Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Record of Decision

DEC 25-H100

In the Matter of

Applicant	Ontario Power Generation Inc.
Subject	Application to Amend Darlington Nuclear Generating Station Power Reactor Operating Licence 13.05/2025 for the Production of Additional Isotopes using the Target Delivery System
Date of Decision	May 23, 2025

RECORD OF DECISION – DEC 25-H100

Applicant:	Ontario Power Generation Inc.
Address/Location:	700 University Avenue, Toronto, Ontario, M5G 1X6
Purpose:	Application to Amend Darlington Nuclear Generating Station Power Reactor Operating Licence 13.05/2025 for the Production of Additional Isotopes using the Target Delivery System
Application received:	February 26, 2024
Date of decision:	May 23, 2025
Panel of Commission:	P. Tremblay

Licence: Amended

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1.0 INTRODUCTION

1. On February 26, 2024, Ontario Power Generation Inc. (OPG) submitted an application to the Canadian Nuclear Safety Commission[1] (CNSC), under subsection 24(2) of the *Nuclear Safety and Control Act*[2] (NSCA), for an amendment to the power reactor operating licence (PROL) for its Darlington Nuclear Generating Station (DNGS) located in the Municipality of Clarington, Ontario. The DNGS site is located on the traditional lands and waters of the Michi Saagiig Anishinaabeg, the Gunshot Treaty (1787-88), the Williams Treaties (1923), and the Williams Treaties Settlement Agreement (2018).

2. The DNGS includes 4 CANDU[3] reactors and their associated equipment. In October 2021,[4] the Commission amended the DNGS PROL to authorize the construction of a target delivery system[5] (TDS) to produce Molybdenum-99 (Mo-99) on DNGS Unit 2.

3. OPG is seeking authorization to use the existing TDS on DNGS Unit 2 to produce two additional isotopes, Lutetium-177 (Lu-177) and Yttrium-90 (Y-90). 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. OPG has not requested authorization to install a TDS on any other DNGS units as part of this licence amendment application.

Issues

4. In considering OPG's licence amendment application, the Commission is first required to determine whether and what requirements the *Impact Assessment Act*[6] (IAA) imposes in relation to the activities sought to be authorized.

5. Pursuant to paragraphs 24(4)(a) and (b) of the NSCA, in considering whether to amend the licence, the Commission must be satisfied that:

    - OPG is qualified to carry on the activity that the amended licence would authorize; and

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[1] The *Canadian Nuclear Safety Commission* is referred to as the "CNSC" when referring to the organization and its staff in general, and as the "Commission" when referring to the tribunal component.
[2] S.C. 1997, c. 9.
[3] All operating nuclear power reactors in Canada are CANDU (Canadian Deuterium-Uranium) reactors. CANDU reactors are pressurized heavy water reactors that use natural uranium as fuel and heavy water as a coolant and moderator.
[4] CNSC Record of Decision, *Application to Amend Power Reactor Operating Licence PROL 13.02/2025 to Authorize the Production of Molybdenum-99 at the Darlington Nuclear Generating Station*, DEC 21-H107, October 26, 2021.
[5] The TDS was referred to as the Mo-99 Isotope Irradiation System (Mo-99 IIS) in CNSC Record of Decision DEC 21-H107. OPG's submissions for this hearing use the terminology TDS as opposed to IIS and, should the Commission accept the proposed licence amendment, the system will no longer be used exclusively to produce Mo-99. For these reasons, the system is referred to as the TDS throughout this Record of Decision.
[6] S.C. 2019, c. 28, s. 1.

- in carrying on that activity, OPG 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.

6. As an agent of the Crown, the Commission recognizes its role in fulfilling the Crown's constitutional obligations, along with advancing reconciliation with Indigenous Peoples of Canada. The Commission's responsibilities include the duty to consult and, where appropriate, accommodate where the Crown contemplates conduct which may adversely impact potential or established Aboriginal[7] or treaty rights.[8] As such, the Commission must determine what engagement and consultation steps and accommodation measures are called for respecting Indigenous interests and whether what has been done satisfies the obligation of consultation and, where appropriate, accommodation of implicated Aboriginal or treaty rights. A determination, of what the duty to consult and accommodate requires, is informed by the principles and the provisions of the *United Nations Declaration on the Rights of Indigenous Peoples*[9] (UNDRIP), as a result of its adoption into Canadian law via the *United Nations Declaration on the Rights of Indigenous Peoples Act*[10] (UNDA).[11] Where the duty to consult is triggered, the Commission must be satisfied that the duty to consult has been met prior to making its licensing decision.

Panel

7. On September 9 2024, the Commission published a *Notice of Hearing in Writing and Participant Funding*[12] for this matter, which invited requests to intervene by February 7, 2025. On February 14, 2025, the Commission published a *Revised Notice of Hearing in Writing*[13] to extend the deadline for interventions to February 28, 2025.

8. Pursuant to section 22 of the NSCA, the President of the Commission established himself to preside as a Panel of one Commission member to consider the application. The Commission, in conducting a public hearing based on written materials, considered written submissions from OPG (Application, CMD 25-H100.1, CMD 25-H100.1A, CMD 25-H100.1C), CNSC staff (CMD 25-H100), and 7 intervenors (see Appendix A – List of Intervenors of this *Record of Decision* for a list of interventions).

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[7] "Aboriginal" is the term used in this document when referring to the Crown's duty to consult as that is the term used in s. 35 of the Constitution Act, 1982. In all other cases, "Indigenous" is the preferred terminology and used accordingly.
[8] *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73; *Taku River Tlingit First Nation v. British Columbia (Project Assessment Director)*, 2004 SCC 74.
[9] *United Nations Declaration on the Rights of Indigenous Peoples*, United Nations, September 2007.
[10] S.C. 2021, c. 14.
[11] *Kebaowek First Nation v. Canadian Nuclear Laboratories*, 2025 FC 319.
[12] *CNSC Notice of Hearing in Writing and Participant Funding*, 2025-H-100, September 9, 2024.
[13] *CNSC Revised Notice of Hearing in Writing*, 2025-H-100 Revision 1, February 14, 2025.

9. In making its decision, the Commission sent questions to CNSC staff and OPG through CMD 24-H100-Q and CMD 24-H100-Q.A. CNSC staff provided responses to the Commission's questions in CMD 25-H100.B and OPG provided responses in CMD 25-H100.1B and CMD 25-H100.1D. The Commission is satisfied with the completeness of the responses provided by CNSC staff and OPG.

Confidentiality Request

10. OPG submitted two requests for confidentiality,[14,15] in accordance with subrule 12(1) of the *Canadian Nuclear Safety Commission Rules of Procedure*[16] (the Rules). The requests for confidentiality included a redacted application and a revised redacted application, respectively, which provided a public summary version of OPG's *Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System*[17] (Enclosure 1 of OPG's application).

11. Under rule 15, references listed in OPG's submissions are not part of the hearing record unless the Commission specifically requests them. As such, the Commission only considered the confidentiality of Enclosure 1 of OPG's application.

12. The Commission is satisfied that:

- as per subrule 12(1)(b) of the *Rules*, the information contained in Enclosure 1 of OPG's application is confidential information of a financial, commercial, scientific, and technical nature that is treated consistently as confidential and that the vendor partners affected have not consented to the disclosure; and
- as per 12(2)(a) and 12(2)(b) of the *Rules*, protection of the information outweighs in importance the public interest in public hearings and disclosure of evidence, and the measures are designed so as not to affect the public nature of the proceeding except to the extent necessary to adequately protect the information

Therefore, as per subrule 12(3)(b) of the *Rules*, the Commission requires that the publication of information given to the Commission in Enclosure 1 be prohibited, and that only the summary version of Enclosure 1, provided in Attachment 4 of OPG's revised redacted application, shall be disclosed.

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[14] *OPG's Request For Confidentiality of Material Submitted in Relation to CD# NK38-CORR-00531-25141*, May 14, 2024.
[15] *OPG's Request For Confidentiality of Material Submitted in Relation to CD# NK38-CORR-00531-25810*, January 24, 2025.
[16] SOR/2000-211.
[17] *Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System*, NK38-REP-03600-10014, OPG, November 30, 2023.

CNSC Participant Funding Program

13. Pursuant to paragraph 21(1)(b.1) of the NSCA, the Commission has established a Participant Funding Program (PFP) to facilitate the participation of Indigenous Nations and communities, members of the public and stakeholders in Commission proceedings. In September 2024, up to $30,000 in funding to participate in this hearing process was made available through the CNSC's PFP. A Funding Review Committee (FRC), independent of the CNSC, reviewed the funding applications received and made recommendations on the allocation of funds. Based on the recommendations from the FRC, the CNSC awarded a total of $30,000 to four applicants.[18]

Mandate of the Commission

14. Several interventions addressed the economic benefits of producing medical isotopes. The Commission notes that, as the regulatory authority over nuclear matters in Canada, it has no economic mandate and does not base its decisions on the economic impact of a facility. The Commission's mandate is found in section 9 of the NSCA and includes the Commission's object to regulate the production and use of nuclear energy to prevent unreasonable risk to national security, the environment, and the health and safety of people, and to implement the international obligations to which Canada has agreed.

2.0 DECISION

15. Based on its consideration of this matter, as described in more detail in the following sections of the *Record of Decision*, the Commission concludes the following:

- the Commission is satisfied that an impact assessment under the IAA is not required
- the contemplated licence amendment does not present any novel adverse impact on any potential or established Aboriginal claim or right
- the Commission's responsibility to uphold the honour of the Crown and its constitutional obligations with regard to engagement and consultation with Indigenous groups have been satisfied
- OPG is qualified to carry on the activities that the amended licence will authorize
- OPG, in carrying on these activities, would 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

[18] CNSC Participant funding notice, *Participant funding for Ontario Power Generation's application to amend the Darlington Nuclear Generating Station operating licence for the production of additional isotopes using the target delivery system*, September 2024.

Therefore,

> the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the power reactor operating licence PROL 13.05/2025 issued to Ontario Power Generation Inc. for its Darlington Nuclear Generating Station located in the Municipality of Clarington, Ontario. The amended licence, PROL 13.06/2025, remains valid until November 30, 2025.

16. The Commission includes in the licence the conditions as recommended by CNSC staff in section 4.1.2 of CMD 25-H100. Specifically, the Commission:

- amends PROL 13.05/2025 section IV (vi) 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."

- amends PROL 13.05/2025 licence condition 15.6 to:

  "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)."

17. The Commission is satisfied with the regulatory hold point proposed by CNSC staff in section 3.4 of CMD 25-H100 and in the draft Licence Conditions Handbook (LCH). The Commission finds that the proposed regulatory hold point will allow CNSC staff to verify that the existing safety case remains valid for the production of Lu-177 and Y-90, prior to OPG declaring the production of the new isotopes available for service.[19]

[19] Available for service (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.

18. The Commission delegates authority for licence condition 15.4 to the following members of CNSC staff:

- Executive Vice-President and Chief Regulatory Operations Officer
- Director General of the Directorate of Power Reactor Regulation

By delegating its authority for the purposes of licence condition 15.4, the Commission delegates the authority to remove the established target delivery system regulatory hold point to the above CNSC staff members.

3.0 ISSUES AND COMMISSION FINDINGS

19. In making its licensing decision, the Commission considered a number of relevant issues and submissions relating to OPG's qualification to carry on the activity the licence amendment would authorize. The Commission also considered the adequacy of OPG's proposed measures for preventing unreasonable risk to the environment, the health and safety of persons and national security, and for compliance with international obligations to which Canada has agreed.

20. The Commission's analyses for its decision in this matter are set out within the following sections of this *Record of Decision*:

- Section 3.1 Overview of the Target Delivery System
- Section 3.2 Applicability of the *Impact Assessment Act*
- Section 3.3 Summary of Views of Hearing Participants
- Section 3.4 Assessment of the Licence Amendment Application
- Section 3.5 OPG's Safety and Control Measures with Respect to the Safety and Control Areas
- Section 3.6 Indigenous Engagement and Consultation
- Section 3.7 Other Matters of Regulatory Importance
- Section 3.8 Licence Amendment

3.1 Overview of the Target Delivery System

21. The TDS utilizes a combination of mechanical, pneumatic, and hydraulic methods of propulsion to transfer target capsules into and out of the reactor core for the purpose of irradiating the target capsules to produce medical isotopes. Fresh targets are 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 by a cable into the reactor core to expose the targets to the reactor's neutron flux, where the targets are irradiated. Following irradiation, the basket is raised

out of the core and held above the reactor for a predefined dwell-time.[20] 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 for processing.[21]

22. The TDS is installed on DNGS Unit 2 and is currently authorized to produce Mo-99 only. OPG is seeking a licence amendment to authorize the production of Lu-177 and Y-90 on the existing TDS.

3.2 Applicability of the *Impact Assessment Act*

23. In coming to its decision, the Commission is first required to determine whether any requirements under the IAA apply to the application and whether an impact assessment is required.

24. Pursuant to the IAA and the *Physical Activities Regulations*[22] made under it, impact assessments are to be conducted in respect of projects identified as having the greatest potential for adverse environmental effects in areas of federal jurisdiction. The proposed licence amendment does not include activities listed in the *Physical Activities Regulations* that require an impact assessment or that meet the definition of a project on federal lands.

25. The Commission concludes that there is no requirement under the IAA for an impact assessment to be completed. The Commission is also satisfied that there are no other applicable requirements of the IAA to be addressed in this matter.[23]

3.3 Summary of Views of Hearing Participants

26. In its consideration of OPG's licence amendment application, the Commission gave careful consideration to all submissions and perspectives received, in accordance with its mandate and the scope of this public hearing in writing. The Commission appreciates the efforts and contributions of all hearing participants.

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[20] 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.

[21] The activity of inserting unirradiated target capsules into the reactor is referred to as "target-seeding" and the activity of removing the target capsules from the reactor after the required irradiation period is referred to as "target-harvesting".

[22] SOR/2019-285.

[23] The IAA can impose other requirements on federal authorities in respect of authorizing projects that are not designated as requiring an impact assessment, including projects that are to be carried out on federal lands, or projects outside of Canada. This licence amendment does not engage any such applicable IAA requirements.

27. In sections 1.2 and 4.0 of Attachment 3[24] of OPG's application, OPG provided a summary of its position with respect to its application:

- operating the TDS is a low-risk activity and no physical design changes to the TDS are required to facilitate the production of Lu-177 and Y-90
- based on a preliminary nuclear safety assessment, OPG is confident that the activities necessary to support production of Lu-177 and Y-90 using the existing TDS are bounded by the safety analysis that was completed for the production of Mo-99 and will not compromise continued safe reactor operation
- OPG committed to completing a detailed safety analysis to confirm and validate the safety impacts of Lu-177 and Y-90 during the detailed engineering phase of the project, and to submitting that analysis to the to the CNSC for review
- OPG will continue to meet Canada's international obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons*

28. In section 1.4 of CMD 25-H100, CNSC staff recommended that the Commission amend PROL 13.05/2025 to authorize OPG to produce Lu-177 and Y-90 using the DNGS Unit 2 TDS. CNSC staff submitted the following:

- OPG has a robust set of programs which are adequate to ensure the safe production of Lu-177 and Y-90 at Darlington NGS
- OPG will continue to utilize its established Engineering Change Control process to complete project documentation
- CNSC staff recommended that the Commission establish a regulatory hold point to support the confirmation by CNSC staff that the final design and safety analysis of the new targets are bounded by the established safety case for the production of Mo-99.

29. The Commission received 7 interventions for this hearing. Intervenors expressed views on the following issues:

- the role of Laurentis Energy Partners, a wholly owned subsidiary of OPG, in the operation of the TDS
- whether OPG's application can be considered complete without a final safety analysis and detailed list of wastes
- concern that the production of Lu-177 and Y-90 may increase tritium emissions
- support for the project and the production of medical isotopes

[24] *Licence Impact Assessment in Support of Lutetium-177 and Yttrium-90 Isotope Production at Darlington Nuclear Generating Station using the Target Delivery System*, OPG, February 26, 2024.

30. The following issues were raised regarding consultation and engagement with Indigenous Nations and communities:

- the application of UNDA and FPIC
- the transport of nuclear substances through treaty and/or traditional territory
- involvement of rights-holding Nations in the removal of the regulatory hold point

31. The issues raised by hearing participants, and their bearing on the deliberations of the Commission, are discussed in the appropriate subject-specific sections of this *Record of Decision*. Issues raised by Indigenous Nations and communities are detailed in 3.6.3 of this *Record of Decision*.

3.4 Assessment of the Licence Amendment Application

32. In order to be complete, a licence amendment application must meet the requirements of the NSCA, the *General Nuclear Safety and Control Regulations*[25] (GNSCR), and other applicable regulations made under the NSCA. The Commission examined the sufficiency of OPG's application.

33. Section 6 of the GNSCR provides that an application for the amendment of a licence shall contain:

a) a description of the amendment, revocation or replacement and of the measures that will be taken and the methods and procedures that will be used to implement it;
b) a statement identifying the changes in the information contained in the most recent application for the licence;
c) a description of the nuclear substances, land, areas, buildings, structures, components, equipment and systems that will be affected by the amendment, revocation or replacement and of the manner in which they will be affected; and
d) the proposed starting date and the expected completion date of any modification encompassed by the application.

34. Section 7 of the GNSCR provides that an application for a licence or for the renewal, suspension in whole or in part, amendment, revocation or replacement of a licence may incorporate by reference any information that is included in a valid, expired or revoked licence.

[25] SOR/2000-202.

35. On February 26, 2024, Ontario OPG applied for an amendment to the power reactor operating licence, PROL 13.05/2025,[26] for its DNGS to authorize the production of Lu-177 and Y-90 using the TDS installed on DNGS Unit 2. On October 15, 2024, OPG submitted a letter[27] to update the information provided in OPG's application regarding the management of empty target shell waste from Lu-177.

36. In Attachment 2[28] of OPG's application, OPG provided a clause-by-clause explanation of how its licence amendment application satisfies the requirements of the NSCA, the GNSCR, and other applicable regulations made under the NSCA.

37. In section 1.1 of CMD 25-H100, CNSC staff reported that it reviewed OPG's application pursuant to section 6 of the GNSCR and section 3 of the *Class I Nuclear Facilities Regulations*[29] (CINFR). CNSC staff submitted detailed information on its review of OPG's application throughout section 2 of CMD 25-H100.

38. Northwatch (CMD 25-H100.7) raised concern that OPG's application did not include a final safety analysis or a complete list of waste to be generated. In sections 2.6.4 and 2.6.11 of CMD 25-H100, CNSC staff submitted that:

- the use of a regulatory hold point would ensure that CNSC staff review OPG's final detailed safety analyses and confirm that OPG's bounding safety case assertion is verified, prior to the production of the new isotopes being declared available for service
- the production of Lu-177 and Y-90 would not result in the production of new types of waste for OPG
- OPG's existing waste management program is adequate to handle waste produced during the maintenance of the TDS

The concerns raised by Northwatch are discussed further in sections 3.5.4 and 3.5.11 of this *Record of Decision*.

39. The Commission concludes that OPG's licence amendment application includes the necessary information for an application for a licence amendment. The Commission finds that OPG has provided sufficient information for the Commission to come to a decision on this matter.

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[26] OPG's application identified the current licence as PROL 13.03/2025. After OPG submitted its application for this matter, the Commission amended the PROL to authorize the production of Co-60 and to reference REGDOC-2.2.3, *Personnel Certification, Volume III: Certification of Reactor Facility Workers*, Version 2. Therefore, the current licence is now PROL 13.05/2025.
[27] Darlington NGS – Update to Application for Amendment to Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production, NK38-CORR-00531-25747, OPG, October 15, 2024.
[28] *Licence Amendment Matrix – Nuclear Safety and Control Act and Applicable Regulations*, OPG, February 26, 2024.
[29] SOR/2000-204.

3.5 OPG's Safety and Control Measures with Respect to the Safety and Control Areas

40. The Commission examined OPG's proposed safety and control measures with respect to the CNSC's safety and control area[30] (SCA) framework, for the purpose of evaluating OPG's licence amendment application.

41. In section 2.6 of CMD 25-H100, CNSC staff submitted that all 14 SCAs apply to OPG's licence amendment application:

- Management System
- Human Performance Management
- Operating Performance
- Safety Analysis
- Physical Design
- Fitness for Service
- Radiation Protection
- Conventional Health and Safety
- Environmental Protection
- Emergency Management and Fire Protection
- Waste Management
- Security
- Safeguards and Non-Proliferation
- Packaging and Transport

3.5.1 Management System

42. The management system SCA covers the framework that establishes the processes and programs required to ensure that OPG achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture. Licence condition 1.1 of PROL 13.05/2025 requires OPG to implement and maintain a management system for the DNGS.

43. Paragraph 3(d) of the CINFR states that a licence application for a Class I nuclear facility shall contain "the proposed management system for the activity to be licensed, including measures to promote and support safety culture." Section 3 of the GNSCR contains requirements that form the basis of a management system.

[30] SCAs are the technical topics used by CNSC staff across all regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance.

44. CSA Group Standard N286, *Management System Requirements for Nuclear Facilities*[31] provides an overall management framework and direction to develop and implement sound management practices and controls for the licensing basis.[32] CNSC regulatory document[33] REGDOC-2.1.2, *Safety Culture*[34] sets out requirements and guidance for fostering a healthy safety culture and conducting safety culture assessments.

45. OPG provided the Commission with information on how its management system applies to the proposed licence amendment, including in the following performance areas:[35]

- Management system
- Organization
- Performance improvement
- Operating experience (OPEX)
- Change management
- Safety culture
- Contractor management
- Business continuity

OPG clarified that no changes to its established management system SCA licensing basis would be required to support the requested licence amendment and that it would continue to prioritize safe reactor operation over medical isotope production.

46. OPG provided information on the following vendors involved in the project:

- Laurentis Energy Partners, a wholly owned subsidiary of OPG located in the Greater Toronto Area, will provide strategic partnerships and project support
- BWXT Nuclear Energy Canada Inc. (BWXT-NEC), located in Peterborough, Ontario, will design, manufacture, and assemble the Lu-177 and Y-90 targets.
- BWXT-Medical, located in Kanata, Ontario, will be responsible for the transportation and processing of the irradiated Lu-177 and Y-90 targets
- BTG PLC (Boston Scientific), located in Ottawa, Ontario, is a pharmaceutical company that will provide the target material to be irradiated.

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[31] CSA Group Standard, CSA N286-12, *Management System Requirements for Nuclear Facilities*, 2012 (R2022).
[32] The licensing basis is a set of requirements and documents for a regulated facility or activity comprising the regulatory requirements set out in the applicable laws and regulations, the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence, and the safety and control measures described in the licence application and the documents needed to support that licence application.
[33] CNSC regulatory documents are typically referred to as REGDOCs.
[34] CNSC Regulatory Document, REGDOC-2.1.2, *Safety Culture*, April 2018.
[35] OPG's application, Attachment 3, Section 2.1.

47. In section 2.6.1 of CMD 25-H100, CNSC staff submitted its assessment of OPG's performance related to the management system SCA, including information on OPG's:

- Engineering change control (ECC) process
- OPEX
- Problem identification and resolution process
- Contractor management and supply chain
- Nuclear safety and security policy

CNSC staff reported that OPG's existing management system complies with CSA N286-12 and is adequate to safely manage the production of Lu-177 and Y-90.

48. CNSC staff reported that, since 2019, it had conducted 3 Type II inspections and 7 field inspections related to OPG's ECC process at its DNGS and Pickering NGS. All inspection findings were of low or negligible safety significance and have since been addressed by OPG. CNSC staff reported no concerns with the sufficiency of OPG's ECC process. The deliverables to be reviewed under the regulatory hold point are being produced under OPG's ECC process. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

49. CNSC staff submitted that OPG has a *Nuclear Safety and Security Policy* in place that complies with the requirements of REGDOC-2.1.2. CNSC staff reported that it would continue to provide regulatory oversight to verify OPG's ongoing implementation of its management system and REGDOC-2.1.2.

50. The intervention by Northwatch (CMD 25-H100.7) questioned the role of Laurentis Energy Partners in the production of medical isotopes at the DNGS. In section 1.9 of Attachment 3 of its application, OPG reported that Laurentis Energy Partners would provide strategic partnerships and project support. In section 2.6.1 of CMD 25-H100, CNSC staff noted that, at the time of submission of CMD 25-H100, there was an open inspection finding against OPG concerning oversight of contractors and the use of Laurentis Energy Partners as a contractor to support isotope-related activities while Laurentis Energy Partners had not been formally qualified for that type of work. CNSC staff expected that OPG would take corrective actions to resolve this issue and return to compliance with their management system requirements.

51. In CMD 25-H100-Q, the Commission asked CNSC staff for more information on the open inspection finding. In CMD 25-H100.B, CNSC staff clarified that the finding was related to work associated with the TDS and was not specific to the production of the new isotopes. Since the submission of CMD 25-H100, CNSC staff issued a warning letter to OPG regarding the finding. The warning letter established 7 outstanding actions for OPG, 2 of which have since been closed. CNSC staff noted that it increased oversight in this area, including additional surveillance and inspection activities focusing on the TDS. CNSC staff added that it would ensure that OPG addresses each outstanding action to CNSC staff's satisfaction. CNSC staff noted that it does not have any concerns regarding the qualifications of the other vendors involved in this project (i.e. those vendors providing the safety analysis and engineering design work).

52. In CMD 25-H100-Q.A, the Commission asked OPG for more information concerning its OPEX/lessons learned from the operation of the TDS to produce Mo-99 and explain how these lessons would applied to the production of Lu-177 and Y-90. In CMD 25-H100.D, OPG responded that its OPEX/lessons learned included aspects related to design engineering for the targets and target assembly, as well as for human factors. The Commission is satisfied with OPG's response.

53. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate management system in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a management system in compliance with regulatory requirements, including CSA N286-12 and REGDOC-2.1.2
- OPG's existing management system is adequate to support the production of Lu-177 and Y-90 on DNGS Unit 2
- OPG's ECC process is sufficient to drive the production of the deliverables associated with the proposed regulatory hold point
- CNSC staff confirmed that the vendors providing the safety analysis and engineering design work for this project are qualified to do so

54. With respect to CNSC staff's ongoing compliance enforcement regarding the TDS, the Commission notes that CNSC staff is conducting increased surveillance and inspection activities focusing on this work. The Commission is satisfied that this compliance enforcement is not specific to the production of isotopes that are the subject of this hearing. The Commission further notes that OPG is required to address the outstanding actions established in CNSC staff's warning letter, to CNSC staff's satisfaction, and that CNSC staff may take additional compliance enforcement measures, if necessary.

3.5.2 Human Performance

55. The human performance management SCA covers activities that enable effective human performance through the development and implementation of processes that ensure that a sufficient number of workers are in all relevant job areas and have the necessary knowledge, skills, procedures, and tools in place to safely carry out their duties.

56. OPG's current PROL 13.05/2025 includes 3 licence conditions related to the human performance management SCA:

- Licence condition 2.1 requires OPG to implement and maintain a human performance program
- Licence condition 2.2 requires OPG to implement and maintain the minimum shift complement and control room staffing for the nuclear facility
- Licence condition 2.3 requires OPG to implement and maintain training programs for workers

57. Paragraph 12(1)(a) of the GNSCR requires the licensee to ensure that there are sufficient qualified workers to carry on the licensed activity safely and in accordance with the NSCA, its regulations and the licence, whereas paragraph 12(1)(b) indicates that the licensee must train workers to carry on the licensed activity in accordance with the Act, its regulations and the licence.

58. Paragraph 3(d.1) of the CINFR provides that a licence application must include information about the proposed human performance program for the activity to be licensed, including the measures to ensure workers' fitness for duty, whereas paragraphs 6(m) and 6(n) indicate that a licence application for a licence for a Class I nuclear facility must include information on the proposed responsibilities, qualification requirements, training program, and measures for the requalification of workers, as well as on the results obtained through the application of the program for the recruitment, training and qualification of workers related to the operation and maintenance of the nuclear facility.

59. REGDOC-2.2.2, *Personnel Training*, Version 2[36] sets out requirements and guidance for the analysis, design, development, implementation, evaluation, documentation and management of training at nuclear facilities within Canada, including the essential principles and elements of an effective training system. REGDOC-2.2.4, *Fitness for Duty, Volumes I, II, and III*[37,38,39] set out the requirements and guidance for managing worker fitness for duty in relation to fatigue, alcohol and drug use, and medical, physical, and psychological fitness, at high security sites. REGDOC-2.2.5, *Minimum Staff Complement*[40] sets out information related to the staffing of a Class I nuclear facility that should typically be included in an application for the issuance, renewal, amendment, or replacement of a licence to operate a facility.

60. OPG provided the Commission with information on how its human performance management program applies to the proposed licence amendment, including in the following performance areas:[41]

- Human performance management
- Personnel training
- Personnel certification
- Work organization and job design
- Fitness for duty

OPG submitted that the production of Lu-177 and Y-90 using the existing TDS will not require any changes to the licensing basis of the human performance management SCA. OPG committed to develop and deliver the necessary training to staff working with the TDS as per OPG's existing governance.

61. In section 2.6.2 of CMD 25-H100, CNSC staff submitted its assessment of OPG's performance related to the human performance management SCA. CNSC staff reported that OPG's existing human performance and training programs are compliant with the requirements of REGDOC-2.2.2, REGDOC-2.2.4, and REGDOC-2.2.5.

62. CNSC staff reported that OPG's existing training program is based on a systematic approach to training and is sufficient to develop, deliver, and manage training for production of Lu-177 and Y-90 using the existing TDS. CNSC staff noted that it would monitor and evaluate OPG's performance in this area through regulatory oversight activities. Regarding personnel certification, CNSC staff noted that the production of Lu-177 and Y-90 would not introduce any new certified positions.

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[36] CNSC Regulatory Document, REGDOC-2.2.2, *Performance Training*, Version 2, December 2016.
[37] CNSC Regulatory Document, REGDOC-2.2.4, *Fitness for Duty, Managing Worker Fatigue*, March 2017.
[38] CNSC Regulatory Document, REGDOC-2.2.4, *Fitness for Duty, Volume II: Managing Alcohol and Drug Use*, Version 3, January 2021.
[39] CNSC Regulatory Document, REGDOC-2.2.4, *Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, Psychological Fitness*, September 2018.
[40] CNSC Regulatory Document, REGDOC-2.2.5, *Minimum Staff Complement*, April 2019.
[41] OPG's application, Attachment 3, Section 2.2.

63. OPG submitted that it would complete a human factors assessment and validation as part of its ECC process to support the production of Lu-177 and Y-90. OPG committed to providing the completed human factors assessment reports to CNSC staff for review.[42] In section 2.6.2 of CMD 25-H100, CNSC staff proposed that OPG be required to submit the human factors assessment reports prior to the consideration of removal of the regulatory hold point. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

64. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate human performance program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained human performance and training programs in compliance with regulatory requirements, including REGDOCs 2.2.2, 2.2.4 (Volumes I, II, and III), and 2.2.5
- OPG's existing human performance program is adequate to support the activities that the amended licence would authorize
- OPG's existing training program is adequate to develop, deliver, and manage training for the production of Lu-177 and Y-90 using the existing TDS
- OPG is required to submit the human factors assessment reports to the CNSC prior to the consideration of removal of the regulatory hold point
- CNSC staff will verify that OPG's human factors assessment reports satisfy regulatory requirements

3.5.3 Operating Performance

65. The operating performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

66. OPG's current PROL 13.05/2025 includes 4 licence conditions related to the operating performance SCA:

- Licence condition 3.1 requires OPG to implement and maintain an operations program, which includes a set of operating limits
- Licence condition 3.2 states that OPG shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or the prior written consent of a person authorized by the Commission
- Licence condition 3.3 requires OPG to notify and report in accordance with REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*[43]
- Licence condition 3.4 requires OPG to implement a periodic safety review in support of its subsequent power reactor operating licence application

[42] OPG's application, Attachment 3, Appendix A.
[43] REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants, Version 3, CNSC, April 2024.

67. Paragraph 6(d) of the CINFR provides that an application for a licence to operate a Class I nuclear facility must include information on the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

68. OPG provided the Commission with information on how its operating performance program applies to the proposed licence amendment, including in the following performance areas:[44]

- Conduct of the licensed activity
- Procedures
- Reporting and trending
- Outage management performance
- Safe operating envelope (SOE)
- Accident management and recovery

OPG submitted that no changes to the licensing basis of the operating performance SCA would be required to facilitate the production of Lu-177 and Y-90 using the existing TDS. OPG explained that the existing TDS operation manual and maintenance procedure will be updated with minor configuration changes to incorporate the production of Lu-177 and Y-90. Specifically, there will be changes to the irradiation time[45] and the dwell-time for the new isotopes. In addition, OPG reported that the introduction of the two new isotopes is not expected to impact accident management or recovery.

69. In section 2.6.3 of CMD 25-H100, CNSC staff submitted that OPG has a robust operations program in place which is compliant with regulatory requirements, and which should be adequate to manage the introduction of Lu-177 and Y-90. CNSC staff noted that OPG successfully used its established processes to produce and revise procedures for the production of Mo-99 using the TDS. As such, CNSC staff is of the view that OPG's processes are adequate to incorporate the production of Lu-177 and Y-90 into the appropriate operating procedures.

70. Regarding the SOE, OPG reported that the production of Lu-177 and Y-90 will not require changes to any SOE documentation for the DNGS. CNSC staff noted that it would confirm the validity of the existing SOE as part of its review of OPG's detailed safety analysis. The safety analysis is discussed further in section 3.5.4 of this *Record of Decision.*

[44] OPG's application, Attachment 3, Section 2.3.
[45] Irradiation time is the period of time that the targets remain in the core.

71. In CMD 25-H100-Q, the Commission asked OPG for additional details on TDS operating procedures, specifically regarding what considerations had been made to keep workers safe and to address malfunctions during the production of Lu-177 and Y-90. In CMD 25-H100.1, OPG submitted that, since there will be no physical or fundamental functional changes to the TDS, OPG did not identify any new contingencies for the production of Lu-177 and Y-90 and the protection of workers. OPG noted that human factors considerations, such as ensuring the correct targets are loaded into the TDS, will be documented in the human factors assessment reports. These reports are deliverables under the proposed regulatory hold point, as discussed in section 3.5.2 of this *Record of Decision*.

72. Regarding potential TDS malfunctions, OPG reported in CMD 25-H100.1 that it had conducted a high-level review of the original TDS failure modes and effects analysis to consider the impact of new isotope production, as described in the *Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System*. This assessment concluded that production of Lu-177 and Y-90 had no significant impact on the safe operation of the DNGS. OPG reported that it will update the failure modes and effects analysis for the new isotopes during the detailed design phase, in accordance with OPG's ECC process. Requirements for OPG to submit final design documentation to the CNSC are discussed in section 3.5.5 of this *Record of Decision*.

73. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate operating performance program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained an operating performance program in compliance with regulatory requirements
- OPG's existing operating performance program is adequate to support the activities that the amended licence would authorize
- OPG's existing processes are adequate to incorporate the production of Lu-177 and Y-90 into the appropriate operating procedures
- OPG is required to submit the detailed nuclear safety analysis to the CNSC, prior to the consideration of removal of the regulatory hold point
- CNSC staff will review the detailed nuclear safety analysis to verify that the existing SOE remains valid

3.5.4 Safety Analysis

74. The safety analysis SCA covers maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of the licensed activity or the operation of a facility. Safety analysis also considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards. Licence condition 4.1 of PROL 13.05/2025 requires OPG to implement and maintain a safety analysis program.

75. Paragraph 6(i) of the CINFR provides that an application for a licence to operate a Class I nuclear facility must include a final safety analysis report demonstrating the adequacy of the design of the nuclear facility.

76. REGDOC-2.4.1, *Deterministic Safety Analysis*[46] sets out requirements and guidance for the preparation and presentation of a safety analysis that demonstrates the safety of a nuclear facility. REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*[47] sets out requirements for a licensee to conduct a probabilistic safety assessment[48] (PSA) for an NPP.

77. OPG reported that it produced the *Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System* to determine the impact of introducing the new isotopes into the TDS. The assessment found that producing Lu-177 and Y-90 with the existing TDS will have a negligible impact on the safe operation of the DNGS and is bounded by the existing Mo-99 safety analysis.[49] OPG committed to completing a detailed safety analysis to confirm and validate the safety impacts of Lu-177 and Y-90 during the detailed engineering phase of the project, and to submitting that analysis to the to the CNSC for review.[50]

78. In section 2.6.4 of CMD 25-H100, CNSC staff submitted that OPG has implemented and maintained a safety analysis program at the DNGS that complies with regulatory requirements, including REGDOCs 2.4.1 and 2.4.2. CNSC staff proposed that OPG be required to submit the final target design, detailed safety analysis, and commissioning report, as well as resolve all CNSC comments to CNSC's satisfaction, prior to the consideration of the removal of the regulatory hold point. CNSC staff noted that it would verify the that the existing Mo-99 safety case remains valid as part of its review of OPG's detailed safety analysis. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

79. Regarding the PSA, CNSC staff submitted that REGDOC-2.4.2 requires licensees to update the PSA for nuclear facilities at least every 5 years, and sooner if the facility undergoes a major change. CNSC staff reported that that production of the new isotopes does 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. CNSC staff noted that OPG will submit the next revision of the Darlington PSA to the CNSC for review as part of the next PSA update cycle in 2025.

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[46] CNSC Regulatory Document, REGDOC-2.4.1, *Deterministic Safety Analysis*, May 2014.
[47] CNSC Regulatory Document, REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*, May 2014.
[48] A probabilistic safety assessment is a comprehensive and integrated assessment of the safety of a facility. The PSA considers the probability, progression and consequences of equipment failures or transient conditions to derive numerical estimates that provide a consistent measure of the safety of the facility.
[49] *Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*, N-REP-03500-0839983, OPG, February 24, 2021.
[50] OPG's application, Attachment 3, Sections 1.2 and 2.4.

80. Northwatch (CMD 25-H100.7) raised a concern that OPG's application did not include a final safety analysis. CNSC staff proposed that the use of a regulatory hold point would ensure that CNSC staff review OPG's final detailed safety analyses and confirm that OPG's bounding safety case assertion is verified, prior to the production of the new isotopes being declared available for service. In section 1.3 of CMD 25-H100, CNSC staff added that, if CNSC staff find that the existing Mo-99 safety analysis is not bounding for the production of the new isotopes, OPG would have to return to the Commission for authorization.

81. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate safety analysis program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a safety analysis program in compliance with regulatory requirements, including REGDOCs 2.4.1 and 2.4.2
- OPG's existing safety analysis program is adequate to support the activities that the amended licence would authorize
- the production of Lu-177 and Y-90 using the existing TDS does not constitute a "major change" and therefore does not warrant a PSA update outside of the normal 5-year cycle
- OPG is required to submit the final target design, detailed nuclear safety analysis, and commissioning report to the CNSC, prior to the consideration of removal of the regulatory hold point
- CNSC staff will review the detailed nuclear safety analysis to verify OPG's assertion that the existing Mo-99 safety analysis will remain bounding for the Lu-177 and Y-90 targets

3.5.5 Physical Design

82. The physical design SCA relates to activities that impact the ability of structures, systems and components (SSCs) to meet and maintain their design basis,[51] given new information arising over time and taking changes in the external environment into account.

[51] The design basis is the range of conditions and events taken explicitly into account in the design of a nuclear facility, according to established criteria, such that the facility can withstand this range without exceeding authorized limits.

83. OPG's current PROL-13.05/2025 includes 3 licence conditions related to the physical design SCA:

- Licence condition 5.1 requires OPG to implement and maintain a design program
- Licence condition 5.2 requires OPG to implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency
- Licence condition 5.3 requires OPG to implement and maintain an equipment and structure qualification program

84. Paragraph 3(1)(d) of the GNSCR requires that a licence application contain a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence. Paragraphs 3(a) and 3(b) of the CINFR indicate that a licence application for a Class I nuclear facility must include a description of the site of the activity to be licensed, as well as plans showing the location, perimeter, areas, structures and systems of the nuclear facility. Paragraphs 6(a) and 6(b) of the CINFR provide that an application for a licence to operate a Class I nuclear facility includes a description of the structures, systems and equipment at the nuclear facility, including their design and their design operating conditions.

85. OPG provided the Commission with information on how its physical design program applies to the proposed licence amendment, including in the following performance areas:[52]

- Design governance
- Site characterization
- Design of the facility and SSCs

OPG reported that no physical design or site characterization changes will be required to facilitate the production of Lu-177 and Y-90 using the existing TDS on DNGS Unit 2. Only a software update will be required to accommodate the different dwell-times for each isotope. The software update will be completed as part of OPG's ECC process.

86. In section 2.6.5 of CMD 25-H100, CNSC staff submitted that it has no concerns regarding the impact of the production of Lu-177 and Y-90 on the physical design of the TDS. CNSC staff are of the view that OPG's ECC process is sufficient to manage the software updates that will be required to conduct the activities under the proposed amended licence.

[52] OPG's application, Attachment 3, Section 2.5.

87. CNSC staff noted that the new isotope target capsules will match the external dimensions and weight of the existing Mo-99 targets, however, the difference in heat generated by the new targets could affect their thermal deformation and movement. CNSC staff reported that, to address this potential issue, OPG established a design requirement for the new isotope targets which requires that the targets' thermal expansion shall not inhibit target movement in the TDS. OPG also committed to conduct a comprehensive nuclear decay heating analysis as part of its detailed nuclear safety analysis. CNSC staff recommended that regulatory review of OPG's detailed nuclear safety analysis and final target designs, and the resolution of all comments to the CNSC's satisfaction, be conditions of the proposed regulatory hold point. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

88. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate physical design program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a physical design program in compliance with regulatory requirements
- OPG's existing ECC process are adequate to manage the software updates required to support the activities that the amended licence would authorize
- OPG is required to submit the detailed nuclear safety analysis and final target designs to the CNSC, prior to the consideration of removal of the regulatory hold point
- CNSC staff will review the detailed nuclear safety analysis and final target designs to ensure that OPG satisfies regulatory requirements

3.5.6 Fitness for Service

89. The fitness for service SCA covers activities that are performed to ensure that SSCs remain effective over time and are available to perform their intended design functions upon request. Licence condition 6.1 of PROL-13.05/2025 requires OPG to implement and maintain a fitness for service program.

90. Paragraph 6(d) of the CINFR requires that an application for a licence to operate a Class I nuclear facility contain the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

91. OPG provided the Commission with information on how its fitness for service program applies to the proposed licence amendment, including in the following performance areas:[53]

- Equipment reliability
- Maintenance
- Structural integrity
- Aging management
- Chemistry control
- Periodic inspection and testing

OPG submitted that no changes to the established licensing basis for the fitness for service SCA would be required to support the requested licence amendment. OPG explained that the production of the new isotopes will not impact the fitness for service or periodic inspections of major components on DNGS Unit 2.

92. In section 2.6.6 of CMD 25-H100, CNSC staff submitted that OPG has a robust maintenance program and equipment reliability program in place at the DNGS. Given that no new equipment will be installed to facilitate the production of Lu-177 and Y-90, CNSC staff found that the production of the new isotopes will not adversely impact the implementation of TDS maintenance procedures.

93. CNSC staff affirmed that OPG's maintenance program and ECC process are sufficient to address potential issues related to the operation of the TDS system. CNSC staff referenced an event in March 2024 during the operation of the TDS to produce Mo-99, where a cable broke and led to a target basket resting at the bottom of the reactor core. CNSC staff reviewed OPG's recovery plans and verified that OPG carried out the necessary repairs safely. Given the physical similarity between the new targets and the existing Mo-99 targets and the fact that no new equipment will be installed, CNSC staff does not anticipate additional operational challenges with the TDS system following the introduction of the new isotopes.

94. Regarding moderator chemistry, CNSC staff submitted that, as with Mo-99, the new isotope materials will be contained within a zirconium shell and will not interact with the moderator. The new isotopes are also not soluble in water and would be filtered out of the moderator by existing systems if they were to be accidentally released. CNSC staff noted that OPG has committed to complete a full chemistry assessment as part of the detailed safety analysis and CNSC staff recommended that regulatory review of OPG's chemistry assessment be a condition of the proposed regulatory hold point. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

[53] OPG's application, Attachment 3, Section 2.6.

95. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate fitness for service program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a fitness for service program in compliance with regulatory requirements
- OPG's existing fitness for service program is adequate to support the activities that the amended licence would authorize
- OPG is required to submit its chemistry assessment to the CNSC, as part of the detailed safety analysis, prior to the consideration of removal of the regulatory hold point
- CNSC staff will review the chemistry assessment to verify that the new isotopes will not adversely impact moderator chemistry

3.5.7 Radiation Protection

96. The radiation protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*.[54] The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled, and maintained as low as reasonably achievable (ALARA), while taking into consideration social and economic factors. Licence condition 7.1 of PROL-13.05/2025 requires OPG to implement and maintain a radiation protection program.

97. Section 4 of the *Radiation Protection Regulations* requires licensees to implement a radiation protection program. As part of this program, licensees must keep effective and equivalent doses received by, and committed to, persons ALARA, taking into account social and economic factors, and ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity. Paragraphs 6(e) and 6(h) of the CINFR require that an application for a licence to operate a Class I nuclear facility contains the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances, as well as the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measure that will be taken to prevent or mitigate those effects.

[54] SOR/2000-203.

98. OPG provided the Commission with information on how its radiation protection program applies to the proposed licence amendment, including in the following performance areas:[55]

- Application of the ALARA principle
- Worker dose control
- Radiation protection program performance
- Radiological hazard control

OPG reported that it had completed a preliminary ALARA assessment for the production of Lu-177 and Y-90, and committed to submit the final revised TDS ALARA assessment for the new isotopes to the CNSC upon completion.

99. In response to a question from the Commission, OPG provided that, due to the absence of physical changes to the TDS and its functionality, no new or additional contingencies were required to protect workers for the production of Lu-177 and Y-90.[56]

100. In section 2.6.7 of CMD 25-H100, CNSC staff submitted that OPG has implemented and maintained an effective radiation protection program at the DNGS that satisfies the requirements set out in the *Radiation Protection Regulations*. In section 2.6.8 of CMD 25-H100, CNSC staff reported that the TDS has barriers built in to protect workers, members of the public, and the environment from radiation exposure. Such barriers include the zirconium target capsules and a closed system of shielded flight tubing between the new target loader, the reactor core, and the new flask loader. The air lock system also includes a high efficiency particulate air (HEPA) filter to filter contaminated exhaust.

101. In section 2.6.7 of CMD 25-H100, CNSC staff notes that OPG's preliminary analysis of the radiation hazard for the new isotope targets shows that, while the initial radioactive source term of the Lu-177 targets is greater than that of Mo-99, 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.

102. CNSC staff recommended that regulatory review of OPG's revised TDS ALARA assessment be a condition of the proposed regulatory hold point. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

[55] OPG's application, Attachment 3, Section 2.7.
[56] CMD 25-H100.1B, page 5.

103. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate radiation protection program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a radiation protection program in compliance with regulatory requirements
- OPG's existing radiation protection program is adequate to support the activities that the amended licence would authorize
- OPG is required to submit an updated TDS ALARA assessment to the CNSC, prior to the consideration of removal of the regulatory hold point
- CNSC staff will review the updated TDS ALARA assessment to ensure that OPG satisfies regulatory requirements

3.5.8 Conventional Health and Safety

104. The conventional health and safety SCA covers the implementation of a program to manage workplace safety hazards and to protect workers. Licence condition 8.1 of PROL-13.05/2025 requires OPG to implement and maintain a conventional health and safety program.

105. Paragraph 3(f) of the CINFR provides that a licence application for a Class I nuclear facility must include a description of the proposed worker health and safety policies and procedures.

106. OPG provided the Commission with information on its conventional health and safety program which outlines the responsibilities of various levels in the organization to ensure that activities are performed to meet the requirements of OPG's healthy and safety policy. OPG reported that the production of Lu-177 and Y-90 using the existing TDS will not require any changes to the licensing basis of the conventional health and safety SCA.[57]

107. In section 2.6.8 of CMD 25-H100, CNSC staff reported that OPG has a robust conventional health and safety program in place that complies with regulatory requirements and relevant provincial legislation, including Ontario's *Occupational Health and Safety Act*[58] and the *Ontario Labour Relations Act*.[59] CNSC staff noted that the conventional safety hazards associated with producing Lu-177 and Y-90 are the same as those associated with the production of Mo-99 and will be managed by OPG using its established conventional health and safety processes. CNSC staff noted that it would continue to monitor OPG's conventional health and safety program to verify that workers are protected from conventional hazards

[57] OPG's application, Attachment 3, Section 2.8.
[58] R.S.O. 1990, c. O.1.
[59] S.O. 1995, c. 1, Sched. A.

108. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate conventional health and safety program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a conventional health and safety program in compliance with regulatory requirements and provincial legislation including Ontario's *Occupational Health and Safety Act* and *Labour Relations Act*
- the conventional safety hazards associated with producing Lu-177 and Y-90 are the same as those associated with the production of Mo-99
- OPG's existing conventional health and safety program is adequate to support the activities that the amended licence would authorize

3.5.9 Environmental Protection

109. The environmental protection SCA covers programs that identify, control, and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities. These programs include effluent and emission control, environmental monitoring, and estimated doses to the public. Licence condition 9.1 of PROL-13.05/2025 requires OPG to implement and maintain an environmental protection program, including a set of action levels.

110. In accordance with the NSCA, licensees are required to make adequate provision for the protection of the environment. Paragraphs 12(1)(c) and (f) of the GNSCR require each licensee to take all reasonable precautions to protect the environment and the health and safety of persons, and to control the release of radioactive nuclear substances and hazardous substances within the site of the licensed activity and into the environment. The *Radiation Protection Regulations* prescribe dose limits for the public, which, pursuant to subsection 1(3), are 1 mSv per calendar year.

111. REGDOC-2.9.1, *Environmental Principles, Assessments, and Protection Measures*[60] describes the CNSC's principles of environmental protection, the scope of an environmental review, the roles and responsibilities associated with an environmental review, as well as the CNSC's requirements and guidance for developing environmental protection measures, including an environmental risk assessment (ERA) where required. The CSA N288 series of standards provides requirements and guidance for the environmental management of nuclear facilities. CSA N288.6-12 *Environmental risk assessments at class I nuclear facilities and uranium mines and mills*[61] specifically addresses requirements for the design, implementation, and management of an environmental risk assessment program.

[60] CNSC Regulatory Document, REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures*, Version 1.2, April 2017.
[61] CSA Group Standard, CSA N288.6-12, *Environmental risk assessments at class I nuclear facilities and uranium mines and mills*, 2012.

112. OPG provided information on its environmental protection program and how it applies to the proposed licence amendment, including that:[62]

- the proposed licence amendment would not impact the derived release limits, action levels, or internal investigation levels for the DNGS
- operation of the TDS to produce the new isotopes will adhere to OPG's existing environmental management system
- OPG has an effluent monitoring program in place to ensure that environmental releases remain below regulatory limits and comply with the principles of ALARA
- in accordance with CSA N288.6-12, OPG previously completed a predictive effects assessment[63] (PEA) which found that operation of the TDS to produce Mo-99 would be protective of people and the environment
- since the number of seeding and harvesting cycles per year for the new isotopes remains unchanged, the introduction of the new target capsules is not expected to have any additional environmental impact beyond what was predicted in the PEA for the production of Mo-99
- OPG committed to review and validate it conclusions regarding the PEA as per OPG's ECC process
- the public dose consequence of the production of Lu-177 and Y-90 is bounded by the production of Mo-99 and will not impact the cumulative public dose resulting from the operation of the DNGS operation, which is well below 1% of the regulatory limit of 1 millisievert per year (mSv/y)

113. In section 2.6.9 of CMD 25-H100, CNSC staff submitted that OPG has implemented and maintained an environmental protection program in compliance with regulatory requirements, including REGDOC 2.9.1 and the CSA N288 series documents. CNSC staff are of the view that OPG's existing environmental protection program is sufficient to manage the activities under the proposed amended licence. CNSC staff are confident that the releases associated with the TDS will continue to make up only a small fraction of the annual DNGS releases, which will not result in additional risk to the public and the environment.

114. CNSC staff recommended that OPG's provision of an updated PEA, or justification of for why an update is not required, be a condition of the proposed regulatory hold point. CNSC staff noted that it would review the information provided by OPG to validate that production of the new isotopes will not have a significant adverse impact on the environment (i.e., beyond what was predicted in the PEA for the production of Mo-99). The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

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[62] OPG's application, Attachment 3, Sections 1.6 and 2.9.

[63] *Predictive Effects Assessment for The DN Molybdenum Isotope Irradiation System (Unit 4)*, NK38-REP-30550-00029, OPG, June 11, 2020.

115. Northwatch (CMD 25-H100.7) raised concern that the production of Lu-177 and Mo-99 may increase tritium emissions from the DNGS. In section 2.6.9 of CMD 25-H100, CNSC staff noted that tritium from residual heavy water collected during harvesting and drying the targets in the TDS airlock was the primary source of emissions attributed to the production and harvesting of Mo-99. In section 1.6 of Attachment 3 of OPG's application, OPG reported that the number of seeding and harvesting cycles per year remains unchanged for the new isotopes. Therefore, the introduction of the new target capsules is not expected to have any additional environmental impact. As stated above, OPG committed to review and validate it conclusions regarding the PEA, and CNSC staff noted that it would review this information prior to consideration of the removal of the proposed regulatory hold point.

116. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate environmental protection program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a radiation protection program in compliance with regulatory requirements, including REGDOC 2.9.1 and the CSA N288 series documents
- OPG's existing environmental protection program is sufficient to manage the activities under the proposed amended licence
- the introduction of the new target capsules is not expected to have any additional environmental impact
- OPG is required to provide of an updated PEA, or justification of for why an update is not required, to CNSC staff prior to the consideration of removal of the regulatory hold point
- CNSC staff will review the updated PEA, or justification, provided by OPG to validate that production of the new isotopes will not have an impact on the environment beyond what was predicted in the PEA for the production of Mo-99

117. As noted by CNSC staff in section 2.6.9 of CMD 25-H100, OPG's established weekly seeding frequency could potentially lead to system idle time during the production of Y-90, which only requires an irradiation time of 3 days. Should OPG should seek to increase the number of Y-90 seeding operations beyond what is currently stated in the PEA, the Commission directs OPG to follow the notification process described in licence condition G.2. Any changes that impact the licensing basis would be required to come back before the Commission.

3.5.10 Emergency Management and Fire Protection

118. The emergency management and fire protection SCA covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions.

119. OPG's current PROL-13.05/2025 includes 2 licence conditions related to the emergency management and fire protection SCA:

- Licence condition 10.1 requires OPG to implement and maintain an emergency preparedness program
- Licence condition 10.2 requires OPG to implement and maintain a fire protection program

120. Paragraph 12(1)(c) of the GNSCR states that the licensee shall "take all reasonable precautions to protect the environment, preserve the health and safety of persons and maintain the security of nuclear facilities and of nuclear substances", while paragraph 12(1)(f) states that the licensee shall "take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances within the site of the licensed activity and into the environment of the licensed activity."

121. Paragraph 6(k) of the CINFR requires that an application for a licence to operate a Class I nuclear facility must include information on the licensee's proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security.

122. REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*, Version 2[64] sets out the CNSC's requirements and guidance for emergency preparedness and applies to licensees and licence applicants for Class I nuclear facilities. REGDOC-2.3.2, *Accident Management: Severe Accident Management Programs for Nuclear Reactors*[65]sets out the CNSC's requirements and guidance for the development, implementation and validation of integrated accident management for reactor facilities. CSA N293, *Fire protection for CANDU nuclear power plants*[66] provides the minimum fire protection requirements for the design, construction, commissioning, operation, and decommissioning of nuclear power plants.

[64] CNSC Regulatory Document, REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*, Version 2, February 2016.
[65] REGDOC-2.3.2, *Severe Accident Management Programs for Nuclear Reactors*, 2013..
[66] CSA Group Standard, CSA N293, *Fire protection for CANDU nuclear power plants*, 2012 (R2022).

123. OPG provided the Commission with information on how its emergency management and fire protection programs apply to the proposed licence amendment, including in the following performance areas:[67]

- Conventional emergency preparedness and response
- Nuclear emergency preparedness and response
- Fire emergency preparedness and response

OPG reported that no changes to the established licensing basis of the emergency management and fire protection SCA would be required to support the proposed licence amendment.

124. In section 2.6.10 of CMD 25-H100, CNSC staff submitted that OPG's existing emergency preparedness and fire protection programs meet the requirements of REGDOC-2.10.1, REGDOC-2.3.2, and CSA N293. 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 and found that the existing programs were adequate. Given that the proposed licence amendment does not involve the installation of any new equipment and the overall process for operating the TDS will remain largely unchanged, CNSC staff found that OPG's existing emergency management and fire protection programs remain adequate for the introduction of Lu-177 and Y-90. CNSC staff noted that it would continue to provide regular regulatory oversight of OPG's emergency management and fire protection programs.

125. Based on the information on record for this hearing, the Commission concludes that OPG has adequate emergency management and fire protection programs in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained emergency preparedness and fire protection programs in compliance with regulatory requirements, including REGDOC-2.10.1, REGDOC-2.3.2, and CSA N293.
- OPG's existing emergency management and fire protection programs are adequate to support the activities that the amended licence would authorize, given that the proposed licence amendment does not involve the installation of any new equipment or significant changes to the operation of the TDS

[67] OPG's application, Attachment 3, Section 2.10.

3.5.11 Waste Management

126. The waste management SCA covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. It also covers the planning for decommissioning. Decommissioning plans and the associated financial guarantee are discussed in section 3.7.2 of this *Record of Decision*.

127. OPG's current PROL-13.05/2025 includes 2 licence conditions related to the waste management SCA:

- Licence condition 11.1 requires OPG to implement and maintain a waste management program
- Licence condition 11.2 requires OPG to implement and maintain a decommissioning strategy

128. Paragraph 3(1)(j) of the GNSCR provides that a licence application must include the name, quantity, form, origin and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including wastes that may be stored, managed, processed, or disposed of at the site of the activity to be licensed, and the proposed method for managing and disposing of that waste. Paragraph 3(k) of the CINFR also requires that a licence application contain the proposed plan for the decommissioning of the nuclear facility or of the site.

129. CSA N292.3, *Management of low- and intermediate-level radioactive waste*[68] specifies requirements for the management of radioactive waste to protect the health and safety of people, physical security, and the environment.

130. OPG provided the Commission with information on how its waste management program applies to the proposed licence amendment. OPG reported that no changes to the established licensing basis of the waste management SCA would be required to support the proposed licence amendment.[69]

131. On October 15, 2024, OPG provided the CNSC with an update to its application regarding the management of empty Lu-177 target shells.[70] OPG informed the Commission that, as the result of a new commercial agreement, BWXT-Medical will manage the empty Lu-177 target shells under its existing waste management program. Therefore, the empty Lu-177 target shells will not be stored at OPG's Western Waste Management Facility (WWMF).

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[68] CSA Group Standard, CSA N292.3, *Management of low- and intermediate-level radioactive waste*, 2014 (R2024).
[69] OPG's application, Attachment 3, Section 2.11.
[70] After the isotope material is processed, the empty target shells are considered low-level radioactive waste.

132. In section 2.6.11 of CMD 25-H100, CNSC staff reported that OPG has a waste management program in place that meets regulatory requirements, including CSA N292.3-08, and that that activities associated with the production and handling of Lu-177 and Y-90 will generate a minimal amount of radioactive waste at the DNGS. CNSC staff found 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. CNSC staff noted that OPG will not retain any responsibility for the residual wastes produced from the processing, commercialization, or use of Lu-177 and Y-90. These wastes will be managed by BWXT-Medical under an existing CNSC licence. CNSC staff would maintain oversight of any additional waste generated and the management of those wastes through existing compliance verification activities.

133. Northwatch (CMD 25-H100.7) raised concern that OPG's application did not include a complete list of wastes to be generated. In section 2.6.11 of CMD 25-H100, CNSC staff acknowledged that OPG's application did not describe the wastes that will be generated through maintenance or routine operations. CNSC staff noted that maintenance of the TDS will require work on the reactivity mechanism deck during outages and may require the use of radiological personal protective equipment and other disposable materials. CNSC staff reported that this does not represent a new type of waste for OPG, and that OPG's existing waste management program is adequate to handle it.

134. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate waste management program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a waste management program in compliance with regulatory requirements, including CSA N292.3-08
- 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
- OPG will not retain any responsibility for the residual wastes produced from the processing, commercialization, or use of Lu-177 and Y-90.

3.5.12 Security

135. The security SCA covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity. Licence condition 12.1 of PROL-13.05/2025 requires OPG to implement and maintain a security program.

136. Paragraph 12(1)(c) of the GNSCR requires the licensee to take all reasonable precautions to protect the environment and the health and safety of persons, and to maintain the security of nuclear facilities and of nuclear substances. Paragraphs 12(1)(g) and 12(1)(h) require the licensee to implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, prescribed equipment or prescribed information, or the illegal use of a nuclear facility, and measures for alerting it to acts or attempts of sabotage, anywhere at the site of the licensed activity. Section 12(1)(j) requires the licensee to instruct workers on the physical security program at the site of the licensed activity and on their obligations under that program.

137. REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material*, Version 2.1[71] provides regulatory expectations and guidance for licensees regarding the CNSC's expectations under the GNSCR for security.

138. OPG provided the Commission with information on how its security program applies to the proposed licence amendment, including in the following performance areas:[72]

- Facilities and equipment
- Response arrangements
- Security practices, drills, and exercises
- Cyber security

OPG reported that no changes to the established licensing basis of the security SCA would be required to support the proposed licence amendment. The production of Lu-177 and Y-90 will not require changes to any security related facilities, equipment, staffing levels, or exercises.

139. In section 2.12 of Attachment 3 of OPG's application, OPG explained that it would periodically receive the new targets, manufactured by BWXT-NEC, at the DNGS. Once irradiated, the targets would be shipped from the DNGS to the BWXT-Medical processing facility in Kanata, using BWXT transportation packaging and equipment, for medical processing. The incoming and outgoing transportation vehicles will be processed by OPG's security staff at the DNGS in accordance with existing procedures.

140. In section 2.6.12 of CMD 25-H100, CNSC staff submitted that OPG has security and cyber security programs in place that satisfy regulatory requirements. CNSC staff found that the proposed licence amendment will not impose new challenges to OPG's security program, and that the existing programs will be able to accommodate the activities associated with the production and possession of the new isotopes while protecting nuclear assets at the DNGS.

[71] CNSC Regulatory Document, REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material,* Version 2.1, September 2020.
[72] OPG's application, Attachment 3, Section 2.12.

141. Regarding the transportation of the new isotopes, CNSC staff reported that a transportation security plan will be required in accordance with REGDOC-2.12.3. CNSC staff noted that BWXT-Medical, as the qualified shipper, will be responsible for preparing the transportation security plan. CNSC staff would review the transport security plans in accordance with established practices to ensure that it meets regulatory requirements. The Commission appreciates that this information was provided for context and notes that this activity is beyond the scope of the licence amendment application, which deals only with OPG.

142. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate security program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a security program in compliance with regulatory requirements, including REGDOC-2.12.3
- OPG's existing security program is adequate to support the activities that the amended licence would authorize.

3.5.13 Safeguards and Non-Proliferation

143. The safeguards and non-proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/ International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons* (NPT).[73] Pursuant to the NPT, Canada has entered into a *Comprehensive Safeguards Agreement*[74] and an *Additional Protocol*[75] (safeguards agreements) with the IAEA. The objective of these safeguards agreements is for the IAEA to provide credible assurance on an annual basis to Canada and to the international community that all declared nuclear material is in peaceful, non-explosive uses and that there is no undeclared nuclear material or activity in this country. Licence condition 13.1 of PROL -13.05/2025 requires OPG to implement and maintain a safeguards program.

144. REGDOC-2.13.1, *Safeguards and Nuclear Materials Accountancy*[76] sets out requirements and guidance for safeguards programs for applicants and licensees who possess nuclear material, operate a uranium and/or thorium mine, carry out specified types of nuclear fuel-cycle related research and development work, and/or carry out specified types of nuclear-related manufacturing activities.

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[73] INFCIRC/140.
[74] INFCIRC/164.
[75] INFCIRC/164/Add.1.
[76] CNSC Regulatory Document, REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*, February 2018.

145. OPG provided the Commission with information on how its safeguards and non-proliferation program applies to the proposed licence amendment, including in the following performance areas:[77]

- Nuclear material and accountancy
- Access and assistance to the IAEA
- Operational and design information
- Safeguards equipment, containment, and surveillance
- Import and export

OPG reported that the activities that would be authorized under the proposed licence will not involve nuclear material that is subject to safeguards requirements pursuant to the safeguards agreements, and will have no impact on IAEA inspections or access to IAEA equipment. Regarding import and export, there will be no requirement to import nuclear material for the irradiation of Lu-177 and Y-90 in the TDS, and OPG will not be responsible for the downstream export of the processed isotopes outside of Canada.

146. In section 2.6.13 of CMD 25-H100, CNSC staff concurred that neither Lu-177 and Y-90 nor their target material are controlled nuclear substances. Therefore, 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 or use of the new isotopes. CNSC staff would evaluate licensees involved in these downstream aspects of the supply chain as needed against regulatory requirements including REGDOC-2.13.2, *Import and Export*,[78] and relevant legislation under the NSCA.

147. In section 2.6.13 of CMD 25-H100, CNSC staff submitted that OPG has implemented and maintained a safeguards program that complies with regulatory requirements, including REGDOC-2.13.1. CNSC staff noted that activities related to production and handling of Lu-177 and Y-90 will not impact existing IAEA safeguards surveillance equipment or be subject to safeguards reporting and verification activities. As such, CNSC staff found that the production of Lu-177 and Y-90 will not impact OPG's ability to fulfill its existing safeguards requirements.

[77] OPG's application, Attachment 3, Section 2.13.
[78] CNSC Regulatory Document, REGDOC-2.13.2, *Import and Export*, Version 2, April 2018.

148. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate safeguards and non-proliferation program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a safeguards and non-proliferation program in compliance with regulatory requirements, including REGDOC-2.13.1
- OPG's existing safeguards and non-proliferation program is adequate to support the activities that the amended licence would authorize
- The production of Lu-177 and Y-90 does not involve nuclear material to which safeguards agreements apply
- OPG does not require a licence to import nuclear material in support of the proposed amendment and will not be responsible for the processing, use, or export of the new isotopes

3.5.14 Packaging and Transport

149. The packaging and transport SCA covers the safe packaging and transport of nuclear substances to and from the licensed facility. Licence condition 14.1 of PROL-13.05/2025 requires OPG to implement and maintain a packaging and transport program.

150. The *Packaging and Transport of Nuclear Substances Regulations, 2015*[79] (PTNSR 2015) provides requirements for the packaging and transport of nuclear substances, including the design, production, use, inspection, maintenance and repair of packages, and the preparation, consigning, handling, loading, carriage and unloading of packages. The *Transportation of Dangerous Goods Regulations*[80] (TDGR) provides requirements for the handling and transport of dangerous goods for all shipments.

151. OPG provided the Commission with information on how its packaging and transport program applies to the proposed licence amendment, including in the following performance areas:[81]

- Package design and maintenance
- Packaging and transport
- Registration for use

OPG reported that no changes to the established licensing basis of the packaging and transport SCA would be required to support the proposed licence amendment.

[79] SOR/2015-145.
[80] SOR/2001-286.
[81] OPG's application, Attachment 3, Section 2.14.

152. OPG clarified that, once irradiated, the Lu-177 and Y-90 target capsules will be shipped from the DNGS to BWXT-Medical's Kanata facility for processing using the same process as the current Mo-99 target capsules. OPG will be responsible for loading the irradiated target capsules into a CNSC certified transportation package and preparing the shipping documents per its existing procedures. BWXT-Medical will be responsible for transportation from the DNGS to BWXT-Medical's facility. BWXT-Medical has ownership of the transportation packaging and will be responsible for packaging design and maintenance.[82]

153. In section 2.6.14 of CMD 25-H100, CNSC staff submitted that OPG has a packaging and transport program in place at the DNGS which meets regulatory requirements, including the PTNSR 2015 and the TDGR. CNSC staff found that OPG's existing radioactive material transport program is sufficient to manage the packaging and shipment of Lu-177 and Y-90.

154. CNSC staff acknowledged that OPG plans to ship the new isotopes in the same CNSC-certified transportation packaging that is used for the Mo-99 targets. CNSC staff noted that the current package certificate does not cover the new isotopes; however, OPG committed to update the package certificate to include them. OPG has procedures in place for the registration for use of certified design transportation packages.

155. CNSC staff noted that CNSC staff concurrence is required prior to the first shipment of the new isotopes in the certified transport packages. OPG has committed to apply for and obtain CNSC concurrence prior to the first shipment. CNSC staff recommended that CNSC staff concurrence be a condition of the proposed regulatory hold point. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

156. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate packaging and transport program in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a packaging and transport program in compliance with regulatory requirements, including the PTNSR 2015 and the TDGR.
- OPG's existing radioactive material transport program is sufficient to manage loading the irradiated Lu-177 and Y-90 target capsules into a CNSC certified transportation package and preparing the shipping documents
- OPG is required to apply for and obtain CNSC certification for the transport package to be used for Lu-177 and Y-90 target capsules, prior to the consideration of removal of the regulatory hold point
- CNSC staff will verify that the certified transport packages can be used for the capsules containing Lu-177 and Y-90, per the PTNSR 2015

[82] OPG's application, Attachment 3, Section 1.5.

3.5.15 Conclusion on OPG's Safety and Control Measures with Respect to the SCAs

157. Based on its analysis of the information provided and discussed above, the Commission is satisfied that OPG is qualified to carry on the licensed activities that the amended licence would authorize. In addition, the Commission finds that OPG has adequate programs and measures in place with respect to the 14 SCAs to ensure that the health and safety of workers, the public and the environment will be protected. The Commission further concludes that OPG has adequate measures in place to provide for the maintenance of national security and to implement international obligations to which Canada has agreed.

158. OPG is required to provide additional information to the CNSC to support OPG's compliance with regulatory requirements under a number of safety and control areas, as described in Table 2 of CMD 25-H100 and throughout section 3.5 of this *Record of Decision*. OPG will have to provide this information to CNSC staff, prior to consideration of the removal of the regulatory hold point. The regulatory hold point is discussed further in section 3.8.2 of this *Record of Decision*.

3.6 Indigenous Engagement and Consultation

159. The Commission considered the information provided by CNSC staff, OPG and intervenors regarding Indigenous consultation and engagement activities in respect of this licence amendment application. Indigenous consultation refers to the common law duty to consult with Indigenous Nations and communities flowing from section 35 of the *Constitution Act, 1982*.[83]

160. The common law duty to consult is grounded in the key principle of the honour of the Crown. The foundation of the duty in the Crown's honour and the goal of reconciliation mean that the duty arises when the Crown has knowledge, real or constructive, of the potential existence of the Aboriginal right or title and contemplates conduct that might adversely affect it.[84] Licensing decisions of the Commission, where Indigenous interests may be adversely impacted, can engage the duty to consult, and the Commission must be satisfied that if the duty is engaged, it has met the duty prior to making the relevant licensing decision. The Commission is also mindful that its determination of what the duty to consult and accommodate requires is informed by the principles and the provisions of the UNDRIP as a result of its adoption into Canadian law via the UNDA.

[83] Schedule B to the *Canada Act, 1982* (UK), 1982, c 11.
[84] *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73 at para 35.

161. The duty to consult does not apply to adverse impacts that have occurred in the past or are ongoing; rather it applies to novel adverse impacts.[85] For this application, the Commission finds that the production of Lu-177 and Y-90 using the existing TDS on DNGS Unit 2 will not create novel adverse impacts to potential or established Indigenous and/or treaty rights. The Commission comes to this conclusion based on the evidence that the proposed licence amendment would not impact the DNGS site characterization, would not result in the construction of new facilities at the site, and that operation of the TDS to produce the new isotopes will fall within the existing safety case for the production of Mo-99, which will be verified prior to removal of the regulatory hold point. The Commission notes that OPG has programs in place to actively monitor and assess its operations to confirm that there are no unforeseen effects on the environment.

3.6.1 Indigenous Consultation by CNSC Staff

162. In section 2.7.2 of CMD 25-H100, CNSC staff identified the following Indigenous Nations and communities who have Aboriginal and/or treaty rights to the lands and waters surrounding and inclusive of the DNGS site:

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

CNSC staff also identified the following 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:

- Mohawks of the Bay of Quinte
- Métis Nation of Ontario (MNO)
- Algonquins of Ontario
- Algonquins of Pikwàkanagàn First Nation (AOPFN)
- Six Nations of the Grand River
- Kitigan Zibi Anishinabeg (KZA)
- Kebaowek First Nation (KFN)

[85] *Rio Tinto Alcan Inc. v. Carrier Sekani Tribal Council*, 2010 SCC 43, [2010] 2 S.C.R. 650 at para. 48.

163. CNSC staff reported that it sent letters of notification to the identified Indigenous Nations and communities in September 2024 to inform them of OPG's application, opportunities to participate in the hearing process, and the availability of participant funding. CNSC staff phoned each Indigenous Nation and community in November 2024 to ensure receipt of the letters and to answer any questions. CNSC staff also encouraged all identified Indigenous Nations and communities to participate in the Commission hearing through written interventions to advise the Commission directly of any concerns they may have in relation to OPG's licence amendment application.

164. CNSC staff added that it had raised OPG's application in its regular meetings under Terms of Reference agreements with CLFN, HFN, MSIFN, MNO, AOPFN, and KFN, and that MSIFN and AOPFN both requested to have additional project-specific discussions with the CNSC staff. At the time of submission of CMD 25-H100, CNSC staff reported that it had met with AOPFN on September 25, 2024 and was scheduled to meet with MSIFN on November 15, 2024.

165. CNSC staff expressed its commitment to ongoing engagement and collaboration with the above noted Indigenous Nations and communities and to continue to provide opportunities for meaningful long-term engagement and collaboration with respect to projects at OPG's DNGS site. CNSC staff have also encouraged OPG to continue engagement with Indigenous Nations and communities about their long-term plans for the DNGS site.

3.6.2 Indigenous Engagement by OPG

166. In OPG's *Isotope Engagement and Communications Plan with Indigenous Communities* (Enclosure 2 of OPG's application),[86] OPG provided information regarding its ongoing engagement with Indigenous Nations and communities with established or asserted rights and/or interests regarding the DNGS. OPG reported that it engaged with the following Indigenous Nations and communities regarding OPG's licence amendment application:

- Alderville First Nation
- Curve Lake First Nation
- Hiawatha First Nation
- Mississaugas of Scugog Island First Nation
- Chippewas of Beausoleil First Nation
- Chippewas of Georgina Island First Nation
- Chippewas of Rama First Nation
- Kawartha Nishnawbe
- Mohawks of the Bay of Quinte
- Métis Nation of Ontario Regions 6 and 8
- Algonquins of Ontario
- Algonquins of Pikwàkanagàn First Nation
- Six Nations of the Grand River
- Kitigan Zibi Anishinabeg

167. In section 3.3 of Attachment 3 of its application, OPG reported that it has implemented its *Indigenous Relations Policy* to provide a framework for engaging with, and providing support to, Indigenous Nations and communities. Under this policy, OPG maintains an Indigenous relations program for its nuclear operations with the goals of informing proximate Indigenous Nations and communities of OPG's nuclear operations and projects, seeking input from Indigenous Nations and communities, and addressing identified concerns as applicable. OPG reported that it also has a *Reconciliation Action Plan* that sets measurable goals to advance reconciliation with Indigenous Nations, communities, and organizations.

[86] *Isotope Engagement and Communications Plan with Indigenous Communities*, NK38-PLAN-00120-00018 R00, OPG, November 19, 2023.

168. In section 2.7.3 of CMD 25-H100, CNSC staff reported that OPG had conducted the following engagement specific to its licence amendment application:

- in November 2023, OPG sent a formal notification letter via e-mail to all identified Indigenous Nations and communities.
- in December 2023, OPG followed-up with Indigenous Nations and communities regarding the notification letter
- in January/February 2024, OPG conducted presentation meetings with Indigenous Nations and communities, as requested.
- from March 2024 onwards OPG conducted additional follow-up meetings, as required.

169. In section 2.7.3 of CMD 25-H100, CNSC staff reported that OPG's engagement activities to date were satisfactory, and that OPG's *Isotope Engagement and Communications Plan with Indigenous Communities* was developed in compliance with REGDOC-3.2.2, *Indigenous Engagement*,[87] which sets out requirements and guidance for licensees on Indigenous engagement. CNSC staff encouraged OPG to continue working with Indigenous Nations and communities through ongoing engagement, including discussing issues and concerns raised and working collaboratively to address them.

3.6.3 Submissions by Indigenous Nations and Communities

170. Four Indigenous Nations and communities submitted written interventions on this matter:

- Algonquins of Pikwàkanagàn First Nation (CMD 25-H100.2)
- Curve Lake First Nation (CMD 25-H100.4)
- Mississaugas of Scugog Island First Nation (CMD 25-H100.5)
- Algonquins of Ontario (CMD 25-H100.8)

[87] REGDOC-3.2.2, *Indigenous Engagement*, Version 1.2, CNSC, February 2022.

Algonquins of Pikwàkanagàn First Nation

171. BWXT-Medical's facility is located within the traditional territory of the Algonquins of Pikwàkanagàn First Nation (AOPFN). In its intervention (CMD 25-H100.2), AOPFN raised concerns that OPG's application would increase the transport and storage of radiological materials into and through AOPFN territory. AOPFN stated that:

- "OPG must seek to work with AOPFN to achieve [free, prior, and informed consent] FPIC for the transport of hazardous materials through AOPFN territory. At the same time, OPG should be collaborating with BWXT and AOPFN on FPIC matters with respect to the storage and processing of hazardous materials on AOPFN territory, including on waste management."
- "Meaningful consultation on these matters has not occurred to date."

AOPFN also made several requests for OPG and BWXT-Medical to provide AOPFN with additional information on the proposed licence amendment.

Curve Lake First Nation

172. The DNGS is located on the treaty and traditional territory of the Williams Treaties First Nations, which include Curve Lake First Nation (CLFN). In its intervention (CMD 25-H100.4), CLFN acknowledged that CNSC staff and OPG have made significant efforts to consult and engage with CLFN, however, CLFN asserts that there needs to be improvement in the following areas:

- "CLFN would like to see a more collaborative approach to engagement with BWXT and OPG as outlined in the *Isotope Engagement and Communications Plan with Indigenous Communities*. Curve Lake First Nation has not to date received robust information about medical isotope production at DNGS or the down the line procedures for isotope mobilization."
- "the CNSC's decision-making … must be consistent with UNDRIPA, address the concerns raised by CLFN, and demonstrate genuine two-way dialogue that goes beyond information sharing to reflect a commitment to understanding and accommodating the perspectives of impacted First Nations. While progress has been made, significant opportunities remain to evolve consultation processes and ensure alignment with the principles of UNDRIP and [UNDA]."

CLFN also noted the importance of having adequate environmental protection, waste management, and safeguards processes in place to prevent any potential environmental impacts from the production of the new isotopes.

Mississaugas of Scugog Island First Nation

173. The DNGS is located on the treaty and traditional territory of the Williams Treaties Frist Nations, which include the Mississaugas of Scugog Island First Nation (MSIFN). In its intervention (CMD 25-H100.5), MSIFN expressed that it is generally supportive of OPG's application, subject to the following two requests:

- "MSIFN Consultation requests the opportunity, concurrent with CNSC staff review, to review OPG's updated Predictive Environmental Assessment (PEA) to confirm that the environmental impacts of the new isotopes are within the previously assessed limits for Mo-99 production. MSIFN understands that this review will be part of the regulatory hold point process before the new isotopes are declared Available for Service (AFS)."
- "MSIFN Consultation requests to be involved by CNSC staff in the review and verification of the Regulatory Holdpoints (RHPs) prior to the CNSC removing the RHPs before declaring the new isotope production available for service (AFS). MSIFN Consultation understands the purpose of these RHPs is to ensure that OPG has conclusively demonstrated that the safety case for the new isotopes is bounded by the existing safety analysis for Mo-99 and that all necessary operational readiness documentation has been reviewed and verified by CNSC staff"

174. In CMD 25-H100-Q, the Commission asked CNSC staff to provide its perspective on MSIFN's requests. In CMD 25-H100.B, CNSC staff informed the Commission that CNSC staff and MSIFN had discussed MSIFN's requests at a meeting on March 28, 2025. CNSC staff reported that the agreed upon path forward from the meeting was that CNSC staff would share the RHP Removal Recommendation Report with MSIFN once it is finalized, noting that some confidential information may require redaction. CNSC staff expressed the view that this approach would help MSIFN gain a clearer understanding of the RHP process and procedures, and provide an opportunity to engage in discussions about their potential involvement moving forward, if desired.

Algonquins of Ontario

175. The Algonquins of Ontario (AOO) is comprised of ten individual Algonquin communities within the watersheds of the Kichisippi (Ottawa River) and the Mattawa River in Ontario. This area includes BWXT-Medical's facility. In its intervention, AOO informed the Commission that AOO had no outstanding concerns with OPG's licence amendment application.

3.6.4 Conclusion on Indigenous Engagement and Consultation

176. Based on the evidence on the record for this hearing in writing, and described throughout section 3.6 of this *Record of Decision*, the Commission is satisfied with CNSC staff's efforts to consult with Indigenous Nations and communities who have established or asserted rights and/or interests regarding the DNGS, on matters relevant to the licence amendment application before the Commission. The Commission also recognizes the engagement activities undertaken by OPG with each Indigenous Nation and community. The Commission is satisfied with the evidence received in this regard to render its decision on OPG's application.

177. Recent jurisprudence confirms that the UNDA incorporates the UNDRIP into Canada's positive legal framework. Accordingly, the Commission has considered, in making its determination on the fulfillment of section 35 rights and of the duty to consult and accommodate, how the UNDRIP and its articles may impact the fulfillment of such rights.[88] The Commission has assessed the application of the duty to consult and accommodate in relation to the licence amendment within the context of and with acknowledgement of the UNDA.

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

[88] *Kebaowek First Nation v. Canadian Nuclear Laboratories, 2025 FC 319.*

179. With respect to the requests for accommodation from MSIFN, the Commission is satisfied with CNSC staff's commitment to provide the RHP Removal Recommendation Report to MSIFN once it is finalized. The Commission notes that that the criteria for removal of a regulatory hold point must be objective. The Commission expects CNSC staff and OPG to continue to engage with MSIFN and to share information, where appropriate, which may be of interest to MSIFN in relation to the RHP.

180. The Commission acknowledges the comments made by AOPFN and CLFN about desiring a more collaborative relationship with OPG. The Commission encourages and expects OPG to build off of the submissions made by Indigenous Nations and communities in respect of OPG's engagement efforts for this hearing, and particularly the recommendations for further engagement and relationship-building. The Commission also acknowledges the comments made with respect to BWXT-Medical, which is not a party to this hearing. The Commission encourages CNSC staff and OPG to bring these comments to that licensee's attention.

3.7 Other Matters of Regulatory Importance

3.7.1 Public Engagement

181. A public information and disclosure program (PIDP) is a regulatory requirement for licence applicants and licensed operators of Class I nuclear facilities. Licence condition G.6 of PROL 13.05/2025 requires OPG to implement and maintain a public information and disclosure program for the DNGS. REGDOC-3.2.1, *Public Information and Disclosure*[89] sets out requirements for public information programs, disclosure protocols, and related documentation as they relate to licensed activities.

182. In sections 3.1 and 3.2 of Attachment 3 of OPG's application, OPG submitted that it has a public information and disclosure program in place to maintain timely and transparent communication with members of the public. OPG noted that it uses a variety of communication methods to distribute information, answer questions, and solicit feedback including, personal contact, community newsletters, community committees, speaking engagements, advertising, and educational outreach. OPG reported that it provided members of the public and interested parties with information regarding the production and transportation of Lu-177 and Y-90 through its regular outreach activities.

183. In section 3.2 of CMD 25-H100, CNSC staff confirmed that OPG's PIDP complies with REGDOC-3.2.1. CNSC staff noted that OPG has adapted its PIDP to respect current health and safety guidelines, executing both hybrid and in-person program models as appropriate. CNSC staff found that OPG's PIDP 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 Durham Region.

[89] REGDOC-3.2.1, *Public Information and Disclosure*, CNSC, May 2018.

184. Based on the information on record, as described above, the Commission concludes that OPG has adequate measures in place to communicate to the public information about the health, safety and security of persons and the environment, including information relevant to the production of Lu-177 and Y-90.

3.7.2 Decommissioning Plans and Financial Guarantee

185. The NSCA and its regulations require licensees to make adequate provision for the safe decommissioning of their facilities and for the long-term management of waste produced during the life of a facility. In order to ensure that adequate resources are available for the safe and secure future decommissioning of the DNGS, the Commission requires that an adequate financial guarantee for the realization of planned activities be put in place and maintained in a form acceptable to the Commission throughout the licence period. Licence condition 11.2 requires OPG to implement and maintain a decommissioning strategy. Licence condition G.5 requires OPG to maintain a financial guarantee for decommissioning that is acceptable to the Commission.

186. In section 2.6.11 of CMD 25-H100, CNSC staff submitted that the production of Lu-177 and Y-90 is not expected to change the decommissioning strategy compared to what was established for the production of Mo-99. CNSC staff reported that the TDS is a relatively small and removable system that will have a minimal effect on future decommissioning activities. As such, the additional isotopes are not expected to impact the existing financial guarantee for the DNGS.

187. The Commission is satisfied that OPG's existing PDP and financial guarantee for the DNGS are adequate to account for the production of Lu-177 and Y-90 using the existing TDS on DNGS Unit 2.

3.7.3 Nuclear Liability Insurance

188. Licensees are required to maintain nuclear liability insurance for designated nuclear installations, in accordance with the *Nuclear Liability and Compensation Act*[90] (NLCA). The NLCA is administered by Natural Resources Canada (NRCan).

189. In section 3.3 of CMD 25-H100, CNSC staff submitted that the DNGS is currently assessed at one billion dollars. This is the maximum limit of liability under the NLCA, therefore, the new activities authorized under the proposed licence amendment will not impact OPG's obligations under the NLCA. CNSC staff added that OPG is meeting its obligation for nuclear liability coverage under the NLCA. Based on the information provided on the record for this hearing, the Commission is satisfied that OPG is compliant with the requirements of the NLCA.

[90] S.C. 2015, c. 4, s. 120.

3.8 Licence Amendment

190. The Commission considered OPG's application for an amendment to its power reactor operating licence for the DNGS, PROL-13.05/2025, to authorize the production of Lu-177 and Y-90 using the existing TDS on DNGS Unit 2. OPG's licence expires on November 30, 2025.

3.8.1 Proposed Licence Amendment

191. In Attachment 1[91] of OPG's application, OPG provided the Commission with its proposed licence amendment to authorize the production of Lu-177 and Y-90 using the existing TDS on DNGS Unit 2.

192. In section 4.1.2 of CMD 25-H100, CNSC staff recommended that the Commission amend PROL-13.05/2025 with specific text that deviated from OPG's proposal. CNSC staff recommended that the Commission amend licensed activities (vi) to authorize the production of Lu-177 and Y-90, as follows:

> "*(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.*"

CNSC staff also recommended that the Commission amend licence condition 15.6 to remove Mo-99 specific wording and to remove language related to requirements to remove established regulatory hold points that is already covered by licence condition 15.4, as follows:

> "*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).*"

193. The Commission accepts the proposed licence amendments as submitted by CNSC staff in section 4.1.2 of CMD 25-H100. The Commission is satisfied that the proposed licence amendments are clear, reasonable and consistent with the activities to be licensed to produce Lu-177 and Y-90 on DNGS Unit 2.

3.8.2 Regulatory Hold Point

[91] *Proposed Amendment to Darlington NGS PROL 13.03/2025*, OPG, February 26, 2024.

194. CNSC staff proposed that the licence include a regulatory hold point (RHP) as part of the compliance oversight strategy. In section 3.4 of CMD 25-H100, CNSC staff proposed that the Commission establish a RHP prior to OPG declaring the production of the new isotopes available for service. In Table 2 of CMD 25-H100, CNSC staff outlined the specific deliverables and completion criteria for the RHP, which fall under the following areas:

- Design
- Radiological hazard assessment
- Safety analysis
- Human factors
- Procedures
- Environment
- Certified transport packages
- Commissioning

195. As described in licence condition 15.4 in the proposed revised LCH, the removal of a RHP requires the licensee to submit evidence that all deliverables related to the RHP have been completed. Prior to removal of the RHP, OPG shall submit, and CNSC staff shall verify, that OPG has completed all required actions in accordance with Table 2 of CMD 25-H100.

196. In section 3.4 of CMD 25-H100, CNSC staff reported that the use of a RHP is reasonable because:

- the proposed change will not require any physical modifications to the TDS or any other systems
- preliminary analysis has shown that production of Lu-177 and Y-90 will be bounded by the existing safety case for the production of Mo-99 using the TDS
- OPG will produce the proposed RHP deliverables under its ECC process which is compliant with the requirements of CSA N286-12
- the use of the RHP would ensure CNSC staff review the final safety analyses and commissioning results to verify that the new isotopes are covered by the existing safety case

197. In CMD 25-H100-Q, the Commission asked CNSC staff to explain how it would inform Indigenous Nations and communities, and the public, about the release of the RHP. In CMD 25-H100.B, CNSC staff submitted that it would use communication methods including social media posts, CNSC website updates, and emails to subscribers to communicate updates on the status of the project and the RHP. CNSC staff noted that, when requested, it would directly inform Indigenous Nations and communities when the RHP is removed. CNSC staff adapt their approach to each Nation’s specific needs, leveraging existing relationships and sharing information as requested or as outlined in the Terms of Reference for long-term engagement.

198. The Commission is satisfied with the RHP proposed by CNSC staff. The Commission finds that the proposed RHP would allow CNSC staff to verify OPG's assertion that the existing safety case remains valid for the production of Lu-177 and Y-90, prior to declaring the production of the new isotopes available for service. The Commission also notes that CNSC staff has experience successfully implementing RHPs for projects such as the Darlington NGS Refurbishment Project. As previously noted, the Commission is satisfied with CNSC staff's commitment to provide the RHP Removal Recommendation Report to MSIFN once it is finalized.

3.8.3 Delegation of Authority

199. In section 3.4.3 of CMD 25-H100, CNSC staff recommended that the Commission delegate authority for licence condition 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.") to the following CNSC staff:

- Director General of the Directorate of Power Reactor Regulation (DG-DPRR)

By delegating its authority for the purposes of licence condition 15.4, the Commission would be delegating the authority to remove the established target delivery system RHP to the above CNSC staff member.

200. In section 3.4.3 of CMD 25-H100, CNSC staff noted that, previously, authority to remove RHPs related to the Darlington PROL had been delegated to the CNSC's Executive Vice-President and Chief Regulatory Operations Officer. CNSC staff was of the opinion that the DG-DPRR would be an appropriate level of authority to remove the proposed RHP because:

- the DG-DPRR is responsible for the regulation of power reactors
- the commissioning of the new isotopes is not a first of a kind activity
- CNSC staff have acquired relevant experience in previous isotope-related licence amendments
- delegation to the DG-DPRR would simplify the administration of RHP removal

201. The Commission accepts the rationale put forward by CNSC staff that the DG-DPRR is the appropriate level of authority to remove the proposed RHP. The Commission notes, however, that it would be prudent for the Executive Vice-President and Chief Regulatory Operations Officer to have the same authority, to ensure the continuity of CNSC regulatory oversight in the event that the DG-DPRR is not available.

202. Therefore, for the purpose of the administration of licence condition 15.4, the Commission delegates authority to the following CNSC staff:

- Executive Vice-President and Chief Regulatory Operations Officer
- Director General of the Directorate of Power Reactor Regulation

This delegation of authority is for the purpose of the removal of the the established target delivery system RHP. The Commission is satisfied that this approach is reasonable.

4.0 CONCLUSION

203. The Commission has considered the information and submissions of OPG, and CNSC staff, as well as the written interventions submitted for the hearing. Based on its consideration of the evidence on the record, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends PROL-13.05/2025, issued to OPG for the DNGS located in the Municipality of Clarington, Ontario, to authorize the production of the medical isotopes Y-90 and Lu-177. The amended licence, PROL-13.06/2025, remains valid until November 30, 2025.

Tremblay, Pierre

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Pierre F. Tremblay
President

Appendix A – List of Intervenors

Intervenors	Document Number
Algonquins of Pikwàkanagàn First Nation	CMD 24-H100.2
Canadian Association of Nuclear Host Communities	CMD 24-H100.3
Curve Lake First Nation	CMD 24-H100.4
Mississaugas of Scugog Island First Nation	CMD 24-H100.5
North American Young Generation in Nuclear	CMD 24-H100.6
Northwatch	CMD 24-H100.7
Algonquins of Ontario	CMD 24-H100.8