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**Written submission from the  
Canadian Association of Nuclear  
Host Communities**

**Mémoire de la  
Canadian Association of Nuclear  
Host Communities**

In the matter of

À l'égard d'

**Ontario Power Generation**

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**Ontario Power Generation**

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**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**

## REVIEW

### **Application for amendment of the Darlington Nuclear Generating Station Power Reactor Operating Licence to allow production of additional medical isotopes**

#### **Introduction and scope**

The Canadian Nuclear Safety Commission (CNSC) amended the Darlington Nuclear Generating Station (DNGS) Power Reactor Operating Licence (PROL) in October 2021, authorising Ontario Power Generation (OPG) to possess, transfer, process, package, manage, and store Molybdenum-99 (Mo-99) and its associated decay products at DNGS. In 2023, the subsequently installed Target Delivery System (TDS) – sometimes termed the Isotope Irradiation System – was commissioned in Unit 2. Comprised of a target loader and four target (basket) elevators (situated in unused adjuster assembly locations) separated by an airlock; the TDS allows strings of Molybdenum-98 (Mo-98) containing target capsules to be inserted (seeded), via cable winch, in perforated baskets through perforated guide tubes into the reactor core for a pre-defined irradiation period. The perforations facilitate heat removal through contact with heavy water moderator. Due to the high neutron flux therein; in the core, neutron capture reactions lead to the production of Mo-99. Once the irradiation period is over, target capsules are removed from the core (harvested) before being sent offsite for processing. At all times, the produced radioisotope and precursor are enclosed within a multibarrier containment system, which from inside out comprises ampules, zirconium capsules, and air lock sealed tubing for sample transport. High Efficiency Particulate Air (HEPA) filters provide further protection in case of exhaust gases becoming contaminated. As resultant capsules are category III sources, their offsite transport requires use of a CNSC-certified type B flask.

After successful production of Mo-99 had been demonstrated, in December 2023, OPG notified the CNSC that it would be seeking amendment of its DNGS Power Reactor Operating Licence (PROL 13.03/2025 initially, but latterly PROL 13.04/2025), to permit production of two additional medical radioisotopes, Lutetium-177 (Lu-177) and Yttrium-90 (Y-90), in the Unit 2 TDS. The public-facing application submitted in 2024 was redacted on request from OPG for commercial-in-confidence reasons, but this was later relaxed.

This review scrutinises the licence amendment application package, including one update disseminated by the CNSC, and the Commission Member Document (CMD) CMD25-H100 prepared by CNSC staff for Commission members, outlining the key findings and commenting on the adequacy of the application, and any notable strengths, weaknesses, or oversights on behalf of the Canadian Association of Nuclear Host Communities and the Municipality of Clarington. As production of Mo-99 and the use of the TDS is permitted under the extant DNGS PROL, they do not form part of OPG's licence amendment application and are out of scope for consideration herein.

For context, the CNSC considers 14 safety and control areas (SCA) in its licensing basis and for compliance verification activities. These are: Management System; Human Performance; Operating Performance; Safety Analysis; Physical Design; Fitness for Service; Radiation Protection; Conventional Health and Safety; Environmental Protection; Emergency Preparedness and Fire Protection; Waste Management; Security; Safeguards and Non-Proliferation; and Packaging and Transport.

### Key findings

OPG seeks only to modify activity (vi) in part IV of the DNGS PROL to state: “possess, transfer, process, package, manage and store Molybdenum-99, Lutetium-177 and Yttrium-90 radioisotopes and their associated decay isotopes” from the extant phrasing that focuses solely on Molybdenum-99. Although this is a “new activity” because the materials are different, in practice it essentially follows the same process and procedures as for Mo-99 production, and the apparatus used is the same. This is the fundamental basis of the case made in the licence amendment application, namely that the new activity is just a minor change as it uses the existing, authorised TDS, follows the same approach used for production of Mo-99 and that in all safety and performance related aspects, is bounded by the safety case for production of Mo-99. Regarding the TDS, after almost two years commissioning and use, OPG reports that it operates as designed, has not had issues with maintaining containment integrity, has not impacted safe operation of the plant in any way, has not led to any radiation protection concerns, and has not resulted in meaningful differences in measured emissions. Staff operating the TDS are in addition to the minimum complement necessary for safe power operation. All-in-all, operating the TDS is a low-risk activity and hence continued use in the same manner appears safe.

Although the manner of operating the TDS will be essentially the same, the irradiation periods specified for production of Lu-177 and Y-90 were still preliminary at the point OPG submitted the application for licence amendment. Whilst Lu-177 production (in Ytterbium-176 targets) is expected to require seven days of irradiation, the same as for making Mo-99, Y-90 production (in Yttrium-89 targets) is expected to need only three days irradiation. It is not clear how this will impact commercial isotope production. It seems that, currently, for Mo-99, one week irradiation campaigns are typical. Lu-177 production clearly fits this model, but Y-90 does not. It is also not clear whether this will lead to more frequent production runs (although it should be noted that in their CMD, CNSC staff recommended to the Commission that it not explicitly restrict the number of seeding operations that OPG can perform in a year), putting additional wear on the TDS mechanisms, and whether this would consequently lead to increased maintenance efforts – potentially increasing worker dose. It is notable that, in their CMD, the CNSC reported that there was a cable failure in the winch mechanism during TDS commissioning. Whilst this was not a safety significant event, in absence of further information, one could speculate that more frequent motions could conceivably result in a similar failure.

As the additional radioisotopes that will be produced are different to Mo-99, the decay products produced will also differ. These products, caused by neutron capture in capsule materials and impurities, are typically short-lived and thus to keep dose rates to workers As-Low-As-Reasonably-Achievable (ALARA), target baskets are held in an out-of-core dwell position under the Reactivity Mechanism Deck (RMD) for a pre-defined dwell period before being transferred to the flask loader for transport off site. This dwell period, which for Mo-99 is not less than two hours for physical, practical and procedural reasons, allows short-lived decay products to be reduced in activity to safer levels. As the radioactive source terms resulting from Lu-177 production are predicted to be higher than for Mo-99, OPG will increase the dwell time accordingly. This may increase the total harvesting and reseed time beyond the current two to three hours. Adjustments to dwell times, along with irradiation periods and necessary labelling, will require minor TDS software changes. Due to its lack of safety significant interfaces with the rest of the plant, the extant PROL already permits these. It was stated that all changes, to software or otherwise, will be made through OPG's existing Engineering Change Control (ECC) program.

The most significant difference between production of Mo-99 and production of Lu-177 or Y-90 are the targets themselves, although OPG asserts that new target designs will be very similar to those previously approved. However, at the point of the licence amendment application being submitted, these designs were only preliminary – a point highlighted by CNSC staff in their CMD. That said, sufficient information was provided by OPG such that it can be understood that the dimensions of each capsule will be essentially the same; that each contiguously-sealed capsule will be made of zirconium (similar to CANDU fuel element cladding); that the (precursor) Ytterbium-176 and Yttrium-89 targets will be in a form amenable for Lu-177 and Y-90 post-irradiation processing; and that they will include a Mo-99 'ballast' to provide comparable weight. OPG has undertaken preliminary reactor physics calculations and have concluded that the reactivity worth, a measure of how a given material positively or negatively impacts neutron multiplication in a reactor, of each new target capsule will be lower than that for Mo-99. Consequently, from this, and their preliminary safety assessment which identified 11 events and potential impacts but did not change conclusions or introduce events not accounted for in Mo-99 production, OPG assert that the Mo-99 safety case is bounding for production of the two new isotopes, and that their production will not present any risk to safe operation of Unit 2.

Due to the preliminary nature of the target designs and necessary safety analysis, in their CMD, CNSC staff have recommended to Commission members that "OPG submit the final target design, safety analyses and commissioning report to be reviewed prior to removing a regulatory hold point prior to AFS of Lu-177 and Y-90, to verify OPG's assertion that the existing Mo-99 safety analysis will remain bounding for the Lu-177 and Y-90 targets and that the SOE will be preserved." A Regulatory Hold Point (RHP), a mechanism used successfully in the original TDS deployment, is essentially a conditional

approval that allows a licence application to be approved but the activities described therein to be permitted on a stepwise basis. At each step, of which there may be only one, CNSC staff verify that the conditional actions are complete and satisfactory prior to allowing a licensee to proceed to the next step (or full operation). In this case, the RHP would be included as part of updated licence condition 15.6, and, until removed, would preclude Lu-177 or Y-90 production being Available for Service (AFS). Whilst swapping out targets in the way described should present no significant additional risks, this due diligence on the part of the regulator is prudent and should allay any concerns intervenors may have over the maturity of technical details included within the application. For the removal of the proposed RHP, in their CMD, CNSC staff also recommend regulatory review of OPG's Predictive Effects Analysis (PEA), human factors assessment, and (plant) chemistry assessment (despite OPG confirming the new isotopes are insoluble in water) for the new targets and isotopes. Although OPG determined that external radiation hazards from the new targets are bounded by those accounted for in Mo-99 production, CNSC staff recommend they also review OPG's revised ALARA Assessment report prior to RHP removal. Administrative or procedural updates made to reflect production of the new isotopes will also be reported to the CNSC.

In their CMD, CNSC staff noted that OPG's application did not describe wastes generated through operation and maintenance but pointed out that such wastes would be of the types handled by OPG's existing waste management program. Similar arguments can be made for wastes created through decommissioning. In other words, the requested new activity will not generate any new wastes at DNGS. In the licence amendment application itself, under the Waste management SCA it had been indicated that empty target shells, classified as Low-Level Waste (LLW), would be returned to OPG. However, in October 2024, in CD# NK38-CORR-00531-25747 P "Darlington NGS – Update to Application for Amendment to Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production" OPG confirmed that this would no longer be the case. Instead, BWXT-Medical will be responsible for managing their storage and disposal.

The licence amendment application requires no changes to the licencing basis for DNGS.

Reflecting the nature of licence amendment, no specific engagement activities appear to have been undertaken, although a communications and engagement plan is referenced. It is unclear whether there was significant post-notification interest to necessitate in-depth engagement or whether first nation communities were satisfied. CNSC noted that, in their engagement on this application, only two nations requested project-specific meetings.

### Conclusions

Global demand for medical radioisotopes is growing, providing OPG with significant new revenue streams at minimal additional cost or risk and significant societal health benefits.

At its heart, the requested licence amendment is trivial, simply swapping out one type of target for another of comparable size and properties and thereafter following the same processes and procedures as used for production of Mo-99. Like with Mo-99 production, analysis suggests there will be no significant external radiation hazard to workers and no meaningful emissions to the environment. Moreover, there will be no residual waste from Lu-177 and Y-90 production stored on site. Consequently, workers, the public, and the environment will all be protected. However, these assertions from OPG are predicated, at least in part, on preliminary analysis and, at point of submission, the new target designs were not finalised and thus the supporting nuclear safety assessment was incomplete. It seems peculiar that OPG proceeded with their application without at least having a final target design, a task that is not particularly hard to complete, but perhaps commercial opportunities necessitated submitting the application with this level of technical maturity. Qualified to undertake the work, OPG have outlined a pathway to satisfactory completion, however the CNSC have recommended to the Commission that a Regulatory Hold Point be added as a licence condition. For the RHP to be removed, and thus for Lu-177 and Y-90 production to be Available for Service, the CNSC has specified a series of verification steps to ensure OPG has completed the target design, and otherwise demonstrated that its assertions are sound. This is a prudent step which should provide interested parties with confidence. Given this, SMR Insights has no technical or safety concerns pertaining to the requested licence amendment.

It is the opinion of SMR Insights that CAHNC and the Municipality of Clarington should have no concerns about the proposed production of Lu-177 and Y-90 in the Unit 2 TDS at Darlington NGS and can confidently support the DNGS PROL amendment with the regulatory hold points as recommended by CNSC staff.

### References

CD# NK38-CORR-00531-25215 “Darlington NGS – Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”, OPG, 2024.

CMD25-H100 “Darlington Nuclear Generating Station Request to amend the PROL for the production of additional isotopes using the Target Delivery System”, CNSC, 2025.

CD# NK38-CORR-00531-25747 P “Darlington NGS – Update to Application for Amendment to Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”, OPG, 2024.