



CMD 25-H100.1B

Date: 2025-04-11

**Response to Commission
Request for Information**

**Réponse à une demande
d'information de la Commission**

**Written Submission from
Ontario Power Generation**

**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

OPG Proprietary

April 11, 2025

CD# NK38-CORR-00531-26112 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 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**

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

The question was regarding OPG’s request to amend the Darlington Nuclear Generating Station (NGS) Power Reactor Operating Licence to allow the production of additional medical isotopes (Reference 2).

Attachment 1 provides OPG’s response to the Commission Panel Member’s question from Table 1 of CMD 25-H100-Q.

OPG is seeking to expand its irradiation capacity by leveraging the existing Darlington NGS Target Delivery System (TDS) and associated infrastructure and expertise to produce two additional isotopes, Lutetium-177 (Lu-177) and Yttrium-90 (Y-90). OPG currently uses the TDS to irradiate target capsules to produce the medical isotope Molybdenum-99 (Mo-99). By loading different material contained within each target capsule, OPG can use the existing TDS to generate these new radioisotopes which will have a significant positive impact on human health across Canada and the globe, expanding Canada’s leadership role in the global community by supporting new and innovative approaches to cancer diagnosis and treatment.

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OPG remains committed to the safe and reliable operation of Darlington NGS and reaffirms that the changes to the TDS required to accommodate production of these two new isotopes will be implemented based on a robust safety case and in accordance with OPG's Engineering Change Control process, which is supported by safety assessments that demonstrate continued safe reactor operation, public safety, and environmental protection.

This submission completes Regulatory Management Action Request 28273919.

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

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

Sincerely,



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

Attach.

cc: CNSC Site Supervisor – Darlington
A. Viktorov - Ottawa
A. Baig - Ottawa
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- References:
1. 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.
 2. 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.

ATTACHMENT 1

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"

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Response to Commission Panel Members Question from Table 1 of CMD 25-H100-Q

Prepared by: A. Hussain

Checked by: J. Samuel

ATTACHMENT 1

Response to the Commission Panel Member's Question from Table 1 of CMD 25-H100-Q

Commission Question - *Provide additional information on the TDS operating procedures and how workers will interface with the system. What additional considerations have been made for the production of Lu-177 and Y-90? What contingencies have been built into the procedures to address malfunctions (e.g. a mechanical failure within the TDS that may require manual intervention or handling) and to protect workers?*

OPG Response – Qualified OPG Nuclear Operators interface with the Target Delivery System (TDS) through the actions described in the TDS Operating Manual (OM), NK38-OM-30550 R003, and the TDS Mechanical Maintenance Procedure (MMP), NK38-MMP-30550. As described in Reference 1, Attachment 3, Section 2.3.2 "Procedures", these documents were developed for the production of Mo-99 and will be updated to incorporate the irradiation of Lu-177 and Y-90. The TDS is operated in accordance with the OM and MMP as per the Darlington NGS Power Reactor Operating Licence, PROL 13.04/2025, Licence Conditions Handbook, LCH-DNGS- R006.

TDS operation is enabled through system software. Minor updates to this software will be implemented and associated documentation will be developed in accordance with OPG's Engineering Change Control (ECC) Process N-PROC-MP-0090. These updates will not alter the fundamental system functionality but will allow for the production of new isotopes with updated irradiation durations and dwell times, as well as corresponding changes to the Human Machine Interface (HMI) panel (e.g. indication of isotope and associated parameters). These updates are further described in Reference 1, Attachment 3, Section 1.4.3 "Software Updates".

As part of the ECC process, Human Factors considerations (e.g ensuring the correct targets are loaded into the TDS and HMI) will be identified and documented in the Human Factors Engineering Summary Reports (R000 and R001). These reports are OPG deliverables under the proposed Regulatory Hold Point (Reference 2).

Per Reference 1, Attachment 3, Section 2.5 "Physical Design" no new equipment will be installed and no physical modifications to the TDS are required to support irradiation of these isotopes. As such, no changes to OPG's Conduct of Maintenance or Equipment Reliability Programs (N-PROG-MA-0004 and N-PROG-MA-0026, respectively) are required. These programs govern the maintenance of station equipment in order to minimize component failures and ensure equipment reliability and personnel safety.

OPG's determination that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Fitness for Service Safety and Control Area is expanded in Reference 1, Attachment 3, Section 2.6 "Fitness for Service". The TDS OM addresses the potential failures which can occur during operation of the installed system (e.g. NK38-OM-30550-05.14, "Stuck Basket") as well as the TDS Operator response actions to ensure that the system can be placed in a safe state following the event. Further, the detailed failure modes and effects analysis developed as part of the original design and installation of the TDS were reviewed at a high level for impact of new isotope production in Attachment 3, Enclosure 1 of Reference 1 ("Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System"). This assessment concluded that production of new isotopes Y-90 and Lu-177 has no significant impact on the safe operation of Darlington NGS. The failure mode

and effects analysis will be updated for Y-90 and Lu-177 during the detailed design phase as per the ECC process. In summary, due to the absence of physical changes to the TDS and considering functionality is unchanged, no new or additional contingencies have been identified for the production of Lu-177 and Y-90 and the protection of workers.

- References:
1. 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.
 2. 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-00531-26112 P

Submission Title: **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**

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.