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**OPG Proprietary**

June 23, 2020

NK38-00531 P  
NK38-CORR-00531-21744 P

Mr. M. Leblanc  
Commission Secretary  
Canadian Nuclear Safety Commission  
P.O. Box 1046  
280 Slater Street  
Ottawa, Ontario  
K1P 5S9

Mr. G. Frappier  
Director General, Power Reactor Regulation  
Canadian Nuclear Safety Commission  
P.O. Box 1046  
280 Slater Street  
Ottawa, Ontario  
K1P 5S9

Dear Mr. Leblanc and Mr. Frappier:

**Darlington NGS – Molybdenum-99: Updated Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025**

The purpose of this letter is to provide an update on Ontario Power Generation's (OPG) Molybdenum-99 (Mo-99) medical isotope project at the Darlington Nuclear Generating Station (NGS) and an updated request for Power Reactor Operating Licence (PROL) amendment.

In Reference 1, OPG requested an amendment of the Darlington NGS PROL 13.01/2025 to add a new licensed activity to possess, transfer, produce, package, manage and store Mo-99 radioisotope and its associated decay isotopes (Reference 1). Subsequent to OPG's original request (Reference 1), Darlington's PROL was amended from 13.01/2025 to 13.02/2025 (Reference 2).

The Mo-99 medical isotope project is an important initiative for the nuclear industry and medical community. Approximately 80% of nuclear medicine procedures rely on Technetium-99m (Tc-99m), the decay isotope of the Mo-99 radioisotope. This translates into over 30 million heart, cancer and bone diagnostic scans, which are performed annually using Tc-99m.

The Mo-99 medical isotope project remains overall on track with submission for CNSC staff review of the design documents on May 22, 2020. The majority of the safety assessments have been submitted with submission of the final consolidated safety and predicted environmental impact assessments by June 30, 2020.

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The design of the Mo-99 Isotope Irradiation System (IIS) will comply with all applicable regulatory requirements, and the safety assessments will demonstrate that installation and operation of the Mo-99 IIS will have no significant impact on continued safe reactor operation, public, employee and environmental safety, which is referred to as the "safety case".

In order to install the reactor portions of the Mo-99 IIS, an outage of the affected reactor unit will be required. Due to a number of factors, including a reassessment and changes to the Darlington's reactor unit outage schedule, a decision was made to change the Mo-99 IIS installation from Darlington's Unit 4 to Unit 2. OPG would like to be ready to install the Mo-99 IIS on Unit 2 if an outage opportunity arises after July 1, 2021.

The original project plan was for OPG to submit for CNSC staff acceptance the safety case for installation of the Mo-99 IIS on Unit 4. However, this updated PROL amendment request is not unit specific. Given the similarities between the Darlington's units, the Unit 4 safety case is expected to be applicable to the other reactor units pending confirmation assessments that will be submitted for CNSC staff acceptance. OPG has not made a decision on Mo-99 IIS installation on other Darlington reactor units at this time.

On this basis, OPG requests that the required Canadian Nuclear Safety Commission proceedings for the Darlington NGS PROL amendment take place in March or April 2021, to support an installation as early as July 2021.

If you have any questions, please contact Mr. Imtiaz Malek, Manager, Darlington Regulatory Affairs, at (905) 623-6670 extension 703 1588.

Sincerely,



Steve Gregoris  
Senior Vice President  
Darlington Nuclear  
Ontario Power Generation Inc.

cc: Ms. K. Hazelton - CNSC (Darlington)  
cns.c.forms-formulaires.ccsn@canada.ca  
Dr. A. Omar – CNSC (Ottawa)

- References:
1. OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS - Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment", December 5, 2018, CD# NK38-CORR-00531-20359.
  2. CNSC letter, "Application for Four Nuclear Power Reactor Operating Licences to Reference REGDOC 2.2.3 Personnel Certification Volume III Certification of Persons Working at Nuclear Power Plants", April 9, 2020, CD# NK38-CORR-00531-21645.

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

**NK38-CORR-00531-21744**

**Submission Title:** Darlington NGS – Molybdenum-99: Updated Request for Amendment of the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025

**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:**

OPG requests that the required Canadian Nuclear Safety Commission proceedings for the Darlington NGS PROL amendment take place in March or April 2021, to support an installation as early as July 2021