



**Written submission from
Northwatch**

Mémoire de Northwatch

In the matter of

À l'égard d'

Ontario Power Generation

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**

**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**

Public Hearing – Hearing in writing based
on written submissions

Audience publique – Audience fondée sur
des mémoires

March 2025

Mars 2025

NORTHWATCH

February 27, 2025

Commission Panel
Canadian Nuclear Safety Commission
280 Slater St PO Box 1046 Stn B
Ottawa ON K1P 5S9

Ref. 2025-H-100

Sent by email interventions@cnsccsn.gc.ca

Commission Panel:

Ontario Power Generation (OPG) has made application to the Canadian Nuclear Safety Commission (CNSC) to amend Darlington Nuclear Generating Station (DNGS) power reactor operating licence to allow production of two additional medical isotopes and the CNSC made a determination that a hearing would be conducted based on written submissions only in spring 2025.

The hearing notice indicates that “the amendment being sought would authorize OPG to commercially produce 2 additional medical isotopes using the existing target delivery system, which is currently licensed only to produce molybdenum-99 (Mo-99)” but in the following paragraph states that “the licence was amended in October 2021 to authorize the production of Mo-99 using a target delivery system, and in June 2024 to authorize the production of cobalt-60 (Co-60) using adjuster rods in the reactor core.”

The hearing notice is unclear as to whether OPG is currently authorized to produce only molybdenum-99 or is also authorized to produce cobalt-60. The hearing notice does not identify which two additional medical isotopes OPG is seeking authorization to produce at the Darlington station. OPG’s application is to amend the license to allow for the production of lutetium-177 (Lu-177) and yttrium-90 (Y-90).

Northwatch has an interest in how the additional production of medical isotopes will result in changes to operations at DNGS, including and particularly changes to waste streams. We are also interested in the characterization of the isotopes as nuclear materials, and in their packaging and safe transportation of these materials.

Northwatch also has an interest in how the Commission exercises its decision-making, including through the practice of hearings-in-writing, and in Commission responses to OPG arguments that portions of the application package should be deemed confidential.

Due to capacity constraints, Northwatch carried out only a limited review of the OPG application and CNSC Commission Member Document (CMD). Our comments and observations are as follows:

- The CNSC staff CMD states that “for production of the proposed additional isotopes, OPG would be responsible for procuring targets, irradiating the targets in the Unit 2 reactor core using the existing TDS, and packaging the irradiated targets for shipment. Transportation and processing of the irradiated targets will be conducted by a qualified third party under a separate CNSC licences” but Laurentis Energy Partners (Laurentis) describes themselves as the entity which will “harvest” the isotopes from OPG’s Darlington Nuclear Generating Station using its “proprietary Target Delivery System (TDS), developed in partnership with BWXT Medical, to produce Y-90”¹

REQUEST: the relationship and division of roles and responsibilities between OPG and their subsidiary Laurentis should be clearly set out, including a clear establishment of how the CNSC exercises its regulatory authority over a licensee when the licensed activities are being carried out not by the licensee but by their corporately separate subsidiary

- The CNSC staff CMD states that separate CNSC licences, held by third parties, are required for activities associated with transportation, nuclear substance processing, and end-use; these downstream activities are out of scope of this licence amendment

REQUEST: in this instance the third-party should be named and the license identified for traceability and transparency

- The CNSC staff CMD indicates that OPG will be responsible for: Receiving and storing Ytterbium-176 and Yttrium-89 targets from a qualified supplier; Seeding and irradiating the targets to produce Lu-177 and Y-90 in the reactor core; Harvesting the irradiated targets containing Lu-177 and Y-90 from the reactor core; Packaging the retrieved capsules in a certified type B transport flask; and Transferring the transport package to a qualified nuclear shipper but as noted above Laurentis Energy describes themselves as being responsible for these activities²

REQUEST: the relationship and division of roles and responsibilities between OPG and their subsidiary Laurentis should be clearly set out, including a clear establishment of how the CNSC exercises its regulatory authority over a licensee when the licensed activities are being carried out not by the licensee but by their corporately separate subsidiary

¹ <https://laurentisenergy.com/releases/laurentis-energy-partners-to-produce-y-90-isotopes-for-life-saving-cancer-treatments-globally/>

² <https://laurentisenergy.com/releases/laurentis-energy-partners-to-produce-y-90-isotopes-for-life-saving-cancer-treatments-globally/>

- In determining whether OPG is a qualified applicant, CNS considered a number of factors including the suitability of OPG’s existing programs to continue to comply with the CNSC Regulatory Framework and appropriate and meaningful engagement with applicable Indigenous Nations and communities, but as noted above it is actually Laurentis Energy that will be carrying out the activities, not OPG – at least according to Laurentis Energy – so the determination of whether the licensee is “qualified” is incomplete if it is not the licensee who is carrying out the activities
- CNSC staff state in their CMD that “the introduction of the new isotopes will not change the overall safety case of the station” but the safety case summarized in the OPG revised application is too general to support this conclusion and as stated in the OPG application a comprehensive assessment has not yet been completed to confirm and validate the safety impacts.³
- CNSC staff are recommending that the licence amendment include a Regulatory Hold Point (RHP), under which regulatory review of the detailed safety analysis and completion of other prerequisites will be performed by CNSC staff, prior to granting OPG approval to declare the new isotope production available for service; while in other instances Northwatch has supported the insertion of regulatory hold points so that matters can be returned to the Commission for Commission members’ review and decision, we do not support the use of regulatory hold points in this instance, and consider the OPG application to be premature; this analysis should have been completed prior to the application being submitted and included in the application package

REQUEST: the Commission return the application to OPG as incomplete, to be considered only after a complete application is provided, including a detailed safety analysis which is made publicly available

- CNSC staff CMD notes that “at the time of writing this CMD there is an open inspection finding against OPG concerning oversight of contractors and the use of Laurentis Energy Partners (LEP) as a contractor to support isotope-related activities while LEP has not been formally qualified for this type of work. CNSC staff expect that OPG will take corrective actions to resolve this issue and return to compliance with their management system requirements”⁴; this note from CNSC staff is consistent with the concerns Northwatch expressed above about the lack of clarity in terms of roles, responsibilities, accountability and authorization between OPG and its contractors, including its corporately separate subsidiary Laurentis

REQUEST: the relationship and division of roles and responsibilities between OPG and their subsidiary Laurentis should be clearly set out, including a clear establishment of how

³ OPG Revised application, Attachment 3, Section 1.6 Safety Case, page 15

⁴ CNSC Staff CMD 25-H100, page 13

the CNSC exercises its regulatory authority over a licensee when the licensed activities are being carried out not by the licensee but by their corporately separate subsidiary

- The CNSC staff description of their intended response to uncovering additional and future non-compliances strongly suggest that such non-compliance events will be tolerated by CNSC staff and the finding of non-compliance will be of little to no consequence to OPG; this overly permissive approach reflects poorly on both CNSC staff and on the Commission, and contributes to the continued erosion of confidence in Canada's nuclear regulatory regime

REQUEST: The Commission should direct staff to respond strongly to non-compliance findings, particularly when they are repeat or continued instances of non-compliance, even if it is the view of CNSC staff that it is of low safety significance.

- CNSC staff stated in their CMC that tritium from residual heavy water collected during harvesting and drying the targets in the TDS airlock was the primary source of emissions attributed to the production and harvesting of Mo-99, but do not indicate whether there will be additional increases in tritium emissions as a result of adding two additional isotopes to the production schedule; tritium emissions from the Darlington station are a matter of public concern, and a potential increase in tritium emissions should be clearly stated identified in the CMD (or conversely, if there is evidence that the additional activities will not result in additional emissions that should be clearly stated).⁵

REQUEST: in their revised CMD (after OPG has resubmitted their application with a complete information set) CNSC staff should make a clear and quantified statement about tritium releases related to medical isotope production

- As noted in the CNSC staff CMD, OPG's application does not describe the wastes as a result of these additional activities, including wastes that will be generated through maintenance or routine operations; CNSC staff "recognize that this waste stream will be handled by OPG's existing waste management program and does not represent a new type of waste for OPG" which Northwatch does not dispute; however, it is a requirement of licensing that a licensee describe the wastes, including volume and type, and as such the OPG application must provide this information. However, this information has not been provided.⁶

REQUEST: the Commission must require of OPG that they include a detailed statement of wastes that will be generated as a result of these activities, and how they will be managed (including management within their existing waste management programs).

⁵ CNSC Staff CMD page 23

⁶ CNSC staff CMD, page 25

- CNSC staff are recommending that the Commission delegate authority for the consent to remove the RHP to the Director General of the Directorate of Power Reactor Regulation (DG-DPRR) of the CNSC; Northwatch disagrees with this recommendation

REQUEST: the Commission return the application to OPG as incomplete, to be considered only after a complete application is provided, including a detailed safety analysis which is made publicly available, and that it return to the Commission in a public hearing for decision

- Ontario Power Generation has redacted significant portions of their application documents on the basis of their containing information that should remain confidential because it is of a “scientific, and technical nature that is treated consistently as confidential”⁷; Northwatch strongly rejects the argument that information should be withheld from the public because it is scientific or technical in nature. In 2024 the CNSC posted a discussion paper “DIS-24-05, Proposals to amend REGDOC-3.2.1, Public Information and Disclosure” for comment; while the comment table is posted on the “Discussion Paper” page of the CNSC web site ⁸ with a note that the now closed period for feedback on the comments was in January 2025, the comment table is not posted on the “Consultations”⁹ of the CNSC web site (Northwatch notes that this is a recurring problem on the CNSC web site).

REQUEST: the Commission should direct that information is not to be withheld on the basis of it being of a scientific and technical nature, and should develop mechanisms such as other tribunals have done to make technical information more available

Thank you for your attention and consideration.



Brennain Lloyd
Northwatch

⁷ OPG Request for Confidentiality of Material Submitted in Relation to CD# NK38-CORR-00531-25810, as posted at <https://api.cnscccsn.gc.ca/dms/digital-medias/CMD25-H100-Revised-request-from-Ontario-Power-Generation-to-protect-confidential-information.pdf/object>

⁸ See <https://www.cnscccsn.gc.ca/eng/acts-and-regulations/consultation/history/>

⁹ See at <https://www.cnscccsn.gc.ca/eng/acts-and-regulations/consultation/>