



25-H100.B - CNSC Staff Submission

Commission Request for Information Regarding a Hearing in Writing

Classification	UNCLASSIFIED
Type of CMD	Original
CMD Number	25-H100.B
Reference CMD(s)	CMD 25-H100.Q, 25-H100, 25-H100-A
Hearing in Writing OR Closed Hearing in Writing date	Spring 2025
Word e-Doc #	7493813
PDF e-Doc #	7493824
Summary	<p>In this CMD, CNSC staff will provide responses in writing to questions from the Commission (25-H100-Q) [1] with respect to the hearing in writing (CMD 25-H100) [2] concerning the request from OPG to amend the Darlington Nuclear Generating Station power reactor operating licence to allow production of additional medical isotopes.</p> <p>As part of a Commission proceeding, this document – including any items mentioned in the footnotes – will be part of the public record unless the Commission rules in favour of a request for confidentiality.</p>
Actions required	There are no actions requested of the Commission. This CMD is for information only.

Questions from the Commission directed to CNSC staff, as well as staff responses, can be found in the [Staff Response](#) section.



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

Canada

CMD 25-H100.B

CNSC Response to Commission Request for Information

Signed by:

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Eric Lemoine,

Acting Director General, Directorate of Power Reactor Regulation



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Staff Response

The Commission's questions, including any quoted text from the original CMD, have been reproduced below in the shaded boxes to provide suitable context for CNSC staff's responses.

#1	Provide CNSC staff's perspective in response to the request from the Mississaugas of Scugog Island First Nation regarding removal of the proposed regulatory hold point.
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In their intervention [3], Mississaugas of Scugog Island First Nation (MSIFN) requested to be "involved by CNSC staff in the review and verification of the Regulatory Holdpoints (RHPs) prior to the CNSC removing the RHPs before declaring the new isotope production available for service (AFS)".

CNSC staff meet regularly with MSIFN representatives as part of the Terms of Reference (ToR) for long-term engagement with the CNSC. During a meeting on March 28th, 2025 CNSC staff discussed this request with MSIFN representatives and asked for clarity on MSIFN's request. During the meeting, CNSC staff explained the process of establishing, verifying and releasing RHPs for this type of project, and offered to have follow-up discussions if desired. CNSC staff noted that, ultimately, the Commission will decide whether staff's proposed RHPs for the project will be established and whether CNSC staff will be authorized to verify that the RHP prerequisites have been met.

The agreed upon path forward from the meeting was that CNSC staff will share with MSIFN the RHP Removal Recommendation Report once it is finalized [4]. This report outlines the completion of the established prerequisites for RHP removal. This would help MSIFN gain a clearer understanding of the RHP process, familiarize themselves with its procedures, and provide an opportunity to engage in discussions about their potential involvement moving forward, if desired.

CNSC staff note that the documentation that will be provided by OPG to support the removal of the RHP may include confidential technical information. CNSC staff are not at liberty to disclose or discuss this confidential information with third parties, including MSIFN, without OPG's consent. While CNSC staff can discuss their review at a high level as well as provide documentation supporting the overall conclusions, some information in the documentation supporting RHP removal (such as CNSC staff's recommendation report) may have to be redacted.

CNSC staff also recommend that OPG continue to engage with MSFIN and other Indigenous Nations and communities in relation to the project, including RHP removal requests as well as sharing any technical details, where appropriate, which may be of interest to MSIFN in relation to the RHP. This is consistent with the intent of the proposed Licence Condition in CNSC staff [CMD 25-H2](#) [5] (for relicensing of the

Darlington Station) specific to Indigenous Engagement, which would encourage OPG to proactively share information with Indigenous Nations and communities.

#2	Explain how CNSC staff would inform Indigenous Nations and communities and the public about the release of the regulatory hold point proposed by staff?
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CNSC communicates publicly using several methods regarding each Regulatory Holdpoint (RHP) to ensure the public is aware of:

- the status of the project,
- the role of CNSC staff in verifying that all prerequisites established by the Commission have been met before recommending the RHP be lifted, permitting Licensees to proceed to the next step in the project

Timeliness is important and public communications are coordinated to follow shortly after the licensee is informed of the removal of the RHP.

Communications methods include:

- Posts on CNSC's social media including X, LinkedIn and Facebook, linking to the letter sent from CNSC to the licensee regarding the removal of the RHP
- CNSC Website updates including:
 - Facility page [Darlington Nuclear Generating Station, Ontario](#) update under Commission proceedings with a link to the letter
 - Posting the CNSC's letter to the licensee releasing the RHP on the website
- Email to subscribers including details about the RHP and site, plus a link to the letter.

As part of the CNSC's tailored engagement approach, CNSC staff would inform Indigenous Nations and communities when the RHP is removed, if requested. To ensure meaningful engagement, CNSC staff adapt their approach to each Nation's specific needs, leveraging existing relationships and sharing information as requested or as outlined in the Terms of Reference (ToR) for long-term engagement. With the recent emergence of interest in the removal of RHPs, CNSC staff remain flexible in addressing evolving needs and communication preferences. Communication methods may include written notifications, phone calls, e-mails, and meetings, either upon request or on a recurring basis.

#3	What is the status of the open inspection finding against OPG concerning the oversight of contractors and the use of Laurentis Energy Partners as a contractor to support isotope-related activities? Does CNSC staff have any concerns regarding OPG's management of contractors for this project?
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Since the time of writing [CMD 25-H100](#) [2], CNSC staff have issued enforcement actions to OPG regarding the noted inspection finding. The enforcement included a warning letter [6] regarding a repeat non-compliant finding for work performed by Laurentis Energy Partners (LEP) that did not adhere to regulatory requirements. The warning letter informed OPG that CNSC staff would be increasing regulatory oversight in this area. As part of this increased oversight, staff are conducting surveillance and inspection activities focusing on other work related to the Target Delivery System (TDS).

OPG responded to the warning letter, and based on the actions described in the response, CNSC staff have closed 2 of the 7 outstanding actions established in the warning letter [7]. The action item associated with this inspection will remain open until CNSC staff are satisfied that OPG has addressed all aspects of the non-compliant findings.

The inspection findings noted in [CMD 25-H100](#) are related to work associated with the TDS and are not specific to the current new isotopes licence amendment application that is the subject of this hearing in writing. CNSC staff's inspection findings have not changed the determination in [CMD 25-H100](#) section 2.6.1 that CNSC staff do not have any concerns regarding the qualifications of the other vendors involved in this project (i.e. those providing the safety analysis and engineering design work).

CNSC staff note that OPG will be responsible for the final documentation used to satisfy the removal of the proposed RHP. Further, CNSC staff are committed to ensuring all prerequisites to the proposed RHP are completed fully in accordance with OPG's management system.

Conclusion

CNSC staff's conclusion remains unchanged, and staff conclude, in accordance with [\(CMD 25-H100\)](#), that OPG:

- (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
- (b) will, in carrying on that activity, 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.

References

Referenced documents in the CMD are available to the public upon request, subject to confidentiality considerations.

[1] Commission Panel Questions CMD, “Commission Request for Information Regarding a Hearing in Writing (CMD-Q) In the matter of Ontario Power Generation Application to amend the Darlington Nuclear Generating Station power reactor operating licence to allow production of additional medical isotopes” CMD 25-H100-Q, 2025-03-31.

[2] CNSC staff CMD, “Submission from CNSC staff on the request to amend the PROL for the production of additional isotopes using the Target Delivery System”, CMD 25-H100, 2025-01-17, [e-Doc 7419259]

[3] Mississaugas of Scugog Island First Nation, “Written Intervenor Submission: OPG – DNGS Request to amend PROL to produce additional isotopes using Target Delivery System,” CMD 25-H100.5, 2025-02-28, [e-Doc 7474617]

[4] Minutes of meeting, “Mississaugas of Scugog Island First Nation and CSNC staff monthly meeting”, virtual meeting held on 2025-03-28, [e-Doc 7497975]

[5] CNSC staff CMD, “Submission from CNSC staff – Application from Ontario Power Generation to renew power reactor operating licence for the Darlington Nuclear Generating Station”, CMD 25-H2, 2025-02-25, [e-Doc 7467160]

[6] CNSC staff letter, A. Mathai to A. Grace "WARNING LETTER– New Action Item 2024-13- 34550: Increased Regulatory Oversight following Reactive Inspection DRPD-2024-20108", 2024- 11-15. [e-Doc 7397463]

[7] CNSC staff letter, A. Mathai to A. Grace “Darlington NGS – CNSC review of OPG Response to Warning Letter – Action Item 2024-13-34550: Increased Regulatory Oversight following Reactive Inspection DRPD-2024-20108”, 2025-02-28, [e-Doc 7457872]