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CMD : 24-H101

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A Licence Amendment

Modification d'un permis

**Ontario Power  
Generation Inc.**

**Ontario Power  
Generation Inc.**

**Darlington Nuclear  
Generating Station**

**Centrale nucléaire de  
Darlington**

Hearing in writing based solely on  
written submissions

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**Summary**

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

- Amendment of the power reactor operating licence (PROL) for the production of cobalt-60 (Co-60) radionuclide at the Darlington Nuclear Generating Station (NGS)

CNSC staff recommend that the Commission:

- Amend the PROL to allow the production of Co-60 radionuclide at Darlington NGS

The following items are attached:

- The proposed PROL 13.04/2025

**Résumé**

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

- Modification du permis d'exploitation d'un réacteur de puissance (PERP) pour autoriser la production du radionucléide cobalt 60 (Co-60) à la centrale nucléaire de Darlington

La Commission pourrait considérer prendre les mesures suivantes :

- Modifier le PERP pour autoriser la production de Co-60 à la centrale nucléaire de Darlington

Les pièces suivantes sont jointes :

- Le permis proposé, PERP 13.04/2025

**Signed/Signé le**

06 February 2024 / 06 février 2024

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Directorate of Power Reactor Regulation

**Directeur général**

Direction de la réglementation des centrales nucléaires

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## Summary of CMD

In April 2020, Ontario Power Generation (OPG) notified CNSC staff of its intention to apply for a licence amendment to allow it to produce the radionuclide cobalt-60 (Co-60) from neutron irradiation of natural cobalt (Co-59) in all reactor units at the Darlington Nuclear Generating Station (NGS). OPG's project is centered around replacing the sixteen existing adjuster absorber (AA) rods in each unit at Darlington NGS with functionally equivalent AA rods primarily made of Co-59. In May 2023, OPG submitted a request to amend the Darlington power reactor operating licence (PROL) to allow OPG to produce, possess, transfer, use, package, manage, and store Co-60 at the Darlington NGS. Nuclear medicine uses Co-60 radionuclides in radiotherapy treatments and equipment sterilization. Further, Co-60 has numerous industrial applications when integrated into radiography, measuring, or sterilization devices.

Production of Co-60 using CANDU reactors has been carried out in Canada since the 1970s. OPG's Pickering NGS is already licenced to produce Co-60, so this is not a first-of-a-kind activity for OPG. As the production of Co-60 was considered during the design of Darlington NGS, OPG's project is introducing limited equipment (new and modified) to each unit. This equipment, and existing equipment such as the overhead cranes, will facilitate installation and harvesting of cobalt AA rods. Following harvesting, each AA rod is transported in a shielded flask to the Irradiated Fuel Bay (IFB) where the AA rods will be dismantled, cut to size, and packaged into a Type B transport package. OPG will not be responsible for processing Co-60 into a viable commercial product. Processing will be performed by Nordion Canada Inc. (Nordion), a third-party holding a CNSC nuclear processing facility licence. Further, through arrangements with Nordion, OPG will receive Co-59 and certified F-231 Type B transport packages from Nordion. As such, information that will be out of scope of this licence amendment includes package certification; processing; sale (including possible export) by Nordion; and information about the commercial use of Co-60.

CNSC staff reviewed the licence amendment application, along with supporting licensing information, design documentation, and safety analyses related to equipment changes, operations related to Co-60, and the potential impact on the existing Darlington NGS licensing basis. Based on this review, CNSC staff have determined that OPG would have adequate provisions in place to ensure the safe production of Co-60. As a result, the production of Co-60 would pose no substantive risk to the operation of the nuclear facility itself. With the measures proposed by OPG, Co-60 harvesting and packaging will not result in significant doses to workers or members of the public. Further, the additional tritium related emissions from Co-60 harvesting are expected to be minimal compared to overall station emissions and well within the release limits established in OPG's environmental protection program. In addition, Co-60 is expected have negligible impact on existing reactor operations and transient response. Lastly, OPG's existing waste management, transportation, security and safeguards programs are sufficient to manage additional activities resulting from Co-60 production. OPG also continues to engage with interested Indigenous Nations and communities on this licence amendment and other relevant activities.

Following CNSC staff's comprehensive review, summarized in this CMD, CNSC staff have determined that OPG is qualified to carry out the proposed activity (namely, the production of Co-60), and will make adequate provision for the protection of the environment, the health and safety of persons, and maintain national security and measures required to implement international obligations to which Canada has agreed. Therefore, CNSC staff recommend that the Commission amend OPG's Darlington NGS PROL to include Co-60 production.

## 1. Overview

### 1.1 Background & Purpose

Ontario Power Generation Inc. (OPG) is seeking a licence amendment from the CNSC to add a new licensed activity to produce, possess, transfer, use, package, manage and store the Cobalt-60 (Co-60) radionuclide [1] (henceforth referred to as the Co-60 project or activities associated with Co-60 operations). Co-60 is a radionuclide used in a wide variety of industries and applications including medical treatments, food & equipment sterilization, and industrial scanning & measuring. Co-60 is produced through transmutation (neutron capture) of Co-59, which is a stable isotope of cobalt (not a nuclear substance).

Pursuant to the CNSC's Nuclear Safety Control Act (NSCA),<sup>1</sup> a licence issued by the CNSC is required to produce, possess, transfer, use, package, manage, store, or otherwise handle, Co-60. The production of Co-60 at Darlington NGS is not currently an activity authorized by the existing Power Reactor Operating Licence (PROL); however, it is an activity currently conducted by OPG at its Pickering NGS and was considered during the initial design of the Darlington station.

OPG's proposal is to produce Co-60 through the irradiation of sixteen Co-59 adjuster absorber (AA) rods that will replace the existing AA rods. OPG intends to produce Co-60 in all four units at the Darlington NGS, including Unit 2, which also contains additional equipment to produce Molybdenum-99 (Mo-99) from natural molybdenum (Mo-98). This system will be referred to in this CMD as the Mo-99 Isotope Irradiation System / Target Delivery System (Mo-99 IIS / TDS). Currently, there are no changes proposed for the Darlington NGS footprint or existing release limits; however, OPG intends to deviate from the original design provisions, perform modifications to structures and systems within the Darlington station, and introduce equipment and materials that were not previously needed. Separate CNSC licences, held by third parties independent of OPG, are required for activities associated with packaging & transport and nuclear substance processing. Information pertaining to these activities and downstream use of Co-60 is out of scope of this licence amendment.

CNSC staff have reviewed OPG's application made pursuant to section 6 of the General Nuclear Safety and Control Regulations (GNSCR).<sup>2</sup> CNSC staff's determinations, conclusions summarized in this CMD are not meant to pre-suppose the decision of the Commission, rather they culminate in recommendations to the Commission.

#### 1.1.1 Station

The Darlington NGS is located in the Province of Ontario on the north shore of Lake Ontario, in the Municipality of Clarington and Regional Municipality of Durham. The facility is owned and operated by the licensee, OPG, a Canadian corporation, whose head office is located in Toronto, Ontario. The site is located on the traditional territory of the Michi Saagiig Anishinaabe people. These lands are also covered by the Williams Treaty between Canada and the Mississauga and Chippewa Nations.

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<sup>1</sup> S.C. 1997, c. 9

<sup>2</sup> SOR/2000-202

The Darlington NGS consists of four 881 megawatt CANDU reactors which came into service between 1990 and 1993. Following Commission acceptance of OPG's request for licence amendment [2], OPG undertook a multi-unit, multi-year program known as *refurbishment*, to replace life-limiting components such as fuel channels, and to make safety improvements to the plant, programs, and processes. Table 1 summarizes OPG's progress and current schedule. As is summarized in section 1.1.3 and Table 2, OPG has been using several of these refurbishment outages to install Co-60 harvesting infrastructure.

**Table 1: OPG refurbishment schedule – by start date**

<i>Unit</i>	<i>Start Date</i>	<i>Status</i>	<i>Completion Date</i>
2	October 2016	Completed	June of 2020
3	September 2020	Completed	July 2023
1	February 2022	In Progress	TCD October 2024
4	July 2023	In Progress	TCD January 2026

### 1.1.2 Scope of OPG's Project and Responsibilities

In the commercial Co-60 supply chain, OPG will only be responsible for the irradiation of Co-59, packaging of Co-60, and taking back spent Co-60 sources at the end of their commercial life. Co-60 operations that are discussed in this CMD, are the general activities that will be authorized by the PROL – specifically the production, possession, transferring, use, packaging, managing and storing of the Cobalt-60 (Co-60) radionuclide – which will be performed through specific tasks such as harvesting, transporting, dismantling, packaging, offering the package for transport. The activities associated with the possession, storage, transfer, and management of spent Co-60 will be covered under an OPG Waste Management Facility Licence, not the Darlington PROL. All other interim activities including transport, processing, source manufacturing, commercialization, export, shipping of cobalt sources, inventory management, and cobalt use will be handled by qualified parties with the necessary registrations, federal certifications, qualifications, and licences. These qualifications, including CNSC issued licences, demonstrate the parties meet, at a minimum, the applicable federal requirements (see section 2.1.1).

For example, the Co-60 radionuclide to be produced at Darlington NGS will be shipped using an approved Type B shielded transport container owned by Nordion (Canada) Inc. (henceforth referred to as Nordion) to a facility operated by Nordion in Kanata, Ontario, where the Co-60 will be processed, commercialized, and sold to market. Nordion operates this Class 1B facility under CNSC issued Nuclear Substance Processing Facility Operating Licence NSPFOL-11A.01/2025, which is valid until October 31, 2025. Nordion's licence already authorizes it to possess and process Co-60, thus an amendment is not needed.

Upstream of the cobalt irradiation, in accordance with its management system, OPG will be procuring, from Nordion, a reliable supply of Co-59 of suitable purity which has been manufactured into AA rods meeting the appropriate design specifications, and nuclear substance inventory management and tracking.



### 1.1.3 Summary of Licence Amendment Application & Project Timelines

1. [3] In January 2020, OPG notified the Directorate of Power Reactor Regulation (DPRR) of its intent to pursue a licence amendment to authorize the production and possession of Co-60. In accordance with CNSC's regulatory approach and philosophy (outlined in REGDOC-3.5.3, *Regulatory Fundamentals*), CNSC staff began reviewing, and providing feedback on, project documentation including design documentation, engineering assessments, safety analyses, requests for CNSC staff consent for code classifications, and notifications of plant modifications.
2. [4] In January 2023, OPG formally notified CNSC staff that plant modifications would commence on Unit 3 to install key hardware proximal to the Reactivity Mechanisms Deck (RMD). Despite the proximity, the installation had no direct interface to the Unit 3 reactor, reactivity mechanism deck, safety systems, systems related to safety or containment boundary. This will be discussed further in section 2.2.3.
3. [1] In April 2023, OPG formally requested a licence amendment from the CNSC. OPG's submission provided an assessment focusing on the licensing impacts of the Co-60 project on existing programs and procedures in OPG's current licensing basis.
4. [5] In May 2023, OPG formally notified CNSC staff that during the Unit 1 refurbishment outage, Co-59 AA rods would be installed in the core. As returning the unit to normal operations in this configuration requires an amended licence, OPG also presented a backout condition that would restore the reactor to the existing licensing basis before surrendering Unit 1's reactor shutdown guarantee<sup>3</sup> if the licence was not amended. This will be discussed further in section 2.2.3.
5. [6] In June 2023, OPG formally submitted a supplement to its application to provide further information and insights into the Co-60 project timelines
6. [7] In December 2023, OPG provided an addendum to its application providing additional information and insights into the technical safety analysis commented on by CNSC staff that OPG referenced in its application.
7. [8] In January 2024, OPG formally notified CNSC staff that plant modifications would commence on Unit 2 to install key hardware proximal to the Reactivity Mechanisms Deck (RMD). Despite the proximity, the installation had no direct interface to the Unit 2 reactor, reactivity mechanism deck, safety systems, systems related to safety or containment boundary. OPG's correspondence also identified that modifications to the Irradiated Fuel Bay, specifically the West Fueling Facility Auxiliary Area, would be commencing. This will be discussed further in section 2.2.3.

Through regulatory oversight, CNSC staff are aware that OPG has been installing the equivalent Co-60 harvesting infrastructure on Unit 1. Further discussion of CNSC staff considerations can be found in section 2.2.3.

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<sup>3</sup> Surrendering the reactor shutdown guarantee is associated with a Regulatory Hold Point (RHP) for the refurbishment project requiring consent from the Commission, or the CNSC CROO-EVP as a person authorized by the Commission to remove the established RHPs associated with Darlington refurbishments.

Unlike OPG’s recent project to produce Mo-99, OPG is not introducing *first-of-a-kind* equipment that may have complex commissioning and turn-over to operations steps. Further, this is an activity that OPG has performed since the 1970s at Pickering NGS. If the Commission accepts CNSC staff’s recommendations, and amends OPG’s PROL to authorize the production of Co-60, OPG intends to commence production and harvest Co-60 in each unit in accordance with the schedule listed in Table 2 [1, 6]. This schedule is based on the first available planned outages and return to service schedules for each unit.

**Table 2: First Co-59 Rod Installation + Co-60 Harvest Schedule for Each Unit**

<i>Unit</i>	<i>Post Outage Installation – Irradiation Start Date</i>	<i>Irradiation Completion Date</i>
1	2024	2028
4	2024	2028
3	2026	2029
2	2027	2030

The proposed licence amendment would incorporate into the licensing basis for Darlington NGS, the activities associated with modifying existing equipment, introducing new components, operating a reactor unit with Co-59 rods, to produce and package Co-60. Throughout this CMD, CNSC staff will refer to OPG’s “Co-60 project” or “activities associated with Co-60 operations” in describing OPG’s Co-60 modifications project as well as proposed operations. As previously mentioned, these will be reflected in the activities section of the PROL authorizing OPG to produce, possess, transfer, use, package, manage, and store the Co-60 radionuclide.

## 1.2 Matters for Consideration

OPG has requested the Commission amend its current PROL, 13.03/2025, to authorize the production of Co-60 at Darlington NGS. In determining whether OPG is a qualified applicant pursuant to paragraphs 24(4)(a) and (b) of the NSCA, OPG’s application was considered against regulatory requirements including:

- Applicable legislation and regulations
- Relevant CNSC REGDOCs
- Existing licencing basis of Darlington NGS
- Suitability of OPG’s existing programs that will accommodate activities associated with handling Co-60 on-site in accordance with the CNSC Regulatory Framework
- Ability of OPG’s existing programs to produce project related documentation
- Engagement with applicable Indigenous Nations and communities
- Other matters of regulatory interest

## 1.3 Highlights

OPG’s Co-60 project seeks to contribute to the global supply chain of Co-60, ensuring a reliable source of Co-60 radionuclides is available for a wide variety of industries and applications including medical treatments, food & equipment sterilization, and industrial

scanning & measuring. The process selected by OPG for implementation at Darlington NGS is similar to that which is conducted at other CANDU stations in Canada (including that which OPG has itself been conducting at Pickering NGS since the 1970's).

OPG's current Darlington PROL does not allow for the production or possession of Co-60. To produce and possess Co-60, OPG submitted a request to the Commission to amend the PROL. OPG has proposed to modify existing components and introduce dedicated equipment at each unit in support of activities related to producing Co-60. Unlike OPG's recent licence amendment in Commission proceeding 21-H107, it was not necessary to authorize the production / possession of the decay products of Co-60 as the decay product is a stable isotope of Nickel.

In the Co-60 supply chain, OPG is responsible for the handling of the stable isotope of Co-59 and radioactive Co-60 at Darlington NGS. Specifically, OPG will take possession of Co-59 rods (not a nuclear substance), install them into the core during an outage, irradiate them over the course of 3-3.5 years of unit operation, harvest the Co-60 AA rods during an outage, and package the irradiated cobalt into certified shielded Type-B transport containers. OPG is responsible for ensuring the continued safe operations of the Darlington NGS, with or without cobalt AA rods, and the conduct of safe harvesting and packaging operations related to the production of Co-60. All other aspects of the supply chain, except for reclaiming the spent cobalt sources, will be handled by Nordion, a third-party company holding its own CNSC nuclear substances processing facility licence for nuclear substance processing and sealed source manufacturing.

Co-59 rods will need to be installed in the 16 AA rod sites, which are in the same location on each reactor, where they will perform the normal function of AA in the reactor regulating system (RRS) for between 3 and 3.5 years. During an outage, following the cobalt irradiation window, OPG will remove the irradiated cobalt AA rods directly into a shielded flask for transport to the irradiated fuel bay (IFB). In the IFB, the rods will be disassembled so the cobalt can be isolated and packaged into a certified Type-B Transport Container to enable shipping of the Co-60 off-site to a Nordion facility for processing.

To support CNSC staff's assessment of potential impacts from OPG's Co-60 project on the existing Darlington licensing basis, CNSC staff reviewed OPG's licence amendment application, supporting licensing information, design documentation, and safety analyses related to station modifications, new equipment and Co-60 operations. While some preparatory work is ongoing to get ready for cobalt related operations, this work is being performed in accordance with OPG's engineering change control (ECC) process, and CNSC staff do not see it impacting the licensing basis. OPG has created several regulatory commitments that will provide CNSC staff with sufficient opportunity for appropriate regulatory oversight s. Most of OPG's regulatory commitments have been identified in Appendix A of its application, however CNSC staff expect more to be created as the project progresses.

## 1.4 CNSC Staff Conclusions & Recommendations to the Commission

CNSC staff's determinations, conclusions and recommendations are for the Commission's information in support of its decision. CNSC staff have determined that operations related to OPG's proposed Co-60 operations through production, possession, handling, and packaging of Co-60 at Darlington NGS pose negligible additional risk to the operation of the nuclear facility itself, and that Co-60 will be produced within the limits of the established safety case of the nuclear facility. OPG will continue to utilize its established

engineering change control (ECC) process, documented in the licence conditions handbook (LCH), with regulatory oversight from CNSC staff to complete project documentation. CNSC staff have concluded that OPG is a qualified applicant pursuant to paragraphs 24(4)(a) and (b) of the NSCA. As such, CNSC staff recommend that the Commission amend OPG's licence to include a new activity and licence condition to authorize OPG to produce, possess, transfer, use, package, manage, and store Co-60.

## 2. CNSC Staff Review of OPG's request for Amendment and Supporting Project Documentation

### 2.1 Overview of CNSC Staff Reviews

As equipment is being introduced or modified, in support of new Co-60 operations, CNSC staff have reviewed considerable pre-licensing technical design documentation and safety assessments, all of which has been referenced in OPG's application [1], supplemental submission [6], and application addendum [7]. CNSC staff's pre-licensing engagement with OPG ahead of the application was done in accordance with REGDOC-3.5.3, *Regulatory Fundamentals*.<sup>4</sup> These confidential submissions, which will be cited as needed, include technical design documentation, safety assessments, and environmental protection documentation provided to CNSC staff between 2020 and 2023.

The purpose of CNSC staff's review was to understand the nature of the modifications being made to the station, assess the design and safety case against applicable regulatory requirements, and to inform CNSC staff's recommendations to the Commission in this CMD. While section 2.2 provides an overview of many of these changes, section 2.5 describes how OPG met the relevant regulatory requirements in all safety and control areas (SCAs).

#### 2.1.1 Regulatory Basis

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

- CNSC's [Nuclear Safety and Control Act](#) (NSCA) [S.C. 1997, c. 9]
- CNSC's [General Nuclear Safety and Control Regulations](#) (GNSCR) [SOR/2000-202]
- CNSC's [Class I Nuclear Facilities Regulations](#) (CINFR) [SOR/2000-204]
- CNSC's [Radiation Protection Regulations](#) (RPR) [SOR/2000-203]
- CNSC's [Nuclear Security Regulations](#) (NSR) [SOR/2000-209]
- CNSC's [Nuclear Non-Proliferation Import and Export Control Regulations](#) (NNIECR) [SOR/2000-210]
- CNSC's [Nuclear Substances and Radiation Devices Regulations](#) (NSRDR) [SOR/2000-207]
- CNSC's [Packaging and Transport of Nuclear Substances Regulations, 2015](#) (PTNSR 2015) [SOR/2015-145]
- Transport Canada's [Transport of Dangerous Goods Regulations](#) (TDGR) [SOR/2001286]

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<sup>4</sup> CNSC Regulatory Document, REGDOC-3.5.3, *Regulatory Fundamentals*, Section 6.3, Pre-licensing and pre-certification engagement

## 2.2 Overview of Co-60 Production

OPG intends to produce Co-60 in all four reactors at Darlington NGS through the irradiation of Co-59 AA rods that will replace the AA rods that are currently used. OPG's existing rods are mostly comprised of stainless-steel, however, some use titanium as the core material as it is a more efficient neutron absorber. Other than the replacement of the irradiated cobalt AA rods at every outage, no other modifications to the core of the reactor are needed. This is in part because Darlington was designed with the production of Co-60 in mind. The impact of OPG's current project on the existing design considerations and provisions that are now being leveraged or modified will be discussed in section 2.2.1.

For OPG to be able to produce Co-60 at Darlington NGS, procurement and installation of new Cobalt Adjuster Element Processing System (CAEPS) equipment and several station modifications are being made under OPG's engineering change control (ECC) process in support of operational needs such as AA rod installation, retrievals, replacements, and packaging. The reader is encouraged to review OPG's submission (the application addendum) for additional details, insights, photos, figures, and schematics of the new equipment and the areas of the station it is being integrated into [7]. OPG has identified several main Master Engineering Changes (MECs). CNSC staff's review of these modifications will be discussed in sections 2.2.2 and 2.2.3.

OPG's application establishes a nominal irradiation window of 3 to 3.5 effective full power years (EFPY). During this period, 16 AA rods comprised primarily of Co-59 will be exposed to neutrons in the core and will be transmuted (through neutron capture) into Co-60. It should be noted that the reactor units at Darlington NGS were designed with 24 vertical AA rods which are normally positioned in the 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 core. For the purposes of the production of Co-60, OPG will only need to replace the sixteen AA rods as the 8 rods that are currently locked out of core will remain locked out. OPG has also noted that there are no plans to completely remove the locked-out-of-service AA rods except on units where a Mo-99 IIS / TDS is installed using four of these eight AA rod ports. The AA rods will be raised and lowered into the core using winch mechanisms on the RMD consistent with existing mechanisms and operations. While in the core, cooling of the AA rods is accomplished by the circulation of moderator water. When being harvested during an outage, no additional cooling is needed to avoid deflagration, impingement, or sheath oxidation.

To recover the Co-60 so that it can be packaged and transported to Nordion's processing facility, the AA rods are withdrawn from the core, drawn into a flask positioned over each AA rod unit position on the RMD using the CAEPS positioner and a custom pedestal. Once in the CAEPS flask, the cobalt is hoisted across the RMD using the overhead reactor deck crane and lowered to a vehicle known as the transport erector. The transport erector with the secured flask is towed by truck to the West Fueling Facilities Auxiliary Area (WFFAA) where the rods will be dismantled and packaged into a Type B transport package within the Wet Cask Handling Bay (WCHB) of the Irradiated Fuel Bay (IFB). Scrap from 30 years worth of cobalt rod-assemblies, estimated to be less than 1500 kg, will be kept in the IFB until the end of commercial operations of the Darlington NGS; following which, this waste would be then transferred to a dry fuel storage container for long term storage [7]. As the rod dismantling, resizing, and packaging happens underwater, and the hot Cobalt rods would turn water in the flask into pressurized steam, an argon purge and vacuum drying will be performed to ensure the integrity of the Type B transport package.

During harvests, portable equipment will be set up, and temporary tie-ins prepared for radiation monitoring and contaminated exhaust, respectively. Through these temporary tie-ins, emissions resulting from cobalt harvests will be routed through the contaminated exhaust stack, which is monitored continuously. CNSC staff receive routine reports about specific Unit emissions through the quarterly and annual compliance monitoring reports as required by REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*. As concluded in OPG's application, the emissions associated with Co-60 production will be minimal compared to overall station emissions [1, 9]. Additionally, the overall emissions will remain well below the Derived Release Limits (DRLs) for the site.

Generally, Co-60 "operations" captures activities including, but not limited to, those in the following steps:

1. installation of Co-59 rods;
2. irradiation during commercial operations;
3. rod removal and flasking;
4. transportation to the West Fueling Facilities Auxiliary Area (WFFAA);
5. discharging the Co-60 in the flask into the Wet Cask Handling Bay (WCHB) of the Irradiated Fuel Bay (IFB);
6. dismantling and packaging the Cobalt elements from the rod; and
7. purging and drying the insides of the transport package.

### **2.2.1 Overview of existing design provisions in current licensing basis**

Darlington NGS was originally designed anticipating the production of Co-60. As such, equipment was designed and installed during the construction of the station to make provisions for Co-60 related operations. OPG's application addendum [7] identified that the main provisions that were implemented in anticipation of cobalt production was the cobalt cooling circuit and a set of rails and rail supports for the CAEPS positioner. Neither of these existing legacy systems or components will be used.

During the design phase of the project, OPG identified that the rail support (installed during initial construction of Darlington NGS) would need to be replaced and updated (to comply with updated codes and standards) due to the implementation of more stringent modern seismic requirements. OPG is completing the installation of the harvesting infrastructure, which includes the updated positioner rail beams and supports ahead of the start of the first irradiation cycle in each respective unit, as summarized in its application [6].

Most notably, Darlington was designed with a cobalt cooling circuit situated underneath the RMD to provide cooling to rods to (1) reduce the risk of deflagration; and (2) prevent the formation of an oxide layer on the external surfaces of the zirconium sheath from the heat of rods that have experienced 2-3 years of exposure to power levels between 80-100% of full power [10]. In pursuing the current amendment, OPG has deemed this cooling system unnecessary as updated safety analyses predict that the cobalt will remain below the minimum deflagration temperature. OPG has identified that only a modest change in values in the Darlington NGS Safety Report will be needed to reflect the revised maximum surface temperature acceptance criterion [11]. Further, cooling was once predicted to be necessary to limit oxide growth on the cobalt rods to ensure the quality of the irradiated cobalt;

however, changes in the packaging and processing techniques used by Nordion have superseded this issue [7].

CNSC staff performed a detailed design review of OPG's proposed changes to the station<sup>5</sup> to ensure that the proposed activity would not introduce unnecessary risk to the continued safe operations of Darlington NGS and activities associated with Co-60 operations, without the main legacy design provisions previously installed during the construction of Darlington NGS.

## 2.2.2 Overview of Co-60 Modifications

OPG has identified several main Master Engineering Changes (MECs) required to introduce new, and modify some existing, equipment. This section will only document an overview of these changes and refer the reader to section 2.5 *Provisions for Safety in accordance with the Safety and Control Area (SCA) Framework*. The comprehensive review of SCAs elaborates on CNSC staffs review of OPG's application and provides conclusions and recommendations to the Commission. Further, discussion of CNSC staff considerations regarding work under OPG's MECs that are already in progress is included in section 2.2.3. Further descriptions of the equipment, functional operations details, and graphical representations, of the new / modified equipment can be found in OPG's application materials [7].

### OPG MEC 142910

This MEC implements a permanent modification to the AA rods, AA units<sup>6</sup>, and the associated shielding supporting conversion to cobalt AA rods. CNSC staff have reviewed detailed design materials provided by OPG and have reviewed the design changes that will replace the existing AA rod design. Safety assessments provided by OPG have demonstrated the equivalence in neutronics between the designs of the existing and cobalt AA rods. Further, OPG will use different "Types" of AA rods, with different numbers and arrangements of cobalt bundles to achieve the desired reactivity in the core. CNSC staff have reviewed OPG's reactor physics submissions and have no concerns with OPG's methodology, interpretation of results, and conclusions on the interchangeable nature of the two AA rod designs. Although the two materials and designs have been demonstrated to be neutronically equivalent, as will be discussed further in section 2.5.4, OPG requires a license amendment to operate the reactor using Co-59 rods as the neutron absorption will result in the production of Co-60. Since Co-60 is a nuclear substance subject to the requirements of the NSCA, a license is required to produce and possess it.

As the neutron absorption cross-section of cobalt is significantly larger than that of stainless-steel / titanium used in the existing AA rods, less mass is needed to achieve the same level of neutron absorption. OPG has reported that the cobalt AA rods will have approximately half the weight of the stainless-steel based design [12]. Thus, CNSC staff find that the in-core consequences of a failed mechanism or rod (resulting in a dropped rod), are bounded by the existing design / use of stainless-steel rods and do not represent an increase in risk.

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<sup>5</sup> Namely, new and modified equipment being introduced to support Co-60 production and retrieval.

<sup>6</sup> AA units refer to the entire AA rod assembly, cable, and additional equipment that provide functionality to the rods, most predominantly the control mechanism on the RMD.



**OPG MECs 142912 & 142914**

These MECs captures Cobalt Adjuster Element Processing System (CAEPS) related changes implemented to facilitate the periodic replacement of cobalt AA rods from the reactor and the RMD (MEC 142912) as well the equipment and tooling required for on-site transportation of cobalt rods in both the stable Co-59 and activated Co-60 states (MEC 142914).

This includes the design and installation of the cobalt positioner, which travels on rails above the RMD and its offline resting place in an adjacent room (MEC 142912); and the design and implementation of the CAEPS flask and the transport erector (MEC 142914). The purpose of the CAEPS positioner and flask is to allow the remote removal of the AA rods to mitigate exposure to the radiological hazard of the Co-60 AA rods. The positioner will introduce the large, shielded flask and pedestal with precision at each AA unit position on the RMD. CNSC staff will discuss OPG's radiation protection program and select supporting assessments from OPG in section 2.5.7.

**OPG MEC 142913**

This MEC introduces equipment, tooling, and modifications required to remove Cobalt bundles from the CAEPS flask and discharge them into a pool of water (shielding) in the Wet Cask Handling Bay (WCHB) for temporary storage and disassembly before packaging. CNSC staff's review of the implementation of this MEC will be discussed under select Safety and Control Areas in section 2.5.4.

**OPG MEC 142915**

This MEC introduces equipment and modifications required for audio communications, video-monitoring, and gamma monitoring of cobalt harvesting operations. CNSC staff's review of the implementation of this MEC will be discussed under select Safety and Control Areas in section 2.5.4.

**OPG MEC 151468**

This MEC documents OPG's updates to the Cobalt Cooling Circuit System. As already discussed in section 2.2.1, OPG does not intend to use this system. Work under this MEC will update the design basis documentation to reflect the isolation and abandonment of this system as well as formally updating the previously discussed design requirements and safety report documentation with the justifications provided by OPG's updated safety analyses. Based on supporting detailed design documentation reviewed early in the project, CNSC staff recognize that the future (*i.e.*, use, removal, isolation, or abandonment) of the cobalt cooling circuit system is not in scope of the MECs associated with OPG's Co-60 project. In these detailed engineering documents, OPG has acknowledged that further pursuing the in-place abandonment of the equipment is contingent on the validation of the assumptions and predictions in the supporting safety analyses of this project [12]. However, OPG has also acknowledged that a recurring temporary modification allows this system to be used for operations related to moderator drains [7]. CNSC staff will provide regulatory oversight of OPG's future use or handling of the cobalt cooling circuit system through existing processes.

**OPG EC 162864 (related to MEC 142912)**

For Unit 2, which is the first, and currently only unit, to host a Mo-99 IIS / TDS system, OPG's application has documented many of the design considerations that had to be considered in support of OPG's intentions to produce both radionuclides concurrently. From an operations perspective, the activities do not physically interfere with each other. Specifically, most on-power handling of molybdenum targets happens above the reactivity mechanisms deck, while the cobalt resides under the RMD, even if drawn out of core. Cobalt harvests occur during outages, and the only foreseeable activities related to a Mo-99 harvest during an outage would occur in the event of a stuck target or a Mo-99 harvest following an unplanned shutdown. Similarly, in the core, the cobalt and molybdenum make use of completely different guide tubes for AA rods. The Mo-99 IIS / TDS guide tube locations were based on replacing unused AA that had been locked out of core since the late 1990's [13]. Due to the physical and operational independence, OPG considered the safety implications of the combined systems separately. As discussed throughout section 2.5, CNSC staff had no concerns with OPG's methodology or the conclusions regarding the negligible impacts on safe reactor operations or event response for a unit producing both Co-60 and Mo-99.

OPG's application describes the results of constructability walkdowns which identified that there would be interferences with some existing components of the Mo-99 IIS and the Co-60 related equipment, such as the CAEPS flask positioner and CAEPS shielding pedestal, that would be corrected during an upcoming planned outage. Further, OPG also identified that these changes would also require changes to design assessments and operating manuals. CNSC staff are satisfied that OPG will carry out this work in accordance with its existing design management and engineering change control programs / processes. CNSC staff will continue to perform regulatory oversight as appropriate.

OPG's request for a licence amendment for the production and possession of Co-60, which is not unit specific, does not have any impact on the Commission's directions to OPG, documented in the record of decision for proceeding 21-H107 [14], to return to the Commission before installing a Mo-99 IIS / TDS on additional units at Darlington.

**2.2.3 OPG's Pre-Amendment Equipment Installation Schedule**

As identified in section 1.1.3, OPG has installed, or is currently pursuing installation of, Co-60 harvesting infrastructure on units 1, 2, and 3. This includes the installation of the CAEPS positioner, support rails, handrails, electrical tie-ins, and in the case of Unit 2, modifications to the Mo-99 IIS / TDS. CNSC staff recognize that these unit modifications are being conducted during outages, in accordance with OPG's ECC process, and do not introduce any new capabilities to the unit that would require a licence amendment. Nevertheless, should the Commission not amend OPG's licence, as OPG has pursued these installations without an amendment, at their own commercial risk, CNSC staff expect that back-out provisions would be triggered and would provide the appropriate regulatory oversight to ensure compliance with the existing licensing / design basis.

Further, CNSC staff received formal notification that OPG was installing cobalt-59 rods during the Unit 1 refurbishment outage [5]. In addition to this notification, OPG's supplemental submission [6] introduces the cobalt related licence amendment into the critical path of Unit 1 refurbishment. So as to not pre-suppose the decision of the Commission, OPG's submission also identifies that if an amendment to the PROL is not granted prior to the project seeking removal of Unit 1 Refurbishment Regulatory Hold

Point 2 (RHP-2) (which occurs prior to surrendering the reactor's guaranteed shutdown state (GSS) and achieving criticality), OPG will remove the cobalt rods and proceed to returning the unit to service with new stainless-steel / titanium AA rods [5]. CNSC staff are monitoring this activity under the oversight being performed during OPG's refurbishment project and will ensure that, before the Commission's delegate authorizes the removal of RHP-2 associated with Unit 1 refurbishment, OPG will have either received the licence amendment or removed the cobalt rods.

CNSC staff emphasize that OPG's current work and plans do not pre-suppose the Commission's decision and that OPG is pursuing this work at their own commercial risk based on its experience with similar equipment and operations at Pickering NGS.

## **2.2.4 Licensee Regulatory Commitments Supporting Co-60 Project**

OPG's application has documented numerous regulatory commitments to provide CNSC staff with completed documentation supporting the Co-60 project, which will be produced in accordance with its existing processes and procedures. This includes safety assessments, confirmatory commissioning documents, maintenance documentation, operating manuals and handling procedures, and updated emergency preparedness plans. Most of these commitments have been identified in OPG's application [1]. While OPG's application addendum has updated the target completion dates for several items, no additional commitments have been added [7].

The use of OPG Regulatory Management Action Requests (REGMs) to track information to be submitted to CNSC staff is part of OPG's normal, well established, interactions with the regulator. 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 determined that this material is not a prerequisite for making a decision regarding the licence amendment.

## **2.3 Impact on existing Co-60 possession & use authorized under the NSRDR**

Any use of Co-60 in sealed sources, not including those activities proposed by the applicant in this licence amendment, must be carried out in accordance with the consolidated CNSC issued Nuclear Substance and Radiation Devices Licence (12861-2-25.3; e-Doc 6934190). This licence (12861-2-25.3) is administered, and compliance is assessed, independent of the PROL and is not affected by the scope of activities that would be authorized by the amended PROL, and thus does not require an amendment to reflect Cobalt production-related activities authorized under the Darlington NGS PROL.

As identified in its application, OPG will track its limited and transitory inventory of Co-60 in the IFB consistently with existing processes for non-fuel nuclear substances currently managed at Darlington and existing Co-60 practices at OPG's Pickering NGS to satisfy regulatory requirements. Further information can be found in 2.5.12.

As was discussed in section 2.2.3, OPG has elected to install the first batch of Co-59 AA rods during the ongoing Unit 1 outage [5]. In support of this decision, OPG provided CNSC staff with a written notification of the work, in accordance with Licence Condition G.2 of the Darlington PROL [5]. In this submission, OPG demonstrated that despite the rods being installed in a fueled core, with the unit being kept in a guaranteed shutdown state (GSS), incidental Co-60 production would remain under the exemption quantities specified in the

NSRDR [5]. CNSC staff also recognize that OPG's submission documented that Co-59 AA would be replaced with new rods, of the original stainless-steel / titanium configuration, if the Commission did not approve OPG's request for licence amendment, or the end of the Unit 1 refurbishment outage did not align with the Commission's decision.

CNSC staff determined that OPG's current request for licence amendment does not conflict with or impact OPG's existing Nuclear Substance and Radiation Devices Licence 12861-2-25.3 and OPG remains compliant with the NSRDR.

## 2.4 Environmental Protection Review

CNSC staff reviewed the application for a licence amendment to identify the type of environmental review required. As part of this process, CNSC staff assessed whether an integrated impact assessment or a federal lands review under the [Impact Assessment Act](#) (IAA) were required. CNSC staff determined that, for this licence amendment application, neither are required because the proposed amendment does not include activities listed in the IAA [Physical Activities Regulations](#) that require an impact assessment or that meet the definition of a project on federal lands.

Further, CNSC staff conduct environmental protection reviews (EPR) for all licence applications with potential environmental interactions, in accordance with CNSC's mandate under the NSCA and associated regulations. EPRs help support the Commission's conclusion on whether the applicant's proposal provides adequate protection of the environment and the health of people. An EPR was conducted for this licence amendment, the results of which are presented as section 2.5.9 (Environmental Protection SCA) of this CMD.

## 2.5 Provisions for Safety in accordance with the Safety and Control Area (SCA) Framework

Any licensed facility or activity must comply with the relevant requirements of a standard set of SCAs. For further information about the specific areas under each SCA of the CNSC's regulatory framework, please refer CNSC Regulatory Document REGDOC-3.5.3, *Regulatory Fundamentals*, and to the CNSC's public webpage, specifically: [Safety and control areas - Canadian Nuclear Safety Commission](#).

CNSC staff conducted a comprehensive review of OPG's application including design documentation, assessments supporting the safety case for the operation of Darlington NGS, and a gap analysis of impacts to the existing licensing basis considering the relevant requirements within all of the 14 SCAs. Lists of relevant CNSC REGDOCs and CSA standards that OPG's programs are required to meet can be found in the Darlington Licence Conditions Handbook and OPG's application. No new REGDOCs or CSA standards need to be added to the compliance verification criteria (CVCs) documented in the LCH to reflect the modifications and operations associated with Co-60 production.

Detailed lists of OPG's governance, programs, processes, and other relevant documentation can be found in the Darlington Licence Conditions Handbook (LCH) and OPG's application. These will not be discussed in detail in the subsections below unless specific exceptions or considerations are warranted. New OPG documents that will be used as CVC for the proposed Cobalt specific licence condition will be documented in the proposed LCH section in Part 2 of this CMD.

The objective of CNSC staff's review of the information supporting the licence amendment application was to determine if the production and possession of Co-60 would have any impacts to the existing safety case, that the design has addressed all current regulatory requirements, and whether the existing programs are sufficient to ensure the protection of workers and continued safe operations of Darlington NGS while producing or harvesting Co-60. CNSC staff's considerations and determinations conclusions are provided in the subsections below.

### 2.5.1 Management System

As identified in OPG's application, OPG is conducting the Co-60 modifications project in accordance with OPG's Engineering Change Control Process, which is a required part of a management system meeting the requirements of CSA N286-12, *Management System Requirements for Nuclear Facilities*. OPG's management system provides the process documentation and contract requirements for the execution of projects. Further, OPG's Nuclear Charter (N-CHAR-AS-0002, *Nuclear Management System*) includes a suite of programs and processes to effectively manage and operate their nuclear facilities, and provides a description of how OPG's business is implemented. The Co-60 modifications project is required to adhere to these management system requirements and demonstrate that the project was conducted and managed in accordance with OPG's management system and the requirements of CSA N286-12.

In particular, the ECC process,<sup>7</sup> ensures that changes are documented, and that governance is appropriately updated, before the changes are implemented. Per CNSC staff's reviews, CNSC staff received and reviewed project documentation<sup>8,9</sup> produced in accordance with OPG's ECC process that defined how the project is planned, executed, monitored, and controlled. CNSC staff were satisfied that this project governance was produced in accordance with OPG's ECC process.

Consistent with OPG's ECC process and the requirements of Nuclear Management Systems, OPG demonstrated that they have identified and considered OPEX from numerous sources. OPG's application, and the operational experience (OPEX) report provided to CNSC staff identified OPEX was collected from OPG's Station Condition Record (SCR) database, the CANDU Owners Group (COG) database, and experience from Pickering NGS staff who have direct experience producing Co-60 in a CANDU reactor. Through collating and evaluating the relevant OPEX OPG has asserted that the design was improved, appropriate tooling was available, lessons learned were incorporated, and operational changes were introduced in a controlled manner. CNSC staff have reviewed OPG's OPEX report<sup>10</sup> and determined that OPG has included significant OPEX which may improve performance of numerous SCAs including Physical Design, Safety Analysis, Conventional Health and Safety, Operating Performance, Radiation Protection, and Packaging and Transport.

Similarly, CNSC staff are satisfied that OPG has a process to identify and document problems, investigate and evaluate results, and implement corrective actions related to

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<sup>7</sup> N-PROC-MP-0090 *Engineering Change Control Process*

<sup>8</sup> NK38-PCH-31780-10001, *Darlington Cobalt-60 Production Modifications [e-Doc 6996856]*

<sup>9</sup> NK38-PMP-00120-00022, *Cobalt-60 Production Modification Project Management Plan [e-Doc 6996858]*

<sup>10</sup> NK38-REP-31780-10009, *OPEX Report – DN Cobalt-60 Production Modification [e-Doc 6904233]*

people, plant, environment, and processes in the Co-60 project moving forward.<sup>11</sup> To-date, during the detailed design phase of this project, CNSC staff have periodically verified that OPG's SCR process was being used to document issues related to the Co-60 project.

OPG is expected to continue to apply the ECC process to manage remaining activities associated with the Co-60 modifications project, particularly leading up to installation and operations. CNSC staff note that OPG, as the licensee, is ultimately responsible for ensuring work is conducted in accordance with its management system and ensuring continued safe operations at Darlington NGS, regardless of the delegated responsibilities delegated to OPG's Engineering Procurement and Construction (EPC) contractor. This includes ensuring that all on-site activities, including those performed by qualified and approved contractors, are conducted in accordance with OPG's safety requirements.

In its application OPG asserted that OPG's governance, programs and processes establishing Darlington NGS's Nuclear Management System would not need to be changed to accommodate the proposed activities associated with the proposed modifications and operations of the Co-60 project. Part of OPG's management system contains a directive<sup>12</sup> for all employees, regardless of their level or role in the organization, to consider safety over schedule, cost and production, in compliance with REGDOC-2.1.2, *Safety Culture*. In its application, OPG has committed that the requirements set out in the Nuclear Safety Policy will not be affected by the operations associated with the Co-60 project. CNSC staff will continue to provide regulatory oversight to verify that the requirements of the PROL, the LCH, and REGDOC-2.1.2 are being met; specifically, that OPG documents their commitment to fostering safety culture in their governing documents, and that OPG ensures that sound nuclear safety is the overriding priority in all activities performed in support of the nuclear facilities, having clear priority over schedule, cost and production.

CNSC staff evaluated OPG's application by considering OPG's current management system, in the context of the Co-60 modifications project and reviewed the information contained in the licence amendment application, against regulatory requirements. Additionally, CNSC staff regularly inspect OPG's management system, and have determined that it is a robust program that complies with the requirements of the PROL, the LCH, and more specifically CSA N286-12.

## 2.5.2 Human Performance

OPG's application has described several measures taken by OPG satisfying the regulatory requirements pertinent to the SCA of human performance. In accordance with the requirements of this SCA, OPG has comprehensive human performance<sup>13</sup> and training programs.<sup>14</sup> CNSC staff regularly inspect these OPG programs against the requirements of REGDOC-2.2.2, *Personnel training*, REGDOC-2.2.4, *Fitness for duty* (volumes I, II, and III), REGDOC-2.2.5, *Minimum Staff Complement*, and REGDOC-2.2.3, *Personnel Certification*.

While OPG's Co-60 project will not require any new certified positions, the introduction of Co-60 production, handling, and packaging, during normal reactor operations and

<sup>11</sup> See the SCR process referenced earlier.

<sup>12</sup> N-POL-0001, *Nuclear Safety Policy*

<sup>13</sup> N-PROG-AS-0002, *Human Performance*

<sup>14</sup> N-PROG-TR-0005, *Training*

outages will affect OPG's certified operations staff (such as authorized nuclear operators and certified senior (responsible) health physicists). In the application, OPG has identified that a Training Needs Analysis (TNA) will be completed as required and training will be developed and delivered to the affected staff in accordance with the existing systematic approach to training (SAT) system OPG has in place. OPG has a well-documented and robust fleet-wide training system based on a Systematic Approach to Training (SAT) that is compliant with CNSC training requirements described in REGDOC-2.2.2 *Personnel Training*. CNSC staff concluded that the various training programs at OPG were defined, designed, developed, evaluated and managed in accordance with the many processes and procedures that constitute the OPG's SAT-based training system and that OPG met regulatory requirements.

The licence amendment application has stipulated that SAT-based training<sup>15</sup> will be completed prior to operation of the Co-60 system [1]. In addition, OPG has stated that Darlington NGS staff will be qualified for the Co-60 related activities as required, in accordance with OPG's training program. Further, OPG has identified that qualifications specific to Co-60 operations and management will be developed based on the Co-60 systems training program from Pickering NGS and will be updated for use at Darlington NGS. CNSC staff will monitor and evaluate OPG's performance in this area through regulatory oversight activities, including onsite inspections and reviews of compliance reporting and revisions to relevant OPG program documents.

Further, OPG's fitness for service program and minimum shift complement (MSC) are not impacted by the Co-60 project. In its application, OPG has emphasized that activities associated with Co-60 operations will be performed by an additional distinct crew that will be separate to the staff comprising the MSC who may be required to respond to events. This meets CNSC staff's expectations and remains compliant with REGDOC-2.2.5.

Lastly, OPG has asserted that there will be no changes to OPG governance, programs and processes that form the licensing basis for Darlington NGS's Human Performance SCA as a result of Co-60 operations. Based on the information reviewed and CNSC staff's existing knowledge of OPG's program, CNSC staff have no concerns with OPG's application / consideration of the human performance program supporting Co-60 design and operations.

CNSC staff evaluated OPG's application by considering OPG's current human performance program, in the context of the Co-60 modifications project and future Co-60 operations, against regulatory requirements. CNSC staff have determined that it is a robust program that complies with the requirements of the PROL, the LCH, and relevant REGDOCs. CNSC staff will continue to provide regulatory oversight to ensure OPG's human performance program appropriately captures OPEX from Co-60 operations at Darlington NGS and leads to corrective actions when necessary.

### 2.5.3 Operating Performance

OPG's application asserts that no significant changes to the Nuclear Operations Program, and to the Operating Policies & Principles (OP&P), are anticipated due to changing the existing AA rods from stainless-steel / titanium to Co-59. CNSC staff conduct regular oversight of OPG's operations program,<sup>16</sup> which is compliant with the requirements of

<sup>15</sup> N-PROC-TR-0008, *Systematic Approach to Training*

<sup>16</sup> N-PROG-OP-0001, *Nuclear Operations*

CSA N286-12, and consistent with OPG's OP&Ps. CNSC staff note that OPG's Nuclear Operations program includes governance for the development and revision of technical procedures, which will be used to develop project-specific documentation. OPG's application also details that a comprehensive list of documents will need to be revised to reflect the substitution of stainless-steel / titanium AA rods with cobalt AA rods. CNSC staff recognize that this will include both administrative changes, and intent changes that will add precision to operator actions / considerations. As committed to by OPG in its application, CNSC staff expect this review to be comprehensive and to ensure the accuracy of governance including, but not necessarily limited to operating procedures, operating manuals, abnormal incident manuals, and maintenance manuals. As such, CNSC staff have determined that OPG's assertion is consistent with CNSC staff's understanding and there are no risks to following the ECC process and other aspects of the Nuclear Operations program to develop documentation and governance related to Co-60 operations at Darlington NGS.

As identified in OPG's application the main procedures that will support effective performance of the conduct of the licensed activities are still being developed. OPG has asserted that the Darlington documentation will be similar to those already in use at Pickering NGS. As such, CNSC staff's draft for the new section to be added to the LCH (presented in part 2 of this CMD) shows placeholders for the documentation that is expected to be used as compliance verification criteria (CVC), consistent with the CVCs established in the Pickering LCH. OPG's application originally committed to "submit the Darlington NGS Cobalt-60 production system operating manual and procedure to CNSC staff by 8 Dec 2023 [REGM 28252894]; however, OPG has since notified CNSC staff that this documentation will not be ready until August 2025 [15]. CNSC staff recognize that OPG has experience with activities similar to the installation of Co-59 rods, which does not rely on the procedures developed under REGM 28252894. Further, if the Commission amends OPG's licence, in the spring of 2024, the first harvest would not be until 2027, which provides adequate time for CNSC staff to review and include OPG's project documentation in the LCH as appropriate. Thus, CNSC staff are satisfied this change in timelines does not introduce any unreasonable risk.

Another aspect of OPG's Nuclear Operations Program includes Accident Management & Recovery and Severe Accident Management & Recovery. Technical submissions provided to CNSC staff concluded that no changes to Operator response to unit transients or other accidents (including severe accidents) are required. In particular, OPG provided an assessment which reviewed severe accident conditions with a core melt-down scenario. In this analysis OPG considered a unit containing cobalt AA rods and molybdenum 99 from the Mo-99 IIS / TDS production system. OPG's qualitative assessment asserted the individual effects of the present quantities of molybdenum and cobalt on the behaviour, evolution, and source term of corium and severe accidents are negligible. CNSC staff were satisfied with the analysis due to the relatively small quantities of molybdenum and cobalt that would be present, and neither of the metals are considered volatile. The relative stability of these elements means that releases from the core attributed to these two metals would be both small and unlikely, in comparison with the other volatile and semi-volatile fission products that are available for release during a severe accident.

CNSC staff recognize OPG has a robust Safe Operating Envelope (SOE) program compliant with CSA N290.15 (2010), *Requirements for the safe operating envelope for nuclear power plants*, including processes that govern keeping the licensing basis documentation up to date with respect to changes in plant design, safety analyses, operating



procedures, and licence requirements. As such, information establishing design requirements, operating limits, descriptions of active configuration management, and results from safety assessments will be captured in the applicable OPG Darlington specific Operational Safety Requirement (OSR) documents. OPG's application has identified six OSR documents to which OPG will have to revise to acknowledge cobalt specific changes and considerations.

Based on the expected impacts from Co-60 operations, OPG's application provided an overview of safety analyses that would be used in revisions to the licensing basis documents supporting the Operating Performance SCA, namely a selection of Darlington OSRs. From CNSC staff reviews of design documents and safety analyses, CNSC staff are satisfied that through Co-60 operations, no significant changes to the SOE are being proposed and no SOE limits or conditions are being invalidated. CNSC staff will review OPG's revised OSR documentation as they are expected to represent neutral / conservative changes reflecting the amended licensing basis.

CNSC staff expect the results from commissioning activities will be documented in commissioning reports and submitted to the CNSC.<sup>17</sup>

CNSC staff determined that OPG has effective processes in its management system and operating performance program to identify impacted or needed procedures, operating manuals, SOE documentation (OSRs), and maintenance procedures. CNSC staff are satisfied that OPG has demonstrated that operations with Co-60 will not invalidate the current SOE limits and conditions.

Further, CNSC staff conclude that there are no fundamental safety concerns or apparent barriers to the safe installation, operation, and handling of Co-60 and that the presence of Co-60 in the reactor core will have no effect on severe accident management and recovery.

#### 2.5.4 Safety Analysis

As presented in OPG's application, the results of the safety analyses performed to support Co-60 operations at Darlington NGS will be documented in OPG's annual submission to the CNSC of the *Darlington Analysis of Record*,<sup>18</sup> and ultimately in the next update of the Darlington Safety Report,<sup>19</sup> in accordance with OPG's update process.<sup>20</sup> Both of these documents are included in the Darlington LCH, and in accordance with licence condition G.2, must be provided to CNSC staff in writing when changes are made.

The inventory of technical safety analyses listed in OPG's application was reviewed by CNSC staff prior to OPG's submission of the application. CNSC staff are satisfied that it was comprehensive and included a sufficient selection of safety analyses to: 1) assess impacts on reactor physics and demonstrate neutronic equivalence between cobalt and the existing AA rods (including commissioning strategies and commitments); 2) assess impacts to fueling; 3) assess impacts to existing risk assessment; 4) assess impacts to design

<sup>17</sup> Including but not limited to confirmatory measurements and assessments of the Cobalt AA reactivity worth and incremental cross sections at the end of their first irradiation cycle at Darlington NGS being submitted under REGM 28258842

<sup>18</sup> NK38-REP-00531.7-10001, *Darlington Analysis of Record*

<sup>19</sup> Updates to all three parts of the Darlington NGS Safety report as applicable

<sup>20</sup> N-PROC-MP-0086, *Safety Analysis Basis and Safety Report*

basis accidents; 5) assess risks for cobalt-specific beyond design basis accidents; 6) assess hazards and failure modes during Co-60 operations (conventional and radiological); 7) consider interactions from combining production of cobalt and molybdenum in the same unit; and 8) assess heat loads in the irradiated fuel bay (thermal hydraulic assessment discussed under OPG MEC 142913 in section 2.2.2);

Overall, CNSC staff are satisfied that OPG has demonstrated, largely through deterministic safety analyses, that Co-60 operations will not require any changes to safety system setpoints and will not impact continued safe reactor operations (including on units with a Mo-99 IIS / TDS). Further, CNSC staff will track completion of OPG's commitment (REGM 28258842) to verify cobalt AA rods reactivity-worth and incremental cross-sections at the end of their first irradiation cycle at Darlington NGS.

In its application, OPG concluded that Co-60 operations will have a negligible impact on the Darlington PSA. Supported by CNSC staff's reviews of detailed safety analyses, CNSC staff have determined that Co-60 modifications, installation, and operations do not constitute a "major change" and does not warrant an update to the Darlington PSA models outside of the normal five-year PSA update cycle as safety goals will continue to be met. CNSC staff will review the next revision of the Darlington PSA, which will be submitted as part of the next PSA update cycle in 2025, in accordance with REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*.

As previous discussed in sections 2.2.1 and 2.2.2, OPG will not be utilising the cobalt cooling circuit originally installed in anticipation of Co-60 production. CNSC staff have reviewed OPG's Thermal Analysis [11] and have no concerns with OPG's methodology, interpretation of the results, and the proposed new safety limits. Specifically, CNSC staff recognize that OPG's previous thermal analysis contained additional conservatism.

In support of Co-60 operations at Darlington NGS, OPG performed two analyses pertaining to a potential drop of the CAEPS flask. The first analysis performed in support of MEC 142912, assessed the beyond design basis impacts of a postulated CAEPS flask drop in the reactor building. Through this assessment, OPG has concluded that when the CAEPS flask is being hoisted towards the transport erector on the lower level of the station, the CAEPS positioner would protect the RMD from the impact and thus the containment system integrity will not be compromised. This analysis also considered a drop of the CAEPS flask as it was being hoisted to the lower level of the station. OPG's assessment of this drop was to confirm there would be no adverse consequence to the foundational slab. The second analysis, supporting MEC 142913, assessed a postulated CAEPS flask drop occurring in the WFFAA. This assessment concluded that the floor would not be perforated, particularly if measures are taken to facilitate keeping the height the CAEPS flask is lifted to around half a meter.

Thus, OPG has determined that there is no risk to the RMD, foundational slab, or to the systems structures and components under the concrete floor in the unit and the WFFAA. CNSC staff have reviewed OPG's assessments and have no concerns with OPG's methodology, interpretation of the results, and their application on the conclusions regarding the consequences of a beyond design basis flask drop. Additionally, CNSC staff are satisfied with the operating limitations that OPG has proposed to minimize the risks if a drop were to occur in both locations [16].

Additionally, in support of storage of Co-60 AA rods in the Darlington IFB WCHB, CNSC staff reviewed a Thermal Hydraulic Safety Analysis based on the existing boiling-time

analyses for a loss of IFB cooling initiating event [17]. While CNSC staff found that OPG's analysis was not fully compliant with REGDOC2.4.1, *Deterministic Safety Analysis*, the principal elements of REGDOC-2.4.1 were included. The analysis also used updated codes and was consistent with the established level of detail in the design basis analysis for IFB accidents currently in the Safety Report. CNSC staff have determined that OPG's analysis has served the purpose of assessing the impact of incremental changes resulting from Co-60 storage in the IFB. CNSC staff also found OPG's commitments to work towards full compliance with REGDOC-2.4.1, to undertake confirmatory work, and to resolve residual issues – all of which would ultimately be documented in a new revision of the *Thermal Hydraulic Analysis for Storage and Processing of Cobalt Adjuster Elements in Darlington Wet Cask Handling Bay*,<sup>21</sup> to be reasonable actions that would add certainty and additional confidence to OPG's current analysis.

Lastly, OPG has also asserted that there are no significant reductions in the margins of safety. CNSC staff ultimately have no concerns with OPG's methodology, interpretation of the results, or their application on the conclusions around the submitted safety analyses, as all results are under the respective thresholds. However, during the review of OPG's beyond design basis analysis, CNSC staff observed that the most restrictive event raised concerns due to potential impacts on the guide tube extensions and the integrity of the pressure boundary [18, 19]. Specifically, OPG's calculated margins, between normal operating conditions and the largest tolerable AA rod temperature, are relatively small. While the probability of the event leading to these circumstances is low, and the event is characterized as a beyond design basis accident, CNSC staff note that this is a circumstance in which OPG's cobalt cooling circuit could have provided additional margin, had the decision not been made to leave it isolated. CNSC staff conclude that this does not represent an unreasonable risk to the pressure boundary and thus the safety of workers, the public, and the environment. In the event of any damage to components under the RMD following an event caused by these or similar circumstances, CNSC staff would conduct appropriate regulatory oversight and take appropriate enforcement actions.

CNSC staff determined that OPG has performed sufficient safety analyses to address the impacts of Co-60 operations on existing normal operating conditions and the existing station safety analysis. CNSC staff are satisfied that OPG has sufficiently demonstrated that operations with Co-60 will not compromise continued safe reactor operations or invalidate existing setpoints of safety systems or safety margins.

## 2.5.5 Physical Design

In accordance with the Darlington PROL, design modifications are required to be controlled to ensure the licensing basis is maintained. As OPG's design management and engineering change control programs / processes are regularly inspected, CNSC staff have determined that these programs are an acceptable means of planning, designing, installing, commissioning, and making modifications or new systems available to operations. In particular, OPG's programs ensure changes are made considering existing design requirements, such as those established to remain within the station's design basis and safe operating envelope, as well as operational considerations and any new requirements. OPG has also asserted that all requirements have been met and that Co-60 modifications would

<sup>21</sup> NK38-REP-34410-0973916, *GOTHIC Safety Analysis of the Darlington Irradiated Fuel Bay*; to be submitted to CNSC staff under REGM 28259126

not result in the construction of new facilities and did not change the Darlington NGS site characterization.

Further, in its application, OPG declared that it provided input and oversight of the design process associated with modifications and equipment to produce and handle Co-60. These aspects of OPG's management system (vendor / EPC oversight) and ECC process have already been discussed in sections 2.5.1 and 2.5.3.

CNSC staff reviewed OPG's submissions to determine whether OPG satisfactorily considered, and met the applicable regulatory requirements associated with human factors engineering, pressure retaining systems, seismic qualification, environmental qualification (EQ), electrical power systems, and instrumentation & control. Further, as much of this equipment is very similar to that which has already been in use at Pickering for decades, CNSC staff were able to see how OPG has started from these designs and integrated OPEX to improve applicability (for equipment use at the new station), functionality, and safety.

In accordance with OPG's Design Management Program,<sup>22</sup> which provides input into, and interfaces with, OPG's ECC process and program, OPG has identified three types of modifications requiring CNSC staff code classification consent to change for each unit. These include loading changes to the RMD and changes to the pressure boundary. In accordance with CSA N285.0-2008, *General requirements for pressure-retaining systems and components in CANDU nuclear power plants*, and Licence condition 5.2 of the PROL, OPG is required to get consent from CNSC staff as the authority having jurisdiction regarding changes to the pressure boundary. CNSC staff completed their reviews and have provided CNSC staff consent for the OPG's code classification requests.

It can be noted from OPG's application that there are still assessments being undertaken and documented and smaller sub-projects underway (*e.g.*, human factors verification and validation, environmental qualification assessments, and introducing portable argon bottles to the flask prepping room). CNSC staff are satisfied that OPG is completing this work in accordance with its ECC process and will provide regulatory oversight to verify completion of required activities. For example, while CNSC staff reviewed OPG's Human Factors Engineering Program Plan (HFEPP) [20] and Human Factors Verification and Validation Plan (HFVVP) [17] to ensure that adherence to human factors guidelines was maintained, further confirmatory work is still required. OPG has committed to keeping CNSC staff updated through submission of the Human Factors Engineering Summary Report (HFESR; REGM 28247842) for the Cobalt-60 project. Details of OPG's commitment can be found in Appendix A of its application [1] and section 2.2.4 of this CMD.

Based on the selection of detailed design documents and engineering assessments provided by OPG, and in accordance with the exceptions already discussed, CNSC staff are satisfied that OPG has and met the applicable regulatory requirements, consistent with OPG's programs, in the modification of existing systems – and design of new components. Additionally, CNSC staff agree that no new facilities or changes to the site characterization will be needed as a result of modifications or operations associated with Co-60.

CNSC staff evaluated OPG's application, and the commitments therein, by considering the past performance of OPG's Co-60 operations at the Pickering NGS and evaluating OPG's detailed design documentation of the proposed modifications and new equipment against relevant regulatory requirements. CNSC staff have determined that OPG has considered

<sup>22</sup> N-PROG-MP-0009, *Design Management*

numerous factors including human factors engineering, pressure retaining systems, seismic qualification, environmental qualification (EQ), electrical power systems, and instrumentation & control. Further, CNSC staff have determined OPG's design management program interfaces with the ECC program providing a robust program compliant with the requirements of the PROL and the LCH.

## 2.5.6 Fitness for Service

Effective fitness for service uses a systematic approach that provides an integrated framework for coordinating all supporting programs (*e.g.*, maintenance, preventative maintenance, monitoring, periodic inspection programs (PIPs), aging management, and research & development) such that the effects of aging materials and components is understood, monitored, controlled, and mitigated. Overall, the Co-60 modifications project has had a minimal impact on the physical condition and fitness for service of existing Structures, Systems and Components (SSCs); and thus, no changes are expected to the measures in place to ensure that they remain effective over time. In particular, OPG has determined that cobalt AA rods will have a negligible impact on moderator and IFB chemistry and the IFB purification system. Nevertheless, OPG has asserted that fitness for service inspections and preventative maintenance has been a design-consideration throughout the project.

In its application OPG has asserted that most maintenance will be performed during unit outages, but not when the equipment is in use for a Co-60 harvest. OPG has committed to following its ECC and work management processes<sup>23</sup> to develop preventative maintenance, testing, and periodic inspection plans before completing the Available for Service (AFS) Declarations. OPG has stated that it expects the details of these plans to be similar to those implemented at Pickering NGS. As OPG has mature work management and ECC programs, and direct experience with the associated activities, CNSC staff are satisfied that OPG is qualified to complete the committed work before AFS, as planned.

OPG has also committed to integrating Co-60 equipment into its aging management program as applicable, in accordance with its ECC process. OPG has committed to assessing the sixteen AA rod mechanisms, after the first irradiation cycle for each unit is completed, for significant or unexpected forms of in-service degradation [21]. CNSC staff are satisfied that through this assessment OPG will ensure the safety and functionality of critical components that maintain the containment boundary.

CNSC staff evaluated OPG's application and the commitments therein by considering the adequacy and past performance of OPG's fitness for service, ECC, and work management programs, in the context of the Co-60 modifications project and future Co-60 operations. OPG's existing programs comply with the requirements of the PROL and the LCH. CNSC staff will continue to provide regulatory oversight to verify that OPG ensures continued safe operations of each unit at Darlington NGS.

<sup>23</sup> Including but not limited to: N-PROC-AS-0028, *Development, Review and Approval of Technical Procedures*; and N-PROC-MP-0090, *Engineering Change Control Process*; which take authority from N-PROG-MP-0001, *Engineering Change Control*; N-PROG-MA-0026, *Equipment Reliability*; N-PROG-MA-0019, *Production Work Management*; and N-PROG-OP-0001, *Nuclear Operations*.

## 2.5.7 Radiation Protection

As presented in its application, OPG will utilize its existing Radiation Protection (RP) program<sup>24</sup> to maintain worker doses below regulatory limits *and as low as reasonably achievable* (ALARA). OPG attests that no changes will be required to any OPG programs and procedures within the RP SCA of the Darlington NGS to accommodate activities related to Co-60 operations. OPG has a mature and robust RP program that meets current regulations and requirements. CNSC staff recognize that qualified OPG staff have used this program to manage significant hazards, for example, those encountered during Co-60 production at Pickering, and the refurbishment of each reactor at Darlington NGS. OPG also continually evaluates the performance of its RP program against industry-based performance metrics and benchmarks against the RP program of other industry-leading stations (nationally and internationally). CNSC staff provide regulatory oversight of OPG's RP program, and are satisfied that it is suitable to protect the health and safety of persons involved in activities associated with Co-60 operations – such as the installation of Co-59 AA rods; the harvest and packaging of Co-60 AA rods; and the maintenance of associated equipment [20].

As documented in its application, OPG will use various types of instrumentation to support radiological monitoring of the hazards associated with Co-60 operations. As reflected above, OPG has experience managing and controlling the radiological hazards associated with the production and handling of Co-60. Thus, CNSC staff expect OPG's RP program to meet regulatory requirements and manage associated risks when Co-60 operations are introduced at Darlington NGS. Based on the review of design documentation, past oversight results of the RP program, and experience with earlier AA rod removals (in support of the Mo-99 production and refurbishment projects at Darlington NGS), CNSC staff are satisfied that OPG will be able to ensure work can be conducted safely and in accordance with radiological work plans. OPG will be leveraging the three basic protective measures associated with the ALARA principle (time, distance and shielding) during Co-60 handling operations. OPG's application, and supporting materials, described the specialized equipment (shielding) and access barriers (to ensure adequate distance) that would be introduced in the work-areas impacted by high radiation fields, specifically those present during Cobalt harvesting and flasking on the RMD.

CNSC staff reviewed detailed assessments that presented these ALARA provisions, and as the predicted dose rates and the corresponding estimates for whole-body and extremity dose. For example, CNSC staff reviewed an assessment provided by OPG demonstrating a dose rate target of 500  $\mu\text{Sv/hr}$  (50 mrem/hr) would be achievable on the external surfaces of the flask, which would allow the on-site transportation of the Co-60 flask to be classified as low-hazard radiological work. CNSC staff have no concerns with OPG's methodology, interpretation of the results, and their application of the conclusions to evaluate ALARA in design, planning of work, and characterization of sites as permanent radiological work areas or temporary exclusion zones, in accordance with its RP program.

As most of the design measures OPG has implemented in support of reducing doses ALARA (*e.g.*, the CAEPS pedestal, shielding blocks, the CAEPS flask) are introduced temporarily and may become radioactively contaminated, they will require appropriate storage when not in use. OPG has confirmed [22], that the selection and approval of safe storage areas is still being pursued but the selected areas will be suitable for working with contaminated materials in accordance with OPG's RP program. This preliminary

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<sup>24</sup> Documented in N-PROG-RA-0013, *Radiation Protection*

information meets the regulatory expectations and OPG has committed to provide the pertinent supporting documentation in accordance with relevant procedures,<sup>25,26,27,28</sup> in the RP program, before the first harvest (REGM 28263819). CNSC staff will review OPG's submission(s); and will continue to conduct regulatory oversight of material storage throughout the protected areas of Darlington NGS to ensure the protection of workers and persons.

Lastly, CNSC staff acknowledge a commitment (REGM 28255219) described in OPG's application to submit an additional engineering evaluation of a scenario that sees a rapid increase in gamma dose rate on the RMD due to withdrawal of a cobalt AA. This evaluation, due to be submitted in the fall of 2027, is expected to confirm that the RMD provides adequate shielding, when accompanied by the inclusion of access controls. In the interim, CNSC staff expect the alarm setpoints of the permanently mounted fixed area alarming gamma meters (FAAGMs) to be an adequate protective measure for workers on or near the RMD. Further, as historically there are few reactivity control manoeuvres involving the AA rods in a year, and because OPG will be establishing radiological work areas with access controls on the RMD, CNSC staff are satisfied there are minimal risks involved in not receiving the results of this assessment until 2027.

CNSC staff evaluated OPG's application, and the commitments therein, and considered the adequacy and past performance of OPG's radiation protection program. CNSC staff have determined that OPG has incorporated radiation protection measures into the Co-60 equipment and activities and have assessed and mitigated potential radiological hazards. CNSC staff have determined OPG's radiation protection program is robust and complies with the requirements of the PROL and the LCH. CNSC staff will continue to provide regulatory oversight to ensure OPG's radiation protection program remains protective of the health and safety of persons involved in activities associated with Co-60 operations.

## 2.5.8 Conventional Health & Safety

OPG has an established occupational health and safety program that consists of documented practices to establish work protections,<sup>29</sup> and systems for maintaining environment health and safety<sup>30</sup> to ensure that all workers work safely, in compliance with the Ontario [Occupational Health and Safety Act](#) and the Ontario [Labour Relations Act](#). In support of Co-60 operations, OPG has asserted that no changes are required to OPG governance, programs and processes that form the licensing basis for Darlington NGS's Conventional Health and Safety SCA. Further, OPG has applied conventional safety principles during the design process to ensure that personnel would be protected from injury to the greatest extent possible. CNSC staff, reviewed OPG hazard analyses and OPEX descriptions related to the most significant conventional hazard associated with the Co-60 project – the handling and hoisting of the CAEPS flask [16, 20, 23]. CNSC staff have no concerns with OPG's methodology and interpretation of the results. CNSC staff are also satisfied that OPG's program is robust enough to ensure adequate measures will

<sup>25</sup> N-PROC-RA-0014, *Radiological Zoning, Personnel / Material Monitoring*

<sup>26</sup> N-PROC-RA-0015, *Contamination Control While Performing Work*

<sup>27</sup> N-PROC-RA-0024, *Hazard Surveys, Postings, and Labeling*

<sup>28</sup> N-PROC-RA-0054, *Minimization, Control and Combustible Material Safety Within the Site*

<sup>29</sup> N-PROG-MA-0015, *Work Protection*

<sup>30</sup> OPG-PROG-0005, *Environmental Health and Safety Managed Systems*

be implemented to ensure that the proposed activities are properly planned and conducted safely by OPG staff and contractors.

CNSC staff will continue to monitor OPG's conventional health and safety program as its being applied to this project to ensure that workers are protected from conventional hazards. In particular, CNSC staff will conduct regulatory oversight during key installation activities such as critical lifts, RMD navigation, and other activities which may present conventional hazards.

CNSC staff evaluated OPG's application by considering OPG's current conventional health and safety program, in the context of the Co-60 modifications project and future Co-60 operations, against regulatory requirements. CNSC staff have determined that it is a robust program that complies with the requirements of the PROL, the LCH, and additional provincial legislation. CNSC staff will continue to provide regulatory oversight to ensure work will be conducted with proper planning and adequate safety measures.

## 2.5.9 Environmental Protection

CNSC staff reviewed OPG's application to confirm that the impacts on environment potentially arising from the Co-60 project are not significant. CNSC staff also performed their own Environmental Protection Review as identified in section 2.4. OPG's application asserted that OPG complies with regulatory requirements codified in REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*, and that the activities associated with Co-60 operations will not require changes to OPG environmental protection program<sup>30</sup> (including effluent monitoring programs<sup>31,32</sup>). OPG's environmental protection program is compliant with the CNSC's requirements<sup>33,34</sup> and expectations. CNSC staff also recognize that OPG has established Action Levels which are set below the Derived Release Limits (DRLs) to provide an early warning system of potential loss of control to the environmental protection program.

OPG maintains an Environmental Risk Assessment (ERA) that is updated every 5 years. OPG completes this assessment in accordance with the requirements in CSA N288.6-12, *Environmental risk assessments at class I nuclear facilities and uranium mines and mills*. In support of its application, OPG performed a comprehensive gap analysis against the existing Darlington Site-wide ERA identify any risks that activities associated with Co-60 operations would introduce that were not already covered by current Environmental Protection programs. OPG refers to this gap analysis as the predictive effects assessment (PEA).

In the PEA, OPG has concluded that Co-60 operations will not result in any additional non-radiological releases or emissions; and that radiological releases (predominantly limited to of tritium in the form of tritiated water vapor) would constitute a negligible incremental increase in the annual public dose (0.004% of the regulatory public dose limit of 1 mSv) [1, 9]. Consequently, OPG's PEA has not identified any unacceptable risks to human and ecological receptors in the vicinity of the Darlington NGS site. CNSC staff are satisfied

<sup>31</sup> N-PROC-OP-0025, *Management of the Environmental Monitoring Programs*

<sup>32</sup> N-STD-OP-0031, *Monitoring of Nuclear and Hazardous Substances in Effluents*

<sup>33</sup> CSA N288.4-10, *Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills*

<sup>34</sup> CSA N288.5-11, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills*



that releases will be collected, processed, discharged, and monitored through the existing contaminated exhaust system.

CNSC staff are satisfied that the PEA was produced in accordance with the requirements of CSA N288.6-12. Further, CNSC staff are satisfied OPG's environmental protection programs remain in compliance with REGDOC-2.9.1, and proposed operations remain within the current licensing basis. Lastly, CNSC staff have no concerns with OPG's methodology, interpretation of the results, and their application on the conclusions regarding the confirmations that releases are negligible and protective of the public and the environment. Overall, CNSC staff found that the information provided by OPG regarding environmental protection is sufficient to meet the applicable regulatory requirements under the NSCA and associated regulations for the licence amendment.

CNSC staff will continue to verify and ensure, through ongoing licensing and compliance activities and reviews, that the environment and the health of persons are protected and will continue to be protected over the proposed licence period. CNSC staff conclude that OPG has met the regulatory requirements in conducting their risk analysis of potential emissions and releases and that the releases associated with Co-60 operations make up a small fraction of the annual station releases, which will not result in additional risk to the public and the environment.

### 2.5.10 Emergency Management and Fire Protection

In its application, OPG has concluded that the modifications and operations associated with Co-60 will not necessitate any new conventional or nuclear emergency response governance, programs, and processes to meet regulatory requirements. As such, OPG's existing emergency preparedness and response program,<sup>35</sup> which includes procedures that govern the conduct of drills and exercises,<sup>36</sup> will not be impacted by the introduction of activities associated with Co-60 operations. CNSC staff have reviewed OPG's application, and supporting safety analysis documentation, and concur with OPG's conclusions around the suitability of their existing programs and the lack of impact that the presence of cobalt AA rods in the core would have on the emergency response provisions. CNSC staff conclude that OPG continues to implement and maintain a comprehensive nuclear emergency preparedness program which will continue to meet the requirements of REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*, Version 2 (2016) during Co-60 operations.

CNSC staff conclude that OPG has met the regulatory requirements in determining that existing hazard assessments, response plans and assets under their program are sufficient in the presence of Co-60. The existing suite of OPG nuclear emergency preparedness and response governance for Darlington NGS is deemed adequate to deal with any potential emergency event that may arise due to Co-60 operations. CNSC staff will continue to provide regular regulatory oversight of OPG's emergency management and fire protection programs.

<sup>35</sup> Documented in N-PROG-RA-0001, *Consolidated Nuclear Emergency Plan*

<sup>36</sup> Including N-PROC-RA-0045, *Emergency Preparedness Drills and Exercises*

### 2.5.11 Waste Management

In support of current activities authorized under the Darlington PROL, OPG already implements a waste management program,<sup>37</sup> which is compliant with CSA N293-08, *Management of low- and intermediate-level radioactive waste*, and meets the regulatory requirements specified in the NSCA, GNSCR, CINFR and Darlington NGS PROL. OPG's waste management program is robust and regularly inspected by CNSC staff.

OPG's application states that OPG's current project is not expected to produce and use chemical or hazardous waste and supplemental information demonstrated that activities associated with Co-60 operations will not produce significant quantities of low or intermediate level waste over the life of the project (less than 1500 kg of AA rod waste components to be stored in the IFB over 30 years of multi-unit operations) [7]. CNSC staff also acknowledge OPG's *Radioactive Liquid Waste Handling* procedure<sup>38</sup> is suitable to ensure heavy water collected during harvesting activities of the cobalt AA rods, will be handled appropriately.

OPG's application does not describe the wastes that will be generated through the installation and harvesting<sup>39</sup> of the cobalt AA rods. CNSC staff recognize that the repeated installation and harvest of the cobalt AA rods will require work on the Reactivity Mechanism Deck (RMD) during outages and may require the use of personal protective equipment (PPE) which will also be treated as a waste stream separate of that being stored in the IFB over the life of the Darlington facility. Further, CNSC staff recognize that handling of the old stainless-steel / titanium AA rods / related components and mechanisms from the first installation phase on each unit will have to be handled by OPG's waste management program, but do not represent a new type of waste for OPG. CNSC staff conclude that the additional waste streams resulting from activities associated with cobalt-60 operations can be safely managed, in accordance with CSA N292.3-08, *Management of low and intermediate level radioactive waste*, through OPG's existing waste minimization and waste management practices and procedures.<sup>40, 41</sup> CNSC staff will verify any additional waste generated and the management of those wastes through compliance verification activities.

OPG's application acknowledges that OPG, but not Darlington NGS will be obligated to take back spent cobalt at the end of their commercial life. OPG's application addendum [7] reports that cobalt sources that have reached commercial end of life will be stored for 25-30 years in the Bruce B Irradiated Fuel Bay. Following this period of cooling, the waste will be transferred to dry storage and managed at an OPG waste management facility, in accordance with OPG's waste management program, for additional cooling and interim storage before final long-term waste management. CNSC staff have reviewed supplemental information from OPG and are satisfied that these sources will continue to be managed until the end of their life under an appropriate CNSC licence.

Lastly, As required by the CINFR and the PROL, OPG is required to have a preliminary decommissioning plan (PDP) for the Darlington station. In its application OPG has identified that the modifications and operations associated with Co-60 is a relatively small

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<sup>37</sup> W-PROG-WM-0001, *Nuclear Waste Management*

<sup>38</sup> D-PROC-RA-0083, *Radioactive Liquid Waste Handling*

<sup>39</sup> For the purposes of this discussion, harvesting refers to the extraction of the cobalt AA rods from the reactor and does not include the disassembly in the IFB.

<sup>40</sup> Including N-PROC-RA-0017, *Segregation and Handling of Radioactive Waste*

<sup>41</sup> OPG-STD-0156, *Management of Waste and Other Environmentally Regulated Materials*

and removable system that will have minimal effect on future decommissioning activities. OPG has referenced the Pickering NGS PDP as a source of OPEX supporting this assertion. The Darlington NGS PDP is periodically reviewed by CNSC staff, who agree with the conclusion that the Co-60 modifications and operations are similar to those performed at the Pickering NGS and can be accommodated through minor changes to the current decommissioning plan. CNSC staff will review OPG's next submission of the Darlington PDP and financial guarantee due in 2027 that covers all of OPG's liabilities.

CNSC staff assessed OPG's application and determined that Co-60 operations will generate a minimal amount of radioactive waste at the Darlington site. All wastes generated through installation, operation and maintenance activities will be managed in accordance with OPG's waste management program currently in place. CNSC staff conclude that OPG's existing waste management program is sufficient to manage the radioactive waste and will continue to satisfy regulatory requirements.

### 2.5.12 Security

OPG's application asserts that Co-60 operations will not require changes to OPG's security program including existing security information, classifications, provisions, processes, or practices. CNSC staff concur that OPG's security program is unimpacted by the proposed activities associated with OPG's Co-60 project as it does not introduce any new systems or requirements that will directly affect security operations. For example, CNSC staff concur with OPG's assertions that activities related to Co-60 operations will not affect or introduce new accommodations from OPG's cybersecurity program or inventory control practices. CNSC staff recognize that OPG has sufficient processes to manage category 1<sup>42</sup> sealed sources. Further, OPG is currently improving its program through updates to existing processes, including addressing non-compliances identified by CNSC staff. CNSC staff are satisfied that these improvements will improve security provisions relevant to the Co-60 project. OPG's security program is regularly inspected and is subject to compliance verification activities against the Nuclear Security Regulations, CNSC Regulatory Documents,<sup>43</sup> and CSA standards listed in the LCH. CNSC staff have increased regulatory scrutiny of OPG's fleet-wide nuclear security program due to specific performance observations documented in the two most recent annual Regulatory Oversight Reports [24, 25].

It is of note that through additional compliance activities of the *Security Practices* SPA at Pickering NGS, conducted by CNSC staff since OPG's submission of the application [1], OPG has identified deficiencies in the fleet-wide security program with the potential to impact activities supporting Co-60 operations. OPG is currently working through its

<sup>42</sup> Per the definitions in REGDOC-2-12.3, not those defined in Schedule 1 of the *Nuclear Substance Regulations*.

<sup>43</sup> Applicable REGDOC's to the Security SCA include:

- REGDOC-2.12.1, *High Security Facilities, Volume I: Nuclear Response Force*, Version 2
- REGDOC-2.12.1, *High-Security Facilities, Volume II: Criteria for Nuclear Security Systems and Devices*
- REGDOC-2.12.2, *Site Access Security Clearance*
- REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material*, Version 2.1
- REGDOC-2.2.4, *Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, and Psychological Fitness*

corrective action program to ensure all applicable requirements are met. CNSC staff have determined that the overlap in security concerns from activities such as an increased volume of shipments – resulting from incoming Co-59 and outgoing Co-60 – are expected to be addressed by OPG’s corrective actions. Specifically, OPG is improving site security measures, access control, site access clearance, *etc.* to address the concerns / open actions noted by CNSC staff. Further, any modifications to the station, now or in the future – including those brought by Co-60 license amendment – will be subject to compliance verification. CNSC staff will continue to monitor OPG’s security program as its being applied to this project. CNSC staff are satisfied, however, that OPG continues to address identified deficiencies and that the issues do not pose an immediate risk to safety or security.

On each end of OPG’s role in the supply chain, shipments are being coordinated with and are coming from / being delivered to Nordion, who is both an approved supplier to OPG in accordance with OPG’s management system and an existing CNSC licensee (with similar program requirements pertaining to Management System, Security, and Packaging and Transport). OPG has indicated that it has entered into a contractual agreement with Nordion to maintain a transportation security plan for Co-60 shipments [7]. OPG’s application addendum declares that Nordion’s transportation security plans will be revised, to cover the transportation from Darlington NGS to the Nordion processing facility, and submitted to CNSC per the requirements of REGDOC-2.12.3 *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material*. As OPG will not be able to ship cobalt, a Category 1 source in accordance with REGDOC-2.12.3, to Nordion without CNSC approval of the transportation security plan, Nordion’s submission must be reviewed and accepted prior to the commencement of Co-60 transportation. CNSC staff will review the transport security plans in accordance with established practices when submitted by Nordion. CNSC staff will continue to provide regulatory oversight of each OPG’s and Nordion’s nuclear security programs to ensure adequate protection of the licenced facility and the nuclear substances.

CNSC staff evaluated OPG’s application by considering OPG’s current security and cyber security programs, in the context of the Co-60 modifications project and future Co-60 operations, against regulatory requirements. CNSC staff have determined that the Co-60 project will not impose new challenges to OPG’s security program, and it will be able to accommodate the new activities associated with the production and possession of Co-60 while fulfilling its objectives of protecting nuclear assets at Darlington NGS.

### 2.5.13 Safeguards and Non-Proliferation

As outlined in its Application, OPG maintains a safeguards program<sup>44</sup> that complies with the requirements of the PROL, LCH, and, specifically, REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*. CNSC staff regularly verify OPG’s program implementation to ensure it conforms to measures required by the CNSC to meet Canada’s international safeguards obligations as well as other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.<sup>45</sup>

Pursuant to the NSCA, a license issued by the CNSC is required to possess and use Co-60. Meanwhile, Co-60 is not a material that is subject to the Canada-IAEA safeguards

<sup>44</sup> N-PROG-RA-0015, *Safeguards and Nuclear Material Accountancy*

<sup>45</sup> [INFCIRC/140 - Treaty on the Non-Proliferation of Nuclear Weapons \(iaea.org\)](https://www.iaea.org/treaties-conventions/infcirc/140)

agreement, and therefore does not require safeguards reporting and verification. Nevertheless, the changes OPG is introducing to the facility design and its processes have been evaluated to determine whether they could have an impact on existing safeguards measures, namely in the irradiated fuel bay (IFB) where the IAEA has existing equipment installed for fuel monitoring.

OPG has identified that facility design modifications and Co-60 operations will have an impact to the IAEA's current inventory verification methods and existing surveillance cameras, which provide continuity of knowledge for spent fuel in the IFBs. Specifically, OPG has identified a potential obstruction of an IAEA camera during Co-60 harvesting and an increase in background radiation, which will impact the IAEA's current spent fuel verification method. OPG is in the process of working with the IAEA to resolve these issues prior to conducting Co-60 activities in the IFB. CNSC staff will monitor OPG's progress and are confident the issues will be resolved in a timely manner. Additionally, OPG's proposed modifications to the spent fuel bay are not expected to affect the frequency of the IAEA's routine Design Information Verification (DIV) activities conducted at the facility.

CNSC staff also note that, as Co-59 is not a controlled nuclear substance, OPG will not have to obtain a licence to import nuclear material in support of Co-60 operations. As discussed earlier, OPG is not responsible for Co-60 processing or any steps further downstream in the supply chain. As a result, it will be Nordion, not OPG, whose qualifications are evaluated against numerous regulatory requirements, including REGDOC-2.13.2, *Import and Export*, to satisfy requirements in the relevant legislation under the NSCA.<sup>46,47</sup> As discussed earlier in section 1.1.2, Nordion operates its Class 1B facility under an existing CNSC issued Nuclear Substance Processing Facility Operating Licence NSPFOL-11A.01/2025, which is valid until October 31, 2025.

CNSC staff evaluated OPG's application by considering OPG's current safeguards measures, the project needs around import and export controls, and the IAEA's verification activities, in the context of the Co-60 modifications project and future Co-60 operations, against regulatory requirements. CNSC staff have determined that the Co-60 project will not significantly affect OPG's programs, and the licensee will be able to accommodate the new activities associated with the production and possession of Co-60 while fulfilling the existing safeguards requirements.

## 2.5.14 Packaging and Transport

As previously discussed in section 1.1.2, OPG is only providing irradiation services. To get the irradiated Co-60 to Nordion's processing facility the cobalt must be shipped. As the nuclear substance is being shipped from Darlington to Nordion, OPG will be the package consignor and Nordion will be the consignee. For this project, as the consignor, the scope of OPG's activities for the Packaging and Transport SCA includes loading the certified Type B transport packages with the authorized contents and preparing the package for shipment in accordance with the CNSC issued package certificate. OPG will also be responsible for marking and labelling the package, preparing the shipping documents and making applicable notifications to the CNSC. In support of these activities, OPG will use existing processes and procedures, and Transport of Dangerous Goods (TDG) Class 7

<sup>46</sup> CNSC *Nuclear Non-Proliferation Import and Export Control Regulations* (NNIECR) [SOR/2000-210]

<sup>47</sup> CNSC *Nuclear Substances and Radiation Devices Regulations* (NSRDR) [SOR/2000-207]

qualified personnel, as described in its application and prescribed by its Radioactive Material Transportation program.<sup>48</sup>

CNSC staff have verified, through compliance activities, that OPG's Radioactive Material Transportation program, implemented at both Darlington and Pickering NGS, also specifies the management system requirements for all aspects of packaging and transport of nuclear substances and ensures compliance with both the *Packaging and Transport of Nuclear Substances Regulations* (PTNSR) 2015 and the TDG Regulations. CNSC staff have reviewed OPG's application and find that it meets the requirements as stated in the PTNSR 2015.

OPG has asserted that no changes are needed in governance, programs and processes that form the licensing basis for Darlington NGS's Packaging and Transport SCA as a result of Co-60 operations. OPG's application also asserts that documentation covering the transportation process specific to Co-60 operations will be developed (REGM 28252894) leveraging operating experience (OPEX) and commonalities from the equivalent Pickering documentation. CNSC staff do not consider the development of this governance to be a barrier to licensing as OPG has decades worth of experience conducting this activity at Pickering and will be able to adapt this for use at Darlington NGS in time for OPG's first cobalt harvest. These documents will be reviewed by CNSC staff when prepared.

OPG's application identifies that Nordion, the owner of the F-231 package, has accountability for obtaining CNSC certification and performing appropriate maintenance activities for the package that will be used to transport Co-60 from Darlington NGS to the Nordion site in Kanata, Ontario. Additionally, Nordion (the consignee) will be responsible for hiring a qualified carrier and arranging conveyance for transport of Co-60 in these certified packages. OPG is a registered user of the F-231 package, which recognizes that OPG has the appropriate instructions to properly prepare the package in accordance with the requirements of the certification. This includes ensuring the authorized radioactive contents in the package are within certificate limits (*i.e.*, Co-60 activity, rod encapsulation and dimensions, moisture removal, closing of the package, *etc.*).

While OPG's existing contractual agreements with Nordion assign the responsibility for the fitness for service of the Type B package and making arrangements for conveyance to Nordion, OPG will still have to process and approve the shipper (carrier) for access to the site<sup>49</sup> and to offer the package for transport. OPG's application addendum [7] acknowledges that Nordion has selected Jade Transport, who has already been qualified to provide similar services for OPG at Pickering NGS. CNSC staff also require that OPG provide procurement oversight, consistent with OPG's management system, of the transport packaging that Nordion provides to verify that the necessary maintenance has been performed and the packages are fit for service.

As noted above, OPG is the package consignor and Nordion is the package consignee.<sup>50</sup> Under the requirements of CNSC PTNSR 2015, if there is an incident during transport, it must be reported to the CNSC by the consignor, the carrier, and the consignee. OPG's application identifies that arrangements between OPG and Nordion will use the proximity of the incident to their respective facilities as a key parameter in deciding who will respond

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<sup>48</sup> W-PROG-WM-0002, *Radioactive Material Transportation*

<sup>49</sup> In accordance with OPG governance N-INS-61400-10016, *Security Process of Vehicle Ingress and Egress to the Controlled and Protected Areas*

<sup>50</sup> Contrary to OPG's application, CNSC staff note that Nordion will not be the carrier, rather Nordion will hire a for-hire freight company to do the transport.

to and assess the situation. CNSC staff find that this is consistent with sections 36 and 37 of the PTNSR 2015, as well as the current response plan for Pickering. As discussed in section 2.5.12, CNSC staff will continue to provide regulatory oversight of each OPG's and Nordion's emergency response programs, including Nordion's Transportation Security Plan, to ensure that they have current and appropriate plans and capabilities, continue to meet their respective obligations in the event of a dangerous occurrence, and comply with the IAEA Regulations as required by PTNSR 2015.

CNSC staff evaluated OPG's application by considering OPG's current Radioactive Material Transport program, interactions with third parties fulfilling the roles of consignee and carrier, and regulatory requirements from Transport Canada, the IAEA, and the CNSC, in the context of Co-60 operations. CNSC staff have determined that the Co-60 project will not affect OPG's Radioactive Material Transport program. CNSC staff conclude that OPG is qualified to ensure compliance with the requirements of both the PTNSR 2015 and the TDG Regulations.

## 2.6 Indigenous Engagement

The common law duty to consult with Indigenous Nations and communities applies when the Crown contemplates actions that may adversely impact potential or established Indigenous and treaty rights. The CNSC ensures that all of its licensing decisions under the Nuclear Safety Control Act (NSCA) uphold the honour of the Crown pursuant to section 35 of the *Constitution Act, 1982*. CNSC staff's considerations include, but are not limited to, the Indigenous Nations and communities established or potential rights pertaining to lands and waters in relation to the facility and the expected and/or potential impacts of the activities conducted on the site in accordance with a CNSC issued licence.

REGDOC-3.2.2 *Indigenous Engagement*,<sup>51</sup> sets out requirements and guidance for licensees whose proposed projects may raise the Crown's duty to consult. While the CNSC cannot delegate its obligation, it can delegate procedural aspects of the consultation process to licensees, where appropriate. The information collected and measures proposed by licensees to avoid, mitigate, or offset potential adverse impacts from the proposed licence amendment may be used by CNSC staff in meeting its consultation obligations.

### 2.6.1 CNSC Staff Engagement Activities

The following Indigenous Nations and communities may have an interest in the proposed licence amendment to introduce activities associated with the production and possession of Co-60 at the Darlington NGS:

- Indigenous Nations and Communities with established Indigenous and treaty rights to the lands and waters surrounding and inclusive of the Darlington NGS site:
  - Alderville First Nation,
  - Curve Lake First Nation,
  - Hiawatha First Nation,
  - Mississaugas of Scugog Island First Nation,

<sup>51</sup> REGDOC-3.2.2, *Indigenous Engagement*, was published in February 2016, and updated in August 2019

- Chippewas of Rama First Nation, Chippewas of Georgina Island First Nation,
- Beausoleil First Nation.
- Indigenous Nations and Communities with interests in the project and the lands and waters surrounding and inclusive of the Darlington NGS site:
  - Six Nations,
  - Mohawks of the Bay of Quinte First Nation, and
  - Métis Nation of Ontario.

These Indigenous Nations and communities were selected due to the proximity of their communities, treaty areas and territories to the Darlington Nuclear Generating Station, or due to previously expressed interest in being informed of CNSC licensed activities occurring in or proximal to their territories or communities.

The CNSC is committed to ongoing engagement and long-term relationships with Nations and communities with interest in CNSC's activities and processes. This engagement fosters discussion on specific projects and activities of potential interest or concern. The CNSC has signed Terms of Reference for long-term engagement with the Mississaugas of Scugog Island First Nation, Hiawatha First Nation, Curve Lake First Nation, and the Métis Nation of Ontario to facilitate ongoing relationships and meaningful engagement and consultation. The CNSC is open to developing Terms of Reference for long-term engagement with other Indigenous Nations and Communities as appropriate.

In October 2023, CNSC staff sent letters of notification for OPG's licence amendment application to all the Indigenous Nations and communities identified above. These letters provided information regarding the proposed licence amendment application, opportunities to participate in the Commission's hearing process, and information about the CNSC's Participant Funding Program to facilitate participation in the hearing process. CNSC staff also followed-up with each identified Indigenous Nation and communities through email to ensure they had received the letters and to answer any questions about the licence amendment application, regulatory process, or participation in the Commission hearing through a written intervention. All of the identified Indigenous Nations and communities have been encouraged to participate in the regulatory review process and in the Commission hearing through written interventions to advise the Commission directly of any concerns they may have in relation to this licence amendment application.

To date, of the Indigenous Nations and communities CNSC staff sent letters to, the Mississaugas of Scugog Island First Nation (MSIFN) have expressed specific interest in the current license amendment application. MSIFN applied for funding through the CNSC's Participant Funding Program to support their participation in the regulatory review and Commission hearing process (further details in section 2.7.1). CNSC staff recognize that MSIFN has consistently raised concerns regarding the Darlington NGS as a whole and the creation and storage of waste on-site. MSIFN and CNSC staff have had ongoing discussions regarding this concern throughout 2023 and CNSC staff have committed to having a specific meeting with MSIFN regarding OPG's license amendment application in advance of the Commission hearing. This will be an important opportunity to further respond to and address any specific issues and concerns that MSIFN may have with regards to OPG's Co-60 project.

In addition, Curve Lake First Nation (CLFN) and Hiawatha First Nation (HFN) have expressed interest in the ongoing operations and activities at the Darlington NGS, including



more recently OPG's Co-60 project and have expressed interest in further discussions with OPG and CNSC staff regarding this project, as well as other nuclear regulatory processes and projects taking place in Williams Treaties Territory. CNSC staff are committed to continuing to work with HFN and CLFN as part of the Terms of Reference for long-term engagement between CNSC staff and each First Nation to ensure they receive up to date information regarding projects and activities of interest and have their questions and concerns addressed.

## 2.6.2 Licensee Engagement Activities

Based on the information received in the proponent's application, the license amendment is unlikely to cause new adverse impacts to the exercise of potential or established Indigenous rights as the Co-60 design will not change the Darlington NGS site characterization or result in the installation of new facilities at the site. Thus, the duty to consult, and potentially accommodate, would not be triggered by this new licensed activity.

Throughout 2020-2023, OPG conducted numerous engagement activities in relation to this license amendment application, including several meetings with all interested Indigenous Nations and communities, sharing videos and presentations, providing ongoing updates, responding to questions, and discussing key areas of interest and concern with Indigenous Nations and communities. CNSC staff conducted a comprehensive review of OPG's engagement activities to ensure they met the expectations documented in REGDOC-3.2.2. staff recognize that OPG has a well-established engagement and communications program with interested Indigenous Nations and communities. CNSC staff encourage OPG to continue engaging with these Indigenous Nations and communities regarding their facilities and activities including this licence amendment application.

Both OPG and the CNSC are committed to meaningful, ongoing engagement and collaboration with Indigenous Nations and communities that have an interest in CNSC-regulated facilities and activities and encourage OPG to continue to engage with interested Indigenous Nations and communities on this license amendment and other ongoing activities of interest.

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

## 2.7 Other Matters of Regulatory Interest

The following table identifies other matters that are relevant to this CMD. The relevant "other matters" of regulatory interest, indicated by the table below, are discussed throughout Section 2 of this CMD. A brief discussion justifying the omission of a more fulsome discussion is provided for a selection of topics (indicated by an \* in Table 3).

**Table 3: Inventory of Other Matters of Regulatory Interest Included in this CMD**

OTHER MATTERS OF REGULATORY INTEREST		
Area	Relevant to this CMD?	Additional information in section
Participant Funding	Yes	2.7.1
Other Consultation	No	
Cost Recovery	No	
Financial Guarantees	No*	2.5.11
Improvement Plans and Significant Future Activities	No	
Licensee's Public Information Program	No*	2.7.2
Impact Assessment Act	No*	2.4 & 2.5.9
Environmental Protection Review	No*	2.4 & 2.5.9
Nuclear Liability Insurance	No*	2.7.3

### 2.7.1 Participant Funding

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

The deadline for applications was 24 Nov 2023. A Funding Review Committee (FRC), independent from CNSC staff, reviewed the funding applications received, and made recommendations on the allocation of funding to eligible applicants. Based on recommendations from the FRC, the CNSC awarded a total of \$12,000 in funding to the following recipients, who are required to submit a written intervention to the Commission Registry by 08 Mar 2023 for the Commission's consideration:

- Mississaugas of Scugog Island First Nation

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

### 2.7.2 Licensee's Public Information Program

OPG implements a fleet-wide public information and disclosure program that covers activities performed at the Darlington site and meets the requirements of CNSC REGDOC-3.2.1, *Public Information and Disclosure*. The primary goal of the program is to ensure

that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of nuclear facilities, is shared with the public in a format relevant to the audience. The program includes a commitment and protocol for ongoing, timely dissemination of information related to the licensed facility.

As discussed in recent annual Regulatory Oversight Report for Canadian Nuclear Power Generating Sites [24, 25], OPG has adapted its public information and disclosure program to respect current health and safety guidelines, executing both hybrid and in-person program models as appropriate. OPG has continued to offer updates through participation in community meetings and events, webinars, newsletters and social media campaigns, and open houses and station tours.

CNSC staff are satisfied that OPG's public information and disclosure program is sufficient to communicate updates to the public, including local community members and elected officials in the region of Durham of updates pertinent to operations surrounding the production and transportation of Co-60 at Darlington NGS.

### **2.7.3 Nuclear Liability Insurance**

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

National Resources Canada is responsible for assessing the limit of liability for each class of nuclear installation. Darlington NGS is currently assessed at \$1 billion dollars, the maximum limit of liability under the NLCA; therefore, the installation of the Mo-99 IIS will not impact OPG's obligations under the act. OPG is meeting its obligation for nuclear liability coverage under the NLCA.

### 3. Proposed Licensing Changes

#### 3.1 Overview

The changes proposed to be made in the Darlington Power Reactor Operating Licence (PROL) and Licence Conditions Handbook (LCH) support the implementation of a program for Co-60 radionuclide production at Darlington Nuclear Generating Station (NGS). If the licence is amended, the production and possession and other related activities specific to Co-60 will be authorized on all units at Darlington NGS.

The draft of the proposed addition to the LCH is appended within this part of the CMD. The final version, which will be needed before OPG's first Co-60 harvest (~2027), will depend on the finalization of several OPG documents and a revision of the LCH to accommodate unrelated updates to the legacy sections of the LCH. Summary of Licence Documents

Table 4 below provides the references of the current and proposed PROL and LCH. An \* is used to identify the documents that will be reproduced in Part 2 of this CMD.<sup>52</sup> A copy of the current PROL (PROL 13.03/2025) and LCH (LCH-PR-13.03/2023-R005) are available upon request to the Commission Registry. Appendix A to this CMD contains the draft PROL (PROL 13.04/2025).

**Table 4: References of existing and proposed license documents**

Proposed			Current		
Version	Word e-Doc	PDF e-Doc	Version	Word e-Doc	PDF e-Doc
*PROL 13.04/2025	7076591	7076592	*PROL 13.03/2025	6542988	6542989
LCH Section 15.6 – Draft LCH-PR-13.04/2023-R00#	See Section 3.3.1		*LCH-PR-13.03/2023-R005	6668656	6668658

#### 3.2 Licence Changes

The proposed amendment to the Darlington PROL introduces:

- A change to the licence number in Part I) *Licence Number*
- A revised presentation of activities, including the introduction of a new activity (item vi) to Part IV) *Licensed Activities*
- A corresponding licence condition (15.7) to Part VI) *Conditions*

As the results of the amendment, PROL 13.03/2025 will become PROL 13.04/2025, indicating the fourth amendment to the PROL since original issuance in January 2016. Other parts of the PROL remain unchanged unless otherwise suspended, amended, revoked, or replaced.

<sup>52</sup> Only in the final version of the CMD saved in e-Doc 7076596 (PDF)

As OPG is seeking to be authorized to produce multiple radionuclides, CNSC staff are proposing to treat these similar activities as a consolidated integrated licensed activity. The reworked Licensed Activities (i & vi) with Licence Conditions 15.6 (for Mo-99) and 15.7 (for Co-60) will make the production of radionuclides at Darlington NGS a core activity with details pertaining to the specific radionuclides OPG is authorized to produce. CNSC staff's proposed Co-60 specific Licence Condition is presented in Table 5 in section 3.2.2.

### 3.2.1 Licensee Proposed Amendments to Darlington NGS PROL 13.03/2025

OPG's application [1] requested the creation of a new licenced activity to be added to its existing PROL 13.03/2025 for the Darlington NGS. The text proposed by OPG was:

PROL PART	LICENSED ACTIVITIES / LICENCE CONDITION	CURRENT TEXT IN PROL 13.03/2025	OPG REQUESTED ADDITION TO THE PROL
IV	(vii)		possess, transfer, produce, package, manage and store the Cobalt-60 radioisotope

Since submission of it's application [1], and based on discussions with CNSC staff, OPG has updated the request for licence amendment [7] combining the activities associated with the operation of each the Mo-99 IIS / TDS and the Co-60 into a single activity.

PROL PART	LICENSED ACTIVITIES / LICENCE CONDITION	CURRENT TEXT IN PROL 13.03/2025	OPG REQUESTED ADDITION TO THE PROL
IV	(i)	operate the Darlington Nuclear Generating Station which includes 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;	operate the Darlington Nuclear Generating Station and the authorized equipment for the production of equipment of medical radionuclides, which includes 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;
IV	(vi)	possess, transfer, process, package, manage and store Molybdenum-99 radioisotope and its associated decay isotopes.  [Added 2021.10]	possess, transfer, process, package, manage and store nuclear substances that are required for associated with, or arise from the activities associated with, described in operations of Darlington Nuclear Generating Station and activities described in (i) as OPG produces (1) Co-60; and (2) Mo-99 (including its decay isotopes).

### 3.2.2 Proposed Amendments to Darlington NGS PROL 13.03/2025

As reflected in Table 5 below, CNSC staff's recommendation to the Commission for specific text in the PROL introduces the following deviations from OPG's request(s):

- (1) CNSC staff added the verb "use" to the authorized activities associated with nuclear substances that required or associated with [...] operations of Darlington NGS as OPG produces Co-60.
  - a. This is because OPG's detailed design documentation has identified a cobalt-60 based calibration bundle that, at this time, will not be managed under a separate CNSC Nuclear Substance and Radiation Devices Licence
  - b. If any restrictions to the use of the radionuclides OPG produces needs to be imposed in the future, these details can be documented in the LCH.
- (2) CNSC staff removed the verb "process" from the list of proposed activities list.
  - a. This is because OPG will not be doing any processing activities. All "processing" of Co-60 will be performed by a licenced third-party.
  - b. While this does inherently change the licence activities previously associated with the production of Mo-99, this does not reflect an intent change. OPG is not processing Mo-99 on-site. OPG is again utilizing a licenced third-party for processing of Mo-99.
  - c. The word "process" was previously proposed in the context of Mo-99 production in CMD 21-H101 to account for possible actions needed if a capsule of Mo-99 got stuck in the flight-tubing. CNSC staff have since determined that any actions to recover from this scenario can be performed in accordance with OPG's existing processes under the language "use, package, manage, and store." It is not necessary to imply that OPG may be conducting activities normally performed under a Nuclear Substance Processing Facility Operating Licence.
- (3) CNSC staff is also proposing a licence condition in section VI of the PROL, and the corresponding LCH.
  - a. The proposed licence condition is similar to the equivalent Co-60 licence condition currently used in the Pickering PROL (PROL 48.01/2028) and Bruce Power PROL (PROL 18.02/2028)

**Table 5: Proposed Text for Parts IV & VI of PROL 13.04/2025**

PROL PART	LICENSED ACTIVITIES / LICENCE CONDITION	CURRENT TEXT IN PROL 13.03/2025	PROPOSED ADDITION TO THE PROL
IV	(i)	operate the Darlington Nuclear Generating Station which includes 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;	operate the Darlington Nuclear Generating Station, <b>including equipment for the production of radionuclides identified in (vi) and the Darlington Tritium Removal Facility</b> 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;
IV	(vi)	possess, transfer, process, package, manage and store Molybdenum-99 radioisotope and its associated decay isotopes.  [Added 2021.10]	<b>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);</b>
VI	LC 15.7		<b>The licensee shall implement and maintain a Co-60 operations program for the activities described in part IV of the licence.</b>

### 3.2.3 Licence Format

No changes to the licence format are being proposed through this CMD.

### 3.2.4 Licence Period

There is no change requested to the licence period being made through this CMD. The proposed amended PROL is to expire on the same date as the current PROL, that is, November 30, 2025, unless otherwise suspended, amended, revoked, or replaced.

## 3.3 Proposed LCH Section on Co-60

The changes made in the proposed Darlington Power Reactor Operating Licence (PROL) and Licence Conditions Handbook (LCH) support the implementation of a program for Co-60 radionuclide production at Darlington Nuclear Generating Station (NGS). If the licence is amended, the activities specific to Co-60 production will be authorized on all units at Darlington NGS.

The preliminary draft of the proposed addition to the LCH is appended within this part of the CMD. The final version will depend on the finalization of several OPG documents and a revision of the LCH to accommodate unrelated updates to the other sections of the LCH.

As OPG's development of certain details of its Co-60 operations program is still ongoing, this section will contain the expected document titles and IDS of the deliverables that OPG will fulfill under regulatory management commitments.

### 3.3.1 Proposed Draft of LCH Section: 15.7 Cobalt-60 Operations Program

LICENCE CONDITIONS HANDBOOK EXCERPT: SECTION 15.7	
LCH-PR-13.04/2025-R00#	<div style="font-size: 4em; color: #c00000; opacity: 0.5;">DRAFT</div>  <div style="font-size: 6em; color: #c00000; opacity: 0.5;">Section 15.7</div>
ASSOCIATED WITH	
DARLINGTON NUCLEAR GENERATING STATION NUCLEAR POWER REACTOR OPERATING LICENCE	
LICENCE # PROL 13.04/2025	

#### **Licence Condition 15.7:**

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

#### **Preamble:**

This LC provides basis for regulatory oversight of activities associated with the production of Cobalt-60. OPG is authorized to produce Cobalt-60 at Darlington NGS Units 1 to 4. Irradiated AA rods containing Co-60 are packaged in the irradiated fuel bay and shipped off-site to a processing facility. OPG is under contractual obligation to take back the spent Cobalt-60 that has reached the end of its service life. Prior to the spent Co-60 being returned to OPG, it is expected to spend 25-30 years of cooling in the Irradiated Fuel Bay of Bruce B. Following this cool-down period, the spent Cobalt-60 arrives at an OPG licenced waste management facility in form of sealed sources and will be transferred to dry storage.



**Compliance Verification Criteria:**

<b>Licensee Documents that Require Notification of Change</b>		
<b>Document #</b>	<b>Title</b>	<b>Prior Notification</b>
NK38-OM-31935-10001	Cobalt Harvest and Processing system - Table of Contents / Revision History	No
NK38-CTP-31935-10001	CAEPS – Cobalt Processing Instructions	No
NK38-OM-31935-10001 04.03.14	Cobalt Handling	No

When managing Cobalt-60 produced at Darlington NGS Units 1 to 4 OPG shall follow the operating manual NK38-OM-31935-10001 and the relevant associated procedures.

Applicable requirements set out in the Transport Canada *Transportation of Dangerous Goods Regulations* and in the CNSC *Packaging and Transport of Nuclear Substances Regulations* shall be met before transferring Cobalt-60 and shipping it off-site.

Cobalt-60 sealed sources are recorded in the CNSC database (the Sealed Source Tracking System) that tracks the location of each significantly hazardous radioactive source (IAEA Category 1 and 2 sources) in Canada.

The licensee shall submit a report in writing within 48 hours of any receipt of a Cobalt-60 sealed source with an activity equal to, or greater than, 0.3 TBq in accordance with the requirements of REGDOC-3.1.1 (LC 3.3). The report shall be submitted to the CNSC in accordance with standard communication protocols. The report shall include:

- (i) The date of receipt of a transfer,
- (ii) The name of the shipper and licence number,
- (iii) The address of the shipper's authorized location,
- (iv) The nuclear substance,
- (v) Activity (radioactivity) (Bq) per source on the reference date,
- (vi) The reference date,
- (vii) The number of sealed source(s), and
- (viii) The aggregate activity (Bq).

**Guidance:**

This section has no contents.

## 4. Overall Conclusions & Recommendations

### 4.1 Conclusions

OPG's Co-60 project seeks to contribute to the global supply chain of Co-60 and provide a reliable source of Co-60 radionuclides for a wide variety of industries and applications including medical treatments, food & equipment sterilization, and industrial scanning & measuring. The process selected by OPG is very similar to that which is conducted at other CANDU stations in Canada, and the process which OPG has itself been conducting at Pickering NGS since the 1970's.

In the Co-60 supply chain, OPG is responsible for the handling of Co-59 and Co-60 at Darlington NGS. Specifically, OPG will take possession of adjuster absorber rods containing Co-59 (not a nuclear substance), install them into the core during an outage, irradiate them over the course of 3-3.5 years of unit operation, harvest the Co-60 adjuster absorber (AA) rods during an outage, and package the irradiated cobalt into certified shielded Type-B transport containers. OPG is responsible for ensuring the continued safe operations of the Darlington NGS, with or without cobalt AA rods, the conduct of safe harvesting and packaging operations related to the production of Co-60, and for reclaiming the spent cobalt sources. All other aspects of the supply chain will be handled by Nordion, a third-party company holding its own licence for nuclear substance processing and sealed source manufacturing.

Based on CNSC staff's review of the licence amendment application and the supporting technical information (design documentation, safety assessments, and licensing impact assessment) related to the modifications being introduced CNSC staff have determined that:

- OPG has adequate provisions in place to ensure the safe production of Co-60 during normal reactor operations.
- The impact of the new Cobalt Adjuster Element Processing System (CAEPS) equipment, station modifications, and cobalt AA rods to the existing Structures, Systems and Components (SSCs) is negligible.
- The reactivity worth of the in-core cobalt AA rods is neutronically equivalent to the rods currently used, with only slight differences in total reactivity across all sixteen rods in the core, which can be managed by the existing reactor regulating system, and specifically the liquid zone control.
- The operation of Darlington NGS with cobalt AA rods, and the harvesting and packaging of the irradiated cobalt, will not result in significant doses to workers or members of the public, and will not result in significant releases to the environment.
- The existing security and safeguards programs in place are sufficient for the production and inventory control of Co-60, meeting both IAEA and CNSC requirements.
- OPG continues to engage with interested Indigenous Nations and communities on this licence amendment and other ongoing activities of interest.

CNSC staff have determined that operations related to Co-60 operations, including production, possession, handling, and packaging, at Darlington NGS remain within the limits of the established safety case of the nuclear facility and introduces minimal additional risk to the operation of the nuclear facility itself, to the environment, and the

health and safety of persons. Thus, CNSC staff have determined that OPG is qualified produce, possess, transfer, use, package, manage and store Co-60 if the Commission amends the PROL to include the proposed activity and licence condition.

CNSC staff's determinations, conclusions and recommendations are for the Commission's information in support of its decision. CNSC staff have concluded the following with respect to paragraphs 24(4)(a) and (b) of the *Nuclear Safety and Control Act* (NSCA), in that OPG:

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

## 4.2 Recommendations

Based on a comprehensive review and assessment of OPG's application and supporting submissions, CNSC staff recommend the Commission approve OPG's request for licence amendment to conduct activities associated with the production and possession of Co-60, and approve the following changes to the PROL (as presented in section 3 of this CMD):

- Amend Part IV, *Licensed Activities*, of the Darlington PROL, to authorize the licensee to:
  - (i) operate the Darlington Nuclear Generating Station, **including equipment for the production of radionuclides identified in (vi)** and the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter "the nuclear facility"), at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario;
  - (vi) **produce, possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities associated with operations of the Darlington Nuclear Generating station and activities described in (i) as OPG produces: (1) Co-60; and (2) Mo-99 (including its decay isotopes);**
- Amend Part VI, *Licence Conditions*, of the Darlington PROL, adding 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.**

## References

*Referenced documents in this CMD are available upon request, subject to confidentiality considerations.*

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- [2] CNSC, "Record of Decision for Application to Renew the Nuclear Power Reactor Operating Licence for the Darlington Nuclear Generating Station," Date of Decision 2016-03-02. [e-Doc 4817567 (Word), 4920689 (PDF)]
- [3] OPG letter, S. Gregoris to G. Frappier, "Darlington NGS – Letter of Intent for OPG's Initiative to Produce Cobalt-60 at Darlington Nuclear Generating Station," 2020-05-06. [CD# NK38-CORR-00531-21591 P, e-Doc 6291808, 6291809] *Pro B(R)*
- [4] OPG email, C. Axler to A. Mathai, "Darlington NGS – Cobalt-60 Production Modifications Project – Notification of Positioner Installation During DNRU3 ", 2023-01-13. [CD# NK38-CORR-00531-24015, e-Doc 6952233] *Pro B(R)*
- [5] OPG letter, R. Geofroy to A. Mathai, "Darlington NGS – Cobalt-60 Production Modifications Project – Prior Written Notification of Installation of Cobalt-59 Adjuster Rods during DNRU1," 2023-05-01. [CD# NK38-CORR-00531-24559, e-Doc 7054617] *Pro B(R)*
- [6] OPG letter, R. Geofroy to D. Saumure, "Darlington NGS – Supplemental Submission to Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.03/2025 Amendment for Production of the Cobalt-60 Radioisotope," 2023-06-01. [CD# NK38-CORR-00531-24619, e-Doc 7078359] *Public*
- [7] OPG letter, R. Geofroy to M. Bacon-Dussault, "Darlington NGS – Addendum to the Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.03/2025 Amendment for Production of the Cobalt-60 Radioisotope," 2023-12-22. [CD# NK38-CORR-00531-25073 P, e-Doc 7194511, 7194514] *Pro B(R)*
- [8] OPG email, L. Moraru to A. Mathai, "Darlington NGS – Cobalt-60 Production Modifications Project – Written Notification of Cobalt-60 Harvesting Infrastructure Installation in Unit 2 and West Fueling Facility Auxiliary Area," 2024-01-11. [CD# NK38-CORR-00531-25081, e-Doc 7200663] *Pro B(R)*
- [9] OPG letter, R. Geofroy to J. Burta, "Darlington NGS – Cobalt-60 Production Modifications Project – Submission of the Predictive Effects Assessment," 2022-04-27. [CD# NK38-CORR-00531-23353 P, e-Doc 6787034] *Pro B(R)*
- [10] OPG letter, S. Gregoris to K. Hazelton, "Darlington NGS – Cobalt-60 Production Modifications Project – Submission of Preliminary Engineering Design Documents (D02-01 and D02-02)," 2021-03-05. [CD# NK38-CORR-00531-22406 P, e-Doc 6507113] *Pro B(R)*
- [11] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Cobalt-60 Production Modifications Project - Submission of Reactor Safety Documents (SA-01)," 2020-09-18. [CD# NK38-CORR-00531-21945, e-Doc 6382737] *Pro B(R)*
- [12] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Cobalt-60 Production Modifications Project - Submission of Preliminary Engineering Design Documents (D01-01 and D01-02)," 2020-09-03. [CD# NK38-CORR-00531-21872 P, e-Doc 6373527] *Pro B(R)*
- [13] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS - Molybdenum-99: Complementary Information to the Requeste for Amendment to the Darlington Nuclear Generation Station Reactor Operating Licence 13.02/2025," 2021-07-23. [CD# NK38-CORR-00531-22562, e-Doc 6612565, 6626688 (Redacted), 6612564] *Public*

- [14] CNSC, "Record of Decision for Application by Ontario Power Generation Inc. for the Application to Amend the Power Reactor Operating Licence PROL 13.02/2025 to Authorize the Production of Molybdenum-99 at the Darlington Nuclear Generating Station," Date of Decision 2021-10-26. [e-Doc 6667685 (Word), 6624873 (PDF)]
- [15] OPG email, L. Moraru to A. Mathai, "Darlington NGS – Co-60 Production Modifications Project – Notification of Due Date Extension for Submission of Cobalt-60 Production System Operating Manual and Procedure to CNSC Staff," 2023-12-07. [CD# NK38-CORR-00531-25068, e-Doc 7183188] *Pro B(R)*
- [16] OPG letter, R. Geofroy to J. Burta, "Darlington NGS – Cobalt-60 Production Modifications Project – Response to CNSC Staff's Review of the Detailed Engineering Design Documents (D03)," 2022-10-31. [CD# NK38-CORR-00531-23780, e-Doc 6904233]
- [17] OPG letter, R. Geofroy to J. Burta, "Darlington NGS – Cobalt-60 Production Modifications Project – Submission of D03-01 and the Human Factors Verification and Validation Plan," 2022-01-12. [CD# NK38-CORR-00531-23083, e-Doc 6718091, 6718089] *Pro B(R)*
- [18] OPG letter, R. Geofroy to J. Burta, "Cobalt-60 Production Modifications Project – Submission of the Evaluation of Limiting Safety Cases for Guide Tube Extension / Cobalt Adapter Thermal Analysis," 2022-08-26. [CD# NK38-CORR-00531-23649, e-Doc 6869952]
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- [20] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Cobalt-60 Production Modifications Project – Submission of Detailed Engineering Design Documents (D03)," 2021-11-12. [CD# NK38-CORR-00531-22945 P, e-Doc 6680085] *Pro B(R)*
- [21] OPG letter, R. Geofroy to A. Mathai, "Darlington NGS – Response to CNSC Staff Request for New Regulatory Commitments Regarding the Co-60 at DNGS Impacts to CSA N285.5 Periodic Inspection Plan," 2023-11-12. [CD# NK38-CORR-00531-25071, e-Doc 7184632] *Pro B(R)*
- [22] OPG letter, R. Geofroy to A. Mathai, "Darlington NGS – Cobalt-60 Production Modifications Project: Response to CNSC Staff Review and Summary of Pre-Application MDR Updates," 2023-12-14. [CD# NK38-CORR-00531-25076, e-Doc 7186955] *Pro B(R)*
- [23] OPG email, A. Palladino to J. Burta, "Darlington NGS - CNSC Staff's Notification of Document Changes: Hazard Analysis for CAEPS Flask and Nordion Shipping Flask Transportation Activities at the WFFAA, NK38-REP-31935-10035 R001," 2022-03-28. [CD# NK38-CORR-00531-23372, e-Doc 6765620, 6765617] *Pro B(R)*
- [24] CNSC, "Regulatory Oversight Report for Canadian Nuclear Power Generating Sites for 2021," in "Annual Program Report," 22-M34, 3 November 2022. [e-Doc 6799928, 6835691] *Public*
- [25] CNSC, "Regulatory Oversight Report for Canadian Nuclear Power Generating Sites for 2022," in "Annual Program Report," 23-M36, 13-14 December 2023. [e-Doc 7044732, 7118809] *Public*

## Acronyms

### Abbreviations Used for Indigenous Nations and Communities

CLFN	Curve Lake First Nation
HFN	Hiawatha First Nation
MSIFN	Mississaugas of Scugog Island First Nation

### Technical Abbreviations

AA	Adjuster absorber
AFS	Available for Service
ALARA	As low as reasonably achievable
AMP	Administrative Monetary Penalty
ANO	Authorized Nuclear Operators
CANDU	Canadian Deuterium Uranium
CINFR	<i>Class I Nuclear Facilities Regulations</i>
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
Co-59	Natural cobalt
Co-60	Cobalt- 60
COG	CANDU Owners Group
CSA	Canadian Standards Association
CVC	Compliance Verification Criteria
DIV	Design Information Verification
DPRR	Directorate of Power Reactor Regulation

DRL	Derived Released Limit
EC	Engineering Change
ECC	Engineering Change Control
EFPY	Effective Full Power Years
EPC	Engineering Procurement and Construction
EPR	Environmental Protection Review
EQ	Environmental Qualification
ERA	Environmental Risk Assessment
FAAGM	fixed area alarming gamma meter
FRC	Funding Review Committee
GNSCR	<i>General Nuclear Safety and Control Regulations</i>
GSS	Guaranteed Shutdown State
HFEP	Human Factors Engineering Program Plan
HFESR	Human Factors Engineering Summary Report
HFVVP	Human Factors Verification and Validation Plan
IAA	Impact Assessment Act
IAEA	International Atomic Energy Agency
IIS	Isotope Irradiation System
LCH	Licence Conditions Handbook
MEC	Master Engineering Change
Mo-98	Molybdenum-98
Mo-99	Molybdenum-99
MSC	Minimum Shift Complement

NGS	Nuclear Generating Station
NLCA	<i>Nuclear Liability and Compensation Act</i>
NLCR	<i>Nuclear Liability and Compensation Regulations</i>
NNIECR	<i>Nuclear Non-Proliferation Import and Export Control Regulations</i>
NPP	Nuclear Power Plants
NSCA	<i>Nuclear Safety and Control Act</i>
NSPFOL	Nuclear Substance Processing Facility Operating Licence
NSR	<i>Nuclear Security Regulations</i>
NSRDL	Nuclear Substance and Radiation Devices Licence
NSRDR	<i>Nuclear Substances and Radiation Devices Regulations</i>
OP&P	Operating Policies & Principles
OPEX	Operating Experience
OPG	Ontario Power Generation
OSR	Operational Safety Requirement
PDP	Preliminary Decommissioning Plan
PEA	Predictive Effects Assessment
PFP	Participant Funding Program
PIP	Periodic Inspection Program
PPE	Personal Protective Equipment
PROL	Power Reactor Operating Licence
PSA	Probabilistic Safety Assessment
PTNSR	<i>Packaging and Transport of Nuclear Substances Regulations</i>
REGM	Regulatory Management Action Request



RHP	Regulatory Hold Point
RMD	Reactivity Mechanisms Deck
RP	Radiation Protection
RPR	<i>Radiation Protection Regulations</i>
RRS	Reactor Regulating System
SAT	Systematic Approach to Training
SCA	Safety Control Area
SCR	Station Condition Record
SOE	Safe Operating Envelope
SS	Stainless-steel
SSC	Structures, Systems, and Components
TCD	Target Completion Date
TDGR	<i>Transport of Dangerous Goods Regulations</i>
TDS	Target Delivery System
TNA	Training Needs Analysis
WCHB	Wet Cask Handling Bay
WFFAA	West Fueling Facilities Auxiliary Area

## APPENDIX A: PROPOSED LICENCE



## NUCLEAR POWER REACTOR OPERATING LICENCE

### DARLINGTON NUCLEAR GENERATING STATION

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- I) LICENCE NUMBER:** **PROL 13.04/2025**
- II) LICENSEE:** Pursuant to section 24 of the [Nuclear Safety and Control Act](#) this licence is issued to:
- Ontario Power Generation Inc**  
**700 University Avenue**  
**Toronto, Ontario**  
**M5G 1X6**
- III) LICENCE PERIOD:** This licence is valid from January 1, 2016 to November 30, 2025, unless suspended, amended, revoked or replaced.
- IV) LICENSED ACTIVITIES:**
- This licence authorizes the licensee to:
- (i) operate the Darlington Nuclear Generating Station, including equipment for the production of radionuclides identified in (vi) and the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter “the nuclear facility”), at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario; [Amended 2024.##]
  - (ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i);
  - (iii) import and export nuclear substances, except controlled nuclear substances, that are required for, associated with, or arise from the activities described in (i);
  - (iv) possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the activities described in (i);
  - (v) possess, transfer, process, package, manage and store the nuclear substances associated with the operation of the Darlington Tritium Removal Facility;
  - (vi) produce, possess, transfer, use, package, manage and store nuclear substances that are required for, associated with, or arise from the activities associated with operations of the Darlington Nuclear Generating station and activities described in (i) associated with production of: (1) Co-60; and (2) Mo-99 (including its decay radionuclides); [Amended 2024.##]
- V) EXPLANATORY NOTES:**
- (i) Nothing in this licence shall be construed to authorize non-compliance with any other applicable legal obligation or restriction.

- (ii) Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the [Nuclear Safety and Control Act](#) and associated Regulations.
- (iii) The Darlington NGS Licence Conditions Handbook (LCH) provides compliance verification criteria including the Canadian standards and regulatory documents used to verify compliance with the conditions in the licence. The LCH also provides information regarding delegation of authority, applicable versions of documents and non-mandatory recommendations and guidance on how to achieve compliance.

## VI) **CONDITIONS:**

### G. **General**

- G.1 The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:
- (i) the regulatory requirements set out in the applicable laws and regulations
  - (ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence
  - (iii) the safety and control measures described in the licence application and the documents needed to support that licence application;
- unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC, hereinafter "the Commission").
- G.2 The licensee shall give written notification of changes to the facility or its operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis.
- G.3 The licensee shall control the use and occupation of any land within the exclusion zone.
- G.4 The licensee shall provide, at the nuclear facility and at no expense to the Commission, suitable office space for employees of the Commission who customarily carry out their functions on the premises of that nuclear facility (onsite Commission staff).
- G.5 The licensee shall maintain a financial guarantee for decommissioning that is acceptable to the Commission.
- G.6 The licensee shall implement and maintain a public information and disclosure program.

### 1. **Management System**

- 1.1 The licensee shall implement and maintain a management system.

### 2. **Human Performance Management**

- 2.1 The licensee shall implement and maintain a human performance program.
- 2.2 The licensee shall implement and maintain the minimum shift complement and control room staffing for the nuclear facility.
- 2.3 The licensee shall implement and maintain training programs for workers. The certification process and supporting examinations and tests shall be conducted in accordance with CNSC regulatory document [REGDOC-2.2.3, PERSONNEL CERTIFICATION, VOLUME III: CERTIFICATION OF PERSONS WORKING AT NUCLEAR POWER PLANTS](#).

[Amended  
2020.04]

Persons appointed to the following positions require certification:

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

### **3. Operating Performance**

- 3.1 The licensee shall implement and maintain an operations program, which includes a set of operating limits.
- 3.2 The licensee shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or prior written consent of a person authorized by the Commission.
- 3.3 The licensee shall notify and report in accordance with CNSC regulatory document [REGDOC-3.1.1 REPORTING REQUIREMENTS: NUCLEAR POWER PLANTS](#).
- 3.4 The licensee shall implement a periodic safety review in support of its subsequent power reactor operating licence application.

### **4. Safety Analysis**

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

### **5. Physical Design**

- 5.1 The licensee shall implement and maintain a design program.
- 5.2 The licensee shall implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency.
- 5.3 The licensee shall implement and maintain an equipment and structure qualification program.

### **6. Fitness for Service**

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

### **7. Radiation Protection**

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

### **8. Conventional Health and Safety**

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

### **9. Environmental Protection**

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

### **10. Emergency Management and Fire Protection**

- 10.1 The licensee shall implement and maintain an emergency preparedness program.
- 10.2 The licensee shall implement and maintain a fire protection program.

**11. Waste Management**

- 11.1 The licensee shall implement and maintain a waste management program.
- 11.2 The licensee shall implement and maintain a decommissioning strategy.

**12. Security**

- 12.1 The licensee shall implement and maintain a security program.

**13. Safeguards and Non-Proliferation**

- 13.1 The licensee shall implement and maintain a safeguards program.

**14. Packaging and Transport**

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

**15. Nuclear Facility-Specific**

- 15.1 The licensee shall implement and maintain an operations program for the Tritium Removal Facility, which includes a set of operating limits.
- 15.2 The licensee shall implement a return to service plan for refurbishment.
- 15.3 The licensee shall implement the Integrated Implementation Plan.
- 15.4 The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.
- 15.5 The licensee shall limit the activities of import and export of nuclear substances to those occurring as contaminants in laundry, packaging, shielding or equipment. [Added 2017.10]
- 15.6 The licensee shall implement and maintain an operations program for the production of Molybdenum-99 and its associated decay isotopes. The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points. [Added 2021.10]
- 15.7 The licensee shall implement and maintain a Co-60 operations program for the activities described in part IV of the licence. [Added 2024.##]

SIGNED at OTTAWA \_\_\_\_\_

XXXXXXXXXXXXXXXX

**President  
CANADIAN NUCLEAR SAFETY COMMISSION**