UNCLASSIFIED/NON CLASSIFIÉ

ORIGINAL/ORIGINAL

CMD : **25-H100**

Date signed/Signé le : **17 JANUARY 2025 / 17 JANVIER 2025**

Reference CMDs/CMD de référence : **25-H100.A, 25-H100.B**

A licence amendment

Ontario Power Generation Inc.

Darlington Nuclear Generating Station

Request to amend the PROL for the production of additional isotopes using the Target Delivery System

Hearing in writing based solely on written submissions

Scheduled for:

March 2025

Submitted by:

CNSC Staff

Modification d'un permis

Ontario Power Generation Inc.

Centrale nucléaire de Darlington

Demande de modification du PERP pour la production d'isotopes supplémentaires à l'aide du système de livraison de cibles

Audience par écrit fondée uniquement sur des mémoires

Prévue pour :

Mars 2025

Soumis par :

Le personnel de la CCSN

This document contains classified information and is not publicly available.

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e-Doc 7190732 (WORD)

e-Doc 7419259 (PDF)

Summary

This CMD presents information about the following matters of regulatory interest with respect to Ontario Power Generation Inc.:

- Amendment of the power reactor operating licence (PROL) for the production of lutetium-177 (Lu-177) and yttrium-90 (Y-90) at the Darlington Nuclear Generating Station (DNGS)

CNSC staff recommend the Commission consider taking the following actions:

- Amend the PROL to allow the production of Lu-177 and Y-90 at DNGS
- Accept the process as set out in section 3.4 of this CMD for the removal of a regulatory hold point and delegation of authority.

The following items are attached:

- The proposed PROL 13.05/2025
- The current PROL 13.04/2025

Résumé

Le présent CMD fournit de l'information sur les questions d'ordre réglementaire suivantes concernant Ontario Power Generation Inc. :

- Modification du permis d'exploitation d'un réacteur de puissance (PERP) pour autoriser la production des radionucléides lutécium 177 et yttrium 90 à la centrale nucléaire de Darlington

La Commission pourrait considérer prendre les mesures suivantes :

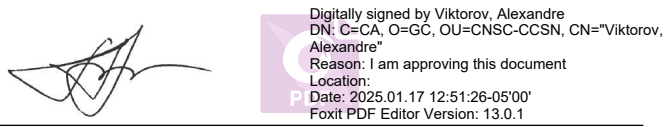
- Modifier le PERP pour autoriser la production de Lu 177 et d'Y 90 à la centrale nucléaire de Darlington
- Accepter le processus décrit dans la section 3.4 du présent CMD pour la levée d'un point d'arrêt réglementaire et la délégation de pouvoirs

Les pièces suivantes sont jointes :

- Permis proposé – PERP 13.05/2025
- Permis actuel – PERP 13.04/2025

Signed/Signé le

17 January 2025 / 17 janvier 2025



Alexandre Viktorov, Ph.D.

Director General

Directorate of Power Reactor Regulation

Directeur général

Direction de la réglementation des centrales nucléaires

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Land Acknowledgement

The Darlington Nuclear Generating Station is located on the traditional lands and waters of the Michi Saagiig Anishinaabeg. These lands are covered by the Gunshot Treaty (1877-88), the Williams Treaties (1923), and the Williams Treaties Settlement Agreement (2018).

Plain Language Summary of CMD

OPG submitted an application to amend the Darlington Nuclear Generating Station power reactor operating licence to produce the radioisotopes lutetium-177 (Lu-177) and yttrium-90 (Y-90) for medical applications. The isotopes would be produced using the existing Target Delivery System (TDS) at Darlington Unit 2, which currently produces molybdenum-99 (Mo-99). The Commission previously granted a licence amendment in October 2021 to permit the installation of the TDS on Unit 2 for production of Mo-99.

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.

OPG's application states that the new isotopes will be irradiated using the same process used for Mo-99, with modification to some parameters including the irradiation time. No new equipment will be installed, and changes will be limited to updates to software and procedures. The targets inserted into the reactor to produce the new isotopes will be externally the same as the existing Mo-99 targets, with different internal composition.

OPG asserts in its application that the impacts introduced by new isotopes will be bounded by the existing safety analysis for Mo-99, and therefore the overall safety case is not changing. The above assertion will be confirmed with the finalized designs and final safety analyses for the new targets.

CNSC staff note that OPG has a mature management system which has been evaluated by the CNSC, as well as adequate expertise to manage this change safely. However, OPG's application is based on preliminary design and safety analysis documentation for the new isotopes. Therefore, CNSC staff propose that the Commission establish a regulatory hold point (RHP) as part of the updated licence condition 15.6. The purpose of the RHP is for CNSC staff to verify OPG's assertion that the new isotope production is bounded by the previously submitted and reviewed safety case, including confirmation via commissioning tests, prior to declaring the new isotope production available for service (AFS). RHPs, established by the Commission, have been used successfully to administer previous operational approvals for Darlington Refurbishment and the installation and commissioning of the Mo-99 TDS.

Based on review of OPG's application, CNSC staff have determined that OPG is qualified to carry out the proposed activity. CNSC staff have also determined that OPG has programs in place to ensure that it will make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed. Therefore, CNSC staff recommend that the Commission amend the Darlington PROL to include the production of Lu-177 and Y-90.

Documents referenced in this CMD are available in CMDs 25-H100.A and 25-H100.B.

1. Overview

1.1 Background

The Commission granted Ontario Power Generation (OPG) a licence amendment in October 2021 in DEC 21-H107[1] authorizing OPG to install a Target Delivery System (TDS) on Unit 2 of the Darlington Nuclear Generating Station (DNGS) to produce molybdenum-99 (Mo-99), a radioisotope which is used in nuclear medicine. In the current application, OPG is seeking an amendment to the DNGS licence to allow for production of two additional medical isotopes, lutetium-177 (Lu-177) and yttrium-90 (Y-90), using the existing TDS on Unit 2. In OPG's application and this CMD Lu-177 and Y-90 are also referred to as the 'new isotopes' or 'additional isotopes'.

In CMD 21-H107[2], CNSC staff referred to the system used to produce Mo-99 as the 'Mo-99 IIS/TDS', where IIS stands for Isotope Irradiation System. DEC 21-H107 refers to the 'Mo-99 IIS' or simply 'IIS'. CNSC staff note that all of OPG's documentation uses the terminology 'TDS' as opposed to IIS. Also, if the Commission accepts the proposed amendment the system will no longer be used exclusively to produce Mo-99, therefore the isotope name should be dropped from the name of the system. For these reasons, CNSC staff refer to the system in this CMD as the 'TDS'.

OPG's original application [1] included a request for confidential filing intended to protect the identity of one of the new isotopes as commercially sensitive information. OPG subsequently resubmitted the application [2] to remove the request for confidentiality.

Pursuant to the *Nuclear Safety and Control Act* (NSCA) clause 26, a licence issued by the CNSC is required to produce, possess, transfer, use, package, manage, or store a nuclear substance such as Lu-177 and Y-90. The production of these isotopes using the TDS is not currently an activity authorized by the Power Reactor Operating Licence (PROL), therefore a licence amendment is required for production of these additional isotopes.

Under OPG's current proposal, there will be no physical changes to the TDS required to produce Lu-177 and Y-90. OPG asserts in the application that modifications to the TDS to accommodate the new isotopes will be limited to software updates and procedural changes. The targets, which will be introduced into the reactor to produce the new isotopes, will be of the same external dimensions as the targets currently used to produce Mo-99, and have a similar weight. The overall sequence to insert (seed), irradiate and remove (harvest) the new isotopes will also remain the same. 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.

CNSC staff have reviewed OPG's application made pursuant to section 6 of the *General Nuclear Safety and Control Regulations* (GNSCR) and section 3 of *the Class I Nuclear Facilities*

[1] Record of Decision DEC 21-H107, eDoc 6667685
[2] CNSC Staff CMD 21-H107, eDoc 6542990

Regulations. CNSC staff's determinations, conclusions and findings as summarized in this CMD are not meant to pre-suppose the decision of the Commission, rather they culminate in recommendations to the Commission.

1.1.1 Station

The Darlington Nuclear Generating Station (DNGS) 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.

The Darlington station consists of four 881 megawatt CANDU reactors which came into service between 1990 and 1993. The Commission most recently renewed the PROL for Darlington in 2015, and OPG is currently in the processes of applying for a licence renewal. The relicensing hearing process will take place in 2025.

1.1.2 Scope of OPG's Project and Responsibilities

Similar to the current process for producing Mo-99, 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
•Transferring the transport package to a qualified nuclear shipper

Currently, OPG is only authorized to install a TDS on Unit 2 at Darlington NGS and per direction from the Commission, will have to return to the Commission via a public proceeding before introducing a TDS on any additional units at Darlington NGS. In the present amendment request OPG has not requested to install a TDS on another unit.

1.2 Matters for Consideration

OPG has requested the Commission to amend the Darlington NGS PROL to authorize the production of Lu-177 and Y-90. In determining whether OPG is a qualified applicant pursuant to paragraphs 24(4)(*a*) and (*b*) of the NSCA, OPG's application was reviewed against regulatory requirements including:

- Applicable legislation and regulations
- Relevant CNSC Regulatory Documents (REGDOC)
- The existing licencing basis of Darlington NGS, including the existing safety case for the TDS

- The suitability of OPG's existing programs to continue to comply with the CNSC Regulatory Framework ensuring:
  - Continued safe operations of the Darlington NGS
  - Safe handling of Lu-177 and Y-90
  - Safely managing the proposed changes
- Appropriate and meaningful engagement with applicable Indigenous Nations and communities
- Other matters of regulatory interest

1.3 Highlights

Under the proposed amendment, OPG's responsibilities with respect to Lu-177 and Y-90 will be the same as for the existing activities associated with Mo-99. In its application OPG has asserted that the existing safety case for Mo-99 production, which was accepted by the Commission during CMD 21-H107, will remain bounding for Lu-177 and Y-90, i.e. the impact of the new isotopes on safety-significant parameters will be the same or less than that of Mo-99. As such, the introduction of the new isotopes will not change the overall safety case of the station. OPG will not install any new equipment to accommodate the proposed activities. The new isotope targets will be loaded, seeded, irradiated, and harvested using the existing TDS and the same operating sequence currently used for Mo-99.

While OPG has asserted that accommodating the additional isotopes will not require any physical modifications to the TDS or Unit 2 in general, software updates will be required to the TDS control system. Specifically, there will be changes to the process to control the irradiation time[3] and the dwell-time[4].

OPG stated in the application that *"the new target capsule design requirements will include a bounding requirement in terms of the existing Mo-99 safety analysis"*. The safety analysis for Mo-99 includes tests, analysis and calculations previously conducted to meet the requirements of GNSCR 3(1)(i) in support of CMD 21-H107 and which informed the Commission's decision to accept the PROL amendment to produce Mo-99 production using the TDS.

Relative to Mo-99, the Lu-177 and Y-90 targets are expected to:

- Have different reactivity worth and absorption cross-sections, which:
  - impacts reactor power regulation and fueling
- Have a different amount of heat generated, which:
  - impacts the moderator heat load
  - affects the potential for ignition in case of an H_2 excursion in the moderator cover gas

[3] Irradiation time is the period of time that the targets remain in the core.
[4] Dwell-time is the period of time when the targets are held above the reactor core but below the reactivity mechanism deck to reduce the radiological hazard associated with short-lived high-energy activation products prior to harvesting and shipment.

    - affects the potential for target deformation
- Have a different magnitude and characterization of radioactive emissions, which
    - affects the dose to workers
    - introduces risks to workers if harvesting is performed without the proper dwell-time
    - impacts considerations for safe shipment

OPG's application provided conclusions from preliminary technical assessments to address some of the above differences. The application also includes regulatory commitments to produce safety analyses, final design documentation, and commissioning reports to confirm that the impact of Lu-177 and Y-90 is indeed bounded by the existing, approved safety case. CNSC staff recognize that all elements of these commitments are proposed in accordance with OPG's existing, CSA N286-12-compliant management system.

CNSC staff are satisfied with the suitability of OPG's programs to manage the proposed change and to produce the required evidence to demonstrate the bounding case assertion, as documented throughout section 2.6 of this CMD. However, the detailed analyses specific to Lu-177 and Y-90 to confirm OPG's bounding case assertion is an outstanding commitment from OPG's application. For this reason, CNSC staff recommend 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. Further information about the scope and rationale for the proposed RHP is discussed in section 3.4.

CNSC staff consider this approach of establishing an RHP in lieu of prior review of complete information to be risk informed, because:

- the proposed change is relatively straightforward; no physical modifications or new equipment will be needed on the TDS or Unit 2 in general, and the operating parameters which will be impacted by the new isotopes are well understood based on experience with Mo-99
- extensive assessments that supported the Mo-99 application were reviewed by CNSC staff for CMD 21-H107 and have contributed considerable knowledge of the bounding case under which the TDS operates
- the preliminary reactor physics information presented in OPG's application indicate that that OPG will be able to demonstrate that the new targets remain bounded by the Mo-99 safety case
- the proposed deliverables are being produced under OPG's Engineering Change Control (ECC) process which CNSC staff inspect and evaluate regularly and which is compliant with CSA N286-12 requirements
- the use of an RHP will ensure CNSC staff review the safety analyses as well as the commissioning results, that will confirm that OPG's bounding case assertion is verified prior to AFS.

CNSC staff recognise that the Commission cannot delegate the responsibility to establish or modify the station's licensing basis[5]; specifically, the conditions and safety and control measures described in the licence and the safety and control measures described in the licence application (including the Mo-99 application described in CMD 21-H107) and supporting documentation referenced therein. Therefore, the activities under the proposed RHP will only be to confirm that the existing calculations and analyses on record, for the use of the TDS to produce Mo-99, remain the bounding safety case that is applicable for all TDS activities, including the new isotopes. If this is confirmed, CNSC staff can conclude that the licensee has met the pre-requisites established to remove the RHP; and that the basis for the commission's approval of the licence amendment (to produce the radioisotopes Lu-177 and Y-90) remains valid and bounded by the previously accepted Mo-99 application described in CMD 21-H107 . If further analysis of the proposed activity finds that parameters are not bounded by the existing documentation from the Mo-99 application and the station safety analysis, OPG will have to return to the Commission for approval.

From a safety perspective, CNSC staff see no risks to safety with the proposed approach, because the RHP will provide a pre-operational verification that the new activities are reasonably bounded by the provisions already in place to protect the safety of workers, the public, and the environment.

CNSC staff recommend that authority to release the RHP be delegated to the Director General of the Directorate of Power Reactor Regulation (DG-DPRR), rather than to the Executive Vice President-Chief Regulatory Operations Officer (EVP-CROO) as has been done in previous licence amendments. CNSC staff's rationale for this recommendation is provided in section 3.4.3.

1.4 CNSC staff Conclusions and Recommendations to the Commission

CNSC staff's determinations, conclusions and recommendations are for the Commission's information in support of its decision.

CNSC staff recommend that the Commission amend the DNGS licence to include production of Lu-177 and Y-90, with the inclusion of an RHP prior to AFS for the new isotopes.

CNSC staff have determined that, in regard to NSCA paragraph 24(4)(a), OPG is qualified to carry on the activity that the licence amendment would allow because OPG has a robust set of programs which are adequate to ensure the safe production of Lu-177 and Y-90 at Darlington NGS. Furthermore, with regards to NSCA paragraph 24(4)(b), OPG has a program which should be able to demonstrate that Lu-177 and Y-90 will be produced within the limits of the established safety case for Mo-99, and to ensure that the new activity will pose a negligible additional risk to the operation of the nuclear facility. OPG will continue to utilize its established Engineering

[5]As established in Licence Condition G.1. The LCH elaborates that "This licence condition does not explicitly prohibit changes (such as in management or operation) with a *neutral or positive* impact on safety"

Change Control (ECC) process, documented in the Licence Conditions Handbook (LCH), to complete project documentation. CNSC staff recommend that the Commission establish an RHP to be released prior to AFS for Lu-177 or Y-90, to support the confirmation by CNSC staff that the final design and safety analysis of the new targets are bounded by the existing Mo-99 safety analysis.

2. CNSC staff review of OPG's application and supporting information

CNSC staff have reviewed OPG's application [1] and responses provided to CNSC staff questions [3, 4]. The purpose of CNSC staff's review was to understand the nature of the proposed change, the impact on the safety case and applicable regulatory requirements, and to inform CNSC staff's recommendations to the Commission in this CMD.

2.1 Regulatory Basis

For Nuclear Power Plants (NPPs), the key requirements come directly from:

- CNSC's *Nuclear Safety and Control Act* (NSCA) [S.C. 1997, c. 9]
- CNSC's *General Nuclear Safety and Control Regulations* (GNSCR) [SOR/2000-202]
- CNSC's *Class I Nuclear Facilities Regulations* (CINFR) [SOR/2000-204]
- CNSC's *Radiation Protection Regulations* (RPR) [SOR/2000-203]
- CNSC's *Nuclear Security Regulations* (NSR) [SOR/2000-209]
- CNSC's *Nuclear Non-Proliferation Import and Export Control Regulations* (NNIECR) [SOR/2000-210]
- CNSC's *Nuclear Substances and Radiation Devices Regulations* (NSRDR) [SOR/2000-207]
- CNSC's *Packaging and Transport of Nuclear Substances Regulations*, 2015 (PTNSR 2015) [SOR/2015-145]
- Transport Canada's *Transportation of Dangerous Goods Regulations* (TDGR) [SOR/2001-286]

2.2 Existing Mo-99 Licensing Basis

OPG intends to produce Lu-177 and Y-90 using the existing Unit 2 TDS at DNGS. The current DNGS PROL 13.04/2025 authorizes OPG to produce molybdenum-99 (Mo-99).

OPG installed a TDS on Darlington Unit 2, following the Commission granting a licence amendment per DEC 21-H107. The purpose of the TDS is to irradiate targets of stable Mo-98 in the reactor core to produce radioactive Mo-99, which is used extensively in nuclear medicine for diagnostic imaging. Prior to 2018, Mo-99 was produced in Canada at the NRU reactor at Chalk River National Laboratories. The NRU system involved separating Mo-99 from irradiated uranium fuel, which produced high level radioactive waste as a by-product, unlike the TDS which does not produce high level waste as a byproduct (this will also be true for Lu-177 and Y-90).

The TDS produces Mo-99 using targets of Mo-98 contained within a zirconium shell. A string of fresh targets is manually loaded into a target loading device, from where they are propelled via a pneumatic/hydraulic system into one of four baskets located above the reactor core. The baskets are lowered via a cable into the reactor core to expose the targets to the reactor's neutron flux, where the Mo-98 absorbs a neutron and is activated into radioactive Mo-99. After a prescribed

irradiation time of 7 days, the basket is raised out of the core and held above the reactor for a pre-defined dwell-time of 2 hours, which allows some of the short-lived activation products to decay, thus reducing the overall radioactive hazard. The targets are then propelled via a pneumatic/hydraulic system to a flask loading device where they are packaged in a shielded flask to be transported off-site. The targets are shipped to a licensed processing facility, where the Mo-99 is extracted and re-packaged for shipment to medical facilities.

Key safety considerations for the TDS include the impact of the targets on the reactor core (neutron absorption and heat generation), the radioactive fields associated with the removed targets, and the integrity of piping connected to the moderator, which forms part of the reactor containment boundary. CNSC staff found in CMD 21-H107 that OPG adequately addressed these safety aspects in the design of the TDS resulting in operations that stayed within the existing operating limits and requiring no additional accident or emergency response procedures. The Commission accepted these finding by amending the PROL to allow production of Mo-99.

2.3 Overview of Lu-177 and Y-90 production

Lu-177 and Y-90 are radioactive isotopes that are used in nuclear medicine, most prominently for targeted radionuclide therapy of certain types of cancer. The proposed production of Lu-177 and Y-90 will proceed in a similar fashion as the process for Mo-99 described above. OPG has specified the Lu-177 and Y-90 target capsules to be the same external dimensions as those used to produce Mo-99 and will have a similar weight. Further, the target capsules will use the same process to seed, irradiate and harvest, while accommodating isotope-specific irradiation times and post-irradiation dwell-times, as required.

2.3.1 Nuclear Substance and Radiation Devices Licence

Any use of Lu-177 or Y-90 in sealed sources, distinct from the activities proposed by OPG in this licence amendment (e.g. sources used for radiation device calibration), must be carried out in accordance with the consolidated CNSC-issued Nuclear Substance and Radiation Devices Licence (NSRDL)[6] . This licence is administered, and compliance is assessed, independently from the PROL and is not affected by the scope of activities that would be authorized by the amended PROL. Therefore, the NSRDL does not require an amendment to reflect Lu-177 and Y-90 production related activities which would be authorized under the amended Darlington NGS PROL discussed in this CMD.

2.4 Bounding Safety Case

In terms of impact on reactor operations, the new isotope targets are expected to differ from the existing Mo-99 targets in a few ways. These are expanded upon in section 2.6.4:

- different reactivity worth and absorption cross-sections

[6] Licence Number 12861-2-25.3; e-Doc 6934190

- different amount of heat generated
- different magnitude and characterization of radioactive emissions

OPG's application provided results and conclusions from preliminary technical assessments. OPG's application also provides regulatory commitments to produce final safety analyses, final design documentation, and to complete commissioning work to verify that the impact of Lu-177 and Y-90 is bounded by the existing safety case for Mo-99.

CNSC staff recommend that the licence amendment includes establishing an RHP. The purpose of the RHP is for CNSC staff to review information pertaining to final design, safety analysis, and commissioning verifications prior to giving OPG approval to declare Available for Service (AFS) for the new isotopes. Further information about the scope and rationale for the proposed RHP is discussed in section 3.4.

CNSC staff consider this approach of establishing an RHP for the new isotopes to be risk informed, because:

- the proposed change is relatively straightforward; no physical modifications or new equipment will be needed on the TDS or Unit 2 in general, and the operating parameters which will be impacted by the new isotopes are well understood based on experience with Mo-99
- extensive assessments that supported the Mo-99 application were reviewed by CNSC staff for CMD 21-H107 and have contributed considerable knowledge of the bounding case under which the TDS operates
- the preliminary reactor physics information presented in OPG's application indicate that that OPG will be able to demonstrate that the new targets remain bounded by the Mo-99 safety case
- the proposed deliverables are being produced under OPG's Engineering Change Control (ECC) process which CNSC staff inspect regularly and which is compliant with CSA N286-12 requirements
- the RHP process allows CNSC staff to review the safety analyses as well as the commissioning results that will confirm, prior to AFS, that OPG's bounding case assertion is verified and that the proposed activity remains within the licensing basis as established by the commission

2.5 Environmental Protection Review

CNSC staff reviewed the application 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, for this licence amendment application, neither are required because the proposed amendment 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, CNSC staff conduct environmental protection reviews (EPR) for all licence applications with potential environmental interactions, in accordance with CNSC's mandate under the NSCA and associated regulations. 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 licence amendment, the results of which are presented as section 2.6.9 of this CMD.

2.6 Assessment of Application against the Regulatory Framework

Any licensed facility or activity must comply with the relevant requirements which are organized under Safety and Control Areas (SCAs). For further information about the SCAs and the CNSC's regulatory framework, please refer CNSC Regulatory Document REGDOC-3.5.3 *Regulatory Fundamentals*, and to the CNSC's public webpage, specifically: *Safety and control areas - Canadian Nuclear Safety Commission*.

CNSC staff conducted a review of OPG's application against the existing licensing basis for all 14 SCAs. Lists of relevant CNSC REGDOCs and CSA standards that OPG's programs are required to meet can be found in the Darlington LCH and OPG's application. No new REGDOCs or CSA standards need to be added to the compliance verification criteria (CVCs) documented in the LCH to reflect the addition of Lu-177 and Y-90 production.

Detailed lists of OPG's governance, programs, processes, and other relevant documentation can be found in the Darlington LCH and OPG's application. These will not be discussed in detail in the subsections below unless specific exceptions or considerations are warranted. The objective of CNSC staff's review of the information supporting the licence amendment application was to determine if the production and possession of Lu-177 and Y-90 would have any impacts to the existing safety case, that the TDS design has addressed all current regulatory requirements, and whether the existing programs are sufficient to ensure the protection of workers and continued safe operations of Darlington NGS while producing Lu-177 and Y-90. CNSC staff's considerations, determinations and conclusions are provided in the subsections below.

2.6.1 Management System

OPG's management system provides the programs and processes to effectively manage and operate their nuclear facilities, to meet the requirements of CSA N286-12, *Management system requirements for nuclear facilities*. CNSC staff concur with OPG's assertion in the application that no changes to the established licensing basis for Management Systems will be required as a result of this amendment.

OPG's application asserts it is conducting the new isotopes project in accordance with their Engineering Change Control (ECC) Process[7]. The purpose of the ECC process is to ensure that design changes are planned, designed, installed, commissioned and placed in service, within the

[7] NK38-PROC-MP-0090 *Engineering Change Control Process*

station's Safe Operating Envelope (SOE), design basis, and licensing conditions, in accordance with the requirements of CSA N286-12.

CNSC staff inspect OPG's application of the ECC process regularly as part of the baseline compliance verification program. Since 2019, CNSC staff have conducted 3 Type II inspections and 7 field inspections related to the ECC process at OPG nuclear power plants (Darlington and Pickering)[8]. While these inspections resulted in some non-compliant findings, all of these findings were assessed to have either a 'low' or 'negligible' safety significance and have been addressed by OPG. CNSC staff have no concerns at this time with the sufficiency of OPG's ECC process to manage changes at their nuclear facilities and to drive production of the deliverables to be reviewed under the RHP described in section 3.4.

OPG stated in the application that a review of Operating Experience (OPEX) will be performed for the new isotopes, consistent with the requirements of the ECC process, to identify relevant experience and lessons learned from OPG's own facilities as well as other CANDU facilities through the CANDU Owner's Group (COG). During the licence amendment to support installation of the TDS (CMD 21-H107), CNSC staff were satisfied that OPG had conducted a thorough review of OPEX relevant to installation and operation of the system. Since the irradiation of the new isotopes will use the same process and equipment as Mo-99, CNSC staff expect much of the same OPEX will remain relevant for the proposed new activity.

OPG has a process to identify and document problems, investigate and evaluate results, and implement corrective actions related to people, plant, environment, and processes[9] to meet the requirements of CSA N286-12. CNSC staff regularly inspect OPG's implementation of the problem identification resolution process and there have been no findings of high or medium safety significance in recent inspections. CNSC staff are satisfied that OPG's problem identification and resolution process meets regulatory requirements. During OPG's progression towards submission of deliverables described in the RHP (section 3.4), CNSC staff will provide regular oversight of any identified problems that are associated with this project.

OPG maintains supply chain[10] and contractor management[11] programs to manage and oversee work performed by contractors. CNSC staff note that a considerable amount of the project work for Lu-177 and Y-90 is being done by contractors, which is not uncommon.

CNSC staff note 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 an 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. OPG's application identified the vendors who will produce the safety analysis and engineering design work for this project, as well as the vendor responsible for manufacturing of the Lu-177 and Y-90 targets; CNSC staff are

[8] Complete list of relevant inspection found in eDoc 7350958
[9] N-PROC-RA-0022 *Processing Station Condition Records*
[10] OPG-PROG-0009 *Items and Services Management*
[11] OPG-PROG-0038 *Contract Management*

familiar with these vendors through previous submission and have no concerns with their qualifications. To mitigate potential risks related to the present amendment, CNSC staff will verify that deliverables provided in support of the RHP (section 3.4.1) have been procured and accepted by OPG in accordance with the requirements of the management system.

CNSC staff will continue to provide oversight of the OPG supply chain and contractor management processes. If CNSC compliance activities uncover any non-compliances which impact this licence amendment application, CNSC staff will evaluate the safety significance and, in accordance with section 3.4, consider if they require resolution as a prerequisite to removing the RHP.

OPG's Nuclear Safety and Security Policy[12] directs that all employees consider safety as the overriding priority over schedule, cost and production, in compliance with *REGDOC-2.1.2 Safety Culture*. In its application, OPG has committed that the requirements set out in the Nuclear Safety Policy will not be affected by the introduction of Lu-177 and Y-90, and that "*continued safe reactor operation, compliance with operating limits and regulatory requirements will take priority over medical isotope production*". CNSC staff will continue to provide regulatory oversight to verify that the requirements of the PROL, the LCH, and REGDOC-2.1.2 are being met; specifically, that OPG documents their commitment to fostering safety culture in their governing documents, and that OPG ensures that sound nuclear safety is the overriding priority in all activities performed in support of the nuclear facilities, having clear priority over schedule, cost and production.

CNSC staff are satisfied that OPG has a robust management system which is compliant with the PROL, LCH and CSA N286-12, and that no changes to the management system will be required to support introduction of Lu-177 and Y-90. CNSC staff are satisfied that OPG's management system is adequate to safely manage the introduction of these new isotopes.

2.6.2 Human Performance Management

OPG has comprehensive programs for human performance[13], and training programs[14]. CNSC staff regularly inspect these OPG programs against the requirements of REGDOC-2.2.2 *Personnel Training,* REGDOC-2.2.4, *Fitness for duty* (volumes I, II, and III), and REGDOC-2.2.5 *Minimum Staff Complement*.

The purpose of OPG's Human Performance program is to reduce the number of events caused by human error. As part of the ECC process, OPG will complete a Human Factors Assessment and validation to evaluate the human factors aspects of the introduction of Lu-177 and Y-90 targets. OPG has committed to provide the Human Factors Engineering Program Plan and the Human Factors Assessment Report for CNSC staff review when complete [1, 4]. This assessment is

[12] N-POL-0001 *Nuclear Safety and Security Policy*
[13] N-PROG-AS-0002 *Human Performance*
[14] N-PROG-TR-0005 *Training*

expected to support final commissioning of the system with the new isotopes and as such, CNSC staff propose that it be reviewed under the RHP presented in section 3.4 to support operational readiness. CNSC staff will review the documents to confirm that Human Factors have been considered in the implementation of the additional isotopes.

OPG has a well-documented and robust fleet-wide training system, based on a Systematic Approach to Training (SAT) that is compliant with CNSC training requirements described in REGDOC-2.2.2 *Personnel Training*. OPG asserted in the application that the production of new isotopes using the existing TDS will not require any changes to OPG training governance documents N-PROG-TR-0005, "*Training*" and N-PROC-TR-0008 "*Systematic Approach to Training*" that form the licensing basis for Darlington NGS's Human Performance Management.

The licence amendment application has stipulated that as a prerequisite for TDS operation, OPG staff are required to successfully complete the TDS training qualification that is compliant with OPG's training governance N-PROG-TR-0005 "*Training*" and N-PROC-TR-0008 "*Systematic Approach to Training*" (and includes irradiation of Lu-177 and Y-90). In addition, OPG has stated that changes to training requirements will be updated according to OPG's governance.

CNSC staff concluded that the training for production of Lu-177 and Y-90 medical isotopes using the existing TDS will be defined, designed, developed, evaluated and managed in accordance with the processes and procedures that constitute the OPG's SAT-based training system. CNSC staff will monitor and evaluate OPG's performance in this area through regulatory oversight activities, including onsite inspections and reviews of compliance reporting and revisions to relevant OPG program documents.

OPG confirmed that, as with Mo-99, the nuclear operators who support the TDS to produce Lu-177 and Y-90 will not be included in the positions required to support the station's minimum shift compliment and that the tasks assigned to certified control room staff associated with isotope production will not impact the minimum shift complement [4].

OPG asserts in the application that this amendment will not introduce any new certified positions, and it will not require any changes to the established licensing basis for personnel certification. Similar to CNSC staff's assessment of OPG's training program, CNSC staff are satisfied that OPG will train certified staff appropriately on the TDS and the operational parameters associated with each isotope. CNSC staff will continue to verify that OPG ensures fidelity between the simulator and the corresponding unit.

CNSC staff are satisfied the OPG has robust Human Performance and Training programs that meet regulatory requirements which are adequate to manage the introduction of Lu-177 and Y-90. CNSC staff recommend that review of OPG's Human Factors Assessment for the new isotopes be completed under the proposed RHP.

2.6.3 Operating Performance

OPG's application asserts that no changes are required to the nuclear operations program[15] or to the Operating Policies & Principles[16] (OP&P) as a result of the proposed new isotopes. CNSC staff conduct regular oversight of OPG's operations program, which is compliant with the requirements of CSA N286-12, and consistent with the OP&Ps. In its application, OPG also asserts that the introduction of Lu-177 and Y-90 will not impact Accident Management and Recovery. CNSC staff find this is consistent with the conclusions of the detailed safety analysis performed to support the production of Mo-99 using the TDS.

CNSC staff note that OPG's nuclear operations program includes governance for the development and revision of technical procedures. OPG stated in their application that the operating manual NK38-OM-30550 *Target Delivery System Operating Manual* and NK38-MMP-30550-13 *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. These documents are listed in the LCH as 'documents requiring written notification of change'. As such, OPG will provide the updated documents for CNSC staff review as part of existing processes.

As was explained in the Mo-99 CMD 21-H107, as part of the installation of the TDS for Mo-99 production, OPG undertook to produce new procedures, and revise applicable existing procedures, to include maintenance and operation for the TDS. Specifically, OPG submitted that approximately 50 procedures would be revised and up to 40 new maintenance procedures would be created in accordance with established OPG processes. CNSC staff have received several revisions of the TDS Operating manual[17] since 2021. CNSC staff are of the opinion that OPG's process will facilitate incorporating Lu-177 and Y-90 into the appropriate procedures if the Commission amends OPG's licence.

OPG implements a Safe Operating Envelope (SOE) program[18] designed to ensure that station operations conform to the safety analysis and accident response procedures to which the station is licensed. OPG states in the application 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 states that production of Lu-177 and Y-90 will not impact any SOE documentation. CNSC staff have included review of the detailed nuclear safety analysis, to confirm the continued validity of the existing SOE, as a condition of the proposed RHP as described in section 3.4.

CNSC staff are satisfied that OPG has a robust operations program which is compliant with regulatory requirements and which should be adequate to manage the introduction of Lu-177 and Y-90. In order to support OPG's assertion that the SOE will be preserved, CNSC staff recommend that regulatory review of OPG's detailed nuclear safety analysis be a condition of the proposed Regulatory Hold Point.

[15] N-PROG-OP-0001 *Nuclear Operations*
[16] NK38-OPP-03600 *Operating Policies and Principles*
[17] NK38-OM-30550 *Darlington Operating Manual – Target Delivery System (TDS)*
[18] N-STD-MP-0016 *Safe Operating Envelope*

2.6.4 Safety Analysis

In accordance with the Darlington PROL and LCH, OPG is required to implement and maintain a safety analysis program. REGDOC-2.4.1 *Deterministic Safety Analysis* and REGDOC-2.4.2 *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants* establish the requirements related to Deterministic and Probabilistic safety analysis, respectively.

REGDOC-2.4.2 *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants* requires licensees to update the PSA for nuclear facilities every 5 years, and sooner if the facility undergoes a major change. OPG's application included the report *Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System*, NK38-REP-03600-10014. In the report, OPG concluded that the introduction of Lu-177 and Y-90 will not introduce any new initiating events or hazards that would impact the conclusions in the current Darlington PSA. CNSC staff concur that the new isotopes do not constitute a "major change" and therefore does not warrant an update to the Darlington PSA models outside of the normal five-year PSA update cycle as safety goals will continue to be met. CNSC staff will review the next revision of the Darlington PSA, which will be submitted as part of the next PSA update cycle in 2025, in accordance with REGDOC-2.4.2.

OPG references in the application the Mo-99 assessment N-REP-03500-0839983, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*", which demonstrated the relatively small impact of producing Mo-99 in the TDS on the operation and safety case for Darlington.

In its application, OPG provided the preliminary estimates for the reactivity worth of the Lu-177 and Y-90 targets, in comparison to Mo-99, which suggest that the targets will have less reactivity worth than the existing Mo-99 targets. Since the reactivity impact of a full load of Mo-99 targets has been demonstrated to be within the capabilities of the Reactor Regulating System (RRS) to control reactor power, a target string with any combination of Mo-99, Lu-177 or Y-90 should also be within the capabilities of the RRS. However, CNSC staff note that the values that OPG presents in the application are based on preliminary estimates for target designs which have not yet been finalized. While the conclusions are not expected to change, CNSC staff have included regulatory review of the detailed nuclear safety analysis, including finalized calculations addressing the impacts of new targets on core reactivity and verification through commissioning activities, as conditions for removal of the proposed RHP, described in section 3.4.

Like Mo-99 targets, the new isotopes targets will produce heat energy during irradiation and will undergo a steady and stable heat transfer to the surrounding moderator water. OPG notes in its application that the amount of heat produced by the Mo-99 targets is a small fraction of the overall heat load of the moderator while the reactor is operating, and that the heat load of the new targets will likewise be insignificant compared to the overall moderator heat load. CNSC staff recognize the considerable heat load regularly managed by the moderator. CNSC staff still require detailed analysis confirming that the accident consequences during a loss of moderator inventory event would be bounded by the Mo-99 target safety analysis (the heat generation should be bounded by the heat generation of Mo-99 targets); and have included the regulatory

review of the detailed nuclear safety analysis, including finalized calculations of time-dependant heat generation of the new targets, as a condition of the proposed RHP as described in section 3.4.

Further to the considerations of target heat generation, OPG states in the application that "The new target capsule design requirements will include a bounding requirement in terms of the existing Mo-99 safety analysis. This will be confirmed through detailed analysis of the two targets to confirm this design requirement and validated through detailed commissioning. This detailed safety assessment will be carried out as per OPG's Nuclear Safety Analysis governance and ECC process."

CNSC staff concur that, if OPG adheres to the design requirement that the Lu-177 and Y-90 target capsules are bounded by the existing Mo-99 safety analysis, the introduction of the new isotopes will not invalidate the current SOE limits or introduce additional risks to the moderator or the existing TDS flight tubing. However, because the final target designs and final safety analyses for Lu-177 and Y-90 are not complete, CNSC staff have included the regulatory review of the detailed nuclear safety analysis, the final target designs, and the resolution of all comments to CNSC staff's satisfaction as conditions of the proposed RHP as described in section 3.4.

As discussed in section 2.6.1, CNSC staff are satisfied that OPG's ECC process will drive the production of the required analyses to demonstrate the above claim and that the RHP process will ensure CNSC staff are satisfied that the new isotopes are bounded by the safety case established by Mo-99 and the station SOE.

CNSC staff are satisfied that OPG has a compliant safety analysis program. CNSC staff concur that the new isotopes do not constitute a "major change" and therefore does not warrant an update to the Darlington PSA models outside of the normal five-year PSA update cycle; and that the Mo-99 assessment demonstrated the relatively small impact of producing Mo-99 in the TDS on the operation and safety case for Darlington.

The final target designs and final safety analyses for Lu-177 and Y-90 are not complete, therefore, CNSC staff recommend 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.

2.6.5 Physical Design

In its application, OPG states that there will be no changes to the physical design of the TDS, or physical SSCs (Systems, structures, components) in Unit 2, as a result of the introduction of Lu-177 and Y-90. Importantly, there will be no modification to the components of the TDS which are part of the station containment boundary. Changes will be limited to updates to the TDS control system software, and changes to procedures; both of which will be made in accordance with OPG's ECC process.

OPG has also stated that the external dimensions of the new isotope target capsules will be identical to the dimensions of the existing Mo-99 targets, to facilitate transfer of the targets into and out of the core. The design of the new isotope targets includes a Mo-99 'ballast' to ensure the weight of the new targets is similar to the existing targets. CNSC staff note that the difference in heat generated by the new targets compared to Mo-99 has the potential to impact the amount of thermal deformation experienced by the targets, which could potentially interfere with the ability of the targets to travel smoothly in the flight tubes even if the as-manufactured dimensions are the same. OPG has identified design requirements for the new isotope targets which include a requirement that thermal expansion shall not result in interferences, and that a comprehensive nuclear decay heating analysis will be performed as part of the detailed nuclear safety analysis [3]. Because this analysis will contain essential information on OPG's ability to adhere to the target design requirements and operating conditions, CNSC staff have included the regulatory review of the detailed nuclear safety analysis, the final target designs, and the resolution of all comments to CNSC staff's satisfaction as conditions of the proposed RHP as described in section 3.4.

CNSC staff have no concerns with respect to the physical structures and components of the TDS for the introduction of the new isotopes. CNSC staff recommend that regulatory review of OPG's detailed nuclear safety analysis and final target designs be condition of the proposed Regulatory Hold Point.

2.6.6 Fitness for Service

OPG has a maintenance program[19], which governs the conduct of maintenance of station equipment, as well as an equipment reliability program[20] to maintain a high level of component reliability and minimize component failures. OPG stated in their application that introduction of the new isotopes will not require any changes to these programs, and that updates will be made to the NK38-OM-30550 *TDS Operating Manual* and the NK38-MMP-30550-13 *Target Delivery System Transport Package Flasking*.

As noted in section 2.6.3 of this CMD, as part of the Mo-99 amendment OPG committed to produce or update a series of maintenance procedures required for the TDS. Since no new equipment is being installed as part of this activity, and hence there will be no additional components to maintain, CNSC staff are satisfied that the present amendment will not adversely impact the development or implementation of maintenance procedures. CNSC staff will continue to perform oversight of TDS maintenance activities as part of CNSC site staff's routine surveillance of Darlington NGS.

CNSC staff note that installing the TDS on Unit 2 was a First-Of-A-Kind (FOAK) activity, which increased the potential for unexpected challenges. For example, in March 2024, the cable which

[19] N-PROG-MA-0004 *Conduct of Maintenance*
[20] N-PROG-MA-0026 *Equipment Reliability*

moves the target baskets into and out of the core did not spool correctly. This caused unanticipated stresses on the cable and in one case a broken cable, resulting in a target basket resting at the bottom of the reactor core. CNSC staff reviewed OPG's recovery plans for these issues, including recovery of the broken cable and basket, and confirmed that the repair activities were completed safely.

CNSC staff are satisfied that OPG's ECC and Maintenance programs are able to safely resolve these issues. Because the new targets will be physically similar the existing Mo-99 targets and there will be no new equipment installed, CNSC staff do not anticipate that the introduction of the new isotopes in the proposed amendment will result in further operational issues for the TDS.

OPG asserts in the application that there is no change required to chemistry controls as part of this amendment. As with Mo-99, the new isotope materials are contained within a zirconium shell, such that the isotope materials will not directly interact or mix with the moderator fluid. OPG clarified, in a supplemental communication, that the new isotopes are not water soluble and thus if the target material was to be released into the moderator it would not impact moderator chemistry [3] and would be filtered by existing systems.

Further, OPG has committed to validate the Failure Mode and Effects Analysis (FMEA) of release of target material into the moderator by a full chemistry assessment [4] as part of the detailed safety analysis for the project, which will be provided for CNSC staff review under the RHP described in section 3.4. CNSC staff find this assertion is consistent with the Mo-99 safety case and are satisfied that the new isotopes will not adversely impact moderator chemistry.

OPG's application asserts that this amendment will not impact structural integrity, aging management or periodic inspection program requirements. Since no new equipment will be installed, CNSC staff are satisfied with this statement.

CNSC staff conclude that OPG has a robust maintenance program[21], which governs the conduct of maintenance of station equipment, as well as an equipment reliability program. CNSC staff evaluated OPG's application by considering the potential impact on maintenance programs for the TDS. CNSC staff determined that the new activity will not adversely impact the ongoing updates to maintenance programs associated with the TDS. CNSC staff are satisfied that introduction of the new isotopes will not adversely impact the chemistry of the moderator.
CNSC staff recommend that regulatory review of OPG's chemistry assessment, be a condition of the proposed Regulatory Hold Point.

[21] N-PROG-MA-0004 *Conduct of Maintenance*

2.6.7 Radiation Protection

OPG's Radiation Protection Program[22] and its associated supporting governance documents are designed to address the requirements set out in the *Radiation Protection Regulations*. In OPG's application, OPG declares that no changes to its radiation protection program are required to accommodate the activities associated with the production and handling of Lu-177 and Y-90.

CNSC staff's past assessments of OPG's program have determined that OPG has implemented and maintained an effective radiation protection program at Darlington NGS that met regulatory requirements and is capable of managing the hazards associated with irradiating and harvesting Mo-99 targets from the TDS.

OPG states in their application that a preliminary analysis of the radiation hazard for the new isotope targets shows that the radiation source term for the new targets can be maintained lower than the source term for Mo-99. While the initial radioactive source term of the Lu-177 targets is greater than that of Mo-99, OPG indicated that the dose rates in areas that are accessible to workers will be reduced to levels at or below those of the Mo-99 targets by increasing the dwell-time of the new targets during harvesting. Dwell-time is the time during which the targets are held prior to harvesting in an intermediate position above the core, out of the neutron flux, to allow for the decay of high-energy short-lived radioisotopes in a location (under the Reactivity Mechanisms Deck) which has adequate shielding.

In its application, OPG committed to complete a revised Target Delivery System Design ALARA Assessment, which will incorporate the production of Lu-177 and Y-90 and to submit this assessment for CNSC staff review. CNSC staff note that OPG has a mature and robust radiation protection program and that qualified staff have used this program to manage significant radiological hazards (*e.g.,* Co-60 rods, refurbishment work and Mo-99). CNSC staff also recognize that OPG RP staff have developed working knowledge of the Mo-99 hazards associated with the TDS during commissioning. As OPG intends to increase the dwell-time for the new isotopes as needed to make the radiological hazard equivalent to or less than that of Mo-99 (consistent with the three basic protective measures associated with the As Low As Reasonably Achievable (ALARA) principle – time, distance shielding), CNSC staff anticipate minimal changes should be needed to support handling and on-site transportation of Lu-177 and Y-90 and that the ALARA considerations of the initial TDS design (against the radiological hazards of Mo-99) should remain acceptable and bounding.

CNSC staff will review the completed ALARA assessment for the new targets, when provided by OPG. Because this ALARA assessment will contain essential details regarding OPG's demonstration that radiation hazards have been fulsomely assessed, and adequately mitigated as necessary, CNSC staff have included the regulatory review of the updated ALARA assessment and that the resolution of all comments to CNSC staff's as a prerequisite of the proposed RHP as described in section 3.4.

[22] N-PROG-RA-0013 *Radiation Protection*

CNSC staff conclude that OPG's radiation protection program is robust and complies with the requirements of the RPRs, the PROL and the LCH, and should be capable of managing the radiation hazards expected to be associated with the new activity.
CNSC staff recommend that regulatory review of OPG's revised ALARA Assessment report be a condition of the proposed Regulatory Hold Point.

2.6.8 Conventional Health and Safety

OPG has an established occupational health and safety program that consists of documented practices to establish work protections, and systems for maintaining environment health and safety to ensure that all workers work safely, in compliance with the Ontario *Occupational Health and Safety Act* and the Ontario *Labour Relations Act*. The conventional safety hazards associated with producing the new isotopes will be the same as those for Mo-99 and will be managed by OPG in the same manner.

CNSC staff have performed oversight of activities associated with TDS commissioning for Mo-99 production and have no concerns with the existing provisions for conventional safety related to the TDS. While OPG's current project will not involve installation of new equipment and the associated hazards (such as the many critical lifts required during initial installation of the TDS), CNSC staff will continue to monitor OPG's conventional health and safety program as it is being applied to this project to verify that workers are protected from conventional hazards.

Similar to the handling of the Mo-99, the new isotopes are contained within a closed system including numerous barriers to mitigate the risks of direct exposure to the isotope materials. These barriers include the ampules, which are contained within zirconium target capsules, and a closed system of flight tubing between the new target loader, the reactor core and new flask loader. The air lock system also includes a High Efficiency Particulate Air (HEPA) filter[23] adding further protection to the contaminated exhaust. Therefore workers, members of the public, and the environment will not be directly exposed to the new isotopes.

CNSC staff evaluated OPG's application by considering OPG's current conventional health and safety program as it is applied to the TDS. CNSC staff have determined that it is a robust program that complies with the requirements of the PROL, the LCH, and relevant provincial legislation. CNSC staff will continue to provide regulatory oversight to ensure work will be conducted with proper planning and adequate safety measures

2.6.9 Environmental Protection

OPG stated in the application that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Environmental Protection SCA. In accordance with Darlington NGS Licence Condition 9.1, "The licensee shall implement and maintain an environmental protection program, which includes a set of action levels", OPG confirmed in its

[23] OPG's application does not credit the HEPA filter; however its contributions towards removing particulates and reducing emissions was discussed in CMD 21-H107.

application that the introduction of Lu-177 and Y-90 will not result in any changes to the Derived Release Limits (DRLs), Action Levels, or Internal Investigation Limits (IILs). OPG further asserted that the public dose consequence of production of Lu-177 and Y-90 will remain bounded by the Mo-99 operation, which will ensure no impact to the cumulative public dose resulting from Darlington NGS operation, which is well below 1% of the regulatory public dose limit of 1 mSv per year.

Regarding environmental impact, OPG's application states "*As the number of seeding and harvesting cycles per year for the new isotopes remains unchanged, which was the primary factor considered in the Mo-99 Predictive Effects Analysis (PEA) assessment, the introduction of the new target capsules is not expected to have any additional environmental impact. This will be reviewed and validated as per OPG's ECC process.*"

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 during CNSC staff's review in support of CMD 21-H107. As Unit 2 has only 4 target elevators and OPG's application has bounded production of all isotopes to a similar weekly frequency that was established for Mo-99 (per CNSC staff's understanding of the quote above), CNSC staff find that these conditions are consistent with the conditions reviewed in the Predictive Effects Analysis (PEA) supporting OPG's Mo-99 licence application.

CNSC staff note that OPG's application states that Y-90 will require an irradiation time of 3 days, compared to 7 days for Lu-177 and Mo-99. OPG's application has established a weekly seeding frequency which could, in theory, lead to system idle time during production of Y-90. At the current seeding frequency, the TDS has a negligible contribution to the annual station emissions. CNSC staff recommend that the Commission not explicitly restrict the number of seeding operations that OPG can perform in a year with the TDS. Rather, if OPG wishes to increase the frequency of harvest beyond what is currently stated in the PEA, CNSC staff recommend that OPG be directed to follow the notification process described in Licence Condition G.2.

In its application, OPG has committed to complying with the requirements of the CSA Standard N288 series documents, as required in Darlington's LCH. CNSC staff expect that when OPG completes its committed review of the Mo-99 PEA a revision will be needed to reflect the additional radionuclides to support the update to the ERA. If this is the case, CNSC staff will confirm it was produced in accordance with the requirements of CSA N288.6[24]. As OPG has done this in support of both recent licence amendments for Mo-99 [5] and Co-60 [6], CNSC staff is of the opinion that this assessment can be completed under the proposed hold point discussed in section 3.4.

CNSC staff are satisfied OPG's environmental protection programs remain in compliance with REGDOC-2.9.1, and proposed operations remain within the current licensing basis. The effect on the environment potentially arising from the new isotopes project as presented in OPG's application appear within the effect assessed for the Mo-99 project and therefore are not

[24] The current PROL references CSA N288.6-12, however future updates may incorporate the latest revision, CSA N288.6-22

considered to be significant. CNSC staff will review OPG's revision of the Mo-99 PEA as part of the proposed Regulatory hold point to confirm this conclusion.

CNSC staff are satisfied OPG's environmental protection programs remain in compliance with REGDOC-2.9.1, and proposed operations remain within the current licensing basis. CNSC staff are confident that the releases associated with the TDS will continue to make up only a small fraction of the annual station releases, which will not result in additional risk to the public and the environment.
CNSC staff recommend that verification of OPG's review of the PEA be included under the proposed regulatory hold point.

2.6.10 Emergency Management and Fire Protection

OPG is required to maintain an emergency preparedness program in accordance with CNSC regulatory documents *REGDOC- 2.10.1 Nuclear Emergency Preparedness and Response* and *REGDOC-2.3.2 Accident Management: Severe Accident Management Programs for Nuclear Reactors*. OPG is also required to maintain a fire protection program in accordance with CSA Standard N293-12 (R2017). CNSC staff conduct regular oversight of these programs through the baseline compliance inspection program.

OPG states in their application that existing conventional, nuclear, and fire emergency preparedness and response programs, will not be impacted by the introduction of activities associated with new isotopes. CNSC staff note that this declaration is consistent with the safety case proposed during the initial introduction of the TDS to Darlington NGS for the production of Mo-99. CNSC staff reviewed the impact of the installation of the TDS on OPG's Emergency Management and Fire Protection programs during the previous Mo-99 licence amendment (CMD 21-H107) and found that the existing provisions were adequate. Specifically, CNSC staff concluded that the introduction of the TDS did not require emergency response personnel to acquire significant knowledge of the TDS, new emergency response skills, nor procure new specialized emergency response equipment to continue to perform their emergency response roles. Further, all fire and nuclear emergency response tasks continue to be adequately covered by existing training.

Since the proposed amendment does not involve the installation of any new equipment and the overall process for seeding and harvesting targets will remain largely unchanged, CNSC staff are satisfied that OPG's existing provisions for emergency management and fire protection remain adequate for the introduction of Lu-177 and Y-90.

CNSC staff conclude that OPG has met the regulatory requirements in determining that existing hazard assessments, response plans and assets under their program are sufficient to support TDS operations with additional radionuclides. The existing suite of OPG nuclear emergency preparedness and response governance for Darlington NGS is deemed adequate to deal with potential emergency events that may arise due to activities associated with the production and

handling of Lu-177 and Y-90. CNSC staff will continue to provide regular regulatory oversight of OPG's emergency management and fire protection programs.

2.6.11 Waste Management

OPG states in the application that there are no changes with regards to the impacts from Lu-177 and Y-90 on Darlington's Waste Management licensing basis documents, and that existing procedures will continue to apply.

OPG's responsibilities for Lu-177 and Y-90 will be similar to the waste arrangements for Mo-99. OPG indicated in a response to CNSC questions that OPG will not retain any responsibility for the residual wastes produced as a result of processing, commercialization, or use of either Lu-177 or Y-90 [7]. These wastes will be managed by BWX Technologies (BWXT)-Medical under an existing CNSC licence.

OPG's application does not describe the wastes that will be generated though maintenance or routine operations. CNSC staff recognize that maintenance of the TDS will require work on the Reactivity Mechanism Deck (RMD) during outages and may require the use of radiological personal protective equipment (RPPE) and other disposable materials. 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.

CNSC staff conclude that the additional waste streams resulting from activities associated with the production of Lu-177 and Y-90 using the TDS can be safely managed, in accordance with CSA N292.3-08, *Management of low and intermediate level radioactive waste,* through OPG's existing waste minimization and waste management practices and procedures.[25] [26] CNSC staff will maintain oversight of any additional waste generated and the management of those wastes through existing compliance verification activities.

CNSC staff conclude that OPG's existing waste management program and arrangements with third parties are sufficient to manage the radioactive waste resulting from the production of Lu-177 and Y-90 and will continue to satisfy regulatory requirements.

The addition of Lu-177 and Y-90 is not expected to change the decommissioning strategy compared to what was established for TDS for Mo-99. In CMD 21-H107 it was noted that the TDS is a relatively small and removable system that will have minimal effect on future decommissioning activities. As such, the additional isotopes are not expected to impact the Financial Guarantee for Darlington.

CNSC staff assessed OPG's application and determined that activities associated with the production and handling of Lu-177 and Y-90 will generate a minimal amount of radioactive waste at the Darlington NGS. All wastes generated through installation, operation and maintenance

[25] Including N-PROC-RA-0017, *Segregation and Handling of Radioactive Waste*
[26] OPG-STD-0156, *Management of Waste and Other Environmentally Regulated Materials*

activities will be managed in accordance with OPG's waste management program currently in place.

CNSC staff conclude that OPG's existing waste management program is sufficient for this radioactive waste and will continue to satisfy regulatory requirements.

2.6.12 Security

OPG's application asserts that activities associated with the production and handling of Lu-177 and Y-90 will not require changes to OPG's security program including existing security information, classifications, provisions, processes, or practices. CNSC staff concur that OPG's security program is not impacted by the proposed activities as it does not introduce any new systems or requirements that will directly affect security operations.

A transportation security plan is required to transportation Category III radionuclides produced using the TDS to fulfill the requirements of REGDOC-2.12.3 *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material.* BWXT, as the qualified shipper, will prepare the transportation security plan. CNSC staff will review the transport security plans in accordance with established practices to ensure that it meets regulatory requirements.

CNSC staff will continue to provide regulatory oversight of OPG's security program to ensure adequate protection of the licensed facility and the nuclear substances.

CNSC staff evaluated OPG's application by considering OPG's current security and cyber security programs, in the context of activities associated with Lu-177 and Y-90, against regulatory requirements. CNSC staff have determined that OPG's proposed amendment will not impose new challenges to OPG's security program, and it will be able to accommodate the new activities associated with the production and possession of the new radionuclides while fulfilling its objectives of protecting nuclear assets at Darlington NGS.

2.6.13 Safeguards and Non-Proliferation

As outlined in its application, OPG maintains a safeguards program that complies with the requirements of the PROL, LCH, and, specifically, *REGDOC-2.13.1 Safeguards and Nuclear Material Accountancy*. CNSC staff regularly verify OPG's program implementation to ensure it conforms to measures required by the CNSC to meet Canada's international safeguards obligations as well as other measures arising from the Treaty on the Non-Proliferation of Nuclear Weapons.

OPG's application asserts that activities associated with the production and handling of Lu-177 and Y-90 will not interfere with the implementation of its safeguards program at the facility and does not involve nuclear material as per the Canada-IAEA Safeguards Agreement and as defined in CNSC REGDOC-2.13.1. As such, activities related to production and handling of Lu-177 and Y-90 will not impact existing IAEA safeguards surveillance and monitoring equipment or be subject to safeguards reporting and verification activities.

CNSC staff also note that, as neither Lu-177 and Y-90, nor their target material Yb-176 and Y-89, are controlled nuclear substances, OPG will not have to obtain a licence to import nuclear material in support of the proposed amendment. Additionally, OPG will not be responsible for processing, medical commercialization, or use of the new isotopes. Licensees involved in these downstream aspects of the supply chain and applications for Lu-177 and Y-90 will be evaluated as needed against numerous regulatory requirements, including *REGDOC-2.13.2 Import and Export,* to satisfy requirements in the relevant legislation under the NSCA.[27,28]

CNSC staff conclude that the production of Lu-177 and Y-90 will not affect OPG's safeguards program, and the licensee will be able to accommodate the new activities while continuing to fulfill the existing safeguards requirements.

CNSC staff evaluated OPG's application by considering the project's impact on OPG's current safeguards measures, import and export controls, and the IAEAs verification activities. CNSC staff have determined that the activities associated with Lu-177 and Y-90 will not significantly affect OPG's programs, and the licensee will be able to continue fulfilling the existing safeguards requirements.

2.6.14 Packaging and Transport

In the application and supplemental information [1, 4], OPG asserts it will use a qualified shipper to transport the new isotopes produced at Darlington NGS to a qualified processing facility using a Type B transport flask that is certified by the CNSC. Additionally, as presented in OPG's application, BWXT is the package designer, owner, and is responsible to maintain the package. OPG will be responsible for ensuring that the radioactive contents and other conditions of the package certificate will be met.

OPG states in their application the new isotopes will be shipped in the same CNSC-certified transportation packaging that is used for the Mo-99 targets. The current package certificate does not cover the new isotopes; however, OPG confirmed in subsequent correspondence that the package certificate will be updated to include the new isotopes [4]. OPG's application acknowledges that CNSC staff concurrence will be needed prior to the first shipment of Lu-177 and Y-90 in the certified transport packages. CNSC staff are including this concurrence as a prerequisite action in the proposed RHP discussed in section 3.4.

CNSC staff have verified, through compliance activities, that OPG's Radioactive Material Transportation program, implemented at both Darlington and Pickering NGS, specifies the management system requirements for all aspects of packaging and transport of nuclear substances and ensures compliance with both the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR 2015) and the *Transportation of Dangerous Goods Regulations*

[27] CNSC *Nuclear Non-Proliferation Import and Export Control Regulations* (NNIECR) [SOR/2000-210]
[28] CNSC *Nuclear Substances and Radiation Devices Regulations* (NSRDR) [SOR/2000-207]

(TDGR). CNSC staff have reviewed OPG's application and find that it meets the requirements as stated in the PTNSR 2015.

CNSC staff evaluated OPG's application by considering OPG's current Radioactive Material Transport program, interactions with third parties fulfilling the roles of consignee and carrier, and regulatory requirements from Transport Canada, the IAEA, and the CNSC. CNSC staff have determined that the packaging and shipment of Lu-177 and Y-90 can be managed by OPG's existing Radioactive Material Transport program. CNSC staff conclude that OPG is qualified to ensure compliance with the requirements of both the PTNSR 2015 and the TDGR.

As discussed in section 2.6.12, CNSC staff will continue to provide regulatory oversight of OPG's and BWXT's emergency response programs, including BWXT's Transportation Security Plan, to ensure that they have current and appropriate plans and capabilities, continue to meet their respective obligations in the event of a dangerous occurrence, and comply with the IAEA Regulations as required by PTNSR 2015.

CNSC staff evaluated OPG's application by considering OPG's current Radioactive Material Transport program, interactions with third parties fulfilling the roles of consignee and carrier, and regulatory requirements from Transport Canada, the IAEA, and the CNSC, in the context of the proposed activities associated with Lu-177 and Y-90.

CNSC staff have determined that the activities that will be authorized by the proposed amendment will not affect OPG's Radioactive Material Transport program. CNSC staff conclude that OPG is qualified to ensure compliance with the requirements of both the PTNSR 2015 and the TDGR.

2.7 Indigenous and Public Consultation and Engagement

2.7.1 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 treaty rights. The CNSC ensures that all of its licencing decisions under the *NSCA* uphold the honour of the Crown pursuant to section 35 of the *Constitution Act, 1982*. CNSC staff's considerations include but are not limited to Indigenous Nations and communities established or potential rights pertaining to lands and waters in relation to the facility and the expected and/or potential impacts of the activities conducted on the site in accordance with a CNSC issued licence.

REGDOC-3.2.2 Indigenous Engagement,[29] sets out requirements and guidance for licensees whose proposed projects may raise the Crown's duty to consult. While the CNSC cannot delegate its obligation, it can delegate procedural aspects of the consultation process to licensees, where

[29] REGDOC-3.2.2, *Indigenous Engagement,* was published in February 2016, and updated in August 2019

appropriate. The information collected and measures proposed by licensees to avoid, mitigate, or offset potential adverse impacts from the proposed licence amendment may be used by CNSC staff in meeting its consultation obligations.

CNSC staff remain 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, seeking feedback and input on CNSC processes, and providing opportunities to participate in environmental monitoring programs, such as the CNSC's Independent Environmental Monitoring Program (IEMP). The CNSC also provides funding support, through its Participant Funding Program (PFP) and Indigenous and Stakeholder Capacity Fund, for Indigenous peoples to meaningfully participate in Commission proceedings and ongoing regulatory activities.

2.7.2 CNSC Staff Engagement Activities

CNSC staff identified several Indigenous Nations and communities that may have an interest in the proposed licence amendment, due to the proximity of their communities, treaty areas and territories to the Darlington NGS, proximity to other facilities associated with isotope production and waste management, or due to previously expressed interest in being informed of CNSC licensed 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 and Northern Affairs Canada's (CIRNAC's) 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 DNGS in the past. Should other Indigenous Nations and communities not included in the list identify interest in the licence application moving forward, they will be added as appropriate.

Indigenous Nations and communities with established Indigenous and treaty rights to the lands and waters surrounding and inclusive of the DNGS site include:

- Alderville First Nation,
- Curve Lake First Nation,
- Hiawatha First Nation,
- Mississaugas of Scugog Island First Nation,
- Chippewas of Beausoleil First Nation.
- Georgina Island First Nation
- Chippewas of Rama First Nation

Indigenous Nations and communities with interests and/or rights in relation to the transportation routes and the facilities associated with isotope production and waste management include:

- Mohawks of the Bay of Quinte

- Métis Nation of Ontario
- Algonquins of Ontario
- Algonquins of Pikwàkanagàn
- Six Nations of the Grand River
- Kitigan Zibi First Nation
- Kebaowek First Nation

The CNSC is committed to ongoing engagement and long-term relationships with Nations and communities with interest in CNSC's activities and processes. This engagement fosters discussion on specific projects and activities of potential interest or concern. The CNSC has signed Terms of Reference for long-term engagement with Curve Lake First Nation, Hiawatha First Nation, Mississaugas of Scugog Island First Nation, Métis Nation of Ontario, Algonquins of Pikwàkanagàn and Kebaowek First Nation and will be integrating discussions on OPG's licence amendment application as part of regular meetings with each Nation. The CNSC is open to developing Terms of Reference for long-term engagement with other Indigenous Nations and communities as appropriate.

On September 12, 2024 CNSC staff sent a letter of notification regarding OPG's licence application to the identified Nations and communities that included the Commission's *Notice of Public Hearing*. These letters provided information regarding the proposed licence amendment application, opportunities to participate in the Commission's hearing process, and information about the CNSC's PFP to facilitate participation in the hearing process.

The CNSC made available up to $30,000 through its PFP to support Indigenous Nations and communities, members of the public and stakeholders in providing value added information to the Commission through informed and topic-specific interventions. This funding was offered to review OPG's application and associated documents, and support participation in the Commission hearing process by providing topic-specific interventions to the Commission. Originally, the deadline for submitting PFP applications was September 27, 2024, but was extended to October 11, 2024, to allow for more time for interested parties to prepare and submit applications. All identified Indigenous Nations and communities were notified of this extension via e-mail on September 26, 2024. CNSC staff also worked with Indigenous Nations and communities that did not respond or submit a funding application by the October 11th deadline to confirm if they are interested in applying for funding and if they needed an extension to apply.

Full details on the participant funding made available and all parties that were awarded funding are available in Section 3.1. Mississaugas of Scugog Island First Nation, Curve Lake First Nation and Algonquins of Pikwàkanagàn First Nation applied for and received funding to participate in this Commission hearing.

Following the initial project notifications and notifications on the funding application extension, CNSC staff followed-up with each identified Indigenous Nation and community via phone calls from November 1st to 4th, 2024, to ensure they had received the letters and to answer any questions about the licence amendment application, regulatory process, or participation in the

Commission hearing through a written intervention. Beausoleil First Nation and Six Nations of the Grand River both expressed that they have no concerns or questions on the project and do not anticipate submitting an intervention. When completing the follow-up phone calls, Hiawatha First Nation, Mohawks of the Bay of Quinte and Kebaowek First Nation all expressed difficulty with keeping track of the many different projects occurring at OPG's DNGS site. CNSC staff expressed that they understood and followed up with e-mails the same day that summarized all relevant OPG DNGS projects, to help differentiate between the key details and dates for each.

CNSC staff offered to meet with all identified Indigenous Nations and communities to discuss the application and raised OPG's application in regular meetings under Terms of Reference for long-term engagement arrangements with Curve Lake First Nation, Hiawatha First Nation, Mississaugas of Scugog Island First Nation, Métis Nation of Ontario, Algonquins of Pikwàkanagàn and Kebaowek First Nation. Two Nations requested project-specific discussions: Algonquins of Pikwàkanagàn First Nation and Mississaugas of Scugog Island First Nation.

OPG's application to amend the Darlington Nuclear Generating Station power reactor operating licence to produce two new radioisotopes was discussed with the Algonquins of Pikwàkanagàn First Nation during a monthly meeting on September 25, 2024. Specific topics of interest that were discussed with CNSC staff are summarized here:

- **Algonquins of Pikwàkanagàn First Nation expressed concern on their ability to be able to effectively participate in project processes when information is still unknown or confidential**. CNSC staff noted that the radioisotopes are to be used in the field of nuclear medicine for radiation therapy. After the isotope material is processed, the empty target shells are considered Low Level Waste and will be managed by the processing facility in Kanata. CNSC staff mentioned that the proposed activities are currently covered under the current licence at the Kanata facility and CNSC staff noted there won't be any novel types of waste or change to the emissions limits from the facility. Although the identity of one isotope remains confidential due to commercial sensitivity reasons, CNSC staff noted that for Y-90, the processing will be done at the BWXT-medical facility in Kanata. CNSC staff committed to providing answers to specific questions Algonquins of Pikwàkanagàn First Nation has regarding the project.
- **Algonquins of Pikwàkanagàn First Nation expressed concern regarding waste management, specifically with the transfer of material; how much waste is coming into Algonquin territory, how it would be processed, and how the waste will be managed.** CNSC staff reiterated that after the isotope material is processed, the empty target shells are considered Low Level Waste and will be managed by the processing facility in Kanata. Algonquins of Pikwàkanagàn First Nation mentioned they would like to receive further information on this topic in writing and CNSC staff committed to follow up with additional information. CNSC staff followed-up by email on October 8th in response to the concerns and questions Algonquins of Pikwàkanagàn First Nation raised during the meeting.

At the time of this report's development, a project-specific meeting with the Mississaugas of Scugog Island First Nation is currently scheduled for November 15, 2024. CNSC staff will work

to address the concerns raised to the greatest extent possible and have encouraged MSIFN to include their views and any concerns in their intervention to the Commission that will be submitted in February 2025.

Based on CNSC staff's engagement activities to date, CNSC staff have not identified any concerns with respect to potential new impacts to Indigenous or treaty rights in relation to the licence amendment application and remain committed to ongoing engagement with all identified Nations and communities moving forward.

All 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 this licence amendment application. CNSC staff are committed to ongoing engagement and collaboration with interested Indigenous Nations and communities and will continue to provide opportunities for meaningful long-term engagement and collaboration with respect to OPG's DNGS site projects. CNSC staff have also encouraged OPG to continue engagement with Indigenous Nations and communities about their long-term plans for the DNGS site.

2.7.3 Licensee Engagement Activities

Based on the information in OPG's application, the licence amendment is unlikely to cause new adverse impacts to the exercise of potential or established Indigenous rights as the production of the new isotopes will not change the Darlington NGS site characterization or result in the construction of new facilities at the site.

OPG's Indigenous Relations Policy, OPG-POL-0027, *Indigenous Relations Policy*, provides a framework for engaging with Indigenous Nations and communities and providing support of community programs and initiatives. As part of its Indigenous Relations policy, OPG maintains and Indigenous Relations program for its nuclear operations with the goals of:

- Keeping proximate Indigenous Nations and communities informed of nuclear station operations, emerging projects and station environmental performance;
- Seeking the input and worldviews of Indigenous Nations and community representatives about OPG's ongoing nuclear operations and projects, and;
- Addressing and resolving identified concerns as applicable.

Additionally, OPG's Reconciliation Action Plan sets out measurable goals to advance reconciliation with Indigenous Nations, communities, and businesses.

OPG's application includes an Indigenous Engagement Plan [30], developed in line with the guidance of REGDOC 3.2.2-*Indigenous Engagement*. The plan states that OPG will engage with identified Indigenous Nations and communities which have inherent and/or Aboriginal and treaty rights or interests regarding the project, with activities including ongoing dialogue and project

[30] NK38-PLAN-00120-00018 *Isotope Engagement And Communications Plan With Indigenous Communities*

overview meetings. Feedback and concerns from Indigenous Nations and communities will be collected during in-person/virtual meetings, correspondence or other methods as determined by OPG and the communities. Actionable feedback will be recorded and tracked in a project-specific Engagement Log.

OPG's engagement specific to the DNGS licence amendment to produce new isotopes has consisted of:

- In November 2023, a formal notification letter sent via e-mail to all identified Indigenous Nations and communities.
- In December 2023, notification letter follow-up.
- In January/February 2024, presentation meetings with Indigenous Nations and communities, as requested.
- March 2024 onwards, follow-up meetings as required.

Full details of all the engagement activities undertaken by OPG can be found in NK38-PLAN-00120-00018 *Isotope Engagement And Communications Plan With Indigenous Communities.*

CNSC staff are satisfied with OPG's engagement activities to date and encourages OPG to continue working with Indigenous Nations and communities through ongoing engagement, including discussing issues and concerns raised and working collaboratively to address them.

The proposed modifications associated with this licence amendment are confined to the existing footprint of OPG's Darlington facility and impacts beyond the existing limits of the operation of DNGS are expected to be negligible. Therefore, CNSC staff have determined that this licensing decision is unlikely to have potential new impacts on Indigenous and/or treaty rights.

For this licence amendment application, both OPG and the CNSC staff conducted engagement activities with interested Indigenous Nations and communities in relation to the DNGS, the project's transportation route and facilities associated with isotope production and waste management, to ensure that each Nation and community has the ability to express any specific issues or concerns with regards OPG's licence application and participate in in the regulatory review process including the Commission hearing. The CNSC is committed to meaningful, ongoing engagement and collaboration with Indigenous Nations and communities that have an interest in CNSC regulated facilities and activities and encourages OPG to continue to engage with interested Indigenous Nations and communities on this licence amendment and other ongoing activities of interest.

3. Other Matters of Regulatory Interest

The following table identifies other matters that are relevant to this licence amendment and where they are discussed in this CMD. A brief discussion justifying the omission of a more fulsome discussion is provided for a selection of topics indicated by an *.

Table 1 - Inventory of Other Matters of Regulatory Interest Included in this CMD

OTHER MATTERS OF REGULATORY INTEREST		
Area	**Relevant to this CMD?**	**Additional information in section**
Participant Funding	Yes	3.1
Other Consultation	No	
Cost Recovery	No	
Financial Guarantees	No*	2.6.11
Improvement Plans and Significant Future Activities	No	
Licensee's Public Information Program	No*	0
Impact Assessment Act	No*	2.5 & 2.6.9
Environmental Protection Review	No*	2.5 & 2.6.9
Nuclear Liability Insurance	No*	3.3

3.1 Participant Funding

The Canadian Nuclear Safety Commission's (CNSC) established the Participant Funding Program (PFP) 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 nuclear 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.

The CNSC made available up to $30,000 through its PFP to support Indigenous Nations and communities, members of the public and stakeholders in providing value added information to the Commission through informed and topic-specific interventions. This funding was offered to review OPG's application and associated documents and to prepare written submissions for the Commission's hearing in writing.

The deadline for applications was September 27th, 2024 but was extended to October 11, 2024 to allow more time to submit applications. A Funding Review Committee (FRC), independent from CNSC staff, reviewed the funding applications received, and made recommendations on the

allocation of funding to eligible applicants. Based on recommendations from the FRC, the CNSC awarded a total of **$30,900** in funding to the following recipients, who are required to submit a written intervention to the Commission Registry by February 7, 2025, for the Commission's consideration:

Applicant	Maximum amount of available funding
Mississaugas of Scugog Island First Nation	$12,420
Curve Lake First Nation	$6,510
Algonquins of Pikwàkanagàn First Nation	$6,000
Canadian Association of Nuclear Host Communities	$5,970
Total	**$30,900**

The CNSC continues to actively promote ongoing communication and dissemination of regulatory and scientific information through social media channels, webinars, outreach in the local communities and postings on the CNSC web site. The CNSC has various mechanisms and processes such as the PFP and mail outs to encourage the public to participate in the Commission's hearing process, as described above. The CNSC has offered assistance to interested members of the public, Indigenous Nations and communities, and other stakeholders, through the PFP, to prepare for and participate in the Commission's hearing process.

3.2 Licensee's Public Information Program

OPG implements a public information and disclosure program that covers activities performed at the Darlington site and meets the requirements of CNSC REGDOC- 3.2.1, *Public Information and Disclosure*. The primary goal of the program 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, is shared with the public in a format relevant to the audience. The program includes a commitment and protocol for ongoing, timely dissemination of information related to the licensed facility.

As discussed in recent annual Regulatory Oversight Report for Canadian Nuclear Power Generating Sites [8, 9], OPG has adapted its public information and disclosure program to respect current health and safety guidelines, executing both hybrid and in-person program models as appropriate. OPG has continued to offer updates through participation in community meetings and events, webinars, newsletters and social media campaigns, and open houses and station tours.

CNSC staff are satisfied that OPG's public information and disclosure program is sufficient to communicate updates related to the production of Lu-177 and Y-90 at Darlington NGS to the public, including local community members and elected officials in the region of Durham.

3.3 Nuclear Liability Insurance

The *Nuclear Liability and Compensation Act* (NLCA) and *Nuclear Liability and Compensation Regulations* (NLCR) establish a compensation and liability regime for Canada in the unlikely event of a nuclear accident resulting in civil injury and damages. The CNSC acts in an advisory role to the Minister of Natural Resources on the designation of nuclear installations and operators.

National Resources Canada is responsible for assessing the limit of liability for each class of nuclear installation. Darlington NGS is currently assessed at one billion dollars. Because this is the maximum limit of liability under the NLCA, the new activities authorized under the proposed amendment will not impact OPG's obligations under the act. OPG is meeting its obligation for nuclear liability coverage under the NLCA

3.4 CNSC staff Proposal for a Regulatory Hold Point and delegation of authority

As discussed throughout section 2.6, OPG's application asserts that the impact of production of Lu-177 and Y-90 will be bounded by the existing safety case for production of Mo-99. However, as discussed throughout section 2.6, at the time of writing this CMD, OPG had not finalized the final safety analysis documentation to fully substantiate this assertion.

CNSC staff recommend that the Commission establish an RHP prior to OPG declaring AFS of the new isotopes. AFS is the point at which OPG will have completed the commissioning activities and will be ready to turn the new isotope production over for normal station operations.

CNSC staff recommend AFS as the appropriate project milestone for the RHP because it will allow OPG to introduce the new isotope targets into the core for the limited purpose of commissioning and validation activities. CNSC staff consider this acceptable because OPG's ECC process requires the safety analysis to be completed before introducing the new targets, and because there is heightened attention to the activity during the commissioning phase, such that there are additional resources available to react to any unexpected system responses.

The purpose of the RHP is for CNSC staff to review documentation that is necessary to confirm OPG has conclusively demonstrated that the safety case for the new isotopes is bounded by the Mo-99 analysis and existing licensing basis limits as applicable, as well as verifying aspects of operational readiness.

If CNSC staff conclude that OPG's analysis demonstrates that the new isotopes are not bounded by the existing safety analysis, the RHP will not be removed, the commission will be informed, and OPG's will not be authorized to operate the TDS for the production of Lu-177 and Y-90.

CNSC staff consider this approach of establishing an RHP in lieu of prior review of complete information to be risk informed, because:

- the proposed change is relatively straightforward; no physical modifications or new equipment will be needed on the TDS or Unit 2 in general, and the operating parameters which will be impacted by the new isotopes are well understood based on experience with Mo-99
- extensive assessments that supported the Mo-99 application were reviewed by CNSC staff for CMD 21-H107 and have contributed considerable knowledge of the bounding case under which the TDS operates

- the preliminary reactor physics information presented in OPG's application indicate that that OPG will be able to demonstrate that the new targets remain bounded by the Mo-99 safety case
- the proposed deliverables are being produced under OPG's Engineering Change Control (ECC) process which CNSC staff inspect regularly and which is compliant with CSA N286-12 requirements
- the use of an RHP will ensure CNSC staff review the safety analyses as well as the commissioning results, that will confirm that OPG's bounding case assertion is verified prior to AFS.

3.4.1 Proposed Scope of Regulatory Hold Point

The specific deliverables proposed under the RHP are described and justified in section 2.6. The deliverables include commitments made by OPG in Appendix A of the application (this list is reproduced in section 3.4.2 for reference), and other information which CSNC staff consider necessary to fulfill the intent of the RHP. All proposed RHP items are listed here along with a description of the deliverable and completion criteria:

Table 2 – Proposed Scope of Regulatory Hold Point

RHP Item	Topic	OPG Deliverables	CNSC review Completion Criteria
1	Design	Finalized designs for the Lu-177 and Y-90 targets: 1.1 Lu-177 and Y-90 Target Capsule Design Requirements 1.2 Final Lu-177 and Y-90 Target Drawings approved by OPG Design Authority	Verify that the design has been accepted by OPG in accordance with the ECC process and that appropriate regulatory requirements have been met.
2	Radiological Hazard Assessment	Updated TDS ALARA assessment NK38-REP-305500-00012, incorporating irradiation of Lu-177 and Y-90	Verify that the ALARA Assessment Report reviewed and approved by OPG RP and Design Authority in accordance with the applicable OPG processes. Verify that OPG DNGS RP staff have reviewed the design change and are capable of managing the radiological hazards associated with the new targets.

3	Safety Analysis	Detailed nuclear safety analysis for Lu-177 and Y-90, and disposition of any changes being introduced against the existing safety case, design, or operating manual.	Verify the reports are procured, reviewed and approved by OPG in accordance with the ECC process and Reactor Safety Program. Verify the scope, methodology, conclusions, and limitations of the safety assessments are consistent with the Mo-99 assessments. Verify that results demonstrate that the new isotopes are bounded the existing station SOE. Verify chemistry assessment confirms no adverse chemistry impact from new isotopes.
4	Human Factors	Human Factors assessment reports: 4.1 Human Factor Engineering Program Plan 4.2 Human Factors Engineering Summary Report R000 4.3 Human Factors Engineering Summary Report R001	Verify that design changes are implemented in accordance with OPG process and relevant standards.
5	Procedures	Marked-up revision to NK38-OM-30550 Darlington Operating Manual – Target Delivery System (TDS) used for commissioning	Verify that all required changes are reflected in the documents.
6	Environmental	Updated Predictive Environmental Assessment NK38-REP-30550-00029, incorporating irradiation of Lu-177 and Y-90 OR Justification based on review under the ECC process for why an update is not required, and how the additional isotopes will be reflected in environmental governance.	Verify that the irradiation of the new isotopes has been included in OPG environmental governance.

7	Certified transport packages	Copy of CNSC confirmation of transport packaging registration	Verify that the certified transport packages can be used for the capsules containing Lu-177 and Y-90 per PTNSR
8	Commissioning	Commissioning documentation in accordance with N-PROC-MP-0090: 9.1 Commissioning specifications for Lu-177 and Y-90 9.2 Commissioning workplans for Lu-177 and Y-90 9.3 Commissioning Reports for Lu-177 and Y-90	Verify that testing is planned and conducted to address attributes specific to the new isotopes. Verify that commissioning results show reasonable agreement with predictions.

3.4.2 Licensee Regulatory Commitments

OPG committed in the Appendix A of the Application to provide the following documentation when completed, which are included in the scope of the RHP:

Table 3 – Regulatory Commitments from Appendix A of OPG's application

#	Description	REGM #
1	Submit the OPG accepted target capsule design for Lu-177 to CNSC staff.	28265351
2	Submit the OPG accepted target capsule design for Y-90 to CNSC staff.	28265352
3	Submit the detailed nuclear safety analysis that confirms and validates the safety impacts during the detailed engineering phase of the project for CNSC staff review.	28265354
4	Submit the revised Target Delivery System Design ALARA Assessment report (NK38-REP-30550-00012,) which incorporates the production of Lu-177 and Y-90 for CNSC staff review.	28265355
5	Submit the Human Factors Assessment completed as part of the detailed engineering phase for CNSC staff review	28265356
6	Submit the commissioning report for Lu-177 for CNSC staff review	28265357
7	Submit the commissioning report for Y-90 for CNSC staff review	28265358

3.4.3 Delegation of authority for removal of RHP

The Commission may include any licence condition it considers necessary for the purposes of the NSCA. The Commission may also delegate authority to a position within CNSC staff with respect to the administration of licence conditions, or portions thereof.

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.

CNSC staff note that previously, authority to remove RHPs related to the Darlington licence (e.g. Mo-99, Refurbishment) has been delegated to the EVP-CROO. CNSC staff are of the opinion that the DG-DPRR, as the CNSC staff member with overall responsibility for the regulation of power reactors, is the appropriate level of authority to remove the proposed RHP because the commissioning of the new isotopes is not a first of a kind activity, and staff have acquired relevant experience in previous isotope-related licence amendments. Delegation to the DG-DPRR will simplify the administration of hold point removal compared to the previous practice.

3.4.4 Process for removing the regulatory hold point

CNSC staff are recommending that the Commission approve the following process for the removal of a regulatory hold point by the Delegated Authorized by the Commission:

1) OPG submits a request to CNSC staff for the removal of the hold point. OPG's request must include sufficient information to demonstrate that all eight (8) of the pre-requisites listed in Table 2 have been satisfied.
2) CNSC staff will review the submitted information and verify OPG's compliance with regulatory requirements and commitments. Any safety significant actions arising from this review shall be closed prior to proceeding with hold point removal.
3) Based on the submitted information, CNSC staff will provide a report to the Delegated Authority, describing whether the pre-requisites specified in the LCH have or have not been met and a recommendation on whether to release the RHP.
4) The Delegated Authority specified by the Commission will then consent or not consent to the removal of the requested regulatory hold point.
5) CNSC staff will administer the removal of the hold point through a confirmation letter to OPG.

CNSC staff will provide the Commission with updates, through the registry, regarding the removal of the RHP.

4. Proposed Licence Changes

The changes proposed to be made in the Darlington Power Reactor Operating Licence (PROL) and Licence Conditions Handbook (LCH) support the implementation of Lu-177 and Y-90 production at Darlington. If the licence is amended, activities specific to Lu-177 and Y-90 production will be authorized using the TDS on Darlington Unit 2.

Table 4 below provides the references of the current and proposed PROL and LCH. An * is used to identify the documents that will be reproduced in Part 2 of this CMD.[31] A copy of the current PROL (PROL 13.04/2025) and LCH (LCH-PR-13.03/2023-R005) are available upon request to the Commission Registry. Appendix A to this CMD contains the draft PROL (PROL 13.05/2025).

Table 4 - References of existing and proposed licence documents

Proposed			**Current**		
Version	**Word e-Doc**	**PDF e-Doc**	**Version**	**Word e-Doc**	**PDF e-Doc**
*PROL 13.05/2025	7364278	7364283	*PROL 13.04/2025	7076591	7076592
LCH Section 15.6 – Draft LCH-PR-13.05/2023-R000	See Section 4.2		*LCH-PR-13.03/2023-R005	6668656	6668658

4.1 Licence Changes

The proposed licence amendment will require changes to the following sections of the PROL

- Licence number: PROL 13.04/2025 will change to 13.05/2025, indicating the fifth revision of the licence since PROL 13.00/2025 was issued in January 2016
- Section IV) LICENSED ACTIVITIES: will be modified to include the new activities associated with Lu-177 and Y-90
- Licence Condition 15.6: this licence condition is currently specific to Mo-99 production and will need to be updated to include the new isotopes. Reference to Regulatory Hold Points will also be removed from this section, since Licence Condition 15.4 already covers the use of RHPs

4.1.1 Licensee Proposed Amendment to the PROL

OPG proposed the following change to the licence in their application:

Table 5 - Proposed Update to PROL in OPG's Application

Current PROL 13.03/2025	**Requested Amendment to PROL 13.03/2025 (Revised**

[31] Only in the final version of the CMD

	proposed amendment in bold and italic)
IV) LICENCED ACTIVITIES: This licence authorizes the licensee to: ... (vi) possess, transfer, process, package, manage and store Molybdenum-99 radioisotope and its associated decay isotopes.	**IV) LICENCED ACTIVITIES:** This licence authorizes the licensee to: ... (vi) possess, transfer, process, package, manage and store Molybdenum-99, **Lutetium-177 and Yttrium-90** radioisotope**s** and **their** associated decay isotopes.

CNSC staff note that in the time since OPG's application, the Darlington NGS licence was amended to include the production on Co-60. The new license, PROL 13.04/2025, modified section IV) of the license. CNSC staff further note that section 15.6 of the licence will also need to be amended, as it is currently specific to production of Mo-99.

4.1.2 CNSC staff proposed Amendment to the PROL

CNSC staff propose the following amended text for the PROL sections IV and 15.6:

Table 6 – CNSC staff's proposed update to the PROL

PROPOSED LICENCE CHANGES	
Current License 13.04/2025	Proposed Text (changes indicated in ***Bold Italics***)
IV) LICENSED ACTIVITIES: This licence authorizes the licensee to: … (vi) produce, possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities associated with operations of the Darlington Nuclear Generating station and activities described in (i) associated with production of: (1) Co-60; and (2) Mo-99 (including its decay radionuclides);	**IV) LICENSED ACTIVITIES** This licence authorizes the licensee to: ... (vi) produce, possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities associated with operations of the Darlington Nuclear Generating station and activities described in (i) associated with production of: (1) Co-60; and (2) ***Y-90***, Mo-99 ***and Lu-177*** Including ***the associated*** decay radionuclides.
Licence Condition 15.6	Licence Condition 15.6

The licensee shall implement and maintain an operations program for the production of Molybdenum-99 and its associated decay isotopes. The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.	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).*** ~~The licensee shall obtain the approval of the Commission, or a person authorized by the Commission, prior to the removal of established regulatory hold points.~~

In the proposed rewording of section IV of the license, the names of the radionuclides have been grouped as "(1) Co-60; and (2) Y-90, Mo-99 and Lu-177" because Co-60 is produced in the adjustor rods, whereas Y-90, Mo-99 and Lu-177 are produced using the TDS; for this reason it is useful to be able to reference these two groups of radionuclides separately.

In the proposed Licence Condition 15.6, the wording has been changed from being specific to Molybdenum-99 to discussing the TDS, since the same system is used to produce all three radionuclides listed in section IV (vi) (2). The wording related to requirements to remove established regulatory hold points has been removed because this instruction is already present in Licence Condition 15.4 and does not need to be repeated.

All text in the PROL not included in Table 6 will remain unchanged.

4.1.3 Licence Format

This CMD does not propose any changes to the format of the licence.

4.1.4 Licence Period

This CMD does not propose any changes to the licence period.

4.2 Proposed amendment text to the LCH

Section 15.4 of the LCH relates to removal of establish regulatory hold points. In the current LCH this section is specific to RHPs associated with the Refurbishment project. Details related to the removal of the RHP proposed for new isotopes will be added to Section 15.4.

Section 15.6 of the LCH is specific to operation of the TDS. This section is reproduced below, with the proposed change indicated by strikethrough of text to be removed and red for text to be added.

The scope of the proposed changes is as follows:

- Replace the name “Mo-99 IIS / TDS” with “TDS”, to align terminology with what is used in OPG documentation
- Include reference to Lu-177 and Y-90 where only Mo-99 is reference in the current version
- Change references to “production of Mo-99” to “operation of the TDS”. Previously these two phrases could be used interchangeably, however with the introduction of additional isotopes they are no longer synonymous
- Remove reference to “process” as an authorized activity, as OPG is not authorized to process the radionuclides produced by the TDS on site, and this word should not have been included in previous version of the PROL and LCH
- Describe the process for removal of the proposed RHP in Section 15.4, under a new heading which separated the Refurbishment RHPs from the TDS RHP. While the proposed text is based on CNSC staff’s recommendation regarding the RHP described in this CMD, it is not meant to presuppose the commission’s decision regarding delegation of its authority. The final text of the LCH will be updated to reflect the Commission’s direction with regards to a potential RHP in the Record of Decision, or will be removed if the Commission elects not to delegate its authority for this amendment.

The proposed text for the amended LCH is presented in Appendix A.

5. Overall Conclusions and Recommendations

5.1 Conclusions

OPG's application seeks an amendment to the DNGS PROL to permit the production of the medical isotopes Lu-177 and Y-90 using the existing TDS.

CNSC staff determined that:

- There will be no impact on existing Structure, Systems and Components, as no new equipment is being installed
- The change does not require an update to the PSR outside the normal update frequency
- The change does not impact safeguards provisions
- OPG has a robust ECC process for managing the changes, which CNSC staff inspect regularly and have reason to be confident will safely manage the change
- OPG asserts that the impact of the new targets will be bounded by (no greater than) the impact of the existing Mo-99; CNSC staff will verify this assertion under a regulatory hold point prior to AFS for the new isotopes
- OPG continues to engage with indigenous groups
- OPG will continue to protect the health and safety of the public and the environment

CNSC staff's determinations, conclusion and recommendation are for the Commission's information to support its decision. CNSC staff have concluded that, with respect to subsection 24(4) of the NSCA, that OPG:

> (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
> (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

5.2 Recommendations

CNSC staff recommend that the Commission approve OPG's request for licence amendment to produce Lu-177 and Y-90 using the TDS at Darlington, and approve the following changes to the PROL and its associated LCH (reproduced this CMD)

IV) LICENSED ACTIVITIES

> This licence authorizes the licensee to:
> ...
> (vi) produce, possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities associated with operations of

the Darlington Nuclear Generating station and activities described in (i) associated with production of:
(1) Co-60; and
(2) ***Y-90***, Mo-99 ***and Lu-177***
including ***the associated*** decay radionuclides.

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).

Furthermore, CNSC staff recommend that the Commission approve an RHP, to be administered via Licence Condition 15.4, for CNSC staff to review and verify, as required, safety analysis and operational readiness documentation for Lu-177 and Y-90, prior AFS for Lu-177 and Y-90.

CNSC staff also recommend that the Commission delegate the authority for the consent to remove the RHP to the Director General of the Directorate of Power Reactor Regulation.

References

[1] OPG letter, A. Grace to D. Saumure, "Darlington NGS - Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production," 2024-02-26. [CD# NK38-CORR-00531-25141, e-Doc 7230117 (application), 7230118 (confidential filings request)] *Pro B(R)*

[2] 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" 2024-11-29. [CD# NK38-CORR-00531-25810 P, e-Doc 7417944] *Public*

[3] OPG email, L. Moraru to A. Oussoren, "Darlington NGS - Response to CNSC Staff Request for Additional Information Regarding OPG's Application for Additional Isotope Production at DNGS - B14B-F6B and B142-4C1," 2024-05-01. [CD# NK38-CORR-00531-25087, e-Doc 7273699, 7274312] *Pro B(R)*

[4] OPG email, L. Moraru to A. Oussoren, "CONFIDENTIAL - Darlington NGS - Response to CNSC Staff Request for Additional Information Regarding OPG's Application for Additional Isotope Production at DNGS - B14B-F6B and B142-4C1, Attachement 1," 2024-05-01. [CD# NK38-CORR-00531-25087P, e-Doc 7273699, 7274314] *Pro B(R)*

[5] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Unit 2 Predictive Effects Assessment (ERA01-01-U2)," 2020-11-24. [CD# NK38-CORR-00531-22155 P, e-Doc 6430304] *Protected B(R)*

[6] OPG letter, R. Geofroy to J. Burta, "Darlington NGS – Cobalt-60 Production Modifications Project – Submission of the Predictive Effects Assessment," 2022-04-27. [CD# NK38-CORR-00531-23353 P, e-Doc 6787034] *Pro B(R)*

[7] OPG letter, A. Grace to C. Salmon, Darlington NGS – Update to Application for Amendment to Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production", 2024-10-16, [CD# NK38-CORR-00531-25747, e-Doc 7382969] *Public*

[8] CNSC, "Regulatory Oversight Report for Canadian Nuclear Power Generating Sites for 2021," in "Annual Program Report," 22-M34, 3 November 2022. [e-Doc 6835691] *Public*

[9] CNSC, "Regulatory Oversight Report for Canadian Nuclear Power Generating Sites for 2022," in "Annual Program Report," 23-M36, 13-14 December 2023. [e-Doc 7118809] *Public*

Acronyms

AFS	Available for Service
ALARA	As Low As Reasonably Achievable
ASL	Approved Suppliers List
CANDU	Canadian Deuterium Uranium reactor
CINFR	Class I Nuclear Facilities Regulations
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
CSA	Canadian Standards Association
DG-DPRR	Director General of the Directorate of Power Reactor Regulation
DNGS	Darlington Nuclear Generating Station
DRL	Derived Release Limit
ECC	Engineering Change Control
EPR	Environmental Protection Reviews
ERA	Environmental Risk Assessment
EVP-CROO	Executive Vice President and Chief Regulatory Operations Officer
FMEA	Failure Modes Effects Analysis
FOAK	First of a Kind
GNSCR	General Nuclear Safety and Control Regulations
IAA	Impact Assessment Act
IIL	Internal Investigation Limit
IIS	Isotope Irradiation System
LCH	Licence Conditions Handbook
LEP	Laurentis Energy Partners
Lu-177	Lutetium 177
Mo-99	Molybdenum 99
NLCA	Nuclear Liability and Compensation Act
NNIECR	Nuclear Non-Proliferation Import and Export Control Regulations
NRU	National Research Universal reactor
NSCA	Nuclear Safety and Control Act
NSR	Nuclear Security Regulations
NSRDL	Nuclear Substance and Radiation Devices Licence
NSRDR	Nuclear Substances and Radiation Devices Regulations
OP&P	Operating Policies and Principles
OPEX	Operating Experience
OPG	Ontario Power Generation
OSR	Operational Safety Requirement
PEA	Predictive Effects Assessment

PFP	Participant Funding Program
PROL	Power Reactor Operating Licence
PSA	Probabilistic Safety Assessment
PTNSR	Packaging and Transport of Nuclear Substances Regulations
REGDOC	Regulatory Document
RHP	Regulatory Hold Point
RMD	Reactivity Mechanism Deck
RPPE	Radiological Personal Protective Equipment
RPR	Radiation Protection Regulations
RRS	Reactor Regulating System
SAT	Systematic Approach to Training
SCA	Safety and Control Area
SOE	Safet Operating Envelope
SpA	Specific Area
TDGR	Transport Canada's Transportation of Dangerous Goods Regulations
TDS	Target Delivery System
Y-90	Yttrium 90

Appendix A – Proposed Changes to the LCH

15.4 Regulatory Hold Points for Return to Service and Continued Operations and the Target Delivery System

Licence Condition:

The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

Refurbishment Regulatory Hold Points

<the existing text in LCH section 15.4, from Preamble to Recommendation and Guidance, will remain unchanged under this heading>

Target Delivery System Regulatory Hold Points

Preamble

In the 2025 Record of Decision for Lu-177 and Y-90 production, the Commission established a regulatory hold point (RHP),and delegated the authority for the removal of the regulatory hold points to the Director General of the Directorate of Power Reactor Regulation. Specifically, the Commission stated:

<quote to be added from the Record of Decision>

Compliance Verification Criteria

For the production of Lu-177 and Y-90 using the TDS on Unit 2, the RHP established by the Commission is to be removed prior to declaration of Available for Service for these radionuclides.

Prior to removing the RHP, CNSC staff shall verify, and the DG-DPRR shall be satisfied, that OPG has completed all required actions in accordance with Table 2 CMD-24-H100 for the following areas:

1) Design
2) Radiological Hazard Assessment
3) Safety Analysis
4) Human Factors
5) Procedures
6) Environmental
7) Certified transport packages
8) Commissioning
9) Resolution of all safety significant issues

Process to remove regulatory hold points

The process for the removal of the regulatory hold point is as follows:

1) The licensee submits a request to CNSC staff for the removal of the hold point. The licensee's request must include sufficient information to demonstrate that all pre-requisites have been satisfied.
2) CNSC staff will review the submitted information and verify the licensee's compliance with regulatory requirements and commitments.
3) Based on the submitted information, CNSC staff will provide a report, including recommendations, to the Delegated Authority specified by the Commission, regarding whether the pre-requisites, specified in the LCH, have or have not been met.
4) The Delegated Authority specified by the Commission will then consent or not consent to the removal of the requested regulatory hold point.
5) CNSC staff will administer the removal of the hold point through a confirmation letter to the licensee.

Recommendation and Guidance

OPG and CNSC staff will bilaterally issue a Lu-177 and Y-90 protocol intended to manage the prerequisites for RHP removal and for production of certain deliverables by both parties, to obtain certainty around the schedule and scope of these deliverables.

15.6 ~~Molybdenum-99 Isotope Irradiation Program~~ Target Delivery System Operation

Licence Condition:

~~The licensee shall implement and maintain an operations program for the production of molybdenum-99 and its associated decay isotopes. The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the~~

~~**removal of established regulatory hold points.**~~

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, ~~process~~, package, manage and store ~~molybdenum-99 radioisotope (Mo-99) and its associated decay isotopes~~Y-90, Mo-99 and Lu-177 (including the associated decay radionuclides)*. Using the ~~Mo-99 Isotope Irradiation System (IIS; also referred to as the TDS – target delivery system – in OPG documentation)~~ Target Delivery System, OPG is only authorized to produce Y-90, Mo-99 and Lu-177 from Y-89, ~~natural molybdenum (~~Mo-98~~)~~ and Yb-189, respectively, at Darlington NGS Unit 2. Units 1, 3, and 4 do not produce ~~Mo-99~~ these radionuclides as OPG has not established a Commission approved safety case for a~~n IIS /~~ TDS designed for these units.

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 by removing the adjuster rod assemblies, and installing target elevators ~~which will~~ that raise and lower ~~molybdenum~~ targets into and out of the core. The ~~Mo-99 IIS~~ TDS ~~will~~ interfaces with numerous existing systems including instrument air and class III & IV electrical power, and ~~will~~ forms a part of the containment boundary. Redundant, interlocked containment valves ~~will be~~ 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 ~~Mo-99~~ various radionuclides through normal commercial operations (~~Mo-99 as a result of the decay chain of~~i.e. fission products and their associated decay products produced in CANDU fuel) and through operation of the ~~Mo-99 IIS /~~ TDS at Darlington NGS – Unit 2. Only ~~Mo-99~~ radionuclides produced with the ~~IIS /~~ 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 ~~Mo-99 IIS /~~ TDS

In accordance with the Record of Decision,[32] the Commission has limited OPG to installing and operating the ~~Mo-99 IIS /~~ TDS on Unit 2 at Darlington NGS. OPG has been directed to return to the Commission if it wishes to ~~expand the licensing basis supporting licence condition 15.6 to produce Mo-99 through the operation of a~~ ~~Mo-99 IIS /~~ install a TDS on additional units at Darlington NGS.

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, *Darlington Operating manual – Target Delivery System*; 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, *Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*. ~~Prior to commercial operations, OPG is required to validate the assumptions made in developing the licensing basis though commissioning activities conducted in accordance with OPG's Engineering Change Control (ECC) process.~~

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 ~~Mo-99~~ Radionuclides

~~When managing Mo-99 produced at Darlington NGS Unit 2,~~ 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 ~~Mo-99~~ 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 ~~Mo-99~~ radionuclides and shipping ~~it~~ them off-site.

At all times, ~~Mo-99~~ radionuclides produced and harvested by the ~~Mo-99 IIS /~~ TDS on Unit 2 ~~is~~ are required to be stored in a certified transport flask. All other uses and storage practises are prohibited.

[32] 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, Date of Decision October 26, 2021. CNSC. 2021. e-Doc 6667685.

When flasking, hoisting, managing, and storing[33] ~~Mo-99~~ radionuclides produced in the TDS (effectively ~~a~~ sealed sources), OPG shall follow NK38-MMP-30550-00013, *Target Delivery System Flask Hoisting and Handling Procedure,* and the relevant associated procedures under OPG's Radiation Protection Program and Nuclear Security program.[34]

Licensed Activities

Prohibition of Use of ~~Mo-99~~ 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 ~~Mo-99~~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.

The following documents require written notification of change:

Document Title	Document #	Prior Notification?
Darlington Operating Manual – Target Delivery System (TDS)	NK38-OM-30550	No
Target Delivery System Flask Hoisting and Handling Procedure	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 HS /~~ TDS on Unit 2*

~~**Regulatory Hold Points**~~

~~In the 2021 Record of Decision for the Mo-99 related Darlington licence amendment, the Commission defined two regulatory hold points (RHPs), and delegated the authority for the~~

[33] 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.
[34] Implementing the requirements of REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*

~~removal of the regulatory hold points to the executive vice president and chief regulatory operations officer, regulatory operations branch. Specifically, the Commission stated:~~

> ~~*In the administration of licence condition 15.6, the Commission also authorizes the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch to release the two regulatory hold points, related to the installation and commissioning of the Mo-99 IIS, upon verifying that the prerequisite steps for release have been taken by the licensee.*~~

~~For the Mo-99 IIS / TDS on Unit 2, the RHPs established by the Commission are to be removed prior to:~~

~~RHP-1) Installation – Modifying the reactor or containment boundary through activities related to the installation of the Mo-99 IIS / TDS. **Note**: OPG is not precluded from installing components or performing work that remains within its licensing basis.~~

~~RHP-2) Commissioning – Commencing any on-power tests or commissioning activities of the Mo-99 IIS / TDS. **Note**: OPG is not prohibited from performing *in situ* testing or commissioning activities, before or during the Mo-99 IIS / TDS installation outage, in accordance with OPG's project documentation.~~

~~EVP-CROO~~

~~1) Demonstrates that all actions are complete in accordance with CMD-21-H107.~~
~~2) Demonstrates that all appropriate OPG approvals have been issued~~
~~3) Demonstrates that any safety significant action items have been addressed~~

~~Process to remove regulatory hold points~~

~~The process for the removal of the regulatory hold point is as follows:~~

~~6) The licensee submits a request to CNSC staff for the removal of the hold point.~~
~~7) The licensee's request must include sufficient information to demonstrate that all pre-requisites have been satisfied.~~
~~8) CNSC staff will review the submitted information and verify the licensee's compliance with regulatory requirements and commitments.~~
~~9) Based on the submitted information, CNSC staff will provide a report, including recommendations, to the Delegated Authority specified by the Commission, regarding whether the pre-requisites, specified in the LCH, have or have not been met.~~
~~10) The Delegated Authority specified by the Commission will then consent or not consent to the removal of the requested regulatory hold point.~~
~~11) CNSC staff will administer the removal of the hold point through a confirmation letter to the licensee.~~

~~1) OPG submits a request to CNSC staff for the removal of the hold point.~~
~~2) OPG's request must include sufficient information to demonstrate that all pre-requisites have been satisfied.~~
~~3) CNSC staff will review the submitted information and verify the licensee's compliance with regulatory requirements and commitments.~~
~~4) Based on the submitted information, CNSC staff will provide a report to the Delegated Authority specified by the Commission, describing whether the pre-requisites specified in the LCH have or have not been met and a recommendation on whether to release the RHP.~~
~~5) The Delegated Authority specified by the Commission will then consent or not consent to the removal of the requested regulatory hold point.~~
~~6) CNSC staff will administer the removal of the hold point through a confirmation letter to the licensee.~~

Recommendations and Guidance

Not applicable to this LC.

Current Licence

Canadian Nuclear Safety Commission / Commission canadienne de sûreté nucléaire

Word Ref.: e-Doc 7076591
PDF Ref.: e-Doc 7076592
File / Dossier: 2.01

NUCLEAR POWER REACTOR OPERATING LICENCE

DARLINGTON NUCLEAR GENERATING STATION

I) LICENCE NUMBER: **PROL 13.04/2025**

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act* this licence is issued to:

Ontario Power Generation Inc
700 University Avenue
Toronto, Ontario
M5G 1X6

III) LICENCE PERIOD: This licence is valid from January 1, 2016 to November 30, 2025, unless suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(i) operate the Darlington Nuclear Generating Station, including equipment for the production of radionuclides identified in (vi) and the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter "the nuclear facility"), at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario; [Amended 2024.06]

(ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i);

(iii) import and export nuclear substances, except controlled nuclear substances, that are required for, associated with, or arise from the activities described in (i);

(iv) possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the activities described in (i);

(v) possess, transfer, process, package, manage and store the nuclear substances associated with the operation of the Darlington Tritium Removal Facility;

(vi) produce, possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities associated with operations of the Darlington Nuclear Generating station and activities described in (i) associated with production of: (1) Co-60; and (2) Mo-99 (including its decay radionuclides); [Amended 2024.06]

V) EXPLANATORY NOTES:

(i) Nothing in this licence shall be construed to authorize non-compliance with any other applicable legal obligation or restriction.

(ii) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and associated Regulations.

(iii) The Darlington NGS Licence Conditions Handbook (LCH) provides compliance verification criteria including the Canadian standards and regulatory documents used to verify compliance with the conditions in the licence. The LCH also provides information regarding delegation of authority, applicable versions of documents and non-mandatory recommendations and guidance on how to achieve compliance.

VI) CONDITIONS:

G. General

G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations
(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence
(iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC, hereinafter "the Commission").

G.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

G.3 The licensee shall control the use and occupation of any land within the exclusion zone.

G.4 The licensee shall provide, at the nuclear facility and at no expense to the Commission, suitable office space for employees of the Commission who customarily carry out their functions on the premises of that nuclear facility (onsite Commission staff).

G.5 The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.

G.6 The licensee shall implement and maintain a public information and disclosure program.

1. Management System

1.1 The licensee shall implement and maintain a management system.

2. Human Performance Management

2.1 The licensee shall implement and maintain a human performance program.

2.2 The licensee shall implement and maintain the minimum shift complement and control room staffing for the nuclear facility.

2.3 The licensee shall implement and maintain training programs for workers. The certification process and supporting examinations and tests shall be conducted in accordance with CNSC regulatory document REGDOC-2.2.3, PERSONNEL CERTIFICATION, VOLUME III: CERTIFICATION OF PERSONS WORKING AT NUCLEAR POWER PLANTS. [Amended 2020.04]

Persons appointed to the following positions require certification:

(i) Responsible Health Physicist;
(ii) Shift Manager;
(iii) Control Room Shift Supervisor;
(iv) Authorized Nuclear Operator; and
(v) Unit 0 Control Room Operator.

3. Operating Performance

3.1 The licensee shall implement and maintain an operations program, which includes a set of operating limits.

3.2 The licensee shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or prior written consent of a person authorized by the Commission.

3.3 The licensee shall notify and report in accordance with CNSC regulatory document REGDOC-3.1.1 REPORTING REQUIREMENTS: NUCLEAR POWER PLANTS.

3.4 The licensee shall implement a periodic safety review in support of its subsequent power reactor operating licence application.

4. Safety Analysis

4.1 The licensee shall implement and maintain a safety analysis program.

5. Physical Design

5.1 The licensee shall implement and maintain a design program.

5.2 The licensee shall implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency.

5.3 The licensee shall implement and maintain an equipment and structure qualification program.

6. Fitness for Service

6.1 The licensee shall implement and maintain a fitness for service program.

7. Radiation Protection

7.1 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

8. Conventional Health and Safety

8.1 The licensee shall implement and maintain a conventional health and safety program.

9. Environmental Protection

9.1 The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

10. Emergency Management and Fire Protection

10.1 The licensee shall implement and maintain an emergency preparedness program.

10.2 The licensee shall implement and maintain a fire protection program.

11. Waste Management

11.1 The licensee shall implement and maintain a waste management program.

11.2 The licensee shall implement and maintain a decommissioning strategy.

12. Security

12.1 The licensee shall implement and maintain a security program.

13. Safeguards and Non-Proliferation

13.1 The licensee shall implement and maintain a safeguards program.

14. Packaging and Transport

14.1 The licensee shall implement and maintain a packaging and transport program.

15. Nuclear Facility-Specific

15.1 The licensee shall implement and maintain an operations program for the Tritium Removal Facility, which includes a set of operating limits.

15.2 The licensee shall implement a return to service plan for refurbishment.

15.3 The licensee shall implement the Integrated Implementation Plan.

15.4 The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

15.5 The licensee shall limit the activities of import and export of nuclear substances to those occurring as contaminants in laundry, packaging, shielding or equipment. [Added 2017.10]

15.6 The licensee shall implement and maintain an operations program for the production of Molybdenum-99 and its associated decay isotopes. The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points. [Added 2021.10]

15.7 The licensee shall implement and maintain a Co-60 operations program for the activities described in part IV of the licence. [Added 2024.06]

Signed on June 5, 2024 – PDF e-Doc 7076592

Dr. Timothy Berube
Acting President on behalf of the Canadian Nuclear Safety Commission

SIGNED -
E-DOCS-#7076592-v

Proposed Licence

Canadian Nuclear Safety Commission / Commission canadienne de sûreté nucléaire

Word Ref.: e-Doc 7076591
PDF Ref.: e-Doc 7076592
File / Dossier: 2.01

NUCLEAR POWER REACTOR OPERATING LICENCE

DARLINGTON NUCLEAR GENERATING STATION

I) LICENCE NUMBER: **PROL 13.05/2025**

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act* this licence is issued to:

Ontario Power Generation Inc
700 University Avenue
Toronto, Ontario
M5G 1X6

III) LICENCE PERIOD: This licence is valid from January 1, 2016 to November 30, 2025, unless suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(i) operate the Darlington Nuclear Generating Station, including equipment for the production of radionuclides identified in (vi) and the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter "the nuclear facility"), at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario; [Amended 2024.06]

(ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i);

(iii) import and export nuclear substances, except controlled nuclear substances, that are required for, associated with, or arise from the activities described in (i);

(iv) possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the activities described in (i);

(v) possess, transfer, process, package, manage and store the nuclear substances associated with the operation of the Darlington Tritium Removal Facility;

(vi) produce, possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities associated with operations of the Darlington Nuclear Generating station and activities described in (i) associated with production of: [Amended 2025.##]

(1) Co-60; and
(2) *Y-90*, Mo-99 *and Lu-177*

Including *the associated* decay radionuclides.

V) EXPLANATORY NOTES:

(i) Nothing in this licence shall be construed to authorize non-compliance with any other applicable legal obligation or restriction.

(ii) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and associated Regulations.

(iii) The Darlington NGS Licence Conditions Handbook (LCH) provides compliance verification criteria including the Canadian standards and regulatory documents used to verify compliance with the conditions in the licence. The LCH also provides information regarding delegation of authority, applicable versions of documents and non-mandatory recommendations and guidance on how to achieve compliance.

VI) CONDITIONS:

G. **General**

G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations
(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence
(iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC, hereinafter "the Commission").

G.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.

G.3 The licensee shall control the use and occupation of any land within the exclusion zone.

G.4 The licensee shall provide, at the nuclear facility and at no expense to the Commission, suitable office space for employees of the Commission who customarily carry out their functions on the premises of that nuclear facility (onsite Commission staff).

G.5 The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.

G.6 The licensee shall implement and maintain a public information and disclosure program.

1. Management System

1.1 The licensee shall implement and maintain a management system.

2. Human Performance Management

2.1 The licensee shall implement and maintain a human performance program.

2.2 The licensee shall implement and maintain the minimum shift complement and control room staffing for the nuclear facility.

2.3 The licensee shall implement and maintain training programs for workers. The certification process and supporting examinations and tests shall be conducted in accordance with CNSC [Amended 2020.04]

regulatory document REGDOC-2.2.3, PERSONNEL CERTIFICATION, VOLUME III: CERTIFICATION OF PERSONS WORKING AT NUCLEAR POWER PLANTS.

Persons appointed to the following positions require certification:

(i) Responsible Health Physicist;
(ii) Shift Manager;
(iii) Control Room Shift Supervisor;
(iv) Authorized Nuclear Operator; and
(v) Unit 0 Control Room Operator.

3. Operating Performance

3.1 The licensee shall implement and maintain an operations program, which includes a set of operating limits.

3.2 The licensee shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or prior written consent of a person authorized by the Commission.

3.3 The licensee shall notify and report in accordance with CNSC regulatory document REGDOC-3.1.1 REPORTING REQUIREMENTS: NUCLEAR POWER PLANTS.

3.4 The licensee shall implement a periodic safety review in support of its subsequent power reactor operating licence application.

4. Safety Analysis

4.1 The licensee shall implement and maintain a safety analysis program.

5. Physical Design

5.1 The licensee shall implement and maintain a design program.

5.2 The licensee shall implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency.

5.3 The licensee shall implement and maintain an equipment and structure qualification program.

6. Fitness for Service

6.1 The licensee shall implement and maintain a fitness for service program.

7. Radiation Protection

7.1 The licensee shall implement and maintain a radiation protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

8. Conventional Health and Safety

8.1 The licensee shall implement and maintain a conventional health and safety program.

9. Environmental Protection

9.1 The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within seven days.

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10.1 The licensee shall implement and maintain an emergency preparedness program.

10.2 The licensee shall implement and maintain a fire protection program.

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11.1 The licensee shall implement and maintain a waste management program.

11.2 The licensee shall implement and maintain a decommissioning strategy.

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12.1 The licensee shall implement and maintain a security program.

13. Safeguards and Non-Proliferation

13.1 The licensee shall implement and maintain a safeguards program.

14. Packaging and Transport

14.1 The licensee shall implement and maintain a packaging and transport program.

15. Nuclear Facility-Specific

15.1 The licensee shall implement and maintain an operations program for the Tritium Removal Facility, which includes a set of operating limits.

15.2 The licensee shall implement a return to service plan for refurbishment.

15.3 The licensee shall implement the Integrated Implementation Plan.

15.4 The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

15.5 The licensee shall limit the activities of import and export of nuclear substances to those occurring as contaminants in laundry, packaging, shielding or equipment. [Added 2017.10]

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). [Amended 2025.##]

15.7 The licensee shall implement and maintain a Co-60 operations program for the activities described in part IV of the licence. [Added 2024.06]