



25-H107 - CNSC Staff Submission

Ontario Power Generation Inc. Request for Commission Approval for Installation and Operation of a Target Delivery System (TDS) on Additional Units at Darlington NGS

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Summary	In 2021, the Commission approved a request from OPG to install a “Target Delivery System” (TDS) for the purposes of producing medical isotopes (in the initial request, this was restricted to Molybdenum-99) on Unit 2 at Darlington NGS. In the Record of Decision that accompanied this approval (DEC 21-H107 e-Doc 6667685), the Commission included a requirement for OPG to seek approval from the Commission, prior to installing the TDS on additional units. OPG’s current application seeks explicit consent from the Commission to install a TDS on the remaining units at Darlington



	NGS, starting with Unit 3. This now includes additional radionuclides as authorized by the Commission in DEC 25-H100. CNSC staff have confirmed that OPG has not altered the design or the expected operations relative to the currently authorized TDS. As such, CNSC staff conclude that installing a TDS on additional units at Darlington NGS is a low-risk activity that remains within the existing station safe operating envelope.
Sommaire	En 2021, la Commission a approuvé une demande d’OPG visant à installer sur la tranche 2 de la centrale de Darlington un « système de livraison de cibles » (SLC) à des fins de production d’isotopes médicaux (la demande initiale se limitait au molybdène 99). Dans le compte rendu de décision qui accompagnait cette approbation (DEC 21-H107 e-Doc 6667685), la Commission a inclus l’obligation pour OPG de demander l’approbation de la Commission avant d’installer le SLC sur d’autres tranches. La demande actuelle d’OPG vise à obtenir le consentement explicite de la Commission pour l’installation d’un SLC sur les tranches restantes de la centrale de Darlington 25-H107 - Mémoire du personnel de la CCSN ii, en commençant par la tranche 3. Cette demande inclut maintenant des radionucléides supplémentaires, comme il a été autorisé par la Commission dans le DEC 25-H100. Le personnel de la CCSN a confirmé qu’OPG n’a pas modifié la conception ni les opérations prévues relativement au SLC actuellement autorisé. Par conséquent, il conclut que l’installation d’un SLC sur des tranches supplémentaires de la centrale de Darlington est une activité à faible risque qui demeure à l’intérieur des paramètres d’exploitation sûre de la centrale existante.



CMD 25-H107

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2025-10-21

Signed by:

2025-10-21

X

Signed by: Viktorov, Alexandre

Alexandre Viktorov, Ph.D.

Director General, Directorate of Power Reactor Regulation

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Land acknowledgement

The Darlington site is located on the north shore of Lake Ontario in Clarington, Ontario, 5 kilometers outside the town of Bowmanville and 10 kilometers southeast of Oshawa. The Darlington site resides on lands in which many Indigenous Nations and communities have a vested interest and rights, lying within the lands and waters of the Michi Saagiig Anishinaabeg, the Gunshot Treaty (1877-88), the Williams Treaties (1923), and the Williams Treaties Settlement Agreement (2018).

Plain Language Summary

Per the Commission's direction in the Record of Decision [DEC 21-H107](#), *authorizing the installation of a Target Delivery System (TDS) for the production of molybdenum-99 (Mo-99) on Unit 2 of the Darlington Nuclear Generating Station (NGS)*, OPG was directed to return to the Commission prior to installing the TDS on any other units at Darlington NGS. As OPG is pursuing installation of a TDS on Unit 3, OPG submitted a request to the Commission to install a system similar to the one that is already installed on Unit 2. CNSC staff have reviewed the information submitted by OPG and have no concerns with the evolutionary and unit specific differences in the next iteration of the TDS design and safety case.

Further, CNSC staff recommends that future installations and operations of TDS on additional units at Darlington NGS be authorized by CNSC staff, specifically the

- Executive Vice President/Chief Operations Officer (EVP/COO);
- Director General of the Directorate of Power Reactor Regulation (DG-DPRR); and/or,
- Regulatory Program Director of the Darlington Regulatory Program Division (RPD-DRPD)

following verification of any pertinent design, safety analysis, and documentation demonstrating adherence to applicable processes. Specifically, the purpose of CNSC staff's verification will be to ensure that the licensing basis, as established in proceedings 21-H107 and 25-H100, remain bounding.

Referenced documents, beyond the application, CMDs, and Record of Decision, in this CMD are available to the public upon request, subject to confidentiality considerations.



CMD Structure

This Commission Member Document (CMD) includes the following:

- An overview of the matter being presented
- Overall conclusions and overall recommendations
- General discussion pertaining to Commission directives that are relevant to this submission
- Discussion about other matters of regulatory interest
- Appendices material that complements items 1 through 4
- Current licence
- Changes proposed to the licence conditions handbook

1 Overview

1.1 Background

Darlington NGS is located in the Province of Ontario on the north shore of Lake Ontario, in the Municipality of Clarington and Regional Municipality of Durham. The facility is owned and operated by the licensee, OPG, a Canadian corporation, whose head office is located in Toronto, Ontario. Darlington NGS consists of four 881 megawatt CANDU reactors which came into service between 1990 and 1993. In September 2025, the Commission renewed the PROL for Darlington. The current licence (PROL 13.06/2025) remains in effect until the end of November 2025, following which the renewed PROL will take effect and remain valid until November 2045 (PROL 13.00/2045).

In 2021, the Commission approved a request from OPG ([DEC 21-H107](#)) to install a “Target Delivery System” (TDS) for the purposes of producing molybdenum-99 (Mo-99) medical isotopes (hereby referred to as “radionuclides”) on Unit 2 at Darlington NGS [1]. In a separate recent decision ([DEC 25-H100](#)), the Commission authorized the production of two additional radionuclides: yttrium-90 (Y-90) and lutetium-177 (Lu-177) and established a regulatory hold point (RHP) prior to permitting full scale production of those radionuclides [2]. This authorization was contingent on OPG validating and demonstrating that operation of the TDS associated with the production and handling of Mo-99 remains the bounding case for the other radionuclides (Y-90 and Lu-177) on Unit 2. As such, this CMD (25-H107) will refer to Mo-99 to encompass CNSC staff’s expectations for managing and handling all authorized radionuclides and their associated hazards.

It is noted that this CMD has simplified the name of the system to *the Target Delivery System (TDS)* from *the Mo-99 Isotope Irradiation System / Target Delivery System (IIS/TDS)* which was used in CMD 21-H107 [3]. This was changed to align with OPG’s language.

In the Record of Decision for the request made in 2021, [DEC 21-H107](#) [1], the Commission required OPG to obtain approval, from the Commission, prior to installing the TDS on additional units. This restriction, while not explicitly documented in PROL 13.06/2025, has been incorporated in the Licence Conditions Handbook (LCH) and is a part of the licensing basis supporting PROL section IV, item (vi) and Licence Condition 15.6 for TDS operations and radionuclide production at Darlington NGS.

OPG’s current submission [4] requests the Commission’s approval to permit the installation of TDS on additional units at Darlington NGS – representing a change to the licensing basis, that, if granted, will be documented in the LCH. OPG’s request is



accompanied by documentation to support a specific TDS installation at Unit 3 (planned for a 2026 outage window) as a basis for their request to authorize expansion of TDS on any additional unit at Darlington NGS without returning to the Commission for each instance.

Should the Commission accept OPG's request, additional installations of TDS beyond Unit 3, will be handled in accordance with processes in place, both for OPG (Engineering Change Control [ECC]) and CNSC staff (regulatory oversight practices), regarding plant modifications to confirm that they remain within OPG's licensing basis.

1.1.1 Scope of OPG's Project and Responsibilities

The request to authorize expansion of a TDS to additional units at Darlington NGS will not change any of the currently authorized activities and conditions of the PROL, nor any of the accompanying licence-related accountabilities and responsibilities. Specifically, and non-exhaustively, in support of using a TDS to facilitate radionuclide production on any unit, OPG will be responsible for:

- Maintaining continued safe station operations within the existing, established, operating parameters
- Receiving and storing the non-nuclear precursor materials molybdenum-98 (Mo-98), ytterbium-176 (Yb-176) and yttrium-89 (Y-89) targets from a qualified supplier in accordance with OPG's management system
- Seeding (introducing capsules containing precursor materials into the core) and irradiating the targets to produce Mo-99, Lu-177 and Y-90 in the reactor core
- Harvesting the irradiated targets containing Mo-99, Lu-177 and Y-90 from the reactor core, which includes a crucial and radionuclide specific dwell interval to allow the highest-energy, shortest-lived activation products to dissipate, and ending in the packaging of the retrieved capsules into a certified type B transport flask (a largely automated process)
- Transferring the transport package to a qualified nuclear shipper for shipment to a licenced processing facility (not operated by OPG or part of this request)

1.2 Highlights

This CMD provides the results of CNSC staff's review of OPG's request and CNSC staff's recommendations to the Commission to permit the installation and operation of additional TDS equipment at OPG's Darlington NGS. It is important to note that due to the fact that a decision was pending regarding renewal of the Darlington NGS PROL, the Commission Registry paused all licensing matters to the conclusion of that decision. A Notice of Hearing was therefore delayed until after DEC 25-H2 was issued, which has



delayed the commencement of public engagement and Indigenous consultation activities. Note that information pertaining to planned and ongoing public engagement indigenous consultation activities are discussed in Section 4.

Since the installation and operation of TDS is currently a licensed activity at Darlington NGS, with an established safety case, discussion of the TDS is focused only on key differences as a result of OPEX, evolution, and/or unit-to-unit design differences. The overall conclusion is that these changes do not have an impact on OPG's licensing basis for the Darlington NGS and should not prevent installation and operation of TDS on additional units.

1.3 Overall conclusions

CNSC staff conclude that:

- 1) installation and operation of additional Target Delivery Systems (TDS) on additional units at Darlington NGS for the purposes of producing Mo-99, Lu-177, and Y-90 is a low-risk activity that can be conducted safely and within the established licensing basis. CNSC staff also conclude that OPG remains qualified and competent in implementing their licensed activities.
- 2) the supporting case brought forth by OPG in its request for the installation and operation of a TDS on Unit 3 confirms that any required design changes to the TDS are being managed adequately within OPG's approved ECC process and do not have an adverse impact on the safety case.
- 3) OPG has made adequate efforts to consult and engage with Indigenous Nations and communities and the public as required by their current operating licence and will continue to do so throughout progress of future projects.

1.4 Overall recommendations

CNSC staff recommend the Commission:

(a) Approves the installation and operation of a TDS on Unit 3 for the production of any radionuclides authorized by the Commission

(b) Authorizes the EVP/COO, DG-DPRR and/or RPD-DRPD of the CNSC to determine whether to accept future TDS installations and operations in other units to produce previously authorized radionuclides (i.e., Mo-99, Y-90 and Lu-177), provided that OPG demonstrates that:

- the ECC process has been followed and produced a design consistent with all applicable regulatory requirements



- a safety case has been prepared and demonstrated that operations will continue to be a low-risk activity
- the activity will remain within the plant's existing licensing basis.

CNSC staff propose that Licence Condition 15.6 in the PROL remain unchanged. CNSC staff will use the LCH to identify the units for which a completed, design and safety case have been accepted, and installations and operations approved. Specifically, the proposed updates to section 15.6 of the LCH states that OPG can produce any radionuclides authorized by the Commission at Darlington NGS Unit 2 and Unit 3. The proposed licence and LCH are included in Appendix A of this CMD.

Lastly, the Commission's direction in [DEC 21-H107](#), specific to producing additional radionuclides [1], continues to be relevant. Specifically, if OPG wishes to produce additional radionuclides (i.e., Mo-99, Y-90 and Lu-177) using any existing TDS at Darlington NGS, OPG will need to bring the matter before the Commission for consideration by providing a revised safety case for the continued safe operation of the TDS and the reactor units with the addition of any proposed radionuclides.

2 Environmental protection review

CNSC staff reviewed OPG's submission to identify the type of environmental review required. As part of this process, CNSC staff assessed whether an integrated impact assessment or a federal lands review under the Impact Assessment Act (IAA) was required. CNSC staff determined that neither are required because the request does not include activities listed in the IAA Physical Activities Regulations that require an impact assessment or that meet the definition of a project on federal lands. Further, in accordance with CNSC's mandate under the [NSCA](#) and associated regulations, CNSC staff conduct environmental protection reviews (EPRs) when considering any request by a licensee where there are potential environmental interactions. EPRs help support the Commission's conclusion on whether the applicant's proposal provides adequate protection of the environment and the health of people. An EPR was conducted for this request, which determined that the environmental impacts of introducing and operating additional TDS equipment for the production of increased volume of medical radionuclides are minimal and OPG's programs are sufficient to protect the environment and the public.

Specifically, CNSC staff conducted a review of the Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3) (NK38-30550-00051 R000), which OPG included as Enclosure 2 of its request [4]. CNSC staff conclude that the information provided by OPG regarding environmental protection is adequate to



demonstrate meeting the applicable regulatory requirements under the [NSCA](#) and associated regulations. Further, CNSC staff conclude that OPG will make adequate provision for the protection of the environment and the health of persons. CNSC staff will continue to verify and ensure through ongoing licensing and compliance verification activities and reviews, that the environment and the health of persons are protected and will continue to be protected.

3 General assessment of applicable Commission directives

This CMD will focus on addressing the Commission's directives from [DEC 21-H107](#) and [DEC 25-H100](#), as they pertain to OPG's performance and readiness to proceed with installing and commissioning a TDS on Unit 3, as well as additional units in the future.

3.1 Commission directives

In 2021, the Commission authorized OPG to install a TDS for the purposes of producing medical radionuclides, namely Mo-99, on Unit 2 in the Darlington NGS ([DEC 21-H107](#)) [1]. The Commission considered that the production of Mo-99 is a low-risk activity and that OPG was qualified to carry out such an activity. The Commission's Record of Decision was accompanied by an amended licence (PROL 13.03/2025), with changes to the list of authorized activities (section IV – item vi) and Licence Condition (section VI – Licence Condition 15.6).

In its decision, the Commission required OPG to obtain approval from the Commission to produce Mo-99 in any other reactor unit at the Darlington NGS, and to demonstrate that the production of Mo-99 in any other unit is a low-risk activity that can be executed safely. Further, the Commission required OPG to request Commission approval in order to use the TDS to produce other types of radioisotopes at the Darlington NGS. In [DEC 25-H100](#), the Commission authorized OPG to produce Lu-177 and Y-90 using the TDS in Unit 2.

Technical details are included in the CMD only if they were to differ materially from those already part of OPG's licensing basis. This CMD provides additional information on the status of the directives issued by the Commission for the Unit 2 TDS and commitments made by both CNSC staff and OPG [1].

In its decisions [DEC 21-H107](#) and [DEC 25-H100](#), the Commission included directives on OPG and CNSC staff as it related to the first application of TDS in Unit 2 and engagement



activities on transportation of nuclear substances. The following subsections provides CNSC staff's assessment on the Commission directives that are applied for Unit 2, and their applicability to TDS expansion on other units at Darlington NGS.

As a note of clarity regarding the presentation of directives in the subsequent subsections of this part of the CMD, any directives pertain to the same topic will be grouped above a single discussion for completeness, rather than addressed individually.

3.1.1 Commission directives from DEC 21-H107 applicable to expanding installation and operations of a TDS on any unit at Darlington NGS

The following are Commission Directives from [DEC 21-H107](#) that are relevant to this CMD as they relate to expanding installation and operation of a TDS on any unit at Darlington NGS.

12. If OPG plans to produce Mo-99 in any other reactor unit at the Darlington NGS, it must obtain approval of the Commission, and demonstrate that the production of Mo-99 in any other unit is a low risk activity that can be executed safely.

79. Due to the first-of-a-kind nature of the Mo-99 IIS design and to allow the public additional opportunity to participate, the Commission directs that OPG must obtain the approval of the Commission, rather than concurrence from CNSC staff, if it means to produce Mo-99 in a unit other than Unit 2.

86. The Commission directs, if OPG plans to produce Mo-99 in any reactor unit at the Darlington NGS other than Unit 2, that OPG must obtain approval of the Commission and demonstrate that the production of Mo-99 in any other unit is a low risk activity that can be executed safely.

OPG's request for installation of a TDS on additional units at Darlington NGS included plans for installation on Unit 3 [4]. The documentation provided in this request indicated that a largely identical design to the TDS installed on Unit 2 will be used in other units [5]. The safety case and operational assessments for Unit 2 were reviewed in depth by CNSC staff as part of a separate licensing process and as documented in CMD 21-H107 [3]. As part of OPG's current application, a safety case was prepared and provided to support the review of the licensing basis for Unit 3 (see confidential Enclosure 1 of [4]).



CNSC staff are satisfied that the changes represent foreseeable evolutions to the design that either:

- are informed on OPEX considered from Unit 2 and continue to offer adequate protection of workers; in particular, OPG is introducing changes to:
 - Target elevator cladding (to improve protection of components above the reactor from wearing)
 - Bolted joint and seismic brace of the air-lock support structure/platform (design change to facilitate installation and fit-up)
 - Target transfer deck plates (optimization to facilitate installation and removal without affecting assembly components)
 - Shut-off rod assemblies (to facilitate maintenance); or,
- account for inherent inter-unit differences that do not require a change to the design basis to accommodate; for example, to support differences in:
 - Vertical alignment (to accommodate slight changes between RMD locations from unit-to-unit)
 - Contaminated exhaust ducting (small pathway change to accommodate for cobalt equipment present in Unit 3)
 - Electrical components that have since been obsoleted (replacement of components with available equivalents)
 - Stairs and handrails (to accommodate Cobalt equipment in Unit 3, includes an additional protective barrier)

CNSC staff's review of OPG's request for installation of a TDS on Unit 3 confirms that the design, methodology and conclusions in the summary safety case submitted by OPG are consistent with those provided to the Commission previously submitted for Unit 2. Further, CNSC staff are satisfied that any changes have negligible or positive impact on safety. Thus, CNSC staff find the installation of a TDS on Unit 3 to be a low-risk activity that OPG is qualified to undertake. The scope of proposed work is in alignment with that the Commission approved for Unit 2, as previously presented to the Commission [5].

3.1.2 Commission directives applicable to the authorized TDS on Darlington Unit 2

As of the writing of this CMD, OPG has declared the Unit 2 TDS available for operations and is supporting its supply chain partners in progressing through other regulatory activities, such as obtaining US Food and Drug Administration (FDA) approval.

OPG has proceeded through its ECC process to complete all activities related to the updated design, installation and commissioning of the TDS for Unit 2. Should the



Commission accept OPG's proposal to install a TDS on Unit 3, CNSC staff will apply the experience from the oversight of Unit 2 TDS in providing regulatory oversight for the Unit 3 TDS, as well as any future TDS installations.

The directives specific to Unit 2, highlighted in boxes throughout this sub-section, were issued by the Commission in [DEC 21-H107](#) [1].

34. OPG asserted that the operation of the Mo-99 IIS would not require any changes to safety limits, special safety system trip set points, accident management procedures, or other aspects of its safe operating envelope (SOE) program. CNSC staff reported that OPG has a mature SOE program that is compliant with CSA N290.15. CNSC staff assessed OPG's submitted documentation and determined that OPG sufficiently demonstrated that the Mo-99 IIS will not invalidate the current SOE. The Commission directs CNSC staff to verify this determination through its review of OPG's final IIS commissioning report.

Following removal of the two RHPs established by the Commission in [DEC 21-H107](#), OPG submitted two TDS Commissioning Reports for Unit 2 to CNSC staff in November 2023 [6, 7] as previously committed. In addition to these reports, CNSC staff conducted additional verification activities to verify that OPG implemented a SOE program, which was designed to ensure that station operations conform to the safety analysis and accident response procedures to which the station is licensed. OPG confirmed that installation of the TDS for Mo-99 did not require revision to the Operational Safety Requirements (OSRs) documentation, which defines the specific technical information for the plant to be operated within the SOE. OPG further stated in their application for a licence amendment to authorize additional radionuclides that production of Lu-177 and Y-90 will also not have an impact on any SOE documentation [4]. CNSC staff proposed including review of the detailed nuclear safety analysis to confirm the continued validity of the existing SOE as a condition of a proposed RHP under Licence Condition 15.4 to support Licence Condition 15.6 of PROL 13.06/2025 [8]; this RHP was included by the Commission in [DEC 25-H100](#).

CNSC staff are not recommending an additional RHP for the TDS for Unit 3. The TDS design for Unit 3 is consistent with the design for unit 2, and the isotopes under consideration have all been authorized by the Commission in prior decisions. CNSC staff are proposing that the Commission grant approval authorization to CNSC staff for the installation, commissioning and operations of TDSs on additional units at Darlington NGS, in a manner similar to current practice regarding projects and modifications proposed under existing licensed activities.



CNSC staff will continue to provide appropriate oversight of OPG's ECC process and the turnover to operations. In particular, CNSC staff will verify selections of project governance and ECC deliverables as the project progresses. As the Unit 2 system has completed its commissioning and turnover to operations, it is subject to oversight as per the CNSC's baseline inspection plan for Darlington NGS and reactive oversight activities, as required. CNSC staff will also ensure that the release of the existing RHP under Licence Condition 15.4 has been completed prior to production of additional isotopes in the first unit (Unit 2) which are predicated on satisfactory completion of those established prerequisites.

35. OPG will submit necessary procedures, including the new IIS operating manual, and the Commission directs CNSC staff to verify prior to the operation of the Mo-99 IIS.

37. The Commission is satisfied that OPG is following its management system process in the development of new procedures for the Mo-99 IIS and directs CNSC staff to check the completion of these documents under planned regulatory oversight.

CNSC staff note that OPG's nuclear operations program includes governance for the development and revision of technical procedures. This program is sufficient for managing changes to necessary documentation as they relate to a TDS on Unit 3.

An operating manual has been produced for TDS on Unit 2 per OPG's process and submitted to CNSC staff, as required by the LCH. Further, as part of OPG's application for the production of additional isotopes, OPG stated that "*the operating manual NK38-OM-30550 Target Delivery System Operating Manual and NK38-MMP30550-13 Molybdenum-99 Target Delivery System Transport Package Flasking will be updated to incorporate production of Lu-177 and Y-90 in accordance with OPG governance*" [9]. CNSC staff will be reviewing the revised operating manual that will be provided by OPG under the RHP established in [DEC 25-H100](#).

Since both documents are listed in the LCH as 'documents requiring written notification of change', OPG will provide the updated documents for CNSC staff review as part of existing processes under Licence Condition G.2. CNSC staff will verify that the updated operational procedures developed for the TDS on Unit 3 will be implemented in a similar manner as to that of Unit 2, and that any operating experience gained from the operation of Unit 2 is appropriately documented and applied to Unit 3 and to subsequent installations, if applicable.



CNSC staff will verify that OPG continues to meet the requirements of CSA N286-12, *Management system requirements for nuclear facilities*, during the various stages of the TDS project, including development of isotope irradiation program documentation that will govern the production of authorized radionuclides using the TDS.

These documents will be subject to regulatory oversight to ensure that OPG continues to manage activities in accordance with their licensing basis.

38. The Commission directs OPG to verify the safety analysis inputs during the commissioning of the Mo-99 IIS and submit them to CNSC staff for review.

39. The Commission directs OPG to validate the models during commissioning and provide the results to CNSC staff for review.

42. The Commission directs CNSC staff to assess OPG's validation of the safety case following OPG's completion of the final Mo-99 IIS commissioning reports.

As mentioned previously, the commissioning report provided limited insights into the scope of OPG's validation of the safety case, particularly to fulfill the intent of the directive (#42) above. To adequately assess OPG's validation efforts following the installation and testing of the TDS in Unit 2, CNSC staff conducted a broader range of oversight activities beyond the review of a single report. These activities included desktop reviews of supporting documentation, reactive inspections, and routine on-site surveillance. Based on these comprehensive efforts, CNSC staff are satisfied that OPG verified the critical parameters of the safety case, ensuring the safe installation and commissioning of the TDS in Unit 2.

Further, CNSC staff's review of OPG's safety case and commissioning documentation in support of the additional isotopes authorized in [DEC 25-H100](#) provides another opportunity to verify that TDS operations do not invalidate the current SOE limits or introduce unexpected risks to continued safe TDS and station operations. CNSC regulatory oversight will continue as TDS activities incorporate additional isotopes through baseline and reactive compliance verification activities.

44. The Commission directs CNSC staff to verify that the detailed Mo-99 IIS maintenance plans meet regulatory requirements prior to operation of the IIS.



46. The Commission directs CNSC staff to verify that OPG's detailed preventive maintenance plans and aging management strategy continue to meet regulatory requirements.

CNSC staff's baseline inspection program regularly looks at critical aspects of OPG's maintenance program. CNSC staff are satisfied that OPG's maintenance program is in compliance with regulatory requirements. As was explained in CMD 21-H107, OPG undertook a commitment to produce new procedures and revise applicable existing procedures to include maintenance and operation for the TDS. Specifically, OPG stated that approximately 50 procedures would be revised and up to 40 new maintenance procedures would be created in accordance with established OPG processes [3]. While most of this documentation will be produced on an as-needed basis, CNSC staff have been provided with maintenance plans, preventative maintenance plans, aging management plans and ALARA assessments for TDS associated tooling. CNSC staff have also received several revisions of the TDS operating manual since 2021, per the process governing documents requiring written notification of change in the LCH.

CNSC staff will verify that the updated maintenance procedures developed for the TDS on Unit 3 will proceed in a similar manner to those used for Unit 2, and that any operating experience gained from the operation of Unit 2 is appropriately documented and applied to Unit 3 and to subsequent installations, as applicable. OPG has only relatively recently declared the Unit 2 TDS available for commercial use (November 2024) and thus there have not been any maintenance documentation provided to CNSC staff as of the writing of this CMD.

These maintenance documents will be subject to the appropriate oversight as required to ensure that OPG continues to manage activities in accordance with regulatory requirements.

78. The Commission directs CNSC staff not to authorize OPG to commence installation or commissioning of the Mo-99 IIS until OPG has satisfied the pre-requisites for the release of each respective hold point. CNSC staff will perform compliance verification activities to confirm that OPG has completed the identified actions.

CNSC staff confirm that all relevant RHPs placed on OPG as part of [DEC 21-H107](#) have been removed to date [1].

Following the Commission's decision to authorize OPG to produce additional isotopes, using the TDS [2], CNSC staff are continuing to provide oversight on OPG's progress in satisfying the pre-requisites for that RHP removal. This oversight may include the development of protocols, regulatory commitments and verification activities as appropriate.



3.2 Conclusion on Commission Directives

CNSC staff conclude that OPG has met the criteria of the Commission's directives (see subsection 3.1.1) regarding the expansion of the TDS to additional units at Darlington NGS as required by [DEC 21-H107](#).

CNSC staff find that the design and safety case presented for Unit 3 is consistent with that which was provided for Unit 2 and its use to produce any radionuclides as authorized by Section IV, Item vi of Darlington NGS PROL.

Based on these conclusions, CNSC staff recommend that the Commission approves OPG's request to install a TDS on Unit 3 and authorizes the EVP/COO, DG-DPRR, and/or RPD-DRPD of the CNSC to determine whether to accept future installation and operation of the TDS in other units for the production of previously authorized radionuclides, provided that OPG demonstrates that:

- the ECC process has been followed and produced a design consistent with all applicable regulatory requirements
- a safety case has been prepared and demonstrated that operations will continue to be a low-risk activity
- the activity will remain within the plant's existing licensing basis.

Note that the approval for installation of a TDS on Unit 3 does not require an amendment to OPG's current Power Reactor Operating Licence (PROL 13.06/2025). Following a Commission decision regarding this matter, CNSC staff will update the LCH.

At this time, CNSC staff do not recommend that a formal Regulatory Hold Point (RHP) be established since the RHPs applied in [DEC 21-H107](#) addressed the first-of-a-kind (FOAK) nature of the isotope production project at that time.

If OPG wishes to pursue production of additional radionuclides using TDS at Darlington NGS, beyond those currently authorized by the Commission in [DEC 21-H107](#) and [DEC 25-H100](#), this will represent a change to the licensing basis that cannot be addressed under Licence Conditions G.1 or 15.6. OPG will therefore need to bring the matter before the Commission for consideration. Such an application will need to be supported by a safety case demonstrating the continued safe operation of the TDS with the addition of new radionuclides.

4 Consultation and engagement

4.1 Indigenous consultation and engagement

The common-law duty to consult with Indigenous Nations and communities applies when the Crown contemplates actions that may adversely affect potential or established Indigenous and/or treaty rights. The CNSC ensures that all of its licence decisions under the [NSCA](#) uphold the honour of the Crown and uphold Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the [Constitution Act, 1982](#).

CNSC staff are committed to building long-term relationships with Indigenous Nations and communities who have interest in CNSC-regulated facilities within their traditional and/or treaty territories. The CNSC's Indigenous engagement practices include sharing information, discussing topics of interest, providing funding and capacity support opportunities, seeking feedback and input on CNSC processes, and providing opportunities for participation in environmental monitoring.

4.1.1 Discussion and conclusion

CNSC Staff's Consultation and Engagement Activities

CNSC staff identified several Indigenous Nations and communities that may have an interest in activities at the Darlington NGS site, due to the proximity of their communities, treaty areas and territories to the Darlington site, located on the north shore of Lake Ontario in Clarington, or due to previously expressed interest in being informed of CNSC licenced activities occurring in or proximal to their territories or communities.

The Indigenous Nations and communities listed below have been identified based on analysis conducted by CNSC staff using Crown Indigenous Relations and Northern Affairs Canada's (CIRNAC) Aboriginal and Treaty Rights Information System (ATRIS) and other mapping tools, as well as through a review of existing CNSC and open resources including records of Indigenous Nations and communities who may have expressed interest in OPG's Darlington NGS in the past. Should other Indigenous Nations and communities not included in the list identify interest in the OPG's application moving forward, they will be added as appropriate.

Indigenous Nations and communities with rights in relation to OPG's application to install additional TDS include:

- Alderville First Nation (AFN)



- Curve Lake First Nation (CLFN)
- Hiawatha First Nation (HFN)
- Mississaugas of Scugog Island First Nation (MSIFN)
- Chippewas of Beausoleil First Nation
- Georgina Island First Nation
- Chippewas of Rama First Nation

In addition, CNSC staff have identified the following Indigenous Nations and communities that have expressed interest in the Darlington NGS site:

- Mohawks of the Bay of Quinte
- Métis Nation of Ontario (MNO)
- Six Nations of the Grand River
- Mississaugas of the Credit First Nation (MCFN)
- Saugeen Ojibway Nation (SON)

A project notification letter was sent to all identified Indigenous Nation and communities on May 23, 2025. These letters provided information regarding OPG's request and opportunities to participate in the Commission's hearing process.

All of the identified Indigenous Nations and communities have been encouraged to participate in the regulatory review process and in the Commission hearing through written interventions to advise the Commission directly of any concerns they may have in relation to the request to install TDS on additional units at Darlington NGS.

CNSC staff will continue to offer to meet with all identified Indigenous Nations and communities to discuss the request and plan to raise OPG's request in regular meetings under Terms of Reference for long-term engagement arrangements with CLFN, HFN and MSIFN. The CNSC currently has a Terms of Reference for long-term engagement with CLFN, HFN, MSIFN, SON and MNO. The CNSC is open to developing Terms of Reference for long-term engagement with other interested Indigenous Nations and communities as appropriate.

In addition, CNSC staff acknowledge previously expressed interest by the Algonquins of Pikwàkanagàn First Nation (AOPFN) with regards to isotope projects at the Darlington NGS and activities that may result in the transport of nuclear materials into their territory for processing or use (see directive 178 in the Record of Decision [DEC 25-H100](#) [2] below). Although this specific application does not directly relate to activities in AOPFN's traditional territory, CNSC staff remain committed to engagement with AOPFN on the transportation of hazardous materials in their territory. CNSC staff continue to engage AOPFN on the matter through ongoing meetings, as outlined in the Terms of Reference (ToR) for long-term engagement signed by CNSC and AOPFN.



178. The Commission recognizes the concerns raised by AOPFN regarding transportation of hazardous materials through AOPFN territory and AOPFN's assertion that their FPIC is required prior to these materials entering their territory. The licence amendment application before the Commission, however, does not seek to authorize transport activities, but rather to authorize the production of the medical isotopes Y-90 and Lu-177. The Commission finds that aspects of the Lu-177 and Y-90 supply chain downstream of their production at the DNGS, including those that occur on AOPFN territory, will be managed under BWXT-Medical's CNSC licence, and not under the DNGS power reactor operating licence for which the Commission is considering OPG's licence amendment application. The Commission directs OPG and CNSC staff to engage with AOPFN regarding the concerns raised in CMD 25-H100.2.

Concurrent with this request, the Commission was in the process of considering OPG's application (see proceeding 25-H2¹) to renew the Darlington NGS Power Reactor Operating Licence (PROL). It was decided by the Commission Registry that the decision on the licence renewal should be made and issued prior to the consideration of any additional licensing matters regarding Darlington NGS, pausing this proceeding. The Notice of Hearing for this proceeding was issued on September 29, 2025. Follow up correspondence on updated hearing timelines and processes has been prepared and at the time of drafting this CMD, CNSC staff have not been made aware of any specific concerns in relation to OPG's request regarding TDS installation on additional units at Darlington NGS. However, should CNSC staff be made aware of any concerns in relation to this request, CNSC staff will provide such information to the Commission at the end of the public intervention period, as appropriate.

Based on the information received in OPG's request, CNSC staff found the installation and operation of TDS in additional units at Darlington NGS is unlikely to cause new adverse impacts to the exercise of established or potential Indigenous and/or treaty rights as continued operations will not change the Darlington NGS site characterization. CNSC staff have notified and engaged all identified Indigenous Nations and communities of OPG's request and have encouraged them to identify any specific concerns and participate in the Commission proceeding process through written interventions as appropriate.

¹ At the time of writing this CMD, DEC 25-H2 has not yet been posted to the CNSC's public website. Information on obtaining a copy of the decision can be found at the following link: [Commission renews Ontario Power Generation Inc.'s power reactor operating licence for its Darlington Nuclear Generating Station - Canada.ca](#)

4.2 Public consultation and engagement

The [NSCA](#) mandates the CNSC to disseminate objective scientific, technical and regulatory information to the public concerning its activities and the activities it regulates. CNSC staff fulfill this mandate in a variety of ways, including hosting in-person and virtual information sessions and through annual regulatory reports.

4.2.1 Discussion and conclusion

CNSC staff is committed to communicating and maintaining informative and productive relationships with the public for which CNSC's mandate serves. The public has been notified of OPG's application to install TDS on additional units at Darlington NGS via a Notice of Hearing, posted September 29, 2025. The compressed timelines for this hearing mean that consultation and engagement activities are in progress at the time of writing this CMD. Should these activities give rise to issues the Commission should include in its consideration of OPG's application, CNSC staff will bring these to the attention of the Commission, as appropriate, at the end of the public intervention period.

4.3 Licensee public information and engagement

A Public Information and Disclosure Program (PIDP) is a regulatory requirement for licence applicants and licensees of Class I nuclear facilities, uranium mines and mills and certain Class II nuclear facilities. These requirements are found in [REGDOC-3.2.1, *Public Information and Disclosure*](#).

The primary goal of the PIDP is to ensure that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of nuclear facilities are effectively communicated to the public. The program must include a commitment to, and protocol for ongoing, timely communication of information related to the licensed facility during the course of the licence period.

CNSC's expectations of a licensee's public information program and disclosure protocol are commensurate with the level of risk of the facility, as well as the level of public interest in the licensed activities. The program and protocol may be further influenced by the complexity of the nuclear facility's lifecycle and activities, and the risks to public health and safety and the environment perceived to be associated with the facility and activities.



4.3.1 Discussion and conclusion

Currently, OPG has a fleet-wide public information and disclosure protocol which addresses all licenced facilities. To ensure compliance, OPG's PIDP program is assessed regularly by CNSC staff (annually and periodically) and has been found to consistently and appropriately communicate with the public regarding events and activities of interest at Darlington NGS. Licensees are expected to review their PIDPs regularly and to update as required. Revisions and change notifications sent to the CNSC are assessed to understand the rationale for and impact of the change and to ensure ongoing compliance. Updates may include improvements or modifications to any element of the program, such as target audiences, mode and frequency of communication, lessons learned from audience feedback or a shift in areas of interest expressed by target audiences.

REGDOC 3.2.1 is currently under review and the updated version will be implemented within the next two years. OPG will be required to comply with any changes to the regulatory requirements. Staff will continue to assess OPGs PIDP (program and protocol) throughout the lifecycle of the licensed facility(ies) to ensure compliance and ongoing improvements which must continue to provide information to the public in a timely and appropriate way.

OPG has demonstrated that both the public information program and its disclosure protocol build upon past activities to address the communication needs of their target audiences. OPG's request [4] included as an enclosure, NK38-PLAN-00120-00027, *"Target Delivery System Engagement and Communications Plan with Indigenous Nations and Communities"*. CNSC staff reviewed this enclosure and identified no concerns though raised a few questions for clarification, for which OPG provided responses. These responses included a log of 2025 engagement activities for which OPG has completed with respect to TDS projects at Darlington NGS.

CNSC staff are satisfied, that OPG has sufficiently engaged interested public and Indigenous communities, through implementation of their PIDP and NK38-PLAN-00120-00027, *"Target Delivery System Engagement and Communications Plan with Indigenous Nations and Communities"*, (Enclosure 4 of OPG's request [4]).

4.4 Participant funding program

The CNSC established the Participant Funding Program (PFP) in 2011 to:

1. enhance individual, not-for-profit organization and Indigenous Nations and Communities participation in the CNSC's environmental assessment (EA) and licensing processes for major nuclear facilities (e.g., uranium



mines, nuclear power plants, nuclear substance processing, or nuclear waste facilities)

2. assist individuals, not-for-profit organizations and Indigenous Nations and Communities to bring value-added information to the Commission through informed and topic-specific interventions related to EAs and licensing (i.e., new, distinctive and relevant information that contributes to a better understanding of the anticipated effects of a project)

4.4.1 Discussion and conclusion

The Commission Registry determined that PFP will not be offered for this CMD. It is recognized that there are alternate means of funding to offer interested parties, which can be utilized as to not introduce significant delays to the timelines requested for this proceeding. These will be explored as part of consultation and engagement with Indigenous nations and communities (in particular).

5 Events and other matters of regulatory interest

5.1 Open inspection items

5.1.1 Medium finding and warning letter escalated non-compliance for contractor management (2024-13-34550)

Per proceeding 21-H107, the Commission documented the following in the Record of Decision [1]:

29. [...] CNSC staff intend to verify that OPG continues to meet the requirements of CSA N286-12 during the various stages of the Mo-99 project, including development of isotope irradiation program documentation that will govern the production of Mo-99. The Commission is satisfied that staff will do the verification and will report to the Commission any information that merits Commission attention in this regard.

CNSC staff note that at the time of writing this CMD there is an open Notice of Non-Compliance issued as a result of an inspection finding against OPG concerning oversight



of contractors to support isotope-related activities. A specific contractor has been used for types of work for which they were not formally qualified. As this inspection finding was a repeat of one pertaining to the same contractor issued in 2021 [10] and closed in 2023 [11]; the action item associated with the Notices of Non-Compliance for the 2024 inspection were communicated using a warning letter [12]. The associated finding was elevated to “medium” to reflect the recurrence of the action and OPG’s failure to implement effective corrective actions to prevent the recurrence.

CNSC staff expect that OPG will continue to take corrective actions to work towards resolving this issue and maintain compliance with their management system requirements. CNSC staff consider this a matter of interest that must be addressed in this CMD per the directive above as it pertains to operation of the existing TDS on Unit 2 and specifically involves compliance with CSA N286-12. However, through follow-up actions to date, CNSC staff are assured that OPG is developing and implementing adequate corrective actions and will apply operational experience to current and future isotope projects at Darlington NGS.

CNSC staff are of the view that, while this issue may be of interest to the Commission in the context of this matter, it does not have a direct bearing on the decision currently before the Commission. As the installation and operation of the TDS in Unit 2 is part of an existing licenced activity for Darlington NGS, this issue pertains to compliance with a licenced activity rather than representing a direct risk to the decision under consideration.

CNSC staff will continue to provide enhanced regulatory oversight of the OPG supply chain and contractor management processes, including monitoring OPG’s implementation of effective corrective actions. CNSC staff expect these issues to be fully resolved by OPG prior to commencing any further installation of a TDS, including that on Unit 3.

6 Overall Conclusions and Recommendations

CNSC staff conclude that:

- 1) installation and operation of additional Target Delivery Systems (TDS) on additional units at Darlington NGS, for the purposes of producing Mo-99, Lu-177, and Y-90 is a low-risk activity that can be conducted safely and within the established licensing basis. Staff also conclude that OPG remains qualified and competent in implementing their licensed activities.



- 2) the supporting case brought forth by OPG in its request for the installation and operation of a TDS on Unit 3 confirms that any required design changes to the TDS are being managed adequately within OPG's approved ECC process and do not have an adverse impact on the safety case.
- 3) OPG has made adequate efforts to consult and engage with Indigenous Nations and communities and the public as required by their current operating licence and will continue to do so throughout progress of future projects.

CNSC staff recommend the Commission:

(a) Approves the installation and operation of a TDS on Unit 3 for the production of any radionuclides authorized by the Commission

(b) Authorizes the EVP/COO, DG-DPRR and/or RPD-DRPD of the CNSC to determine whether to accept future TDS installations and operations in other units for the production of previously authorized radionuclides (Mo-99, Y-90 and Lu-177), provided that OPG demonstrates that:

- the ECC process has been followed and produced a design consistent with all applicable regulatory requirements
- a safety case has been prepared and demonstrated that operations will continue to be a low-risk activity
- the activity will remain within the plant's existing licensing basis.

CNSC staff propose that Licence Condition 15.6 in the PROL remain unchanged. CNSC staff will use the LCH to identify the units for which a completed, design and safety case have been accepted, and installations and operations approved. Specifically, the proposed updates to section 15.6 of the LCH states that OPG can produce any radionuclides authorized by the Commission at Darlington NGS Unit 2 and Unit 3. The proposed licence and LCH are included in Appendix A of this CMD.

Lastly, the Commission's direction in [DEC 21-H107](#), specific to producing additional radionuclides [1], continues to be relevant. Specifically, if OPG wishes to produce additional radionuclides (i.e., Mo-99, Y-90 and Lu-177) using any existing TDS at Darlington NGS, OPG will need to bring the matter before the Commission for consideration by providing a revised safety case for the continued safe operation of the TDS and the reactor units with the addition of any proposed radionuclides.



References

- [1] CNSC, "Record of Decision for Application by Ontario Power Generation Inc. for the Application to Amend the Power Reactor Operating Licence PROL 13.02/2025 to Authorize the Production of Molybdenum-99 at the Darlington Nuclear Generating Station," DEC 21-H107, Date of Decision 2021-10-26. [e-Doc 6667685 (Word), 6624873 (PDF)] *Public*
- [2] CNSC, "Record of Decision for Application by Ontario Power Generation Inc. for the Application to Amend the Power Reactor Operating Licence PROL 13.05/2025 for the Production of Additional Isotopes using the Target Delivery System," DEC 25-H100, Date of Decision 2025-05-23. [e-Doc DANIZHJW66V33-166150894-1608] *Public*
- [3] CNSC staff CMD, "Request for licence amendment for the production of Mo-99 at the Darlington Nuclear Generating Station," CMD 21-H107, 2021-06-23. [e-Doc 5682560, 6542990] *Public*
- [4] OPG letter, A. Grace to C. Salmon, "Darlington NGS – Amendment to the Licensing Basis of the Power Reactor Operating Licence 13.06/2025 for the Installation and Operation of Target Delivery Systems in Additional Units," 2025-08-08. [CD# NK38-CORR-00531-26277, e-Doc 7559777 (Application), 7559781 (Attachments)] *Public*
- [5] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025," 2021-02-12. [CD# NK38-CORR-00531-22275 P, e-Doc 6489932, 6489938] *Public*
- [6] OPG letter, R. Geofroy to A. Mathai, "Darlington NGS – Molybdenum Isotope Irradiation System / Target Delivery System: Submission of TDS Commissioning Report and Associated Documentation," 2023-11-22. [CD# NK38-CORR-00531-25033, e-Doc 7171918] *Pro B(R)*
- [7] OPG email, C. Bedard to A. Mathai, "Darlington NGS: Molybdenum-99 Target Delivery System – Submission of the Unit 2 TEL Supplemental Commissioning Report," 2024-09-27. [CD# NK38-CORR-00531-25687, e-Doc 7373273 (transmital), 7373268 (report)] *Pro B(R)*
- [8] CNSC staff CMD, "Request to amend the PROL for the production of additional isotopes using the Target Delivery System," CMD 25-H100, 2025-01-17. [e-Doc 7190732 (Word), 7419259 (PDF), 7358118 & 7420253 (Word and PDF - Unclassified Reference Package), 7396478 & 7420252 (Word and PDF Classified Reference Package)] *Public*



- [9] OPG letter, A. Grace to C. Salmon, "Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production," 2025-04-17. [CD# NK38-CORR-00531-25810 R001, e-Doc 7504635] *Public - Redacted*
- [10] CNSC staff letter, J. Burta to S. Gregoris, "Darlington NGS: CNSC Field Inspection Report: DRPD-2021-FIR-11708 – Molybdenum 99 Project, New Action Item 2021-13-24039," 2022-10-21. [e-Doc 6655021] *Pro B(R)*
- [11] CNSC staff letter, A. Mathai to R. Geofroy, "Darlington NGS – CNSC Staff Review of OPG Update and Request for Closure of CNSC Staff's Field Inspection Report: DRPD-2021-FIR-11708 - Molybdenum 99 Project, Action Item 2021-13-24039," 2023-07-27. [e-Doc 7041148] *Pro B(R)*
- [12] CNSC staff letter, A. Mathai to A. Grace, "WARNING LETTER – New Action Item 2024-13-34550: Increased Regulatory Oversight following Reactive Inspection DRPD-2024-20108," 2024-11-15. [CD# NK38-CORR-00531-25813, e-Doc 7397463 (letter); 7375644 (Enclosure - inspection report)] *Pro B(R)*

APPENDIX A:

Proposed Licence Changes

Overview

OPG's request does not require an amendment to the PROL at Darlington NGS. It should be noted that at the time of writing this CMD the version of the licence in effect is PROL 13.06/2025, which expires on November 30, 2025. The Commission has recently renewed OPG's operating licence and PROL 13.00/2045 will come into effect on December 1, 2025. There will be no change to the Licence Conditions, as written, for either version of the licence, should the Commission approve or deny OPG's request, as a result of proceeding 25-H107.

If the Commission accepts CNSC staff's recommendations, changes to the current status of TDS installations and operations for operating units at Darlington NGS will be specified in the LCH. At the time of writing this CMD, the current LCH version is LCH-PR-13.06/2025-R006. A draft revision of the LCH is currently being finalized to reflect the Commission's decision regarding production of additional radionuclides at Darlington NGS (DEC 25-H100) and LCH-PR-13.06/2025-R007 is expected to be published before this matter is brought before the Commission. It is important to note that the text for LCH-PR-13.06/2025-R007 is identical to that which is expected to be issued with LCH-PR-13.00/2045-R00 to accompany PROL 13.00/2045, when it becomes effective. Therefore, the proposed text to the LCH below will either be implemented in LCH-PR-13.06/2025-R008 or LCH-PR-13.00/2045-R001 in accordance with the PROL in effect at the time of the Commission's decision on this matter.

Current Licence Condition

Since there is no PROL amendment associated with this request, the applicable Licence Condition is stated below. This Licence Condition will not change from PROL 13.06/2025 to PROL 13.00/2045.

Licence Condition 15.6:

The licensee shall implement and maintain an operations program for the use of the Target Delivery System to produce the radionuclides described in section IV (vi) (2).
--

Draft Licence Conditions Handbook Section

changes in red; ~~strikethrough~~ denotes deletions, **bold denotes additions

15.6 Target Delivery System Operation Program

Licence Condition:

The licensee shall implement and maintain an operations program for the use of the Target Delivery System to produce the radionuclides described in section IV (vi) (2).

Preamble

The PROL authorizes OPG to *possess, transfer, package, manage and store Y-90, Mo-99, and Lu-177 (including associated decay radionuclides)*. Using the Target Delivery System, OPG is only authorized to produce Y-90, Mo-99, and Lu-177 from Y-89, Mo-98, and Yb-189, respectively at Darlington NGS Unit 2 **and Unit 3**. Units 1 and 4 do not produce ~~Mo-99 as radionuclides~~. **If OPG has not established a Commission approved wishes to install a TDS on either of these units, OPG must submit to the EVP/COO, DG-DPRR and/or Director-DRPD of the CNSC for approval the design documentation, a safety case for a TDS designed for these units, and confirmation that demonstrates that the additional unit will remain within the licensing basis for Darlington NGS.**

Reactor units at Darlington NGS have eight of the original 24 adjuster rods permanently locked out of core. OPG has modified 4 of these out-of-service Adjuster Rod Ports (31780-AA1, AA8, AA17, and AA24) on Unit 2 **and Unit 3** by removing the adjuster rod assemblies and installing target elevators that raise and lower molybdenum targets into and out of the core. The TDS interfaces with numerous existing systems including instrument air and class III & IV electrical power, and forms part of the containment boundary. Redundant, interlocked containment valves are used on both the inboard and outboard side of the target airlock to ensure the containment boundary is maintained at all times.

Compliance Verification Criteria

LC 15.6 provides the basis for regulatory oversight related to the licensed activity associated with the Mo-99 radioisotope production program. The Darlington PROL authorizes the production and possession of various radionuclides through normal commercial operations (*i.e., fission products and their associated decay products produced in CANDU fuel*) and through operation of the TDS at Darlington NGS – Unit 2 **and Unit 3**. Only radionuclides produced with the TDS may be harvested, packaged, and transported off-site under the provisions of this licence condition.

All activities associated with the operation of the Mo-99 IIS / TDS and flask handling are required to be integrated into the management system framework.

The process for removing Regulatory Hold Points established by the Commission related to the TDS are discussed in section 15.4 of this LCH.

Operation of the TDS

In accordance with the Record of Decision,² the Commission has ~~limited OPG to installing and operating the TDS on Unit 2 at Darlington NGS. OPG has been directed to return to the Commission if it wishes to install a TDS on additional units at Darlington NGS~~**authorized the installation and operation of TDS on operating units at Darlington NGS, provided that OPG submits to the EVP/COO, DG-DPRR and/or Director-DRPD of the CNSC for approval, a clear demonstration that the proposed modification remains within the licensing basis established by the Commission in DEC 25-H107. Currently this requirement is satisfied for Unit 2 and Unit 3 only.**

~~Due to the first-of-a-kind nature of the Mo-99 IIS design and to allow the public additional opportunity to participate, the Commission directs that OPG must obtain the approval of the Commission, rather than concurrence from CNSC staff, if it means to produce Mo-99 in a unit other than Unit 2.~~

The licensee shall operate the Mo-99 IIS / TDS in accordance with NK38-OM-30550, *Target Delivery System (TDS)*; the operating parameters therein; and all associated operating procedures, including NK38-MMP-30550-13, *Target Delivery System Transport Package Flasking*. Operation is bounded by the conditions and reactor states assessed in N-REP-03500-0839983,

² Record of Decision for Application by Ontario Power Generation Inc. for the Application to ~~Amend the Power Reactor Operating Licence PROL 13.02/2025 to~~ Authorize the ~~Production-Installation and Operation of Molybdenum-99a Target Delivery System (TDS) on Additional Units~~ at the Darlington Nuclear Generating Station, Date of Decision ~~October 26, 2021~~**TCD**. CNSC. ~~2021~~**2025. DEC 25-H107**, e-Doc ~~6667685~~**XXXXXXX**.

Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington.

As required by REGDOC-3.1.1, deviations from established operating parameters, equipment configuration, predicted consequences of operation and unexpected RRS interactions, should be considered reportable under clauses D-14 or D-18.

Managing Packaged Radionuclides

OPG shall follow the operating manual NK38-OM-30550 and the relevant associated procedures when managing radionuclide production using the TDS. Applicable requirements regarding the preparation and shipment of radionuclides off-site, in accordance with Transport Canada *Transportation of Dangerous Goods Regulations* and CNSC *Packaging and Transport of Nuclear Substances 2015 Regulations* shall be met before transferring radionuclides and shipping them off-site.

At all times, radionuclides produced and harvested using the TDS on Unit 2 **and Unit 3** are required to be stored in a certified transport flask. All other uses and storage practises are prohibited. When flasking, hoisting, managing, and storing³ radionuclides using the TDS (effectively sealed sources), OPG shall follow NK38-MMP-30550-13, *Target Delivery System Transport Package Flasking*, and the relevant associated procedures under OPG's Radiation Protection Program and Nuclear Security program.⁴

Licensed Activities

Prohibition of Use of Radionuclides Produced with the TDS and Associated Decay Radioisotopes

The licensee is not authorized by the licence to conduct activities related to nuclear medicine; therefore, OPG is prohibited to process radionuclides produced with the TDS and use nuclear substances in or on human beings. CNSC staff will verify by whatever means available that the licensee is not using radioactive prescribed substances in or on humans.

³ In the event where transportation to remove the flask from Darlington NGS is unavailable, the alternative location for the storage of the flask will be at Combustible Material Storage (CMS) D-22-0004. In accordance with OPG correspondence NK38-CORR-00531-23164; e-Doc [6722668](#), this location has been designated for contingency storage of a loaded transportation flask containing irradiated targets.

⁴ Implementing the requirements of REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*

The following documents require written notification of change:

Document Title	Document #	Prior Notification?
Target Delivery System (TDS)	NK38-OM-30550	No
Target Delivery System Transport Package Flasking	NK38-MMP-30550-13	No
Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington	N-REP-03500-0839983	No*

**Until the Darlington Analysis of Record or Safety Report is updated to reflect the addition of the Mo-99 IIS / TDS on Unit 2*

Recommendations and Guidance

This section has no contents applicable to this LC.