

Commission canadienne de sûreté nucléaire

Canadian Nuclear Safety Commission

Record of Decision

DEC 24-H101

In the Matter of

Applicant Ontario Power Generation Inc.

Subject Application to Amend Power Reactor Operating Licence PROL-13.03/2025 to Authorize the Production of Cobalt-60 at the Darlington Nuclear Generating Station

Date of June 5, 2024 Decision

RECORD OF DECISION – DEC 24-H101

Applicant:	Ontario Power Generation Inc.
Address/Location:	700 University Avenue, Toronto, Ontario, M5G 1X6
Purpose:	Application to Amend Power Reactor Operating Licence PROL-13.03/2025 to Authorize the Production of Cobalt-60 at the Darlington Nuclear Generating Station
Application received:	April 28, 2023
Hearing:	<i>Notice of Hearing in Writing and Participant Funding</i> published on October 23, 2023
	<i>Revised Notice of Hearing in Writing and Participant Funding</i> published on January 8, 2024
Date of decision:	June 5, 2024
Panel of Commission:	Dr. T. Berube, Acting President Dr. M. Lacroix

Licence: Amended

Table of Contents

1.0 INTR	ODUCTION	1
2.0 DECISION		
3.0 ISSUE	ES AND COMMISSION FINDINGS	4
3.1 Des	cription of Co-60 Project	5
3.2 Sun	nmary of Views of Intervenors	6
3.3 App	licability of the Impact Assessment Act	6
3.4 Ass	essment of the Licence Amendment Application	7
3.5 OPC	G's Safety and Control Measures with Respect to the SCAs	8
3.5.1	Management System	8
3.5.2	Human Performance	10
3.5.3	Operating Performance	11
3.5.4	Safety Analysis	13
3.5.5	Physical Design	15
3.5.6	Fitness for Service	17
3.5.7	Radiation Protection	18
3.5.8	Conventional Health and Safety	20
3.5.9	Environmental Protection	21
3.5.10	Emergency Management and Fire Protection	23
3.5.11	Waste Management	24
3.5.12	Security	27
3.5.13	Safeguards and Non-Proliferation	29
3.5.14	Packaging and Transport	30
3.5.15	Conclusion on OPG's Safety and Control Measures with Respect to the SCAs	31
3.6 Indi	genous Engagement and Consultation	31
3.6.1	Conclusion on Indigenous Engagement and Consultation	37
3.7 Oth	er Matters of Regulatory Importance	38
3.7.1	Public Engagement	38
3.7.2	Decommissioning Plans and Financial Guarantee	38
3.7.3	Nuclear Liability Insurance	39
3.8 Lice	ence Amendment	39
4.0 CONC	CLUSION	40
Appendix	A – Intervenors	42

1.0 INTRODUCTION

- On April 28, 2023, Ontario Power Generation Inc. (OPG) submitted an application to the Canadian Nuclear Safety Commission¹ (CNSC), under subsection 24(2) of the <u>Nuclear Safety and Control Act</u>² (NSCA), for an amendment to the power reactor operating licence for its Darlington Nuclear Generating Station (NGS) located in the Municipality of Clarington, Ontario. The Darlington NGS site is located on the traditional lands and waters of the Michi Saagiig Anishinaabeg. These lands are covered by the Gunshot Treaty (1877-88), the Williams Treaties (1923), and the Williams Treaties Settlement Agreement (2018). The current licence, PROL-13.03/2025, expires on November 30, 2025.
- 2. The current licence authorizes OPG to operate the Darlington NGS, which includes 4 CANDU³ reactors and their associated equipment. OPG is seeking an amendment to its current licence to authorize the production of the radioisotope cobalt-60 (Co-60) in all 4 units at the Darlington NGS. Co-60 is a radioisotope with a variety of applications including nuclear medicine and the sterilization of medical and industrial equipment.

Issues

- 3. In considering OPG's licence amendment application, the Commission is first required to determine whether and what requirements the *Impact Assessment Act*⁴ (IAA) imposes in relation to the activities sought to be authorized.
- 4. 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
 - 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.
- 5. As an agent of the Crown, the Commission recognizes its role in fulfilling the Crown's constitutional obligations, along with advancing reconciliation with Canada's Indigenous peoples. The Commission's responsibilities include the duty to consult and, where appropriate, accommodate Indigenous interests where the Crown contemplates conduct

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 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 S.C. 2019, c. 28, s.1

which may adversely impact potential or established Aboriginal⁵ or treaty rights⁶. As such, the Commission must determine what engagement and consultation steps and accommodation measures are called for, respecting Indigenous interests.

Hearing in Writing

- On October 23, 2023, the Commission published a <u>Notice of Hearing in Writing and</u> <u>Participant Funding</u>⁷ for this matter, which invited requests to intervene by March 8, 2024. On January 8, 2024, the Commission published a <u>Revised Notice of</u> <u>Hearing in Writing and Participant Funding</u>⁸ to announce an extension to the dates for filing submissions.
- 7. Pursuant to section 22 of the NSCA, the Acting President of the Commission established a Panel of the Commission over which he would preside, including Dr. M. Lacroix, to consider the application. The Commission, in conducting a public hearing based on written materials, considered written submissions from OPG (<u>CMD 24-H101.1</u>, <u>CMD 24-H101.1A</u>, <u>CMD 24-H101.1B</u>) and CNSC staff (<u>CMD 24-H101</u>). The Commission also considered written submissions from 12 intervenors (see Appendix A for a list of interventions).
- 8. In making its decision, the Commission sent questions to CNSC staff and OPG through <u>CMD 24-H101-Q</u>. CNSC staff and OPG provided responses to the Commission's questions in <u>CMD 24-H101.A</u> and <u>CMD 24-H101.1D</u>, respectively. Following the responses, the Commission sent additional questions to CNSC staff and OPG in <u>CMD</u> <u>24-H101-Q.A</u>. CNSC staff and OPG provided responses to the Commission's questions in <u>CMD 24-H101.B</u> and <u>CMD 24-H101.1E</u>, respectively. The Commission is satisfied with the completeness of the responses provided by CNSC staff in CMD 24-H101.A and CMD 24-H101.B, and by OPG in CMD 24-H101.1D, and CMD 24-H101.1E.

Confidentiality Request

9. Alongside its application and supplemental submission, OPG submitted requests for confidentiality^{9,10} in accordance with subrule 12(1)(b) of the <u>CNSC Rules of Procedure</u>¹¹ (the Rules). OPG requested that the confidential references in its application and supplemental submission be protected from public disclosure and submitted public

⁵ "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.

⁶ 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.

⁷ Notice of Hearing in Writing and Participant Funding, CNSC, October 23 2023.

⁸ Revised Notice of Hearing in Writing and Participant Funding, CNSC, January 8 2024.

⁹ Request to Protect Confidential Information Accompanying Submission, Ontario Power Generation, 28 April 2023.

¹⁰ <u>Request to Protect Confidential Information Accompanying Submission</u>, Ontario Power Generation, 30 June 2023.

¹¹ SOR/2000-211.

summaries of the confidential documents, which are available in Appendix B of <u>CMD 24-H101.1A</u> and in <u>CMD 24-H101.1C</u>. Persons with an interest in OPG's request for confidentiality were <u>invited</u>¹² to send comments to the Commission Registry by January 22, 2024. Three submissions were received (<u>CMD 24-H101.2</u>). On March 25, 2024, the Commission issued its <u>decision</u>¹³ on OPG's request for confidentiality, setting out the measures it would take to protect information, pursuant to subrule 12(3).

CNSC Participant Funding Program

10. 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 October 2023, 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 \$12,000 to 1 applicant, the Mississaugas of Scugog Island First Nation (MSIFN). MSIFN was required to submit a written intervention respecting OPG's application.

2.0 DECISION

- 11. 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 of 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 respecting Indigenous interests have been satisfied
 - OPG is qualified to carry on the activities that the amended licence will authorize
 - OPG, in carrying out 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

¹² Notice of Request for Confidentiality, CNSC, January 10 2024.

¹³ Commission Ruling on Request to Protect Confidential Information in the Matter of OPG's application to amend its Darlington Nuclear Generating Station Power Reactor Operating Licence to authorize the production of the Cobalt-60 Radioisotope, CNSC, 25 March 2024.

Therefore,

the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the power reactor operating licence PROL-13.03/2025 issued to Ontario Power Generation Inc. for its Darlington Nuclear Generating Station located in the Municipality of Clarington, Ontario. The amended licence, PROL-13.04/2025, remains valid until November 30, 2025.

- 12. The Commission includes in the licence the conditions as recommended by CNSC staff in section 3.2.2 of CMD 24-H101:
 - amend licensed activity (i) to read:

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

• amend licensed activity (vi) to read:

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

• add new licence condition 15.7 as follows:

"The licensee shall implement and maintain a Co-60 operations program for the activities described in part IV of the licence."

3.0 ISSUES AND COMMISSION FINDINGS

- 13. In making its licensing decision, the Commission considered a number of relevant issues and submissions relating to OPG's qualification to carry out the activity the licence amendment would authorize. The Commission also considered the adequacy of OPG's proposed measures for protecting the environment, the health and safety of persons, national security and international obligations to which Canada has agreed.
- 14. The matter before the Commission is an application to amend an existing power reactor operating licence to authorize the production of Co-60 at the Darlington NGS. The Commission's decision focuses on the issues that it considers the most relevant for this application, specifically:

- the applicability of the *Impact Assessment Act*
- assessment of the licence amendment application
- provisions for safety relevant to the proposed licence amendment in accordance with all 14 <u>safety and control areas</u>¹⁴ (SCAs)
- Indigenous engagement and consultation
- other matters of regulatory importance
- the proposed licence amendment
- 15. The Commission notes that the application before it is for the production of Co-60, a radioisotope with a variety of applications in the medical sector, including cancer treatment. In keeping with the <u>Directive to the Canadian Nuclear Safety Commission</u> <u>Regarding the Health of Canadians</u>¹⁵, the Commission takes into account the health of Canadians who, for medical purposes, depend on Co-60 produced by nuclear reactors.

3.1 Description of Co-60 Project

- 16. In CMD 24-H101.1A, OPG informed the Commission that OPG has produced the Co-60 radioisotope at the Pickering NGS's for decades, providing 15-20% of the worldwide production of Co-60. OPG submitted that the Co-60 project at Darlington NGS would provide an opportunity to maintain long-term supply of Co-60 following the eventual end of commercial operation of Pickering NGS.
- 17. In section 1 of CMD 24-H101.1A, Attachment 3, OPG provided detailed information on the Co-60 project and related modifications. As part of the Co-60 project, OPG is proposing to replace the 16 in-service¹⁶ stainless steel adjuster absorber (AA) rods¹⁷ in each reactor unit at the Darlington NGS with functionally equivalent AA rods primarily made of Co-59. Co-59 is a stable isotope of cobalt which can be converted to radioactive Co-60 through irradiation in the reactor core. OPG intends to produce Co-60 in all four reactor units at the Darlington NGS, including Unit 2, which also contains additional equipment to produce Molybdenum-99 (Mo-99). OPG noted that Co-60 is already being produced at the Pickering NGS and at the Bruce B NGS using a similar method.
- OPG submitted that the cobalt AA rods would remain in the reactor core for up to 3.5 years and would be harvested during each unit's regularly scheduled maintenance outage.

¹⁴ SCAs are the technical topics used by CNSC staff across al regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance.

¹⁵ SOR/2007-282.

¹⁶ Reactor units at Darlington NGS were designed with 24 AA rods which are normally positioned in the reactor core. Early in operation of the Darlington NGS, eight of these AA rods were determined to be unneeded and were permanently removed from service and locked out of the core. In each reactor unit, 16 AA rods remain in-service. ¹⁷ The purpose of the AA rods is to act as part of the reactor regulating system in maintaining control of reactor

¹⁷ The purpose of the AA rods is to act as part of the reactor regulating system in maintaining control of reactor power during normal operation by absorbing neutrons.

OPG reported that it plans to install Cobalt Adjuster Element Processing System (CAEPS) equipment to facilitate the harvest of Co-60. Co-60 AA rods would be withdrawn from the reactor core and into a shielded CAEPS flask positioned at each AA rod unit on the reactivity mechanism deck using the CAEPS flask positioner and a custom pedestal. The CAEPS flask would then be hoisted across the reactivity mechanism deck using the overhead reactor deck crane and lowered to a vehicle known as the transport erector. The transport erector with the secured flask would be towed to the West Fueling Facilities Auxiliary Area where the rods would be dismantled within the wet cask handling bay of the irradiated fuel bay and packaged for transportation to Nordion (Canada) Inc.'s <u>Class IB nuclear processing facility</u> in Kanata, ON. OPG provided details on its Co-60 project schedule in CMD 24-H101.1B.

19. In CMD 24-H101.1A, OPG clarified that OPG would be responsible for the receipt and storage of Co-59 rods, the irradiation of Co-59 rods in the Darlington NGS's reactors, the harvesting of the irradiated rods from the reactor core, the preparation and packaging of the Co-60 for shipment, and for the Co-60 shipments until they are received by Nordion at their facility in Kanata, ON. OPG reported that Nordion would be responsible for arranging the conveyance of Co-60 to Nordion's processing facility and for all subsequent steps in the processing of Co-60 for end-users. Spent Co-60 sources¹⁸ will be returned to OPG for waste management at the end of their commercial life.

3.2 Summary of Views of Intervenors

- 20. All interventions, except for the intervention submitted by Saugeen Ojibway Nation (SON), were supportive of OPG's application. The Mississaugas of Scugog Island First Nation provided their "provisional support" of OPG's application, as detailed further in section 3.6 of this *Record of Decision*.
- 21. In its intervention, SON expressed concern that OPG had not informed SON that OPG planned to transport spent cobalt sources into SON territory. SON requested that the Commission delay its decision on OPG's application until CNSC staff could consult with SON about the proposed Co-60 project. SON's concerns related to consultation are detailed further in section 3.6 of this *Record of Decision*.

3.3 Applicability of the Impact Assessment Act

22. In coming to its decision, the Commission is first required to determine whether any requirement under the IAA apply to the project and whether an impact assessment of the proposal is required.

¹⁸ Spent cobalt refers to cobalt sources returned to OPG at the end of their commercial life.

- 23. Pursuant to the IAA and the <u>Physical Activities Regulations</u>¹⁹ 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 IAA Physical Activities Regulations that require an impact assessment or that meet the definition of a project on federal lands.
- 24. 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 matter²⁰.

3.4 Assessment of the Licence Amendment Application

- 25. In order to be complete, OPG's licence application must meet the requirements of the NSCA, the <u>General Nuclear Safety and Control Regulations</u>²¹ (GNSCR), and other applicable regulations made under the NSCA. The Commission examined the sufficiency of OPG's application.
- 26. 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.
- 27. 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.
- 28. In Attachment 2 of CMD 24-H101.1A, 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.

¹⁹ SOR/2019-285.

²⁰ 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. ²¹ SOR/2000-202.

29. 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.

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

- 30. The Commission examined OPG's safety and control measures for the proposed production of Co-60 at the Darlington NGS. The Commission's evaluation includes consideration of OPG's proposed safety and control measures with respect to all 14 SCAs.
- 31. In section 3 of CMD 24-H101.1A, Attachment 3, OPG provided information on how operations related to Co-60 at the Darlington NGS would impact each of the 14 SCAs. In section 2.5 of CMD 24-H101, CNSC staff informed the Commission that it reviewed OPG's application and supporting documentation, and analyzed potential impacts to the existing licensing basis, considering the relevant requirements of each SCA. In section 4.1 of CMD 24-H101, CNSC staff reported that operations related to Co-60 at the Darlington NGS would remain within the limits of the established safety case and would introduce minimal additional risk to the operation of the nuclear facility.

3.5.1 Management System

- 32. Licence condition 1.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a management system. 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.
- 33. Paragraph 3(d) of the <u>Class I Nuclear Facilities Regulations</u>²² 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.
- 34. CSA Group Standard N286-12, Management System Requirements for Nuclear Facilities²³ provides an overall management framework and direction to develop and implement sound management practices and controls for the licensing basis. CNSC regulatory document²⁴ <u>REGDOC-2.1.2</u>, Safety Culture²⁵ sets out requirements and guidance for fostering a healthy safety culture and conducting safety culture assessments.

²² SOR/2000-204.

²³ N286-12, Management System Requirements for Nuclear Facilities, CSA Group, 2012 (R2022).

²⁴ CNSC <u>regulatory documents</u> are typically referred to as REGDOCs.

²⁵ REGDOC-2.1.2, Safety Culture, CNSC, April 2018.

- 35. In section 3.1 of CMD 24-H101.1A, Attachment 3, OPG provided the Commission with information on its management system and how it applies to the Co-60 project, including that OPG:
 - has a nuclear management system in place that is compliant with the requirements of CSA N286-12
 - has a healthy safety culture in compliance with REGDOC-2.1.2
 - is conducting the Co-60 project under OPG's engineering change control process which is part of its nuclear management system
 - has engaged a qualified vendor as the general contractor to provide engineering procurement and construction services for the Co-60 project
 - has, and will continue to, conduct contractor oversight activities throughout the Co-60 project
- 36. Regarding operating experience, OPG reported that its has been producing Co-60 at the Pickering NGS since the 1970's. In section 3.1.6 of CMD 24-H101.1, Attachment 3, OPG informed the Commission that it reviewed internal operating experience from the Pickering NGS along with external operating experiences from the CANDU Owners Group database. OPG then applied the relevant lessons learned to the Darlington NGS Co-60 project.
- 37. In section 2.5.1 of CMD 24-H101, CNSC staff confirmed that OPG has a management system in place that is compliant with CSA N286-12. CNSC staff found that OPG had produced Co-60 project governance in accordance with its engineering change control process and considering a variety of relevant operating experience. CNSC staff noted that OPG is ultimately responsible for ensuring that Co-60 related work, including work done by contractors, is conducted in accordance with OPG's management system. CNSC staff reported that it will continue to provide regulatory oversight to verify OPG's implementation of its management system and REGDOC-2.1.2.
- 38. Based on the information on record as described above, the Commission concludes that OPG has an appropriate management system in place to carry on the activities that would be authorized by the proposed licence amendment. The Commission finds that:
 - OPG has implemented and maintained a management system and safety culture in compliance with regulatory requirements
 - OPG has produced Co-60 project governance in accordance with its management system
 - OPG's management system is adequate to provide oversight of Co-60 project activities, including those conducted by contractors
 - OPG incorporated relevant operating experience from multiple sources into the Co-60 project

3.5.2 Human Performance

- 39. Licence condition 2.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a human performance program. Human performance management encompasses activities to ensure that OPG workers are sufficient in number in all relevant job areas, and have the necessary knowledge, skills, procedures, and tools in place to safely carry out their duties.
- 40. 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.
- 41. Paragraph 3(d.1) of the *Class I Nuclear Facilities Regulations* 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.
- 42. <u>REGDOC-2.2.2, Personnel Training, Version 2²⁶ 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. <u>REGDOC-2.2.3, Personnel Certification, Volume III: Certification of Persons Working at Nuclear Power Plants²⁷ sets out requirements aiming to ensure that persons seeking a certification by the CNSC for a position referred to in the licence of a nuclear power plant are qualified to carry out the duties of that position in accordance with the NSCA and its regulations. REGDOC-2.2.4, *Fitness for Duty* (Volumes I, II, and III)^{28,29,30} 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.</u></u>

²⁶ REGDOC-2.2.2, *Performance Training*, Version 2, CNSC, December 2016.

²⁷ REGDOC-2.2.3, *Personnel Certification, Volume III: Certification of Persons Working at Nuclear Power Plants,* CNSC, September 2019.

²⁸ REGDOC-2.2.4, *Fitness for Duty, Managing Worker Fatigue*, CNSC, March 2017.

²⁹ REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3, CNSC, January 2021.

³⁰ REGDOC-2.2.4, *Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, Psychological Fitness,* CNSC, September 2018.

- 43. In section 3.2 of CMD 24-H101.1A, Attachment 3, OPG provided the Commission with information on its human performance management program and how it applies to the Co-60 project, including that:
 - OPG has a human performance management system in place that is compliant with the requirements of REGDOC-2.2.2, REGDOC-2.2.3, *Volume III*, and REGDOC-2.2.4, *Fitness for Duty* (Volumes I, II, and III)
 - OPG has a systematic approach to training (SAT) in place and will conduct SATbased staff training prior to operation of the Co-60 system
 - workers have the necessary knowledge and skills, and are sufficient in number, to carry out Co-60 project work
 - the Co-60 project will not impact minimum shift complement at Darlington NGS
- 44. In section 2.5.2 of CMD 24-H101, CNSC staff confirmed that OPG has implemented and maintained a human performance program at the Darlington NGS that is compliant with regulatory requirements. CNSC staff reported that OPG has a robust SAT-based training program that is sufficient to develop and deliver training to staff that will be impacted by the Co-60 project. CNSC staff further noted that activities associated with Co-60 production will be performed by a distinct crew that will be separate to minimum shift complement staff. This meets CNSC staff's expectations and remains compliant with <u>REGDOC-2.2.5, *Minimum Staff Complement*³¹.</u>
- 45. Based on the information on record as described above, the Commission concludes that OPG has adequate measures in place to manage human performance for the conduct of the licensed activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG has a human performance management system and SAT-based training program in place that meet regulatory requirements
 - OPG will conduct SAT-based staff training prior to operation of the Co-60 system
 - OPG has an adequate number of workers to safely operate the Co-60 system
 - the Co-60 project will not impact minimum shift complement at the Darlington NGS

3.5.3 *Operating Performance*

46. Licence condition 3.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain an operations program, which includes a set of operating limits. Operating performance includes an overall review of the conduct of the licensed activities and the activities that enable effective performance at the Darlington NGS, as well as improvement plans and significant future activities.

³¹ REGDOC-2.2.5, *Minimum Staff Complement*, CNSC, April 2019.

- 47. Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* 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.
- 48. <u>REGDOC-2.3.2, Accident Management</u>³² sets out requirements and guidance for the development, implementation and validation of integrated accident management for reactor facilities. <u>REGDOC-2.3.3, Periodic Safety Reviews</u>³³ sets out the requirements for the conduct of a periodic safety review for a nuclear power plant. <u>REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants</u>³⁴ sets out requirements and guidance for reports and notifications that licensees of nuclear power plants must submit to the CNSC.
- 49. In section 3.3 of CMD 24-H101.1A, Attachment 3, OPG submitted information on its nuclear operations program and how it applies to the Co-60 project, including that:
 - OPG's existing operating performance program complies with the requirements of REGDOC-2.3.2, REGDOC-2.3.3, REGDOC-3.1.1, and CSA N290.15, *Requirements for the safe operation envelope for nuclear power plants*³⁵
 - the Co-60 project will not impact the safe operating envelope, safety limits, or accident management plans for the Darlington NGS
 - the Co-60 project would not require significant changes to the nuclear operations program or the operating policies and principles for the Darlington NGS
 - the predicted reactivity worth of the cobalt AA rods is similar enough to that of the existing stainless steel AA rods that no changes to the reactor regulating system parameters or control logic are required
 - OPG identified a list of existing documentation, including operational safety requirement documentation, that would require revision should the Commission accept the proposed licence amendment and authorize Co-60 production at the Darlington NGS
 - OPG has a regulatory commitment to submit the Darlington Co-60 production system operating manual and procedures to CNSC staff by August 29, 2025
- 50. In section 2.5.3 of CMD 24-H101, CNSC staff submitted that OPG's existing nuclear operations program satisfies regulatory requirements and includes governance for the development and revision of technical procedures, which will be used to develop Co-60 project-specific documentation. CNSC staff noted that, pending Commission authorization, OPG is targeting to complete the first Co-60 harvest at the Darlington NGS in 2027, allowing sufficient time for CNSC staff to assess the adequacy of OPG's project documentation following the August 2025 deadline. CNSC staff reported that it would also review OPG's revised operational safety requirement documentation and Co-60 system commissioning reports, once available.

³² REGDOC-2.3.2, Accident Management, CNSC, September 2015.

³³ REGDOC-2.3.3, Periodic Safety Reviews, CNSC, April 2015.

³⁴ REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants, Version 2, CNSC, April 2016.

³⁵ CSA N290.15, Requirements for the safe operation envelope for nuclear power plants, CSA Group, 2010.

- 51. Based on the information on record as described above, the Commission concludes that OPG has a sufficient operations program in place to accommodate for the conduct of the licensed activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG has a nuclear operations program in place that meets regulatory requirements
 - the Co-60 project would not require significant changes to OPG's nuclear operation program and would not impact the safe operating envelope, safety limits, or accident management plans for the Darlington NGS
 - OPG has committed to submit an operating manual and operating procedures for the Co-60 system to CNSC staff by August 29, 2025, and that CNSC staff are of the view that this deadline is adequate
 - OPG has produced a list of documentation that it will update should the Commission authorize the production of Co-60 at the Darlington NGS

3.5.4 Safety Analysis

- 52. Licence condition 4.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a safety analysis program. Safety analysis, which supports the overall safety case for a facility, includes 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.
- 53. Paragraph 6(c) of the *Class I Nuclear Facilities Regulations* provides that an application for a licence to operate a Class I nuclear facility must include a final safety analysis report demonstrating that the adequacy of the design of the nuclear facility.
- 54. <u>REGDOC-2.4.1, Deterministic Safety Analysis³⁶</u> sets out requirements and guidance for the preparation and presentation of a safety analysis that demonstrates the safety of a nuclear facility. <u>REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants³⁷</u> sets out requirements for a licensee to conduct a probabilistic safety assessment³⁸ (PSA) for a nuclear power plant. CSA N286.7, *Quality assurance of analytical, scientific and design computer programs for nuclear power plants³⁹* specifies requirements applicable to the development, modification, maintenance, and use of computer programs in analytical, scientific, and design applications during any phase of the nuclear plant lifecycle.

³⁶ REGDOC 2.4.1, *Deterministic Safety Analysis*, CNSC, May 2014.

³⁷ REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants, CNSC, May 2014.

³⁸ 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.

³⁹ CSA N286.7, *Quality assurance of analytical, scientific and design computer programs for nuclear power plants,* CSA Group, 1999 [R2012].

- 55. In section 3.4 of CMD 24-H101.1A, Attachment 3, OPG provided information on its safety analysis program and how it applies to the Co-60 project, including that:
 - OPG has a safety analysis program in place that complies with the requirements of REGDOC-2.4.1, REGDOC-2.4.2, and CSA N286.7
 - OPG conducted various safety assessments for the Co-60 system in accordance with REGDOC-2.4.1, REGDOC-2.4.2, and CSA N286.7 and determined that the impacts of the Co-60 system on the existing Darlington NGS safety case are expected to be insignificant
 - the Co-60 system will not require any changes to safety system setpoints
 - OPG assessed the impacts of having the Co-60 system and the Mo-99 system in the same operating unit at the Darlington NGS and found that both systems had a negligible effect on reactor safety and operations
 - OPG has a regulatory commitment to verify cobalt AA rod reactivity worth and incremental cross-sections at the end of their first irradiation cycle
 - OPG performed a hazard analysis to assess potential hazards during Co-60 harvesting and transfer to the irradiated fuel bay, and put in place appropriate design and procedural measures to mitigate identified hazards
 - OPG will include the Co-60 system in its annual *Darlington Analysis of Record* and in the next update of the *Darlington NGS Safety Report*
- 56. During its review of OPG's safety analyses, CNSC staff found that a thermal hydraulic safety analysis submitted by OPG to assess the impact of Co-60 on existing analyses pertaining to a loss of irradiated fuel bay cooling event was not fully compliant with REGDOC-2.4.1. CNSC staff noted that the analysis did, however, use updated codes and include the principal elements of REGDOC-2.4.1. CNSC staff reported that OPG has a regulatory commitment to resolve residual issues with the analysis and to issue a new revision of the analysis in compliance with REGDOC-2.4.1. CNSC staff's view is that OPG's proposed actions are reasonable and would add certainty to OPG's current analysis.
- 57. In section 2.5.4 of CMD 24-H101, CNSC staff submitted that OPG has a safety analysis program in place that satisfies regulatory requirements and that, in accordance with that program, OPG submitted comprehensive safety analyses to support its licence amendment application. CNSC staff confirmed that OPG had performed sufficient safety analyses to assess the impacts of Co-60 operations on normal operating conditions and the existing station safety analysis. CNSC staff's view is that OPG demonstrated that Co-60 operations will not compromise continued safe reactor operations or invalidate existing setpoints of safety systems or safety margins.
- 58. Regarding PSA, CNSC staff submitted that the Co-60 project does not warrant an update to the Darlington PSA models outside of the normal five-year update cycle, given that safety goals will continue to be met. CNSC staff reported that it would review OPG's next revision of the Darlington NGS PSA, which will be submitted in 2025, in accordance with REGDOC-2.4.2.

- 15 -

- 59. Based on the information on record as described above, the Commission concludes that OPG has a safety analysis program in place that is sufficient to accommodate for the licensed activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG has a safety analysis program in place that meets regulatory requirements
 - OPG has performed sufficient safety analyses to assess the safety-related impacts of Co-60 operations
 - the Co-60 system is expected to have an insignificant impact on the existing Darlington NGS safety case
 - the Co-60 project does not require a specific update to the Darlington NGS PSA
 - OPG has committed to revise the thermal hydraulic analysis that CNSC staff determined to not be in full compliance with REGDOC-2.4.1
 - OPG has sufficiently demonstrated that Co-60 operations will not compromise continued safe reactor operations or invalidate existing setpoints of safety systems or safety margins

3.5.5 Physical Design

- 60. Licence condition 5.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a design program. Physical design includes the activities to design systems, structures and components to meet and maintain the design basis of a facility. The design basis is the range of conditions, according to established criteria, that the facility must withstand without exceeding authorized limits for the planned operation of safety systems.
- 61. Paragraph 3(1)(d) of the GNSCR requires that a licence application shall contain a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.
- 62. Paragraphs 3(a) and 3(b) of the *Class I Nuclear Facilities Regulations* 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 *Class I Nuclear Facilities Regulations* 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.
- 63. CSA N285.0, General requirements for pressure-retaining systems and components in CANDU nuclear power plants⁴⁰ specifies the technical requirements for the design, procurement, fabrication, installation, modification, repair, replacement, testing, examination, and inspection of pressure-retaining and containment systems, components, and supports at a nuclear power plant. CSA N291, *Requirements for safety related*

⁴⁰ CSA N285.0, General requirements for pressure-retaining systems and components in CANDU nuclear power plants, CSA Group, 2008.

*structures for CANDU nuclear power plants*⁴¹ provides material, design, construction, fabrication, inspection, and examination requirements for safety-related structures for CANDU nuclear power plants.

- 64. In section 3.5 of CMD 24-H101.1A, Attachment 3, OPG provided information on its physical design program and how it applies to the Co-60 project, including that:
 - OPG has a physical design program in place that complies with regulatory requirements including CSA N285.0 and CSA N291
 - OPG's engineering change control process ensures that design changes, such as the Co-60 project, are executed such that the facility configuration is managed in accordance with the facility's design basis and licensing basis, and so that the facility remains within the safe operating envelope
 - the design and operation of the Co-60 system would be similar to that already performed by OPG at the Pickering NGS
 - the Co-60 system and Mo-99 target delivery systems were designed to prevent unintended interactions when installed on the same reactor unit, with minor potential interactions being managed as part of the Co-60 project
- 65. In section 2.5.5 of CMD 24-H101, CNSC staff submitted that OPG has a physical design program in place that meets regulatory requirements and provides an acceptable means of planning and implementing modifications such as the Co-60 project. CNSC staff reviewed OPG's submissions and found that OPG had satisfactorily considered factors in the Co-60 system design including seismic qualification, environmental qualification, pressure retaining systems, and instrumentation & control. CNSC staff noted that OPG was still conducting some assessments, such as human factors verification; however, CNSC staff is satisfied that OPG is completing this work in accordance with its engineering change control process and will ensure that the design basis of the Darlington NGS is maintained. CNSC staff will provide regulatory oversight to verify completion of required activities.
- 66. Based on the information on record as described above, the Commission concludes that OPG has an adequate physical design program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission notes that:
 - OPG has implemented and maintained a physical design program that meets regulatory requirements
 - OPG is conducting its Co-60 project in alignment with its engineering change control process
 - the design of the Darlington NGS Co-60 system is similar to that already installed at the Pickering NGS
 - CNSC staff will provide regulatory oversight to ensure that outstanding assessments are completed as required
 - the Co-60 project has considered, and is managing, minor potential interactions between the Co-60 system and the Mo-99 system on Darlington NGS Unit 2

⁴¹ CSA N291, Requirements for safety related structures for CANDU nuclear power plants, CSA Group, 2008.

3.5.6 Fitness for Service

- 67. Licence condition 6.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a fitness for service program. The fitness for service SCA covers activities that are performed to ensure that systems, structures and components at the Darlington NGS continue to effectively fulfill their intended purpose.
- 68. Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* 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. <u>REGDOC-2.6.1, *Reliability Programs for Nuclear Power Plants*⁴² sets out the requirements for the development and implementation of a reliability program for a nuclear power plant in Canada. <u>REGDOC-2.6.2, *Maintenance Programs for Nuclear Power Plants*⁴³ sets out guidance and requirements for maintaining an effective maintenance program for a nuclear power plant. <u>REGDOC-2.6.3, *Aging Management*</u>⁴⁴ sets out guidance and the requirements for managing aging of structures, systems, and components for reactor facilities.</u></u>
- 69. CSA N285.4, *Periodic inspection of CANDU nuclear power plant components*⁴⁵ defines the requirements for the periodic inspection of pressure retaining systems, components, and supports that form part of a CANDU nuclear plant. CSA N285.5, *Periodic inspection* of CANDU nuclear power plant containment components⁴⁶ provides rules for the periodic inspection of containment components in CANDU nuclear power plants. CSA N285.8, *Technical requirements for in-service inspection evaluation of zirconium alloy in pressure tubes in CANDU reactors*⁴⁷ specifies the technical requirements to ensure the structural integrity of zirconium alloy pressure tubes in operating CANDU reactors.
- 70. In section 3.6 of CMD 24-H101.1A, Attachment 3, OPG provided the Commission with information on its fitness for service program and how it applies to the Co-60 project, including that:
 - OPG has a fitness for service program in place that complies with:
 - REGDOC-2.6.1, REGDOC-2.6.2, and REGDOC-2.6.3
 - o CSA N285.4, CSA N285.5, and CSA N285.8
 - the Co-60 system will not impact the fitness for service or periodic inspections of major components at the Darlington NGS
 - OPG will incorporate Co-60 system equipment into OPG's existing aging management program
 - the installation of cobalt AA rods will have a negligible impact on moderator chemistry and irradiated fuel bay chemistry

CANDU reactors, CSA Group, 2015.

⁴² REGDOC-2.6.1, *Reliability Programs for Nuclear Power Plants*, CNSC, August 2017.

⁴³ REGDOC-2.6.2, *Maintenance Programs for Nuclear Power Plants*, CNSC, August 2017.

⁴⁴ REGDOC-2.6.3, Aging Management, CNSC, March 2014.

⁴⁵ CSA N285.4, Periodic inspection of CANDU nuclear power plant components, CSA Group, 2014.

⁴⁶ CSA N285.5, Periodic inspection of CANDU nuclear power plant containment components, CSA Group, 2018.

⁴⁷ CSA N285.8, Technical requirements for in-service inspection evaluation of zirconium alloy in pressure tubes in

- 71. In addition, OPG submitted that it is developing preventative maintenance, testing, and periodic inspection plans for the Co-60 system in accordance with OPG's engineering change control process. OPG reported that the plans will be similar to those implemented at the Pickering NGS. OPG committed to complete the plans prior to completing Available for Service Declarations for the Co-60 system.
- 72. In section 2.5.6 of CMD 24-H101, CNSC staff confirmed that OPG's existing fitness for service program satisfies regulatory requirements. Regarding fitness for service of the Co-60 system, CNSC staff recognized OPG's commitment to complete preventative maintenance, testing, and periodic inspection plans for the Co-60 system prior to declaring the system available for service. CNSC staff is of the view that OPG is qualified to complete the committed work because it has a mature work management program and experience with Co-60 production. CNSC staff further noted that the Co-60 system would have minimal impact on the fitness for service of existing structures, systems, and components at the Darlington NGS.
- 73. Based on the information on record as described above, the Commission concludes that OPG has an adequate fitness for service program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission notes that:
 - OPG has implemented and maintained a fitness for service program that meets regulatory requirements
 - OPG will integrate the Co-60 system into its existing aging management program
 - the Co-60 system would have minimal impact on the fitness for service of existing structures, systems, and components at the Darlington NGS
 - OPG has committed to complete preventative maintenance, testing, and periodic inspection plans for the Co-60 system prior to completing Available for Service Declarations

3.5.7 Radiation Protection

- 74. Licence condition 7.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a radiation protection program. Radiation protection includes measures for protecting the health and safety of persons from hazards associated with ionizing radiation. Radiation protection ensures 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.
- 75. Section 4 of the <u>Radiation Protection Regulations</u>⁴⁸ 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 *Class I Nuclear Facilities Regulations* require that an application for a licence to operate

⁴⁸ SOR/2000-203.

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.

- 76. <u>**REGDOC-2.7.1**</u>, *Radiation Protection*⁴⁹ provides guidance on radiation protection programs, the principles of worker dose control and the principles of radiological hazard control to ensure the protection of workers and the public.
- 77. In section 3.7 of CMD 24-H101.1A, Attachment 3, OPG provided information on its radiation protection program and how it applies to the Co-60 project, including that:
 - OPG has a radiation protection program in place that meets the requirements of the *Radiation Protection Regulations* and the <u>Nuclear Substances and Radiation Devices</u> <u>Regulations</u>⁵⁰
 - OPG applied ALARA principles during design of the Co-60 system to minimize worker and public dose in alignment with REGDOC-2.7.1
 - OPG incorporated operating experience from the Pickering NGS and the Bruce NGS to support ALARA principles
 - the estimated accumulated whole body dose increase to workers will be maintained well below regulatory limits
- 78. In section 2.5.7 of CMD 24-H101, CNSC staff submitted that OPG has a robust radiation protection program in place that satisfies regulatory requirements and is suitable to protect the health and safety of persons involved in activities associated with Co-60 operations. CNSC staff reviewed OPG's application and found that OPG had assessed and mitigated potential radiological hazards by incorporating radiation protection measures into the Co-60 design.
- 79. In section 2.5.7 of CMD 24-H101, CNSC staff noted that OPG has committed to submit an additional engineering evaluation of a specific scenario in which gamma dose rate may increase on the reactivity mechanism deck during withdrawal of a cobalt AA rod. This assessment is due to be submitted to the CNSC in 2027. CNSC staff submitted that, due to access controls and the presence of permanent fixed area alarming gamma meters around the reactivity mechanism deck, there is minimal risk associated with a 2027 deadline for this assessment.
- 80. Based on the information on record as described above, the Commission concludes that OPG has a radiation protection program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission notes that:
 - OPG has implemented and maintained a radiation protection program that meets regulatory requirements

⁴⁹ REGDOC-2.7.1, Radiation Protection, CNSC, July 2021.

⁵⁰ SOR/2000-207.

- worker dose will be maintained well below regulatory limits
- OPG has adequate compensatory measures in place to ensure worker safety until it submits to the CNSC an additional engineering evaluation of the withdrawal of a cobalt AA rod scenario

3.5.8 Conventional Health and Safety

- 81. Licence condition 8.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a conventional health and safety program. A conventional health and safety program's objective is to minimize risk to the health and safety of workers posed by conventional (non-radiological) hazards in the workplace. A conventional health and safety program manages conventional workplace safety hazards and ensures compliance with applicable labour codes. The NSCA provides that the Commission must ensure that a licence applicant takes the necessary measures to safeguard the health of persons.
- 82. The NSCA provides that the Commission must ensure that the applicant takes the necessary measures to safeguard the health of persons. Paragraph 3(f) of the *Class I Nuclear Facilities Regulations* 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.
- 83. In section 3.8 of CMD 24-H101.1A, Attachment 3, OPG provided information on its conventional health and safety program and how it applies to the Co-60 project, including that:
 - OPG has a conventional health and safety program in place that complies with the requirements of the NSCA, the GNSCR, and the Ontario <u>Occupational Health and</u> <u>Safety Act</u>⁵¹
 - OPG assessed conventional safety principles during the Co-60 system design process
 - all Co-60 related activities will be conducted by means of safe work planning following OPG standards
 - all contractors are required to comply with OPG's conventional health and safety protocols while onsite
- 84. In section 2.5.8 of CMD 24-H101, CNSC staff confirmed that OPG has a conventional health and safety program in place that satisfies regulatory requirements. CNSC staff noted that OPG's program can ensure that Co-60 project-related activities are safely planned and executed by both OPG staff and contractors. CNSC staff noted that the most significant conventional hazard associated with the Co-60 project is the handling and hoisting of the flask used to contain cobalt AA rods removed from the reactor core.

⁵¹ R.S.O. 1990, c. O.1.

- 85. Based on the information on record as described above, the Commission concludes that OPG has an adequate conventional health and safety program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission notes that:
 - OPG has a conventional health and safety program in place that meets regulatory requirements
 - OPG considered conventional health and safety principles during the design of the Co-60 system
 - OPG has conducted hazards analyses for significant conventional safety hazards
 - CNSC staff will conduct regulatory oversight during key Co-60 installation activities that may present conventional safety hazards

3.5.9 Environmental Protection

- 86. Licence condition 9.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain an environmental protection program. Environmental protection programs are intended to identify, control, and monitor all releases of radioactive and hazardous substances, and aim to minimize the effects on the environment that may result from licensed activities. These programs include effluent and emission control, environmental monitoring, and estimated doses to the public.
- 87. In accordance with the NSCA, licensees are required to ensure that there are adequate provisions 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.
- 88. <u>REGDOC-2.9.1, Environmental Principles, Assessments, and Protection Measures</u>⁵² 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 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

⁵² REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures*, Version 1.1, CNSC, April 2017.

*class I nuclear facilities and uranium mines and mills*⁵³ specifically addresses requirements for the design, implementation, and management of an environmental risk assessment program.

- 89. In section 3.9 of CMD 24-H101.1A, Attachment 3, OPG provided information on its environmental protection program and how it applies to the Co-60 project, including that:
 - OPG has implemented and maintained an environmental protection program that complies with the requirements of REGDOC-2.9.1 and the CSA N288 series of standards
 - operation of the Co-60 system will comply with OPG's existing environmental management system
 - OPG completed a predictive effects assessment (PEA) for the Co-60 system which included human health and ecological risk assessments and also considered the cumulative impacts of Co-60 and Mo-99 production
 - the PEA found that the operation of the Co-60 system would not result in any unacceptable risks to human and ecological receptors near the Darlington NGS
 - operation of the Co-60 system is expected to produce minimal tritium emissions
 - OPG has an effluent monitoring program in place to ensure that environmental releases remain below regulatory limits
 - the cumulative increase in public dose is estimated to be 0.004% of the regulatory public dose limit of 1 millisievert per year (mSv/y)
- 90. CNSC staff confirmed that the activities that would be authorized by the proposed licence amendment would not result in additional risk to the public or the environment. In section 2.5.9 of CMD 24-H101, CNSC staff submitted that OPG has an existing environmental protection program in place that complies with regulatory requirements and is sufficient to accommodate the activities that the proposed licence amendment would authorize. CNSC staff informed the Commission that it conducted an environmental protection review for OPG's licence amendment application, including a review of OPG's PEA. CNSC found that OPG's PEA complied with the requirements of CSA N288.6-12 and demonstrated that potential radiological releases associated with Co-60 operations (predominantly limited to tritium in the form of tritiated water vapour) would make up a small fraction of the annual radiological releases from the Darlington NGS.
- 91. Based on the information on record as described above, the Commission concludes that OPG has an environmental protection program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission notes that:
 - OPG has implemented and maintained an environmental protection program that meets regulatory requirements and includes an environmental management system and environmental monitoring program

⁵³ CSA N288.6-12, Environmental risk assessments at class I nuclear facilities and uranium mines and mills, CSA Group, 2012.

- OPG completed a PEA for the Co-60 system which found that potential releases associated with Co-60 operations would make up a small fraction of the annual releases from the Darlington NGS
- the cumulative increase in public dose from Co-60 operation is estimated to be 0.004% of the regulatory public dose limit of 1 mSv/yr

3.5.10 Emergency Management and Fire Protection

- 92. Licence condition 10.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain an emergency preparedness program. Licence condition 10.2 requires OPG to implement and maintain a fire protection program. Emergency management and fire protection programs cover the measures for preparedness and response capabilities implemented by OPG in the event of emergencies and non-routine conditions at the Darlington NGS. These measures include nuclear emergency management, conventional emergency response, and fire protection and response.
- 93. Subsection 24(4) of the NSCA provides that the applicant, in carrying out the proposed licensed activity, will take 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.
- 94. 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", 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".
- 95. Paragraph 6(k) of the *Class I Nuclear Facilities Regulations* 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.
- 96. <u>REGDOC-2.10.1, Nuclear Emergency Preparedness and Response, Version 2</u>⁵⁴ sets out the CNSC's requirements and guidance for emergency preparedness and applies to licensees and licence applicants for Class I nuclear facilities. CSA N293-12, *Fire protection for CANDU nuclear power plants*⁵⁵ provides the minimum fire protection requirements for the design, construction, commissioning, operation, and decommissioning of nuclear power plants.

⁵⁴ REGDOC 2.10.1, Nuclear Emergency Preparedness and Response, Version 2, CNSC, February 2016.

⁵⁵ CSA N293-12, Fire protection for CANDU nuclear power plants, CSA Group, 2012.

- 97. In section 3.10 of CMD 24-H101.1A, Attachment 3, OPG provided information on its emergency management and fire protection program and how they apply to the Co-60 project, including that:
 - OPG has an emergency management program in place that complies with the requirements of REGDOC-2.10.1
 - OPG has a fire protection program in place that complies with the requirements of CSA N293-12
 - the Co-60 system will not impact OPG's existing emergency preparedness or fire response programs
 - the Co-60 system does not introduce any new fire hazards
- 98. In section 2.5.10 of CMD 24-H101, CNSC staff confirmed that OPG has emergency preparedness and response programs in place that meets regulatory requirements. CNSC staff reported that, following its review of OPG's application and supporting analyses, CNSC staff is of the view that OPG's existing emergency preparedness and response programs are adequate to manage any potential emergency event that may arise due to Co-60 operations.
- 99. Based on the information on record as described above, the Commission concludes that OPG has adequate emergency management and fire protection programs in place to accommodate the activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG has emergency management and fire protection programs in place that meet regulatory requirements
 - the Co-60 project will not present any new fire hazards
 - OPG's existing emergency preparedness and response programs are adequate to manage any potential emergency event that may arise due to Co-60 operations

3.5.11 Waste Management

- 100. Licence condition 11.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a waste management program at the Darlington NGS. Waste management covers waste-related programs that form part of a facility's operations up to the point where the waste is removed from the licensed site for storage, treatment, or disposal at another licensed location, and includes waste minimization, segregation, characterization, and storage programs. Waste management covers the waste generated during the operations of the Darlington NGS.
- 101. 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 *Class I Nuclear Facilities Regulations* also requires that a licence application contains the proposed plan for the decommissioning of the nuclear facility or of the site.

- 102. CSA N292.3, *Management of low- and intermediate-level radioactive waste*⁵⁶ specifies requirements for the management of radioactive waste to protect the health and safety of people, physical security, and the environment. CSA N294, *Decommissioning of facilities containing nuclear substances*⁵⁷ provides direction on defining, planning, and executing decommissioning work.
- 103. In section 3.11 of CMD 24-H101.1A, Attachment 3, OPG provided information on its waste management program and how it applies to the Co-60 project, including that:
 - OPG has a waste management program in place that complies with the requirements of CSA N292.3 and CSA N294
 - Co-60 operations would produce two radioactive waste streams production scrap from disassembly activities in the irradiated fuel bay and spent cobalt
 - Co-60 production would not generate non-radioactive hazardous waste
 - cobalt sources that have reached end of commercial life will be returned to OPG and stored for 25-30 years in the Bruce B NGS irradiated fuel bay
 - spent cobalt (once received back from Bruce B irradiated fuel bay) will be transferred to dry storage and managed at an OPG waste management facility
- 104. In section 2.5.11 of CMD 24-H101, CNSC staff confirmed that OPG has implemented and maintained a waste management program that satisfies regulatory requirements and is sufficient to handle waste generated from Co-60 operations. CNSC staff noted that OPG's submissions did not describe all wastes that would be generated through the installation and harvesting of the cobalt AA rods, particularly personal protective equipment and the old stainless steel AA rods. However, CNSC staff found that these are not new waste streams for OPG and that they can also be adequately managed under OPG's existing waste management program.
- 105. Regarding the long-term responsibility for spent Co-60 sources, CNSC staff highlighted, in the draft Licence Conditions Handbook in section 3.3.1 of CMD 24-H101, that OPG is under contractual obligation to take back spent cobalt that has reached the end of its service life. In CMD 24-H101.B, CNSC staff clarified that all aspects of the Co-60 supply chain downstream of the production of Co-60 at the Darlington NGS including interim management of spent Co-60 sources are authorized within the licensing bases⁵⁸ of existing licences or certificates, though not the Darlington NGS power reactor operating licence. Storage of the spent cobalt in the Bruce B NGS irradiated fuel bay would be managed under the Bruce NGS power reactor operating licence and interim dry storage of the spent cobalt sources are subject to regulatory oversight from the

⁵⁶ CSA N292.3, Management of low- and intermediate-level radioactive waste, CSA Group, 2008.

⁵⁷ CSA N294, *Decommissioning of facilities containing nuclear substances*, CSA Group, 2019.

⁵⁸ 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.

CNSC. Any operations outside of the bounds of the licensing bases of the existing licences would require an application to the Commission for consideration and authorization.

- 106. In CMD 24-H101-Q, the Commission asked OPG to explain why cobalt sources that have reached the end of commercial life will be stored in the Bruce B NGS irradiated fuel bay, rather than at the Darlington NGS. In CMD 24-H101.1D, OPG informed the Commission that the Darlington NGS does not have the capability to receive cobalt sources that have reached their end of commercial life. OPG explained that storage of the spent cobalt at the Bruce B NGS, which already produces Co-60, would facilitate consolidation with existing spent cobalt, and leverage the existing procedures, expertise, and equipment available at Bruce B NGS to store spent cobalt sources on an interim basis. OPG also noted that industry recycling efforts maximize the useful life of the cobalt sources before they are placed in interim storage. In CMD 24-H101.1E, OPG specified that recycling efforts are expected to defer the shipment of spent cobalt sources to the Bruce B NGS until the mid-2030s and that no spent cobalt sources have been transported to the Bruce B NGS since mid-2020.
- 107. In CMD 24-H101-Q.A, the Commission asked OPG to explain the lifecycle and commercial lifespan of a Co-60 source, including processing, recycling, interim storage, disposal and the end-state of a decayed Co-60 source. The Commission also asked OPG to confirm its detailed plans for managing cobalt sources from the time they reach end of commercial life until disposal, including interim storage. In CMD 24-H101.1E, OPG provided memos from Nordion, Bruce Power, and the Nuclear Waste Management Organization (NWMO) to answer the Commission's questions:
 - the memo from Nordion included specific details regarding the lifecycle and commercial lifespan of a Co-60 source, transportation, processing, transportation security regulations, recycling, and detailed plans for interim storage until there is sufficient inventory to make a shipment to the Bruce B NGS. Nordion specified that Co-60 sealed sources are typically used for 20 years, at which point their level of radioactivity has reduced to 7% of what it was when it was manufactured
 - the memo from Bruce Power provided specific details regarding the interim storage of spent Co-60 sources in the Bruce B NGS secondary irradiated fuel bay and the transport of spent Co-60 to dry storage at an OPG waste management facility
 - the memo from the NWMO provided specific details regarding the eventual disposal of spent Co-60 sources in a deep geological repository for intermediate and non-fuel high-level radioactive waste
- 108. Based on the information on record as described above, the Commission concludes that OPG has an adequate waste management program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG has a waste management program in place that meets regulatory requirements and is sufficient to manage the waste generated from the Co-60 project and operations

- OPG provided sufficient additional information in response to Commission's questions related to waste management and the lifecycle of Co-60 sources
- OPG is under contractual obligation to take back and manage cobalt sources that have reached the end of their service life
- OPG has a plan in place to effectively manage the spent cobalt sources when it receives them back from Nordion

3.5.12 Security

- 109. Licence condition 12.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a security program. The security SCA covers the implementation of a program to prevent the loss, unauthorized removal and sabotage of nuclear substances, nuclear materials, prescribed equipment, or information.
- 110. 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. In addition, sections 21 to 23 of the GNSCR provide obligations for all licensees on the identification, storage, handling, and transfer requirements of information designated as "prescribed information."
- 111. REGDOC-2.12.1, High Security Facilities, Volume I: Nuclear Response Force, Version 2⁵⁹ sets out expectations with respect to the minimum requirements for establishing, equipping, training, testing, and deploying an onsite nuclear response force. REGDOC-2.12.1, High-Security Facilities, Volume II: Criteria for Nuclear Security Systems and Devices⁶⁰ provides an approach for meeting the requirements in the <u>Nuclear</u> Security Regulations⁶¹ aimed at preventing and detecting unauthorized entry into a protected area or inner area at high-security sites, including the unauthorized entry of weapons or explosive substances. <u>REGDOC-2.12.2, Site Access Security Clearance</u>⁶² sets out guidance for granting, denying or revoking a site access security clearance for authorized unescorted entry to a protected area at a high-security site. <u>REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2.1⁶³ provides regulatory expectations and guidance for licensees regarding the CNSC's expectations under the GNSCR for security.</u>

⁵⁹ REGDOC-2.12.1, *High Security Facilities, Volume I: Nuclear Response Force*, Version 2, CNSC, September 2018. This REGDOC contains prescribed information and is not publicly available.

⁶⁰ REGDOC-2.12.1, *High Security Facilities, Volume II: Criteria for Nuclear Security Systems and Devices*, CNSC, April 2018. This REGDOC contains prescribed information and is not publicly available.

⁶¹ SOR/2000-209.

⁶² REGDOC-2.12.2, Site Access Security Clearance, CNSC, April 2013.

⁶³ REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2.1, CNSC, September 2020.

- 112. CSA N290.7, *Cyber security for nuclear power plants and small reactor facilities*⁶⁴ covers the cyber security of new and existing nuclear power plants and small reactor facilities.
- 113. In section 3.12 of CMD 24-H101.1A, Attachment 3, OPG provided information on its security program and how it applies to the Co-60 project, including that:
 - OPG has a security program in place that satisfies the requirements of the *Nuclear Security Regulations*, REGDOC-2.12.1, *Volume I*, REGDOC-2.12.1, *Volume II*, REGDOC-2.12.2, REGDOC-2.12.3 and CSA N290.7
 - the Co-60 project will not require any changes to OPG's security program
 - incoming and outgoing cobalt shipments will follow OPG's existing security processes

Security matters specific to the transport of Co-60 packages are discussed in section 3.5.14 of this *Record of Decision*.

- 114. CNSC staff submitted that OPG's security program will adequately accommodate the new licensed activities associated with the production and possession of Co-60. In section 2.5.12 of CMD 24-H101, CNSC staff submitted that it has recently increased regulatory scrutiny of OPG's fleet-wide nuclear security program due to specific performance observations, which it documented in the two latest *Regulatory Oversight Reports*^{65,66}. CNSC staff informed the Commission that OPG is currently working through a corrective action program to ensure that all applicable requirements are met. Regarding the Co-60 project, CNSC staff reported that the overlap in security concerns from Co-60 related activities such as an increased volume of shipments are expected to be addressed by OPG's corrective actions.
- 115. Based on the information on record as described above, the Commission concludes that OPG has a security program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG is completing a corrective action plan to ensure that its security program is fully compliant with all regulatory requirements
 - OPG's corrective action program will address security concerns that also apply to the Co-60 project, such as an increase in shipments to and from the Darlington NGS
 - OPG's security program will be able to accommodate the new activities associated with the production and possession of Co-60

⁶⁴ CSA N290.7, Cyber security for nuclear power plants and small reactor facilities, CSA Group, 2014.

⁶⁵ CMD 22-M34, <u>Regulatory Oversight Report for Canadian Nuclear Power Generating Sites for 2021</u>, CNSC, 18 July 2022.

 ⁶⁶ CMD 23-M36, <u>Regulatory Oversight Report for Canadian Nuclear Power Generating Sites for 2022</u>, CNSC, 31 August 2023.

3.5.13 Safeguards and Non-Proliferation

- 116. Licence condition 13.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a safeguards program. The CNSC's regulatory mandate includes ensuring conformity with measures required to implement Canada's international obligations under the <u>Treaty on the Non-Proliferation of Nuclear Weapons</u> (NPT)⁶⁷. Pursuant to the NPT, Canada has entered into a <u>Comprehensive Safeguards</u> <u>Agreement</u>⁶⁸ and an <u>Additional Protocol</u>⁶⁹ (safeguards agreements) with the International Atomic Energy Agency (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.
- 117. <u>REGDOC-2.13.1, Safeguards and Nuclear Materials Accountancy</u>⁷⁰ 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.
- 118. In section 3.13 of CMD 24-H101.1A, Attachment 3, OPG submitted information on its safeguards program and how it applies to the Co-60 project, including that:
 - OPG has a safeguards program in place that complies with REGDOC-2.13.1
 - the production of Co-60 does not involve nuclear material that is subject to safeguard requirements pursuant to the safeguards agreements

OPG also identified that the Co-60 modifications and operations would cause a temporary partial obstruction of an IAEA camera and an increase in background radiation, which would impact the IAEA's current spent fuel verification method. OPG reported that it is in the process of resolving these items with the IAEA prior to starting Co-60 activities in the irradiated fuel bay. As discussed in section 3.5.11 of this *Record of Decision*, OPG is not responsible for Co-60 processing or any steps further downstream in the supply chain for its commercial use.

119. In section 2.5.13 of CMD 24-H101, CNSC staff confirmed that OPG maintains a safeguards program that complies with regulatory requirements and is sufficient to accommodate the new activities associated with the production and possession of Co-60. CNSC staff confirmed that Co-60 is not a material that is subject to the safeguards agreements and therefore does not require safeguards reporting and verification. Regarding the temporary impact to some IAEA equipment identified by OPG, CNSC staff reported that it will monitor OPG's progress to ensure that the issues are resolved in a timely manner.

⁶⁷ INFCIRC/140.

⁶⁸ INFCIRC/164.

⁶⁹ INFCIRC/164/Add.1.

⁷⁰ REGDOC-2.13.1, Safeguards and Nuclear Material Accountancy, CNSC, February 2018.

- 120. Based on the information on record as described above, the Commission concludes that OPG has an adequate safeguards program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG has a safeguards program in place that meets regulatory requirements
 - the production of Co-60 does not involve nuclear material to which the safeguards agreements apply
 - potential export of Co-60 would fall under Nordion's jurisdiction, not OPG's

3.5.14 Packaging and Transport

- 121. Licence condition 14.1 of the Darlington NGS power reactor operating licence requires OPG to implement and maintain a packaging and transport program. The packaging and transport SCA covers the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility. OPG must adhere to the *Packaging and Transport of Nuclear Substances Regulations*, 2015⁷¹ (PTNSR, 2015) and Transport Canada's *Transportation of Dangerous Goods Regulations*⁷² (TDGR) for all shipments. These regulations apply to the packaging and transport of nuclear substances at the Darlington NGS, including the design, production, use, inspection, maintenance and repair of packages, and the preparation, consigning, handling, loading, carriage and unloading of packages.
- 122. In section 3.14 of CMD 24-H101.1A, Attachment 3, OPG submitted information on its packaging and transport program and how it applies to the Co-60 project, including that:
 - OPG has a packaging and transport program that complies with the requirements of the PTNSR, 2015 and the TDGR
 - OPG will be responsible for preparing and packaging irradiated Co-60 for shipment, whereas Nordion will arrange for the transportation of the packages from the Darlington NGS to the Nordion site in Kanata, Ontario
 - Co-60 will be transported in CNSC-certified radioactive material transportation packages
 - both OPG and Nordion have plans and resources in place to respond to transportation accidents. Nordion may request OPG's assistance in the event of a transportation accident depending on the proximity of the accident to OPG's nuclear facilities
- 123. In section 1.4 of CMD 24-H101.1A, Attachment 3, OPG provided additional clarity on the responsibilities of OPG and Nordion as they pertain to the security of Co-60 shipments. OPG reported that, as the consignor, OPG has ultimate responsibility for the Co-60 shipments until they are received by Nordion at its facility in Kanata, ON. OPG also submitted that OPG has a contractual agreement with Nordion, which requires Nordion to maintain a transportation security plan for Co-60 shipments in compliance

⁷¹ SOR/2015-145.

⁷² SOR/2001-286.

with the requirements of REGDOC-2.12.3. In section 2.5.12 of CMD 24-H101, CNSC staff noted that it will review the transportation security plans when submitted by Nordion prior to the commencement of Co-60 transportation.

- 124. In section 2.5.14 of CMD 24-H101, CNSC staff confirmed that OPG maintains a packaging and transport program that complies with regulatory requirements and is adequate to cover the Co-60 packaging and transport activities that are the responsibility of OPG. CNSC staff noted that OPG has committed to developing documentation specific to the Co-60 packaging transportation process prior to OPG's first cobalt harvest. CNSC staff will review these documents when submitted.
- 125. Based on the information on record as described above, the Commission concludes that OPG has an adequate packaging and transport program in place to accommodate the activities that the proposed licence amendment would authorize. The Commission finds that:
 - OPG has a packaging and transport program in place that meets regulatory requirements and is adequate to cover Co-60 packaging and transport activities
 - Co-60 will be transported in CNSC certified transportation packages
 - both OPG and Nordion are prepared to respond to potential transportation accidents
 - OPG has ultimate responsibility for the Co-60 shipments until they are received by Nordion at their facility in Kanata, ON

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

126. 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 licence amendment 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.

3.6 Indigenous Engagement and Consultation

127. 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 pursuant to section 35 of the <u>Constitution Act, 1982</u>⁷³.

⁷³ Schedule B to the *Canada Act, 1982* (UK), 1982, c 11.

- 128. The common law duty to consult with Indigenous Nations and communities is engaged when the Crown contemplates action that may adversely affect established or potential Aboriginal and/or treaty rights. The CNSC, as an agent of the Crown and as Canada's nuclear regulator, recognizes and understands the importance of building relationships and engaging with Canada's Indigenous Nations and communities. The CNSC ensures that its licensing decisions under the NSCA uphold the honour of the Crown and consider potential impacts to claimed or established Aboriginal and/or treaty rights pursuant to section 35 of the *Constitution Act, 1982*.
- 129. The duty to consult is engaged wherever the Crown has "knowledge, real or constructive, of the potential existence of an Aboriginal right or title and contemplates conduct that might adversely affect it"⁷⁴. 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 it has met the duty prior to making the relevant licensing decision.
- 130. The <u>United Nations Declaration on the Rights of Indigenous Peoples Act</u>⁷⁵ (UNDA) came into force in Canada on June 21, 2021. The Government of Canada has clarified that "[t]he Act itself does not immediately change Canada's existing duty to consult Indigenous groups"⁷⁶. Nonetheless, the Commission acknowledges that its commitment to reconciliation, the <u>United Nations Declaration on the Rights of Indigenous Peoples</u> (UNDRIP)⁷⁷, and section 35, including the Crown's duty to consult and accommodate, have aspects that intersect and that this is an evolving area of law. The Commission also acknowledges the need to consider the <u>Principles Respecting the Government of</u> <u>Canada's Relationship with Indigenous Peoples</u>⁷⁸. The statutory obligation to consult and cooperate in section 5 of UNDA is distinct from the constitutional duty to consult. The Commission recognizes the need to uphold the honour of the Crown during its review of this matter.
- 131. The Commission also notes, however, this is a rapidly evolving area of law. As recently articulated in *Thomas and Saik'uz First Nation v. Rio Tinto Alcan Inc.* (Thomas and Saik'uz), while the effect of UN Declaration legislation on the common law has yet to be determined by the courts, it supports a robust interpretation of Indigenous rights⁷⁹. Additionally, the Supreme Court of Canada has stated that "through [UNDA] [...] the Declaration is incorporated into the country's domestic positive law"⁸⁰.

⁷⁴ Haida Nation v. British Columbia (Minister of Forests), 2004 SCC 73 at para 35.

⁷⁵ S.C. 2021, c.14

⁷⁶ Department of Justice Canada, *Implementing the United Nations Declaration on the Rights of Indigenous Peoples Act, About the Act*, retrieved from the Department of Justice – Government of Canada's website: <u>https://www.justice.gc.ca/eng/declaration/legislation.html</u>, May 31, 2024.

⁷⁷ United Nations Declaration on the Rights of Indigenous Peoples, The United Nations Department of Economic and Social Affairs, September 2007.

⁷⁸ Department of Justice Canada, *Principles Respecting the Government of Canada's Relationship with Indigenous Peoples*, 2018.

⁷⁹ Thomas and Saik'uz First Nation v. Rio Tinto Alcan Inc., 2022 BCSC 15 at para 212.

⁸⁰ Reference re An Act respecting First Nations, Inuit and Métis children, youth, and families, 2024 SCC 5 at para 15.

132. In section 2.6 of CMD 24-H101, CNSC staff reported that the proposed physical modifications associated with the Co-60 project are confined to the existing footprint of the Darlington NGS and that impacts beyond the existing limits of the operation of the site are expected to be negligible. Therefore, CNSC staff found that the licence amendment requested by OPG is unlikely to have potential new impacts on Indigenous and/or treaty rights.

Indigenous Consultation by CNSC Staff

- 133. In section 2.6 of CMD 24-H101, CNSC staff provided the Commission with information about its consultation activities with the Indigenous Nations and communities that were identified as having a potential interest in OPG's licence amendment application. CNSC staff identified the following Indigenous Nations and communities with established Indigenous and treaty rights to the lands and waters surrounding and inclusive of the Darlington NGS site:
 - Williams Treaties First Nations:
 - o Alderville First Nation
 - Curve Lake First Nation (CLFN)
 - Hiawatha First Nation (HFN)
 - o Mississaugas for Scugog Island First Nation (MSIFN)
 - Chippewas of Rama First Nation
 - Chippewas of Georgina Island First Nation
 - Beausoleil First Nation

CNSC staff identified the following Indigenous Nations and communities with interests in the Co-60 project and the lands and waters surrounding and inclusive of the Darlington NGS site:

- Six Nations of the Grand River
- Mohawks of the Bay of Quinte First Nation
- Métis Nation of Ontario
- 134. CNSC staff reported that it sent letters of notification to the identified Indigenous Nations and communities in October 2023 to inform them of OPG's application, opportunities to participate in the hearing process, and the availability of participant funding. CNSC staff also followed up with each Indigenous Nations and community via email.
- 135. CNSC staff informed the Commission that, at the time of the submission of CMD 24-H101, only MSIFN had expressed interest in OPG's licence amendment application. CNSC staff reported that it has had ongoing discussions with MSIFN regarding the Darlington NGS and, in section 2.6.1 of CMD 24-H101, CNSC staff committed to having a dedicated meeting with MSIFN regarding OPG's licence amendment application ahead of the Commission hearing. CNSC staff noted that CLFN and HFN had also expressed interest in being kept informed about ongoing operations at

the Darlington NGS, including the Co-60 project. CNSC staff reported that it is committed to continuing to work with CLFN and HFN as part of the Terms of Reference for long-term engagement with each Nation.

Indigenous Engagement by OPG

- 136. In section 5 of CMD 24-H101.1A, Attachment 3, OPG provided information regarding its ongoing engagement with Indigenous Nations and communities with established or asserted rights and/or interests regarding the Darlington NGS. OPG reported that it engaged with the following Indigenous Nations and communities regarding the Co-60 project:
 - Williams Treaties First Nations
 - Mohawks of the Bay of Quinte
 - Métis Nation of Ontario, Region 8
 - Six Nations of the Grand River
- 137. OPG reported that it began engagement with the aforementioned Indigenous Nations and communities regarding the Co-60 project in October 2021. OPG submitted that its engagement activities included virtual meetings and presentations. OPG also committed to conduct ongoing engagement activities related to the Co-60 project such as community information sessions, written communication, and/or workshops. In section 2.6.2 of CMD 24-H101, CNSC staff reported that it reviewed OPG's engagement activities to verify that they met the expectations documented in <u>REGDOC-3.2.2</u>, *Indigenous* <u>Engagement</u>⁸¹, which sets out requirements and guidance for licensees on Indigenous engagement.
- 138. In CMD 24-H101-Q, the Commission asked OPG to describe the engagement activities that OPG had or would conduct with Indigenous Nations and communities along Co-60 transportation routes. In CMD 24-H101-Q.1D, OPG responded that it had provided information to Indigenous Nations and communities regarding production and harvesting of Co-60 and that it had held meetings with members from the William's Treaties First Nations, Six Nations of the Grand River, and Métis Nation of Ontario Region 8. In addition to information sharing presentations, follow up emails with briefing notes were distributed, as well as offers to deliver further sharing sessions if requested. OPG noted that its Indigenous engagement process is continuous and ongoing.

Submissions by Indigenous Nations and Communities, Organizations and Individuals

139. Two Indigenous Nations submitted written interventions on this matter to the Commission, MSIFN and SON.

⁸¹ REGDOC-3.2.2, *Indigenous Engagement*, Version 1.2, CNSC, February 2022.

140. In its submission, <u>CMD 24-H101.13</u>, MSIFN provided information on its review of OPG's licence amendment application, discussed the rationale behind the Co-60 project, acknowledged OPG's Indigenous engagement efforts, and noted its general satisfaction with OPG's application. MSIFN also raised questions regarding the security SCA and the passing of Bill C-21⁸². Overall, MSIFN submitted that OPG's application had MSIFN's "provisional support":

"MSIFN Consultation ... recommend that MSIFN provide provisional support for the application pending the above clarification on the potential passing of Bill C-21 and the adoption of the proposed security-related changes to the Nuclear Safety and Control Act to give security personnel the authority to carry out limited peace officer function at nuclear facilities."

The Commission discusses its views on MSIFN's request in section 3.6.1 of this *Record* of Decision.

141. In CMD 24-H101.14, SON reported that it had been unaware that OPG planned to transport spent cobalt sources into SON territory until Bruce Power had informed SON of the matter⁸³. SON submitted that it would not accept the continued importation of radioactive wastes into SON territory from new or expanded operations without evidence that OPG is prepared to meaningfully address the historical and ongoing impacts from its existing operations. SON is of the view that OPG has not engaged SON in a good faith process to resolve these issues. Referencing Canada's commitments under UNDA, SON requested that the Commission delay its decision on OPG's application until CNSC staff could consult with SON about the proposed Co-60 project:

"As an agent of the Crown and court of record, the Commission has a critical role in ensuring the Crown's constitutional obligations to Indigenous peoples are met. The continued and compounding infringements of SON rights must not occur under the Commission's watch. We ask that you delay a decision on OPG's current application until the CNSC, as Crown representative, consults with SON about this proposed project so that our concerns about it and its broader implications can be properly understood and addressed."

The Commission discusses its views on SON's request in section 3.6.1 of this *Record of Decision*.

142. In CMD 24-H101-Q.A, the Commission asked OPG to describe OPG's engagement activities with SON regarding the proposed licensed activities as well as the transportation, interim storage, and potential final disposal of cobalt-60 sources on SON territory. In CMD 24-H101.1E, OPG submitted that it can only respond regarding its engagement on its own licensed activities. OPG noted that the full lifecycle of the Co-60 that will be produced at the Darlington NGS is a collaborative effort between OPG,

⁸² <u>Bill C-21: An act to amend certain Acts and to make certain consequential amendments (firearms)</u>, First Session, forty-fourth Parliament, 70-71 Elizabeth II – 1 Charles III, 2021-2022-2023.

⁸³ In Enclosure 2 of CMD 24-H101.1E, Bruce Power specified that it notified SON of this matter on April 12, 2024.

Nordion, Bruce Power and NWMO, and that each party has accountabilities under licences issued by the Commission. OPG's reported that its accountabilities pertain to Co-60 production at the Darlington NGS which is in the traditional territory of the Williams Treaties First Nations. OPG's engagement with these Nations, as well as with the Métis Nation of Ontario, are described earlier in section 3.6 of this *Record of Decision*.

- 143. In CMD 24-H101-Q.A, the Commission also asked CNSC staff to describe the CNSC's consultation activities with SON, the Historic Saugeen Métis, and the Métis Nation of Ontario regarding the proposed licensed activities as well as the transportation, interim storage, and potential final disposal of Co-60 sources. In CMD 24-H101.B, CNSC staff acknowledged SON's interest in the downstream Co-60 activities which were first raised to CNSC staff in a meeting with SON on April 16, 2024. CNSC staff committed to engage further on this topic with SON, and other Indigenous Nations and communities, through existing Terms of Reference for long-term engagement and regular meetings.
- 144. On SON's concerns regarding the management of spent cobalt sources on SON territory, CNSC staff provided additional information on how the management of spent cobalt sources related to the licence amendment being sought by OPG. In CMD 24-H101.B, CNSC staff clarified that the proposed production of Co-60 at Darlington would not result in any new activities to be carried out in the Co-60 supply chain. Furthermore, all aspects of the Co-60 supply chain downstream of the production of Co-60 at the Darlington NGS are to be carried out within the existing licensing bases of other existing licence). This includes the interim management of spent Co-60 sources at the Bruce B NGS site. The management of spent cobalt sources, and how it relates to the Darlington NGS power reactor operating licence, was discussed previously in section 3.5.11 of this *Record of Decision*.
- 145. In CMD 24-H101.1B, CNSC staff submitted that it would respond in writing to SON's concerns regarding the management of spent cobalt on SON territory. CNSC staff reported that it will provide in its response information to distinguish the activities associated with the proposed amendment application currently before the Commission, and the relationship to other existing CNSC licences.
- 146. In CMD 24-H101.B, CNSC staff noted that it is open to engaging with other interested Nations and communities, including the Historic Saugeen Métis and the Métis Nation of Ontario, should they express an interest in the management of spent cobalt sources at the Bruce NGS. CNSC staff reported that, to date, neither the Historic Saugeen Métis nor the Métis Nation of Ontario had expressed interest in this matter. CNSC staff emphasized the importance of ongoing engagement and dialogue to address any concerns raised as activities related to the Co-60 supply chain evolve throughout the industry.

3.6.1 Conclusion on Indigenous Engagement and Consultation

- 147. The Commission is satisfied with CNSC staff's efforts to consult with Indigenous Nations and communities who may have interest in OPG's licence amendment application and on matters relevant to the licence amendment application before the Commission. The Commission finds that it has received sufficient evidence in this regard to render its decision on OPG's application.
- 148. The Commission finds that the efforts made by CNSC staff to consult with Indigenous Nations and communities are key to the important work of the Commission toward reconciliation and relationship-building with Canada's Indigenous peoples. The Commission expects CNSC staff to continue to build meaningful long-term relationships with Indigenous Nations and communities as part of the CNSC's reconciliation efforts.
- 149. The Commission recognizes Canada's commitment to UNDRIP and the framework for reconciliation and implementation of UNDRIP set out within UNDA. The Commission has assessed the duty to consult and accommodate in relation to the licence amendment within the context of and with acknowledgement of UNDA.
- 150. The Commission acknowledges the concern raised by MSIFN regarding Bill C-21. The Commission finds these concerns to be relevant to the general security of the Darlington NGS and not specific to the Co-60 project. The Commission nonetheless directs CNSC staff and OPG to engage with MSIFN to answer their questions pertaining to nuclear security, Bill C-21 and its implementation.
- 151. Based on the information presented on the record for this hearing, the Commission is satisfied that the proposed physical modifications associated with the Co-60 project are confined to the existing footprint of the Darlington NGS. The Commission further finds that aspects of the Co-60 supply chain downstream of the production of Co-60 at the Darlington NGS will be managed within the existing licensing bases of other CNSC licences and certificates which are also subject to regulatory oversight from the CNSC. Therefore, the Commission is satisfied that the proposed licence amendment is unlikely to have potential new impacts on Indigenous and/or treaty rights.
- 152. The Commission recognizes the concerns raised by SON regarding the future management of spent cobalt sources. The Commission finds that aspects of the Co-60 supply chain downstream of the production of Co-60 at the Darlington NGS will be managed within the existing licensing bases of other CNSC licences and certificates, not under the Darlington NGS power reactor operating licence for which the Commission is considering OPG's licence amendment application. The Commission directs CNSC staff to respond to SON regarding the concerns raised in CMD 24-H101.14, as CNSC staff committed to in CMD 24-H101.1B.

3.7 Other Matters of Regulatory Importance

3.7.1 Public Engagement

- 153. The Commission considered OPG's public information and disclosure program (PIDP) and whether OPG's existing program is sufficient to communicate updates to the public surrounding the production and transportation of Co-60 at the Darlington NGS.
- 154. In section 4 of CMD 24-H101.1A, OPG informed the Commission that it has a PIDP under which it disseminates information to the public and engages in two-way communication with interested parties. OPG reported that it will continue providing the public with information on the Co-60 project under its existing PIDP. In section 2.7.2 of CMD 24-H101, CNSC staff confirmed that OPG's PIDP complies with <u>REGDOC-3.2.1</u>, <u>Public Information and Disclosure</u>⁸⁴ which sets out requirements for public information programs, disclosure protocols, and related documentation as they relate to licensed activities and that OPG's PIDP would be sufficient to communicate information on the Co-60 project to the public.
- 155. 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 Co-60 project.

3.7.2 Decommissioning Plans and Financial Guarantee

- 156. Licence condition 11.2 requires OPG to implement and maintain a decommissioning strategy. 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 lifespan of a facility. In order to ensure that adequate resources are available for the safe and secure future decommissioning of the Darlington NGS, 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.
- 157. In CMD 24-H101.1, Attachment 2, OPG informed the Commission that its existing financial guarantee would not change as a result of the requested licence amendment. In section 3.11.6 of CMD 24-H101.1A, Attachment 3, OPG noted that the Co-60 system is a relatively small and removable system that, based on the preliminary decommissioning plan (PDP) for the Pickering NGS, would have minimal effect on future decommissioning activities. In section 2.5.11 of CMD 24-H101, CNSC staff agreed that the Co-60 modifications and operations could be accounted for through minor changes to the current Darlington PDP. CNSC staff reported that it will review OPG's next submission of its financial guarantee and the Darlington PDP, due in 2027.

⁸⁴ REGDOC-3.2.1, Public Information and Disclosure, CNSC, May 2018.

158. The Commission is satisfied that the Darlington PDP will only require minor changes to account for the Co-60 project and that such changes will be incorporated during the next update of the Darlington PDP. The Commission is further satisfied that OPG's existing financial guarantee is sufficient to account for the Co-60 modifications and operations and is acceptable to the Commission.

3.7.3 Nuclear Liability Insurance

- 159. The <u>Nuclear Liability and Compensation Act</u>⁸⁵ (NLCA) and the regulations made under it establish a compensation and liability regime for Canada in the unlikely event of a nuclear accident resulting in civil injury and damages.
- 160. In section 2.7.3 of CMD 24-H101, CNSC staff submitted that the Darlington NGS is currently assessed at \$1 billion dollars, the maximum limit of liability under the NLCA. Therefore, the Co-60 project would not impact OPG's obligations under the NLCA. CNSC staff also reported that OPG is meeting its obligation for nuclear liability coverage under the NLCA.
- 161. Based on the information provided on the record for this hearing, the Commission is satisfied that the Co-60 project would not impact OPG's obligations under the NLCA.

3.8 Licence Amendment

- 162. The Commission considered OPG's application for an amendment to its current power reactor operating licence for the Darlington NGS, PROL 13.03/2025, to authorize the production of Co-60 at the Darlington NGS. OPG's current licence expires on November 30, 2025.
- 163. In CMD 24-H101.1, Attachment 1, OPG provided the Commission with its proposed amendment to PROL-13.03/2025 to authorize the production of Co-60. In CMD 24-H101.1A, Attachment 1, OPG revised its request and proposed new wording to amend PROL-13.03/2025.
- 164. In section 3.2.2 of CMD 24-H101, CNSC staff recommended that the Commission amend PROL-13.03/2025 with specific text that deviated from OPG's proposal. CNSC staff recommended that the Commission amend licensed activities (i) and (vi) to authorize the production of Co-60, as well as add a new licence condition 15.7 for the licensee to implement and maintain a Co-60 operations program. CNSC staff noted that the proposed licence condition is similar to the equivalent Co-60 licence conditions currently used in the Pickering NGS and Bruce NGS power reactor operating licences.

⁸⁵ S.C. 2015, c. 4, s. 120.

- 165. In section 3.3 of CMD 24-H101, CNSC staff also informed the Commission of its planned changes to the Licence Conditions Handbook (LCH), relevant to the proposed new licence condition 15.7. CNSC staff noted that, as OPG's development of certain details of its Co-60 operations program is still ongoing, the new LCH section will contain the expected document titles of the deliverables that OPG will fulfill under its regulatory commitments⁸⁶.
- 166. The Commission accepts the proposed licence amendments as submitted by CNSC staff in section 3.2.2 of CMD 24-H101. The Commission is satisfied that the proposed licence amendments are consistent with the Co-60 related activities to be licensed. The Commission accepts the inclusion of the new licence condition 15.7 as a reasonable condition that is consistent with similar Co-60 related conditions in the Pickering NGS and Bruce NGS power reactor operating licences.

4.0 CONCLUSION

- 167. The Commission has considered OPG's licence amendment application, the information and submissions of OPG, and CNSC staff, as well as the written interventions submitted for the hearing. The Commission also recognizes the importance of maintaining the supply of Co-60 to the medical sector to support the health of Canadians. 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-13.03/2025, issued to OPG for the Darlington NGS located in the Municipality of Clarington, Ontario as follows:
 - amend licensed activity (i) in Part IV of the licence to read:

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

• amend licensed activity (vi) in Part IV of the licence to read:

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

⁸⁶ OPG's application documented numerous regulatory commitments to provide CNSC staff with completed documentation supporting the Co-60 project. As these submissions are largely outputs from OPG's engineering change control process and contribute more to confirmation of operational readiness than the establishment of the licensing basis, CNSC staff is of the view that this material is not a prerequisite for making a decision regarding the licence amendment.

• add new licence condition 15.7 as follows:

"The licensee shall implement and maintain a Co-60 operations program for the activities described in part IV of the licence."

The amended licence, PROL-13.04/2025, remains valid until November 30, 2025.

Dr. Timothy Berube Presiding Member

Appendix A – Intervenors

Intervenors – Written Submissions	Document Number
Canadian Nuclear Isotope Council	CMD 24-H101.3
International Irradiation Association	CMD 24-H101.4
Becton, Dickinson and Company	CMD 24-H101.5
Gamma Industry Processing Alliance	CMD 24-H101.6
Gammatom s.r.l.	CMD 24-H101.7
CANDU Owners Group	CMD 24-H101.8
Regional Municipality of Durham	CMD 24-H101.9
Bruce Power	CMD 24-H101.10
Nordion (Canada) Inc.	CMD 24-H101.11
Kinectrics	CMD 24-H101.12
Mississaugas of Scugog Island First Nation	CMD 24-H101.13
Saugeen Ojibway Nation	CMD 24-H101.14