CMD 25-H100.1D

Date: 2025-05-05

Response to Commission Request for Information

Written Submission from Ontario Power Generation Réponse à une demande d'information de la Commission

Mémoire d' Ontario Power Generation

In the matter of

À l'égard d'

Ontario Power Generation

Application to amend the Darlington Nuclear Generating Station power reactor operating licence to allow production of additional medical isotopes

Ontario Power Generation

Demande visant à modifier le permis d'exploitation d'un réacteur de puissance pour la centrale nucléaire de Darlington en vue d'obtenir l'autorisation de produire des isotopes médicaux supplémentaires

Hearing in Writing

Audience par écrit

March 2025

mars 2025





Allan Grace Senior Vice President Darlington Nuclear

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OPG Proprietary

May 5, 2025 CD# NK38-CORR-00531-26131 P

Ms. C. Salmon Commission Registrar Canadian Nuclear Safety Commission P.O. Box 1046 280 Slater Street Ottawa, Ontario, K1P 5S9

Dear Ms. Salmon:

Darlington NGS – OPG Response to Commission Panel Member's Question in CMD 25-H100-Q.A Regarding the Application to Amend the Darlington NGS Power Reactor Operating Licence to Allow Production of Additional Isotopes

The purpose of this letter is to provide the Canadian Nuclear Safety Commission with a response to the question addressed to OPG in Commission Member Document (CMD) 25-H100-Q.A (Reference 1).

The Commission, in conducting a public Hearing in Writing to consider OPG's application to amend the Darlington NGS Power Reactor Operating Licence to authorize the production of additional isotopes (Reference 2), has sent questions to OPG through CMD 24-H100-Q (Reference 3) and CMD 24-H100-Q.A (Reference 1).

OPG's response to CMD 24-H100-Q was provided in Reference 4.

Attachment 1 provides OPG's response to the Commission Panel's Member's question from CMD 25-H100-Q.A.

This submission completes Regulatory Management Action Request 28274156.

No new regulatory commitments have been undertaken as a result of this submission.

Should you have any questions please contact Ms. Aditi Bhardwaj, Senior Manager, Regulatory Affairs at 289-387-2110 or at <u>aditi.bhardwaj@opg.com</u>.

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Sincerely,

Allan Grace Senior Vice President Darlington Nuclear Ontario Power Generation Inc.

Attach.

- cc: CNSC Site Supervisor Darlington
 - A. Viktorov Ottawa

A. Baig – Ottawa forms-formulaires@cnsc-ccsn.gc.ca registry-greffe@cnsc-ccsn.gc.ca

References:

- Registry/Registrar email, J. Samson to A. Grace, "Commission Request for Information Regarding a Hearing in Writing (CMD-Q)", April 22, 2025, CMD 25-H100-Q.A, Doc ID: DAMZHJW66V33-166150894-922, CD# NK38-CORR-00531-26139.
 - OPG letter, A. Grace to D. Saumure, "Darlington NGS Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production", February 26, 2024, CD# NK38-CORR-00531-25141.
 - Registry/Registrar email, C. Salmon to A. Grace, "Commission Request for Information Regarding a Hearing in Writing (CMD-Q)", March 31, 2025, CMD 25-H100-Q, Doc ID:DAMZHJW66V33-166150894-362.
 - OPG letter, A. Grace to C. Salmon, "Darlington NGS OPG Response to the Commission Panel Member's Question Regarding the Application to Amend the Darlington NGS Power Reactor Operating Licence to Allow Production of Additional Medical Isotopes", April 11, 2025, CD# NK38-CORR-00531-26112

ATTACHMENT 1

OPG letter, A. Grace to C. Salmon, "Darlington NGS – OPG Response to Commission Panel Member's Question in CMD 25-H100-Q A Regarding the Application to Amend the Darlington NGS Power Reactor Operating Licence to Allow Production of Additional Isotopes"

CD# NK38-CORR-00531-26131 P

Response to Commission Panel Member's Question in CMD 25-H100-Q.A

Prepared by: A. Hussain Checked by:

J. Samuel

ATTACHMENT 1

Response to Commission Panel Member's Question in CMD 25-H100-Q.A

Commission Question – In Attachment 3 of OPG's application, OPG states that:

"OPEX [operating experience] review will be conducted during the preliminary engineering phase to identify previous applicable experience and lessons learned... The results of the OPEX reviews will be documented and incorporated into this project."

Provide the OPEX/lessons learned from OPG's operation of its Target Delivery System to produce Molybdenum-99 (Mo-99) and explain how these lessons have been/will be incorporated into the production of Lu-177 and Y-90.

OPG Response – The objectives of the preliminary design engineering phase incorporated the use of OPEX to ensure that the design of the Lutetium-177 (Lu-177) and Yttrium-90 (Y-90) targets remained within the bounds of the Mo-99 production targets, confirming that the target capsule geometry was maintained. In addition, primary design considerations from OPEX/lessons learned during OPG's operation of the Target Delivery System (TDS), while commissioning and validating the TDS for Mo-99 production, showed that the mass of the targets affects the operation of the system. This has been incorporated into the design of the new target assembly to ensure there is sufficient mass and that it remains within the analyzed impact of the core. Furthermore, recognizing that the reactivity worth of the targets was an important consideration, the design of the new isotope targets includes molybdenum as ballast. This ensures that the Authorized Nuclear Operator will observe a similar response to target movement during the production of Lu-177 and Y-90. These aspects were reflected in the Nuclear Safety Impact Assessment included with the application (Reference 1).

OPEX also identified the need for early engagement with Human Factors Engineering (HFE) to ensure that HFE considerations are identified, documented, verified and validated. For example, this includes ensuring operators can identify the correct target magazine to load into the TDS and corresponding changes to the Human-Machine Interface panel. HFE assessments will be documented in the Human Factors Engineering Summary Reports (R000 and R001), which are OPG deliverables under the proposed Regulatory Hold Point (Reference 2).

- References: 1. Enclosure 1 of OPG letter A. Grace to D. Saumure, "Darlington NGS – Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production", February 26, 2024, CD# NK38-CORR-00531-25141.
 - CNSC Staff CMD 25-H100 "Ontario Power Generation Inc., Darlington Nuclear Generating Station: Request to amend the PROL for the production of additional isotopes using the Target Delivery System", January 17, 2025, e-Doc# 7419259.

Summary of Regulatory Commitments, Regulatory Obligations and Regulatory Management Actions Made/Concurrence Requested

CD# NK38-CORR-00531-26131 P

Submission Title: Darlington NGS – OPG Response to Commission Panel Member's Question in CMD 25-H100-Q.A Regarding the Application to Amend the Darlington NGS Power Reactor Operating Licence to Allow Production of Additional Isotopes

Regulatory Commitments (REGC):

| No. | Description | Date to be Completed |
|-----|-------------|-------------------------|
| | None | |

Regulatory Management Action (REGM):

| No. | Description | Date to be Completed |
|-----|-------------|-------------------------|
| | None | |

Regulatory Obligation Action (REGO):

| No. | Description | Date to be Completed | |
|-----|-------------|-------------------------|--|
| | | None | |

| Concurrence | |
|-------------|-------|
| Requested: | None. |