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Written submission from the Mississaugas of Scugog Island First Nation

In the matter of

Ontario Power Generation

Ontario Power Generation - Application to amend the Darlington Nuclear Generating Station power reactor operating license to allow production of additional medical isotopes

Public Hearing – Hearing in writing based on written submissions

March 2025

Mémoire de la Première Nation des Mississaugas de Scugog Island

À l'égard d'

Ontario Power Generation

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

Audience publique – Audience fondée sur des mémoires

Mars 2025

Canada

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Written Intervenor Submission:

OPG – DNGS Request to amend PROL to produce additional isotopes using Target Delivery System

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Mississaugas of Scugog Island First Nation

February 28, 2025

MISSISSAUGAS OF SCUGOG ISLAND
FIRST NATION

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To the attention of:

Tribunal Officer, Commission Registry

Canadian Nuclear Safety Commission

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February 28, 2025

Re: Ontario Power Generation - Darlington Nuclear Generating Station Request to amend the PROL for the production of additional isotopes using the Target Delivery System

The Mississaugas of Scugog Island First Nation (MSIFN) Consultation Department ("MSIFN Consultation") is pleased to provide comments on the **Darlington Nuclear Generating Station Request to amend the PROL for the production of additional isotopes using the Target Delivery System**. Comments on behalf of MSIFN Consultation are below.

I. Summary

MSIFN Consultation provides comments on the proposed amendment to the Darlington Nuclear Generating Station (DNGS) Power Reactor Operating Licence (PROL) to allow for the production of additional medical isotopes using the Target Delivery System. MSIFN holds a rights-bearing position in this project, as DNGS is located within the Williams Treaties First Nations' Treaty and traditional territory, about 37 km from MSIFN's reserve community, and aspects of the project operate within the unceded lakebed of Lake Ontario. Given the historical lack of consultation and accommodation in CNSC regulated nuclear projects, MSIFN emphasizes the need for meaningful engagement and adherence to the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). While generally supportive of the license amendment, MSIFN requests the opportunity to review OPG's updated Predictive Environmental Assessment (PEA)

alongside CNSC staff, and to be involved in the review and verification of the Regulatory Hold Points (RHPs) before their removal.

II. Introduction & Background

MSIFN's community is located on the shores of Lake Scugog in Durham Region, Ontario. MSIFN has a long history in this part of Ontario and is part of the Williams Treaties First Nations (WTFNs). The WTFNs' territory extends from the shore of Lake Ontario in the south, Georgian Bay in the west, the Ottawa Valley in the east, and as far north as the French River. Lake Ontario and its lakebed adjacent to the WTFN treaty lands, and south to the border with the United States, are unceded lands and waters. Within these Treaty and unceded territories, MSIFN's priority is the protection and preservation of the lands, waters, wildlife, and fisheries that we rely on.

The first Mississauga people settled in the basin of Lake Scugog around 1700. Game and fur animals, waterfowl and fish abounded, and wild rice grew in profusion in the shallow waters. The people flourished in this paradise for nearly a century until the British arrived with their insatiable appetite for Aboriginal land. Having just lost the American War of Independence, British refugees came flooding north into Upper Canada seeking new land.

Crown government officials were soon conducting land acquisition treaties, including the "Gunshot Treaty" with Anishinaabe, made up of the Michi Saagiig and Chippewa people, who neither understood the language of these powerful strangers nor fully grasped the revolutionary concept of permanently selling their Mother Earth. Millions of acres of valuable native lands were given up through these treaties with very little received in return. Unfortunately, fair dealings were not the order of the day. In one instance, a 160 kilometer stretch of land about 20 kilometers wide along Lake Ontario from roughly Trenton to Toronto was ceded, but the treaty was so flawed, government officials later privately agreed that it was invalid. Mississauga people, however, were not so informed, and that land was quickly taken up by non-native settlers.

In another case, the Crown completely ignored and by-passed MSIFN when it granted the land west of Lake Scugog north to Lake Simcoe to non-native settlers who promptly chopped down the forest for their farms. With increasing settlement at Scugog, the only land available was an 800-acre landlocked parcel on Scugog Island. And despite the thousands of acres west of Lake

Scugog earlier taken from them, Mississauga people were required to purchase these 800 acres with their own money.

MSIFN are cultural partners of the Michi Saagiig (Mississauga) Nation, with traditional territories expanding through most of southeastern Ontario, including lakebeds, tributaries, and watersheds. MSIFN contested Crown hunting regulations into the 1980s when Supreme Court decisions began recognizing Aboriginal harvesting rights.

In 2018, MSIFN became a signatory to the Williams Treaties of 1923, which after 90 years of dispute came to a final settlement agreement that reaffirmed our pre-confederation treaty rights to hunt and harvest. MSIFN is also signatory to the Framework Agreement for First Nations Lands Management, the First Nations Fiscal Management Act, and other political Aboriginal arrangements all of which support our Inherent Right as a self-governing authority. After a 90-year fight to have our rights recognized, MSIFN insists the CNSC and other federal and provincial Crown authorities respect the weight of this recognition in dealing with us.

As outlined in the 2018 Settlement Agreement, constitutionally protected rights for hunting, fishing, and trapping were affirmed for the WTFNs across their traditional territories. These ways of life have been practiced sustainably since time immemorial and represent fundamental cultural markers of Indigenous identity and self-determination. Hunting includes trapping, snaring and fishing supplemented by firearm usage. Despite inherent and long-held rights, the Williams Treaties of 1923 opened the door for decades of discrimination and legally sanctioned harassment by officers of the Crown against First Nations for exercising their cultural harvesting practices. The Crown only began addressing these impacts on MSIFN and the other WTFNs in 2018 with the Settlement Agreement.

III. Connection to MSIFN

The Darlington Nuclear Generating Station is located within the treaty and traditional territory of the Michi Saagiig WTFNs, giving MSIFN a rights holding position in the project. MSIFN's reserve community is about 37 km from the project and members have expressed concerns and uncertainty surrounding the safety, management, and security of the nuclear facilities and operations within their treaty area, regulated by the CNSC. MSIFN members, employees, and businesses are active in and around the DNGS in many ways.

The DNGS has been here for decades, playing a key role in shaping Canada's nuclear energy landscape. Its development involved lands taken up by the Crown, with construction and operations proceeding prior to 2018 without consultation or accommodation of MSIFN's rights and interests. This involved construction and operation of cooling structures in the unceded lakebed of Lake Ontario. The Williams Treaties and the 2018 Williams Treaties Settlement Agreement are silent on the lakebed and water in the WTFN's traditional territory. The CNSC has acknowledged Crown-Indigenous Relations and Northern Affairs Canada affirmation of this, and that Canada does not have a position on this. The waters and lakebeds in the WTFNs treaty areas and traditional territories have never been ceded. As such MSIFN claims jurisdiction to the lakebed and water adjacent to the DNGS and all current and future CNSC regulated nuclear facilities along the shoreline of Lake Ontario. Any activity which impacts these lands and water requires consultation, not simply a process of sharing information, and the consent of MSIFN.

Nuclear safety is paramount to MSIFN. Nearly every aspect of the nuclear fuel lifecycle occurs within our territory, except for uranium mining. These post-colonial activities will continually impact our community. It is the future generations who will bear this burden and MSIFN. The CNSC and OPG have legal obligations to ensure our safety.

MSIFN has commented on previous CNSC proceedings with respect to medical isotope proceedings, including:

- Ontario Power Generation – Licence amendment application for the Darlington Nuclear Generating Station regarding the commercial production of Cobalt-6 – April 2024.
- CNSC Discussion Paper DIS-24-04: "Future Amendments the Nuclear Security Regulations: Granting Peace Officer Powers, Initiating a Complaints Investigation Mechanism, and Transferring of Firearm Ownership to Licensees", May 2024.
- Regulatory Oversight Report for Canadian Nuclear Laboratories Sites: 2023 – Comments from the Mississaugas of Scugog Island First Nation (MSIFN) Consultation Department, October 7, 2024
- Regulatory Oversight Report for Canadian Nuclear Power Generating Sites: 2023, January 27, 2025

MSIFN, through its economic development corporation, Minogi Corp., is an active member of the Canadian Nuclear Isotope Council (CNIC), the second First Nation entity to join CNIC following Saugeen Ojibway Nation's membership acceptance. MSIFN understands the value of

isotopes for the global fight against cancer, keeping hospitals and medical facilities clean, helping save lives, and supporting various industrial processes.

MSIFN's Chief and Council, in conjunction with their teams, act as their community's regulatory body. The process MSIFN must undertake to discharge their legal obligations to their citizens and the WTFN community is complex and not something that the Crown can legally rush or disregard. The UN Declaration on the Rights of Indigenous Peoples (UNDRIP) exists to protect this, and our duty is to ensure it is upheld.

IV. UNDRIPA and FPIC

As a Crown agency the CNSC is bound by federal law. In 2021 the *United Nations Declaration on the Rights of Indigenous Peoples Act*[1] came into force. *UNDRIPA* embeds the principles of the *United Nations Declaration on the Rights of Indigenous Peoples*[2] into Canadian positive law. A subsequent Action Plan[3] was released to help facilitate the integration of *UNDRIPA* throughout Canadian federal Ministries and agencies, including Natural Resources Canada, the governing Ministry of the CNSC.

The Declaration Articles 18, 19, 26, 29(2) and 32(2) pertain to the CNSC.

- Article 18 provides for the right to partake in decision-making on matters affecting MSIFN rights;
- Article 19 provides that States consult Indigenous peoples and get their consent before adopting measures that will affect them;
- Article 26 provides for Indigenous control over traditional lands and the State's respect of those lands;
- Article 29(2) says “States shall take effective measures to ensure that no storage or disposal of hazardous materials shall take place in the lands or territories of Indigenous peoples without their free, prior and informed consent;” and

[1] *The United Nations Declaration of the Rights of Indigenous Peoples Act* SC 2021, c 14 [*UNDRIPA*].
[2] *United Nations Declaration of the Rights of Indigenous Peoples*, GA Res 61/295, UNGAOR, 61st Sess, A/RES/61/295 (2 October 2007). ["UNDRIP" or "the Declaration"]
[3] Government of Canada, "The *United Nations Declaration on the Rights of Indigenous Peoples Act* Action Plan" (2023), online (pdf): Justice Canada < https://www.justice.gc.ca/eng/declaration/ap-pa/ah/pdf/unda-action-plan-digital-eng.pdf>. ["Action Plan"]

- Article 32(2) provides that "States shall consult and cooperate in good faith with the Indigenous Peoples concerned through their own representative institutions in order to obtain their free and informed consent prior to the approval of any project affecting their land or territories and other resources…" ("FPIC").

REGDOC 3.2.2, which outlines the CNSC's Indigenous Engagement, is silent on the Declaration, UNDRIPA and the Action Plan. There is no official CNSC document which incorporates any of the Declaration's Articles.

The official silence from the CNSC regarding the Declaration, UNDRIPA, and the Action Plan in their regulatory documents and regulatory report is troubling. It is inconsistent with the state of current law and with the CNSC's repeated promise of reconciliation. At the DNNP Licence to Construct (LTC) Hearing Part 1 in October 2024, Adam Levine characterized the CNSC Staff approach to consultation as being mindful of the Declaration articles including FPIC. However, being mindful is not the legal requirement. The CNSC's approach to the Declaration during Indigenous consultation and engagement has been consistent with their regulatory documents; silent.

Free, prior and informed consent is the basic foundation for creating any long-term relationship. MSIFN has been requesting this approach for many years. A healthy and positive long-term relationship needs a power balance which respects the position of each party and one that is built on trust. As a Treaty partner and title holder, FPIC is the standard First Nations require for long-term relationships.

V. Technical Overview

MSIFN Consultation has reviewed available documentation for the licence amendment, including:

- Darlington NGS – Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production
- Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production
- CMD 25-H100 - Submission from CNSC staff on the request to amend the PROL for the production of additional isotopes using the Target Delivery System

These documents refer to OPG's request to amend its operating licence for the DNGS at Darlington Unit 2 to allow the production of additional medical isotopes, specifically lutetium-177 and yttrium-90, using an existing Target Delivery System. This amendment will allow OPG to produce these isotopes for medical applications, in addition to the already authorized production of molybdenum-99 (Mo-99). The amendment includes necessary updates to the Power Reactor Operating Licence (PROL) and the Licence Conditions Handbook (LCH) to reflect these changes and ensure compliance with regulatory requirements.

MSIFN Consultation understands that the amendment to the licence for Darlington Nuclear Generating Station does not require changes to the existing environmental protection measures. OPG asserts that the production of the new isotopes, Lu-177 and Y-90, will not result in any changes to the Derived Release Limits (DRLs), Action Levels, or Internal Investigation Limits (IILs). OPG also asserts that the public dose consequence of producing these isotopes will remain bounded by the existing Mo-99 operation, ensuring no impact on the cumulative public dose, which is well below the regulatory public dose limit of 1 mSv per year.

Additionally, OPG is committing to validating the impacts of the production of the new isotopes through their Engineering Change Control (ECC) process and ensuring that the new isotopes are included in their environmental governance. CNSC staff will review OPG's updated Predictive Environmental Assessment (PEA) to confirm that the environmental impacts of the new isotopes are within the previously assessed limits for Mo-99 production. This review will be part of the regulatory hold point process before the new isotopes are declared Available for Service (AFS).

OPG further asserts that the expected emissions from the production of Lu-177 and Y-90 at the DNGS are anticipated to be minimal and within the existing safety and environmental limits established for Mo-99 production. The primary source of emissions during the production and harvesting of these isotopes is tritium from residual heavy water collected during the target handling process.

OPG has stated that the number of seeding and harvesting cycles per year for the new isotopes will remain unchanged from the current operations for Mo-99, which was the primary factor considered in the Mo-99 Predictive Effects Analysis (PEA). Therefore, OPG expects the introduction of the new target capsules will not have any additional environmental impact.

CNSC staff have determined that the releases associated with the Target Delivery System (TDS) will continue to make up only a small fraction of the annual station releases, ensuring that there will be no significant additional risk to the public and the environment.

The waste generated from the production of Lu-177 and Y-90 at the DNGS will be managed similarly to the waste from Mo-99 production. OPG will not retain responsibility for the residual wastes produced as a result of processing, commercialization, or use of either Lu-177 or Y-90. These wastes will be managed by BWX Technologies (BWXT)-Medical under an existing CNSC licence.

For maintenance and routine operations, any waste generated, such as radiological personal protective equipment (RPPE) and other disposable materials, will be handled by OPG's existing waste management program. This program is compliant with CSA N292.3-08, Management of low and intermediate level radioactive waste, and includes waste minimization and management practices and procedures.

CNSC staff will maintain oversight of any additional waste generated and the management of those wastes through existing compliance verification activities. The introduction of Lu-177 and Y-90 is not expected to change the decommissioning strategy compared to what was established for the TDS for Mo-99, and the additional isotopes are not expected to impact the Financial Guarantee for the DNGS.

MSIFN Consultation understands OPG ensures compliance with waste management regulations through a comprehensive waste management program that adheres to the requirements set out in CSA N292.3-08, Management of low and intermediate level radioactive waste. This program includes:

1. **Documented Practices and Procedures**: OPG has established documented practices for the segregation, handling, and disposal of radioactive waste. These practices ensure that all waste is managed safely and in compliance with regulatory requirements.
2. **Regular Inspections and Oversight**: CNSC staff conduct regular inspections and oversight activities to verify that OPG's waste management practices comply with the conditions of their licence and regulatory requirements.

3. **Waste Minimization**: OPG implements waste minimization strategies to reduce the volume and toxicity of waste generated. This includes measures to prevent waste generation at the source and to recycle or reuse materials where possible.
4. **Qualified Third-Party Management**: For specific waste streams, such as those resulting from the processing of Lu-177 and Y-90, OPG partners with qualified third parties like BWX Technologies (BWXT)-Medical, which manage the waste under separate CNSC licences.
5. **Compliance with Environmental Protection Programs**: OPG's waste management program is integrated with its environmental protection program, ensuring that all waste management activities are conducted in a manner that protects the environment and public health.
6. **Training and Awareness**: OPG provides training to its staff on waste management procedures and regulatory requirements to ensure that all personnel are aware of their responsibilities and the importance of compliance.

OPG asserts that by maintaining these practices and procedures, OPG can ensure that all radioactive waste is managed in a safe, compliant, and environmentally responsible manner. Wastes generated from the production of Lu-177 and Y-90 at the DNGS will be managed and stored as follows:

1. **On-Site Storage**: Any waste generated during the production process, such as radiological personal protective equipment (RPPE) and other disposable materials, will be stored on-site at Darlington in accordance with OPG's existing waste management program. This program ensures that waste is stored safely and securely until it can be processed or disposed of.
2. **Certified Transport Flasks**: The irradiated targets containing Lu-177 and Y-90 will be stored in certified transport flasks. These flasks are designed to safely contain the radioactive materials and will be used for both on-site storage and transportation to off-site processing facilities.
3. **Off-Site Processing and Storage**: Residual wastes produced as a result of processing, commercialization, or use of Lu-177 and Y-90 will be managed by BWX Technologies

(BWXT)-Medical under an existing CNSC licence. BWXT will handle the processing and long-term storage of these wastes at their licensed facilities.

4. **Contingency Storage**: In the event that transportation to remove the flasks from Darlington is unavailable, an alternative location for the storage of the flasks has been designated at the Combustible Material Storage (CMS) D-22-0004. This location is prepared to safely store the loaded transport flasks containing irradiated targets temporarily.

OPG asserts that through these processes, all radioactive waste is managed and stored in a manner that complies with regulatory requirements and protects the health and safety of workers, the public, and the environment.

The regulatory hold points (RHPs) being considered for the production of Lu-177 and Y-90 at the Darlington Nuclear Generating Station are as follows:

1. **Design**: Finalized designs for the Lu-177 and Y-90 targets, including target capsule design requirements and final target drawings approved by OPG Design Authority.
2. **Radiological Hazard Assessment**: Updated Target Delivery System (TDS) ALARA assessment incorporating irradiation of Lu-177 and Y-90.
3. **Safety Analysis**: Detailed nuclear safety analysis for Lu-177 and Y-90, including disposition of any changes introduced against the existing safety case, design, or operating manual.
4. **Human Factors**: Human Factors assessment reports, including the Human Factor Engineering Program Plan and Human Factors Engineering Summary Reports.
5. **Procedures**: Marked-up revision to the Darlington Operating Manual – Target Delivery System (TDS) used for commissioning.
6. **Environmental**: Updated Predictive Environmental Assessment incorporating irradiation of Lu-177 and Y-90 or justification based on review under the ECC process for why an update is not required.
7. **Certified Transport Packages**: Copy of CNSC confirmation of transport packaging registration.

8. **Commissioning**: Commissioning documentation in accordance with OPG's Engineering Change Control (ECC) process, including commissioning specifications, workplans, and reports for Lu-177 and Y-90.

These RHPs are to be removed prior to declaring the new isotope production available for service (AFS). The purpose of these RHPs is to ensure that OPG has conclusively demonstrated that the safety case for the new isotopes is bounded by the existing safety analysis for Mo-99 and that all necessary operational readiness documentation has been reviewed and verified by CNSC staff.

The Canadian Nuclear Safety Commission (CNSC) will verify the safety analysis for the production of Lu-177 and Y-90 at the Darlington Nuclear Generating Station through the following steps:

1. **Review of Detailed Nuclear Safety Analysis**: CNSC staff will review the detailed nuclear safety analysis provided by OPG. This analysis will include finalized calculations addressing the impacts of the new targets on core reactivity, heat generation, and radioactive emissions.
2. **Verification of Compliance with ECC Process**: CNSC staff will ensure that the safety analysis reports are procured, reviewed, and approved by OPG in accordance with the Engineering Change Control (ECC) process and Reactor Safety Program.
3. **Assessment of Methodology and Conclusions**: CNSC staff will verify that the scope, methodology, conclusions, and limitations of the safety assessments are consistent with the Mo-99 assessments. This includes ensuring that the results demonstrate that the new isotopes are bounded by the existing station Safe Operating Envelope (SOE).
4. **Chemistry Assessment**: CNSC staff will review the chemistry assessment to confirm that there are no adverse chemistry impacts from the new isotopes.
5. **Commissioning Results**: CNSC staff will review the commissioning documentation, including specifications, workplans, and reports, to ensure that testing is planned and conducted to address attributes specific to the new isotopes. They will verify that the commissioning results show reasonable agreement with predictions.

6. **Resolution of Safety Significant Issues**: CNSC staff will ensure that any safety significant issues identified during the review process are resolved to their satisfaction before the regulatory hold point is removed.

By following these steps, CNSC staff will confirm that OPG's assertion that the new isotope production is bounded by the existing safety case for Mo-99 is verified and that the new activities can be safely integrated into the existing operations at the Darlington Nuclear Generating Station.

OPG will provide the following specific deliverables for verification by CNSC staff:

1. **Design**:
    - Finalized designs for the Lu-177 and Y-90 targets, including:
        - Lu-177 and Y-90 Target Capsule Design Requirements
        - Final Lu-177 and Y-90 Target Drawings approved by OPG Design Authority
2. **Radiological Hazard Assessment**:
    - Updated Target Delivery System (TDS) ALARA assessment incorporating irradiation of Lu-177 and Y-90
3. **Safety Analysis**:
    - Detailed nuclear safety analysis for Lu-177 and Y-90, including disposition of any changes introduced against the existing safety case, design, or operating manual
4. **Human Factors**:
    - Human Factors assessment reports, including:
        - Human Factor Engineering Program Plan
        - Human Factors Engineering Summary Report R000
        - Human Factors Engineering Summary Report R001
5. **Procedures**:

- Marked-up revision to the Darlington Operating Manual – Target Delivery System (TDS) used for commissioning

6. **Environmental**:
   - Updated Predictive Environmental Assessment incorporating irradiation of Lu-177 and Y-90, or justification based on review under the ECC process for why an update is not required, and how the additional isotopes will be reflected in environmental governance
7. **Certified Transport Packages**:
   - Copy of CNSC confirmation of transport packaging registration
8. **Commissioning**:
   - Commissioning documentation in accordance with OPG's Engineering Change Control (ECC) process, including:
     - Commissioning specifications for Lu-177 and Y-90
     - Commissioning workplans for Lu-177 and Y-90
     - Commissioning Reports for Lu-177 and Y-90

MSIFN Consultation understands these deliverables will be reviewed by CNSC staff to ensure that all regulatory requirements and commitments are met before the regulatory hold point is removed and the new isotope production is declared available for service.

The Delegated Authority for the removal of the Regulatory Hold Point (RHP) is the Director General of the Directorate of Power Reactor Regulation (DG-DPRR) of the Canadian Nuclear Safety Commission (CNSC).

VI. MSIFN Consultation Comments and Requests

MSIFN Consultation is generally supportive of the application, subject to the CNSC agreeing to the following requests:

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1. MSIFN Consultation requests the opportunity, concurrent with CNSC staff review, to review OPG's updated Predictive Environmental Assessment (PEA) to confirm that the environmental impacts of the new isotopes are within the previously assessed limits for Mo-99 production. MSIFN understands that this review will be part of the regulatory hold point process before the new isotopes are declared Available for Service (AFS).

2. MSIFN Consultation requests 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). MSIFN Consultation understands the purpose of these RHPs is to ensure that OPG has conclusively demonstrated that the safety case for the new isotopes is bounded by the existing safety analysis for Mo-99 and that all necessary operational readiness documentation has been reviewed and verified by CNSC staff.