ONTARIO POWER GENERATION

Steve Gregoris
Senior Vice President

Darlington Nuclear

P.O. Box 4000, Bowmanville, ON L1C 3Z8

Tel: 905-623-6670 ext 7030099 Fax: 905-697-7596
steve.gregoris@opg.com

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NK38-00531 P
NK38-CORR-00531-20359

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

Dear Mr. Leblanc

Darlington NGS – Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment

The purpose of this letter is to request Canadian Nuclear Safety Commission (the Commission) pursuant to Section 24(2) of the Nuclear Safety and Control Act and Section 6 of the General Nuclear Safety and Control Regulations, to amendment Darlington Nuclear Generating Station (NGS) Power Reactor Operating Licence (PROL) 13.01/2025.

Ontario Power Generation (OPG) is requesting the amendment to add a new licensed activity under PROL 13.01/2025 Section IV for the authorization to possess, transfer, produce, package, manage, and store Molybdenum-99 radioisotope and its associated decay isotopes.

Background

OPG, in partnership with BWX-Technologies (BWXT), have chosen Darlington NGS as the facility for the installation of an Isotope Irradiation System intended to irradiate Molybdenum to produce Molybdenum-99 (Mo-99) isotope for the medical industry.

Approximately 80% of nuclear medicine procedures rely on Technetium-99m (Tc-99m), the decay isotope of the Mo-99 radioisotope. Over 30 million heart, cancer and bone diagnostic scans are performed annually using Tc-99m.

Over the years, the traditional Mo-99 supply chain has encountered numerous challenges with unreliable production. The OPG - BWXT solution will provide assurance of reliable production and long-term supply of Mo-99 using neutron capture of natural molybdenum targets, while reducing concerns related to nuclear proliferation and nuclear waste by-products associated with traditional Mo-99 production.

The current Darlington's PROL 13.01/2025 does not permit the possession, transfer, production, packaging, management and storage of Mo-99 radioisotope and its associated decay isotopes, therefore in order to proceed with this project beneficial to Canadians and worldwide, OPG is requesting a licence amendment.

Schedule

In order to implement the required Mo-99 Isotope Irradiation System, plant modifications and installation of new equipment will be required. OPG, as the licence holder, is ultimately responsible for safe operation of Darlington NGS. As such, OPG would not authorize this project to proceed unless it has been thoroughly assessed and demonstrated to be safe.

The Mo-99 Isotope Irradiation System project is now in the detailed design phase. Over the next several months, OPG will submit for CNSC staff review and acceptance the design and modification details along with a comprehensive set of safety analysis. After CNSC staff's review and acceptance of the design and the safety case for this project, the plant modifications for the Mo-99 Isotope Irradiation System will be implemented in accordance with regulatory requirements of Darlington NGS PROL 13.01/2025 and Licence Conditions Handbook LCH-PR-13.01/2025-R002.

OPG expects to be ready to start producing Mo-99 for the medical industry in first half 2020. Given the current challenges with the supply of this important medical isotope, OPG requests that the necessary Commission proceedings to take place and that a decision be rendered on the licence amendment to allow the production of Mo-99 to occur in a timely manner.

Attachment 1 provides information pertaining to Section 6 of the General Nuclear Safety and Control Regulations and Attachment 2 provides the proposed amendment to Darlington's PROL 13.01/2025.

OPG requests an amendment to Darlington NGS PROL 13.01/2025, as outlined in Attachments 1 and 2, at your earliest convenience and a subsequent update of Darlington's Licence Conditions Handbook LCH-PR-13.01/2025-R002.

If you have any questions, please contact Mr. Mark Bosley, Manager, Darlington Regulatory Affairs, at (905) 623-6670 ext. 7032059.

Sincerely,

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

Attch.

cc: Mr. G Frappier – CNSC (Ottawa)
Ms. N. Riendeau – CNSC (Ottawa)
Ms. K. Hazelton - CNSC (Darlington)
Mr. A. Omar - CNSC (Ottawa)

ATTACHMENT 1

OPG letter S. Gregoris to M. Leblanc, "Darlington NGS – Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment"

CD# NK38-CORR-00531-20359

Information Required for Amendment, Revocation or Replacement of a Licence Pursuant to Section 6 of the General Nuclear Safety and Control Regulations

Prepared by: **R. MacEacheron**

Checked by: **M. Bosley**

ATTACHMENT 1

Information Required for Amendment, Revocation or Replacement of a Licence Pursuant to Section 6 of the General Nuclear Safety and Control Regulations

Reference: Subsection 24(2) of the *Nuclear Safety and Control Act* and Section 6 of the *General Nuclear Safety and Control Regulations:*

(a) a description of the amendment, revocation or replacement and of the measures that will be taken and the methods and procedures that will be used to implement it;

This is a request for licence amendment to Darlington's PROL 13.01/2025 to authorize as a new licensed activity:

(vi) to possess, transfer, produce, package, manage, and store Molybdenum-99 and its associated decay isotopes.

An Isotope Irradiation System to allow insertion and removal from the nuclear reactor and transfer of Molybdenum irradiated targets to transportation flasks is currently being designed. More information on the design and operating procedures will be forthcoming in supporting Commission Members Document and supplemental submissions for the hearing.

The expected changes to the licensing basis will be for the addition of a new licensed activity authorizing the possession, transfer, production, management and storage of Molybdenum-99 radioisotope.

For the Molybdenum-99 Isotope Irradiation System, OPG is scheduled to submit, by July 2019 for CNSC staff's review and acceptance, the detailed design documentation, supporting safety analyses, radiation protection impact report and gap analysis of the current Environmental Risk Assessment (ERA). OPG asserts that the Molybdenum-99 Isotope Irradiation System will comply with all regulatory and licensing requirements outlined in Darlington NGS PROL 13.01/2025 and the associated Licence Condition Handbook LCH-PR-13.01/2025-R002.

(b) a statement identifying the changes in the information contained in the most recent application for the licence;

As this is a new activity for OPG and a new design, the latest application for Darlington NGS licence renewal applications (References [1] and [2]) did not include details of the Molybdenum Isotope Irradiation System.

(c) a description of the nuclear substances, land, areas, buildings, structures, components, equipment and systems that will be affected by the amendment, revocation or replacement and of the manner in which they will be affected; and

Molybdenum-99 radioisotope and its associated decay product Technetium-99m are nuclear substances that OPG currently does not possess, produce or manage.

As described in Reference [3] and updated in Reference [4], the Isotope Irradiation System will use four out-of-service Adjuster Absorber (AA) Rod openings. The AA Rod mechanisms will be replaced with a new mechanism for the insertion into and removal of Molybdenum targets from the reactor core. After an irradiation period, the targets will be transferred to certified transportation flasks for shipment to an external processing facility for the extraction of Technetium-99m by an external company for the medical industry.

(d) the proposed starting date and the expected completion date of any modification encompassed by the application;

OPG expects to be ready to install the Isotope Irradiation System modification in the fourth quarter of 2019 and expects to be ready (pending the licence amendment) to start producing Molybdenum-99 for the medical industry in the first half of 2020.

References:

[1]. OPG Letter, B. Duncan to M. Leblanc, "Darlington NGS - Application for Renewal of the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.00/2014", December 13, 2013, CD NK38-CORR-00531-16490

[2]. OPG Letter, B. Duncan to M. Leblanc, "Darlington NGS - Additional Information in Support of Application for Renewal of Darlington's Power Reactor Operating Licence (PROL) 13.011/2015", January 30, 2015, CD NK38-CORR-00531-17206.

[3]. OPG Letter, G. Jager to G. Frappier, "Letter of Intent for OPG's Initiative to Irradiate Natural Molybdenum at Darlington Nuclear Generating Station", May 18, 2018, CD# NK38-CORR-00531-19510.

[4]. OPG Letter, S. Gregoris to N. Riendeau, "Darlington NGS - Molybdenum-99 Isotope Irradiation System: Submission of Conceptual Design Report Revision, Safety Analysis Project Execution Plan and Engineering Oversight Plan", November 14, 2018, CD# NK38-CORR-00531-20289.

ATTACHMENT 2

OPG letter S. Gregoris to M. Leblanc, "Darlington NGS – Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment"

CD# NK38-CORR-00531-20359

Proposed Amendment to Darlington NGS PROL 13.01/2025

Prepared by: **R. MacEacheron**

Checked by: **M. Bosley**

ATTACHMENT 2

Proposed Amendment to Darlington NGS PROL 13.01/2025

Current PROL 13.01/2025	Requested Amendment to PROL 13.01/2025 (new activity in bold and italic)
IV) LICENSED ACTIVITIES:	**IV) LICENSED ACTIVITIES:**
This licence authorizes the licensee to:	This licence authorizes the licensee to:
(i) operate the Darlington Nuclear Generating Station which includes the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter "the nuclear facility") at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario;	(i) operate the Darlington Nuclear Generating Station which includes the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter "the nuclear facility") at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario;
(ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i);	(ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i);
(iii) import and export nuclear substances, except controlled nuclear substances, that are required for, associated with, or arise from the activities described in (i);	(iii) import and export nuclear substances, except controlled nuclear substances, that are required for, associated with, or arise from the activities described in (i);
(iv) possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the activities described in (i);	(iv) possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the activities described in (i);
(v) possess, transfer, process, package, manage and store the nuclear substances associated with the operation of the Darlington Tritium Removal Facility;	(v) possess, transfer, process, package, manage and store the nuclear substances associated with the operation of the Darlington Tritium Removal Facility;
	(vi) ***possess, transfer, produce, package, manage, and store Molybdenum-99 radioisotope and its associated decay isotopes.***

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

NK38-CORR-00531-20359

Submission Title: **Darlington NGS – Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment**

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 an amendment to Darlington NGS PROL 13.01/2025 as outlined in Attachments 1 and 2, at your earlier convenience and an update of Darlington NGS LCH-PR-13.01/2025-R002.