Record of Decision

DEC 25-H108

In the Matter of

Licensee Subject to Decision

2352767 Ontario Inc.

Purpose

Review of Designated Officer Order 7476217 and Recommendation for Licence Revocation under Section 25 of the *Nuclear Safety and Control Act*

Date of Hearing

April 8, 2025

Summary Record of Decision Date April 11, 2025

Detailed Record of Decision Date

June 20, 2025

RECORD OF DECISION – DEC 25-H108

Licensee Subject to Decision: 2352767 Ontario Inc.

Address/Location: 250 Marlee Avenue, North York, Ontario, M6B 3H7

Purpose: Review of Designated Officer Order 7476217 and

Consideration of Recommendation for Licence Revocation under Section 25 of the *Nuclear Safety*

and Control Act

Order Issued: March 20, 2025

Date of Receipt of Licence

Revocation Recommendation:

March 21, 2025

Date of Commission's Review: April 8, 2025

Hearing Location: Virtual via MS Teams

Date of Decision: June 20, 2025

Panel of Commission: P. Tremblay, President

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Designated Officer Order: Replaced Licence: Not Revoked

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1.0 INTRODUCTION

- 1. 2352767 Ontario Inc., operating as North York Diagnostic and Cardiac Centre (the licensee), holds Canadian Nuclear Safety Commission¹ (CNSC) nuclear substances and radiation devices licence no. 15033-1-25.0. This licence allows the licensee to perform diagnostic nuclear medicine procedures and is valid until June 30, 2025.
- 2. The licensee is located at 250 Marlee Avenue in North York, Ontario. This is on Treaty 13 territory and the traditional territory of many nations, including the Mississaugas, the Anishnabeg, the Chippewa, the Haudenosaunee and the Wendat peoples, and is now home to many diverse First Nations, Inuit and Métis peoples.
- 3. On March 20, 2025, a CNSC Designated Officer (DO) issued an Order² to the licensee under subsection 35(1) and paragraph 37(2)(f) of the Nuclear Safety and Control Act (NSCA).³ The Order requires the licensee to complete the following three actions:
 - a) transfer all nuclear substances and radiation devices in its possession to one or more licensees who are authorized to possess the nuclear substances by April 14, 2025
 - b) decommission the nuclear medicine rooms located at 250 Marlee Avenue in North York Ontario in accordance with licence condition 2571-6 (Decommissioning), as specified on licence no. 15033-1-25.0
 - c) provide transfer records for the nuclear substances and radiation devices and documented evidence that decommissioning has been completed to the CNSC by April 17, 2025
- 4. Pursuant to subsection 37(6) of the NSCA, the DO referred the Order to the Commission for review to confirm, amend, revoke or replace the Order.
- 5. In addition, CNSC staff recommended to the Commission on March 21, 2025, that it revoke licence no. 15033-1-25.0 on its own motion under section 25 of the NSCA and paragraphs 8(2)(a) and (c) of the <u>General Nuclear Safety and Control Regulations</u> (GNSCR).^{4,5}
- 6. On April 11, 2025, the Commission issued a *Summary Record of Decision* declining to revoke licence no. 15033-1-25.0. Additionally, it issued a Commission Order⁶ replacing the DO Order. As a result, the licence remains valid until June 30, 2025.⁷ This *Detailed Record of Decision* provides the reasons for that decision.

⁵ CNSC staff submission, CMD 25-H108.

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 ORDER BY A DESIGNATED OFFICER UNDER PARAGRAPH 37(2)(F) OF THE NUCLEAR SAFETY AND CONTROL ACT, March 20, 2025 (CNSC e-Doc 7476217).

³ S.C. 1997, c. 9.

⁴ SOR/2000-202.

⁶ Commission order 25-01, *ORDER BY THE CANADIAN NUCLEAR SAFETY COMMISSION UNDER SUBSECTION 37(6) OF THE NUCLEAR SAFETY AND CONTROL ACT REPLACING AN ORDER BY A DESIGNATED OFFICER*, April 11, 2025 (CNSC Document ID DAMZHJW66V33-166150894-870).

⁷ Summary Record of Decision DEC 25-H108, *Review of Designated Officer Order 7476217 and Licence Revocation under Section 25 of the Nuclear Safety and Control Act*, April 11, 2025 (CNSC Document ID DAMZHJW66V33-166150894-871).

2.0 DECISIONS

- 7. As part of its decision, the Commission considered the DO Order and the information referred to in the Order, as well as submissions from CNSC staff (CMD 25-H108) and from the licensee (CMD 25-H108.1).
- 8. For the reasons described below, the Commission:
 - replaces the DO Order issued to 2352767 Ontario Inc. on March 20, 2025, with Commission Order 25-01,8 and
 - is not revoking licence no. 15033-1-25.0 issued to 2352767 Ontario Inc. 9
- 9. As a result, the licence remains in place.
- 10. Pursuant to section 41 of the NSCA, the licensee shall comply with the Commission Order.
- 11. With its decision, the Commission directed CNSC staff to inspect 2352767 Ontario Inc. in May 2025 to verify:
 - a) whether the licensee has complied with Commission Order 25-01
 - b) whether the licensee has implemented the commitments made in its submissions to the Commission, including with respect to training and the duties of the Applicant Authority and the Radiation Safety Officer
 - c) that measures are in place to protect the health and safety of persons and the environment

3.0 ISSUES

- 12. The Commission must review the DO Order and determine whether to confirm, amend, revoke or replace it.¹⁰ In reviewing the DO Order, the Commission assesses the reasonableness of the actions and measures set out in the order, and whether they are necessary to protect the environment or the health or safety of persons or to maintain national security or compliance with international obligations to which Canada has agreed.
- 13. In addition, the Commission may, on its own motion, renew, suspend in whole or in part, amend, revoke or replace a licence under the prescribed conditions. Subsection 8(2) of the GNSCR provides the conditions under which the Commission may exercise these powers.

⁸ See subsection 37(6) of the NSCA.

⁹ See section 25 of the NSCA.

¹⁰ See subsection 37(6) of the NSCA.

¹¹ See section 25 of the NSCA.

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4.0 COMMISSION PROCEDURES

- 14. Pursuant to section 22 of the NSCA, the President of the Commission established himself as a Panel of the Commission to review the DO Order, and to consider the recommendation for licence revocation. The Commission held a virtual oral hearing on April 8, 2025, via MS Teams.
- 15. Pursuant to paragraph 40(1)(d) of the NSCA, the Commission provided the licensee an opportunity to be heard in respect to the review of the DO Order. In addition, pursuant to paragraph 40(1)(b) of the NSCA, the Commission provided the licensee an opportunity to be heard before considering the potential revocation of its licence under section 25 of the NSCA.¹²
- 16. Both opportunities to be heard were provided in accordance with part 3 of the *Canadian Nuclear Safety Commission Rules of Procedure*¹³ (the *Rules*). The licensee exercised its right to be heard on both issues and made submissions on both issues as part of the hearing.

5.0 COMMISSION FINDINGS

- 17. In reviewing the DO Order, the Commission considered the actions and measures identified in the Order and the information on which the Order was based, as identified in the Order and the submission from CNSC staff, as well as the actions taken by the licensee since the making of the order.
- 18. In considering whether to revoke licence no. 15033-1-25.0 issued to 2352767 Ontario Inc., the Commission considered the applicability of the conditions set out in subsection 8(2) of the GNSCR.

5.1 Circumstances leading to the making of the Designated Officer Order and the recommendation for licence revocation

- 19. CNSC staff submitted that the licensee failed to do the following:¹⁴
 - demonstrate proper management and management oversight of its Radiation Protection Program¹⁵
 - fulfill the licence condition requiring an updated Radiation Safety Manual by September 30, 2024
 - provide timely and acceptable corrective actions addressing non-compliances identified during an inspection performed on September 20, 2024

¹⁴ See section 3 of CMD 25-H108.

¹² Part 3 of the Rules applies in the case of an Opportunity to be Heard by the Commission.

¹³ SOR/2000-211.

¹⁵ CNSC staff submitted that the licensee's Applicant Authority and Radiation Safety Officer failed to meet the CNSC's expectations for these roles as presented in the CNSC regulatory documents <u>REGDOC-1.6.1, Licence Application Guide</u>: <u>Nuclear Substances and Radiation Devices</u> (May 2017) and <u>REGDOC-1.6.2, Radiation Protection Programs for Nuclear Substances and Radiation Devices Licences</u> (August 2021).

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- 20. CNSC staff also submitted detailed circumstances leading to the making of the DO Order and the recommendation to revoke the licence, including the following:¹⁶
 - deficiencies that CNSC staff identified in the Radiation Safety Manual in June 2024
 - non-compliances identified during the CNSC's inspection in September 2024
 - the licensee's failure to address these deficiencies and non-compliances in a timely way
 - the licensee's lack of involvement in key aspects of managing the Radiation Protection Program
 - the licensee's lack of responsiveness to communications from the CNSC
- 21. In section 2.2 of CMD 25-H108, CNSC staff submitted that the licensee had paid and met the financial guarantee requirement for fiscal year 2024-25. In section 2.3 of CMD 25-H108, CNSC staff submitted its opinion that revoking the licence would not affect the availability of diagnostic nuclear medicine procedures as there are many licensees authorized to perform such procedures in the Greater Toronto Area. Is
- 22. Based on the information available at the time, the Commission is satisfied that the DO had sufficient evidence and a reasonable basis for issuing an Order to protect the health and safety of persons and the environment and to maintain the security of nuclear substances.

5.2 After the DO made the Order, the licensee took actions to improve regulatory compliance

- 23. CNSC staff submitted that, at the time of writing CMD 25-H108, the licensee had not submitted a satisfactory Radiation Safety Manual or corrective actions addressing non-compliances identified during the inspection on September 20, 2024.
- 24. On April 4, 2025, the licensee filed a written submission as part of its opportunity to be heard in the two matters.¹⁹ In its submission, the licensee listed efforts made to improve regulatory compliance, including the following:²⁰
 - the appointment of a new radiation safety team from February 2025 to April 2025, including a new Applicant Authority, a new Radiation Safety Officer, and an Alternate Radiation Safety Officer

¹⁷ Subsection 24(5) of the NSCA, paragraph 3(1)(l) of the GNSCR, and CNSC regulatory document REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities* (January 2021) require a licensee to provide a financial guarantee, to cover costs incurred by the CNSC in providing safe termination of licensed activities, in case of licensee default due to financial impairment or regulatory actions.

¹⁶ See the DO Order and section 1.3 of CMD 25-H108.

¹⁸ Section 1 of the <u>Directive to the Canadian Nuclear Safety Commission Regarding the Health of Canadians</u> requires the CNSC, in regulating the production, possession and use of nuclear substances in order to prevent unreasonable risk to the health of persons, to take into account the health of Canadians who, for medical purposes, depend on nuclear substances produced by nuclear reactors.

¹⁹ See CMD 25-H108.1.

²⁰ CMD 25-108.1, pages 11 to 12, para. 28 to 33.

- the appointment of a consultant to assist with resolving non-compliances
- the hiring of an experienced consultant to help bring the licensee into regulatory compliance²¹
- the April 3, 2025, revision of the Radiation Safety Manual²² intended to address all previously identified deficiencies.

5.3 Opportunities to be heard

- 25. During the hearing, the licensee asked the Commission to revoke the DO Order and to renew its licence. Specifically, the licensee submitted that "[t]here has never been any risk of harm to the public or to anyone else, all of the CNSC's concerns have been remedied or are in the process of being addressed, and there is new management at the clinic which engages in ongoing oversight by several highly credentialled and eminently-qualified individual[s]."²³
- 26. The licensee submitted the following:
 - reasons for non-compliance included the neglect and failure of the former Radiation Safety Officer who was no longer employed by the licensee, and the impacts of a July 2024 flood²⁴
 - there would be significant impacts to patient care and public hospital resources should the licence be revoked²⁵
 - the satisfactory compliance results from Accreditation Canada's inspection in January 2025 and February 2025²⁶
- 27. In addition, the licensee submitted its plan to achieve full compliance and to ensure future compliance,²⁷ which included:
 - staff training programs and training records
 - planned inspections by the consultant in the upcoming year (monthly inspections from May 2025 to October 2025, quarterly inspections from November 2025 to April 2026)
 - activities of the Radiation Safety Officer including quarterly internal inspections similar to a CNSC Type II inspection, quarterly reports to all nuclear energy workers to emphasize the As Low as Reasonably Achievable (ALARA) principle, and weekly verifications of proper recordkeeping

²¹ CMD 25-108.1, pages 226 to 230.

²² CMD 25-108.1, pages 61 to 163.

²³ CMD 25-108.1, page 17, para. 39 and 42.

²⁴ CMD 25-108.1, pages 10 to 11, para. 20 to 27.

²⁵ CMD 25-108.1, pages 17 to 19, para. 43 to 51.

²⁶ CMD 25-108.1, pages 57 to 59, *Post-Inspection Report of Accreditation Canada*, March 7, 2025. Note: Accreditation Canada is the inspecting body for oversight of quality and patient safety standards in Ontario pursuant to the *Integrated Community Health Services Centre Act*, 2023.

²⁷ CMD 25-108.1, pages 13 to 16, para. 34.

- timely responses to all CNSC communications by either the Radiation Safety Officer or the Applicant Authority
- 28. During the hearing, CNSC staff reported on its findings during the past year, along with the reasons for making the DO Order and the licence revocation recommendation. Regarding the licensee's submission of April 4, 2025, CNSC staff acknowledged the licensee's efforts and confirmed that it is taking steps in the right direction. CNSC staff noted that, based on its preliminary review, the updated Radiation Safety Manual still did not meet all regulatory requirements.²⁸
- 29. CNSC staff noted that it is rare for it to recommend licence revocation in the nuclear medicine sector, and that the DO Order and the recommendation for licence revocation were results of escalated enforcement actions that reflect the seriousness of CNSC staff's concerns. CNSC staff reaffirmed its position that any potential impact on the health of Canadians is outweighed by the unreasonable risks to health and safety posed by an unqualified licensee conducting licensed activities.²⁹
- 30. The Commission asked about CNSC staff's regulatory oversight efforts with respect to the licensee. CNSC staff reported that it had spent considerable additional effort reviewing the multiple revisions of the Radiation Safety Manual and conducting compliance inspections. This additional effort triggered the application of a compliance coefficient³⁰ to the licensee's fee formula that started in October 2024.³¹
- 31. CNSC staff explained that the remaining deficiencies in the Radiation Safety Manual included the type of dosimeter technology being used, refresher training, and expectations for pregnant nuclear energy workers. CNSC staff noted that if this were a new application, it would not recommend issuing a licence based on the revised Radiation Safety Manual.³² The licensee's consultant characterized these deficiencies as largely administrative in nature.³³
- 32. In response to a question from the Commission, CNSC staff said that it had not had the same level of concern with the licensee's performance prior to 2024.³⁴ The licensee's Applicant Authority explained that they were one of the six co-owners and directors of the clinic. They found that the period of performance decline aligned with the transition in January 2024 from one Radiation Safety Officer to another.
- 33. While the Applicant Authority had recently assumed the role and was not previously involved in the management or oversight of the Radiation Protection Program, the Applicant Authority acknowledged the errors made by the licensee, emphasized the considerable efforts that were recently made, and repeated their responsibility and

²⁸ Transcript, April 8, 2025, pages 4 to 10, 94 to 96.

²⁹ Transcript, April 8, 2025, pages 4 to 10, 94 to 96.

³⁰ The compliance coefficient is a tool under the <u>Canadian Nuclear Safety Commission Cost Recovery Fees</u>
<u>Regulations</u> that reflects the additional number of hours of direct regulatory activities spent by the CNSC as a result of non-compliance by a licensee with regulatory requirements.

³¹ Transcript, April 8, 2025, pages 67 to 73.

³² Transcript, April 8, 2025, pages 70 to 72.

³³ Transcript, April 8, 2025, pages 78 to 83.

³⁴ Transcript, April 8, 2025, pages 76 to 78.

- commitment to ensuring regulatory compliance, with full support from the rest of the owners and directors.³⁵
- 34. As part of the hearing, CNSC staff confirmed that the next part of the regulatory process, provided there are no issues with the licensee's operations in the meantime, would be for the licensee to apply to renew its licence before it expires in June 2025.³⁶

5.4 The Commission is replacing the DO Order and maintaining the validity of the licence

- 35. The Commission agrees with CNSC staff's findings as detailed in section 5.1 above and finds that CNSC staff took appropriate steps to escalate this matter.
- 36. The Commission finds that, since the issuance of the DO Order, the licensee has taken concrete steps to return to regulatory compliance. The Commission is also satisfied that the licensee has an adequate plan to address the remaining issues. The Commission is of the view that, having taken these steps, the licensee no longer poses a current unreasonable risk to the health and safety of persons and the environment. The Commission notes, however, that more serious risks could arise if the outstanding issues remain unaddressed.
- 37. In order to prevent unreasonable risks to the health and safety of persons and the environment, the Commission replaces the DO Order dated March 20, 2025, with Commission Order 25-01.³⁷
- 38. The Commission Order requires the licensee to address all identified issues by the deadlines outlined in the Order, and to do so before the next licence renewal. In addition, the Commission directs CNSC staff to inspect the licensee in May 2025 to verify compliance and performance, as set out in paragraph 11.
- 39. The Commission has also decided not to revoke licence no. 15033-1-25.0 on its own motion. Rather, the licence shall remain valid until its expiry date. The Commission notes that it will not renew the licence, as requested by the licensee; rather, that decision will be subject to the CNSC's renewal process for this type of licence.
- 40. In reaching its decision, the Commission considered the conditions under subsection 8(2) of the GNSCR, the licensee's progress and plan to achieve full regulatory compliance, the impending expiration of licence no. 15033-1-25.0 on June 30, 2025, the licensee's compliance record prior to 2024 and its provision of a financial guarantee for fiscal year 2024-25. The Commission also notes the balance between risks to the health and safety of persons and the environment and impacts to the health of Canadians.³⁸

³⁵ Transcript, April 8, 2025, pages 83 to 94.

³⁶ Transcript, April 8, 2025, pages 94 to 95.

³⁷ Subsection 37(6) of the NSCA.

³⁸ SOR/2007-282.

6.0 CONCLUSION

- 41. Based on all the evidence and submissions presented on the record in regard to the opportunities to be heard, the Commission replaces the DO Order dated March 20, 2025, with Commission Order 25-01. Commission Order 25-01 requires the licensee to address all identified issues.
- 42. In addition, the Commission is not revoking licence no. 15033-1-25.0 issued to 2352767 Ontario Inc.



Pierre F. Tremblay President Canadian Nuclear Safety Commission June 20, 2025 Date