantee have been at the least, inaccurate. There is an established process in place for a licensee to have its financial guarantee reviewed, and Best Theratronics failed to follow that process. Best Theratronics' view that its financial guarantee amount was too high does not excuse it from its obligation under its licence.
- 31. Therefore, the Commission confirms action 1 of the order. The Commission emphasizes that Best Theratronics is not authorized to conduct operational activities. As indicated in the order, Best Theratronics must continue to maintain its inventory of nuclear substances and prescribed equipment in a safe and secure manner.

Action 2

32. The Commission considered Best Theratronics' request that the Commission amend the second action of the order, which requires that Best Theratronics submit for Commission acceptance a financial guarantee "that is in alignment with the Commission's decision on this matter from 2017 and in accordance with REGDOC-3.3.1, Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities." Best Theratronics proposed an amendment that would require Best Theratronics to submit a financial guarantee for Commission acceptance "in the amount of \$1,564,000 (in addition to BTL's already existing guarantee from BMO) or an amount sufficient to meet BTL's obligations under REGDOC-3.3.1, as established by the Commission on review."

- 33. The Commission understands that action 2 is intended to require Best Theratronics to reestablish the financial guarantee that it is required to maintain under its licence. The Commission finds Best Theratronics' position that it is now seeking to follow the required process to update its financial guarantee to be somewhat disingenuous. Best Theratronics has failed to meet this requirement since 2022. The Commission is of the view that Best Theratronics has had ample opportunity to follow the required process and can still do so. To be clear: BTL's obligations are under the licence and until the revision and review process under licence condition G.3 is done, it is the \$1.8 million amount, in some form that accords with REGDOC-3.3.1, that is required.
- 34. In light of the above, the Commission amends the second action of the order just to clarify the language of the requirement. The amended action 2 is as follows:

Best Theratronics Ltd. shall reestablish a financial guarantee acceptable to the Commission in the amount of \$1.8 million, and in accordance with REGDOC-3.3.1, Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities.

- 35. As Best Theratronics currently has the BMO letter of credit in place, the Commission expects Best Theratronics to submit, for Commission acceptance, a financial guarantee instrument in the amount of \$1,564,000, to replace the expired ICICI letter of credit. REGDOC-3.3.1 includes a list of acceptable financial guarantee instruments, as well as the CNSC's financial guarantee acceptance criteria.
- 36. Once Best Theratronics reestablishes its financial guarantee in accordance with the order, the Commission expects that, under its licence, Best Theratronics will submit a revised PDP and decommissioning cost estimate to the CNSC, and submit for Commission acceptance an updated financial guarantee, in accordance with REGDOC-3.3.1.

Action 3

37. The Commission agrees with action 3 of the order, which requires that Best Theratronics provide a plan, acceptable to the DO, that describes the measures it will take to ensure that resumption of operations can be done in a safe and secure manner, protective of the environment and the public. Best Theratronics did not propose amending this condition. Therefore, the Commission confirms action 3 of the order.

4.0 CONCLUSION

38. The Commission has considered the information in the order issued to Best Theratronics and the information submitted by the DO, and Best Theratronics. Pursuant to subsection 37(6) of the NSCA, the Commission amends designated officer order 7396415, issued to Best Theratronics on November 6, 2024, in the manner described in this *Record of Decision*.

39. The Commission emphasizes the regulatory concern with Best Theratronics' attention to, and performance with respect to, its financial guarantee. The recent failure to maintain a financial guarantee, the inaccurate reports to the CNSC regarding the validity of its existing financial guarantee, and inattention to the periodic review of its PDP and financial guarantee are significant matters. Given Best Theratronics' compliance history respecting financial guarantees, the Commission expects that CNSC staff will focus regulatory scrutiny on verifying Best Theratronics' compliance with requirements under licence condition G.3.



Pierre F. Tremblay President, Canadian Nuclear Safety Commission February 14, 2025

Date