Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

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**ORIGINAL/ORIGINAL**

**CMD: 21-H107**

**Date signed/Signé le : 23 JUNE 2021**

A Licence Amendment

Une modification de permis

# Ontario Power Generation Inc.

# Darlington Nuclear Generating Station

# Ontario Power Generation Inc.

# Centrale nucléaire de Darlington

Hearing in writing based solely on written submissions

Audience fondée uniquement sur des mémoires

Scheduled for:

August 2021

Prévue pour :

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Submitted by:

CNSC Staff

Soumise par :

Le personnel de la CCSN

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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 molybdenum-99 (Mo-99) radioisotope at the Darlington Nuclear Generating Station (NGS)

CNSC staff recommend that the Commission:

- Amend the PROL to allow the production of Mo-99 radioisotopes at Darlington NGS
- Accept the process as set out in Section 4.5 of this CMD for the removal of two regulatory hold points and delegation of authority

The following items are attached:

- The proposed PROL 13.03/2025
- The proposed Licence Conditions Handbook section 15.6 (draft)
- The current PROL 13.02/2025
- The current Licence Conditions Handbook

**Résumé**

Le présent CMD présente de l'information sur un ensemble de questions d'ordre réglementaire concernant Ontario Power Generation Inc.:

- Modification du permis d'exploitation d'un réacteur nucléaire de puissance (PERP) pour la production du radio-isotopes de molybdène-99 à la centrale nucléaire de Darlington

La Commission pourrait considérer prendre les mesures suivantes :

- Modifier le PERP pour la production de Mo-99 à la centrale nucléaire de Darlington
- Accepter le processus pour la levée de deux point d'arrêt réglementaires décrits dans la section 4.5 du présent CMD et déléguer l'autorité

Les pièces suivantes sont jointes :

- Permis proposé – PERP 13.03/2025
- Manuel des conditions de permis (preposé) – Section 15.6
- Permis actuel – PERP 13.02/2025
- Manual des conditions de permis actuel

**Signed/signé le**

23 June 2021

Digitally signed by Viktorov, Alexandre
DN: C=CA, O=GC, OU=CNSC-CCSN, CN="Viktorov, Alexandre"
Reason: I am approving this document
Location: your signing location here
Date: 2021-06-23 08:40:12
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Alexandre Viktorov, Ph. D.

**Director General**

Directorate of Power Reactor Regulation

**Directeur général**

Direction de la réglementation des centrales nucléaires

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# Summary of CMD

In May 2018, Ontario Power Generation (OPG) notified CNSC staff of its intention to apply for a licence amendment to allow it to produce the radioisotope molybdenum-99 (Mo-99) from neutron irradiation of natural molybdenum (Mo-98) in reactor units at Darlington Nuclear Generating Station (NGS). The discipline of nuclear medicine uses radionuclides in diagnostic imaging. The continuous online production and retrieval of Mo-99 in a CANDU reactor from natural molybdenum is considered a *first-of-a-kind* initiative in the development of a Canadian supply chain that would be able to provide a constant and reliable supply of Mo-99 for diagnostic nuclear medicine. OPG will package the retrieved Mo-99 so that it may be shipped by an external third party to a processing facility which will produce metastable technetium-$99^m$ (Tc-$99^m$) generators for diagnostic nuclear medicine.

OPG has selected Unit 2 at Darlington NGS as the location for the installation and operation of the first Mo-99 Isotope Irradiation System (IIS). The current licensed activities under Part IV of the Darlington Power Reactor Operator Licence (PROL) 13.02/2025 do not allow for the deliberate production of any medical isotopes at Darlington NGS. In December 2018, OPG submitted a request to amend the PROL to allow OPG to possess, transfer, produce, package, manage, and store Mo-99 and its associated decay products at Darlington NGS.

In the proposed supply chain for Mo-99, OPG would be responsible for the irradiation of natural molybdenum. All other aspects of the overall process would be handled by third parties external to OPG and are thus out of scope in this license amendment request. Despite being out of scope to the current licensing process, the following aspects of the supply chain also require a valid CNSC licence, obtained from a distinct CNSC licensing process:

- Certification of Type-B package to be used for off-site transportation of Mo-99
- Radioisotope processing and disposal of associated radioactive wastes
- Manufacturing, use, and disposal of Tc-$99^m$ generators

To deliver the natural molybdenum into the reactor core for irradiation and recover it after irradiation, OPG's Mo-99 IIS would utilize a mechanical elevator and multi-fluid target transport system to propel molybdenum to and from the reactor. After irradiation of the molybdenum, a worker would use the Mo-99 IIS to transfer the targets into a Type-B transport flask, which would then be shipped offsite to an external third party (BWXT) for processing.

CNSC staff reviewed the licence amendment application, and the supporting licensing information, design documentation, and safety analyses of the Mo-99 IIS and the 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 Mo-99. As a result, the production of Mo-99 would pose no substantive risk to the operation of the nuclear facility itself. The installation and operation of the Mo-99 IIS would not result in significant doses to workers or members of the public. Further, the emissions for Mo-99 production are expected to be minimal compared to overall station emissions and well within the release limits established in its environmental protection program. In addition, operation of the Mo-99 IIS would have a negligible impact on existing reactor operations. Lastly, the existing security and safeguards program in place is sufficient for accommodating radioisotope production. OPG also continues to engage with interested Indigenous and First Nations groups on this licence amendment and other ongoing activities of interest.

CNSC staff have reviewed OPG's safety case in support of the licence amendment; however, not all project documentation related to installation and commissioning has been completed. Consistent

with Licence Condition G.1, CNSC staff note that outstanding documentation produced by OPG preparing for installation and commissioning of a Mo-99 IIS on Darlington NGS Unit 2 will be the subject to ongoing regulatory oversight, including compliance verification activities. CNSC staff propose using Regulatory Hold Points (RHPs) authorized under the proposed Licence Condition 15.6, and OPG's established Regulatory Action Management process to verify OPG's operational readiness and continued safe operations of the Darlington NGS.

CNSC staff are issuing their recommendations to the Commission, following a comprehensive review of OPG's application and supporting technical information. As a result of this review, summarized in this CMD, CNSC staff have concluded that OPG is qualified to carry out the proposed activity (namely the production of Mo-99), and that OPG would make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed. Therefore, CNSC staff recommend that the Commission accept OPG's licence amendment request, specifically by:

- Approving CNSC staff's recommendations for regulatory hold points and delegation of authority
- Adding a new activity (vi) to part IV of the Darlington NGS PROL authorizing OPG to possess, transfer, produce, package, manage, and store Mo-99, and its associated decay isotopes
- Adding a new licence condition (15.6) to part VI of the Darlington NGS PROL to manage the proposed activity and remove regulatory hold points

# CMD Organization

This Commission Member Document (CMD) is presented in two parts.

Part One includes:

- An overview of the matter being presented
- A summary of CNSC staff's review of the Mo-99 design and safety analyses
- A discussion about other matters of regulatory interest
- Overall conclusions and recommendations
- Appendix A – SCA framework
- Appendix B – SCA review
- Appendix C – List of Acronyms

Part Two provides all available information pertaining directly to the current and proposed licence. Specifically, part two of this CMD contains:

- A description of all proposed changes to the existing licence
- The proposed Mo-99 related section of the licence conditions handbook
- An appended PDF of the proposed licence
- An appended PDF of the current licence
- An appended PDF of the current licence conditions handbook

# PART ONE

# 1. Overview

## 1.1 Background & Purpose

Ontario Power Generation Inc. (OPG), in partnership with BWX Technologies Inc. (BWXT), has chosen Darlington Nuclear Generating Station (NGS) Unit 2 as the location for the installation and operation of an isotope irradiation system (IIS) to irradiate natural molybdenum (Mo-98) to produce Mo-99 [1]. The Mo-99 produced by OPG will be used to produce technetium-99$^{m}$ (Tc-99$^{m}$) generators for the discipline of nuclear medicine to facilitate diagnostic imaging. As the parent isotope of Tc-99$^{m}$, one of the most prevalently used diagnostic imaging agents used in nuclear medicine, Mo-99 is an essential radionuclide in the nuclear medicine supply chain.

The continuous production of Mo-99 in a CANDU reactor from natural molybdenum is considered a first-of-a-kind innovative solution leading to a source of Mo-99 radionuclides that will be able to provide a constant and reliable supply of Mo-99, and thus Tc-99$^{m}$ for diagnostic nuclear medicine.

Canada's previous production methods of Mo-99 required (highly) enriched U-235 (HEU) targets which were irradiated in the National Research Universal (NRU) reactor located in Chalk River, Ontario. HEU is subject to international safeguards and when irradiated, results in long-lived nuclear waste and fissile hazards. OPG and BWXT's selected process to produce Mo-99 through neutron capture of natural molybdenum targets reduces concerns associated with nuclear waste and proliferation.

### 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 Darlington NGS consists of four 881 megawatt CANDU reactors which came into service between 1990 and 1993. Unit 2 began a refurbishment project in October 2016, and returned to service in June of 2020. Refurbishment is a multi-year program to replace life-limiting components such as fuel channels, and to make safety improvements to the plant, programs, and processes.

### 1.1.2 Mo-98 – Mo-99 – Tc-99$^{m}$ Generator Supply Chain

In the medical radioisotope supply chain, OPG will only be responsible for the irradiation of natural molybdenum and packaging of irradiated molybdenum into the approved Type-B shielded transport container. Upstream, BWXT will be responsible for procuring a stable supply of natural molybdenum of suitable purity, target manufacturing, and nuclear substance inventory management and tracking. All other aspects of the supply chain downstream of OPG's production of Mo-99 (transport, radioisotope processing, generator manufacturing, shipping, use, and disposal) will be handled by qualified parties with the necessary CNSC nuclear facility and nuclear substances & radiation devices (NSRD) licences. In particular, BWXT-Medical and the hospital end users will be responsible for all wastes associated with the processing and use of Mo-99 and Tc-99$^{m}$.

All activities pertaining to the production, possession, transportation, management, and processing of Mo-99 and its decay isotopes will be conducted in Ontario by licensees, holding the appropriate federal licenses, complying with, but not necessarily limited to:

- CNSC's *Class I Nuclear Facilities Regulations* (CINFR) [SOR/2000-204]
- 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/2001-286]

### 1.1.3 Contributing Organizations (Vendors and Processing Facility)

OPG is utilizing several experienced vendors to provide services in support of the design, safety case, environmental impact gap assessment, construction, and installation of the Mo-99 IIS. OPG has demonstrated through larger projects (such as the refurbishment of Unit 2) that it is able to maintain oversight of its contractors. CNSC staff have verified OPG's contractor management abilities through compliance verification activities such as inspections. The roles and responsibilities of each vendor are summarized below:

1) BWXT-Nuclear Energy Company (NEC) – Peterborough Ontario
   - Designed the Mo-99 IIS
   - Manufactured the unique Mo-99 IIS components (*i.e.* target elevators, airlock, diverters, new target loader and flask loader)
   - Will perform Factory Acceptance Testing (FAT)
   - Will assemble the target capsules with natural molybdenum (note: the zirconium capsule sheath will be manufactured at a BWXT facility in Arnprior, ON)
   - Will provide quality control of targets

2) BWXT-Canada Ltd. – Cambridge, Ontario
   - Engineer Procure Construct (EPC) Contractor for the Mo-99 IIS project

3) Kinectrics – Toronto, Ontario
   - Prepared the safety analysis and assessments studying the impact the Mo-99 IIS will have on continued safe reactor operation

4) Ecometrix – Mississauga, Ontario
   - Prepared the Predictive Effects Assessments [2, 3] to determine the environmental impact of the Mo-99 IIS

In addition to the 4 vendors described above, OPG will be engaging with:

5) BWXT-Medical [formerly BWXT-ITG (Isotope Technologies Group)] – Kanata, Ontario
   - Is responsible for obtaining transportation packaging certification through a separate CNSC licensing process
   - Is responsible for shipping and is the primary point of contact in the event of a transportation accident

- Owns and operates the processing facility, which is also undergoing a parallel CNSC licensing process
- Will process the solid Mo-99 and produce generators that will convert Mo-99 into Tc-99$^{m}$ for distribution to, and use in diagnostic nuclear medicine

As BWXT-NEC and BWXT-Canada are contracted vendors, they do not need to hold a CNSC licence to provide the scope of services identified above to OPG for the production of Mo-99. However, as BWXT-Medical will be conducting the activities associated with processing the Mo-99 and manufacturing Tc-99$^{m}$ generators, BWXT-Medical will require, and is in the process of obtaining, a CNSC nuclear substances processing facility licence (NSPFL).

During installation, commissioning, and operation of the Mo-99 IIS, OPG, as the licence holder, has the ultimate responsibility for ensuring the safe production of Mo-99 and the continued safe operations of the Darlington NGS.

The Nuclear Medicine Production Facility where BWXT-Medical proposes to process the Mo-99, has historically been used to process Mo-99 from highly enriched uranium targets. In the new process the irradiated targets will be transported, in Type-B transportation flasks supplied by BWXT-Medical, to the Nuclear Medicine Production Facility for processing.

BWXT-Medical proposed in its licence application to manufacture nuclear substances in excess of 1E+15 Bq/year. BWXT-Medical Ltd's licence application hearing is scheduled for June 10-11 2021. OPG will not send irradiated targets to BWXT-Medical unless the Commission approves BWXT-Medical's application.

### 1.1.4 Licence Amendment Application & Project Timelines

In December 2018, OPG submitted to the CNSC, an application [4] requesting an amendment of its Darlington Power Reactor Operating Licence (PROL) to authorize the production and possession of Mo-99 radioisotope. In February 2021, OPG provided an application addendum [5] focusing on the licensing impacts of the Mo-99 IIS on existing programs and procedures in the Licence Conditions Handbook (LCH). In support of the application, OPG submitted:

- A comprehensive suite of safety analyses
- Results of engineering assessments
- Design documentation
- Requests for code classification
- Notifications of permanent plant modifications

CNSC staff reviewed OPG's submissions and provided formal letters containing CNSC staff's observations and requests for clarifications, during the detailed design phase of the project, to verify whether the Mo-99 IIS would meet existing regulatory requirements and expectations. The review clarified OPG's process and helped CNSC staff to identify whether there were any barriers to the installation and operation of a Mo-99 IIS at Darlington NGS.

It should be noted that OPG's original intention was to host the first Mo-99 IIS at Unit 4; however, in June 2020, OPG notified the CNSC that circumstances had necessitated a change and OPG would be pursuing a Mo-99 IIS at Darlington NGS Unit 2 [1]. Given the

progress already made, and the similarities between Units 2 and 4, OPG elected to complete the submission of the final detailed design package [6] and integrated safety and operational assessment [7] for Unit 4. OPG completed a gap assessment between Unit 2 and Unit 4 to identify any required changes to the design and design documentation [8]. OPG also performed a gap assessment against the suite of safety analyses specific to Unit 4 that were submitted to CNSC staff, and identified the need to revise five of the safety assessments [9]. Once the final Unit 2 specific design documentation [10] and safety analyses [11] were complete, CNSC staff reviewed the applicable submissions.

It is OPG's intent to start the installation of Mo-99 non-reactor system equipment in the second half of 2021, as these components will not affect the licensing basis or the existing safety case [12].

Pending authorization from the Commission or a person authorized by the Commission, OPG expects to be ready to enter an outage and install the Mo-99 IIS on Unit 2 within the first quarter of 2022. If the Commission accepts CNSC staff's recommendations and amends OPG's PROL to authorize the production of Mo-99, OPG intends to commence production of Mo-99 in the second half of 2022.

The proposed licence amendment would incorporate into the licensing basis for Darlington NGS, the activities associated with the installation and operation of a Mo-99 IIS to produce and package Mo-99. CNSC staff's recommendations are based off the review of OPG's safety case for the installation and operation of a Mo-99 IIS in Unit 2 at Darlington NGS. As such, the Darlington LCH will limit the units OPG is authorized to install and operate a Mo-99 IIS at Darlington NGS to those with a current safety case developed in accordance with OPG's Engineering Change Control (ECC) process. To ensure that installation and operation of a Mo-99 IIS on future units remain in accordance with the amended licensing basis, OPG will be required to submit to CNSC staff: (1) a formal request to install and operate an additional Mo-99 IIS in accordance with licence condition G.1 and (2) the relevant safety case, design documentation, and licensing impact assessments demonstrating that installation of an additional Mo-99 IIS at another unit will not introduce additional risk to the operation of Darlington NGS. If CNSC staff conclude that the introduction of a Mo-99 IIS on additional units at Darlington NGS would be outside the existing licensing basis, then CNSC staff would refer the matter to the Commission for a decision.

## 1.2 Highlights

OPG's current Darlington PROL does not allow for the production or possession of Mo-99 which does not arise from operation of Darlington NGS. To produce and possess Mo-99 and its decay radioisotopes, OPG submitted a request to the Commission to amend the PROL. The Mo-99 IIS is a custom system designed to irradiate high purity molybdenum metal (Mo-98) in the Unit 2 CANDU reactor at Darlington NGS. The Mo-98 is enclosed in special cylindrical zirconium capsules designed to be transported through the shielded flight tubes of the Mo-99 IIS. These zirconium capsules containing Mo-98 are referred to as *targets*.

The Mo-99 IIS will modify four (4) out-of-service adjuster rod ports that were deemed not to be needed early in the operation of Darlington NGS. During an outage, OPG will remove the adjuster rod assemblies from the reactivity mechanism deck (RMD) and install target elevators and flight tubes. Once installed, the Mo-99 IIS will form part of the reactor containment boundary – relying on redundant, interlocked containment valves to ensure

the containment boundary is maintained at all times. The system uses pneumatic propulsion, supplied by station instrument air, for target propulsion outside of containment – and hydraulic propulsion, supplied by moderator grade heavy water ($D_2O$), for target propulsion inside containment. For insertion and retrieval of molybdenum targets inside the reactor core, the system uses an instrumented winch mechanism.

Once the irradiation period has been completed, targets will be harvested and transferred to a certified Type-B Transport Container to enable the Mo-99 to be shipped off-site to BWXT-Medical for processing.

Based on CNSC staff's review conducted, CNSC staff have not identified any barriers to the installation, commissioning, and operation of the Mo-99 IIS in Darlington NGS Unit 2; however, several outputs of OPG's ECC process have not been reviewed by CNSC staff as they can only be produced closer to their associated installation or commissioning stages. For example, OPG will complete detailed installation plans, commissioning plans, and training materials after all necessary pre-requisite work has been completed and approved in accordance with its ECC process.

To verify that design and safety analyses requirements have been met through commissioning test results, CNSC staff will perform compliance verification assessments on OPG's factory acceptance testing and final commissioning reports. Additionally, CNSC staff will verify any outstanding matters that have been identified, or will be raised, by OPG (such as document updates, additional analyses work, training requirements, installation plans, details of commissioning activities, etc.).

To facilitate these compliance reviews, CNSC staff have proposed that the Commission establish two regulatory hold points and a delegation of authority for their removal. CNSC staff are proposing regulatory hold points which must be released: (1) prior to commencing installation of components in the reactor or affecting the containment boundary ; and (2) prior to start of the on-power commissioning program of the Mo-99 IIS. Once established, the proposed regulatory hold points would allow CNSC staff to confirm the operational readiness of OPG to install and commission the Mo-99 IIS ahead of the initial operation for the commercial production of Mo-99.

CNSC staff are recommending the Commission approve the process defined in Section 4.5 for the release of the proposed hold points through a delegation of authority. If the Commission approves CNSC staff's recommendations for the use of regulatory hold points, OPG will not be allowed to commence installation or commissioning of the Mo-99 IIS if it cannot meet the pre-requisites for the release of the hold point. CNSC staff will also perform compliance verification activities to confirm that the identified actions have been completed.

## 1.3 Overall Conclusions

In the Mo-99 IIS supply chain, OPG is responsible for the handling of Mo-98 and Mo-99 at Darlington NGS. Specifically, OPG will take possession of magazines of Mo-98 (not a nuclear substance), provide irradiation services to produce Mo-99, and package the irradiated targets into certified shielded Type-B transport containers. OPG is responsible for ensuring the continued safe operations of the Darlington NGS, including the safe operation of the Mo-99 IIS. All other aspects of the supply chain will be handled by an external third party company holding its own CNSC nuclear substances processing facility

licence for processing and Tc-99$^{m}$ generator manufacturing (pending completion of its own licensing process).

Although numerous system are being impacted by the installation of the Mo-99 IIS, CNSC staff have determined that the operation of the Mo-99 IIS poses minimal additional risk to the operation of the nuclear facility itself, and that Mo-99 will be produced within the existing safe operating envelope (SOE) of the nuclear facility. Based on CNSC staff's review of the licence amendment application and the Mo-99 IIS supporting technical information (design documentation, safety assessments, and licensing impact assessment) CNSC staff have determined that:

- The impact of the Mo-99 IIS to the existing Structures, Systems and Components (SSCs) is negligible
- The reactivity worth of in-core components associated with the Mo-99 IIS and the targets is insignificant compared to the total reactivity worth of the reactor core.
- Reactivity changes introduced by seeding and harvesting Mo-99 targets in the elevator baskets remains within the capabilities of the Reactor Regulating System (RRS).
- The impact of the Mo-99 IIS on Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) is also negligible.
- OPG has adequate provisions in place to ensure the safe production of Mo-99.
- The installation and operation of the Mo-99 IIS 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 program in place is sufficient for the production of Mo-99.
- OPG continues to engage with interested Indigenous groups on this licence amendment and other ongoing activities of interest.
- OPG will continue to protect the health and safety of the public, as well as the environment.

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

(b) Will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

## 1.4 Overall Recommendations

Due to the evolving and sequential nature of the design process for the Mo-99 IIS project, a number of documents (such as the installation and commissioning documentation (plans and specifications), operating manual, training materials, associated processes documents, and operating procedures, etc.) can only be finalized closer to the commissioning and initial operating stages of the Mo-99 IIS. Through a regulatory commitment established by OPG,

CNSC staff will receive OPG's final commissioning report and will verify that design and safety analyses requirements have been met [13].

CNSC staff recommend that the Commission introduce two regulatory hold points (RHPs) to track completion of key activities associated with the operational readiness of the Mo-99 IIS ahead of the initial operation of the Mo-99 IIS.

RHPs have been used effectively at Darlington NGS for much larger projects, such as the Unit 2 Refurbishment project. CNSC staff are recommending the Commission approve the process defined in Section 4.4 for the release of the proposed RHPs through a delegation of authority. If the Commission approves CNSC staff's recommendations for the use of RHPs, OPG will not be allowed to commence installation or commissioning of the Mo-99 IIS if it cannot meet the pre-requisites for the release of the RHP. CNSC staff will also perform compliance verification activities to confirm that the identified actions have been completed. Finally, CNSC staff will provide the Commission with updates, when available, regarding the release of RHPs through the Nuclear Power Plant (NPP) Status Updates presented at every Commission proceeding.

The proposed section of the LCH specifies that OPG can only produce Mo-99 at Darlington NGS Unit 2. If OPG plans to produce Mo-99 in other units in the future, it must obtain concurrence from CNSC staff, and demonstrate that it is a low risk activity, and the activity will remain within the plant's existing SOE and licensing basis. Further, if OPG wishes to produce other types of radioisotope in the same unit at Darlington NGS, OPG will need to bring the matter before the Commission for consideration demonstrating a safety case for the continued safe operation of the unit with the addition of the new activities.

CNSC staff recommend the Commission to approve OPG's request for licence amendment to produce Mo-99, and approve the following changes to the PROL and its associated LCH (as presented in part 2 of this CMD):

- The amendment to the PROL Part IV, Licensed Activities, adding new licensed activity (vi) authorizing the licensee to :
    - possess, transfer, process, package, manage and store molybdenum-99 radioisotope and its associated decay isotopes.
- The amendment to the PROL Part VI, Licence Conditions, adding new Licence Condition (15.6):
    - The licensee shall implement and maintain an operations program for the production of molybdenum-99 and its associated decay isotopes. The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

Furthermore, as indicated in the proposed Licence Condition 15.6, CNSC staff recommend that the Commission approve two regulatory hold points (RHPs) to track completion of key activities associated with the operational readiness of the Mo-99 IIS ahead of the initial operation of the Mo-99 IIS, as described in Section 4.5.

CNSC staff also recommend that the Commission delegate authority for the consent to remove the regulatory hold points associated with the proposed Licence Condition 15.6 to the Executive Vice-President and Chief Regulatory Operations Officer, as was previously managed for Licence Condition 15.4.

# 2. Matters for Consideration

## 2.1 Relevant Safety and Control Areas (SCAs)

The functional areas of any licensed facility or activity consist of a standard set of SCAs. For further information about SCAs, please refer to Appendix A, *Safety & Control Area Framework*.

CNSC staff conducted a comprehensive review of all the 14 SCAs and the conclusions are provided in Appendix B of this CMD.

## 2.2 Other Matters of Regulatory Interest

The following table identifies other matters that are relevant to this CMD.

| OTHER MATTERS OF REGULATORY INTEREST | |
|---|---|
| **Area** | **Relevant to this CMD?** |
| Impact Assessment | No |
| Indigenous Consultation | Yes |
| Other Consultation | No |
| Cost Recovery | No |
| Financial Guarantees | No |
| Improvement Plans and Significant Future Activities | No |
| Licensee's Public Information Program | No |
| Nuclear Liability Insurance | No |

The relevant "other matters" of regulatory interest are discussed in Section 4 of this CMD.

## 2.3 Environmental Review

Staff conducted an Environmental Protection Review under CNSC's licensing process for this licence application. CNSC staff conclude that the information provided by OPG regarding environmental protection is adequate to meet the applicable regulatory requirements under the NSCA and associated regulations for the proposed licence amendment. More information on CNSC staff's assessment of the environmental protection SCA can be found in Appendix B.9 of this CMD. CNSC staff conclude that OPG will make adequate provision for the protection of the environment and the health of persons.

CNSC staff will continue to verify and ensure that, through ongoing licensing and compliance activities and reviews, the environment and the health of persons are protected and will continue to be protected over the proposed licence period.

## 2.4 Regulatory Basis

For 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/2001-286]

The design and addition of the Mo-99 IIS to the Darlington NGS has not required any new standards be considered, and the licensing basis remains consistent with that already established in:

- OPG's Darlington PROL 13.02/2025
- The associated LCH

# 3. Summary of CNSC Staff Review of the Molybdenum-99 Isotope Irradiation System

## 3.1 Mo-99 IIS – Design and Testing Overview

The Mo-99 IIS is a *first-of-a-kind* design; as such, there are no comparable irradiation systems currently operating that introduce and retrieve material through containment in a commercial CANDU reactor. Despite the uniqueness of the proposed system, OPG has demonstrated that they have identified and considered Operational Experience (OPEX) from numerous sources relevant to the irradiation of isotopes, modification of a nuclear power plant, and the design process for *first-of-a-kind* projects [5, 14].

CNSC staff do not consider the *first-of-a-kind* nature of the design to be a barrier to safe installation or operation, as OPG and their vendors have established a robust design and testing process. CNSC staff have received updates during this process regarding proof-of-concept tests performed on select components and concepts. Further, OPG has conveyed that BWXT is constructing a full-scale mock-up Mo-99 IIS at BWXT's facility in Peterborough Ontario, for system testing and training purposes. Furthermore, prior to installation at Darlington NGS, system integration testing (SIT) and factory acceptance testing (FAT) will be performed (and summarized in the FAT report) to demonstrate the functionality of individual components and the complete assembled system, respectively. CNSC staff will review the FAT report to confirm that the design requirements of the Mo-99 IIS are met. Additionally, CNSC staff will perform a review of the installation plans, commissioning plans, and detailed commissioning specifications, for the purposes of releasing the proposed RHP. Finally, once installed and fully commissioned, CNSC staff will review OPG's final commissioning reports to confirm that OPG has:

- Verified that all design requirements have been met
- Verified and validated all assumptions made during the safety analysis
- Demonstrated that the Mo-99 IIS can be operated safety

## 3.2 Mo-99 IIS – System and Operation Overview

The Mo-99 IIS is a custom system designed to allow irradiation of high purity non-radioactive molybdenum metal (Mo-98) in the Unit 2 CANDU reactor at Darlington NGS. The Mo-98 is enclosed in special cylindrical zirconium capsules designed to be transported through the shielded flight tubes of the Mo-99 IIS using station instrument air and moderator grade heavy water. These zirconium capsules containing Mo-98 are referred to as *targets*, as the purpose of the system is to produce Mo-99 through neutron capture by nuclei of the Mo-98.

The reactor units at Darlington NGS were designed with 24 vertical adjuster rods which are normally positioned in the core. Early in operation of the Darlington NGS, eight of these adjusters rods were determined to be unneeded and were permanently removed from service and locked out of core. For the purposes of the Mo-99 IIS project, OPG proposes to modify four of the out-of-service adjuster rod ports by removing the adjuster rod assemblies from the RMD, and installing target elevators connected to flight tubes. Once installed, the Mo-99 IIS will form part of the reactor containment boundary. New redundant

interlocked containment valves will be used to ensure the containment boundary is maintained at all times.

The target elevators use an instrumented winch and cable mechanism to lower and raise a basket containing a series of targets into and out of the reactor core (operations referred to as seeding and harvesting, respectively). While in the core, cooling of the targets is accomplished by the circulation of moderator water around the targets.

The system uses pneumatic propulsion, supplied by station instrument air, for target movement outside of containment; and hydraulic propulsion, supplied by an independent tank of moderator grade heavy water ($D_2O$), for target movement inside containment.

Propulsion outside containment moves new targets pneumatically from equipment referred to as *the new target loader* to an airlock during seeding, and from the airlock to a distinct piece of equipment known as *the flask loader* during harvesting. Propulsion inside containment moves irradiated targets hydraulically between the airlock and the target elevators. The target airlock acts as the transfer point between the pneumatic and hydraulic propulsion systems. The airlock is also one of the interface points between the Mo-99 IIS and the Unit 2 contaminated exhaust system.

Shielding will be installed along the flight tubes (the path the targets follow between the airlock and the target elevators) to reduce the radiation fields present during harvesting operations. During harvesting, the targets will be held for period of time under the RMD out of the flux fields of the reactor, a stage referred to as the *dwell period*, to allow for decay of some short-lived high energy activation products to reduce the radiation hazard. Following harvesting, targets will be automatically loaded into a type B transport flask for shipment. Minimal operator involvement will be needed to secure the bolts of the flask lid. The final processing of the irradiated targets to produce $Tc\text{-}99^m$ generators will be performed by BWXT-Medical at an off-site facility holding a valid CNSC Class IB nuclear substance processing facility operating licence.[1]

Control of the Mo-99 IIS will be managed by an operator at a local control panel located near the reactivity mechanism deck. A control panel in the Main Control Room (MCR) will consist of system status indicators and a permissive switch which the on-duty Unit 2 Authorized Nuclear Operator (ANO) must enable to allow the local panel to be used to operate the system.

The Mo-99 IIS design includes tie-ins to the existing Unit 2 contaminated exhaust system. Emissions resulting from operation of the system 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. The emissions for Mo-99 production are expected to be minimal compared to overall station emissions and well below the Derived Release Limits (DRLs) for the site.

## 3.3 Overview of CNSC Staff Reviews

In late 2018, OPG began submitting design documentation and safety analyses in support of the Mo-99 IIS project for CNSC staff's review. The purpose of OPG's submissions, completed in early 2021, was to demonstrate that the Mo-99 IIS will not have a negative impact on the existing safety case for Darlington NGS and that OPG will continue to ensure

[1] Pending successful completion of the active licensing process associated with CMD 21-H5; currently scheduled for June 9-10, 2021.

the safe operation of the nuclear facility. In particular, these submissions provide technical insights into whether:

- Design work and safety analyses associated with the Mo-99 IIS have been conducted in accordance with regulatory requirements and have met expectations
- There are any technological and regulatory barriers to the installation, commissioning and operation of a Mo-99 IIS in Darlington NGS Unit 2

CNSC staff performed a comprehensive review of OPG's submissions against each of the 14 SCAs to determine whether: (1) the production and possession of Mo-99 would have any impacts to the existing safety case; (2) the design has addressed all regulatory requirements; and (3) OPG's existing programs are sufficient to ensure the safe installation, commissioning, and operation of a Mo-99 IIS in Darlington NGS Unit 2.

The following subsections of section 3 in this CMD provide: a summary of the detailed design review (subsection 3.4); a summary of the design and safety analysis reviews (subsection 3.5); and a summary of the conclusions against the SCAs indirectly affected by the Mo-99 IIS (subsection 3.6). A comprehensive review on each of the 14 SCAs is provided in Appendix B of this CMD.

Due to the evolving and sequential nature of the Mo-99 IIS project execution, a number of documents (including the installation and commissioning documentation, Available For Service (AFS) reports, final design manual, training materials for the Mo-99 IIS, and the associated Mo-99 IIS processes documents and operating procedures) can only be finalized closer to the commissioning and initial operating stages of the Mo-99 IIS. CNSC staff will perform regulatory oversight on these submissions to verify that design and safety analyses requirements have been met.

The design and testing related to the certification of the Type B transport flasks that will be loaded by the Flask Loader component of the Mo-99 IIS and used to transport the radioisotope material is out of scope of OPG's licence amendment. This certification activity is undergoing its own CNSC licensing process. This topic is further discussed in Appendix B.14 of this CMD.

## 3.4 CNSC Staff Review of Mo-99 IIS Design Submissions

The purpose of the design review is to determine whether applicable CNSC design requirements and expectations have been met. CNSC staff's review was based on the design documentation included in OPG's application [5] and OPG's submission of the final design packages for both Unit 2 [10] and Unit 4 [6].

OPG utilized its existing management system for the engineering change and design work associated with Mo-99 project; including, but not limited to: problem identification and resolution, change management, and contractor management. As OPG is utilizing several experienced vendors to provide services in support of the design, safety case, environmental impact, construction, and installation of the Mo-99 IIS, CNSC staff have verified that OPG has plans and processes in place to perform oversight of the work performed by contractors [15]. CNSC staff concluded that OPG's management system meets regulatory requirements.

CNSC staff reviewed the details related to the major mechanical components used in the Mo-99 IIS. CNSC staff determined that, from a mechanical and process perspective, the Mo-99 IIS design meets the applicable regulatory requirements.

In particular, CNSC staff reviewed the impact of the Mo-99 IIS on the containment boundary. The Mo-99 IIS design includes two sets of containment isolation valves, which use hardware interlocks to ensure that one set is always closed to maintain the integrity of containment. In its submission requesting code classification approval of the Mo-99 IIS from CNSC staff [16], OPG demonstrated that modifications made for installation of the Mo-99 IIS will have a negligible impact on existing SSCs, and that the reactor containment boundary will continue to be maintained. CNSC staff reviewed and approved OPG's code classification request [17].

The Mo-99 IIS control system is responsible for the control of the Mo-99 IIS system. CNSC staff reviewed OPG's documentation related to the Mo-99 IIS control system in the final design package [10] and determined that it meets the applicable regulatory requirements for design of instrumentation and control systems. In particular, the Mo-99 IIS control system is physically separated from, and functionally independent of, the two reactor shutdown systems and the Digital Control Computers (DCCs). This separation means the operation of Mo-99 IIS control system does not affect the operation of reactor control programs or the shutdown systems.

Components associated with the Mo-99 IIS will be supplied from the Class III, Class II and Class I electrical power supplies. CNSC staff reviewed electrical design documentation in the final design package [10], including the supporting short circuit, load flow and voltage drop analysis, and determined that the Mo-99 IIS electrical design meets the applicable regulatory requirements and that the addition of the Mo-99 IIS load has negligible impact on the existing Class III/II/I power systems.

The design of the Mo-99 IIS is required to meet the environmental qualification (EQ) requirements of CSA N290.13-05, *Environmental Qualification of Equipment for CANDU Nuclear Power Plants*. OPG is applying its existing EQ governance to the Mo-99 IIS. OPG confirmed in its application that the Mo-99 IIS design takes into account the EQ of components and identified the impact the Mo-99 IIS will have on the EQ of the surrounding systems [18]. CNSC staff are satisfied that OPG's existing EQ program can accommodate the Mo-99 IIS and that the system does not pose additional risk to the EQ of the units at Darlington NGS.

OPG has a seismic qualification process that meets the requirements of CSA N289.1, *General Requirements for Seismic Design and Qualification of CANDU Nuclear Power Plants*, and is applying this process to the design of the Mo-99 IIS. CNSC staff have reviewed information provided by OPG following the detailed design phase of the Mo-99 IIS project [6, 10]. Of the documents reviewed to date, CNSC staff have determined that OPG's approach to seismic qualification is consistent with their program requirements. CNSC staff will continue to provide regulatory oversight during the Mo-99 IIS installation phase, supported by ongoing reviews of OPG's detailed design documentation [10], to verify that the Mo-99 IIS design conforms to seismic design requirements.

The Mo-99 IIS will require installation of a platform where the Mo-99 IIS components will be installed [5, 10]. OPG provided details regarding the Mo-99 IIS platform design in the final design packages for the Mo-99 IIS [6, 10]. Based on the documents reviewed, CNSC staff concluded that the design of the supporting Mo-99 IIS component platform meets regulatory requirements.

OPG is applying its ECC program to the Mo-99 IIS, which includes consideration of Human Factors Engineering (HFE), to meet regulatory requirements found in CSA

N290.12-14, *Human Factors in Design for Nuclear Power Plants*. CNSC staff have reviewed OPG's Human Factors Engineering Program Plan (HFEPP) [19] which described the HFE activities and objectives for the Darlington Mo-99 IIS project, including: engineering design, build, manufacturing, installation and commissioning information for the tooling and associated systems. CNSC staff are satisfied that OPG is following its governance by considering human factors in the design of the Mo-99 IIS. CNSC staff will verify through review of OPG's subsequent submissions that the Mo-99 IIS design continues to meet all applicable regulatory requirements.

During past and on-going station operations, OPG's existing radiation protection program and implementing procedures have demonstrated that OPG has made adequate provisions for the protection of workers and members of the public, and that doses have been kept As Low As Reasonably Achievable (ALARA) [5, 13]. The three basic protective measures associated with the ALARA principle are time, distance and shielding. OPG has applied these protective measures to the design of the Mo-99 IIS. Specifically, time delays were incorporated into the Mo-99 production phase to allow short-lived radionuclides to decay away thereby reducing the radiological hazard; equipment that requires personnel access is to be installed in low background radiation areas away from components that emit high radiation fields; and shielding was incorporated into the design to reduce external radiation hazards [20-23]. OPG estimated that the incremental increase to an individual worker's whole body dose from the licensed activity, together with all other occupational exposures at Darlington NGS in the course of the year, will be below OPG's Exposure Control Levels (10 mSv/y) and Administrative Control Levels (20 mSv/year), both of which are set below the regulatory limit (50 mSv/y) [20-23].

CNSC staff reviewed the information and conclusions presented in OPG's assessments and concluded that OPG has sufficiently applied their ECC process to the design and are meeting the requirements of all applicable codes and standards. CNSC staff will continue to provide further regulatory oversight during the remaining stages of the project. In particular, CNSC staff will review OPG's FAT report and installation plans, to verify OPG continues to utilize their ECC process and ensure the continued safe operations of the Darlington NGS.

CNSC staff concluded that OPG is meeting the requirements of all applicable codes and standards to ensure the continued safe operations of the Darlington NGS. CNSC staff determined that OPG has adequate provisions in place to ensure the Mo-99 IIS will not negatively impact the existing SSCs such as electrical systems, instrumentation and control, and containment boundary of Darlington NGS Unit 2. CNSC staff have also determined that OPG has applied the principles of ALARA to the design of the Mo-99 IIS and will take adequate provisions to protect workers. Where necessary, CNSC will confirm, through reviews and inspections, that the Mo-99 IIS continues to meet regulatory requirements.

## 3.5 CNSC Staff Review of Mo-99 IIS Safety Analysis Submissions

The purpose of the safety analysis review is to determine whether operation of the Mo-99 IIS will have an impact on the overall safety case for Darlington NGS Unit 2. CNSC staff reviewed all of the supporting safety analyses listed in OPG's application [5], as well as in the *Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington* [24].

OPG followed a systematic assessment process to assess the impact of the Mo-99 IIS on the Darlington Safety Report to identify the event categories of the current safety analysis impacted by the Mo-99 IIS and the new initiating events resulting directly from the installation of the Mo-99 IIS.

In the area of deterministic analysis, OPG has conducted assessments to demonstrate the impact of the introduction of the Mo-99 IIS. CNSC staff reviewed OPG's analyses and concluded they were completed in accordance with the requirements of REGDOC-2.4.1, *Deterministic Safety Analysis*. OPG's assessments [11] demonstrated that:

- The introduction of the Mo-99 IIS will have no impact on existing accident progression or consequences as detailed in the Darlington Safety Report
- Public dose consequence arising from the addition of the Mo-99 IIS are either bounded by existing analyses or are significantly less than the allowable single failure dose limits
- Following a postulated loss of moderator inventory event, there is no potential for a hydrogen deflagration event caused by the molybdenum targets because their surface temperature will remain below the self-ignition temperature for hydrogen
- The effectiveness of the Neutron Overpower Protection (NOP) trip setpoint is not affected by the operation of the Mo-99 IIS and no changes will be required to any safety system setpoints

CNSC staff concluded that with the introduction of the Mo-99 IIS the existing safety case for Darlington NGS remains valid.

OPG also performed operational analyses to identify how normal operation of Unit 2 would be affected by the installation and operation of the Mo-99 IIS. OPG assessed the reactivity worth of the system's in-core components and assessed the impact of the operation of the Mo-99 IIS on core neutronics [7, 11]. The operating scenarios analyzed included cases for various core configurations including those associated with normal operation, off-nominal liquid zone levels, newly fueled channels and withdrawn adjuster rods. In all cases, the effects of the Mo-99 IIS on parameters, such as bundle and channel powers, average zone level, individual liquid zone controller fill level, were determined to be well within the capability of the RRS to maintain sufficient margin to current licensing limits. CNSC staff conclude that the operational analyses performed are sufficient in demonstrating that operation of the Mo-99 IIS will have negligible impact on current operational practices at Darlington NGS.

As required by REGDOC-2.4.1 and CSA N286.7 *Quality assurance of analytical, scientific and design computer programs for nuclear power plants*, OPG performed an assessment to confirm the applicability and accuracy of the suite of codes used in the analysis to support the installation of the Mo-99 IIS [11, 24]. The intent of the code applicability and accuracy assessment is to demonstrate that the codes used to perform the analyses are qualified for the applications for which they are used. OPG's assessment identified those core representation and material properties that needed to be modified to account for the molybdenum and associated components of the Mo-99 IIS in the core. To implement these changes, the incremental effects of the new material on the core neutronics were calculated. OPG's assessment demonstrated that the Mo-99 IIS will not introduce new phenomena or behaviour to the affected Unit. CNSC staff reviewed OPG's assessment and determined that it met the requirements of REGDOC-2.4.1. CNSC staff concluded that

the codes used by OPG to support installation and operation of the Mo-99 IIS are appropriate.

In support of its application [5], OPG completed a qualitative assessment [11, 25] to determine the impact of installing and operating the Mo-99 IIS on existing hazard assessments and to identify if any new internal hazards need to be considered in the Darlington PSA. Based on this assessment, OPG generated a list of applicable hazards (see Table 2 in Appendix B.4), and assessed them as part of the Darlington Hazards Screening Analysis [11, 25]. CNSC staff's review of the information associated with the Hazard Analysis determined that the assessments conducted were comprehensive and aligned with the requirements of REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*. CNSC staff concluded that the new hazards have been accounted for and that their impact on the Darlington PSA will be negligible.

OPG conducted an assessment of the impact of the Mo-99 IIS on the existing Darlington PSA [11, 26], including the following elements:

- Darlington Level 1 and 2 At-Power and Outage Internal Events
- Internal Fire, Internal Flood, Seismic and High Wind

OPG determined that the Mo-99 IIS has a negligible impact on all elements of the Darlington PSA listed above. The impact of the Mo-99 IIS on the quantification of Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) in the various PSA elements were also found to be negligible.

OPG performed an assessment of the impacts the installation and operation of the Mo-99 IIS would have on the severe accident fission products source terms and accident progression [11]. OPG's qualitative assessment indicated that the Mo-99 IIS would have a negligible impact on the severe accidents source terms, and will have no effect on severe accident management and recovery. OPG's assessment was based on results from the MAAP5-CANDU code, which also indicated that no modifications are necessary for this code parameter file in order to use it for the Mo-99 IIS applications. OPG also concluded that under accident scenarios, the Mo-99 IIS would not result in releases outside of containment. CNSC staff reviewed OPG's assessment of the impacts of the Mo-99 IIS on severe accidents [11, 24] and concluded that it was acceptable.

In their application [5], OPG states that the Mo-99 IIS will have no impact on the management of safety issues and OPG's Research and Development programs. Further, OPG performed a survey of the category 2 CANDU Safety Issues (CSIs) and determined that the installation and operation of the Mo-99 IIS has negligible impact on the management of the CSIs [27].

Overall, OPG has assessed the impacts of the targets and associated Mo-99 IIS equipment on the reactor core and event progression, and has adequately demonstrated that the installation and operation of the Mo-99 IIS remain within the capabilities of the RRS and OPG's existing procedures for accident and severe accident management. CNSC staff will continue to provide regulatory oversight of OPG's performance and will review OPG's final commissioning report to verify the accuracy of the information supporting safety analysis assessments.

CNSC staff reviewed the analyses in support of the Mo-99 IIS in the areas of operational analyses, code applicability assessment, deterministic safety analysis, PSA, hazard

analysis and severe accident management. Based on this review, CNSC staff concluded that assessments performed by OPG are acceptable and systematic, and OPG has adequate provisions in place to ensure the safe production of Mo-99. Furthermore, CNSC staff concur that the Mo-99 IIS will have a negligible impact on reactor operations and the existing safety case for Darlington NGS.

## 3.6 CNSC Staff Review of Impacts to Remaining Areas of the SCA Framework

In addition to the design and safety analysis reviews discussed in subsections 3.4 and 3.5, CNSC staff performed a comprehensive review of OPG's application and supporting submissions against the SCAs not directly impacted by the design or safety analyses to determine whether the applicant has addressed all regulatory requirements regarding the protection of its workers, the public, the environment, and the international safeguards agreements to which Canada has agreed. As OPG identified that there would be no changes to the existing programs to accommodate the operations of the Mo-99 IIS, CNSC staff considered whether the existing programs are sufficient to ensure the safe installation, commissioning, and operation of the Mo-99 IIS.

OPG's programs and procedures are well established within its management system, and meet all the regulatory requirements defined in the licence and licence conditions handbook. There are programs and procedures in place for managing design changes, self-assessments and audits, configuration management, records management, management of contractors, and training, among others. OPG also has established business continuity documentation that governs operation, and documentation to enforce their commitment to fostering and implementing safety culture in their governing documentation. Further, OPG has a well-established occupational health and safety program, confirmed to be adequate to ensure that the work associated with the installation, commissioning and operation of the Mo-99 IIS is executed safely.

OPG will manage the operation of the Mo-99 IIS under its existing nuclear operations program. As there are no certified positions that will be created as a result of the proposed licensed activity, OPG will utilize its existing training programs to ensure that its workers will be trained and qualified to carry out the proposed licensed activity for the production of Mo-99.

Maintenance of the Mo-99 IIS will be managed through its existing maintenance and aging management programs. A high level strategy identifying the goals of online and outage-based maintenance was provided by OPG [28]. OPG has also committed to preparing preventive maintenance plans. CNSC staff will review these plans to confirm that the Mo-99 IIS will be safely and adequately maintained.

Through operations of the Mo-99 IIS, there are no expected increases in non-radiological releases or emissions from Darlington NGS as there are no chemicals being used. In its application and supporting documentation, OPG estimated that tritium emissions from operation of the Mo-99 IIS would result in a potential additional dose to a member of the public of no more than 0.006 μSv/year. For context, this represents an additional 1% dose above the current dose estimate based on current Darlington emissions, or 0.0006% of the regulatory dose limit of 1 mSv/year [20-23]. The design of the Mo-99 IIS includes an on-line tritium monitoring system with an alarm and manual isolation valves capable of isolating potential leaks. CNSC staff will review the results of system commissioning, as

well as OPG's compliance monitoring reports, to confirm that the Mo-99 IIS does not have a negative impact on station emissions.

The existing security and safeguards measures in place at Darlington NGS are sufficient to accommodate the proposed activities associated with the Mo-99 IIS project. There are also appropriate plans to deal with emergencies at the Darlington NGS.

The waste produced from routine operation of the Mo-99 IIS will be minimal and managed by OPG's existing waste management program. The waste associated with Mo-99 and its processing will be owned by BWXT and will be managed under their own Class IB nuclear substance processing facility operating licence.[2]

BWXT-Medical is responsible for the package design, certification, maintenance and transportation between the Darlington NGS to BWXT-Medical's medical isotope processing facility in Kanata, Ontario. The scope of OPG's responsibility with respect to transportation is limited to loading the transport packages with irradiated Mo-99 targets produced in the Mo-99 IIS and managing the on-site transportation requirements [5]. OPG has a radioactive materials transportation program that meets regulatory requirements and CNSC staff concluded that there will be no impact on Darlington's packaging and transport licensing basis documents as a result of the proposed activities associated with the production of Mo-99.

CNSC staff reviewed OPG's application and concur that OPG's existing management system; nuclear operations; training; maintenance and aging management; conventional health and safety; environmental protection; emergency management and preparedness; waste and decommissioning; security; safeguard; and packaging and transport programs and governance are sufficient for accommodating radioisotope production through installation and operation of the Mo-99 IIS. OPG also continues to engage with interested Indigenous and First Nations groups on this licence amendment and other ongoing activities of interest.

## 3.7 CNSC Staff Conclusions from Review of OPG Application and Supporting Submissions

Based on the information submitted, CNSC staff have determined that OPG has applied the appropriate codes and standards and met regulatory requirements. CNSC staff concur with OPG's assessment that the Mo-99 IIS design will have negligible impact on existing station operations, reactor safety, and on the existing SSCs and safety related systems; including containment, electrical systems, and instrumentation and control systems. The Mo-99 IIS will have a negligible impact on the current safety case of Darlington NGS Unit 2 and OPG has adequate provisions in place to ensure that Mo-99 will be safely produced without additional risks to the environment and the health of persons.

Overall, CNSC staff have not identified any barriers to the installation, commissioning, and operation of the Mo-99 IIS in Darlington NGS Unit 2. Due to the evolving and sequential nature of the design process, a number of design documents and reports were not finalized at the time of the application and thus have not been reviewed by CNSC staff. CNSC staff will perform regulatory oversight activities concerning any outstanding matters

[2] Pending successful completion of the active licensing process associated with CMD 21-H5; currently scheduled for June 9-10, 2021.

that have been identified (*e.g.*, document updates, additional analyses work, training requirements, installation plans, commissioning activities) in accordance with the identified actions and proposed regulatory hold points presented in subsection 4.5 of this CMD. CNSC staff's planned regulatory oversight activities of the information to be provided in these *outstanding matters* are not expected to impact the design work or safety analyses already reviewed. CNSC staff review has not identified any fundamental barriers to the safe installation, commissioning, and operation of the Mo-99 IIS.

# 4. Other Matters of Regulatory Interest

## 4.1 Impact Assessment

CNSC staff reviewed OPG's licence application in the context of the *Impact Assessment Act* (IAA). CNSC staff determined that the IAA does not apply because the proposed activities are not captured in the IAA's *Physical Activities Regulations* nor are they considered a project on federal lands.

## 4.2 Indigenous Engagement

The common law duty to consult with Indigenous groups applies when the Crown contemplates actions that may adversely impact potential or established Indigenous and/or treaty rights. The CNSC ensures that all of its licensing decisions under the NSCA uphold the honour of the Crown and consider Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the *Constitution Act, 1982*.

### 4.2.1 Discussion

CNSC staff have identified the Indigenous groups who may have an interest in the proposed licence amendment for OPG's Mo-99 IIS at Darlington NGS. These groups include Alderville First Nation, Curve Lake First Nation, Hiawatha First Nation, the Mississaugas of Scugog Island First Nation, the Chippewas of Rama First Nation, the Chippewas of Georgina Island, Beausoleil First Nation, the Métis Nation of Ontario, and the Mohawks of the Bay of Quinte.

These Indigenous groups were identified due to the proximity of their communities, treaty areas and/or traditional territories to the Darlington Nuclear Generating Station, or due to previously expressed interest in being kept informed of CNSC licensed activities occurring in or proximal to their territories. The CNSC has signed Terms of Reference for long-term engagement with both the Métis Nation of Ontario and Curve Lake First Nation to facilitate ongoing relationships and meaningful engagement and consultation.

**CNSC Staff Engagement Activities**

CNSC staff sent letters of notification for the licence amendment application to the interested Indigenous groups identified above in May 2019. 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.

In December 2018 and spring 2019, CNSC staff held in-person meetings with the Métis Nation of Ontario, the Mohawks of the Bay of Quinte, Curve Lake First Nation, Hiawatha First Nation, the Mississaugas of Scugog Island First Nation, and the Chippewas of Rama First Nation to provide information and to respond to questions about OPG's proposed licence amendment application and the CNSC's regulatory role.

CNSC staff sent follow-up letters to each Indigenous group in May 2021, providing updated information on the Commission hearing, further details on how to participate in the Commission's hearing process, and updated information on the availability of participant funding. Subsequently, CNSC staff followed-up with each identified Indigenous group through email and/or phone 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 groups 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, the identified Indigenous groups have not expressed any specific concerns with regards to the licence amendment application. However, CNSC staff will provide additional information with regards to on-going engagement activities, including any concerns expressed by Indigenous groups, to the Commission and the public in a supplemental CMD, where appropriate.

### Licensee Engagement Activities

REGDOC-3.2.2 *Indigenous Engagement*, published in February 2016 (updated in August 2019), 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.

OPG's licence amendment application does not raise the formal requirements of REGDOC-3.2.2. However, CNSC staff recognize that OPG has a well-established engagement and communications program with interested Indigenous groups on this project. Throughout 2019-2021, OPG, in partnership with its business partner, BWXT, has conducted numerous engagement activities in relation to this license amendment application, including several meetings with all interested Indigenous groups, sharing videos and presentations, providing ongoing updates, responding to questions and discussing key areas of interest and concern with Indigenous groups. CNSC staff encourage OPG to continue engaging with these Indigenous groups regarding their facilities and activities including the licence amendment application.

## 4.2.2 Conclusion

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

Nevertheless, the CNSC is committed to meaningful, ongoing engagement with Indigenous groups that have an interest in CNSC-regulated facilities and activities. CNSC staff engaged with all interested Indigenous groups in relation to this licence amendment application and encouraged them to identify any concerns and participate in the regulatory review process. CNSC staff encourage OPG to continue to engage with interested Indigenous communities on this licence amendment and other ongoing activities of interest.

## 4.3 Participant Funding

The CNSC made available up to $30,000 through its Participant Funding Program (PFP) to 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.

### 4.3.1 Discussion

The deadline for applications was May 31, 2021. 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 $20,600 in funding to the following recipients, who are required to submit a written intervention to the Commission Secretariat by August 18, 2021 for the Commission's consideration:

- David Winfield
- Curve Lake First Nation
- Dr. Helmy Ragheb
- Anna Tilman
- Canadian Environmental Law Association

### 4.3.2 Conclusion

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 groups, and other stakeholders, through the PFP, to prepare for and participate in the Commission's hearing process.

## 4.4 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.

## 4.5 CNSC staff proposal for the use of RHPs and delegation of authority

CNSC staff have concluded that the installation and operation of the Mo-99 IIS will have negligible impacts on the existing safety case and will not result in significant doses to workers or members of the public, and will not result in significant releases to the environment. In addition, the existing security and safeguards programs in place at Darlington NGS are sufficient to accommodate the additional activities associated with the production of Mo-99.

Due to the evolving and sequential nature of the Mo-99 IIS project, a number of project outputs can only be finalized during or after future stages of the project such as installation and commissioning. CNSC staff will perform regulatory oversight to track the completion of outstanding actions and established regulatory commitments (including planned submissions to CNSC staff). CNSC staff will review these outputs to ensure regulatory requirements were met.

CNSC staff are also proposing to use regulatory hold points (RHPs) to ensure key aspects of the ECC process are performed in accordance with regulatory requirements. Additionally, the RHPs will ensure the operational readiness of the Mo-99 IIS has been confirmed, as OPG progresses through the installation and commissioning phases. RHPs have been used effectively at Darlington NGS for much larger projects, such as the Unit 2 Refurbishment project under Licence Condition 15.4 of the existing PROL.

In accordance with their ECC process, OPG has established two internal Quality Release Hold Points (QRHPs), each with their own set of criteria that must be met to allow the installation and commissioning of a Mo-99 IIS on Unit 2 to proceed [29]. Similar to the QRHPs established by OPG, CNSC staff propose the use of two RHPs, to be removed by a person authorized by the Commission (discussed further in subsection 4.5.2), to provide CNSC staff the opportunity to complete key regulatory oversight activities associated with the installation and commissioning of a Mo-99 IIS on any unit.

If the Commission deems the use of RHPs appropriate, CNSC staff are recommending the Commission define two RHPs to be removed by delegation of authority, prior to installation[3] and commissioning[4] a Mo-99 IIS on any unit at Darlington NGS:

RHP-1) Installation – Modifying the reactor or containment boundary through activities related to the installation of the Mo-99 IIS
RHP-2) Commissioning – Commencing any on-power tests or commissioning activities of the Mo-99 IIS

### 4.5.1 Scope of regulatory requirements for removal of proposed RHPs

CNSC staff propose using RHPs, authorized under the proposed Licence Condition 15.6, to verify operational readiness and continued safe operations of the Darlington NGS within the approved licensing basis. CNSC staff will conduct compliance verification activities to ensure the requirements of each RHP are met, and any identified issues are resolved. The

[3] The RHP associated with installation does not exclude OPG from installing components in rooms 302 and 304 that remain within their licensing basis.
[4] The RHP associated with Commissioning does not prohibit any testing or commissioning activities performed *in situ* in accordance with OPG's detailed installation work plans etc., reviewed by CNSC staff as part of RHP-1, during the outage while the Mo-99 IIS is being installed.

scope of regulatory requirements pertinent to each proposed RHP for the installation and commissioning of a Mo-99 IIS (described below) inform the identification of specific activities which need to be completed.

**Regulatory Requirements Associated with Installation (RHP-1)**

- That OPG has a design that meets all regulatory requirements and has incorporated existing OPEX
- That OPG has conducted a thorough safety analysis that verifies the impact of the Mo-99 IIS is negligible and operation poses minimal additional risk to the operation of the unit
- That OPG has accepted the results of the factory acceptance tests demonstrating the Mo-99 IIS is functioning as intended and can safely be installed
- That OPG has prepared the necessary work plans in accordance with existing procedures, processes, and programs within its management system and is ready to install the Mo-99 IIS

**Regulatory Requirements Associated with Commissioning (RHP-2)**

- That OPG has prepared the necessary work plans, identified the relevant commissioning tests, acceptance criteria, and back-out conditions; and is ready to safely test and commission the Mo-99 IIS on an operating reactor

**Current Status of Regulatory Requirements for Unit 2**

The Unit 2 activities detailed in Table 1 (below) have been identified to satisfy the scope of regulatory requirements associated with each RHP, and are based on the current status of CNSC staff's review of OPG's information provided in support of its application for an amendment to the PROL [4, 5]. CNSC staff have reviewed OPG's application, including the design documentation and safety analyses submitted in support of the application, and as they are the focus of this CMD and will be considered in the Commission's decision, these aspects will not be part of the proposed Installation RHP (RHP-1) for Unit 2. Should OPG pursue the installation of a Mo-99 IIS on another unit at Darlington NGS, the use of RHPs as defined would provide equivalent regulatory oversight to ensure the additional units remain within the licensing basis. In support of these RHPs, OPG would be required to identify sufficient activities, subject to CNSC staff concurrence, which demonstrate that the regulatory requirements establishing the proposed RHPs would be satisfied.

### 4.5.2 Delegation of authority for approval to remove RHPs

The Commission may include any licence condition it considers necessary for the purposes of the NSCA. The Commission may also delegate authority to a position within CNSC staff with respect to the administration of licence conditions, or portions thereof. CNSC staff are recommending that the Commission delegate authority for the consent to remove the regulatory hold points (described above) associated with the proposed Licence Condition 15.6 for the installation and commissioning of the Mo-99 IIS to the Executive Vice-President and Chief Regulatory Operations Officer of the CNSC. CNSC staff note that this approach is consistent with delegation of authority associated with Licence Condition 15.4 of the existing Darlington PROL to approve removal of established RHPs for refurbishment.

### 4.5.3 Process for removing the regulatory hold point

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

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

### 4.5.4 Pre-requisites for the removal of RHPs

Prior to the removal of a RHP, OPG's request will be evaluated against the following pre-requisites, which will be captured in the LCH. If the RHP approach is approved by the Commission, the licensee will receive permission to: (1) install the Mo-99 IIS on the reactor; or (2) proceed to on-power commissioning only if it has completed the pre-requisites and associated actions of the RHP in question.

**List of pre-requisites to be applied for removal of the regulatory hold point**

1. Demonstration that all licensee actions are complete (*e.g.* actions identified in Table 1)
2. Demonstration that all appropriate OPG approvals have been issued
3. Confirmation that any safety significant action items have been addressed
4. Completion of CNSC staff report summarizing verification activities[5]

**Unit 2 actions in support of pre-requisites to RHP removal**

In their proposal regarding RHPs for Unit 2 [29], OPG identified key submissions in support of RHP removal. CNSC staff's proposal for activities to be completed by OPG under the RHPs for Unit 2, is summarized in Table 1. OPG will not be allowed to commence installation or commissioning of the Mo-99 IIS if it cannot complete the activities described in Table 1, or meet the pre-requisites for the removal of the RHP.

CNSC staff will provide the Commission with updates, when available, regarding the removal of RHPs through the NPP Status Updates presented at every Commission proceeding.

[5] CNSC staff's report will document that all required activities have been successfully completed in accordance with regulatory requirements

**Table 1: Proposed activities to request removal of RHPs associated with Unit 2**

| RHP | Activity | Task Description | Completion Criteria | Target Completion Dates |
|---|---|---|---|---|
| RHP-1.1 | Factory Acceptance Testing (FAT) | • FAT procedure steps executed satisfactorily.<br>• FAT report prepared, verified, approved by the vendor, BWXT, and accepted by OPG. | • FAT report (NK38-REP-30550-00022) accepted by OPG and a copy provided to CNSC staff. | 2021-09-30 (to be confirmed) (Four weeks after FAT report is accepted by OPG) |
| RHP-1.2 | Reactor Modification Installation Readiness | • Installation plan for TDS reactor modification approved/ issued. | • Installation plan (stage 2 & 3) approved/issued and provided to CNSC staff. | 2021-07-15 |
| RHP-1.3 | Reactor Modification Installation Readiness | • Installation plan for TDS reactor modification approved/ issued. | • Submit flask hoisting and handling procedure to CNSC staff. | 2021-08-31 |
| RHP-1.4 | Change to Reactor Shutdown Guarantee | • Submit for CNSC staff concurrence the Reactor Shutdown Guarantee #9 (RSG #9), which is to prevent Mo-99 IIS heavy water from entering the moderator during Over-poisoned Guaranteed Shutdown State (OPGSS). | • Submit for CNSC staff concurrence the Unit 2 RSG #9 changes. | 2021-07-15 |
| RHP-2.1 | Reactor Modification Commissioning Readiness | • Commissioning specification (NK38-DSC-30550-00001) approved/ issued. | • Commissioning specification (NK38-DCS-30550-00001) approved/issued and provided to CNSC staff. | 2021-10-15 |
| RHP-2.2 | Reactor Modification Commissioning Readiness | • Detailed commissioning plan for TDS approved/issued. | • Detailed Commissioning plan approved/issued and provided to CNSC staff. | 2021-11-15 |

# 5. Overall Conclusions & Recommendations

## 5.1 Conclusions

OPG's Mo-99 project seeks to provide a reliable source of Mo-99 radionuclides for medical diagnostic imaging. The process selected by OPG relies on the use of natural molybdenum, resulting in fewer hazards associated with fissile products and reduced safeguards concerns compared with Canada's previous approach to Mo-99 production.

In the Mo-99 IIS supply chain, OPG is responsible for the handling of Mo-98 and Mo-99 at Darlington NGS. Specifically, OPG will take possession of magazines of Mo-98 (not a nuclear substance), provide irradiation services to produce Mo-99, and package the irradiated targets into certified shielded Type-B transport containers. OPG is responsible for ensuring the continued safe operations of the Darlington NGS, including the safe operation of the Mo-99 IIS. All other aspects of the supply chain will be handled by an external third party company holding its own CNSC nuclear substances processing facility licence for processing and $Tc\text{-}99^{m}$ generator manufacturing (pending completion of its own licensing process).

Although numerous system are being impacted by the installation of the Mo-99 IIS, CNSC staff have determined that the operation of the Mo-99 IIS poses minimal additional risk to the operation of the nuclear facility itself, and that Mo-99 will be produced within the existing safe operating envelope (SOE) of the nuclear facility. Based on CNSC staff's review of the licence amendment application and the Mo-99 IIS supporting technical information (design documentation, safety assessments, and licensing impact assessment) CNSC staff have determined that:

- The impact of the Mo-99 IIS to the existing Structures, Systems and Components (SSCs) is negligible
- The reactivity worth of in-core components associated with the Mo-99 IIS and the targets is insignificant compared to the total reactivity worth of the reactor core.
- Reactivity changes introduced by seeding and harvesting Mo-99 targets in the elevator baskets remains within the capabilities of the Reactor Regulating System (RRS).
- The impact of the Mo-99 IIS on Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) is also negligible.
- OPG has adequate provisions in place to ensure the safe production of Mo-99.
- The installation and operation of the Mo-99 IIS 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 program in place is sufficient for the production of Mo-99.
- OPG continues to engage with interested Indigenous groups on this licence amendment and other ongoing activities of interest.
- OPG will continue to protect the health and safety of the public, as well as the environment.

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

(b) Will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

## 5.2 Recommendations

Based on a thorough review and assessment of OPG application and supporting submissions, CNSC staff recommend the Commission to approve OPG's request for licence amendment to produce Mo-99, and approve the following changes to the PROL and its associated LCH (as presented in part 2 of this CMD):

- The amendment to the PROL Part IV, Licensed Activities, adding new licensed activity (vi) authorizing the licensee to :
  - possess, transfer, process, package, manage and store molybdenum-99 radioisotope and its associated decay isotopes.
- The amendment to the PROL Part VI, Licence Conditions, adding new Licence Condition (15.6):
  - The licensee shall implement and maintain an operations program for the production of molybdenum-99 and its associated decay isotopes. The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.

Furthermore, as indicated in the proposed Licence Condition 15.6, CNSC staff recommend that the Commission approve two RHPs to track completion of key activities associated with the operational readiness of the Mo-99 IIS ahead of the initial operation of the Mo-99 IIS, as described in Section 4.5.

CNSC staff also recommend that the Commission delegate authority for the consent to remove the regulatory hold points associated with the proposed Licence Condition 15.6 to the Executive Vice-President and Chief Regulatory Operations Officer, as was previously managed for Licence Condition 15.4.

## References – Part One

The following documents are referenced in Part One of this CMD. Note that a number of these documents are marked **Protected B(R)**, as they contain commercial confidential information related to the design of the Mo-99 IIS / TDS. Members of the public may follow the Access to Information and Privacy (ATIP) process in order to request access to the ***Protected B(R)*** documents listed in this CMD.


[1] OPG letter, S. Gregoris to M. Leblanc and G. Frappier, "Darlington NGS – Molybdenum-99: Updated Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025," 2020-06-23. [NK38-CORR-00531-21744 P, e-Doc 6326945]

[2] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Predictive Effects Assessment (ERA01-01)," 2020-06-11. [NK38-CORR-00531-21626 P, e-Doc 6316948] *Protected B(R)*

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

[4] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS - Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment," 2018-12-05. [NK38-CORR-00531-20359, e-Doc 5729847]

[5] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025," 2021-02-12. [NK38-CORR-00531-22275 P, e-Doc 6489932]

[6] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Target Delivery System Design Packages (D04-02 and D06-01)," 2020-07-20. [NK38-CORR-00531-21808 P, e-Doc 6347238] *Protected B(R)*

[7] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Integrated Nuclear Safety and Operational Assessment of the Target Delivery System (SA06-01)," 2020-08-31. [NK38-CORR-00531-21845, e-Doc 6371714] *Protected B(R)*

[8] OPG letter, S. Gregoris to J. Burta, "Molybdenum Isotope Irradiation System: Submission of Unit 2 Design Gap Assessment (D04-02-U2 and D06-01-U2)," 2020-12-02. [NK38-CORR-00531- 22156, e-Doc 6435639] *Protected B(R)*

[9] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Update on Unit 2 Target Delivery System Safety Analysis Gap Assessment (SA06-01-U2)," 2020-12-18. [NK38-CORR-00531-22182 P, e-Doc 6449800] *Protected B(R)*

[10] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Unit 2 Design Documents (D04-02-U2 and D06-01-U2)," 2021-01-28. [NK38-CORR-00531-21808 P, e-Doc 6475628] *Protected B(R)*

[11] OPG letter, S. Gregoris to K. Hazelton, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Five Updated Safety Assessment Reports for the Unit 2 Target Delivery System (SA06-01-U2)," 2021-03-10. [NK38-CORR-00531-22385 P, e-Doc 6510325] *Protected B(R)*

[12] OPG letter, S. Gregoris to N. Riendeau, "Darlington NGS – Molybdenum Isotope Irradiation System: Response to CNSC Staff's Review of OPG's Request to Amend the Darlington Power Reactor Operating Licence," 2020-01-27. [NK38-CORR-00531-21246 P, e-Doc 6107184] *Protected B(R)*

[13] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Supplementary Information for Licence Amendment Application for Molybdenum Isotope Irradiation System: Submission of Licensing Impact Assessment (L01-02)," 2020-11-12. [NK38-CORR-00531-22104 P, e-Doc 6422251] *Protected B(R)*

[14] OPG letter, S. Gregoris to N. Riendeau, "Molybdenum-99 Isotope Irradiation System: Submission of Conceptual Design Report Revision, Safety Analysis Project Execution Plan and Engineering Oversight Plan," 2018-11-14. [NK38-CORR-00531-20289 P, e-Doc 5715229] *Protected B(R)*

[15] OPG email, L. Moraru to S. Baskey, "Darlington NGS - Reponses to CNSC Staff's Requests for Additional Information- Tracking Code 8D24," 2021-04-29. [NK38-CORR-00531-22543, e-Doc 6551717, 6551706]

[16] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Request for Code Classification Consent for Unit 2 Target Delivery System and Prior Written Notification for Permanent Change to Containment Boundary (D03-01-U2)," 2020-12-02. [NK38-CORR-00531-22139 P, e-Doc 6435622] *Protected B(R)*

[17] CNSC staff letter, J. Burta to S. Gregoris, "CNSC staff Consent for Code Classification Consent for Unit 2 Target Delivery System and Prior Written Notification for Permanent Change to Containment Boundary (D03-01-U2)," 2021-02-12. [e-Doc 6450519] *Protected B(R)*

[18] OPG report, "Target Delivery Equipment Design Requirement," NK38-DR-30552-00001 R000, 2020-01-28. [e-Doc 6109187] *Protected B(R)*

[19] OPG report, "Darlington Target Delivery System Human Factors Engineering Program Plan," NK38-PLAN-30550-00002 R002, 2020-12-18. [e-Doc 6481788] *Protected B(R)*

[20] OPG report, "Darlington Nuclear - Target Delivery System - System Design ALARA Assessment," NK38-REP-30550-00012 R001, 2021-01-22. [e-Doc 6481799] *Protected B(R)*

[21] OPG report, "Darlington Nuclear - TDS Shielding - Design Calculation," NK38-CALC-30552-00002 R001, 2021-01-11. [e-Doc 6481547] *Protected B(R)*

[22] OPG report, "Darlington Nuclear - Target Delivery System - ALARA Design Guide," NK38-GUID-30550-00001 R01, 2021-01-22. [e-Doc 6481786] *Protected (B)*

[23] OPG report, "Darlington Nuclear - Target Delivery System - ALARA Design Plan," NK38-PLAN-30550-00008 R001, 2021-01-14. [e-Doc 6481790] *Protected B(R)*

[24] OPG report, "Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington," N-REP-03500-0839983, 2021-02-24. [e-Doc 6510324] *Protected B(R)*

[25] OPG report, "Assessment of Target Delivery System for Molybdenum Irradiation on the Darlington Internal and External Hazard Screening," N-REP-03611-0764525, 2021-02-23. [e-Doc 6510313] *Protected B(R)*

[26] OPG report, "Assessment of Impact of Target Delivery System for Molybdenum Irradiation on the Darlington Probablistic Safety Assessment (PSA)," N-REP-03611-0778355, 2021-02-23. [e-Doc 6510317] *Protected B(R)*

[27] OPG email, L. Moraru to S. Baskey, "FW: OPG's Further Response to CNSC Staff Request: Mo-99 IIS CNSC staff Requests: 2021-03-23," 2021-04-20. [NK38-CORR-00531-22539, e-Doc 6542629, 6542623, 6547923] *Protected B(R) *

[28] OPG letter, S. Gregoris to K. Hazelton, "Darlington NGS – Molybdenum Isotope Irradiation System: Update to CNSC Staff on the Installation, Commissioning and Maintenance Strategies for the Unit 2 Target Delivery System," 2021-03-10. [NK38-CORR-00531-22384 P, e-Doc 6510680] *Protected B(R)*

[29] OPG letter, S. Gregoris to K. Hazelton, "Darlington NGS – Molybdenum Isotope Irradiation System: Quality Release Hold Points for Operation of the Target Delivery System in Unit 2," 2021-04-11. [NK38-CORR-00531-22468 P, e-Doc 6537718] *Protected B(R)*

# PART ONE – APPENDECIES

# A. Safety & Control Area Framework

## A.1 Safety and Control Areas Defined

The safety and control areas comprised of specific areas of regulatory interest which vary between facility types. The following table provides a high-level definition of each Safety and Control Area (SCA).

| SAFETY AND CONTROL AREA FRAMEWORK | | |
|---|---|---|
| **Functional Area** | **Safety and Control Area** | **Definition** |
| Management | Management System | Covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture. |
| Management | Human Performance Management | Covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties. |
| Management | Operating Performance | Includes an overall review of the conduct of the licensed activities and the activities that enable effective performance. |
| Facility and Equipment | Safety Analysis | Covers maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards. |
| Facility and Equipment | Physical Design | Relates to activities that impact the ability of structures, systems and components to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account. |
| Facility and Equipment | Fitness for Service | Covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This area includes programs that ensure all equipment is available to perform its intended design function when called upon to do so. |

| SAFETY AND CONTROL AREA FRAMEWORK | | |
|---|---|---|
| **Functional Area** | **Safety and Control Area** | **Definition** |
| Core Control Processes | Radiation Protection | Covers the implementation of a radiation protection program in accordance with the Radiation Protection Regulations. The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained ALARA. |
| Core Control Processes | Conventional Health and Safety | The implementation of a program to manage workplace safety hazards and to protect workers. |
| Core Control Processes | Environmental Protection | Covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities. |
| Core Control Processes | Emergency Management and Fire Protection | Covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises. |
| Core Control Processes | Waste Management | Covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning. |
| Core Control Processes | Security | Covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity. |
| Core Control Processes | Safeguards and Non-Proliferation | Covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*. |
| Core Control Processes | Packaging and Transport | Programs that cover the safe packaging and transport of nuclear substances to and from the licensed facility. |

## A.2 Specific Areas for this Facility Type

The following table identifies the specific areas that comprise each SCA for nuclear facilities:

| SPECIFIC AREAS FOR THIS FACILITY TYPE | | |
|---|---|---|
| **Functional Area** | **Safety and Control Area** | **Specific Areas (SpAs)** |
| Management | Management System | ▪ Management System<br>▪ Organization<br>▪ Performance Assessment, Improvement and Management Review<br>▪ Operating Experience (OPEX)<br>▪ Change Management<br>▪ Safety Culture<br>▪ Configuration Management<br>▪ Records Management<br>▪ Management of Contractors<br>▪ Business Continuity |
| Management | Human Performance Management | ▪ Human Performance Programs<br>▪ Personnel Training<br>▪ Personnel Certification<br>▪ Initial Certification Examinations and Requalification Tests<br>▪ Work Organization and Job Design<br>▪ Fitness for Duty |
| Management | Operating Performance | ▪ Conduct of Licensed Activity<br>▪ Procedures<br>▪ Reporting and Trending<br>▪ Outage Management Performance<br>▪ Safe Operating Envelope<br>▪ Severe Accident Management and Recovery<br>▪ Accident Management and Recovery |
| Facility and Equipment | Safety Analysis | ▪ Deterministic Safety Analysis<br>▪ Hazard Analysis<br>▪ Probabilistic Safety Analysis |

| SPECIFIC AREAS FOR THIS FACILITY TYPE | | |
|---|---|---|
| **Functional Area** | **Safety and Control Area** | **Specific Areas (SpAs)** |
| | | ▪ Criticality Safety<br>▪ Severe Accident Analysis<br>▪ Management of Safety Issues (including R&D Programs) |
| Facility and Equipment | Physical Design | ▪ Design Governance<br>▪ Site Characterization<br>▪ Facility Design<br>▪ Structure Design<br>▪ System Design<br>▪ Component Design |
| Facility and Equipment | Fitness for Service | ▪ Equipment Fitness for Service/Equipment Performance<br>▪ Maintenance<br>▪ Structural Integrity<br>▪ Aging Management<br>▪ Chemistry Control<br>▪ Periodic Inspection and Testing |
| Core Control Processes | Radiation Protection | ▪ Application of ALARA<br>▪ Worker Dose Control<br>▪ Radiation Protection Program Performance<br>▪ Radiological Hazard Control |
| Core Control Processes | Conventional Health and Safety | ▪ Performance<br>▪ Practices<br>▪ Awareness |
| Core Control Processes | Environmental Protection | ▪ Effluent and Emissions Control (releases)<br>▪ Environmental Management System (EMS)<br>▪ Protection of People<br>▪ Assessment and Monitoring |

| SPECIFIC AREAS FOR THIS FACILITY TYPE | | |
|---|---|---|
| **Functional Area** | **Safety and Control Area** | **Specific Areas (SpAs)** |
| | | ▪ Environmental Risk Assessment |
| Core Control Processes | Emergency Management and Fire Protection | ▪ Conventional Emergency Preparedness and Response<br>▪ Nuclear Emergency Preparedness and Response<br>▪ Fire Emergency Preparedness and Response |
| Core Control Processes | Waste Management | ▪ Waste Characterization<br>▪ Waste Minimization<br>▪ Waste Management Practices<br>▪ Decommissioning Plans |
| Core Control Processes | Security | ▪ Facilities and Equipment<br>▪ Response Arrangements<br>▪ Security Practices<br>▪ Drills and Exercises<br>▪ Cyber Security |
| Core Control Processes | Safeguards and Non-Proliferation | ▪ Nuclear Material Accountancy and Control<br>▪ Access and Assistance to the IAEA<br>▪ Operational and Design Information<br>▪ Safeguards Equipment, Containment and Surveillance<br>▪ Import and Export |
| Core Control Processes | Packaging and Transport | ▪ Package Design and Maintenance<br>▪ Packaging and Transport<br>▪ Registration for Use |

# B. General Assessment of SCAs

The specific areas that comprise the SCAs for this facility or activity type are identified in Appendix A. CNSC staff performed a comprehensive review of OPG's application [1] against each of the 14 SCAs to determine if the production and possession of Mo-99 through the operation of a Mo-99 IIS at Darlington NGS Unit 2 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 safe commissioning and operation of the Mo-99 IIS.

For any outstanding matters (such as document updates, supplemental analyses, additional reviews, additional training requirements, additional radiation protection measures that need to be taken, etc.), CNSC staff will review OPG's submission and the actions that have been taken to ensure that those matters have been addressed.

## B.1 Management System

The Management System SCA covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

This CMD covers the following SpAs within the Management System SCA:

- Management System & Organization
- Performance Assessment, Improvement and Management Review
- Problem Identification and Operating Experience (OPEX)
- Change Management, Configuration Management, & Records Management
- Management of Contractors
- Safety Culture
- Business Continuity

### Discussion

The installation and operation of the Mo-99 IIS involves a number of management system elements, to which OPG is expected to apply its management system to; including, but not limited to:

- Organizational arrangements (which includes accountabilities and responsibilities)
- Change management
- Work management
- Documentation management
- Planning
- Qualification of suppliers
- Management of contractors
- Adequacy of documentation used engineering change control (design changes, installation, commissioning, completion assurance, turnover)

- Oversight/verifications performed by OPG of work performed by suppliers
- Supplier performance monitoring performance
- Communication with stakeholders

## Regulatory Requirements

OPG has a management system that meets the regulatory requirements of CSA N286-12, *Management System Requirements for Nuclear Facilities*. 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. CNSC staff evaluated OPG's application by considering OPG's current management system, in the context of the Mo-99 IIS project, against regulatory requirements, including but not limited to the following:

- CSA N286-12, *Management System Requirements for Nuclear Facilities*
- REGDOC-2.1.2, *Safety Culture*

## Regulatory Focus

### Management system and Organization

In its application [1], 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 operation of the Mo-99 IIS. CNSC staff have determined that the OPG Nuclear Management System managing the current licensed activities will accommodate the proposed installation and operation of the Mo-99 IIS.

CNSC staff regularly inspect OPG's management system, and have determined that it complies with the requirements of the PROL, the LCH, and more specifically, CSA N286-12. CNSC staff will continue to provide regulatory oversight to verify that OPG continues to follow, apply, and maintain its management system.

### Performance assessment, improvement and management review

OPG has identified that no changes to program documents, N-PROG-RA-0010, *Independent Assessment* and N-PROG-AS-0001, *Managed Systems*, will be required to accommodate the proposed activities associated with the installation and operation of the Mo-99 IIS [1]. CNSC staff have determined that OPG has processes in place for self-assessment and audits that meet regulatory requirements. Further, OPG is required to assess activities associated with the Mo-99 IIS and will implement corrective actions and improvements in accordance with existing OPG processes.

### Problem identification and operating experience (OPEX)

OPG has a Station Condition Record (SCR) process to identify and document problems, investigate and evaluate results, and implement corrective actions related to people, plant, environment, and processes. 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 Mo-99 IIS project. OPG has proposed no changes to process documents, N-PROC-RA-0035, *Operating experience process* and N-PROC-RA-0022,

*Processing Station Conditions Records* for OPEX and problem identification, respectively [1]. CNSC staff expect that activities regarding the Mo-99 IIS will continue to be conducted in accordance with OPG's existing processes.

For design and safety analysis, OPG demonstrated that they have identified and considered OPEX from numerous sources including OPG's SCR database, CANDU Owners Group (COG) database, and international experience relevant to the irradiation of isotopes, modification of a nuclear power plant, and the design process for *first-of-a-kind* projects [1, 2]. OPG also identified and considered CANDU-specific OPEX related to fuel power ramping, moderator cover gas compositions, and deflagration [3].

As there is no direct OPEX for an equivalent target delivery system in an operating CANDU reactor, OPG and BWXT have performed proof-of-concept tests on components and are preparing a mock-up for testing and training. CNSC staff do not consider the lack of OPEX to be a barrier to the installation of the Mo-99 IIS. However, based on the lack of available experimental and operating data, CNSC staff emphasize the importance of the commissioning tests to confirm the design and operation of the Mo-99 IIS. CNSC staff have concluded that OPG has addressed requirements associated with problem identification and OPEX.

## Change management, configuration management, records management

OPG's process document N-PROC-MP-0090 *Engineering Change Control [ECC] Process* establishes the framework for managing design changes. In particular, the ECC process ensures that changes are documented and that governance is appropriately updated before the changes are implemented. OPG has applied N-PROC-MP-0090 for the planning and tracking of the Mo-99 IIS project. Further, OPG is expected to continue to apply this process to manage activities associated with Mo-99 IIS installation, commissioning, and the available for service (AFS) declaration ahead of the turn-over to operations.

Through review of ECC process records for this project and observation of key design review meetings, CNSC staff concluded the ECC process has been satisfactorily applied and followed. CNSC staff will continue to review the application of ECC activities (e.g. installation, commissioning, turnover, completion assurance) through planned compliance verification activities.

To accommodate the proposed activities associated with the installation and operation of the Mo-99 IIS [1], OPG has asserted that no changes to the following licensing basis governance are required: N-PROC-MP-0090, *Engineering Change Control Process* for engineering and design change management; N-PROG-AS-0001, *Managed Systems*, N-STD-MP-0027 *Configuration Management,* and N-STD-OP-0024 *Nuclear Safety Configuration Management* for configuration management; and OPG-PROG-0001 *Information Management* for records management.

Based on the review of information provided, CNSC staff concluded that OPG has sufficient engineering and design change management, configuration management and records management processes in place.

## Management of contractors

OPG has contracted four primary vendors for the Mo-99 IIS project: BWXT-NEC; BWXT-Canada; Kinectrics; and EcoMetrix [4]. One of the requirements of OPG's vendor qualification program is that vendors implement their own management system according

to the applicable requirements in CSA N286-12 [1]. OPG identified that the vendors contracted to perform the following aspects of the project are qualified by OPG Supply Chain Quality Services, in accordance with OPG-PROG-009, *Items and Services Management*:

- Design the Mo-99 IIS
- Engineer, procure & construct (EPC) the Mo-99 IIS
- Conduct supporting safety analyses for the Mo-99 IIS

The overall EPC execution of the project is intended to be carried out by BWXT-Canada for construction and BWXT-NEC for engineering and procurement under the BWXT Quality Assurance (QA) program and Certificate of Authorization. Through this model, OPG is required to ensure that BWXT-Canada/NEC uses sub-suppliers that are properly qualified and working effectively under the BWXT QA program [5].

The Mo-99 IIS Project Management Plan (PMP), *NK38-PMP-00120-00014* [5], defines how the project is planned, executed, monitored, and controlled. NK38-PLAN-30550-00006, *Engineering Oversight Plan for The Molybdenum-99 Isotope Project* defines the strategy for all phases of design of the Mo-99 project [6]. The OPG design and project team will perform oversight to ensure all supplied services and materials comply with OPG QA Program requirements [4]. The PMP also states that Laurentis Energy Partners (LEP), a wholly owned subsidiary of OPG, is the Project Owner, and that OPG and LEP will have a joint oversight role of the project's execution [5].

OPG's management system provides the process documentation and contract requirements for the execution of projects. The Mo-99 IIS 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. OPG, as the licensee, is ultimately responsible for continued safe operations at the Darlington NGS. Further, OPG is responsible for ensuring that all on-site activities, including those performed by contractors, are conducted in accordance with OPG's safety requirements.

CNSC staff will perform compliance verification activities to verify the adequacy of the contractor management program applied to the activities associated with the procurement and installation of the Mo-99 IIS. Specifically, CNSC staff are planning a technical assessment to assess OPG's oversight and completion assurance of the design/engineering, procurement, fabrication and testing of selected sample components of the Mo-99 IIS. Further, during planned regulatory oversight following the commissioning phase of the Mo-99 IIS, CNSC staff will review the key construction, commissioning, and the availability for service reports to verify they were successfully completed and demonstrate OPG's new Mo-99 IIS is compliant with CSA N286-12.

## Safety Culture

Part of OPG's management system includes N-POL-0001, *Nuclear Safety Policy*, which contains a directive 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. In its application, OPG has committed that the requirements set out in the Nuclear Safety Policy will not be affected by the operation of the Mo-99 IIS. Further, OPG has committed that the Mo-99 IIS operating manual will reinforce the pertinent regulatory requirements

and emphasize that continued safe reactor operation, compliance with operating limits and regulatory requirements will take priority over medical isotope production [1, 4].

OPG has also indicated that OPG-PROG-0010, *Health and Safety Management System Program*, which defines the overall process for managing safety and the responsibilities of the parties, specifically at the corporate level, and N-PROC-AS-0077, *Nuclear Safety Culture Assessment*, which is used to develop a safety culture self-assessment methodology, will not require any changes to apply to the activities associated with the production of Mo-99.

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.

#### Business Continuity

As part of OPG's management system, OPG has established governance to ensure strategic plans are in place for safe shutdown and follow-up activities in the event of labour disruptions. In its application [1, 4], OPG has stated that OPG-PROG-003, *Business Continuity Program* and N-GUID-09100-10000, *Contingency Guideline for Maintaining Staff in Key Positions When Normal Station Access Is Impeded* will not require changes to accommodate the new activities introduced during operation of the Mo-99 IIS.

### Conclusion

CNSC staff have determined that OPG has a management system that meets regulatory requirements with adequate processes in place to manage and ensure the successful completion of the Mo-99 project. CNSC staff recognize that OPG and its vendors integrated OPEX to identify, evaluate, and apply lessons learned to improve plant safety, reliability, and commercial performance.

CNSC staff concluded that OPG's established process to foster a healthy safety culture and to ensure business continuity will not be impacted by the installation and operation of the Mo-99 IIS.

CNSC staff concur with OPG's determination that the OPG Nuclear Management System, managing the current licensed activities, will be adequate to accommodate the proposed installation and operation of the Mo-99 IIS and that OPG's suite of governance continues to meet regulatory requirements. Through continued regulatory oversight, CNSC staff will verify that the requirements of CSA N286-12 are met during the various stages of the project, including design, procurement, installation, commissioning, and development of Mo-99 isotope irradiation program documentation that will govern the production of Mo-99 radioisotope.

## B.2 Human Performance

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

This CMD covers the following SpAs within the Human Performance SCA:

- Human Performance Program
- Work Organization and Job Design
- Fitness for Duty
- Personnel Training

## Discussion

This CMD does not cover the SpAs of *Personnel certification* and *Initial certification examinations and requalification tests* because the introduction of the Mo-99 IIS will not require any new certified positions. Prior to operation of the Mo-99 IIS and pending completion of the Mo-99 IIS operating manual, OPG is expected to provide training for Main Control Room (MCR) Authorized Nuclear Operators (ANOs) to qualify them to authorize field operations (seeding or harvesting).

In its application [1], OPG asserted that OPG's rigorous human performance program, N-PROG-AS-0002, *Human Performance*, would be applied to the Mo-99 IIS project. OPG has also identified that none of OPG's governance specific to human performance would need to be changed to accommodate the proposed activities associated with the operation of the Mo-99 IIS.

### Regulatory Requirements

#### Human Performance Program and Human Factors Engineering

As stated in the Darlington LCH, REGDOC-2.2.1, *Human Factors,* describes how the CNSC will take human factors into account during licensing and compliance activities. The CNSC provides additional guidance in REGDOC-2.5.1, *General Design Considerations: Human Factors*.

#### Fitness for Duty

OPG has a fitness for duty program which meets the requirement of REGDOC-2.2.4, *Fitness for Duty;* specifically*:*

- REGDOC-2.2.4, *Fitness for Duty: Managing Worker Fatigue* sets out the CNSC's requirements and guidance with respect to managing worker fatigue for workers at high security sites
- REGDOC-2.2.4, *Fitness for Duty, Volume II: Managing Alcohol and Drug use, Version 2* sets out the CNSC's requirements and guidance for managing fitness for duty of workers in relation to alcohol and drug use and abuse at all high-security sites

As part of OPG's fitness for duty program, OPG has in place a continuous behaviour observation program that trains supervisors and managers to monitor workers for fatigue or other factors that could adversely impact worker performance [4]. OPG also implements hours of work requirements in N-PROC-OP-0047, *Hours of Work Limits and Managing Worker Fatigue* that sets limits for the number of hours within a specified time period that station staff can work.

### Work Organization and Job Design

OPG is required to ensure the presence of a sufficient number of qualified workers to safely carry out all licensed activities. Furthermore, OPG must maintain a minimum shift complement (MSC) at all times in accordance with their PROL. The MSC is specific to each Nuclear Power Plant (NPP) and is influenced by the design of the facility, operating and emergency procedures, and organizational functions. REGDOC-2.2.5, *Minimum Staff Complement*, describes the CNSC's recommended approach for defining the minimum complement and sets out the key factors that CNSC staff will take into account when assessing whether the licensee has made adequate provision for ensuring the presence of a sufficient number of qualified staff.

### Personnel Training

Systematic approach to training (SAT) is the framework endorsed by the CNSC for establishing and maintaining training for persons working in nuclear facilities. A SAT-based training program provides the basis for the analysis, design, development, implementation, evaluation, documentation and management of training for workers. It also provides a method to demonstrate that the required knowledge, skills and safety-related attributes have been attained through a performance-based assessment, and that program evaluations are carried out to ensure training programs reflect the operating state of the facility.

REGDOC-2.2.2, *Personnel Training* sets out CNSC requirements for licensees regarding the development and implementation of a SAT-based training program. REGDOC-2.2.2 also provides guidance on how these requirements should be met.

The licence amendment application [1] asserted that OPG's SAT-based training program will be applied to ensure workers operating the Mo-99 IIS will be trained and qualified to carry out their duties.

## Regulatory Focus

### Human Performance Program and Human Factors Engineering

In its application [1], OPG acknowledged that human factors engineering (HFE) principles were applied during the design of the Mo-99 IIS, by BWXT-NEC, to reduce the probability of human errors. OPG also acknowledged that OPG HFE specialists were involved in this process providing oversight and guidance [1]. During this process, CNSC staff were provided with documentation summarizing work to date, and plans for completing the final reports related to HFE. CNSC staff will review these final reports under planned regulatory oversight when they have been accepted by OPG.

CNSC staff has determined that OPG's Human Performance Program at Darlington NGS will not be impacted and continues to meet regulatory requirements as a result of the proposed installation and operation of the Mo-99 IIS. Assurances to date that the application of HFE has been integrated in the design of the Mo-99 IIS have been comprehensive and will continue to be assessed under continuing CNSC regulatory oversight. Further details regarding CNSC's review of OPG's application of Human Factors in Design for the Mo-99 IIS are provided in Appendix B.5.

## Fitness for Duty

In its application [1], OPG stated that operation of the Mo-99 IIS will not impact OPG's fitness for duty program or compliance with hours-of-work requirements. CNSC staff reviewed the information provided by OPG and determined that installation and operation of the Mo-99 IIS will not impact OPG's fitness for duty program or compliance to hours-of-work requirements [4].

## Work Organization and Job Design

OPG's submission indicates that the impact on MSC was evaluated against, and informed by, the existing MSC technical basis documents (D-PROC-OP-0009 and N-INS-03490-10003) and the task analysis [7]. The task analysis identified that the ANO will have increased workload based on the additional activities identified. Specifically, OPG has stated that [8]:

- The field staff operating and maintaining the Mo-99 IIS will not be part of the station MSC
- The workload increase for the ANO will be minimal and will not affect the minimum shift compliment
- The staff operating the Mo-99 IIS will be dedicated to the seeding and harvesting of the targets and will not perform normal plant operations and maintenance tasks

OPG plans [7] to measure workload as part of the validation exercises as per REGDOC-2.2.5, *Minimum Staff Complement*. When OPG has completed the HFE Summary Reports, CNSC staff will review the workload measures for the ANO, and the recommendations provided by OPG if workload is determined to be too high, to verify continued compliance with OPG's governance and REGDOC-2.2.5.

As discussed in greater detail in Appendix B.4, OPG's safety analysis for the Mo-99 IIS concluded that the system does not introduce any new design basis events (DBEs). No additional operator actions were credited in order to mitigate the consequences of an accident involving the Mo-99 IIS. As such, there is no additional burden on operations with respect to required actions and no additional requirements on the MSC from a safety analysis point of view [8].

## Personnel Training

OPG has a well-established SAT-based training system described in OPG documents N-PROG-TR-0005 *Training*, N-PROC-TR-0008 *Systematic Approach to Training* and associated processes, procedures, instructions and job aids. OPG's training system is compliant with the CNSC training requirements in REGDOC-2.2.2, *Personnel Training*.

OPG's SAT-based training system includes a training-change control process to systematically assess and analyze equipment and procedural changes to determine training needs. OPG provided supplemental information demonstrating that Preliminary Training Assessments (PTA) and Training Needs Analysis (TNA) documentation for the worker groups impacted by the Mo-99 IIS are complete, with the exception of one TNA for Engineering/Reactor Safety (targeted to be available by Q2 2021) and the assessments for TDS Auxiliary Tooling [9].

As a result of the analyses received to date, OPG identified additional training for Non-Licensed Operators for activities to operate the Mo-99 IIS, Authorized Operators for control room interfacing, mechanical maintenance for flask activities and transportation package related activities, as well as engineering/reactor safety, and fuel and physics in support of ongoing Mo-99 IIS operations and maintenance. No other work groups were identified by OPG as having additional training needs.

OPG stated that specific training details remain outstanding and will be provided to CNSC staff following completion of the Factory Acceptance Testing (FAT) [4].

In its application [1], OPG has described that a mock-up of the Mo-99 IIS will be assembled at BWXT's facility in Peterborough Ontario, to facilitate training and finalize operating procedures. OPG has also indicated that a Mo-99 IIS simulator will be used to provide further training [1]. OPG further stated they are working closely with BWXT to finalize any additional awareness training for the Mo-99 IIS related to maintenance work and that the scope of all maintenance will be defined as per the Fitness for Service documentation targeted to be submitted to CNSC staff in Q4 2021 [9].

Based on the above, CNSC staff concluded that OPG has demonstrated use of their SAT-based training system to conduct preliminary analyses of training impacts for Mo-99 production. Specific training details and the scope of maintenance activities remain outstanding, which CNSC staff will review under planned regulatory oversight to ensure that workers are trained and qualified prior to carrying out activities associated with various milestones for the production of Mo-99.

### Conclusion

Based on the information provided by OPG to date, CNSC staff concluded that the Mo-99 IIS met regulatory requirements for Human Performance or, where information is outstanding, there is sufficient evidence that OPG is following its program governance to ensure that regulatory requirements will be met.

CNSC staff will continue to monitor OPG's Human Performance Program, Fitness for Duty, Work Organization and Job Design, and Personnel Training at Darlington NGS through planned regulatory oversight specific to the Mo-99 IIS project and established processes including field inspections, review of reportable events as per REGDOC 3.1.1, *Reporting Requirements for Nuclear Power Plants*, and review of OPG quarterly reports.

## B.3 Operating Performance

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

This CMD covers the following SpAs within the Operating Performance SCA; further, the impact of the Mo-99 IIS on the following topics of interest are discussed:

| SpA | Topics of Interest |
|---|---|
| ➢ Procedures | ➢ Impact on physics and fuel operating procedures |
| ➢ Safe Operating Envelope | ➢ Impact on reactivity management program |
| ➢ Severe Accident Management and Recovery | ➢ Establishment of a commissioning plan for confirmation of IIS characteristics |

- Accident Management and Recovery
- Efficacy of core monitoring software
- Impact on fueling practices
- Impact on compliance with channel and bundle power limits

# Discussion

## Regulatory Requirements

As discussed in appendix B.1, OPG is required to comply with REGDOC-2.1.2, *Safety Culture* and prioritize safe reactor operation over Mo-99 isotope production. Further, CSA N286-12, *Management system requirements for nuclear facilities* clause 7.9.6 requires that plant operations be performed in accordance with procedures that contain information and direction for operating workers to understand and perform work.

Additionally, in accordance with the Darlington PROL, OPG is required to implement and maintain operations programs. These programs shall consist of, at a minimum, a safe operating envelope (SOE), a set of operating policies and principles (OP&Ps), and accident management procedures and/or guides for design basis and beyond design basis accidents, including overall strategies for recovery. These programs are required to meet the requirements set out in:

- REGDOC-2.3.2, *Accident Management: Severe Accident Management Programs for Nuclear Reactors*
- CSA N290.15, *Requirements for the safe operating envelope for nuclear power plants.*

## Regulatory Focus

### Safe Operating Envelope

OPG has a mature SOE program that includes established processes and procedures to meet the requirements of CSA N290.15. In its application, OPG asserted that the SOE and the licensing basis will not require any changes to accommodate the activities associated with the operation of the Mo-99 IIS. OPG also noted that Mo-99 IIS operation will not impact safety limits, special safety system trip setpoints, or accident management procedures [1].

Specifically, OPG evaluated the change in reactivity worth from the Mo-99 IIS targets [3]. OPG's analysis determined that the installation, harvesting and reseeding of the Mo-99 IIS has no meaningful impact to the flux shape and/or power distribution. OPG also provided an analysis of the applicability of existing fuel management models [3]. The existing fuel management SORO model was updated using the DRAGON code to calculate the incremental cross sections of Mo-99 IIS and no deficiencies in the fuel management models were identified from the resulting model.

CNSC staff reviewed OPG's assessment of the efficacy of core monitoring software, the impact on fuelling practices, and the impact on compliance with channel and bundle power limits. CNSC staff conclude that OPG's assessment and supporting justification was adequate to demonstrate that the Mo-99 IIS will not have an impact on compliance with power limits. CNSC staff also reviewed the analysis providing verification of fuel

management code capabilities and determined that OPG's conclusions and supporting justification are reasonable.

In addition, CNSC staff reviewed OPG's assessment of the Mo-99 IIS on existing operating manuals, design manuals and governance including the reactivity management program and fuel and physics procedures [10]. CNSC staff found that the list of impacted governance, and the proposed scope of recommended changes for each document, is reasonable.

Overall, CNSC staff concur with OPG's conclusion that the Mo-99 IIS will not invalidate the current SOE limits and conditions. OPG will need to verify, through commissioning test results, that the reactivity worth of Mo-99 targets will have the predicted impact on bundle power and channel power distribution. CNSC staff will review OPG's final commissioning report to confirm this requirement has been met.

## Procedures

OPG's nuclear operations program, N-PROG-OP-0001, *Nuclear Operations,* which complies with the requirements of CSA N286-12. This program includes procedures for the development and revision of technical procedures.

As discussed above, OPG has provided a list of operating manuals and procedures that will be impacted by the Mo-99 IIS, and will require revision [1, 4, 10]. To this end, OPG has informed CNSC staff that all applicable control maintenance, mechanical maintenance, and operations procedures are currently being revised to integrate Mo-99 IIS maintenance and operations. OPG has also identified that it will develop numerous new procedures where necessary, in support of providing the appropriate maintenance for the Mo-99 IIS. During follow-up correspondences with CNSC staff [8], OPG has declared that it currently expects approximately:

- 50 procedures will be impacted
- 30 – 40 new maintenance procedures will be created to address periodic maintenance

Documentation reviewed by CNSC staff to date demonstrates that procedure writing for the Mo-99 IIS will follow established OPG processes and practices [7]. Prior to operation of the Mo-99 IIS, OPG has committed to providing a subset of these updated procedures which are of interest to CNSC staff, including a new operating manual and the procedure for flasking and transportation package preparation [8]. CNSC finds the list of impacted operating manuals and procedures to be consistent with CNSC staff's expectations.

## Accident Management & Recovery

OPG has performed a systematic review of the impact assessment of the Mo-99 IIS installation and operation on each of the event categories covered in the Darlington Safety Report [3, 11, 12]. The assessment demonstrated that there would be no material change in accident analysis results and event progression, and thus, the impact on accident management and recovery would also be negligible.

## Severe Accident Management & Recovery

Severe accident response and recovery is managed as part of N-PROG-OP-0001, *Nuclear Operations*. In addition, severe accident management for the Mo-99 IIS utilizes the existing concepts, structures, roles, and processes defined in OPG's Consolidated Nuclear

Emergency Response Plan (CNEP) to execute the mitigating measures necessary during a severe accident.

OPG performed analyses that assessed the impact of the Mo-99 IIS on severe accident conditions [3, 11]. Under severe accident conditions with core melt-down scenario, the Mo-99 IIS in-core components (target basket assembly, capsule assembly and molybdenum targets) have the potential to become part of the corium melt which can affect the accident progression. However, given the small Mo-99 IIS material addition, OPG's assessment showed no impact on the severe accident source term due to the installation and/or operation of the Mo-99 IIS. OPG also concluded that no changes would be required to the Darlington MAAP-CANDU parameter file due to the Mo-99 IIS, and that the Mo-99 IIS would have no impact on the release categories assigned to the different plant damage states. Therefore, OPG's analysis demonstrates that Mo-99 production would not result in release outside of containment and would have no impact on severe accident management and recovery.

CNSC staff reviewed OPG's submissions related to severe accident scenario and determined that the assessment was acceptable. As the operation of the Mo-99 IIS will have no impact on OPG's existing program for severe accident management and recovery, OPG continues to meet the requirements of REGDOC-2.3.2. Further details are available in Appendix B.4, *Safety Analysis.*

### Conclusion

CNSC staff determined that OPG is following its management system process in identifying impacted procedures and developing new maintenance procedures and manuals. CNSC staff will confirm the completion of these documents under planned regulatory oversight.

CNSC staff reviewed OPG's submitted documents and concluded that OPG has sufficiently demonstrated that the Mo-99 IIS will not invalidate the current SOE limits and conditions, including compliance with power limits. Overall, CNSC staff determined that OPG's submissions supporting the Mo-99 IIS have been comprehensive and are aligned with the regulatory requirements for Operating Performance. CNSC staff conclude that there are no fundamental safety concerns or apparent barriers to the safe installation and operation of the Mo-99 IIS and that the Mo-99 IIS will have no effect on severe accident management and recovery.

OPG has committed to providing installation and commissioning plans which will support CNSC staff verification of these conclusions. CNSC staff will review these plans when submitted, supported by a future submission providing the commissioning results, to verify that OPG continues to meet regulatory requirements and will have validated the assumptions and analysis results.

## B.4 Safety Analysis

The Safety Analysis SCA covers maintenance of the safety analysis that supports the overall safety case of the facility and in this case, specifically as it applies to the production of Mo-99 at the Darlington NGS. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards.

This CMD covers the following SpAs within the Safety Analysis SCA; further, the impact of the Mo-99 IIS on the following topics of interest are discussed in support of this SCA:

| SpA | Topics of Interest |
|---|---|
| ➢ Deterministic safety analysis<br>➢ Probabilistic safety analysis<br>➢ Hazard analysis<br>➢ Severe accident analysis<br>➢ Management of safety issues and research and development | ➢ Operational analyses<br>➢ Code applicability assessment<br>➢ Initiating event identification and classification |

## Discussion

This CMD will not discuss the Criticality Safety SpA as the installation and operation of the Mo-99 IIS will not change aspects of criticality safety and therefore does not introduce any concerns to criticality safety at Darlington NGS.

### Regulatory Requirements

In accordance with the Darlington PROL and LCH, OPG is required to implement and maintain a safety analysis program. REGDOC-2.4.1 *Deterministic Safety Analysis* and REGDOC 2.4.2 *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants* establish the requirements related to Deterministic and Probabilistic safety analysis, respectively. OPG completed its Mo-99 IIS project deterministic safety analysis, code applicability, and probabilistic safety assessment in accordance with REGDOC-2.4.1 and REGDOC-2.4.2.

In its application [1], OPG stated that its safety analyses were conducted in accordance with its ECC process, which is compliant with all applicable CSA standards in the N286 series, including CSA N286.7, *Quality assurance of analytical, scientific and design computer programs for nuclear power plants*. CSA N286.7 provides the specific requirements related to the development, modification, maintenance and use of computer programs used in analytical, scientific and design applications.

OPG's reactor safety and risk and reliability programs, supported by their implementing procedures and standards, govern the management of issues related to nuclear safety analysis and their impact on safe operation.

### Regulatory Focus

#### Deterministic Safety Analysis & Event Identification and Classification

In its application [1], OPG asserted its deterministic safety analysis for the Mo-99 IIS was completed in accordance with the requirements of REGDOC-2.4.1. Specifically, OPG determined that:

- The introduction of the Mo-99 IIS will have no impact on existing accident progression or consequences as detailed in the Darlington Safety Report
- Public dose consequences are either bounded by existing analyses or are significantly less than the allowable single failure dose limits

- There is no potential for a hydrogen deflagration event following a postulated loss of moderator inventory
- The effectiveness of the Neutron Overpower Protection (NOP) trip setpoint is not affected by the operation of the Mo-99 IIS and no changes will be required to any safety system setpoints

The installation of the Mo-99 IIS includes the insertion of new components into the calandria vessel. As such, the Mo-99 IIS has a direct interface with the moderator system and indirectly interacts with the primary heat transport system through potential changes to the neutron flux and the power distribution within the reactor core. With respect to deterministic safety analysis, this CMD will focus on the impact of the Mo-99 IIS on the Darlington NGS safety analysis.

OPG followed a systematic assessment process to assess the impact of the Mo-99 IIS on the Darlington Safety Report to identify the event categories of the current safety analysis impacted by the Mo-99 IIS and the new initiating events resulting directly from the Mo-99 IIS. This process included a review and assessment of the existing event categories, the relevant bounding analysis, the important phenomena, and key parameters. Using feedback from the aforementioned assessments along with engineering judgement, OPG determined whether a particular accident category required a quantitative or qualitative analysis.

Following this approach, OPG determined that the installation and operation of the Mo-99 IIS does not introduce any new phenomenon not considered in the current Safety Report. Further, OPG determined that the Mo-99 IIS will not significantly impact parameters associated with the main heat transport and secondary side systems. This result formed the basis for excluding additional quantitative analysis for accident categories driven by the behaviour of the main heat transport and secondary side systems. The following two lists summarize the event categories which OPG considered unaffected by the Mo-99 IIS, and those which were affected by the Mo-99 IIS and required further analysis.

| **Safety report event categories unaffected by the Mo-99 IIS:** | **Safety report event categories affected by the Mo-99 IIS:** |
|---|---|
| ➢ Fuel handling system failures | ➢ In-Core Loss of Coolant Accident |
| ➢ Feed water system failures | ➢ Loss of Moderator Inventory (LOMI) |
| ➢ Steam supply system failures | ➢ Loss of Moderator Forced Circulation |
| ➢ Loss of coolant accidents outside containments | ➢ Slow Loss of Regulation (Control failures) |
| | ➢ Loss of flow events |
| | ➢ Failure of the Mo-99 IIS Out-of-Core |

CNSC staff concluded that the methodology for OPG's determinations regarding which accident categories required quantitative analysis be performed to account for the installation and operation of the Mo-99 IIS is acceptable [3, 13]. Further, CNSC staff have determined the list of impacted accident categories in the current Safety Report and the new initiating events introduced by the installation and operation of the Mo-99 IIS is comprehensive.

Through their assessments, OPG has demonstrated that in all events where the targets are in-core, the presence of the Mo-99 IIS basket and the targets were found to have no impact on the consequences of the event. OPG has also demonstrated that there is substantial margin to the established acceptance criteria for the postulated out-of-core failure events.

Overall, CNSC staff determined that OPG sufficiently demonstrated that the response to these events will not be affected.

With respect to the loss of moderator inventory (LOMI) events, OPG has demonstrated [3, 12] that surface temperatures will remain below the surface ignition temperature following the postulated event. This surface temperature is also bounded by the results of the current analysis for adjuster heating. Therefore, CNSC staff concluded that there is no potential for a hydrogen deflagration event following a postulated loss of moderator inventory.

OPG has also performed a sensitivity study of the neutron overpower (NOP) trip set point. The assessment showed a small range of variation in the required trip set point, when comparing the reference trip set point to those calculated when impacted by the Mo-99 IIS. CNSC staff reviewed OPG's relevant submissions [3, 12, 14] and were satisfied with the assessment conducted. CNSC staff concluded that the impact of the Mo-99 IIS on the installed NOP trip set point would be insignificant.

While the Mo-99 IIS does not have a direct connection to the heat transport system (HTS), seeding/harvesting activities would result in flux shape changes and subsequently may affect bulk power. OPG has shown, that the Mo-99 IIS effects on the important bulk thermal-hydraulic parameters (*i.e.* total power, headers temperature and pressure, and coolant flowrate) are relatively insignificant; and as a result, CNSC staff concluded that the system response to relevant events will not be affected.

The Mo-99 IIS also has local effects on the axial power distribution of the individual fuel channels, particularly for channels located at close proximity to the molybdenum targets and those located at close proximity to the liquid zone control. The changes in axial power distribution have a potential impact on the critical channel power (CCP) and dryout characteristics of the affected channel. The CCP influence the trip timing and single channel response to these events. OPG has performed an assessment of the CCP with the four targets in core and demonstrated that the impact of the Mo-99 IIS is insignificant.

In addition to the systematic assessment of the impact of the Mo-99 IIS on the accidents from the Darlington Safety Report, OPG performed an Event Identification and Classification (EIC) review as the installation of the Mo-99 IIS may introduce new, or alter the existing, initiating events. The likelihood and the consequences of coincidence of the Mo-99 IIS initiating events with the current safety report initiating events were assessed as well. CNSC staff determined that OPG's EIC review has met the requirements of Sections 4.2.1, 4.2.2 and 4.2.3 of REGDOC-2.4.1.

Eleven (11) new initiating events, consisting of nine (9) design basis accidents (DBAs) and two (2) Anticipated Operational Occurrences (AOOs) were identified as a result of the installation and operation of the Mo-99 IIS. OPG's assessment also identified three (3) safety report events impacted by the Mo-99 IIS [3, 15]. OPG has determined that the reactor control systems and the safety systems are able to deal with these events as only a small perturbation will be introduced by the installation and operation of the Mo-99 IIS. CNSC staff have reviewed OPG's assessments and determined that the existing safety case remains valid.

Overall, CNSC staff concluded that for each appendix of the Safety Report, initiating events, event progression, input parameters, and important factors relevant to the event were considered. For the key parameters and factors that were quantitatively assessed, the impact of the Mo-99 IIS was determined to be negligible.

## Operational Safety Analysis

OPG also performed operational analyses to identify how normal operation of Unit 2 would be affected by the installation and operation of the Mo-99 IIS. The operating scenarios analyzed included cases for various core configurations; including, but not limited to the following:

- Normal operation
- Off-nominal liquid zone levels
- Newly fueled channels
- Withdrawn adjuster rods

In all cases, the effects of the Mo-99 IIS on parameters, such as bundle and channel powers, average zone level and individual liquid zone controller fill level were determined to be manageable by the reactor regulating system (RRS) with sufficient margin to current licensing limits. CNSC staff conclude that the operational analyses performed are sufficient to demonstrate that operation of the Mo-99 IIS will have negligible impact on current operational practices at Darlington NGS.

## Probabilistic Safety Assessment (PSA)

In support of its application [1], OPG conducted an assessment of the impact of the Mo-99 IIS on the existing Darlington PSA [3, 11], including the following elements, in accordance with REGDOC-2.4.2:

- Darlington Level 1 and 2 At-Power and Outage Internal Events
- Internal Fire, Internal Flood, Seismic and High Wind

Overall, OPG concluded that the installation and operation of the Mo-99 IIS has a negligible impact on all elements of the Darlington PSA listed above. The impact of the Mo-99 IIS on the quantification of Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) in the various PSA elements is negligible and the safety goals will continue to be met.

As a result, OPG has declared that the installation of the Mo-99 IIS does 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.

Based on the information reviewed, CNSC staff conclude that the PSA assessment performed by OPG is aligned with the requirements of REGDOC-2.4.2, and that the expected impact of installing and operating the Mo-99 IIS on the Darlington PSA is negligible.

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.

## Code Applicability

As required by REGDOC-2.4.1 and CSA N286.7, OPG performed a code applicability and accuracy assessment to confirm the applicability and accuracy of the suite of codes used in the analysis to support the installation and operation of the Mo-99 IIS. The intent of the

code applicability and accuracy assessment is to demonstrate that codes used to perform the analysis are qualified for the applications for which they are used.

CNSC staff reviewed OPG's assessment of the applicability of the computer codes used to support of the installation and operation of the Mo-99 IIS [3, 12]. OPG has demonstrated that the Mo-99 IIS will not introduce new phenomena or behaviour to the plant. As a result of the code applicability assessment, OPG did not propose changes to the reactor physics and thermal hydraulic tools or methods, but it did recognize a requirement to modify the core representation and material properties to account for the Mo-99 IIS; specifically, the presence of molybdenum in the core. To implement these changes, the incremental effects of the new material on the core neutronics were calculated and assumptions were assessed.

CNSC staff have determined that the framework of the evaluation model for core simulations met the requirements of REGDOC-2.4.1 and is unchanged by the introduction of the Mo-99 IIS. CNSC staff also determined that the justification supporting the requirement to modify the core representation and material properties to account for the Mo-99 IIS to be technically reasonable. CNSC staff conclude that the codes used by OPG to support installation and use of the Mo-99 IIS are appropriate.

In the supporting safety assessments referenced in OPG's application, CNSC staff noted that OPG supplemented the nuclear data library with approximations for the new materials associated with introducing molybdenum into the core [3]. Using Industry Standard Toolset codes, OPG benchmarked the results obtained using these approximations against an additional code (MCNP). OPG reported that the results between the two codes were similar, indicating the approximations made were reasonable. CNSC staff have determined the modelling methodology utilized by OPG is acceptable and expect that OPG will verify the adequacy of these approximations. OPG has identified that the models will be validated during commissioning, the results of which will be provided to CNSC staff for review. CNSC staff will review OPG's final commission through planned regulatory oversight activities following OPG's commissioning activities.

### Hazard Analysis

In support of its application [1], OPG completed a qualitative assessment for the Mo-99 IIS project [3, 16] to determine the impact of installing and operating the Mo-99 IIS on existing hazard assessments and to identify if any new internal hazards need to be considered in the Darlington PSA. Based on this assessment, OPG generated a list of applicable hazards (refer to summary in Table 2), and assessed them as part of the Darlington Hazards Screening Analysis [3, 16]. OPG then evaluated the resulting hazards that could not be screened to determine the impact of the Moly-99 IIS on the PSA.

CNSC staff's review of the information associated with the Hazard Analysis, determined that the assessments conducted were comprehensive and aligned with the requirements of REGDOC-2.4.2. CNSC conclude that the new hazards have been accounted for in the Hazard Analysis and that their impact on the Darlington PSA will be negligible.

**Table 2: Summary of Internal Hazards Affected by the Mo-99 IIS (Modified from [16])**

| # | Main Hazard Type(s) | Hazard |
|---|---|---|
| *1.* | In-Core Hazard | Target breaks apart during hydraulic transfer with release of its fragments into moderator |

| | | |
|---|---|---|
| *2.* | In-Core Hazard | Target damage in Target Elevator or in-core with release of its fragments into the moderator |
| *3.* | Radiation Hazard | Failure of Mo-99 IIS Exhaust System exhaust flow during Target Airlock Purging |
| *4.* | Radiation Hazard | Failure to purge the Airlock during harvesting or re-seeding |
| *5.* | Radiation Hazard | Failure of pneumatic tubing between the Airlock and the Flask Loader |
| *6.* | Radiation Hazard | Failure of containment isolation due to incorrect Target Airlock closing |
| *7.* | Radiation Hazard<br>Fire and Deflagration Hazards | Failure of Target Propulsion System hydraulic pressure boundary between Target Airlock and Target Elevator |
| *8.* | Loss of Reactivity Control<br>Radiation hazards | Human error resulting in a simultaneous harvesting of strings from two separate sites |
| *9.* | Loss of Reactivity Control | Failure to position Targets at the required in-core location |
| *10.* | Loss of Reactivity Control | Human error in proceeding with harvesting without confirming reactor state |
| *11.* | Fire and Deflagration Hazard | Failure to recombine $D_2$ and $O_2$ generated in adjuster thimbles during Mo-99 IIS operation |
| *12.* | Radiation Hazards | Target stuck in pneumatic or hydraulic transfer tubing |
| *13.* | Interfacing and Support System Failures | Loss of Class III electrical power supply to the Mo-99 IIS during harvesting or re-seeding |
| *14.* | Interfacing and Support System Failures | Loss of instrument air supply to the Mo-99 IIS during harvesting |
| *15.* | Interfacing and Support System Failures | Loss of communication to Mo-99 IIS |
| *16.* | Radiation Hazards | Target withdrawal from the core without dwell time for radioactive decay in the guide tube gas space |
| *17.* | Target Flask Hazards | Shield plug not removed from flask |
| *18.* | Target Flask Hazards | Shield plug not replaced |
| *19.* | Target Flask Hazards | Incorrect Magazine loading |
| *20.* | Target Flask Hazards | Incorrect replacement of shield plug |
| *21.* | Target Flask Hazards | Incorrect loading leads to targets left in pneumatic piping |
| *22.* | In-Core Hazards<br>Loss of Reactivity Control | Winch of cable failures |
| *23.* | Radiation hazards | Diverter failure, two strings sent to same site |
| *24.* | Radiation Hazards<br>Fire and Deflagration Hazards | Other combinations of equipment failures leading to a loss of containment |
| *25.* | Target Flask Hazards | Incorrect positioning of the flask in flask loader |
| *26.* | Radiation Hazards | Loss of $D_2O$ |
| *27.* | Jib Crane Hazards | Flask falls from jib crane (freefall or dropped) |

| | | |
|---|---|---|
| | Radiation Hazard | |
| *28.* | Jib Crane hazards<br>Radiation Hazards | Crane stalls during flask lowering (due to loss of power or lack of maintenance) |
| *29.* | Jib Crane Hazards<br>Radiation Hazard<br>Mechanical Rotation Hazard | Crane boom failure |
| *30.* | In-Plan Transportation Hazards | In-plant Transportation Accident |
| *31.* | On-Site Vehicle Movement Hazards | On-Site Vehicle Movement (outside of plant) |
| *32.* | Target Flask Hazards | Failure to load flask magazine |
| *33.* | Radiation Hazards<br>Fire and Deflagration Hazards | Zirconium Dust |

## Severe Accident Analysis

OPG's operational procedures ensure that the operation of the facility can be returned to a safe and controlled state should operation deviate from normal. In addition to the operational guidance for abnormal and emergency states, OPG maintains a severe accident management program to address residual risks posed by severe accidents. OPG has concluded that the Mo-99 IIS will have a negligible impact on the source term and that installation and operation of the Mo-99 IIS will not impact the procedures for accident and severe accident management.

OPG performed a qualitative assessment of the impact the installation and operation of the Mo-99 IIS would have on the severe accident fission products source terms and accident progression [3]. Under severe accident conditions, the Mo-99 IIS in-core components have the potential to melt and mix with the corium, which can affect the accident progression. By adding the Mo-99 IIS material to the corium mass, OPG has assessed if there are any required changes to either the OPG Darlington MAAP5-CANDU parameter file, or the severe accident release categorization and source term.

OPG's analysis demonstrated that the Mo-99 IIS would have no impact on either of the MAAP-CANDU parameter file or the severe accidents source terms. In addition OPG concluded that the Mo-99 IIS would not result in release outside of containment.

CNSC staff reviewed OPG's submission related to the assessment of the impact of the Mo-99 IIS on severe accidents analysis [3, 12] and determined that the assessment was acceptable and the impact of Mo-99 IIS on the severe accidents source term was negligible.

## Management of safety Issues, and research and development

In their application [1], OPG states that the Mo-99 IIS will have no impact on the management of CANDU Safety Issues (CSIs) and OPG's Research and Development programs. Further OPG performed a survey of the category 2 CSIs and determined that the installation and operation of the Mo-99 IIS has negligible impact on the management of the CSIs [10].

CNSC staff reviewed the impact of installing and operating the Mo-99 IIS on the LOMI analysis [3, 12], and conclude that there is no potential for deflagration following a postulated LOMI due to the presence of the Mo-99 IIS. CNSC staff also reviewed OPG's assessment of the impact of the Mo-99 IIS on coolant void reactivity (CVR),[3, 14]. CNSC staff determined that OPG's assessment of the matter and the supporting justification are acceptable and conclude that the impact of the Mo-99 IIS on CVR is negligible.

### Conclusion

OPG has asserted that the safety case of the facility will not be altered by the introduction of the Mo-99 IIS; the frequency of the DBAs and Beyond Design Basis Accidents (BDBAs) are not affected by the introduction of this system; and that the ability to control power, cool the fuel, and contain radioactivity is also not affected.

CNSC staff have assessed OPG's licence amendment application and supporting safety and operational analyses and conclude that:

- The submissions supporting the Mo-99 IIS project are aligned with the requirements for Safety Analysis
- There are no fundamental concerns regarding the safety analysis, which would represent a barrier to the installation of the system
- The Mo-99 IIS will have a negligible impact on the suite of Deterministic Safety Analyses which comprise the Darlington Safety Report
- The unit response to analyzed events will not be affected by the Mo-99 IIS
- The Mo-99 IIS will have a negligible impact on SCDF and LRF in the various PSA elements and that the safety goals will continue to be met
- The Mo-99 IIS will have a negligible impact on the source term during severe accidents
- The Mo-99 IIS will not impact severe accident management and recovery
- The Mo-99 IIS will have no impact on the management of CSIs and OPG's Research and Development programs
- The Mo-99 IIS does not introduce new potential for deflagration following a postulated LOMI
- The impact of the Mo-99 IIS on coolant void reactivity is negligible

To support safe operations, OPG is expected to verify the safety analysis inputs, simulation-generated key parameters, and analytical tools during the commissioning of the Mo-99 IIS. CNSC staff will confirm the adequacy of OPG's planned commissioning activities and will review the results under planned regulatory oversight following OPG's completion and submission of the final commissioning reports.

## B.5 Physical Design

The Physical Design SCA relates to activities that impact the ability of structures, systems and components to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

This CMD covers the following SpAs within the Physical Design SCA; further, the impact of the Mo-99 IIS on the following topics of interest are discussed in support of this SCA (note that the topics of interest in this section are used for sub-headings as they apply multiple SpAs):

| SpA | Topics of Interest |
|---|---|
| ➢ Structure Design | ➢ Process and Mechanical |
| ➢ System Design | ➢ Instrumentation and Control |
| ➢ Component Design | ➢ Electrical Power System |
| | ➢ Environmental Qualification |
| | ➢ Human Factors in Design |
| | ➢ Pressure Boundary |
| | ➢ Structure Design |
| | ➢ Seismic Qualification |

## Discussion

As this CMD is specific to the Mo-99 IIS, the following subsections will discuss CNSC staff's review of OPG's supporting submissions against the indicated topics of interest with respect to whether OPG's proposed design meets regulatory requirements.

### Regulatory Requirements

CNSC staff performed a review of the design information submitted by OPG for the Mo-99 IIS against the requirements detailed in the Darlington LCH. Specifically, CNSC staff reviewed the design against the following established standards providing the regulatory requirements for pressure retaining systems, seismic qualification, environmental qualification (EQ), and instrumentation & control:

- CSA N285.0 with Update No1 and No2, *General requirements for pressure retaining systems and components in CANDU Nuclear Power Plants*
- CSA N289.1, *General requirements for seismic design and qualification of CANDU nuclear power plants*
- CSA N289.3, *Design procedures for seismic qualification of CANDU nuclear power plants* [guidance]
- CSA N290.12, *Human factors in design for nuclear power plants*
- CSA N290.13, *Environmental qualification of equipment for CANDU nuclear power plants*
- CSA N290.14, *Qualification of digital hardware and software for use in instrumentation and control applications for nuclear power plants* [guidance]
- CSA N291-15: *Requirements for safety-related structures for CANDU nuclear power plants*

## Regulatory Focus

### Process and Mechanical

CNSC staff reviewed OPG's submitted design documentation, safety analyses, and operational assessments related to process and mechanical design of the Mo-99 IIS [3, 13, 17, 18]. Based on the review, CNSC staff determined that OPG and its vendor, BWXT-NEC, made adequate technical considerations to design the major components of the Mo-99 IIS, in compliance with regulatory requirements. Further validation that the system has met the design requirements and operates as expected will be obtained through review of OPG's FAT report and *in situ* tests during installation and commissioning.

In the design of the Mo-99 IIS, OPG has applied standard NPP design practices such as redundancy and isolation. For example, the Mo-99 IIS design includes two sets of Containment Isolation Valves (CIVs) on the flight-path (piping the targets are hydraulically or pneumatically propelled within), with each set containing two valves. The Mo-99 IIS control system utilizes a hardware interlock circuit to ensure that at least one set of valves will always be closed, which ensures that the containment boundary is maintained at all times. Furthermore, during upset conditions (*i.e.* a loss of power) the CIVs automatically *fail-closed*, with the exception of the flight-path CIVs which fail *as-is* in order to eliminate the chance of accidental closure on a target traversing the system. CNSC staff concluded that the design of the Mo-99 IIS will ensure that the containment boundary is maintained during normal operations and accident scenarios.

CNSC staff also assessed the impact of the Mo-99 IIS on the interfacing process/mechanical systems, which include Instrument Air System, Contaminated Exhaust System, and Moderator Cover Gas System. CNSC staff reviewed the impact calculations and analyses which confirmed that the additional load on each interfacing system is within each system's respective design basis. CNSC staff have identified, and communicated to OPG [19], additional components that should have been included in this assessment. CNSC staff will review OPG's updated impact calculations prior to installation of the Mo-99 IIS at Darlington NGS.

Based on the documentation reviewed to date, CNSC staff have determined that the Mo-99 IIS meets the applicable regulatory requirements for process and mechanical design. CNSC staff will continue to verify compliance through planned regulatory oversight and verification of the FAT.

### Instrumentation and Control

CNSC staff reviewed design documentation submitted by OPG related to instrumentation and control [3, 13, 17, 18].

The Mo-99 IIS control system is responsible for the control of the Mo-99 IIS system. The Mo-99 IIS control system is comprised of a local control console (next to the reactivity mechanism deck (RMD) and a MCR operator interface panel. The MCR interface panel consists of a control panel and a graphic human machine interface (HMI). The MCR console is meant to inform the ANO about the operational status of the Mo-99 IIS and grant permission for the local panel operator to control the Mo-99 IIS. In addition, a general Mo-99 IIS alarm is displayed on the alarm annunciation window on the unit specific MCR panel.

The Mo-99 IIS control system is physically separated from, and functionally independent of, the two shutdown systems and the Digital Control Computers (DCCs). This separation means the operation of Mo-99 IIS control system does not affect the operation of reactor control programs or the shutdown systems. The Mo-99 IIS control system includes a software-based system, which is implemented by a pair of redundant programmable logic controllers (PLCs), along with the control software. The PLCs are rated as Safety Integrated Level (SIL) 2 according to IEC Standard 61508, *Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems*. Furthermore, the control software is Category II in accordance with OPG's design governance. Category II software corresponds to SIL 2 according to the CSA N290.14-15, *Qualification of digital hardware and software for use in instrumentation and control applications for nuclear power plants*. To further improve the performance, OPG designed the Mo-99 IIS control system to use SIL 3 PLCs, which is one level higher than the required SIL 2 PLCs. CNSC staff consider that this is a conservative decision and is acceptable.

CNSC staff have determined that OPG's design governance for the control hardware and software for the Mo-99 IIS control system is in accordance with CSA N290.14-15, *Qualification of digital hardware and software for use in instrumentation and control applications for nuclear power plants*. CNSC staff consider that OPG's qualification of hardware and software for the Mo-99 IIS control system meets regulatory requirements.

CNSC staff determined that the Mo-99 IIS control system meets the applicable regulatory requirements for design of instrumentation and control systems.

## Electrical Power Systems (EPS)

Various components associated with the Mo-99 IIS will be supplied from the high reliability and redundant Class III, Class II and Class I electrical power supplies. OPG performed the relevant electrical analyses for Class III, standby generators, and Class I/II in order to validate that the additional loading to the existing Electrical Power System (EPS) is insignificant.

CNSC staff reviewed electrical design documentation [3, 13, 17, 18] submitted by OPG, including the supporting short circuit, load flow and voltage drop analysis and confirmed that the addition of the Mo-99 IIS has negligible impact on the overall EPS.

Based on the information submitted by OPG, CNSC staff determined that the Mo-99 IIS electrical design meets the applicable regulatory requirements and that the additional load has negligible impact on the existing Class III/II/I power systems.

## Environmental Qualification (EQ)

OPG identified in its application that it is applying existing EQ governance N-PROG-RA-0006, *Environmental Qualification* to the Mo-99 IIS to meet the requirements of CSA N290.13-05, *Environmental qualification of equipment for CANDU nuclear power plants* [1]. The design takes into account the EQ of the Mo-99 IIS components and the impact the Mo-99 IIS will have on the EQ of the existing surrounding systems [20]. OPG has committed to environmentally qualify all of the Mo-99 IIS required equipment to ensure the effect of the harsh environmental conditions will not affect the system [3, 13, 21].

Based on the information provided, CNSC staff conclude that the operation of Mo-99 IIS does not pose additional risk to the EQ of the units at Darlington NGS. CNSC staff will

continue to verify that the detailed EQ activities associated with the Mo-99 IIS meet regulatory requirements related to EQ.

## Human Factors in Design

OPG is applying its ECC process to the Mo-99 IIS, which includes consideration of HFE to meet regulatory requirements found in CSA N290.12-14, *Human factors in design for nuclear power plants.*

As discussed in Appendix B.2 of this CMD, OPG has provided interim information that provided an overview of human factors work done to date for the Mo-99 IIS project as well as the plans for completing the final reports related to HFE. CNSC staff have reviewed OPG's Human Factors Engineering Program Plan (HFEPP) for installation of the Mo-99 IIS on Unit 2 [7]. This plan described the HFE activities and objectives for the Darlington Mo-99 IIS project including engineering design, build, manufacturing, installation and commissioning information for the tooling and associated systems.

CNSC staff also reviewed OPG's Human Factors Verification and Validation Plan (HFVVP) [22] to ensure that adherence to human factors guidelines was maintained. OPG's Mo-99 IIS HFVVP described the intended processes that will be used to demonstrate that the Mo-99 IIS has been designed as specified. CNSC staff also used the HFVVP to determine the degree to which the human-machine system design and supporting mechanisms facilitate the achievement of overall safety and operational goals. Together, the HFEPP and HFVVP provided CNSC staff with evidence that OPG is following its program and considering HFE.

As the planning and conduct of the installation and commissioning phases commence, OPG has identified that a final HFE Summary Report will be produced after post-installation verification and validation activities have been completed. CNSC staff will review the planned post-design and post-installation versions of this report, as well as additional deliverables, such as the HF Verification Activities Results, under planned regulatory oversight in order to confirm that OPG has met the requirements of CSA N290.12.

Based on the information provided to date, CNSC staff conclude that OPG is following its governance in considering human factors in the design of the Mo-99 IIS. CNSC staff will verify, through review of OPG's subsequent submissions, that the Mo-99 ISS design continues to meet all applicable regulatory requirements.

## Pressure Boundary and Containment boundary

OPG has a pressure boundary program, N-PROG-MP-0004, Pressure *Boundary Program*, for Darlington NGS that meets the requirements of CSA N285.0. There is a formal agreement in place for the Technical Standards and Safety Authority (TSSA) to act as an Authorized Inspection Agency to provide services for the pressure boundary components.

In its application, OPG stated that the Mo-99 IIS will result in a change to the existing containment boundary [1]. Changes will be made to four of the existing, unused (locked out of core) Adjuster Rod mechanisms, which will be removed and substituted with Mo-99 IIS components [1]. As required by NK38-DBD-34280-00001, *Containment Boundary Manual*, a qualified (Class 2) containment boundary will be maintained at all times.

In its submission requesting code classification approval of the Mo-99 IIS from CNSC staff [23], OPG demonstrated that modifications made for installation of the Mo-99 IIS will

have a negligible impact on existing Structures, Systems and Components (SSCs), and that the reactor containment boundary will continue to be maintained. CNSC staff reviewed and approved OPG's request for CNSC staff consent for code classification [24].

CNSC staff concluded that the Mo-99 IIS design will have negligible impact on existing SSCs, and that pressure boundary and containment boundary requirements have been met.

### Structure Design

In its application, OPG stated that the Mo-99 IIS will require installation of a platform where the Mo-99 IIS components will be installed [1, 17]. In the final design packages for the Mo-99 IIS submitted by OPG, details regarding the Mo-99 IIS platform design were provided [17, 18]. Based on documents reviewed to date from these design packages, CNSC staff conclude that the design of the Mo-99 IIS component platform meets regulatory requirements. CNSC will confirm, through planned regulatory oversight during the Mo-99 IIS installation phase, supported by continued review of final design documentation, that the system continues to meet regulatory requirements.

### Seismic Qualification

OPG has a seismic qualification process that meets the requirements of CSA N289.1, which it is applying to the design of the Mo-99 IIS. CNSC staff have reviewed information provided by OPG following the detailed design phase of the Mo-99 IIS project [17, 18]. Of the documents reviewed to date, CNSC staff have determined OPG's approach to seismic qualification is consistent with their program/process requirements. CNSC staff will continue to provide regulatory oversight during the Mo-99 IIS installation phase, supported by continued review of OPG's detailed design documentation [17], to verify that the Mo-99 IIS design conforms to seismic design requirements.

### Impact on core neutronics and reactivity characteristics

In their application [1] and supporting documents [3, 13] submitted to CNSC staff, OPG assessed the reactivity worth of the system's in-core components and considered the impact of the operation of the Mo-99 IIS on core neutronics. As a result of these assessments, OPG has concluded that the operation of the Mo-99 IIS remains within the capabilities of the Reactor Regulating System (RRS). Specifically:

- The impact of the Mo-99 IIS on normal and perturbed core states, based on a set of qualitative and quantitative case studies, is determined to be negligible based on the limited impact to bundle powers, channel powers and zone levels.
- The reactivity worth of the Mo-99 IIS is evaluated and judged to be small, relative to the effects of regular fueling activities.
- The change in reactivity worth of the Mo-99 IIS targets was evaluated for periods of 7 days, 30 days, 3.5 years and 7.0 years in-core. The change in reactivity worth of the targets was evaluated to be small enough to have no impact on the core power distribution or core characteristics.
- The impacts of harvesting and reseeding on core parameters were determined to be negligible for normal operations as well as other possible operating scenarios including nominal liquid zone levels, newly fueled channels, and withdrawn adjuster rods.
- The incremental cross sections are evaluated and used to estimate the reactivity worth of the Mo-99 IIS.

- The neutron detector readings for a series of operational cases are analyzed and the effects of the Mo-99 IIS harvesting and reseeding operations are small but observable.

CNSC staff reviewed the technical basis and conclusions presented in OPG's assessments and concluded that OPG has sufficiently considered the impacts of the Mo-99 targets on the core, and have demonstrated that the impact of Mo-99 IIS operation remains within the capabilities of the RRS.

CNSC staff note that in its application [1], OPG has committed to updating the reactivity management plan to predict and ensure that the reactivity effects match the analysis predictions of target insertion and removal, and that reactivity returns to steady state following target movement.

Prior to operation of the Mo-99 IIS, CNSC staff expect that OPG will evaluate and validate the accuracy of the tools and methods used to estimate the incremental cross sections using the data obtained during the commissioning process. OPG has identified that these results will be documented in the final commissioning report, which will be provided to CNSC staff [4]. Ahead of this final assessment, CNSC staff will review the detailed commissioning plans and specifications, under planned regulatory oversight, to ensure that OPG sufficiently validates the analyses in the supporting documentation [3] of its application [1].

### Conclusion

CNSC staff have determined that OPG has ensured that the design meets all regulatory requirements through application of appropriate programs. CNSC staff have found that OPG has met regulatory requirements regarding: EPS; instrumentation and control; pressure and containment boundaries; and process and mechanical systems. Further, based on the documents reviewed to date, CNSC staff have found OPG's approach to human factors engineering and seismic and environmental qualification to be consistent with their program requirements. As several planned reports will not be completed until prerequisite work is carried out during the respective pre- and post- installation/commissioning phases, CNSC staff will continue to conduct technical assessments, inspections, and planned regulatory oversight to verify that OPG continues to use its programs and meet regulatory requirements.

## B.6 Fitness for Service

The Fitness for Service SCA covers activities that impact the physical condition of SSCs to ensure that they remain effective over time. This area includes programs that ensure the Mo-99 IIS equipment is available to perform its intended design function when called upon to do so.

This CMD covers the following SpAs within the Fitness for Service SCA:

- Maintenance
- Aging management
- Chemistry Control

## Discussion

Effective aging management uses a systematic approach that provides an integrated framework for coordinating all supporting programs (e.g., a maintenance program, a periodic inspection program) and activities associated with the understanding, control, monitoring and mitigation of aging effects on the SSCs that will be newly installed in the Mo-99 IIS project. As this CMD is specific to the Mo-99 IIS, there is no impact to aging management of SSCs or OPG's Periodic Inspection Plan (PIP).

### Regulatory Requirements

OPG's maintenance programs are required to meet the requirement of REGDOC-2.6.1, *Reliability Programs for Nuclear Power Plants* and REGDOC-2.6.2, *Maintenance Programs for Nuclear Power Plants*.

OPG's program for aging management is required to meet the requirements described in REGDOC-2.6.3, *Aging Management*, as well as CSA N285.4-14, *Periodic inspection of CANDU nuclear power plant components* and N285.5-08 (with Update No.1), *Periodic inspection of CANDU nuclear power plant containment components.* Further guidance and recommendations are included in REGDOC-2.5.2, *Design of Reactor Facilities: Nuclear Power Plants.*

OPG's chemistry control program is required to meet the chemistry management requirements of CSA N286-12 *Management System Requirements for Nuclear Facilities*.

### Regulatory Focus

#### Maintenance & Aging Management

OPG implements and maintains a maintenance program, N-PROG-MA-0019 *Production Work Management Program*, to meet the regulatory requirements for maintenance. In its application [1], OPG stated that Mo-99 IIS maintenance activities will be scheduled and conducted in accordance with N-PROG-MA-0019, *Production Work Management*. OPG also stated that aging management of the Mo-99 IIS components will be managed through its existing aging management program N-PROG-MP-0008, *Integrated Aging Management Program*. This program meets the regulatory requirements to ensure the condition of critical equipment are understood, and required activities are in place to ensure the health of these components and systems while the station ages.

CNSC staff reviewed OPG's high-level maintenance strategy for the Mo-99 IIS [25]. Based on the strategy, the development of a detailed maintenance program is to be based on the failure modes and effects analysis (FMEA) and the reliability analysis of the system. The strategy also lists the anticipated preventive maintenance activities for the major components and equipment, such as valves, operator control console and circuit breakers. Additionally, the design takes into account the maintainability of the Mo-99 IIS and the impact of the new system on the maintenance of the existing surrounding systems [2, 20, 26]. CNSC staff determined that the maintenance strategy of the Mo-99 IIS, which accounts for maintainability, complies with the regulatory requirements for maintenance programs.

As discussed in Appendix B.3, OPG has stated that approximately 50 impacted control maintenance, mechanical maintenance, and operations procedures are currently being

revised to accommodate Mo-99 IIS maintenance and operations. Additionally, OPG is expecting that approximately 30 – 40 new maintenance procedures will be created to address periodic maintenance on the Mo-99 IIS [8].

At the time of drafting this CMD, the detailed Mo-99 IIS specific preventive maintenance and aging management documentation (*e.g.*, plans, manuals, assessments) were still in development. OPG has committed to provide the Mo-99 IIS preventive maintenance plans to CNSC staff prior to system operation as part of a regulatory commitment provided to CNSC staff [4]. CNSC staff considered this OPG commitment to be acceptable, and will verify through continuing oversight that the Mo-99 IIS will be safely and adequately maintained.

### Chemistry Control

In their application [1] and supporting technical documentation submitted to CNSC staff [3, 13], OPG stated that chemicals will not be used during Mo-99 IIS operation. Therefore, Mo-99 IIS operation will not generate undesirable chemical interactions. OPG determined that the proposed installation and operation of the Mo-99 IIS will have negligible impact on the chemistry control of the reactor. OPG's assessment considered the inadvertent release of the solid metal targets directly into the moderator and the interactions between molybdenum and existing species found in the calandria to determine that there would be negligible impact on the chemistry control of the reactor. Specifically, OPG's analysis claimed:

- Under normal operating conditions of the moderator system, molybdenum will not disperse into the moderator heavy water by a dissolution mechanism. Molybdenum dispersion in moderator heavy water by chemical reaction is impossible due to unfavorable electrode potentials of the two half-cell reactions involved.
- Molybdenum will not cause the precipitation of chemicals in the moderator, such as the gadolinium poison (gadolinium nitrate) or the boron poison (boric acid) under normal operating conditions, and hence there is no risk from a chemical reaction.
- The loss of gadolinium by precipitation as gadolinium molybdate, which could occur under the conditions of a guaranteed safe shutdown state, would not significantly alter the neutron poison conditions and would not place the moderator system outside of safety margins.
- If the molybdenum metal comes into contact with metals inside the calandria (i.e., stainless steel), there will be a tendency for it to go into solution by the process of galvanic corrosion. However, the corrosion process is expected to be sufficiently slow that the moderator's purification system would mitigate any operational risk.
- The presence of molybdenum would not create any additional risks because of contact with corium (in the case of BDBAs), beyond the risks already associated with the formation of corium itself.

CNSC staff reviewed the technical basis for OPG's conclusions with respect to chemistry impact of the Mo-99 IIS. Specifically, molybdenum dispersion in the moderator, potential for precipitation of moderator poisons, corrosion effects on moderator structures and contact with corium in a BDBA. CNSC staff determined that OPG's assessment of the impact of the Mo-99 IIS on system chemistry [3, 13] meets the applicable regulatory requirements and concluded that the installation and operation of the Mo-99 IIS will have minimal impact on the chemistry control of the units.

### Conclusion

CNSC staff concluded that OPG met the fitness for service requirements at the current stage of development of the Mo-99 IIS. The maintenance and aging management of the Mo-99 IIS will be managed under OPG's existing programs to ensure that the installation and operation of the Mo-99 IIS continues to meet regulatory requirements. CNSC staff will review OPG's submission of the Mo-99 IIS detailed preventive maintenance plans and aging management strategy under planned regulatory oversight.

## B.7 Radiation Protection

The Radiation Protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. This program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained As Low As Reasonably Achievable (ALARA).

This CMD covers the following SpAs within the Radiation Protection SCA:

- Application of ALARA
- Worker Dose Control
- Radiological Hazard Control
- Radiation Protection Program Performance

### Discussion

#### Regulatory Requirements

The *Radiation Protection Regulations* require licensees to establish a radiation protection program to keep exposures ALARA, taking economic and social factors into account, through the implementation of a number of control programs, including:

- Management control over work practices
- Personnel qualification and training
- Control of occupational and public exposures to radiation
- Planning for unusual situations

OPG's radiation protection program (N-PROG-RA-0013) and its associated supporting governance documents are designed to address the requirements set out in the *Radiation Protection Regulations.*

CNSC staff's past assessments of the adequacy of OPG's program have determined that OPG has implemented and maintained an effective radiation protection program at Darlington NGS that met regulatory requirements.

With respect to the Mo-99 IIS, OPG has identified [1, 4] that it will utilize its existing Radiation Protection program and implementing procedures to maintain worker doses below regulatory limits and ALARA, and to protect the health and safety of persons involved in the installation, operation and maintenance of the Mo-99 IIS.

## Radiation Protection Program Performance

The oversight applied by OPG in implementing and improving its Radiation Protection program is effective in protecting workers at Darlington NGS. OPG continually measures the performance of its Radiation Protection program against industry-established objectives, goals and targets and benchmarks its program against industry leading stations.

OPG has indicated [1] that they will apply their Radiation Protection program to protect the health and safety of persons involved in the installation, operation and maintenance of the Mo-99 IIS. OPG reported [1, 4] that the Radiation Protection program and supporting governance documents that form the licensing basis for the Mo-99 IIS include:

- N-MAN-03416-10000, *Radiation Dosimetry Program – General Requirements*
- N-MAN-03416.1-10000, *Radiation Dosimetry Program – External Dosimetry*
- N-MAN-03416.2-10000, *Radiation Dosimetry Program – Internal Dosimetry*
- N-PROC-RA-0019, *Dose Limits and Exposure Control*
- N-PROC-RA-0027, *Radioactive Work Planning, Execution and Close Out*
- N-PROG-RA-0013, *Radiation Protection*
- N-REP-03420-10001, *Occupational Radiation Protection Action Levels for Power Reactor Operating Licences*
- N-STD-RA-0018, *Controlling Exposure As Low As Reasonably Achievable*
- OPG-PROC-0132, *Respiratory Protection*

In identifying these documents, OPG stated that their Radiation Protection program had recently undergone an independent third party review and that they strengthened the program based on the review findings. OPG also reported that the Mo-99 IIS does not necessitate any changes to radiation protection governance or to the Radiation Protection Action Levels.

CNSC staff expect that OPG will continue to apply their radiation protection program performance metrics, to track performance and to identify areas for improvement.

CNSC have no concerns related to this specific area.

## Application of ALARA

OPG's Radiation Protection program adheres to the ALARA principle by integrating ALARA measures into planning, scheduling, and work control; and by establishing and monitoring performance against ALARA targets for work conducted at Darlington NGS.

With respect to the Mo-99 IIS design, OPG identified [1, 4] that it followed CNSC guidance document G-129 *Keeping Radiation Exposures and Doses As-Low-As-Reasonably-Achievable* (ALARA). During the design phase, OPG applied the three basic protective measures associated with the ALARA principle (time, distance and shielding) [27-30]. To minimize worker dose: time delays were incorporated into the Mo-99 production phase to allow short-lived radionuclides to decay away, thereby reducing the radiological hazard; equipment that require personnel access were installed in low background radiation areas away from components that emit high radiation fields; and shielding was incorporated into the design to reduce external radiation hazards. The Mo-99 IIS design requirements included radiation safety design requirements that were

consistent with the ALARA elements found in OPG's Radiation Protection program and implementing procedures [31]. CNSC staff conclude that OPG suitably applied the ALARA principles to the Mo-99 IIS design, and that the design was consistent with OPG's Radiation Protection program requirements.

Lastly, as OPG indicated in its application [1], that the Mo-99 IIS will be subject to its existing radiation protection program, CNSC staff expect the day-to-day operation and maintenance will be subject to the same ALARA planning and oversight requirements specified in OPG's established radiation protection program. CNSC staff will monitor OPG's operation and maintenance of the Mo-99 IIS through ongoing regulatory oversight.

## Worker Dose Control

OPG's Radiation Protection program is designed to ensure that doses to workers are controlled and do not exceed regulatory limits. During the current licensing period, OPG has maintained radiation doses to workers below the regulatory dose limits and Action Levels established in their Radiation Protection program. There have been no adverse trends or safety-significant unplanned exposures due to the licensed activities at Darlington NGS.

With respect to the Mo-99 IIS design [27-30], OPG used numerous criteria to minimize and control worker doses including material selection, equipment layout, system automation, engineered barriers, shielding, radiation monitors, tooling and procedures. CNSC staff note that in their submissions, OPG estimated that the incremental increase to an individual worker's whole body dose from the licensed activity, together with all other occupational exposures at Darlington NGS in the course of the year, will be below OPG's Exposure Control Levels (10 mSv/y) and Administrative Control Levels (20 mSv/year); both of which are set below the regulatory limit (50 mSv/y). Information provided by OPG did not reveal any accident scenarios that posed radiation protection conditions of regulatory concern. CNSC staff are satisfied with how the Mo-99 IIS design will achieve control over worker doses.

As previously noted, OPG indicated that the operation and maintenance of the Mo-99 IIS will be subject to its Radiation Protection program. OPG identified the continued use of administrative levels, and the use of work planning and monitoring (of people and materials) to manage worker exposures and prevent uncontrolled releases of contamination or radioactive materials. This methodology aligns with the worker dose control requirements in OPG's Radiation Protection program that have been successful at keeping worker exposures below regulatory limits and ALARA. OPG also reported that the Mo-99 IIS does not necessitate any changes to the Radiation Protection Action Levels.

CNSC staff conclude that OPG has processes in place, and has suitably applied worker dose control measures to the Mo-99 IIS design.

## Radiological Hazard Control

OPG's Radiation Protection program requires monitoring and control of all radiological hazards at Darlington NGS. The program measures related to radiological hazard control include radiological zoning, contamination control, dose rate control, and area and airborne radiation monitoring and control. Radiological hazards are eliminated (when possible), or controlled with engineered barriers and signage identifying the level and extent of hazard

areas. Where possible, radiation fields encountered by workers during operation and maintenance activities are further reduced using temporary shielding.

With respect to the Mo-99 IIS design, OPG identified that they need to manage the associated radiation hazards to ensure compliance with OPG's Radiation Protection program [1]. To ensure compliance, OPG implemented various criteria to achieve effective radiological hazard control including material selection, media filtration, air/exhaust control, shielding, engineered barriers, radiation monitors (alarming), manual isolation valves, tooling and procedures [27-30, 32, 33]. OPG also provided estimated dose rates associated with key locations that operators or maintainers may need to occupy (or at the closest points of bystander approach) during Mo-99 target harvesting. CNSC staff have no concerns related to how the Mo-99 IIS design will achieve control over radiological hazards.

As previously noted, OPG indicated that the operation and maintenance of the Mo-99 IIS will be subject to its Radiation Protection program. In their submissions [27-30], OPG described their use of source term control, time, distance, shielding, and radiological monitoring to aid in controlling the Mo-99 IIS radiological hazards. These techniques align with practices found in OPG's Radiation Protection program, which have been successful at controlling the radiological hazards at Darlington NGS.

CNSC staff conclude that OPG suitably applied radiological hazard control measures to the Mo-99 IIS design.

## Regulatory Focus

OPG aims to utilize its existing Radiation Protection program and implementing procedures to maintain worker doses below regulatory limits and ALARA; and to protect the health and safety of persons involved in the installation, operation and maintenance of the Mo-99 IIS. OPG has a robust Radiation Protection program that has matured over a number of years managing significant hazards, such as those encountered while disassembling and reassembling the Unit 2 reactor during refurbishment. The radiological hazards associated with the Mo-99 IIS are not unique and CNSC staff expect OPG's Radiation Protection program to be able to manage their associated risks.

CNSC staff's review of the Mo-99 IIS submissions [27-30] verified that OPG's Mo-99 IIS design assessed and addressed the radiological hazards that have the potential to occur during normal operation of the system. CNSC staff determined that the design of the Mo-99 IIS included radiation protection requirements to ensure workers will be protected from the radiological hazards associated with the system.

To further demonstrate that OPG will keep worker doses ALARA, as required by paragraph 4(a) of the *Radiation Protection Regulations*, CNSC staff will review OPG's future submissions on the maintenance activities associated with the Mo-99 IIS. CNSC staff expect that OPG's submission will confirm that the equipment layout, and the maintenance philosophy, contribute to reducing worker doses by providing for efficient operation, and by facilitating and expediting radioactive work associated with inspection, maintenance and repair/replacement.

As OPG has committed to provide CNSC staff with the final Commissioning report, CNSC staff will review this report to verify whether the final installed Mo-99 IIS complies with section 4 of the *Radiation Protection Regulations*. In particular CNSC staff will confirm that OPG has:

- Established actual baseline radiological conditions associated with the Mo-99 IIS design, to include Mo-99 activity in irradiated targets, dose rates across the Mo-99 IIS system (in particular, at key locations where operators or maintainers may need to occupy, or at the closest points of bystander approach)
- Verified the validity of Radiation Protection design assumptions (e.g., target transfer duration, flask loading durations, shielding effectiveness, etc.)
- Confirmed the radiation protection measures implemented in the Mo-99 IIS design will ensure that dose to workers will remain below regulatory limits and OPG administrative levels
- Identified whether any additional measures can be taken to further reduce worker doses ALARA

### Conclusion

CNSC staff conclude that OPG has incorporated radiation protection measures into the Mo-99 IIS design and have assessed and mitigated potential radiological hazards. CNSC staff further conclude that the Mo-99 IIS design, together with OPG's Radiation Protection program will ensure contamination levels and radiation doses received by individuals involved in installation, operation, and maintenance of the Mo-99 IIS will be monitored, controlled and maintained within prescribed limits and As Low As Reasonably Achievable (ALARA).

During the installation and commissioning phases of the project, CNSC staff will continue to verify the Mo-99 IIS that OPG effectively implements their radiation protection processes to ensure that dose to workers remain below regulatory limits and are maintained ALARA.

## B.8 Conventional Health & Safety

The Conventional Health and Safety SCA covers the implementation of a program to manage workplace safety hazards and to protect workers. The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed worker health and safety policies and procedures. Further, NPPs in Ontario are regulated by the Ontario *Occupational Health and Safety Act* and the Ontario *Labour Relations Act*.

### Discussion

OPG has an established occupational health and safety program to ensure that workers continue to work safely. To protect personnel from injury to the extent practical during the operation of the Mo-99 IIS, OPG prepared, and submitted to CNSC staff, NK38-REP-30550-00007, *Darlington Nuclear Target Delivery System Personnel Safety Analysis Report* [34], which presented the personnel conventional safety principles assessed during the Mo-99 IIS design process. CNSC staff reviewed OPG's considerations, identified hazards, risk reduction controls, and protective measures presented in this report. OPG has identified no impacts on governance, programs and processes that form the licensing basis for OPG's conventional health and safety program at Darlington NGS.

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.

While OPG's submission of the detailed installation work plans is pending, CNSC staff will review OPG's submission to verify that OPG is applying its occupational health and safety program to adequate work protection measures are in place to protect workers from injury.

### Conclusion

CNSC staff concluded that OPG's existing occupational health and safety management system is acceptable, and that Ontario Power Generation Darlington NGS will ensure that the work associated with the Mo-99 IIS project will be conducted safely.

## B.9 Environmental Protection

This SCA covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.

This CMD covers the following SpAs within the Environmental Protection SCA:

- Environmental management system (EMS)
- Environmental risk assessment
- Assessment and monitoring
- Effluent and emissions control (releases)
- Protection of people

### Discussion

#### Regulatory Requirements

OPG's Environmental Management program is required to meet the requirements of REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments.* Additionally, OPG is required to implement and maintain effluent and environmental monitoring programs complying with CSA N288.5-11, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills* and an environmental monitoring program which complies with CSA N288.4-2010, *Environmental monitoring programs at nuclear facilities and uranium mines and mills* respectively.

There are established Derived Release Limits (DRLs) in place and OPG has established Action Levels which are set below the DRLs to provide an early warning system of potential loss of control to the environmental protection program.

OPG is required to implement and maintain an effective environmental protection and management program, (including an environmental risk assessment[6] (ERA), to assess,

[6] OPG updates its ERA every five years. OPG's latest (2020) ERA (e-Doc 6527728), was provided to CNSC staff in March 2021 and is presently under review.

evaluate, and mitigate environmental risks in accordance with CSA N288.6-12, E*nvironmental risk assessments at Class I nuclear facilities and uranium mines and mills*.

## Regulatory Focus

### Environmental management system (EMS)

During the construction and the operation of the Mo-99 IIS, OPG will continue to implement and maintain an Environmental Management System (EMS) in compliance with REGDOC-2.9.1. OPG will operate the Mo-IIS in accordance with OPG EMS documents OPG-PROG-0005 *Environmental Management Systems* and OPG-POL-0021 *Environmental Policy*.

### Environmental risk assessment

In accordance with CSA N288.6-12, OPG is required to perform periodic updates of the ERA. In the next version of the Darlington site ERA, expected in 2025, OPG will include the results of the Predictive Environmental Assessment (PEA; a gap analysis against the current ERA), including the contribution and characterization of station releases associated with the Mo-99 IIS. OPG has bounded the predicted HTO emissions by including analyzed scenarios that used the new moderator tritium concentration limit of 1.11 TBq/kg (30 Ci/kg), conditionally authorized by CNSC staff [35, 36], so when low tritium $D_2O$ can be used, CNSC staff expect releases would be below 0.001% of the current DRL.

### Assessment and monitoring

In case tritium is released into the ground, OPG's site-wide groundwater monitoring network would provide timely detection of any potential leakage to the groundwater. OPG has committed to implementing and meeting the requirements of CSA N288.7-15, *Groundwater protection programs at Class I Nuclear Facilities and Uranium Mines and Mills*, in 2022.

### Effluent and emissions control (releases)

CNSC staff reviewed OPG's PEA [32, 33] which evaluated the impact of the Mo-99 IIS on emissions to the environment and to the public dose. In these assessments, OPG determined that the total tritium emission from the operation of the Mo-99 IIS will constitute 0.001% of the current DRL. As a result, DRLs, Action Levels, and Internal Investigation Levels are not expected to change as a result of the installation and operation of the Mo-99 IIS. CNSC staff are satisfied that the emissions related to the installation and operation of Mo-99 IIS predicted in OPG's assessment, compared to the annual DRLs for the site, and conclude that the emissions will be minimal and existing DRLs will be maintained.

The Mo-99 IIS will utilize moderator grade heavy water to propel the target capsule to and from the elevators on the RMD. Normal operation of the Mo-99 IIS will use 74 GBq/kg (2 Ci/kg; low tritium) heavy water from the Tritium Removal Facility (TRF) to reduce the tritium released during seeding and harvesting. The majority of the Mo-99 IIS releases to the contaminated exhaust occur during harvesting cycle when the system purges the heavy water and dries the targets in the air-lock.

OPG will connect the required components of the Mo-99 IIS, including the target airlock, the $D_2O$ reservoir, the flask loader and the $D_2O$ fill station to the reactor unit contaminated exhaust system. Upstream of the contaminated exhaust, the emissions of the Mo-99 IIS will pass through a cyclone separator and a High Efficiency Particulate Air Filter (HEPA), sequentially, which will contribute towards removing particulates and reduce emissions.

The unit contaminated exhaust system contains monitoring equipment for tritium and particulates. OPG reports emission data to CNSC staff through quarterly and annual compliance monitoring reports.

As previously mentioned, OPG has committed to submit the final commissioning report to CNSC staff. This report will specifically confirm that emissions during Mo-99 IIS operation are within PEA predictions [4]. CNSC staff will review the results of this commissioning report as well as OPG's future compliance monitoring reports for impacts on station emissions.

Lastly, as the operation of the Mo-99 IIS does not involve any chemicals, there is no expected increase of non-radiological releases or emissions from Darlington NGS [1, 4, 32, 33].

### Protection of People

OPG's analysis of predicted emissions of tritium and particulates [32, 33] (discussed further in subsection B.7) estimated that the highest potential dose to a member of the public from Mo-99 IIS operation would not exceed 0.006 μSv/year. Considered in context with the current Darlington emissions, the additional dose to a member of the public from Mo-99 IIS operation is estimated as an additional 1% dose above the current dose estimate of 0.4 μSv. This additional dose for a theoretical member of the public represents 0.0006% of the regulatory dose limit of 1 mSv/year.

CNSC staff conclude that the releases associated with the Mo-99 IIS will not result in additional risk to the public.

## Conclusion

Since the associated releases from operation of the Mo-99 IIS predicted in the PEA would only contribute a small fraction of the environmental releases measured and reported, CNSC staff conclude that OPG continues to meet the requirements provided in CSA N288.6-12 and remains within the limits specified in the 2017 Darlington ERA, even considering the operation of the Mo-99 IIS. Thus, no specific changes are required to OPG's environmental protection programs. OPG is expected to include the contribution of station releases associated with the Mo-99 IIS in the 2025 revision of the Darlington Site ERA.

CNSC staff will continue to provide regulatory oversight to ensure that OPG installs and operates the Mo-99 IIS as committed, and that the commissioning report provide sufficient information to verify the PEA conclusions.

CNSC staff also conclude that the releases associated with the Mo-99 IIS make up a small fraction of the annual station releases and will not result in additional risk to the public.

# B.10 Emergency Management and Fire Protection

The Emergency Management and Fire Protection SCA covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions.

This CMD covers the following SpAs within the Emergency Management and Fire Protection SCA:

| SpA | Topics of Interest |
|---|---|
| ➢ Conventional emergency preparedness and response<br>➢ Nuclear emergency preparedness and response<br>➢ Fire emergency preparedness and response | ➢ Emergency management<br>➢ Fire protection design considerations |

## Discussion

### Regulatory Requirements

#### Conventional emergency preparedness and response

OPG continues to maintain conventional emergency response programs at Darlington NGS. Emergency Response personnel are located on-site 24 hours a day and are capable of responding to any type of emergency. Emergency Response personnel receive regular training and are continuously assessed through quarterly drills and annual corporate-level exercises. Moreover, the equipment required to respond to medical events, incidents involving hazardous materials and other conventional risks continues to be maintained. CNSC staff conclude that OPG's conventional emergency response programs meet the regulatory requirements of REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*.

#### Nuclear emergency preparedness and response

OPG has the capability to respond to a nuclear emergency at the Darlington NGS site in accordance with regulatory requirements, as demonstrated through the conduct of emergency drills and exercises. OPG continues to support and maintain its emergency response organization including support of off-site emergency management organizations. The licensee's CNEP addresses emergencies that pose a risk to the safety of on-site staff, the environment and the public.

CNSC staff monitor OPG's nuclear emergency preparedness program as part of ongoing regulatory oversight. CNSC staff conclude that OPG continues to implement and maintain a comprehensive nuclear emergency preparedness program which meets the requirements of REGDOC-2.10.1.

#### Emergency Management

CNSC staff evaluated the impacts of the Mo-99 IIS on OPG's emergency management program against REGDOC-2.10.1, volume 1, *Nuclear Emergency Preparedness and*

*Response*, which sets out the requirements and guidance related to the development of emergency measure for class I nuclear facilities licensees.

CNSC staff also assessed OPG's application against applicable regulatory requirements found in CSA standards on fire response, such as CSA N1600, *General requirements for nuclear emergency management programs*.

### Fire emergency preparedness and response

Licensees must maintain a comprehensive Fire Protection Program (FPP), which meets the requirements of CSA N293-12. This ensures that the licensed activities do not result in unreasonable risk to the health and safety of persons and to the environment due to fire. This also ensures that the licensee is able to efficiently and effectively respond to emergency fire situations.

OPG continues to demonstrate its preparedness to prevent and respond to a fire by maintaining a comprehensive fire protection program which includes a fulltime, 24/7 dedicated industrial fire brigade response capability. Firefighting equipment at Darlington NGS meets CSA N293 requirements and is well maintained.

OPG continues to maintain its fire response capabilities through its fire protection program through multiple oversight initiatives which include internal program reviews, industry peer reviews, and audits by independent third parties. CNSC staff continue to monitor this area as part of its compliance program, including through the conduct of inspections and desktop reviews.

### Fire protection design considerations

Fire Protection at Darlington NGS is achieved through the implementation of OPG's fire protection program to minimize the risk to the health and safety of persons and to the environment from fire, through appropriate fire protection system design, fire safe operation and fire prevention.

The risk to the health and safety of persons, and to the environment from fire, is expected to be addressed and minimized through appropriate fire protection system design, fire safe operation and fire prevention. OPG's fire protection program is required to meet the requirements of:

- CSA N293-12, *Fire protection for nuclear power plants*
- National Building Code of Canada (NBCC)
- National Fire Code of Canada (NFCC)

## Regulatory Focus

OPG completed safety assessments [37, 38] to determine the impact the installation of the new Mo-99 IIS may have on existing systems as well as to identify any new hazards it may introduce. OPG identified 32 hazardous events associated with the operation of the Mo-99 IIS (refer to Table 2 in Appendix B.4). These hazardous events include: in-core hazards; loss of reactivity control; radiation hazards; fire and deflagration hazards; interfacing and support system failures; target flask hazards; and jib crane hazards. Additionally, transportation accidents include: in-plant transportation collisions; on-site transportation

collisions; vehicle fire; flask falling off a vehicle; and external events (such as tornados and other natural disasters).

Through these assessments OPG asserted that operation of the Mo-99 IIS would remain within the bounds of existing safety analyses and that any the radiological consequences of any new postulated accidents are below relevant public dose limits. CNSC staff have reviewed OPG's submissions and conclude that OPG's existing emergency response programs (Conventional, Nuclear, and Fire Response) remain sufficient to enable an effective response to an emergency occurring at the Unit 2 reactor where the Mo-99 IIS will be installed and operated.

Specifically, based on CNSC staff's review of OPG's methodology and results, CNSC staff conclude that no new operating limits or revised Operator actions would be necessary as a result of the installation of the Mo-99 IIS. CNSC staff also conclude the introduction of the Mo-99 IIS will not require Emergency Response personnel to acquire significant knowledge of the Mo-99 IIS, new emergency response skills, nor procure new specialized emergency response equipment to continue to perform their emergency response roles. Further, all fire and nuclear emergency response tasks continue to be adequately covered by existing training. CNSC staff will continue to verify any updates to the emergency response personnel training related to the Mo-99 IIS.

As required by CSA N293-12, OPG commissioned an independent third party review (TPR) [39] of the impact of the modification associated with installation and operation of the Mo-99 IIS to fire safety. The results from the TPR concluded that the modifications associated with the installation and operation of the Mo-99 IIS are determined to meet the fire protection goals and criteria of CSA N293 and the requirements of the NBCC and NFCC. In addition, the impact of the modifications associated with Mo-99 IIS on fire safety is negligible and does not require an update to the Darlington Fire Hazard Assessment, and Fire Safe Shutdown Assessments outside of the normal five-year update cycle. CNSC staff concluded that OPG's fire protection assessment meets regulatory requirements.

OPG performed analyses that included an evaluation of the initiated events that may result in consequential fire [3]. CNSC staff concurred with OPG's findings and final assessment that the installation and operation of the Mo-99 IIS will have no significant impact on the safe operation of Darlington NGS.

OPG has an adequate fire protection program which minimizes both the probability of occurrence and the consequences of fire at Darlington NGS, and complies with CSA N293-12 requirements. CNSC staff are satisfied with the fire protection provisions at Darlington NGS for the installation and operation of the Mo-99 IIS. CNSC staff will continue to monitor the implementation of the FPP through regulatory oversight activities, including on-site inspections and desktop reviews of relevant program documentation.

CNSC staff will perform regulatory oversight of OPG staff's abilities to respond to potentially hazardous events associated with the operation of the Mo-99 IIS and the onsite handling and transport (including hoisting) of the Type-B transport containers. CNSC staff will further verify that Emergency Response personnel continue to have the skills and equipment required to safely and effectively respond under all conditions to support Operations staff (*e.g.*, control technicians, mechanics, operators), if needed.

CNSC staff will monitor OPG's performance in these areas, and ensure that they are complaint with the pertinent regulatory requirements (as documented in the PROL and LCH) through regulatory oversight activities including onsite inspections and desktop

reviews of OPG compliance reporting and revisions to relevant program documentation pertaining to this SCA.

### Conclusion

OPG has sufficient programs, preparedness and response provisions in place at the Darlington NGS to mitigate and manage the effects of accidental releases of nuclear and hazardous substances on the environment and the health and safety of persons.

CNSC staff concluded that the installation and operation of the Mo-99 IIS will not add additional requirements to OPG's emergency management and fire protection programs, which address prevention, mitigation, preparedness, response, and recovery at Darlington NGS.

The existing suite of OPG nuclear emergency preparedness and response governance for DNGS is deemed adequate to deal with any potential emergency event that may arise due to the operation of the Mo-99 IIS.

CNSC staff are satisfied that OPG has conducted adequate assessments and made adequate preparations to respond to any emergency that may arise during any of the proposed activities associated with the operation of the Mo-99 IIS. OPG's emergency management and fire protection programs at Darlington NGS meet regulatory requirements of REGDOC-2.10.1 and CSA N293.

## B.11 Waste Management

The Waste Management SCA covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This SCA also covers the planning for decommissioning.

This CMD covers the following SpAs within the Waste Management SCA:

- Waste characterization
- Waste minimization
- Waste management practices
- Decommissioning plans

### Discussion

CNSC staff have reviewed OPG's waste management programs and have determined that they are acceptable and will adequately cover the additional waste management activities of the Darlington NGS associated with the Mo-99 IIS. OPG's existing programs are sufficient to manage operational waste generated from the production of the Mo-99 radioisotope.

## Regulatory Requirements

### Waste Characterization, Waste Minimization and Waste Management Practices

In accordance with the *General Nuclear Safety and Control Regulations*, CINFR and Darlington NGS PROL, OPG is required to have a waste management program for the operation of the Darlington NGS that meets the requirements of CSA N292.3-08, *Management of low and intermediate level radioactive waste*.

OPG's waste management program is implemented and maintained through a suite of OPG Guides, Standards, Policies, and Procedures; including OPG's waste management standard, OPG-STD-0156, *Management of Waste and Other Environmentally Regulated Materials*, and OPG procedure N-PROC-RA-0017, *Segregating and Handling of Radioactive Waste*, which include strategies for waste minimization, waste characterization and waste management practices as per CSA N292.3-08.

### Decommissioning Plans

As part of the regulatory requirements stemming from the CINFR, OPG is required to have a decommissioning program for the operation of the Darlington NGS. This program must meet the requirements set out in the licensing basis document CSA N294-09, *Decommissioning of facilities containing nuclear substances*.

OPG's program document W-PROG-WM-0003, *Decommissioning Program*, documents how OPG meets the applicable standards and regulatory requirements for decommissioning Darlington NGS. CNSC staff have reviewed OPG's decommissioning program and have concluded that it meets the applicable requirements [40].

## Regulatory Focus

### Waste Characterization, Minimization and Management Practices

OPG's application stated that operation of the Mo-99 IIS does not anticipate generating any waste; however, some waste will be generated through maintenance activities. CNSC staff expect Mo-99 IIS specific wastes, such as zirconium particulates, to be captured by the cyclone separator or HEPA filters installed up-stream of the contaminated exhaust vent [17, 33]. As such, these wastes will be isolated and contained and managed during system maintenance activities, well within the capabilities of OPG-PROC-RA-0017.

Bulk wastes associated with the zirconium sheaths and irradiated Mo-99 will not be managed by OPG. The stainless steel magazines containing the natural molybdenum targets (Mo-98 in a zirconium sheath) provided to OPG by BWXT will be returned, uncontaminated, to BWXT-NEC [1]. The irradiated Mo-99 targets will be shipped in Type-B transport containers to an off-site processing facility. This facility will be responsible for managing its own wastes from the targets under its own CNSC Class I facility licence.[7]

CNSC staff recognize that the installation of the Mo-99 IIS will require work on existing reactor SSCs, and may require the use of personal protective equipment (PPE). While OPG's submission does not describe the wastes that will be generated though the

[7] Pending approval by the Commission

installation of the Mo-99 IIS [1], this phase of the project is expected to generate some wastes, including components removed from the reactor (*i.e.*, old Adjuster Rod(s) / related components/mechanisms) and PPE. As the waste streams expected from the installation phase do not represent new types of waste for OPG, CNSC staff conclude that they can be safely managed, in accordance with CSA N292.3-08 through OPG's existing waste management procedures and programs. CNSC staff will verify any additional waste generated and the management of those wastes through compliance verification activities.

CNSC staff will continue to monitor OPG's Waste Management program through regulatory oversight, including on-site inspections and desktop reviews of relevant program documentation.

#### Decommissioning Plans

OPG has identified that the Mo-99 IIS is a relatively small and removable system that will have minimal effect on future decommissioning activities [1]. OPG concluded that based on their assessment the Mo-99 IIS would have no impact and would require no changes to the current decommissioning plan [1, 41]. CNSC staff will review OPG's next submission of the decommissioning plan and financial guarantee due in 2022 that covers all of OPG's liabilities.

### Conclusion

CNSC staff assessed OPG's application and determined that the production of Mo-99 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 generated from the production of Mo-99 and will continue to satisfy regulatory requirements.

## B.12 Security

The Security SCA covers the programs which implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity. Additionally, the security SCA requires the licensee to develop, implement and maintain a cyber-security program to protect against cyber-attacks on the critical cyber assets for nuclear safety, nuclear security, and emergency preparedness functions.

This CMD covers the following SpAs within the Security SCA; further, the impact of the Mo-99 IIS on the following topics of interest are discussed in support of this SCA (note that the topics of interest in this section are used for sub-headings as they apply multiple SpAs):

| SpA | Topics of Interest |
|---|---|
| ➢ Facilities and equipment | ➢ General Considerations |
| ➢ Response arrangements | ➢ Prescribed Information |
| ➢ Security practices | ➢ Site Security Measures |

| | |
|---|---|
| ➢ Drills and exercises | ➢ Access Control<br>➢ Site Access Clearance<br>➢ Security Arrangements with Offsite Response Force<br>➢ Physical Security<br>➢ Cyber Security<br>➢ Nuclear Security Officer Program |

## Discussion

OPG continues to provide the information needed (e.g., in the form of site procedures) to ensure that CNSC staff have full situational awareness during the current licensing period. CNSC staff concur with OPG's assertion that OPG's security program at Darlington NGS will not be impacted, nor will it need to be modified during the implementation of activities associated with the operation of the Mo-99 IIS.

OPG's nuclear security program supports the protection of nuclear assets at Darlington NGS. Key elements of this program include responding to threats of theft and sabotage of nuclear material as well as identifying, classifying, and protecting cyber essential assets, and maintaining compliance with regulatory requirements.

Security considerations (including cyber security) were assessed against OPG's Nuclear Security Program, N-PROG-RA-0011, *Nuclear Security* and Cyber Security procedure, N-PROC-RA-0135, *Cyber Security*. CNSC staff concluded that OPG's security and cyber security programs would not have to be modified during the implementation and production of Mo-99.

### Regulatory Requirements

OPG's Nuclear Security Programs have been developed to meet the requirements specified in:

- *General Nuclear Safety and Control Regulations* (GNSCR) [SOR/2000-202]
- *Class I Nuclear Facilities Regulations* (CINFR) [SOR/2000-204]
- *Nuclear Security Regulations* (NSR) [SOR/2000-209]
- REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants, Version 2*
- REGDOC-2.2.4, *Fitness for Duty, Volume II: Managing Drug and Alcohol use, Version 3*
- REGDOC-2.2.4, *Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, and Physiological Fitness*
- 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*
- CSA N290.7-14, *Cyber security for nuclear power plants and small reactor facilities*

## Regulatory Focus

CNSC staff determined that OPG continues to implement a security program that meets the security requirements stipulated in the regulations. As previously discussed, the security program will not need to be modified for the production of Mo-99.

### General Considerations

CNSC staff reviewed OPG's application [1] and the Darlington NGS Security program, as it relates to the Mo-99 IIS Project. CNSC staff's review concluded that OPG's Nuclear Security program and associated procedures, instructions, and guides, meets the requirements of the applicable regulatory documents. Security measures in compliance with the *Nuclear Security Regulations* have been implemented, and are well established, by OPG and will not change as a result of the proposed activities associated with the production of Mo-99 IIS.

### Prescribed and Security Sensitive Information

OPG's Information Management program, OPG-PROG-0001, governs the access to use, store, and transmit prescribed and security protected information. OPG's staff and contractors are required to comply with the requirements of the Information Management Program and its supporting procedures. Prescribed and security sensitive information are only provided to persons with a valid security clearance and a *need-to-know*. The Mo-99 IIS Project will not have any impact or require any changes with regards to prescribed and security sensitive information.

### Site Security Measures

Security considerations with regards to the site security measures currently in place at Darlington NGS are implemented as per OPG's Nuclear Security Program, N-PROG-RA-0011. CNSC staff performed a review of this program document, and conclude that OPG's Site Security Measures at Darlington NGS will not have to be modified for the production of Mo-99.

### Access Control

The Darlington NGS site is contained within the Darlington NGS Controlled Area. Public access to the Controlled Area of Darlington NGS is restricted with the use of additional barriers, including fencing and signage. Nuclear Security Officers (NSO) at Darlington NGS patrol the Controlled Area on a continuous basis. Access Control to Darlington NGS will not have to be modified as a result of the Mo-99 IIS project.

### Site Access Clearance

OPG maintains a security clearance and site access program at Darlington NGS that complies with the *Nuclear Security Regulations* and REGDOC-2.12.2, *Site Access Security Clearance*. OPG procedures, including OPG-PROC-0119, *Clearance Process* and OPG-STD-0064, *Facility Security and Access Control*, meet regulatory requirements. OPG's Site Access Clearance Program will not have to be modified during the implementation of the Mo-99 IIS project.

## Security Arrangements with Off-site Response Forces

OPG has a Memorandum of Understanding (MOU) with the Durham Regional Police Service (DRPS) for the provision of off-site armed response to Darlington NGS facilities. The MOU ensures the necessary resources are available to address design basis security events. OPG conducts drills and exercises that include testing the integrated response with the DRPS off-site response force. Lessons-learned from these drills and exercises are implemented within OPG's security program. The MOU ensures that OPG and off-site response have requirements and measures in place to ensure compliance with subsection 35(1) of the *Nuclear Security Regulations*. No changes to the MOU documenting the security arrangements with off-site response forces are anticipated during the implementation of the proposed activities associated with the Mo-99 IIS project.

## Physical Security

A description of the Darlington site's existing security equipment, systems and procedures, as well as a description of proposed on-site and off-site communications equipment, systems, and procedures is contained within OPG's Security Program. CNSC staff have determined that physical security measures for the Darlington site will not be impacted during the implementation of the Mo-99 IIS project and production of Mo-99. Security measures to comply with the *Nuclear Security Regulations* and applicable regulatory documents are being used and maintained throughout the licensing period.

## Cyber Security

OPG stated in its licence amendment request [1] and supporting submissions [42, 43] that the Mo-99 IIS design complies with OPG's cyber security requirements, having been considered during the design scoping phase of OPG's ECC process, and that no changes to cyber security related programs and procedures were needed to accommodate the activities associated with the Mo-99 IIS project.

CNSC staff reviewed the information submitted by OPG and determined that OPG's cyber security program can manage the cyber security for any new cyber asset and cyber essential assets (CEAs) associated with the Mo-99 IIS as well as the modification of the existing CEAs from the proposed new activities.

## Nuclear Security Officer (NSO) Program

OPG selects, trains, and equips Nuclear Security Officers (NSOs) at Darlington NGS in accordance with the *Nuclear Security Regulations* and REGDOC-2.12.1, *High Security Facilities, Volume I: Nuclear Response Force*, Version 2 and REGDOC-2.2.4, *Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, and Psychological Fitness*. Details related to the selection, training, and equipment provided to both armed and unarmed NSOs is contained in OPG's Security Program at Darlington NGS.

The activities associated with the production of Mo-99 will not require any changes to be made to the structure and organization of the NSO service, including the duties, responsibilities and training of NSOs, which are documented in OPG's Darlington NGS Security Program.

### Conclusion

CNSC staff conclude that OPG continues to implement a security program that meets the security requirements stipulated in the regulations. CNSC staff also conclude that OPG's cyber security program can manage the cyber security of the licensee's proposed Mo-99 IIS activities as OPG's cyber security program meets the regulatory requirements under its licence. CNSC staff concluded that the security program and cyber security program will not need to be modified to accommodate the proposed activities associated with the Mo-99 IIS. In addition, no changes were identified with respect to regulations, codes, standards and practices that would necessitate an update to licensing basis materials previously submitted in the area of Security.

CNSC staff will continue to monitor the production of Mo-99 in relation to the security and cyber security programs, ensuring that there are adequate provisions of security prior to and during the installation, commissioning, and operation of the Mo-99 IIS.

## B.13 Safeguards and Non-Proliferation

The Safeguards and Non-Proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

The scope of the non-proliferation program is limited to the tracking and reporting of foreign obligations and origins of nuclear material. This tracking and reporting assists the CNSC in the implementation of Canada's bilateral Nuclear Cooperation Agreements with other countries. Finally, the import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations* require separate authorization from the CNSC, consistent with section 3(2) of the *General Nuclear Safety and Control Regulations*.

This CMD covers the following SpAs within the Safeguards and Non-Proliferation SCA:

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

### Discussion

The CNSC provides the mechanism for the implementation of safegaurds through the *Nuclear Safety and Control Act*, regulations and licenses. Conditions for the application of safeguards are contained in the operating license and the criteria to meet those conditions are contained in the LCH and in regulatory document REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*.

OPG continues to maintain a safeguards program that complies with its licence requirements. The program 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*.

Pursuant to that treaty, Canada has entered into a Comprehensive Safeguards Agreement and an Additional Protocol with the IAEA (hereafter, the safeguards agreements). The objective of the safeguards agreements is for the IAEA to provide annual assurance to Canada and to the international community that all declared nuclear material is used in peaceful, non-explosive uses and that there is no indication of undeclared material.

CNSC staff will continue to monitor and evaluate the OPG's performance through participation in IAEA inspections, CNSC evaluations, and ongoing assessments of compliance with reporting requirements.

## Regulatory Requirements

REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*, sets out requirements and guidance for safeguards programs for applicants and licensees who possess nuclear material, operate a uranium and/or thorium mine, carry out specified types of nuclear fuel-cycle related research and development work, and/or carry out specified types of nuclear-related manufacturing activities. The requirements and guidance in this document are essential to Canadian compliance with the safeguards agreements entered into with the IAEA, and are consistent with modern national and international practices.

Compliance activities include the timely provision of reports on the movement and location of nuclear material, provision of access and assistance to IAEA inspectors for safeguards activities, support for IAEA equipment, and the submission of annual operational information, additional protocol updates as well as accurate design information.

## Regulatory Focus

### Nuclear Material Accountancy and Control

Mo-99 is not nuclear material subject to safeguards requirements pursuant to the Canada/IAEA Safeguards Agreement, and as defined in REGDOC-2.13.1.

### Access and Assistance to the IAEA

As Mo-99 radioisotope is not a nuclear material that is subject to safeguards requirements, routine IAEA verification is not expected. However, the Mo-99 IIS and related activities may be subject to IAEA design information verification and complementary access. Additional information regarding the requirements of the IAEA are discussed in the following sub-sections.

### Operational and Design Information

The submission of operational information to the IAEA on the production of radioisotopes will be required. This includes advance information and declarations in OPG's safeguards annual operational program and quarterly updates; updates to the facility's design information questionnaire; and an update to the facility's annual submission pursuant to the Additional Protocol on the site layout, buildings and functions. The IAEA will inform the CNSC when the updates will be required, and CNSC staff will contact OPG to provide this information.

### Safeguards equipment, containment and surveillance

OPG has stated that the production of Mo-99 radioisotope will not impact the IAEA's existing surveillance cameras and other installed equipment.

### Import and Export

Mo-99 is not a controlled nuclear substance under the *Nuclear Non-Proliferation Import and Export Control Regulations* (NNIECR) and does not require a CNSC import or export licence. An Item may only be controlled for import or export licensing, if it meets the specifications of an entry in the schedule to the NNIECR and is crossing Canada's border either as an export or import. OPG is encouraged to assess items that may be imported or exported in support of this project against the NNIECR to determine if licensing is required. OPG has asserted that there will be no requirement to import nuclear material for Mo-99 IIS installation and operation. OPG will not be exporting the irradiated molybdenum, and thus BWXT-Medical will be responsible for obtaining the required export licenses for exporting the processed Tc-$99^{m}$ outside of Canada.

## Conclusion

CNSC staff have assessed OPG's application for amendment to the PROL for Darlington NGS in the matter of adding a new licensed activity concerning the production of Mo-99 radioisotope and have found it to be acceptable and compliant with regulatory requirements under the Safeguards and Non-Proliferation SCA.

The production of Mo-99 has no significant impact on the Safeguards and Non-Proliferation SCA and CNSC staff conclude that OPG's existing safeguards and non-proliferation program is sufficient.

# B.14 Packaging and transport

The Packaging and Transport SCA covers the safe packaging and transport of nuclear substances associated with the production of Mo-99 to and from the licensed facility.

This CMD covers the following SpAs within the Packaging and Transport SCA:

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

## Discussion

For this project, the scope of OPG's activities for the Packaging and Transport SCA is limited to loading the transport packages with irradiated Mo-99 targets produced at Darlington NGS. BWXT-Medical is responsible for the package design, certification, maintenance and transportation of these packages from Darlington facility to the BWXT-Medical processing facility in Kanata.

The packages that are intended to be used for shipments of Mo-99 produced at Darlington NGS are required to be certified by the CNSC. These packages are required to undergo stringent testing requirements so that in the unlikely event of a severe accident, significant radiological consequences do not occur. Testing must simulate both normal and

hypothetical accident conditions of transport and include free-drop testing, puncture testing, water immersion and thermal testing.

## Regulatory Requirements

For off-site shipments, OPG and BWXT-Medical are required to comply with both the CNSC's *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR) and Transport Canada's *Transportation of Dangerous Goods Regulations* (TDGR).

OPG has a radioactive materials transportation program as described in its program document W-PROG-WM-00002, *Radioactive Material Transportation* that ensures compliance with the PTNSR and the TDGR. This program specifies the management system requirements for all aspects of packaging and transport of nuclear substances.

In its application [1], OPG confirms that OPG staff will package the irradiated targets for shipment in CNSC certified transport packages, and will prepare the shipping document for receipt at a facility licensed by the CNSC to receive the specific material in accordance with W-PROG-WM-00002 and regulatory requirements.

In accordance with the PTNSR, OPG will have to apply for and obtain CNSC confirmation to use the certified transport package prior to the first shipment. Additionally, OPG is required to have appropriate training for personnel involved in the handling and offering for transport of dangerous goods and to issue a training certificate to those workers in accordance with the TDGR.

## Regulatory Focus

### Packaging and transport

CNSC staff have performed a desktop review of OPG's program document, W-PROG-WM-00002, *Radioactive Material Transportation* and verified through compliance activities that the OPG transportation program ensures compliance with both the PTNSR and the TDGR.

CNSC staff conducted compliance activities at Darlington NGS in 2020, and have noted no packaging and transport SCA related non-compliances. Based on the results of these compliance activities, CNSC staff conclude that the current OPG programs in place will continue to ensure compliance with the requirements of both the PTNSR and the TDGR.

### Package design and maintenance

BWXT-Medical is responsible for the package design, certification, maintenance and transportation of the Mo-99 packages from Darlington NGS to BWXT-Medical's medical isotope processing facility in Kanata, Ontario. Therefore, this specific area is out of scope of the current OPG amendment application.

### Registration for use

In accordance with the PTNSR, for the Mo-99 IIS project, OPG will have to apply for, and obtain, CNSC confirmation to use the certified transport package prior to the first shipment. In its application [1], OPG confirms that it has procedures in place for the registration for use of certified design transport packages.

## Conclusion

CNSC staff conclude that OPG is qualified to ensure compliance with the requirements of both the PTNSR and the TDGR. OPG's programs specify the management system requirements for all aspects of packaging and transport of nuclear substances.

CNSC staff conclude that there will be no impact on OPG's packaging and transport licensing basis documents as a result of the proposed activities associated with the production of Mo-99. CNSC staff also conclude that OPG's existing programs and procedures in place at Darlington NGS associated with packaging and transport of nuclear substances meet regulatory requirements and are sufficient to manage activities associated with the production and possession of Mo-99.

## B.15 References – General Assessment of SCAs

The following documents are referenced in Appendix B to Part One of this CMD. Note that a number of these documents are marked **Protected B(R)**, as they contain commercial confidential information related to the design of the Mo-99 IIS / TDS. Members of the public may follow the Access to Information and Privacy (ATIP) process in order to request access to the ***Protected B(R)*** documents listed in this CMD.


[1] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025," 2021-02-12. [NK38-CORR-00531-22275 P, e-Doc 6489932]

[2] OPG letter, S. Gregoris to N. Riendeau, "Molybdenum-99 Isotope Irradiation System: Submission of Conceptual Design Report Revision, Safety Analysis Project Execution Plan and Engineering Oversight Plan," 2018-11-14. [NK38-CORR-00531-20289 P, e-Doc 5715229] *Protected B(R)*

[3] OPG letter, S. Gregoris to K. Hazelton, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Five Updated Safety Assessment Reports for the Unit 2 Target Delivery System (SA06-01-U2)," 2021-03-10. [NK38-CORR-00531-22385 P, e-Doc 6510325] *Protected B(R)*

[4] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Supplementary Information for Licence Amendment Application for Molybdenum Isotope Irradiation System: Submission of Licensing Impact Assessment (L01-02)," 2020-11-12. [NK38-CORR-00531-22104 P, e-Doc 6422251] *Protected B(R)*

[5] OPG report, "Project Management Plan: Molybdenum-99 Target Delivery System (TDS) Project," NK38-PMP-00120-00014, 2021-04-08. [e-Doc 6534525] *Protected B(R)*

[6] OPG report, "Engineering Oversight Plan for the Molybdenum-99 Isotope Project," NK38-PLAN-30550-00006, 2019-03-26. [e-Doc 6536442] *Protected B(R)*

[7] OPG report, "Darlington Target Delivery System Human Factors Engineering Program Plan," NK38-PLAN-30550-00002 R002, 2020-12-18. [e-Doc 6481788] *Protected B(R)*

[8] OPG email, L. Moraru to S. Baskey, "FW: OPG's Response to CNSC Staff Request: Mo-99 IIS CNSC staff Requests: 2021-03-23," 2021-04-12. [NK38-CORR-00531-22473, e-Doc 6534887, 6534886]

[9] OPG email, L. Moraru to S. Baskey, "Darlington NGS - Response to CNSC Staff's Mo-99 Request: In support of multiple CNSC staff review of OPG submissions," in Darlington NGS - Response to CNSC Staff's Mo-99 Request: In support of multiple CNSC staff review of OPG submissions, 2021-03-18. [NK38-CORR-00531-22420, e-Doc 6517509, 6517544] *Protected B(R)*

[10] OPG email, L. Moraru to S. Baskey, "FW: OPG's Further Response to CNSC Staff Request: Mo-99 IIS CNSC staff Requests: 2021-03-23," 2021-04-20. [NK38-CORR-00531-22539, e-Doc 6542629, 6542623, 6547923] *Protected B(R) *

[11] OPG report, "Assessment of Impact of Target Delivery System for Molybdenum Irradiation on the Darlington Probablistic Safety Assessment (PSA)," N-REP-03611-0778355, 2021-02-23. [e-Doc 6510317] *Protected B(R)*

[12] OPG report, "Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington," N-REP-03500-0839983, 2021-02-24. [e-Doc 6510324] *Protected B(R)*

[13] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Integrated Nuclear Safety and Operational Assessment of the Target Delivery System (SA06-01)," 2020-08-31. [NK38-CORR-00531-21845, e-Doc 6371714] *Protected B(R)*

[14] OPG report, "Operational Assessment of the TDS Installation in Darlington," NK38-REP-03100-0838344, 2021-02-19. [e-Doc 6510322] *Protected B(R)*

[15] OPG report, "Project Alpha: Initiating Event Identification and Classification," N-REP-03500-0735634, 2021-02-08. [e-Doc 6510326] *Protected B(R)*

[16] OPG report, "Assessment of Target Delivery System for Molybdenum Irradiation on the Darlington Internal and External Hazard Screening," N-REP-03611-0764525, 2021-02-23. [e-Doc 6510313] *Protected B(R)*

[17] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Unit 2 Design Documents (D04-02-U2 and D06-01-U2)," 2021-01-28. [NK38-CORR-00531-21808 P, e-Doc 6475628] *Protected B(R)*

[18] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Target Delivery System Design Packages (D04-02 and D06-01)," 2020-07-20. [NK38-CORR-00531-21808 P, e-Doc 6347238] *Protected B(R)*

[19] CNSC staff email, S. Baskey to P. Herrera, "Mo-99 IIS CNSC staff Requests: A4AC + Topical Meeting Request," 2021-04-19. [e-Doc 6541297] *Protected B(R)*

[20] OPG report, "Target Delivery Equipment Design Requirement," NK38-DR-30552-00001 R000, 2020-01-28. [e-Doc 6109187] *Protected B(R)*

[21] OPG letter, S. Gregoris to J. Burta, "Molybdenum Isotope Irradiation System: Submission of Unit 2 Design Gap Assessment (D04-02-U2 and D06-01-U2)," 2020-12-02. [NK38-CORR-00531- 22156, e-Doc 6435639] *Protected B(R)*

[22] OPG report, "Darlington Target Delivery System Human Factors Engineering Verification and Validation Plan," NK38-PLAN-30550-00003 R02, 2020-12-17. [e-Doc 6481789] *Protrected B(R)*

[23] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Request for Code Classification Consent for Unit 2 Target Delivery System and Prior Written Notification for Permanent Change to Containment Boundary (D03-01-U2)," 2020-12-02. [NK38-CORR-00531-22139 P, e-Doc 6435622] *Protected B(R)*

[24] CNSC staff letter, J. Burta to S. Gregoris, "CNSC staff Consent for Code Classification Consent for Unit 2 Target Delivery System and Prior Written Notification for Permanent Change to Containment Boundary (D03-01-U2)," 2021-02-12. [e-Doc 6450519] *Protected B(R)*

[25] OPG letter, S. Gregoris to K. Hazelton, "Darlington NGS – Molybdenum Isotope Irradiation System: Update to CNSC Staff on the Installation, Commissioning and Maintenance Strategies for the Unit 2 Target Delivery System," 2021-03-10. [NK38-CORR-00531-22384 P, e-Doc 6510680] *Protected B(R)*

[26] OPG report, "Conceptual Design Report - Project Alpha Target Delivery System," NK38-REP-31710-10002 R01, 2018-11-09. [e-Doc 5715229] *Protected B(R)*

[27] OPG report, "Darlington Nuclear - Target Delivery System - System Design ALARA Assessment," NK38-REP-30550-00012 R001, 2021-01-22. [e-Doc 6481799] *Protected B(R)*

[28] OPG report, "Darlington Nuclear - TDS Shielding - Design Calculation," NK38-CALC-30552-00002 R001, 2021-01-11. [e-Doc 6481547] *Protected B(R)*

[29] OPG report, "Darlington Nuclear - Target Delivery System - ALARA Design Guide," NK38-GUID-30550-00001 R01, 2021-01-22. [e-Doc 6481786] *Protected (B)*

[30] OPG report, "Darlington Nuclear - Target Delivery System - ALARA Design Plan," NK38-PLAN-30550-00008 R001, 2021-01-14. [e-Doc 6481790] *Protected B(R)*

[31] OPG report, "Target Delivery System Design Requirements," NK38-DR-30550-00001 R02, 2020-05-11. [e-Doc 6480953] *Protected B(R)*

[32] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Predictive Effects Assessment (ERA01-01)," 2020-06-11. [NK38-CORR-00531-21626 P, e-Doc 6316948] *Protected B(R)*

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

[34] OPG report, "Darlington Nuclear Target Delivery System Personnel Safety Analysis Report," NK38-REP-30550-00007 R000, 2020-04-20. [e-Doc 6304262] *Protected B(R)*

[35] CNSC staff letter, J. Burta to S. Gregoris, "Darlington NGS - CNSC Staff's Conditional Acceptance of a Permanent Change to Operating Policies and Principles Moderator Tritium Concentration Limit – New Action Item 2020-13-20755," 2020-04-06. [e-Doc 6272125] *Protected B(R)*

[36] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Request for CNSC Staff's Acceptance of a Permanent Change to Operating Policies and Principles Moderator Tritium Concentration Limit," 2020-03-12. [NK38-CORR-00531-21468, e-Doc 6262149] *Protected B(R)*

[37] OPG letter, S. Gregoris to N. Riendeau, "Darlington NGS - Molybdenum Isotope Irradiation System: Submission of the Out of Core Break Plan (SA04-02), Moderator Fluctuation Assessment (SA04-05), Qualitative Assessment (SA04-07), and Hazards Assessment (SA04-09)," 2019-06-04. [NK38-CORR-00531-20764, e-Doc 5920733] *Protected B(R)*

[38] OPG letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Revised Radiological Consequences of Out of Core Events Report (SA04-11 R1)," 2020-05-28. [NK38-CORR-00531-21628, e-Doc 6307769] *Protected B(R)*

[39] OPG report, "DNGS U2 Target Delivery System Fire Protection Assessment," NK38-REP-30550-00018 R000, 2020-11-26. [e-Doc 6481801] *Protected B(R)*

[40] CNSC staff CMD, "Submission from CNSC staff on OPG Consolidated Financial Guarantee 2018-2022," CMD 17-H11, 2017-08-03. [e-Doc 5306917]

[41] OPG email, P. Herrera to J. Burta, "RE: CNSC staff request for clarification: DNGS Mo-99 IIS missing LCH documents in L01-02 and Licence Application Addendum," 2021-03-10. [NK38-CORR-00531-22308, e-Doc 6510882] *Protected B(R)*

[42] OPG report, "Target Delivery Control System – Computer Systems Design Description," NK38-CSD-63055-00001 R00, 2020-04-30. [e-Doc 6304274] *Protected B(R)*

[43] OPG report, "Target Delivery Control System – Computer Systems Requirements," NK38-CSD-63055-00001 R00, 2019-12-06. [e-Doc 6109189] *Protected B(R)*

# C. Acronyms

| | |
|---|---|
| AFS | Available for Service |
| ALARA | As Low As Reasonably Achievable |
| ANO | Authorized Nuclear Operator |
| AOO | Anticipated Operational Occurrences |
| BDBA | Beyond Design Basis Accidents |
| BWXT | BWX Technologies |
| BWXT-NEC | BWXT-Nuclear Energy Company |
| CCP | Critical Channel Power |
| CINFR | *Class I Nuclear Facilities Regulations* |
| CMD | Commission Member Document |
| CEAs | Cyber Essential Assets |
| CNEP | Consolidated Nuclear Emergency Response Plan |
| CNSC | Canadian Nuclear Safety Commission |
| COG | CANDU Owners Group |
| CSA | Canadian Standards Association – Operating as CSA Owners Group |
| CSI | CANDU Safety Issues |
| CVR | Coolant Void Reactivity |
| DBA | Design Basis Accidents |
| DCC | Digital Control Computers |
| DRLs | Derived Release Limits |
| DRPS | Durham Regional Police Service |
| ECC | Engineering Change Control |

| | |
|---|---|
| EIC | Event Identification and Classification |
| EPC | Engineer Procure Construct |
| EPS | Electrical Power Systems |
| EQ | Environmental Qualification |
| ERA | Environmental Risk Assessment |
| FAT | Factory Acceptance Testing |
| FMEA | Failure Modes and Effects Analysis |
| FRC | Funding Review Committee |
| GNSCR | *General Nuclear Safety and Control Regulations* |
| HEU | Highly enriched uranium U-235 |
| HFE | Human Factors Engineering |
| HFEPP | Human Factors Engineering Program Plan |
| HFVVP | Human Factors Verification and Validation Plan |
| HTS | Heat Transport System |
| IAA | *Impact Assessment Act* |
| IAEA | International Atomic Energy Agency |
| IIS | Isotope Irradiation System |
| LCH | Licence Conditions Handbook |
| LOMI | Loss of Moderator Event |
| LRF | Large Release Frequency |
| MCR | Main Control Room |
| Mo-98 | Natural Molybdenum |
| Mo-99 | Molybdenum 99 |

| | |
|---|---|
| MOU | Memorandum of Understanding |
| MSC | Minimum Shift Complement |
| NBCC | National Building Code of Canada |
| NFCC | National Fire Code of Canada |
| NGS | Nuclear Generating Station |
| NLCA | *Nuclear Liability and Compensation Act* |
| NNIECR | *Nuclear Non-Proliferation Import and Export Control Regulations* |
| NOP | Neutron Overpower Protection |
| NPP | Nuclear Power Plant |
| NRU | National Research Universal |
| NSCA | *Nuclear Safety and Control Act* |
| NSO | Nuclear Security Officers |
| NSPFL | Nuclear Substances Processing Facility Licence |
| OP&Ps | Operating Policies and Principles |
| OPEX | Operating Experience |
| OPG | Ontario Power Generation |
| PFP | Participant Funding Program |
| PIP | Periodic Inspection Plan |
| PLC | Programmable Logic Controller |
| PPE | Personal Protective Equipment |
| PROL | Power Reactor Operating Licence |
| PSA | Probabilistic Safety Analysis |
| QA | Quality Assurance |

| | |
|---|---|
| QRHPs | Quality Release Hold Points |
| RHP | Regulatory Hold Point |
| RMD | Reactivity Mechanism Deck |
| RPR | *Radiation Protection Regulations* |
| RRS | Reactor Regulating System |
| SAT | Systematic Approach to Training |
| SCA | Safety and Control Area |
| SCDF | Severe Core Damage Frequency |
| SIL | Safety Integrated Level |
| SIT | System Integration Testing |
| SOE | Safe Operating Envelope |
| SpA | Specific Area |
| SSCs | Structures, Systems and Components |
| Tc-99$^{m}$ | Metastable Technetium-99$^{m}$ |
| TNA | Training Needs Analysis |
| TSSA | Technical Standards and Safety Authority |
| PTNSR | *Packaging and Transport of Nuclear Substances Regulations, 2015* |
| TDGR | Transport Canada's *Transportation of Dangerous Goods Regulations* (TDGR) |

# PART TWO

# Proposed Licence Changes

## Overview

The changes made in the proposed Darlington Power Reactor Operating Licence (PROL) and Licence Conditions Handbook (LCH) support the implementation of a program for Mo-99 radioisotope production at Darlington Nuclear Generating Station (NGS). If the licence is amended, the production of Mo-99 using a Mo-99 IIS will be authorized at Darlington NGS Unit 2.

The preliminary draft of the proposed addition to the LCH is appended within this part of the CMD. The final version depends on the finalization of several OPG documents.

## Summary of Licence Documents

Table 3 provides the references of the proposed PROL and LCH that will be appended to this CMD.

**Table 3: References of existing and proposed license documents**

| Proposed | | | Current | | |
|---|---|---|---|---|---|
| **Version** | **Word e-Doc** | **PDF e-Doc** | **Version** | **Word e-Doc** | **PDF e-Doc** |
| PROL 13.03/2025 | 6542988 | 6542989 | PROL 13.02/2025 | 6114405 | 6114417 |
| LCH Section 15.6 – Draft LCH-PR-13.03/2023-R005 | 6275733 | NA | LCH-PR-13.03/2023-R004 | 6109607 | 6283938 |

## Licence Conditions

The proposed amendment to the Darlington PROL introduces:

- A change to the licence number in Part I) *Licence Number*
- A new activity (vi) to Part IV) *Licensed Activities*
- A corresponding licence condition (15.6) to Part VI) *Conditions*

As the results of the amendment, PROL 13.02/2025 will become PROL 13.03/2025, indicating the third amendment to the PROL since original issuance in January 2016. The new the Licensed Activities (vi) and Licence Condition 15.6 will add the new text as shown below in Table 4. Other parts of the PROL, including the expiration date of November 30, 2025, remain unchanged unless otherwise suspended, amended, revoked or replaced.

In its application [1], OPG requested that the production, possession, processing, and transportation of the radioisotope Molybdenum-99 be authorized through the isotope irradiation system (also known as the target delivery system) at Darlington NGS. The particular reactor unit at Darlington NGS where Mo-99 radioisotopes can be produced and the operating limits of the system will be specified in the LCH.

**Table 4: New licensed activities (vi) and associated licence condition (15.6)**

| PROL PART | LICENSED ACTIVITIES / LICENCE CONDITION | PROPOSED ADDTION TO THE PROL |
|---|---|---|
| IV | (vi) | possess, transfer, process, package, manage and store Molybdenum-99 radioisotope and its associated decay isotopes. |
| VI | 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. |

## Licence Format

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

## Licence Period

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

## References – Part Two

[1] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS - Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment," 2018-12-05. [NK38-CORR-00531-20359, e-Doc 5729847]

# PART TWO – ATTACHMENTS

# PROPOSED LCH SECTION 15.6

## 15.6 Molybedenum-99 Isotope Irradiation Program

**Licence Condition 15.6:**

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

**Preamble**

The PROL authorizes OPG to *possess, transfer, process, package, manage and store molybdenum-99 radioisotope (Mo-99) and its associated decay isotopes*. Using the Mo-99 Isotope Irradiation System (IIS; also referred to as the TDS – target delivery system – in OPG documentation), OPG is only authorized to produce Mo-99 from natural molybdenum (Mo-98) at Darlington NGS Unit 2. Units 1, 3, and 4 do not produce Mo-99 as OPG has not established a safety case for an IIS design for these units.

Reactor units at Darlington NGS have eight of the original 24 adjuster rods permanently locked out of core. OPG has modified 4 of these out-of-service Adjuster Rod Ports (31780-AA1, AA8, AA17, and AA24) on Unit 2 by removing the adjuster rod assemblies, and installing target elevators which will raise and lower molybdenum targets into and out of the core. The Mo-99 IIS will interface with numerous existing systems including instrument air and class IV electrical power, and will form a part of the containment boundary. Redundant, interlocked containment valves will be used on both the inboard and outboard side of the target airlock to ensure the containment boundary is maintained at all times.

**Compliance Verification Criteria**

LC 15.6 provides the basis for regulatory oversight related to the licensed activity associated with the Mo-99 radioisotope production program. The Darlington PROL authorizes the production and possession of Mo-99 through normal commercial operations (Mo-99 as a result of the decay chain of CANDU fuel) and through deliberate operation of the Mo-99 IIS at Darlington NGS – Unit 2. Only Mo-99 produced with the IIS may be harvested, packaged, and transported off-site.

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

**Operation of the Mo-99 IIS**

The licensee shall operate the Mo-99 IIS in accordance with NK380-OM-30550, O*perating manual;* the operating parameters therein; and all associated operating procedures, including NK38-MMP-30550-00013, *Flask handling*. Operation is bounded by the conditions and reactor states assessed within the

licensing basis established by the Record of Decision.[1] OPG is required to validate the assumptions made in developing the licensing basis though extensive commissioning activities.

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

**Managing Packaged Mo-99**

When managing Mo-99 produced at Darlington NGS Unit 2, OPG shall follow the operating manual NK380-OM-30550 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 Mo-99 and shipping it off-site.

At all times, Mo-99 produced and harvested by the Mo-99 IIS on Unit 2 is required to be stored in a certified transport flask. All other uses and storage practises are prohibited. When managing and storing Mo-99 sealed sources, OPG shall follow the Operating Manual, NK380-OM-30550, section X.X.X "YYYYYY"[2] and the relevant associated procedures.

**Licensed Activities**

Prohibition of Use of Mo-99 and Decay Radioisotopes

The licensee is not authorized by the licence to conduct activities related to nuclear medicine; therefore, OPG is prohibited to process Mo-99 and use nuclear substances in or on human beings. CNSC staff will verify by whatever means available that the licensee is not using radioactive prescribed substances in or on humans.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Operating manual | NK380-OM-30550 | No |
| Flask handling | NK380-MMP-30550-00013 | No |

**Regulatory Hold Points**

[*…Insert text here reflecting the Commission decision for the Darlington NGS licence amendment regarding approval of the process for the release of the hold point. Possible text for this paragraph and related context pursuant to the Commission decision could be:*

[1] REFERENCE PLACE HOLDER TO RECORD OF DECISION ASSOCIATED WITH CMD 21-H107

[2] To be updated when Operating manual is complete – this section would be a section relevant to Mo-99 Handling or equivalent

In the 2021 Record of Decision for Darlington NGS licence amendment, the Commission defined two regulatory hold points (RHPs), to be removed by delegation of authority[3], prior to installation[4] and commissioning[5] a Mo-99 IIS on any unit at Darlington NGS as summarized in Table 1.

**Table 1: Definition of RHPs and associated regulatory requirements associated with a Mo-99 IIS at Darlington NGS**

| | **RHP-1** | **RHP-2** |
|---|---|---|
| Prior to | Installation – Modifying the reactor or containment boundary through activities related to the installation of the Mo-99 IIS | Commissioning – Commencing any on-power tests or commissioning activities of the Mo-99 IIS |
| Associated Regulatory Requirements | ▪ That OPG has a design that meets all regulatory requirements and has incorporated existing OPEX<br>▪ That OPG has conducted a thorough safety analysis that verifies the impact of the Mo-99 IIS is negligible and operation poses minimal additional risk to the operation of the unit<br>▪ That OPG has accepted the results of the factory acceptance tests demonstrating the Mo-99 IIS is functioning as intended and can safely be installed<br>▪ That OPG has prepared the necessary work plans in accordance with existing procedures, processes, and programs within its management system and is ready to install the Mo-99 IIS | ▪ That OPG has prepared the necessary work plans, identified the relevant commissioning tests, acceptance criteria, and back-out conditions; and is ready to safely test and commission the Mo-99 IIS on an operating reactor |

Process to remove regulatory hold points

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

1) The licensee submits a request to CNSC staff for the removal of the hold point.
2) The licensee's request must include sufficient information to demonstrate that all pre-requisites have been satisfied.
3) CNSC staff will review the submitted information and verify the licensee's compliance with regulatory requirements and commitments.

[3] In the 2021 record of decision, the Commission delegated the authority for this licence condition for the removal of the regulatory hold point for commissioning of the Mo-99 IIS to the Executive Vice-President and Chief Regulatory Operations Officer

[4] The RHP associated with installation does not exclude OPG from installing components in rooms 302 and 304 that remain within their licensing basis.

[5] The RHP associated with Commissioning does not prohibit any testing or commissioning activities performed *in situ* in accordance with OPG's detailed installation work plans etc., reviewed by CNSC staff as part of RHP-1, during the outage while the Mo-99 IIS is being installed.

4) Based on the submitted information, CNSC staff will provide a report, including recommendations, to the Delegated Authority specified by the Commission, regarding whether the pre-requisites, specified in the LCH, have or have not been met.
5) The Delegated Authority specified by the Commission will then consent or not consent to the removal of the requested regulatory hold point.
6) CNSC staff will administer the removal of the hold point through a confirmation letter to the licensee.

During the process above, CNSC staff will consider that the following list of prerequisites, and the Associated Regulatory Requirements (summarized in Table 1 above) have been fulfilled by the licensee's submission.

1) Demonstration that all licensee actions are complete (*e.g.*, actions identified in Table 2)
2) Demonstration that all appropriate OPG approvals have been issued
3) Confirmation that any safety significant action items have been addressed
4) Completion of CNSC staff report summarizing verification activities[6]

**Table 2: Proposed activities to request removal of RHPs associated with Unit 2**

| RHP | Activity | Task Description | Completion Criteria | Target Completion Dates |
|---|---|---|---|---|
| RHP-1.1 | Factory Acceptance Testing (FAT) | • FAT procedure steps executed satisfactorily.<br>• FAT report prepared, verified, approved by the vendor, BWXT, and accepted by OPG. | • FAT report (NK38-REP-30550-00022) accepted by OPG and a copy provided to CNSC staff. | 2021-09-30 (to be confirmed) (Four weeks after FAT report is accepted by OPG) |
| RHP-1.2 | Reactor Modification Installation Readiness | • Installation plan for TDS reactor modification approved/ issued. | • Installation plan (stage 2 & 3) approved/issued and provided to CNSC staff. | 2021-07-15 |
| RHP-1.3 | Reactor Modification Installation Readiness | • Installation plan for TDS reactor modification approved/ issued. | • Submit flask hoisting and handling procedure to CNSC staff. | 2021-08-31 |
| RHP-1.4 | Change to Reactor Shutdown Guarantee | • Submit for CNSC staff concurrence the Reactor Shutdown Guarantee #9 (RSG #9), which is to prevent Mo-99 IIS heavy water from entering the moderator during Over-poisoned Guaranteed Shutdown State (OPGSS). | • Submit for CNSC staff concurrence the Unit 2 RSG #9 changes. | 2021-07-15 |

[6] CNSC staff's report will document that all required activities have been successfully completed in accordance with regulatory requirements

| | | | | |
|---|---|---|---|---|
| RHP-2.1 | Reactor Modification Commissioning Readiness | • Commissioning specification (NK38-DSC-30550-00001) approved/ issued. | • Commissioning specification (NK38-DCS-30550-00001) approved/issued and provided to CNSC staff. | 2021-10-15 |
| RHP-2.2 | Reactor Modification Commissioning Readiness | • Detailed commissioning plan for TDS approved/issued. | • Detailed Commissioning plan approved/issued and provided to CNSC staff. | 2021-11-15 |

]

**Recommendations and Guidance**

Not applicable to this LC.

# PROPOSED LICENCE

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Word Ref.: e-Doc 6542988
PDF Ref.: e-Doc 6542989
File / Dossier: 2.01

# NUCLEAR POWER REACTOR OPERATING LICENCE

# DARLINGTON NUCLEAR GENERATING STATION

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**I) LICENCE NUMBER:** **PROL 13.0~~23~~/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 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;

(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) possess, transfer, process, package, manage and store Molybdenum-99 radioisotope and its associated decay isotopes. [Added 2021.##]

**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.##]

SIGNED at OTTAWA _____

_____

**Rumina Velshi**
**President**
**CANADIAN NUCLEAR SAFETY COMMISSION**

# CURRENT LICENCE

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Word Ref.: e-Doc 6114405
PDF Ref.: e-Doc 6114417
File / Dossier: 2.01

# NUCLEAR POWER REACTOR OPERATING LICENCE

# DARLINGTON NUCLEAR GENERATING STATION

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**I) LICENCE NUMBER:** **PROL 13.02/2025**

**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 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;

(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;

**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]

SIGNED at OTTAWA April 9, 2020

**Rumina Velshi**
**President**
**CANADIAN NUCLEAR SAFETY COMMISSION**

# CURRENT LICENCE CONDITIONS HANDBOOK

Canada's Nuclear Regulator

e-Doc 6109607 (Word)

e-Doc 6283938 (pdf)

# LICENCE CONDITIONS HANDBOOK

# LCH-PR-13.02/2025-R004

# DARLINGTON NUCLEAR GENERATING STATION NUCLEAR POWER REACTOR OPERATING LICENCE

# LICENCE # PROL 13.02/2025

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

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**Licence Conditions Handbook** **Effective: 16 June 2021**
**LCH-PR-13.02/2025-R004**

# Darlington Nuclear Generating Station

# Nuclear Power Reactor Operating Licence

PROL 13.02/2025

SIGNED at OTTAWA ___ June 2021.

**Dr. Alex Viktorov**
**Director General, Directorate of Power Reactor Regulation**
**CANADIAN NUCLEAR SAFETY COMMISSION**

**Revision History**

| Effective Date | Revision # | LCH e-Doc # | Section(s) Changed | Description of the Changes | DCR List e-Doc # |
|---|---|---|---|---|---|
| January 1, 2016 | R000 | Word e-Doc 4415208 (PDF embedded) | | First Issue | Word e-Doc 4415208 (PDF embedded) |
| February 13, 2017 | R001 | Word e-Doc 4913346 (PDF embedded) | Several Refer to DCR | Various, Refer to DCR | Word e-Doc 5167730 (PDF embedded) |
| February 28, 2018 | R002 | Word e-Doc 5253657 (PDF embedded) | Several Refer to DCR | Various, Refer to DCR | Word e-Doc 5455787 (PDF embedded) |
| December 20, 2019 | R003 | Word e-Doc 5467554 (PDF embedded) | Several Refer to DCR | Various, Refer to DCR | Word e-Doc 5467535 (PDF embedded) |
| June 16, 2021 | R004 | Word e-Doc 6109607 PDF e-Doc 6283938 | Several Refer to DCR | Various, Refer to DCR | Word e-Doc 6109614 PDF e-Doc 6283962 |
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# PART I – INTRODUCTION

The general purpose of the Licence Conditions Handbook (LCH) is to identify and clarify the regulatory requirements and other relevant parts of the licensing basis for each licence condition. This will help ensure that the licensee maintains facility operation in accordance with the licensing basis for the facility and the intent of the nuclear power reactor operating licence (PROL).

The LCH is not intended to introduce new requirements but simply to elaborate upon the requirements in the licensing basis. The LCH should be read in conjunction with the licence. The LCH provides compliance verification criteria (CVC) that the staff of the Canadian Nuclear Safety Commission (CNSC) uses to verify compliance with each licence condition. These regulatory criteria are written in mandatory language. The CVC also contain operational limits and information regarding delegation of authority and applicable versions of documents referenced in the licence. Furthermore, the LCH provides non-mandatory recommendations and guidance on enhancing the effectiveness of the safety and control measures.

Direct references to most Canadian standards and CNSC regulatory documents have been removed from the associated PROL as a last step in the CNSC licence reform for operating licences for nuclear power reactors. The licensee is required to meet the requirements of any standard or regulatory document that is explicitly mentioned in the CVC sections of this LCH, as they were referenced in the licence applications or supplemental updates and; therefore, form part of the licensing basis of the nuclear facility. However, the standards and regulatory documents referenced in the Recommendations and Guidance section should be considered by the licensee as a means to meet or exceed requirements.

Where the LCH refers to licensee submissions to CNSC staff or requests for consent of CNSC staff, if the proposed action or request would lead to operation outside the licensing basis, licence condition G.1 applies. For these submissions and requests, the prevailing communications protocol shall be followed, unless stated otherwise in the CVC for the applicable licence condition.

Current versions of the written notification (WN) documents cited in this LCH are tracked in the document “OPG Darlington NGS PROL Written Notification Documents in LCH” (e-Doc 3959167). This spreadsheet is controlled by Darlington Regulatory Program Division (DRPD). This document is available upon request from DRPD.

This LCH includes appendices A to E which contain administrative information, a glossary of terms and lists of LCH-related documents. Appendices F through H provide tables of approvals and consents granted to the licensee.

# PART II – FACILITY SPECIFIC

## G. GENERAL

### *G.1 Licensing Basis for the Licensed Activities*

**Licence Condition 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").**

**Preamble**

The licensing basis, as defined in LC G.1, is discussed in CNSC document REGDOC-3.5.3, *Regulatory Fundamentals (2018)*.

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity, thus establishing the basis for the CNSC compliance program with respect to that regulated facility or activity. This LCH aligns specific parts of the licensing basis with each LC. For those LCs that require the licensee to implement and maintain a particular program, the licensing basis includes the licensee document(s) that describe the program. This could be a single document, or multiple documents, depending on the licensee's document structure.

**Compliance Verification Criteria**

Part (i) of the licensing basis, lists the applicable laws and regulations that are set out in several federal statutes and agreements, including the following:

- *Nuclear Safety and Control Act;*
- *Canadian Environmental Assessment Act;*
- *Canadian Environment Protection Act;*
- *Nuclear Liability and Compensation Act;*
- *Transportation of Dangerous Goods Act;*
- *Radiation Emitting Devices Act;*
- *Access to Information Act; and*
- *Canada/IAEA Safeguards Agreement.*

Part (ii) of the licensing basis consists of the safety and control measures described in the licence application and the documents needed to support that licence application. The safety and control measures include important aspects of that documentation, as well as important aspects of analysis, design, operation, etc. They may be found in high-level, programmatic licensee documents but might also be found in lower-level, supporting licensee documentation.

Part (iii) of the licensing basis also includes safety and control measures in the CNSC regulatory documents, CSA standards, and other standards and references that are cited in the application or in the licensee's supporting documentation. Those support documents could cite other documents that also contain safety and control measures (i.e., there may be safety and control measures in "nested" references in the application).

LC G.1 requires the licensee to conform to, and/or implement, all the safety and control measures. Note, however, that not all details in referenced documents are necessarily considered to be safety and control measures.

- Details that are not directly relevant to safety and control measures for facilities or activities authorized by the licence are excluded from the licensing basis.
- Details that are relevant to a different safety and control area (i.e., not the one associated with the main document), are only part of the licensing basis to the extent they are consistent with the main requirements for both safety and control areas.
- Informative or guidance sections in referenced documents are not considered to be part of the licensing basis.

The licensing basis is established by the Commission at the time the licence is issued. Per LC G.1, operation during the licence period that is not in accordance with the licensing basis is only allowed based on the written approval of the Commission. Similarly, only the Commission can change the licensing basis during the licence period; and this would also be expected to be recorded in writing.

Where the licensing basis refers to specific configurations, methods, solutions, designs etc., and the licensee is free to propose alternate approaches that differ from those in the CVC as long as they remain in accordance with the licensing basis for the facility.

This LC is not intended to unduly inhibit the ongoing management and operation of the facility or the licensee's ability to adapt to changing circumstances and continuously improve. This LC does not explicitly prohibit changes (such as in management or operation) with a neutral or positive impact on safety. Changes shall be in accordance with the licensing basis and shall be made in accordance with the licensee's management system (see LC 1.1). Changes to licensee documents may require written notification to the CNSC, even if they are in accordance with the licensing basis; see LC G.2.

For unapproved operation that is not in accordance with the licensing basis, the licensee shall take action as soon as practicable to return to a state consistent with the licensing basis, taking into account the risk significance of the situation.

In the event of any conflict or inconsistency between two elements of the licensing basis, the licensee shall direct the conflict or inconsistency to CNSC staff for resolution. Any such conflict or inconsistency identified would be discussed between the licensee and CNSC staff; the outcome of such discussions will be documented to ensure a common understanding.

In case of a conflict between Canadian Standards Association (CSA) standards, CNSC will consult with the CSA before reaching a conclusion on the resolution.

Resolutions made pursuant to this LC are recorded in Appendix H of the LCH. This appendix lists the subject of the conflict or inconsistency and will give the reference to the electronic record (e-Doc #######) documenting the resolution as well as the licensee's identifying correspondence number. Any resolution made will be formally communicated to all other power reactor licensees as appropriate, ensuring consistency of CNSC regulatory oversight amongst all nuclear facilities in Canada. The appropriate changes will be reflected in the CVC of the affected LC and compliance to the resolution will therefore be subject to verification.

The licensee's safety and control measures are described in the following documentation provided at the time of the licence application, or in support of thereafter:

| Date | Document Title | Document # | E-Doc # |
|---|---|---|---|
| December 13, 2013 | Darlington NGS - Application for Renewal of Darlington Nuclear Generating Station Power Reactor Operating Licence 13.00/2014 | NK38-CORR-00531-16490 | 4261350 |
| May 1, 2014 | Darlington NGS- Updated Application Requirements for Renewal of the Darlington Nuclear Generating Station Power Reactor Operating Licence- Transition Plans for New and Revised Standards and Regulatory Documents | NK38-CORR-00531-16780 | 4429709 |
| January 30, 2015 | Darlington NGS- Additional information in Support of Application for Renewal of Darlington's Power Reactor Operating Licence (PROL) 13.01/2015 | NK38-CORR-00531-17206 | 4635419 |

**Recommendations and Guidance**

When the licensee becomes aware that a proposed change or activity might be outside the licensing basis, it should first seek direction from CNSC staff regarding the potential acceptability of this change or activity. The licensee should take into account that certain types of proposed changes might require significant lead times before CNSC staff can make recommendations and/or the Commission can properly consider them. Examples of these types of changes are discussed under various licence conditions in this LCH.

## *G.2 Notification of Changes*

**Licence Condition 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.**

**Preamble**

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity and thus establishes the basis for the CNSC's compliance program in respect of that regulated facility or activity. Licensees are required to operate nuclear facilities in accordance with the licensing basis; however, as changes to the documents included or referenced in the licence application are to be expected during the licensing period, licensees are expected to assess changes for impact on the licensing basis. Any changes to the licensing basis require evaluation to determine impact as related to the 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.

In general, it is expected that changes for which the licensee shall notify the CNSC will be captured as changes to specific licensee documents. This LCH identifies licensee documents that require written notification (WN) of changes to the CNSC. They are primarily selected from the set of documents supporting the application and which describe the licensee's safety and control measures (part (iii) of the licensing basis, as defined in LC G.1). In identifying the WN documents for each LC, CNSC staff select licensee documents that provide reasonable assurance that adequate safety and control measures are in place to satisfy the LC. See LC G.1 for additional discussion of the licensing basis.

Tables under each LC in the LCH identify the documents (if any) requiring written notification of change. Appendix A.4 describes some of the general criteria that CNSC staff will use to assess changes to documents subject to the WN requirement. WN documents are subdivided into ones that require prior written notification of changes and those that require written notification only (changes implemented at the time of notification).

CNSC staff will track the version history of all WN documents cited in the LCH with the exception of security-related documents. A spreadsheet list controlled by the DRPD entitled "OPG - Darlington NGS PROL Written Notification Documents in LCH" (e-Doc 3959167) has been created for this purpose.

**Compliance Verification Criteria**

The licensee shall, as a minimum, provide written notification to the CNSC of changes to the specific licensee documents identified in this LCH under the most relevant LC.

The changes for which CNSC requires written notification consist, primarily, of those captured as changes to specific licensee documents. Licensee documents that require written notification of change are identified in this LCH under the most relevant LC. These documents represent the minimum subset of documents. For any change that is not captured as a change to a document listed in the LCH, if it

negatively impacts designs, operating conditions, policies, programs, methods, or other elements that are integral to the licensing basis, the licensee shall provide written notification of the change.

Written notification (WN) is defined as a physical or electronic communication from a person authorized to act on behalf of the licensee to a CNSC delegated authority or a CNSC staff member acting on behalf of a CNSC delegated authority. WN documents are subdivided into ones that require prior written notification of changes and those that require written notification only. For the former type, the licensee shall submit the WN to the CNSC prior to implementing the change. Typically, the requirement is to submit the proposed changes 30 days prior to planned implementation; however the licensee shall allow sufficient time for the CNSC to review the change proportionate to its complexity and the importance of the safety and control measures being affected. For the latter type, the licensee need only submit the WN at the time of implementing the change. All WNs shall include a summary description of the change, the rationale for the change, and a summary explanation of how the licensee has concluded that the changed document remains in accordance with the licensing basis. A copy of the revised WN document shall accompany the notification.

Changes to the licensing basis that are not clearly in the safe direction require further assessment of impact to determine if prior Commission approval is required in accordance with LC G.1. Additional considerations for changes to facility operation or operating limits, conditions or procedures are discussed under LC 3.1 and those for facility design or equipment are discussed under LC 5.2.

In the event of a discrepancy between the tables in any section of this LCH that contain numbers and limits drawn from licensee documents (e.g., minimum shift complement, action levels, derived releases limits and environmental action levels) and the licensee documentation upon which they are based, the licensee documentation shall be considered the authoritative source, provided that their change control process was followed. Since these limits are considered safety and control measures, any change to them in the licensee documents listed in the WN tables will be reviewed by CNSC staff to confirm they remain within the licensing basis, using the criteria in Appendix A.4 and any other applicable criteria.

Should a change to a WN document listed in this LCH also require submission for approval/acceptance per a standard referenced in the PROL, the licensee shall submit that document for approval/acceptance to comply with the governing standard and the associated LC.

Submission of a proposed WN document for approval, in accordance with a LC does not alleviate the licensee from also providing the written notification of the revised (approved) document.

OPG shall follow its process OPG-PROG-0001, *Information Management*, for any changes related to a document listed in Appendix D.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Information Management | OPG-PROG-0001 | No |

**Recommendations and Guidance**

For proposed changes that would not be in accordance with the licensing basis, the Recommendations and Guidance for LC G.1 apply.

## *G.3 Land Use and Occupation*

**Licence Condition G.3:**

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

**Preamble**

The *General Nuclear Safety and Control Regulations* require that a licence application contain a description of the nuclear facility.

The siting guide used at the time of design of all Canadian NPPs (AECB-1059, e-Doc 3000249) stipulated an exclusion zone that extended at least 914 metres (3000 feet) from the exterior of any reactor building.

**Compliance Verification Criteria**

The licensee shall ensure that the use and occupancy of land within the exclusion zone does not compromise the safety and control measures in the licensing basis. Specifically, the licensee shall consider emergency preparedness and ALARA with respect to land use within the exclusion zone. This applies to land the licensee occupies as well as to land occupied by others.

The licensee shall not permit a permanent dwelling to be built within the exclusion zone. "Permanent dwelling" refers to housing that is meant to be fixed. The licensee may erect, for a short time without prior notification, a temporary dwelling (e.g., a trailer).

The licensee shall notify the CNSC of changes to the use and occupation of any land within the exclusion zone. The notice shall be submitted prior to the change, with lead time in proportion to the expected impact of the change on the licensee's safety and control measures.

The licensee shall notify the CNSC of changes to the licence agreement with the Municipality of Clarington, which ensures safe public access to the waterfront trail that traverses the Darlington site.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington NGS-A Plant Survey June 7, 1999 | LO4254-DZS-10162-0531 | Yes |
| Darlington NGS Safety Report: Part 1 – Plant/Site Description | NK38-SR-03500-10001 | No |
| Ontario Hydro layout drawing, Rev. 9, November 1981 | NK38-D0H-10220-1001 | No |
| Ontario Hydro layout drawing, Rev. 4, March 1982 | NK38-D0H-10220-1002 | No |

LO4254-DZS-10162-0531, *Darlington NGS-A Plant Survey*, NK38-D0H-10220-1001, *Ontario Hydro layout drawing, Rev. 9*, and NK38-D0H-10220-1002, *Ontario Hydro layout drawing, Rev. 4*, describe the exclusion zone, identifying the parcels of land that are not owned by OPG and provide information on land use. These documents shall be revised to reflect any transfer of land within the exclusion zone to non-licensee ownership. The Plant Survey also appears in NK38-SR-03500-10001, *Darlington NGS Safety Report, Part 1 – Plant/Site Description*, which provides added details on the plant and site description.

**Recommendations and Guidance**

Not applicable to this LC.

## *G.4 Office for CNSC On-Site Inspectors*

**Licence Condition 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 (on-site Commission staff).**

### Preamble

CNSC staff require suitable office space and equipment at the nuclear facility in order to satisfactorily carry out its regulatory activities.

### Compliance Verification Criteria

Any changes of accommodation or equipment shall be made based on discussion, and subsequent agreement, between the CNSC and the licensee.

Suitable office space is office space that is separated from the remainder of the building in which it is located by walls or other suitable structures.

### Recommendations and Guidance

Not applicable to this LC.

## *G.5 Financial Guarantee*

**Licence Condition G.5:**

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

### Preamble

The *General Nuclear Safety and Control Regulations* requires that a licence application contain a description of any proposed financial guarantee relating to the activity to be licensed.

The licensee is responsible for all costs of decommissioning and all such costs are included in the decommissioning cost estimates and are covered by licensee's consolidated financial guarantee for decommissioning.

OPG conducted a complete decommissioning cost estimate review as part of the 5-year Ontario Nuclear Funds Agreement reference plan update cycle. Gaps identified between the preliminary decommissioning plan and CSA standard N294, *Decommissioning of facilities containing nuclear substances*, that could impact on the decommissioning costs, were addressed by OPG in the cost estimate review.

The financial guarantee is composed of the following components:

- segregated funds established pursuant to the Ontario Nuclear Funds Agreement (ONFA) between the licensee and the Province of Ontario as amended and effective March 1, 2010;
- trust fund for the management of used fuel established pursuant to the *Nuclear Fuel Waste Act*; and
- Provincial Guarantee pursuant to the Provincial Guarantee Agreement between the CNSC and the Province of Ontario, which was amended March 1, 2010.

### Compliance Verification Criteria

The financial guarantee for decommissioning the nuclear facility shall be reviewed and revised by the licensee every five years or when the Commission requires or following a revision of the preliminary decommissioning plan that significantly impacts the financial guarantee.

The next full update to the 5 year reference plan for financial guarantee purposes is expected in 2022.

The licensee shall submit annually to the Commission a written report confirming that the financial guarantees for decommissioning costs remain valid and in effect and sufficient to meet the decommissioning needs. The licensee shall submit this report by the end of February of each year, or at any time as the Commission may request.

Relevant documents that require version control:

| Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|
| CNSC Financial Security and ONFA Access Agreement and Provincial Guarantee Agreement, effective January 1, 2013 | N/A | Amended 2013-01-01 | 2016-01-01 |

**Recommendations and Guidance**

CNSC guidance document G-206, *Financial Guarantees for the Decommissioning of Licensed Activities*, provides guidance when reviewing the financial guarantees for decommissioning.

## *G.6 Public Information and Disclosure*

**Licence Condition G.6:**

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

**Preamble**

A public information and disclosure program (PIDP) is a regulatory requirement for licence applicants and licensees under the *Class I Nuclear Facilities Regulations*, which requires that a licence application contain a program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects of the licensed activity on the environment, health and safety of persons.

**Compliance Verification Criteria**

The licensee shall implement and maintain a program for public information and disclosure. This program shall comply with the requirements set out in CNSC regulatory document REGDOC-3.2.1, *Public Information and Disclosure*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Public Information and Disclosure | REGDOC-3.2.1 | 2018 | 2020-12-11 |

Where the public has indicated an interest to know, the PIDP shall include a commitment to and disclosure protocol for ongoing, timely communication of information related to the licensed facility during the course of the licensing period.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Nuclear Public Information Disclosure | N-STD-AS-0013 | No |

**Recommendations and Guidance**

It is recommended that OPG submit annually to CNSC staff a report summarizing the events and developments involving OPGs nuclear facilities.

# 1 SCA – MANAGEMENT SYSTEM

The safety and control area "Management System" covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

Performance Objective(s)

There is an effective management system that integrates provisions to address all regulatory and other requirements to enable the licensee to achieve its safety objectives, continuously monitor its performance against those objectives and maintain a healthy safety culture.

## 1.1 *Management System Requirements*

**Licence Condition 1.1:**

| |
|---|
| **The licensee shall implement and maintain a management system.** |

**Preamble**

The *General Nuclear Safety and Control Regulations* require that a licence application contain information related to the organizational management structure and responsibilities.

The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed quality assurance program.

Safe and reliable operation requires a commitment and adherence to a set of management system principles and, consistent with those principles, the establishment and implementation of processes that achieve the expected results. CSA standard N286, *Management system requirements for nuclear facilities*, contains the requirements for a management system throughout the life cycle of a nuclear power plant and extends to all safety and control areas.

The management system must satisfy the requirements set out in the, regulations made pursuant to the *Nuclear Safety and Control Act*, the licence and the measures necessary to ensure that safety is of paramount consideration in implementation of the management system. An adequately established and implemented management system provides CNSC staff confidence and evidence that the licensing basis remains valid.

**Compliance Verification Criteria**

The licensee shall implement and maintain a management system. This management system shall comply with the requirements set out in CSA standard N286, *Management system requirements for nuclear facilities*.

The licensee shall ensure that the management system meets the requirements of CSA N286 at all times throughout operation, refurbishment and return to service for all units.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | Management system requirements for nuclear facilities | N286 | 2012 | 2016-01-01 |
| CNSC | Safety Culture | REGDOC-2.1.2 | 2018 | 2019-05-24*<br>2020-11-26** |

** With the exception nuclear security culture*
*** Including nuclear security culture*

**Management System**

The management and operation of OPG nuclear facilities is defined by the programs and associated nuclear governing documents as described in N-CHAR-AS-0002, *Nuclear Management System*. The management system documentation shall contain sufficient detail to demonstrate that the described processes stated directly or by reference, provides the needed direction to comply with the conditions stated in the PROL and the criteria herein.

**Organization**

The licensee shall document the organizational structure for safe and reliable conduct of licensed activities and shall include all positions with responsibilities for the management and control of the licensed activity. OPG's organization is defined by N-STD-AS-0020, *Nuclear Management Systems Organization*, OPG's role documents for certified positions and OPG correspondence "Persons Authorized to Act on Behalf of OPG in Dealings with the CNSC".

**Safety Culture**

Licensees shall ensure that the management of the organization supports the safe conduct of nuclear activities. The licensee shall ensure that sound nuclear safety is the overriding priority in all activities performed in support of the nuclear facilities and has clear priority over schedule, cost and production. The licensee's approach to worker safety is governed by OPG-PROG-0010, *Health and Safety Management System Program*, which defines the overall process for managing safety and the responsibilities of the parties, specifically at the corporate level.

A safety culture self-assessment methodology is developed following a continuous improvement process, which is governed by N-PROC-AS-0077, *Nuclear Safety & Security Culture Assessment*.

**Business Continuity**

Business continuity is addressed in N-GUID-09100-10000, *Contingency Guideline for Maintaining Staff in Key Positions When Normal Station Access is Impeded*, which provides a strategic plan for safe shutdown and follow-up activities in the event of labour disruptions, and OPG-PROG-0033, *Business Continuity Program*. These are also key documents in support of the minimum shift complement (see LC 2.2).

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Management System | | |
| Nuclear Management System | N-CHAR-AS-0002 | Yes |
| Nuclear Management System Administration | N-PROG-AS-0001 | No |
| Information Management | OPG-PROG-0001 | No |
| Project Management Program | OPG-PROG-0039 | No |
| Managing Change | OPG-STD-0140 | No |
| Organization | | |
| Nuclear Management Systems Organization | N-STD-AS-0020 | No |
| Organization Design Change | OPG-PROC-0166 | No |
| Plant Management (including Safety Culture) | | |
| Nuclear Safety & Security Policy | N-POL-0001 | No |
| Nuclear Safety Oversight | N-STD-AS-0023 | No |
| Health and Safety Management System Program | OPG-PROG-0010 | No |
| Nuclear Safety & Security Culture Assessment | N-PROC-AS-0077 | No |
| Independent Assessment | N-PROG-RA-0010 | No |
| Contingency Guideline for Maintaining Staff in Key Positions When Normal Station Access is Impeded | N-GUID-09100-10000 | No |
| Business Continuity Program | OPG-PROG-0033 | No |
| Items and Services Management | OPG-PROG-0009 | No |

**Recommendations and Guidance**

The management system should be used to promote and support a healthy safety culture. The CNSC recognizes the following characteristics that form the framework for a healthy safety culture:

- Safety is a clearly recognized value;
- Accountability for safety is clear;
- Safety is integrated into all activities;
- A safety leadership process exists, and
- Safety culture is learning-driven.

Additional information can be found in CNSC regulatory document REGDOC-2.1.1, *Management System.*

# 2 SCA – HUMAN PERFORMANCE MANAGEMENT

The safety and control area "Human Performance Management" covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

Performance Objective(s)

The licensee has an integrated approach to managing human performance so that all workers have the necessary knowledge, skills and attributes, are fit for duty, are sufficient in number, and are supported to carry out their work tasks safely.

## 2.1 *Human Performance Program*

**Licence Condition 2.1:**

| |
|---|
| **The licensee shall implement and maintain a human performance program.** |

**Preamble**

Human performance relates to reducing the likelihood of human error in work activities. It refers to the outcome of human behaviour, functions and actions in a specified environment, reflecting the ability of workers and management to meet the system's defined performance under the conditions in which the system will be employed.

Human Factors are factors that influence human performance as it relates to the safety of a nuclear facility or activity over all design and operations phases. These factors may include the characteristics of the person, task, equipment, organization, environment, and training. The consideration of human factors in issues such as interface design, training, procedures, and organization and job design may affect the reliability of humans performing tasks under various conditions.

The *General Nuclear Safety and Control Regulations* require different elements related to the human performance program.

CNSC regulatory document REGDOC-2.2.1, *Human Factors*, describes how the CNSC will take human factors into account during its licensing, compliance and standards-development activities.

For clarification, CNSC regulatory oversight related to hours of work is for the purpose of "nuclear safety" not for the purpose of "worker protection". Worker protection is covered under the SCA "Conventional Health and Safety" (LC 8.1).

**Compliance Verification Criteria**

In order to establish, maintain and improve human performance, the licensee shall monitor and control the work hours and shift schedules of nuclear workers, in accordance with governance N-PROC-OP-0047, *Limits of Hours of Work*. All workers performing safety related tasks or working on safety-related systems are subject to these hours of work and scheduling limits.

The licensee shall also monitor and control the fitness for duty of its workers at all times by implementing and maintaining their "Continuous Behaviour Observation Program", N-CMT-62808-00001, which covers aspect related to fitness for duty. Specific fitness for duty requirements for certified personnel can be found in CNSC regulatory document REGDOC-2.2.3, *Personnel Certification, Volume III: Certification of Persons Working at Nuclear Power Plants*, and those for nuclear security officers can be found in CNSC regulatory document REGDOC-2.2.4, Fitness for Duty, Volume III: *Nuclear Security Officer Medical, Physical and Psychological Fitness*. See LC 2.3 for version control of REGDOC-2.2.3.

REGDOC-2.2.4 *Fitness for Duty, Volume II: Managing Alcohol and Drug Use Version 3*, published in January 2021, sets out requirements and guidance for managing fitness for duty of workers in relation to alcohol and drug use and abuse. As detailed in CNSC letter e-doc 5969253, CNSC staff-have accepted the implementation timeline described in OPG correspondence N-CORR-00531-19643 (e-doc 5865465). OPG will implement all REGDOC-2.2.4 Vol II requirements, other than random alcohol and drug testing, 6 months from the publication of REGDOC-2.2.4 Vol II, version 3. OPG will implement random alcohol and drug testing 12 months from the publication of REGDOC-2.2.4 Vol II, version 3.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Personnel Certification, Volume III: *Certification of Persons Working at Nuclear Power Plants* | REGDOC-2.2.3 | 2019 | 2020-04-09 |
| CNSC | Fitness for Duty: Managing Worker Fatigue | REGDOC-2.2.4 | 2017 | 2019-01-01 |
| CNSC | Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3 | REGDOC-2.2.4 | 2021 | 2021-07-22*<br>2022-01-22** |
| CNSC | Nuclear Security Officer Medical, Physical, Psychological Fitness | RD-363 | 2008 | 2013-09-01 |
| CNSC | Fitness for Duty, Volume III Nuclear Security Officer Medical, Physical, Psychological Fitness | REGDOC-2.2.4 | 2018 | 2020-12-31 |

* For all requirements other than random alcohol and drug testing
** For random alcohol and drug testing requirements

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Limits of Hours of Work | N-PROC-OP-0047 | Yes |
| Listing of Broad Population and Safety Sensitive Job Codes | N-LIST-09110-10005 | Yes |
| Human Performance | N-PROG-AS-0002 | No |
| Procedure Use and Adherence | N-STD-AS-0002 | No |
| Communications | N-STD-OP-0002 | No |
| Self-Check | N-STD-OP-0004 | No |
| Conservative Decision Making | N-STD-OP-0012 | No |
| Second Party Verification | N-STD-RA-0014 | No |
| Pre-Job Brief / Safe Work Plan and Post-Job Debriefing | N-PROC-OP-0005 | No |
| Continuous Behaviour Observation Program (CBOP) – Participants Materials – Workbook Components | N-CMT-62808-00001 | No |
| Leadership and Management Training and Qualification Description | N-TQD-601-00001 | No |

**Recommendations and Guidance**

Licensees should implement a program that continuously monitors human performance, takes steps to identify human performance weaknesses, improves human performance, and reduces the likelihood of human performance related causes and root causes of nuclear safety events.

The Human Performance Program should address and integrate the range of human factors that influence human performance, which include, but may not be limited to the following:

- The provision of qualified staff
  - Certification and Training
  - Staffing
  - Minimum Shift Complement
  - Fitness for duty
    - Hours of Work
    - Fatigue Management
- The reduction of human error
  - HF in Design
  - Procedures Development
  - Procedural Compliance
  - Work protection and Work Permit Systems
  - Shift Turnover
  - Pre and Post Job Briefings
  - Safe work strategies/practices
- Organizational support for safe work activities
  - Human Actions in Safety Analysis
  - Organizational Performance and Safety culture
- The continuous improvement of human performance

Additional guidance is provided in CNSC regulatory document REGDOC-2.5.1, *General Design Considerations: Human Factors*.

## 2.2 *Minimum Shift Complement*

**Licence Condition 2.2:**

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

**Preamble**

The *General Nuclear Safety and Control Regulations*, require that the licensee ensure the presence of a sufficient number of qualified workers at the nuclear facility.

The minimum shift complement specifies the numbers of qualified staff that are required to operate and maintain unit(s) safely under all operating states including normal operations, anticipated operational occurrences, design basis accidents and emergencies.

This licence condition ensures the presence of a sufficient number of qualified workers who must be present at all times to ensure safe operation of the nuclear facility, and to ensure adequate emergency response capability.

**Compliance Verification Criteria**

**Minimum Shift Complement**

The licensee's minimum shift complement (MSC) documentation, D-PROC-OP-0009, *Station Shift Complement*, describes the minimum number of workers with specific qualifications required for the safe operation of the nuclear facilities under all operating states and the measures in place to mitigate the impact of any MSC violations until minimum complement requirements are restored.

The licensee shall operate the nuclear facility in accordance with these documents and shall monitor and keep records of each shift's complement. The licensee shall provide a rolling five year profile of certified operators on an annual basis.

The MSC is considered part of the licensing basis. Changes to the MSC are subject to LC G.1. The following tables summarize the facility's MSC. These tables are taken from D-PROC-OP-0009. In the event of a discrepancy between these tables below and the licensee documentation upon which they are based, the licensee documentation shall be considered the authoritative source (assuming that the licensee has followed its own change control process).

***Shift Complement by Work Group (Normal Operation)***

*Operations Work Group Minimum Complement*

| Position | Minimum Complement # (3 Units Fueled) | Minimum Complement # (4 Units Fueled) | Scheduled Complement # |
|---|---|---|---|
| Authorized Nuclear Operators (ANO) | 5 (7) | 6 (7) | 7 |
| Unit 0 Control Room Operators (CRO) | 2 | 2 | 2 |
| Field Shift Operating Supervisor (FSOS) | 1 | 1 | 1 |
| Unit 0 Nuclear Operators | 3 | 3 | 3 |
| Nuclear Operators (NO) (Units 1 – 4) | 11 (7) | 10 (7) | 12 |
| Shift Advisor Technical Support (SATS) | 1 | 1 | 1 |
| Shift Manager (SM) | 1 | 1 | 1 |
| Control Room Shift Supervisor (CRSS) | 1 | 1 | 1 |
| Supervising Nuclear Operators (SNO) | 4 | 4 | 4 |
| Unit 0 Field Supervising Nuclear Operator | 1 | 1 | 1 |
| **Operations Sub-Total** | **30** | **30** | **33** |

*Other Work Groups Minimum Complement*

| Work Group | Position | Minimum Complement # | | | | Scheduled Complement # | | | |
|---|---|---|---|---|---|---|---|---|---|
| TRF | Control Room SNO | 1 | | | | 1 | | | |
| TRF | Major Panel Operator (MPO) | 1 | | | | 1 | | | |
| TRF | Nuclear Operators | 2 (1) | | | | 2 (1) | | | |
| Lab | Chemical Technician | 2 | | | | 2 | | | |
| FP | Emergency Response Maintainer (ERM) | 6 | | | | 6 | | | |
| FP | Shift Emergency Response Manager (SERM) | 1 | | | | 1 | | | |
| Maint | FLM – Control | 1 | | | | 1 | | | |
| Maint | Shift Control Technician (SCT) (3) (4) | 2 [1] | | | | 3 [2] | | | |
| Maint | Mechanical Maintainer (3) | 1 [0] | | | | 2 [0] | | | |
| Maint | FH Mech. Maintainer/Control Technician (4) | 1 [0] | | | | 2 [0] | | | |
| Maint | FLM – FH (4) | 1 [0] | | | | 1 [0] | | | |
| Security | Nuclear Security Officer (NSO) | NS (5) | | | | NS (5) | | | |
| **Number of FH Trolleys Operated** (6) | | 0 | 1 | 2 | 3 | 0 | 1 | 2 | 3 |
| FH | Field Shift Operating Supervisor | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| FH | Supervising Nuclear Operator (2) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| FH | Major Panel Operator (2) | 0 | 1 | 2 | 3 | 0 | 1 | 2 | 3 |
| FH | Nuclear Operator (2) | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| **Other Work Groups Sub-Total (4)** | | 22 [18] | 24 [20] | 25 [21] | 26 [22] | 26 [21] | 28 [23] | 29 [24] | 31 [26] |
| **All Work Groups (including Operations) Total (4)** | | 52 [48] | 54 [50] | 55 [51] | 56 [52] | 59 [54] | 61 [56] | 62 [57] | 64 [59] |

(1) TRF Nuclear Operators minimum and scheduled complements are reduced to 1 during TRF outage (i.e. hydrogen, deuterium and tritium inventories have been removed from the TRF process). Default complement is 2 (TRF in service).

(2) The workgroup minimum complement for Fuel Handling is one (1) SNO and one (1) Nuclear Operator, when no trolleys are being operated. However, the station strives to staff to allow for one trolley to be operated (1 SNO, 1 MPO and 2 NO's).

(3) One SCT has Design Basis Accident response duties while FH Operations staff (or other qualified staff as per N-PROC-MA-0012) assist with PPT verification (refer to N-INS-03490-10003 for details on credited response to Loss of Instrument Air event and PHT LRV Fail Open event).

(4) Night shift complement, where different from days, shown in square brackets [ ].

(5) NS = not specified in this document – security protected. Refer to Site Security Report.

(6) For the purposes of MCCP alarm limits, complement numbers for 1 trolley operation are used.

(7) When a reactor unit is in a defueled state the minimum complement of certified ANOs required to be present in the facility is reduced to five (5) and the minimum complement of Nuclear Operators for units 1-4 is increased to 11. The number of NOs is increased in order to provide a second emergency MCRA (CSP) qualified operator as per the following table: ERO Requirements (for emergency conditions) Notation 8. Any certified ANO surplus to minimum complement can also fill this role.

***Shift Complement for Emergency Response Organization (ERO)***

*ERO Requirements (for emergency conditions)*

| Position | Work Group (1) | Minimum Complement # | Scheduled Complement # |
|---|---|---|---|
| Authorized Nuclear Operators (ANO) | Operations | 6 (8) | 7 |
| Unit 0 Control Room Operator (CRO) | Operations | 2 | 2 |
| Chemical Technician | Chemistry | 2 | 2 |
| Crew Accounting Supervisor | Fuel Handling | 1 | 1 |
| Emergency MCRA (CSP Monitor) | Operations | 1 (8) | 1 |
| Emergency Response Maintainer (ERM) | Fire Protection | 6 | 6 |
| Emergency TRF Operator | TRF | 1 | 1 |
| Emergency Unit Operator (Units 1–4) | Operations | 5 | 5 |
| EPGQO - Unit 0 Nuclear Operators/FSNO (2) | Operations | 3 | 3 |
| In-Plant Survey Team | Operations | 2 | 3 |
| In-Plant Coordinator | Operations | 1 | 1 |
| Off-Site Survey Team Captain (3) | Maintenance | 1 [0] | 1 [0] |
| Off-Site Survey Team (3) | Maintenance | 2 [0] | 2 [0] |
| Out-of-Plant Coordinator (3) | Maintenance | 1 [0] | 1 [0] |
| Emergency Shift Assistant (ESA) | Operations | 1 | 1 |
| Shift Emergency Response Coordinator | Fire Protection | 1 | 1 |
| Shift Manager (4) | Operations | 1 | 1 |
| Control Room Shift Supervisor (CRSS) | Operations | 1 | 1 |
| Shift Resource Coordinator | Maintenance | 1 | 1 |
| TRF SNO | TRF | 1 | 1 |
| TRF Major Panel Operator | TRF | 1 | 1 |
| Supervising Nuclear Operator (Units 1–4) | Operations | 4 | 4 |
| Mechanical Maintainer (7) – DBA action | Maintenance | 1 | 1 |
| Shift Control Technician (7) – DBA action | Maintenance | 1 | 1 |
| Security (5) | Security | NS (6) | NS (6) |
| **Total** | | **47 [44]** | **49 [45]** |

(1) To ensure the assignment of ERO roles is managed, the assignment of staff by each Work Group is identified in the above table. Nevertheless, these positions may be filled by staff from any work group provided they are qualified and incremental to the roles that are Work Group specific.

(2) The Unit 0 complement requirements for a Main Steam Line Break or a Common Mode Event are one (1) EPGQO and two (2) Unit 0 NO's. In order to facilitate tracking of the EPG Qualified Operators and the Unit 0 NO's together in the Minimum Complement Coordination Program, the station shall continue to ensure that all Unit 0 NO's are EPG qualified. They are to be available to restore EPS/ESW to all affected units within 30 minutes.

(3) Day shift only position (12 hours/day, 7 days/week). Night shift complement, where different from days, shown in square brackets [ ].

(4) The Shift Manager executes both the emergency Shift Manager role and the ERM role until such time as the Site Management Center is declared operational.

(5) Security shall provide two drivers for the Off-Site Survey Team.

(6) NS = not specified in this document – security protected. Refer to Site Security Report.

(7) One MM and one SCT have Design Basis Accident response duties (refer to N-INS-03490-10003 for details on credited MM/CM response to Loss of Instrument Air event and PHT LRV Fail Open event).

(8) When a reactor unit is in a defueled state, the minimum complement of certified ANOs required to be present in the facility is reduced to five (5) and the minimum complement of Emergency MCRAs (CSP Monitors) is increased to two (2) to maintain overall Operations minimum complement unchanged. Any certified ANO surplus to minimum complement can also fill the role of emergency MCRA.

***Control Room Staffing***

The licensee shall comply with the minimum certified personnel requirements for the nuclear facility and for the main control room. The certified positions are listed in LC 2.3.

In conjunction with the minimum shift complement for the facility, the licensee shall maintain adequate control room staffing. For the following certified positions, the licensee shall have the following certified personnel at all times:

(i) in the nuclear facility, at least one certified shift manager, one certified control room shift supervisor, two certified unit 0 control room operators, and the following number of authorized nuclear operators for the specified number of reactor units with fuel in the core.

  (a) Five authorized nuclear operators for three fueled units; and

  (b) Six authorized nuclear operators for four fueled units.

(ii) in the main control room, at least the following number of certified authorized nuclear operators for the specified number of reactor units with fuel in the core:

  (a) Three authorized nuclear operators for three fueled units; and

  (b) Four authorized nuclear operators for four fueled units.

(iii) in the main control room, at least one certified unit 0 control room operator, except for brief absences to determine the origin of fire alarms.

(iv) in the main control room, a certified authorized nuclear operator in direct attendance at the control panels of each reactor unit with fuel in the core.

The minimum certified personnel requirements for the main control room that this condition imposes do not apply where this minimum cannot be met due to emergency conditions that could cause an unwarranted hazard to personnel in the main control room, in which case the licensee shall place the reactor(s) in a safe shutdown state and the nuclear facility in a safe condition.

"In direct attendance" means the certified person must physically be in the direct line of sight and in close proximity to the control room panels to continuously monitor, recognize and differentiate panel displays, alarms and indications.

A certified person shall be in a position to rapidly respond, in accordance with his/her role, to changing unit conditions, at all times, as described in D-PROC-OP-0009, *Station Shift Complement*.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Station Shift Complement | D-PROC-OP-0009 | Yes |
| Duty Crew Minimum Complement Assurance | D-INS-09260-10001 | Yes |

**Recommendations and Guidance**

The adequacy of the minimum shift complement should be determined through a systematic analysis of the most resource-intensive conditions under all operating states, design basis accidents, and emergencies. The results of the analysis should then be validated to determine the degree to which the minimum shift complement facilitates the achievement of the overall safety goals.

Recommendations and guidance for the development and validation of the minimum shift complement are provided in the following CNSC guidance documents:

- REGDOC-2.2.5, Minimum Shift Complement describes the CNSC recommended approach for defining the minimum shift complement and sets out the key factors that CNSC staff will take into account when assessing whether the licensee has made, or the applicant will make, adequate provision for ensuring the presence of a sufficient number of qualified staff.
- REGDOC-2.5.1, General Design Considerations: Human Factors describes the elements of effective human factors verification and validation planning, including a suggested format for documenting these elements.

## 2.3 *Training, Certification and Examination Program*

**Licence Condition 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 CNSC Regulatory Document REGDOC-2.2.3, PERSONNEL CERTIFICATION, VOLUME III: CERTIFICATION OF PERSONS WORKING AT NUCLEAR POWER PLANTS.**

**Persons appointed to the following positions require certification:**

**(i) Responsible Health Physicist;**

**(ii) Shift Manager;**

**(iii) Control Room Shift Supervisor;**

**(iv) Authorized Nuclear Operator; and**

**(v) Unit 0 Control Room Operator.**

**Preamble**

The *General Nuclear Safety and Control Regulations* require the licensee to train the workers to carry on the licensed activity in accordance with the *Nuclear Safety and Control Act*, the associated regulations and the licence.

The *Class I Nuclear Facilities Regulations* requires that:

- A licence application to operate a Class I nuclear facility contain the proposed responsibilities of and qualification requirements and training program for workers, including the procedures for the requalification of workers; and
- The licensee submits the necessary information for certification or renewal of certification of the applicable positions.

The licensee's documentation describes the authority and responsibilities of certified positions.

This LC provides the regulatory requirements for the development and implementation of training programs for workers, and for the initial certification, the renewal of certification and training of persons for the positions listed in the LC.

It also provides the requirements regarding the program and processes necessary to support the certification and training of persons at the nuclear facility.

As defined by the *General Nuclear Safety and Control Regulations*, workers include contractors and temporary employees who perform work that is referred to in the licence. Training requirements apply equally to these types of workers as to the licensees own employees.

**Compliance Verification Criteria**

The licensee shall implement and maintain programs for training of personnel, including programs for the certification of persons working at an NPP in positions that have a direct impact on nuclear safety. The certification program, including all supporting examinations, shall comply with the requirements set out in CNSC regulatory document REGDOC-2.2.3, *Personnel Certification, Volume III: Certification of Persons Working at Nuclear Power Plants*.

The licensee shall implement and maintain initial and continuing training programs for all workers in accordance with CNSC regulatory document REGDOC-2.2.2, *Personnel Training*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | *Personnel Certification, Volume III:* Certification of Persons Working at Nuclear Power Plants | REGDOC-2.2.3 | 2019 | 2020-04-09 |
| CNSC | Personnel Training | REGDOC-2.2.2 | 2014 | 2016-01-01 |

During refurbishment of the nuclear facility, the refresher training specified in subsection 32.1 of REGDOC-2.2.3 shall be modified as required to account for the fact that certified persons will not be able to perform most of the operations and maneuvers that are regularly performed during normal operation of the facility.

The licensee shall implement and maintain an overall training policy, including initial and continuing training sub-programs for all workers. The program shall be based on long-term qualifications and competencies required for job performance, as well as training goals that acknowledge the critical role of safety.

**Training Programs for All Workers**

The licensee shall ensure that all workers are qualified to perform the duties and tasks required of their position.

All training programs related to workers in positions where the consequence of human error poses a risk to the environment, the health and safety of persons, or to the security of the nuclear facilities and licensed activities, are evaluated against the criteria for a systematic approach to training (SAT).

**Training and Certification for Staff Appointed to Certified Positions**

The Senior Health Physicist referred to in REGDOC-2.2.3 is equivalent to the Responsible Health Physicist position at Darlington NGS.

The Plant Shift Supervisor at a multi-unit plant referred to in REGDOC-2.2.3 is equivalent to the Shift Manager position at Darlington NGS.

The Reactor Operator referred to in REGDOC-2.2.3 is equivalent to the Authorized Nuclear Operator position at Darlington NGS.

The licensee shall ensure persons appointed to the position of Responsible Health Physicist, Shift Manager, Authorized Nuclear Operator, Control Room Shift Supervisor, or Unit 0 Control Room Operator, at the nuclear facility hold a certification for the position to which they have been appointed, in accordance with the requirements of the *Class I Nuclear Facilities Regulations*.

Certified personnel shall carry out their authorities and responsibilities as per their respective role documents.

Any person who holds a certification as Shift Manager shall also be qualified to act in the position of Control Room Shift Supervisor.

The Control Room Shift Supervisor position may also be filled by a certified Shift Manager.

When applying for certification or renewal of certification of a person for the positions listed, the licensee shall submit the information required pursuant to section 9 of *Class I Nuclear Facilities Regulations* and shall confirm that the person meets the relevant certification requirements applicable to that position, specified in REGDOC-2.2.3.

The authorities and responsibilities of the certified positions listed above are considered safety and control measures. Any changes to them will be reviewed by CNSC staff to confirm they remain within the licensing basis, in consultation with the designated officer to certify and decertify persons referred to in sections 9 and 12 of the *Class I Nuclear Facilities Regulations* and the Director of the Personnel Certification Division. The general criteria for reviewing changes include those described in Appendix A.4. Any changes outside the licensing basis would require prior written approval of the Commission, per LC G.1.

Until further notification, the incumbent in paragraphs 25.2.6 and 26.7 of REGDOC-2.2.3 may either be a certified:

a) Control Room Shift Supervisor (CRSS) who is working in the certified position of CRSS (duty CRSS), or
b) Shift Manager (SM) who is assigned to work in the certified position of CRSS (duty CRSS)

and must be qualified to evaluate the performance of the candidate as per section 6.0 of REGDOC-2.2.3.

Until the revision of REGDOC-2.2.3, the procedures specified in section 6.0 shall include the qualification requirements specifying the prerequisite knowledge and level of experience required for the certified incumbent to effectively monitor and evaluate candidate knowledge and performance in that position.

**Conduct of Examinations and Tests for Certified Personnel**

Currently, the following three CNSC internal documents contain the requirements for administering the certification examinations and requalification tests required by REGDOC-2.2.3:

- CNSC-*EG1, Rev.0: Requirements and Guidelines for Written and Oral Certification Examinations for Shift Personnel at Nuclear Power Plants*,
- CNSC-*EG2, Rev.0: Requirements and Guidelines for Simulator-based Certification Examinations for Shift Personnel at Nuclear Power Plants*, and
- CNSC document: *Requirements for the Requalification Testing of Certified Shift Personnel at Nuclear Power Plants, Revision 2.*

Under a pilot program approved by CNSC staff (e-Doc 6352433), OPG may choose to administer the General Written Initial Certification Examinations (specified in CNSC-EG1) using Multiple Choice Question (MCQ) format. During this pilot program, the development, conduct, and marking of MCQ General initial certification examinations shall be in accordance with the following OPG document(s):

- N-INS-08920-10004, Written and Oral Initial Certification Examination for Shift Personnel

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Training | N-PROG-TR-0005 | No |
| Systematic Approach to Training | N-PROC-TR-0008 | No |
| Written and Oral Initial Certification Examination for Shift Personnel | N-INS-08920-10004 | Yes |
| Simulator-Based Initial Certification Examinations for Shift Personnel | N-INS-08920-10002 | No |
| Requalification Testing of Certified Shift Personnel | N-INS-08920-10001 | No |
| Responsible Health Physicist | N-MAN-08131-10000-CNSC-031 | Yes |
| Shift Manager, Darlington Nuclear | N-MAN-08131-10000-CNSC-006 | Yes |
| Authorized Nuclear Operators | N-MAN-08131-10000-CNSC-010 | Yes |
| Control Room Shift Supervisor | N-MAN-08131-10000-CNSC-008 | Yes |
| Unit 0 Control Room Operator | N-MAN-08131-10000-CNSC-025 | Yes |

**Recommendations and Guidance**

With regard to refurbishment activities planned for Darlington NGS, it is recommended that OPG start preparing, in advance, for the additional future training-related requirements, including continuing training for personnel requiring certification or maintenance thereof.

# 3 SCA – OPERATING PERFORMANCE

The safety and control area "Operating Performance" includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

Performance Objective(s)

Plant operation is safe and secure, with adequate regard for health, safety, security, radiation and environmental protection, and international obligations.

## 3.1 *Operations Program*

**Licence Condition 3.1:**

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

**Preamble**

The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.

The operations program establishes safe operating practices within the nuclear facility, under all operating conditions (routine and non-routine), and provides the ability to ensure the facility is operated in such a manner that:

- Applicable regulations, licence conditions, and standards are followed;
- The requirements of the Operating Policies and Principles (OP&Ps) are implemented; and
- Limits are established in accordance with a Safe Operating Envelope (SOE) are not exceeded.

The OP&Ps:

- Define the operating rules consistent with the safety analyses and other licensing support documentation within which the facility will be operated, maintained and modified, all of which should ensure nuclear safety;
- Specify the authorities of the facility staff positions to make decisions within the defined boundaries; and
- Identify and differentiate between actions where discretion may be applied and where jurisdictional authorization is required.

The SOE is defined in CSA standard N290.15, *Requirements for the safe operating envelope for nuclear power plants*, as "the set of limits and conditions within which the nuclear generating station must be operated to ensure compliance with the safety analysis upon which reactor operation is licensed and which can be monitored by or on behalf of the operator and can be controlled by the operator."

The SOE consists of a number of parameters:

- Safe operating limits;
- Conditions of operability;
- Actions and action times; and
- Surveillances.

The safe operating limits are derived from the safety analysis limits. The SOE parameters are currently identified in various station documents, including Operational Safety Requirements (OSR), Instrument Uncertainty Calculations (IUC), the Abnormal Incidents Manual and surveillance documentation. Power limit specifications set limits on parameters that affect reactor core, channel, and fuel bundle powers, to ensure compliance with limits imposed by the Design and Safety Analysis assumptions. The magnitude of the initial reactor power, channel powers and bundle powers in the reactor prior to an accident are the fundamental parameters governing whether fuel or fuel channel failure will occur during anticipated transients and the postulated Design Basis Accidents (DBA).

Heat sinks are combination of systems or portions of systems that contribute to conveying heat to the atmosphere or body of water, known as the ultimate heat sink (UHS). The goal of the heat sink systems is to provide heat removal from the heat source (reactor core, pump heat) to the UHS, where the residual heat can always be transferred.

The outage heat sink management defines the strategy to ensure the plant is safe throughout the outage duration when the normal (at high power) heat sinks may not be available. The outage is considered to be terminated when the normal heat sinks are re-established as part of the plan to proceed to sustained high power operation.

Accident management provisions are to ensure effective defences against radiological hazards resulting from DBAs and Beyond Design Basis Accidents (BDBAs). The fundamental premise underlying accident management is that the licensee has established and maintained overlapping measures for accident prevention and, should an accident occur, is able to:

- Prevent the escalation of the accident;
- Mitigate the consequences of the accident; and
- Achieve a long-term safe stable state after the accident.

**Compliance Verification Criteria**

The licensee shall implement and maintain operations programs. These programs shall consist of, at a minimum, a safe operating envelope, a set of operating policies and principles, and accident management procedures and/or guides for design basis and beyond design basis accidents, including overall strategies for recovery. These programs shall comply with the requirements set out in:

- CNSC regulatory document REGDOC-2.3.2, Accident Management: Severe Accident Management Programs for Nuclear Reactors; and
- CSA standard N290.15, Requirements for the safe operating envelope for nuclear power plants.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | Requirements for the safe operating envelope for nuclear power plants | N290.15 | 2010 | 2016-01-01 |
| CNSC | Accident Management: Severe Accident Management Programs for Nuclear Reactors | REGDOC-2.3.2 | 2013 | 2016-01-01 |

Operation in states not considered in, or not bounded by, the safety analyses is not permitted.

Aspects of operations or procedures that impact the limits documented in the operating policies and principles or safe operating envelope are considered safety and control measures and therefore subject to LC G.1.

**Power Limits**

In accordance with the Safety Analysis (refer to LC 4.1) and the Licensing Basis (refer to LC G.1), during operation:

- The total power generated in any one fuel bundle shall not exceed the applicable channel-specific bundle power limit as defined in the current licensing submissions under steady-state operating conditions. The maximum value in the channel-specific bundle power limit map is 908.5 kilowatts.
- The total power generated in any fuel channel shall not exceed the applicable channel-specific channel power limit as defined in the current licensing submissions under steady-state operating conditions. The maximum value in the channel-specific power limit map is 7200 kilowatts.
- The total thermal power from the reactor fuel shall not exceed 2776 megawatts under steady-state operating conditions.
- The reactor, channel and bundle power limits are considered safety and control measures. Any changes to them, or planned operations outside of these limits are subject to LC G.1.

**Operating Policies and Principles**

The operating policies and principles shall provide direction for the safe operation and as a minimum, reflect the safety analyses that have been previously submitted to the Commission.

The licensee shall, at all times, maintain and operate the nuclear facility within the limits of the OP&Ps and SOE. If operation outside the operating boundaries as defined in the OP&Ps and SOE is discovered, the licensee shall take immediate action to return the facility within the boundaries of safety analyses, in a safe manner.

**Safe Operating Envelope**

The licensee's safe operating limits, conditions and surveillance requirements, as well as their bases are documented in station and system specific OSR documents along with any associated IUCs. The limits and conditions defined in the OSRs, including any requirements for corrective or mitigating actions and action times, are specified in the applicable operations and maintenance tests, procedures and processes to ensure compliance with the SOE.

The licensee shall maintain a set of OSRs and IUCs that define the limits and conditions of the safe operating envelope.

The SOE is considered part of the licensing basis. Changes to the SOE documentation (OSRs and IUCs) are subject to LC G.1. Changes that may reduce safety margins require Commission approval prior to implementation.

In addition, any changes to the safety and control measures listed in the SOE documentation (including OSRs) require Prior Written Notification, subject to LC G.2.

**Accident Management**

The licensee shall implement and maintain operational procedures for operation in all states analyzed in the design basis, including abnormal and emergency states.

The licensee's operational procedures ensure that the operation of the facility can be returned to a safe and controlled state should operation deviate from normal operation. The licensee shall ensure all abnormal operational scenarios analyzed in the design basis are accounted for in the operational procedures with the purpose of mitigating situations that may arise which cause a deviation from the expected state. These documents are conceived to return the plant to a safe and controlled state and to prevent the further escalation of the abnormal incident into a more serious deviation.

In addition to the operational guidance for abnormal and emergency states, the licensee shall implement and maintain a severe accident management program to address residual risks posed by severe accidents. The licensee shall also ensure clear instruction is provided directing operations to use an appropriate set of severe accident management guidelines (SAMGs), if a severe accident is detected.

Incorporating lessons learned from world events, OPG has issued a series of emergency operating procedures, the Emergency Mitigating Equipment Guidelines (EMEGs). EMEGS were developed to enable the use of portable diesel pumps and generator to provide coolant inventory make up (to steam generators, moderator and heat transport systems), and electrical power to essential instrumentation. The EMEGs are initiated following a total loss of Class IV and Class III electrical power or a Seismic Event where both Emergency Power Generators fail and cannot be restored, with the intention of preventing a Fukushima type core damage event.

The licensee shall ensure clear instruction is provided directing operations in abnormal scenarios to the appropriate set of procedures or guides.

OPG is compliant with the 2013 version of REGDOC-2.3.2, *Accident Management: Severe Accident Management Programs for Nuclear Reactors* as of January 1, 2016.

**Other Requirements**

All work related tasks shall be supported by procedures that are fit for purpose and are used appropriately to minimize the potential for human error.
Additionally, the licensee shall maintain a set of technical basis documents describing the design basis for chemistry control.

In addition to the documents listed in the table below, the licensee shall provide WN to CNSC staff prior to implementation, of any changes to any procedures that could potentially impact on the reactor, the channel or the bundle power limits. Changes that would impact these limits are subject to LC G.1.

In 2013, CNSC staff agreed to the implementation of Rod-based Guaranteed Shutdown State as a Guaranteed Shutdown State at Darlington NGS (e-Doc 4192803). In 2019, CNSC staff provided concurrence to OPG's request to extend the applicability of RBGSS for outages up to 375 days in length, without the need to notify CNSC staff (e-Doc 5979625). RBGSS is established through the application of physical barriers and procedural controls guaranteeing that the shut-off absorbers, control absorbers, and adjuster absorber rods remain in-core to ensure a sub-critical reactor status. In addition, to the inserted rods, a concentration of at least 3.3 ppm of Gadolinium Nitrate (Gd) is maintained in the moderator as a "poison" providing additional defence-in-depth. The licensee shall provide prior written notification for changes to operations or procedures for the Rod-based Guaranteed Shutdown State. CNSC staff will use the criteria in Appendix A.4 and any other applicable criteria to confirm the changes remain within the licensing basis. Changes outside of the licensing basis will require prior written approval by the Commission, per LC G.1.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington Nuclear Operating Policies and Principles | NK38-OPP-03600 | Yes |
| Safe Operating Envelope | N-STD-MP-0016 | Yes |
| Heat Sink Management | N-STD-OP-0025 | No |
| Nuclear Safety Configuration Management | N-STD-OP-0024 | No |
| Conduct of Operations/Nuclear Operations | N-PROG-OP-0001 | No |
| Chemistry | N-PROG-OP-0004 | No |
| Conservative Decision-Making | N-STD-OP-0012 | No |
| Operational Decision Making | N-STD-OP-0036 | No |
| Beyond Design Basis Accident Management | N-STD-MP-0019 | No |
| Operations Performance Monitoring | N-STD-OP-0011 | No |

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Operating Experience Process | N-PROC-RA-0035 | No |
| Processing Station Conditions Records | N-PROC-RA-0022 | No |
| Performance Improvement | N-PROG-RA-0003 | No |
| Response to Transients | N-STD-OP-0017 | No |
| Reactor Safety Program | N-PROG-MP-0014 | No |
| Reactivity Management | N-STD-OP-0009 | No |
| Control of Fuelling Operations | N-STD-OP-0021 | No |

**Recommendations and Guidance**

The licensee should manage all outage heat sink work activities in accordance with CSA standard N290.11, *Requirements for heat removal capability during outage of nuclear power plants*.

Licensees are to take in consideration the October 2014 version of CNSC regulatory document REGDOC-2.3.2, *Accident Management*.

## 3.2 *Approval to Restart After a Serious Process Failure*

**Licence Condition 3.2:**

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

**Preamble**

The definition of serious process failure and the associated reporting requirements are provided in CNSC regulatory document REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*.

**Compliance Verification Criteria**

When an event is found to be a serious process failure or where the determination as to the cause and/or extent of condition has proved inconclusive (i.e. a serious process failure cannot be ruled out), a request for restart of the reactor shall be submitted in writing and approval to restart the reactor must be obtained from the CNSC.

If there is sufficient assurance that the cause of the serious process failure has been resolved and it is now safe to return the facility to service, a CNSC authorized person has the authority to give the consent to the licensee to proceed with the restart of the reactor.

The written request for restart of the reactor is to include the following information:

- Description of the event;
- Causes of the event;
- Consequences and safety significance of the event;
- Recovery plan including corrective actions, and fitness for service assessment on the systems/components impacted from the failure if applicable. This shall be completed prior to reactor restart;
- A statement regarding plant readiness to resume safe operation. This shall include any conditions that the licensee proposes to impose upon reactor restart and/or subsequent reactor operation to ensure safe operation of the nuclear facility; and
- Extent of completion of the conditions mentioned in the statement regarding plant readiness to resume safe operation.

General criteria for CNSC's review of these requests are provided in Appendix A.4.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Reactor Safety Program | N-PROG-MP-0014 | No |
| Response to Transients | N-STD-OP-0017 | No |

**Recommendations and Guidance**

In addition to the requirements listed above, the written request to restart a reactor after a serious process failure should also include the following information:

- A statement specifying that an extent of condition has been completed;
- Documentation and communication to licensee staff (including additional training, if necessary); and
- Applicable historical Operating Experience (OPEX) review for comparable events.

## 3.3 *Reporting Requirements*

**Licence Condition 3.3:**

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

**Preamble**

CNSC regulatory document REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*, has comprehensive reporting requirements (scheduled and unscheduled) for operation of NPPs. It describes information that the CNSC needs to evaluate the performance of the facilities it regulates. This document is complementary to the reporting requirements in the *Nuclear Safety and Control Act* and the associated regulations.

**Compliance Verification Criteria**

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Reporting Requirements for Nuclear Power Plants | REGDOC-3.1.1 | 2014 | 2016-01-01 |

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Written Reporting to Regulatory Agencies | N-PROC-RA-0005 | No |
| Preliminary Event Notifications | N-PROC-RA-0020 | No |

**Recommendations and Guidance**

To ensure consistency of reporting across the fleet of Canadian NPPs, CNSC staff have prepared a list (e-Doc 4525925) which provides additional clarification and interpretation of the requirements of REGDOC-3.1.1. The list, which is expected to become a controlled CNSC document, was developed in consultation with industry and should be used as guidance, as appropriate.

## 3.4 *Periodic Safety Review*

**Licence Condition 3.4:**

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

**Preamble**

In support of refurbishment activities and continued long term operation, OPG has conducted an Integrated Safety Review in accordance with CNSC regulatory document RD-360, *Life Extension of Nuclear Power Plants*.

An Integrated Safety Review (ISR) is a process which includes an assessment of the current state of the plant and plant performance to determine the extent to which the plant conforms to modern standards and practices, and to identify any factors that would limit safe long-term operation. The process starts with a comprehensive review of the facility and its operations and results in the production of an integrated implementation plan (IIP) which describes practical and reasonable modifications to be carried out by the licensee.

The periodic safety review (PSR) process mirrors this approach. The PSR process requires OPG submittal and CNSC staff acceptance of a PSR basis document, safety factor reports, a global assessment report and an Integrated Implementation Plan, The PSR-IIP will require Commission approval in a public proceeding. The intent is to provide a seamless transition from the refurbishment-IIP to the PSR-IIP with no compromise in safety.

**Compliance Verification Criteria**

The licensee shall conduct a PSR to confirm that the facility remains consistent with a set of modern codes and standards intended to demonstrate that the safety basis remains valid. The PSR shall be conducted in accordance with CNSC regulatory document REGDOC-2.3.3, *Periodic Safety Reviews*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Periodic Safety Reviews | REGDOC-2.3.3 | 2015 | 2016-01-01 |

OPG shall submit the PSR basis document, along with the subsequent licence renewal application no later than one year prior to the expiry of the licence.

**Recommendations and Guidance**

To ensure a seamless transition from the refurbishment-IIP to the PSR-IIP, OPG should submit the PSR safety factor reports two years following the submittal of the PSR basis document. OPG should submit the global assessment report and Integrated Implementation Plan one year following the submittal of the PSR safety factor reports.

When preparing the subsequent OPG Darlington licence application, OPG should refer to REGDOC-1.1.3, *Licence Application Guide: Licence to Operate a Nuclear Power Plant*, and ensure that the application addresses it to the extent practicable. This document provides information that supplements and clarifies the basic requirements of the regulations to assist an applicant in providing a sufficient level of detail in the application. It contains clearly separated references to CNSC REGDOCs and industry codes and standards that an applicant must comply with and those which an applicant is recommended to address. Additionally, descriptions of the contents of the programs to be submitted are contained in this REGDOC.

# 4 SCA – SAFETY ANALYSIS

The safety and control area "Safety Analysis" covers maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.

Performance Objective(s)

There is demonstration of the acceptability of the frequency and consequences of design-basis and beyond design basis events, and the ability of protective systems and emergency mitigating equipment to adequately control power, cool the fuel and contain or limit any radioactivity that could be released from the plant.

## 4.1 *Safety Analysis Program*

**Licence Condition 4.1:**

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

**Preamble**

The *General Nuclear Safety and Control Regulations* require that a licence application contain a description and the results of any analyses performed.

The *Class I Nuclear Facilities Regulations* require, amongst other requirements, that a licence application contain a final safety analysis report, and additional supporting information.

A deterministic safety analysis evaluates the NPP's responses to such events by using predetermined rules and assumptions (conservative or best-estimate methods). The objectives of the deterministic safety analysis are stated in CNSC regulatory document REGDOC-2.4.1, *Deterministic Safety Analysis*.

Probabilistic safety assessment (PSA) is a comprehensive and integrated assessment of the safety of the nuclear power plant that, by considering the initial plant state and the probability, progression, and consequences of equipment failures and operator response, derives numerical estimates of a consistent measure of the safety of the design. Such assessments are most useful in assessing the relative level of safety. The objectives of the probabilistic safety analysis are stated in CNSC regulatory document REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*.

CSA standard N286.7, *Quality assurance of analytical, scientific and design computer programs for nuclear power plants*, provides the specific requirements related to the development, modification, maintenance and use of computer programs used in analytical, scientific and design applications. These requirements apply to the design, development, modification and use of computer programs that are used in analytical, scientific and design applications at nuclear power plants.

**Compliance Verification Criteria**

The licensee shall implement and maintain programs for the development and updates of safety analyses. These programs shall comply with the requirements set out in:

- CNSC regulatory document REGDOC-2.4.1, Deterministic Safety Analysis;
- CNSC regulatory document REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants; and
- CSA standard N286.7, Quality assurance of analytical, scientific and design computer programs for nuclear *power plants*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Deterministic Safety Analysis | REGDOC-2.4.1 | 2014 | 2016-01-01 |
| CNSC | Probabilistic Safety Assessment (PSA) for Nuclear Power Plants | REGDOC-2.4.2 | 2014 | 2020-01-01 |
| CSA | Quality assurance of analytical, scientific and design computer programs for nuclear power plants | N286.7 | 1999 (Reaffirmed 2012) | 2016-01-01 |

The licensee shall demonstrate compliance of computer programs used in analytical, scientific and design applications used to support the safe plant operation in accordance with CSA N286.7.

**Deterministic Safety Analysis**

The licensee shall conduct and maintain a deterministic safety analysis as documented in the plant Final Safety Analysis Report. The deterministic safety analysis shall demonstrate that the radiological consequences of the postulated initiating events do not exceed the accident-dependent reference public dose limits in the following table:

| | **Reference Dose Limit (most exposed member of the public)** | |
|---|---|---|
| **Class of Postulated Event** | Thyroid Dose (mSv) | Whole Body Dose (mSv) |
| Class 1 | 5 | 0.5 |
| Class 2 | 50 | 5 |
| Class 3 | 300 | 30 |
| Class 4 | 1000 | 100 |
| Class 5 | 2500 | 250 |

All new analysis will be performed in accordance with REGDOC-2.4.1.

REGDOC-2.4.1 includes modern requirements associated to the lessons learned from the Fukushima nuclear events. OPG has developed an implementation plan for 2014 to 2017, N-PLAN-03500-0500515 R003 (e-Doc 4776487), while undertaking gap identification and prioritization in compliance with REGDOC-2.4.1. During this licence period, OPG shall begin to upgrade the individual sections and appendices that form Part 3, Accident Analysis, of the Darlington Safety Report, in a staged manner in accordance with the implementation plan. To support continued safe operation and the refurbishment project, OPG has a well-structured approach to identifying, prioritizing and updating analyses that will be upgraded beyond 2017. The implementation plan was revised and submitted to CNSC in 2017 (e-Doc 5408759) to describe the phase of implementation beyond 2017. CNSC staff is currently reviewing the revised implementation plan.

Recognizing that full implementation of REGDOC-2.4.1 may not be practicable or provide substantial safety benefit beyond the current safety case; a method of evaluating the significance of gaps (applying a graded approach) against REGDOC-2.4.1 and their importance to safety shall be established and applied on an as-needed basis to determine if corrective actions are required.

Criteria for implementation of REGDOC-2.4.1 include the following elements:

- Assessment of the current safety analysis practices against REGDOC-2.4.1 to identify gaps;
- Prioritization of the identified gaps using formal methods;
- Justification of non-conformances (e.g., full compliance with REGDOC-2.4.1 is not practicable or does not provide a demonstrable safety benefit); and
- Development and execution of corrective action plans to address the important gaps.

OPG, along with industry partners, has developed a set of derived acceptance criteria (DAC) for slow events, as documented in COG-13-9035-R00, *Derived Acceptance Criteria for Deterministic Safety Analysis*. These DAC were reviewed and accepted by CNSC staff (e-Doc 4981431) and shall be used by OPG when conducting deterministic safety analysis.

Additional Requirements

CSA standard N293, *Fire protection for nuclear power plants*, contains specific requirements for deterministic analysis related to fire protection. CNSC staff review the fire safety assessment primarily to verify that the licensee employs appropriate assumptions, uses validated models, applies adequate scope, and demonstrates results that are within the design acceptance criteria. See LC 10.2 for version control of CSA N293.

**Probabilistic Safety Assessment**

The licensee shall complete the transition to compliance with REGDOC-2.4.2 over this licence period. The licensee shall provide the subsequent updated PSA within five years of 2015 (2020). This update shall be in full compliance with REGDOC-2.4.2. Full details of this implementation plan can be found in OPG letters dated October 31, 2014 (e-Doc 4572122) and December 10, 2014 (e-Doc 4596974), which have been included in Appendix G of this LCH.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington NGS Safety Report: Part 2 – System Descriptions | NK38-SR-03500-10001 | No |
| DN 1-4 Safety Report: Part 3-Accident Analysis | NK38-SR-03500-10002 | No |
| Darlington Analysis of Record | NK38-REP-00531.7-10001 | No |
| Beyond Design Basis Accident Management | N-STD-MP-0019 | No |
| Reactor Safety Program | N-PROG-MP-0014 | No |
| Safety Analysis Basis and Safety Report | N-PROC-MP-0086 | No |
| Risk and Reliability Program | N-PROG-RA-0016 | No |
| Preparation, Maintenance and Application of Probabilistic Safety Assessment | N-STD-RA-0034 | No |
| Software | N-PROG-MP-0006 | No |
| RWPB Safety Analysis Summary Report | NK38-REP-09701-10344 | Yes |
| Darlington Retube Waste Processing Building - Safety Assessment | NK38-REP-09701-10326 | Yes |
| RWPB Worker Dose During Normal Operation and Under Accident Conditions | NK38-CORR-09701-0597849 | Yes |

**Recommendations and Guidance**

Detailed methodologies and derived acceptance criteria for the conduct of deterministic safety analysis are described in the following COG documents:

- COG-09-9030-R02, Principles & Guidelines For Deterministic Safety Analysis;
- COG-11-9023-R00, Guidelines for Application of the Limit of Operating Envelope Methodology to Deterministic Safety Analysis;
- COG-06-9012-R01, Guidelines for Application of the Best Estimate Analysis and Uncertainty (BEAU) Methodology to Licensing Analysis;
- COG-08-2078-R00, Principles and Guidelines for NOP/ROP Trip Setpoint Analysis for CANDU Reactors.

Updates to deterministic safety analysis should contain a revision summary sheet highlighting the key differences between the existing analyses and updated analysis. The revision summary should include:

- Summary of changes (key differences) such as:
  - In acceptance criteria;
  - In event characterization;
  - In safety analysis assumptions;
  - In methodology, or in elements of a methodology;
  - In plant models;
  - In use of computer codes and embedded models;
  - In trip coverage.
- Reasons for updating the analysis and for updating models, assumptions, initial conditions or boundary conditions;
- Significance of changes, and their justification;
- Significant changes in results that may affect the conclusions of the analysis for the design; operational or emergency safety requirements for a particular situation or event; and
- Impact on operating and safety margins.

The licensee should maintain a Safety Report Basis consisting of a listing of Analysis of Record Items and auxiliary documents. The licensee should continue to provide CNSC staff with regular updates of the list indicating the submissions to be included in the next Safety Report update (Part 3).

When the deterministic safety analysis methodology is modified as a result of improved knowledge, or to address emerging issues, the licensee should assess the impact of such a modification on the operating limits, as well as procedural and administrative rules.

The licensee should not credit results obtained with a modified safety analysis methodology to relax operating conditions and/or change safety margins until the modification of the methodology has been reviewed by CNSC staff. If CNSC staff indicate that the modified methodology is appropriate, the licensee must still fulfill any other requirements or criteria associated with the changes to the operating conditions or safety margins, as documented under other LCs such as those in Section 3. General criteria that CNSC will consider when reviewing such methodologies are provided in Appendix A.4.

In addition to industry standards, CNSC staff will refer to the applicable industry verification and validation process practices related to computer codes and software used to support the safe plant operation.

# 5 SCA – PHYSICAL DESIGN

The safety and control area "Physical Design" relates to activities that impact on the ability of systems, components and structures to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

Performance Objective(s)

There is confirmation that systems, structures and components that are important to nuclear safety and security continue to meet their design basis in all operational states and design basis accidents until the end of their design life.

## 5.1 *Design Program*

**Licence Condition 5.1:**

| |
|---|
| **The licensee shall implement and maintain a design program.** |

**Preamble**

The *Class I Nuclear Facilities Regulations* require that a licence application contain a description of the structures, systems and components (SSC), and relevant documentation of the plant design.

A design program ensures that the plant design is managed using a well-defined systematic approach. Implementing and maintaining a design program confirms that safety-related SSCs and any modifications to them continue to meet their design bases given new information arising over time and taking changes in the external environment into account. It also confirms that SSCs continue to be able to perform their safety functions under all plant states. An important cross-cutting element of a design program is design basis management.

A design program should be composed of elements that consider topics including but not limited to: pressure boundary design, civil structure design, seismic design, mechanical design, fuel design, core nuclear design, core thermal-hydraulic design, safety system design, fire protection design, electrical power system design, as well as instrumentation and control system design.

**Compliance Verification Criteria**

The licensee shall ensure that all safety-related SSCs are designed to perform their required functions under all plant states for which the system must remain available. OPG shall ensure that any modifications made to the facility are in accordance with OPG engineering change control process, and CSA standards:

- CSA standard N291, *Requirements for safety related structures for CANDU nuclear power plants (update no. 2, 2011);*
- CSA standard N290.0, *General requirements for safety systems of nuclear power plants;* and
- CSA standard N290.12, *Human Factors in Design for Nuclear Power Plants Compliance Assessment Summary.*

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | Requirements for safety related structures for CANDU nuclear power plants | N291 | 2008 and update no. 2, 2011 | 2016-01-01 |
| CSA | General requirements for safety systems of nuclear power plants | N290.0 | 2011 | 2016-01-01 |
| CSA | Human Factors in Design for Nuclear Power Plants Compliance Assessment Summary | N290.12 | 2014 | 2018-03-31 |

**Design Basis Management**

The licensee shall ensure that plant status changes (design modifications) are controlled such that the plant is maintained and modified within the limits prescribed by the design and licensing basis. Aspects of design are considered safety and control measures if changes to them could:

- Invalidate the limits documented in the operating policies and principles or safe operating envelope referred to in LC 3.1;
- Introduce hazards different in nature or greater in probability or consequence than those considered by the safety analyses and probabilistic safety assessment; and/or
- Adversely impact other important safety and control measures, such as those related to operations, radiation protection, emergency preparedness, etc.

The licensee shall ensure that changes to those aspects of design remain within the licensing basis and shall notify the CNSC when such changes are planned. When reviewing such changes, CNSC staff will use the criteria in Appendix A.4 and any other applicable criteria. Changes outside the licensing basis would require prior written approval by the Commission.

The licensee shall ensure that plant design and changes to plant design are accurately reflected in the safety analysis (see section 4.1 for licensee documents that contain the facilities descriptions and the final safety analysis reports). Where specific reports (e.g., external third party reviews as required by CSA standard N293, *Fire protection for nuclear power plants*, which is cited in LC 10.2) are required by the standards in the licensing basis, these shall be submitted to the CNSC.

**Design Sub-programs**

See LC 5.2 for compliance verification criteria on pressure boundary design and LC 5.3 for compliance verification criteria on equipment and structure qualification.

Modification of the special safety systems (Shutdown System 1, Shutdown System 2, Emergency Core Cooling System and Containment System) or significant changes to systems connected to the special safety systems (e.g. change that would impact safety margins) would require prior notification and engagement of CNSC. When reviewing such changes, CNSC staff will use the criteria in Appendix A.4 and any other applicable criteria. Changes outside the licensing basis would require prior written approval by the Commission. Prior notification is not required for changes to items that serve the same functional characteristics of the originally designed item and does not result in a change to operating procedures or safety system testing.

All changes or modifications, temporary or permanent, to the special safety systems (SSS) and systems related to safety (SRS) shall be identified in the annual reliability report.

The licensee shall have sub-program elements that address the design and modification of concrete containment structures and safety-related structures.

The licensee shall design, build, modify and otherwise carry out work related to the nuclear facility with potential to impact protection from fire in accordance with CSA N293. Any changes that have the potential to impact fire protection are assessed for compliance with CSA N293 and, if required, an external third party review shall be performed and the results submitted to the CNSC. See LC 10.2 for version control of CSA N293.

The plant electrical power system design shall include the safety classifications of the systems. Its design shall be adequate for all modes of operation under steady-state, voltage and frequency excursion, and transient conditions, as confirmed by electrical analysis. The electrical power systems shall be monitored and tested to demonstrate they comply with the design requirements and to verify the operability for AC systems and DC systems.

The licensee shall ensure that the plant overall instrumentation and control (I&C) system and electrical power systems is designed to satisfy the following:

- The safety classification of the I&C system is in compliance with plant level system classification and is justified by analysis;
- System meets separation requirements between the groups and channels;
- Safety features for enhancing system reliability and integrity are identified and implemented in the design, for example, fail safe design, redundancy, independence and testing capability
- System is not vulnerable to common cause failures; and
- I&C and electrical power systems of safety systems meet the requirements of single failure criteria.

The licensee shall demonstrate survivability of the I&C systems and component that are critical to the management of BDBAs, and the availability of power supply to necessary equipment and associated I&C for BDBAs.

Prior to making use of a new fuel bundle/fuel bundle string or fuel assembly design in the reactor, the licensee shall perform design verification activities, analyses and testing to demonstrate that design requirements are met. The length and complexities of those activities depend on the novelty of the design. When considering possible design changes to fuel bundles and fuel assemblies, the licensee shall provide prior notification and engage CNSC staff early enough to confirm that the changes are within the licensing basis. When reviewing such changes, CNSC staff will use the criteria in Appendix A.4 and any other applicable criteria. Changes outside the fuel design basis would require prior written approval by the Commission.

The licensee shall update and maintain the reactor core nuclear design information found in the safety report and supporting design manuals. Core surveillance activities shall be implemented to ensure compliance with reactor core nuclear design and operation within the design envelope. Significant changes to core nuclear design would require prior notification and engagement of CNSC. When reviewing such changes, CNSC staff will use the criteria in Appendix A.4 and any other applicable criteria. Changes outside the reactor core nuclear design basis would require prior written approval by the Commission.

The design of the existing safety-related structures and components and any modification shall include consideration for human factors. For proposed modifications, modern requirements that are consistent with the current licensing basis of the plant shall be applied to the extent practicable.

The licensee shall ensure configuration management is aligned with the design and safety analysis and incorporated into purchasing, construction, commissioning, operating and maintenance documentation. Conformance is to be maintained between design requirements, physical configuration and facility configuration information. The licensee shall establish a design authority function with the authority to review, verify, approve (or reject), document the design changes and maintain design configuration control.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Conduct of Engineering | N-STD-MP-0028 | No |
| Engineering Change Control | N-PROG-MP-0001 | No |
| Configuration Management | N-STD-MP-0027 | No |
| Design Management | N-PROG-MP-0009 | No |
| Fuel | N-PROG-MA-0016 | No |
| Procurement from Licensed Canadian Nuclear Utilities | N-INS-08173-10050 | No |
| Engineering Change Control Process | N-PROC-MP-0090 | Yes |

As per the agreement reached in CNSC letter dated June 22, 2012 (e-Doc 3947068) a number of design-related codes and standards, associated effective dates and conditions were established. The purpose of the agreement is to ensure consistent and stable design requirements are applied throughout the Darlington Refurbishment Project. For refurbishment design, the agreement took effect upon issuance of the letter; for

other design activities the agreement took effect on October 30, 2013. The agreement will remain valid until the end of the Darlington Refurbishment Project, which is expected to be complete in 2025.

OPG shall provide to the CNSC the code-over-code reviews conducted for any subsequent editions, addendums and/or updates of the codes and standards that were agreed upon, with OPG's assessment of the changes and their significance upon completion of the review and assessment of significance (e-Doc 3947068 and 4058619). OPG shall submit such assessments on an annual basis.

**Recommendations and Guidance**

With regard to modifications, the design basis for the plant should be documented and maintained to reflect design changes to ensure adequate configuration management. The design basis should be maintained to reflect new information, operating experience, safety analyses, and resolution of safety issues or correction of deficiencies. The impacts of the design changes should be fully assessed, addressed and accurately reflected in the safety analyses prior to implementation.

The design program should minimize the potential for human error and promote safe and reliable system performance through the consideration of human factors in the design of facilities, systems, and equipment. Recommendations and guidance for considering human factors in design programs are provided in CNSC regulatory document REGDOC-2.5.1, *General Design Considerations: Human Factors*.

Recommendations and guidance are found in the following documents:

- CSA standards N287 Series (287.1 to 287.6), which covers concrete containment structures;
- CSA standards N289 Series (289.1 to 289.5), which covers seismic qualification;
- CSA standards N290 series (290.1 to 290.6), which covers shutdown systems, emergency core cooling, containment systems, reactor control, electrical power and instrument air systems, and monitoring and display functions;
- CSA standard N290.14, Qualification of pre-developed software;
- REGDOC-2.5.2, Design of Reactor Facilities: Nuclear Power Plants; and
- UFC 3-340-02, which covers structures to resist accidental explosions.

The licensee's design program should provide a table or roadmap that identifies relevant design basis documents, design sub-programs and processes that are maintained by the licensee.

## 5.2 *Pressure Boundary Program*

**Licence Condition 5.2:**

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

**Preamble**

This licence condition provides regulatory oversight with regards to the licensee's implementation of a pressure boundary program and holds the licensee responsible for all aspects of pressure boundary registration and inspections.

A pressure boundary program is comprised of the many programs, processes and procedures and associated controls that are required to ensure compliance with CSA standard N285.0, *General requirements for pressure-retaining systems and components in CANDU nuclear power plants*, which defines the technical requirements for the design, procurement, fabrication, installation, modification, repair, replacement, testing, examination and inspection of pressure-retaining and containment systems, including their components and supports.

This LC also ensures that an Authorized Inspection Agency (AIA) will be subcontracted directly by the licensee. An AIA is an organization recognized by the CNSC as authorized to register designs and procedures, perform inspections, and other functions and activities as defined by CSA N285.0 and its applicable referenced publications (e.g. CSA standard B51, *Boiler, pressure vessel and piping*, National Board Inspection Code). The AIA is accredited by the American Society of Mechanical Engineers (ASME) as stipulated by NCA-5121 of the ASME *Boiler and Pressure Vessel Code* (BPVC).

A pressure boundary is a boundary of any pressure retaining vessel, system or component of a nuclear or non-nuclear system, where the vessel, system or component is registered or eligible for registration.

**Compliance Verification Criteria**

The licensee shall implement and maintain a pressure boundary program. This program shall be in accordance with CSA standard N285.0, *General requirements for pressure retaining systems and components in CANDU nuclear power plants*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | General requirements for pressure-retaining systems and components in CANDU nuclear power plants | N285.0 | 2008 and update no. 2* | 2016-01-01 |

**Note: (a) Including update no. 1, (b) Annex M and Annex K are accepted to be used as "Normative" Annexes.*

Transitional Provisions to CSA N285.0-08 and update no. 2 with Annex M and Annex K:

Pressure boundary activities shall be compliant with CSA N285.0-08 and update no.2, CSA B51-09 and update no. 1, ASME BPVC 2010 ED with 2011 ADD, ASME B31.1-2010, *Power Piping*, ASME B31.3-2010, *Process Piping Code*, and ASME B31.5-2010, *Refrigeration Piping and Heat Transfer Component Code*, except as provided below:

a) Work packages compliant with CSA N285.0-08 and update no.1, being produced or underway prior to October 30, 2013 will remain valid for implementation until June 30, 2019.
b) Design modifications classified (approved by CNSC or using the OPG Classification procedure) after January 1, 2011 and before October 30, 2013 will be designed and installed to the CSA N285.0 and ASME edition or version specified in the System Classification List, when installed no later than June 30, 2019.
c) Purchase orders compliant with CSA N285.0-08 and update no. 1 issued prior to October 30, 2013 will remain valid for installation.
d) The Code Effective Dates do not apply to "non-design-related" requirements under the codes and standards listed above. CNSC may require OPG's programs or processes to be updated for "non-design-related" requirements to meet the new version of the standards once it is published.
e) OPG shall provide to the CNSC the code-over-code reviews conducted for any subsequent editions, addendums and/or updates of the codes and standards listed above, with OPG's assessment of the changes and their significance upon completion of the review and assessment of significance. OPG shall submit such assessments on an annual basis.

Engineering planning activities for the Darlington Refurbishment Project follow CSA N285.0-08 with update no.2, CSA B51-09 and update no. 1, ASME BPVC 2010 ED with 2011 ADD, ASME B31.1-2010, ASME B31.3-2010, and ASME B31.5-2010.

The licensee shall maintain a Pressure Boundary Program Document roadmap in compliance with Annex N of CSA N285.0-12 and update no. 1.

The licensee shall operate vessels, boilers, systems, piping, fittings, parts, components, and supports safely and keep them in a safe condition. OPG shall:

a) Follow work plans and procedures, accepted by the AIA, to test, maintain, or alter over-pressure protection devices;
b) Comply with operating limits specified in certificates, orders, designs, overpressure protection reports, and applicable codes and standards; and
c) Have any certified boiler or vessel that is in operation or use inspected and certified by an authorized inspector according to an accepted schedule.

Personnel conducting non-destructive examinations shall be certified in accordance with the edition of CAN/CGSB 48.9712/ISO 9712 currently adopted for use by the National Certification Body (NCB) of Natural Resources Canada for the appropriate examination method. If the NCB does not offer certification for a specific inspection method, the relevant alternate requirements of Clause 11.3 of CSA N285.0 shall apply to ensure that personnel are appropriately trained and qualified.

The licensee shall use the accepted variance to CSA N285.0-08 and Update No. 2, clause 3 and clause 14.2.7, to perform external weld overlay repairs based on the OPG document N-INS-01913.11-10024 "External Weld Buildup to Repair Pressure Retaining Item" (Enclosure 1 of N-CORR-00531-19208, e-Doc 5575333), under the conditions described in CNSC acceptance letter e-Doc 5635890.

**Classification, Registration and Reconciliation Procedures**

Licensee procedures describing the classification, registration and reconciliation processes and the associated controls shall form part of the pressure boundary program. The licensee shall provide prior notification of any changes to the procedures describing the classification, registration and reconciliation processes.

**Overpressure Protection Reports**

The licensee shall provide written notification to CNSC staff, of new or revised overpressure protection reports, after the final registration of the system. General criteria for CNSC's review of such notices are provided in Appendix A.4.

**Quality Assurance Program**

The licensee's pressure boundary quality assurance program shall comply with clause 10 of CSA N285.0 with the exception of sub-clause 10.2.6. Repair and replacement activities shall comply with subclause 10.3 of CSA N285.0.

**Classification and Registration of Fire Protection Systems**

Fire protection systems and associated fittings and components are to be classified at least as Code Class 6, designed to ASME B31.1 and registered, unless the exemption criteria noted below are met.

The following fittings and components may be exempt from requiring a Canadian Registration Number (CRN) provided they meet the following exemption criteria:

a) Fittings and components that are cUL or ULC and suitable for the expected environmental conditions and maximum pressure; or
b) pressurized cylinders and tubes, such as extinguishers, inert gas and foam tanks, that bear Transport Canada approvals and suitable for the expected environmental conditions and maximum pressures; or
c) buried fire protection piping that is in compliance with NFPA 24, *Standard for the Installation of Private Fire Service Mains and Their Appurtenances*.

Buried fire protection piping designed to the ASME piping code may be exempt from the ASME pressure testing requirements if the pressure testing is performed to NFPA 24.

The requirements of CSA N285.0 apply for components higher than Code Class 6.

**Formal Agreement with an Authorized Inspection Agency**

The licensee shall always have in place a formal agreement with an AIA to provide services for the pressure boundaries of the nuclear facility as defined by CSA N285.0 and its applicable referenced publications. The AIA must be accredited by the ASME as stipulated by NCA-5121 of the ASME *Boiler and Pressure Vessel Code*.

Design registration services for pressure boundaries shall be provided by an AIA legally entitled under the Provincial Boilers and Pressure Vessels acts and regulations to register designs. Registration of piping systems shall be done by the Technical Standards and Safety Authority (TSSA), who is legally entitled to register designs in Ontario.

A copy of the signed Agreement shall be provided to the CNSC. During the licence period, the licensee shall notify the CNSC in writing of any change to the terms and conditions of the Agreement, including termination of the Agreement.

The licensee shall arrange for the AIA inspectors to have access to all areas of the facility and records, and to the facilities and records of the licensee's pressure boundary contractors and material organizations, as necessary for the purposes of performing inspections and other activities required by the standards. Inspectors of the AIA shall be provided with information, reasonably in advance with notice and time necessary to plan and perform inspections and other activities required by the standards.

For a variance or deviation from the requirements of CSA N285.0, the licensee must first submit the proposed resolution to the AIA for evaluation, and then to the CNSC for consent. Per the agreement with the AIA, the evaluated resolution shall not be implemented without the prior written consent of CNSC staff. General criteria for obtaining prior written consent/approval for a proposed resolution from the CNSC can be found in Appendix A.4.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Pressure Boundary Program | N-PROG-MP-0004 | Yes |
| System and Item Classification | N-PROC-MP-0040 | Yes |
| Design Registration | N-PROC-MP-0082 | Yes |
| Pressure Boundary Program Manual | N-MAN-01913.11-10000 | No |
| Index to OPG Pressure Boundary Program Elements | N-LIST-00531-10003 | No |
| Authorized Inspection Agency for Pressure Boundary Inspection and Registration Services | N-CORR-00531-19076 | Yes* |

** Termination of the agreement is considered a change that requires written notification to the CNSC.*

**Recommendation and Guidance**

Recommendations and guidance are found in the following CSA standards and ASME codes:

- CSA standards N285.6 Series, which covers material standards for CANDU reactor components;
- CSA standards N289 Series, which covers seismic qualification;
- ASME *Boiler and Pressure Vessel Code*;
- ASME B31.1, *Power Piping*;
- ASME B31.3, *Process Piping Code*;
- ASME B31.5, *Refrigeration Piping and Heat Transfer Component Code*; and
- CSA standard B51, *Boiler, pressure vessel and piping*.

Note: Where these standards/codes or portions thereof are required for compliance with a governing standard referenced in the LCH under LC 5.2, compliance to the referenced standards/codes or portions thereof is required for compliance with the governing standard and the LC referencing the overlying standard.

The AIA, and its authorized inspectors, should be familiar with and capable of applying the CSA N285.0 provisions to perform their activities as defined by the standard.

Leak mitigation must be undertaken using a managed process, including engineering review, and additional controls to ensure it is not applied inappropriately. Furthermore, leak mitigation should be managed in accordance with the approved white paper, N-REF-01913.11-00001, 2018, *Temporary Leak Maintenance by Leak Mitigation Process* (Enclosure to N-CORR-00531-19502, e-Doc 5823652).

## 5.3 *Equipment and Structure Qualification Program*

**Licence Condition 5.3:**

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

**Preamble**

Environmental qualification (EQ) ensures that all required equipment in a nuclear facility are qualified to perform their safety functions if exposed to harsh environmental conditions resulting from credited Design Basis Accidents (DBA) and that this capability is preserved for the life of the plant.

Condition monitoring assesses variables that indicate the physical state of the equipment, and assesses its ability to perform its intended function following the period of observation. Environmental monitoring measures environmental stressors, such as temperature, radiation and operational cycling during normal operating conditions.

Seismic qualification (SQ) ensures that all seismically credited safety-related SSCs in a Nuclear Power Plant are designed, installed and maintained to perform their safety function during and/or after (as needed and pre-defined) a design basis earthquake or site design earthquake and also ensures an adequate margin against review level earthquakes.

**Compliance Verification Criteria**

The licensee shall implement and maintain environmental and seismic qualification programs. The programs shall be in accordance with CSA standards:

- CSA standard N290.13, *Environmental qualification of equipment for CANDU nuclear power plants*; and
- CSA standard N289.1, *General requirements for seismic, design and qualification of CANDU nuclear power plants*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | Environmental qualification of equipment for CANDU nuclear power plants | N290.13 | 2005 and update no. 1 (2009) | 2016-01-01 |
| CSA | General requirements for seismic, design and qualification of CANDU nuclear power plants | N289.1 | 2008 | 2016-01-01 |

**Environmental Qualification**

In addition to the criteria set out in CSA N290.13, the EQ program shall include a monitoring program

consisting of condition monitoring and environmental monitoring, to measure degradation and failures of qualified equipment, including cables.

**Seismic Qualification**

Seismically credited safety-related SSCs in a nuclear facility shall be designed, installed and maintained to perform their safety function against earthquakes.

Seismic qualification or modification of a seismically qualified SSC would require prior notification and engagement of CNSC. When reviewing such changes, CNSC staff will use the criteria in Appendix A.4 and any other applicable criteria. Changes outside the licensing basis would require prior written approval by the Commission.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Environmental Qualification | N-PROG-RA-0006 | No |

As per the agreement reached in CNSC letter dated June 22, 2012 (e-Doc 3947068) a number of design-related codes and standards, associated effective dates and conditions were established, including application of CSA N290.13. The purpose of the agreement is to ensure consistent and stable design requirements are applied throughout the Darlington Refurbishment Project. For refurbishment design, the agreement took effect upon issuance of the letter; for other design activities the agreement took effect on October 30, 2013. The agreement will remain valid until the end of the Darlington Refurbishment Project, which is expected to be complete in 2025.

OPG shall provide to the CNSC the code-over-code reviews conducted for any subsequent editions, addendums and/or updates of CSA N290.13-05 and update no.1, with OPG's assessment of the changes and their significance upon completion of the review and assessment of significance (e-Doc 3947068). OPG shall submit such assessments on an annual basis.

**Recommendations and Guidance**

The processes and procedures related to the EQ program should meet the requirements of recognized industrial standards.

In addition to addressing the detailed requirements of CSA N289.1, the licensee SQ sub-program should:

- Identify the methods for establishing SQ, including code effective dates;
- Identify the SSCs for which evaluation of their capacity beyond the Design Basis Earthquake has been done;
- Identify the methods used for Beyond Design Basis Earthquake evaluation;
- Include procedural controls for periodic inspection and maintenance of conditions to ensure SQ of existing SSCs for the life of the plant;
- Identify the seismic monitoring system and its design and maintenance requirements; and
- Include procedural controls for establishing SQ for new and replacement items.

The processes and procedures related to the SQ program should address the following CSA standards:

- CSA standard N289.2, *Ground motion determination for seismic qualification of nuclear power plants*;
- CSA standard N289.3, *Design procedures for seismic qualification of nuclear power plants*;
- CSA standard N289.4, *Testing procedures for seismic qualification of nuclear power plant structures, systems and components*; and
- CSA standard N289.5, *Seismic instrumentation requirements for nuclear power plants and nuclear facilities*.

# 6 SCA – FITNESS FOR SERVICE

The safety and control area "Fitness for Service" covers activities that impact on the physical condition of systems, components and structures to ensure that they remain effective over time. This includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

Performance Objective(s)

Systems, structures and components whose performance may affect safe operations or security remain available, reliable and effective, and are consistent with the design, quality control measures and analysis documents.

## 6.1 *Fitness for Service Programs*

**Licence Condition 6.1:**

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

**Preamble**

The *Class I Nuclear Facilities Regulations* requires that a licence application contain the proposed measures, policies, methods and procedures to maintain the nuclear facility.

The following program elements ensure fitness for service of SSCs:

- Maintenance program defining the policies, processes and procedures that provide direction for maintaining SSCs of the plant;
- Effective control of plant chemistry to ensure critical plant equipment performs safely and reliably;
- Aging management activities to ensure the reliability and available of required safety functions of SSCs;
- Periodic and in-service inspection programs to ensure that pressure-boundary components; containment structures and components, continue to meet their design requirements;
- In-service inspection of balance of plant to ensure safety significant pressure retaining systems, components and safety-related structures are monitored for degradation; and
- Proper reliability program and implementation to ensure that Systems Important to Safety continue to meet their performance requirements.

**Compliance Verification Criteria**

The licensee shall implement and maintain programs to ensure fitness for service of systems, structures and components. These programs shall be in accordance with:

- CNSC regulatory document REGDOC-2.6.2, *Maintenance Programs for Nuclear Power Plants*;
- CNSC regulatory document REGDOC-2.6.1, *Reliability Programs for Nuclear Power Plants*;
- CNSC regulatory document REGDOC-2.6.3, *Aging Management*;
- CSA standard N285.4, *Periodic inspection of CANDU nuclear power plant components*;
- CSA standard N285.5, *Periodic inspection of CANDU nuclear power plant containment components*;
- CSA standard N285.8, Technical requirements for in-service inspection evaluation of zirconium alloy in pressure tubes in CANDU reactors; and
- CSA standard N287.7, *In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plants*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Maintenance Programs for Nuclear Power Plants | REGDOC-2.6.2 | 2017 | 2020-09-15 |
| CNSC | Reliability Programs for Nuclear Power Plants | REGDOC-2.6.1 | 2017 | 2020-09-15 |
| CNSC | Aging Management | REGDOC-2.6.3 | 2014 | 2017-07-15 |
| CSA | Periodic inspection of CANDU nuclear power plant components | N285.4 | 2014<br>(2019†) | 2019-07-01 |
| CSA | Periodic inspection of CANDU nuclear power plant containment components | N285.5 | 2008<br>Update no. 1 (January 2011)<br>2018* | 2016-01-01<br><br>2019-02-19 |
| CSA | Technical requirements for in-service inspection evaluation of zirconium alloy in pressure tubes in CANDU reactors | N285.8 | 2015 | 2020-12-15 |
| CSA | In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plants | N287.7 | 2008 | 2016-01-01 |

** Compliance with the 2018 edition of CSA N285.5 is only for the clauses specified under "CVC related to CSA N285.5" in this LCH.*
*† Compliance with the 2019 edition is only for the clauses specified under "CVC related to CSA N285.4" in this LCH.*

**Maintenance**

An NPP maintenance program consists of policies, processes and procedures that provide direction for maintaining structures, systems or components (SSCs) of the plant.

The intent of a maintenance program is to ensure that the SSCs remain capable of maintaining their function as described in the safety analysis. A maintenance program uses organized activities, both administrative and technical, to keep SSCs in good operating condition, and to ensure that they function as per design.

CNSC regulatory document REGDOC-2.6.2, *Maintenance Programs for Nuclear Power Plants* outlines the requirements for a maintenance program. In 2017, this document replaced RD/GD-210, *Maintenance Programs for Nuclear Power Plants* in the regulatory framework. Given that REGDOC-2.6.2 has no material changes from RD/GD-210, for compliance purposes where RD/GD-210 is referenced in OPG governing documents, it shall be taken to mean REGDOC-2.6.2. OPG will update the references to RD/GD-210 in their governance in accordance with their regular document review cycle.

Implementation of REGDOC-2.6.2 is verified by CNSC staff through the maintenance-related findings from routine inspections, cross-cutting system inspections and monitoring of maintenance related performance indicators.

Maintenance activities include planning and scheduling, SSC monitoring and work execution. Maintenance performance indicators are monitored and compared to best industry practice where practicable.

**Management of Planned Outages:**

The maintenance program shall include provisions for the management of planned outages. The licensee's program related to management of planned outages is documented in N-PROC-MA-0013, *Planned Outage Management*.

The licensee shall make outage-related information (including Level 1 and Level 2 Outage Plans, detailing all major work on safety related structures, systems and components to be carried out during the planned outage) available to CNSC staff.

Planned outages represent a key activity that has a high regulatory significance. Therefore a review is required to ensure proper scoping (of safety-related commitments), planning and execution of the commitments (e.g., for heat sinks, dose control, etc.).

**Reliability of Systems Important to Safety**

CNSC regulatory document REGDOC-2.6.1, *Reliability Programs for Nuclear Power Plants* outlines the requirements for a maintenance program. In 2017, this document replaced RD/GD-98, *Reliability Programs for Nuclear Power Plants* in the regulatory framework. Given that REGDOC-2.6.1 has no material changes from RD/GD-98, for compliance purposes where RD/GD-98 is referenced in OPG governing documents, it shall be taken to mean REGDOC-2.6.1. OPG will update the references to RD/GD-98 in their governance in accordance with their regular document review cycle.

The licensee shall establish a reliability program that includes setting reliability targets, performing reliability assessments, testing and monitoring, and reporting for plant systems whose failure affect the risk of a release of radioactive or hazardous material.

The reliability program assures that the risk-related system functions credited in the PSA and systems important to safety at the plant, can, and will, meet the availability and reliability requirements as stated or assumed in the PSA throughout the lifetime of the facility.

**Chemistry Control**

The chemistry control sub-program shall specify processes, specifications, overall requirements, parameter monitoring, data trending and evaluation to ensure effective control of plant chemistry during operational and lay-up conditions. The licensee shall maintain a set of technical basis documents describing the design basis for chemistry control.

**Aging Management**

OPG is compliant with the 2014 version of REGDOC-2.6.3, *Aging Management*, as of July 15, 2017.

SSC-specific aging management plans (AM plans - also in some cases referred to as life cycle management plans (LCMPs)), shall be implemented in accordance with the overall integrated aging management program framework, and address the attributes of an effective aging management program as listed in REGDOC-2.6.3. The SSC-specific AM plans or LCMPs shall include structured, forward looking inspection and maintenance schedules, requirements to monitor and trend aging effects and any preventative actions necessary to minimize and control aging degradation of the SSCs.

The SSC-specific AM plans or LCMPs which are submitted with, or in support of, the application are licensing basis documents. As such any changes to the SSC-specific AM plans or LCMPs will be reviewed by CNSC staff to confirm that they remain within the licensing basis and provide adequate justification for changes to prior licensee commitments with respect to the inspection scope and other relevant commitments related to the continued operation of the facility. When considering possible changes to activities identified in the AM plans or LCMPs, the licensee shall engage CNSC staff early and provide confirmation that the changes are within the licensing basis prior to implementing the change. Administrative or other such changes to the documents are subject to normal notification requirements as indicated in the WN table for this section.

<u>Fuel Channel Aging Management</u>

The current operating limit for the Darlington NGS pressure tubes is to a maximum of 235,000 Effective Full Power Hours (EFPH), which was approved by the Commission on December 23, 2015. For further details see the Summary Record of Decision (e-Doc 4908897). Operation of any unit beyond 235,000 EFPH is not permitted unless approved by the Commission in accordance with LC G.1.

*Continued use of Fracture Toughness Model(s)*

OPG shall submit an impact assessment for CSA N285.8-15 Clause 7 evaluations whenever a fracture toughness test result challenges the model's lower prediction bound, and where the model is applied in the Clause 7 evaluation(s).

*Validation of the Cohesive Zone-based Fracture Toughness Model (Clause D13.2.3 of CSA N285.8-15)*

OPG shall produce and submit an uncertainty assessment report for the next revision of the Cohesive Zone-based fracture toughness model (CZM-R2) (CNSC letter, e-Doc 6366701, N-CORR-00531-22348).

**Periodic and In-Service Inspection Programs**

OPG shall carry out the periodic inspections programs (PIPs) in accordance with the accepted PIP documents. If a deviation from the accepted PIP program is anticipated during inspection planning activities OPG shall obtain CNSC acceptance of the deviation prior to conducting the affected inspections. However, for any findings, discoveries or deviations from the accepted PIP that are identified when conducting an inspection, OPG shall follow OPG governance to provide justification to CNSC in the inspection report submission, based on OPEX and best industry practices. For permanently required exemptions to the requirements of CSA PIP standards, OPG shall document these exemptions in a revised PIP document and submit to the CNSC for acceptance.

When PIP requirements are addressed exclusively within an AMP or LCMP document, only those elements of the document that directly address the PIP requirements of the governing CSA standard require acceptance from CNSC staff prior to implementation.

Personnel conducting non-destructive examinations shall be certified in accordance with the edition of CAN/CGSB 48.9712/ISO 9712 currently adopted for use by the National Certification Body (NCB) of Natural Resources Canada for the appropriate examination method. If the NCB does not offer certification for a specific inspection method, the relevant alternate requirements of Clause 5 of CSA N285.4 or Clause 6 of CSA N285.5, as applicable, shall apply, to ensure that personnel are appropriately trained and qualified.

Selection Criteria for Pressure Tube Inspection

In reference to inspected pressure tubes, and to resolve probabilistic core assessment flaw removal assumptions, OPG is to continue to provide evidence that a sample of the pressure tubes with the highest cumulative probability of developing through-wall cracking determined from probabilistic core assessments is included in their pressure tube volumetric inspection program (CNSC letter 6415008; N-CORR-00531-22440). To validate probabilistic core assessment predictions, OPG is to include consideration for higher risk tubes from the probabilistic core assessments in the selection criteria for fuel channel inspection campaigns.

CVC Related to CSA N285.4:

OPG shall comply with the 2014 edition of this standard, May 2014, with the exception of Clauses (including the sub-Clauses) 6.1.4.2, 7.6.1, 8.2.2, 8.2.5(b), 8.3.1, 8.3.2, 8.3.3, 9.4 and Table 5 for which OPG shall comply with the 2019 edition of this standard (see CNSC letter e-Doc 6067846) and any applicable exemptions accepted by the CNSC. The Darlington NGS CSA N285.4 PIP is divided into four system/component groups addressing specific clauses of CSA N285.4 including the General Pressure Boundary Components, Fuel Channel Pressure Tubes, Fuel Channel Feeder Pipes, and Steam Generators

Tubes. CNSC staff have accepted the Darlington NGS PIP documents listed in the WN table for this section. Notable elements of the acceptance process for the PIP documents are discussed below.

Fuel Channel (FC) Pressure Tubes (PT) (N285.4 Clause 12)

CNSC staff have accepted OPG's PIP documents for Darlington Fuel Channels (e-Doc 5853238).

*Evaluation of results and dispositions for Darlington NGS pressure tubes*

With respect to CSA N285.4-14 clause 12.2.5.1.3, CNSC staff have reviewed and conditionally accepted OPG's compliance plan N-REP-31100-10061 R005 (N-CORR-00531-22279, e-Doc 6366785) for the use of CSA N285.8-15, *Technical requirements for in-service evaluation of zirconium alloy pressure tubes in CANDU reactors*, as the evaluation method used for the fitness-for-service assessment of Darlington fuel channels. CNSC staff's acceptance of the revised plan includes conditions as detailed in CNSC letter (e-Doc 6441842).

*PT Flaw Assessments (hydrided region overload)*

With respect to CSA N285.8-15 Clause 5.4.3.1 (g), regarding the evaluation of the initiation of delayed hydride cracking of detected flaws during Service Level B transients, due to fracture of hydrided region, OPG has submitted a short term and long term plan (e-Doc 5223024). CNSC staff accepted OPG's request to extend the trial use of the two-tiered approach to August 2022 (e-Doc 6555785, N-CORR-00531-22693).

*PT Material Testing*

With respect to N285.4 clause 12.4.4.2, CNSC staff have accepted (e-Doc 3895468) OPG's procedural updates and technical justifications for pressure tube material testing (e-Doc 3848127, N-CORR-00531-05488). OPG's most recent update (e-Doc 5981143, N-CORR-00531-19754) is currently under review.

*Probabilistic Leak-Before-Break (PLBB) Assessments (CSA N285.8)*

With respect to Clause 7.4.3.2 of CSA N285.8-15, the maximum allowable conditional probability over the evaluation period of pressure tube failure caused by a growing axial crack exceeding the critical crack length during the sequence of events from pressure tube through-wall penetration to reactor shutdown shall be less than or equal to 0.10 ruptures per through-wall crack. This applies to the assessed most limiting pressure tube in the reactor core. This interim acceptance criterion remains in effect as was accepted for use until February 28, 2021 (e-Doc 5421207) and extended (e-Doc 6543544, N-CORR-00531-22678).

*Probabilistic Fracture Protection Assessments (CSA N285.8)*

CNSC staff have accepted OPG's use of an annual probability of rupture of $1x10^{-6}$ per pressure tube per year, as the acceptance criterion for Probabilistic Fracture Protection (PFP) applications, subject to the following conditions (e-Doc 6264964, N-CORR-00531-20176):

1. PFP evaluation shall not apply to pressure tubes in excess of 50 years of operation.

2. For the operational life of the reactor core, from the date of first net power to the date of planned end of operation, a best estimate reliability against pressure tube rupture of greater than 97.5% must be achieved for the core, with no individual tube exhibiting a best estimate reliability less than 99.99%.
3. OPG shall report the sensitivity of the results to key input parameter assumptions and shall develop an approach to quantify uncertainty in the estimated annual probability of rupture prior to the expiration of the interim use period.
4. Companion deterministic fracture protection assessments shall demonstrate deterministic margin for all design basis transients to the end of the evaluation period.

CNSC staff accept the proposed criterion for use on an interim basis until December 31, 2021.

*Fuel Channel Annulus Spacers*

Fuel channels in Darlington NGS units are equipped with tight-fitting Inconel X-750 spacers. OPG have completed the transition of the Long Term Darlington Life Management Plan for Inconel X-750 Spacers (NK38-PLAN-31160-10000) into the Fuel Channel Life Cycle Management Plan (N-PLAN-01060-10002).

CNSC staff have accepted continued operation of Inconel X-750 spacers in current operating fuel channels at Darlington NGS (e-Doc 6270657). The predictions of the FFS assessment shall be continually evaluated by new in-service inspections of fuel channels and material surveillance test results of ex-serviced spacers, per CSA N285.4-14 and OPG's Fuel Channel Life Cycle Management Plan.

*Fuel Channel Feeder Pipes (N285.4 Clause 13)*

CNSC staff have accepted the Darlington Feeder PIP, with an exemption from periodic inspection for outlet feeder dissimilar metal welds. This exemption was based on OPG's preliminary Leak-Before-Break (LBB) assessment and commitment to complete additional work in support of the requested exemption (e-Doc 3689595 and 4137777). OPG's final LBB assessment for the feeder dissimilar welds was submitted to the CNSC for acceptance in 2016 and is currently being reviewed.

With respect to CSA N285.4 clause 8.2.1(d) and clause 13.2.5.1.3, CNSC staff have accepted OPG's request to use COG report COG-JP-4107-V06-R03, *Fitness-for-Service Guidelines (FFSG) for Feeders in CANDU Reactors*, (e-Doc 3922168 and 4001054).

*Steam Generator Tubes (N285.4 Clause 14)*

CNSC staff have accepted OPG's steam generator tubes PIP for Darlington station.

CNSC staff have accepted the "*performance based disposition process*" (e-Doc 3615950) for steam generator inspections and dispositions, which allows the restart of the NGS without a formal CNSC approval of the disposition before restart, subject to an agreed upon set of conditions. Under this process, OPG will analyze and assess the inspection results and disposition the findings using the applicable FFSG. Prior to returning the steam generators to service, OPG is required to confirm, in writing, that the current CNSC accepted disposition for the unit has not been invalidated by the latest inspection findings.

With respect to CSA N285.4 clause 14.2.5.1.3, CNSC staff has accepted OPG's request to use COG report COG-07-4089–R02, *Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes*, with the following conditions (e-Doc 5503070):

- Paragraph IB-2 (d), Requirements for Application of FFSG: Before the CNSC can grant regulatory acceptance of a steam generator disposition using steam generator tube loading based on actual operating transient data rather than on design basis transients, the licensee must justify that the loads used are conservatively bounding for future operation. OPG is expected to provide the necessary supporting information with a request for acceptance of a disposition.
- Table ID-2, Maximum Allowable Probabilities of Not Satisfying Leak-before-Break for a Reactor Unit: If the licensee intends to use probabilistic assessment methods for Leak-Before-Break as described in Section ID-2.3.2.2 then it must be demonstrated that the probabilistic acceptance criteria in Table ID-2 (10-2) appropriately demonstrates that steam generator tube structural integrity margins are maintained when compared to deterministic Leak-Before-Break acceptance criteria

CVC Related to CSA N285.5

OPG shall comply with the 2008 edition of this standard, including update no. 1, January 2011, with the exception of Clauses (including the sub-clauses) 7.1, 7.5, 7.7, 9.2.2, 9.2.5, 9.3.1, 9.3.2, 9.3.3, 9.3.4 and Table 4, for which OPG shall comply with the 2018 edition of this standard (see CNSC letter e-Doc 5785001).

CNSC staff have accepted the Darlington NGS PIP Program, which meets the requirements of CSA N285.5 (e-Doc 4042937). OPG has committed to completing the transition of the periodic inspection programs to comply with the 2018 edition of CSA N285.5 by May 2, 2022 (e-Doc 6030108 and 6030126).

CVC Related to CSA N287.7

CNSC staff have accepted the Darlington NGS CSA N287.7 PIP documents listed in the "Document Version Control" table of this section including the leakage rate test documents for the concrete containment structures and the technical specification for the post-tensioning system inspection (e-Doc 4788314).

OPG shall carry out the inspections and tests of the vacuum building, the dousing system and the pressure relief duct at least once every twelve years, as agreed upon in CNSC correspondence "Vacuum Building Test and Inspection Frequency" (e-Doc 967920).

OPG conducted a Vacuum Structure Positive Pressure Test in 2015 based on CNSC staff acceptance of OPG's request to defer it from the 2009 Vacuum Building Outage (VBO). OPG also performed a test to measure the leakage rate, at full positive design pressure, of the Main Containment Structure in 2015. These tests shall be repeated every twelve years (e-Doc 4429280).

In addition, OPG shall inspect the concrete structures of the Main Containment Structures and their components once every six years in accordance with the CSA N287.7 PIP.

**In-service Inspection of Balance of Plant**

The licensee shall have adequate knowledge of the current state of BOP pressure retaining systems, components and safety-related structures to ensure that they are capable of operating within their design intent and perform required safety functions if called upon.

The licensee shall develop, implement and maintain in-service inspection program(s) and LCMPs for these systems in keeping with industry best practices including:

a) An ISI sub-program for safety-significant BOP pressure retaining systems and components; and

b) An ISI sub-program for BOP safety-related structures, excluding concrete containment structures in accordance with CSA standard N291, *Requirements for safety-related structures for CANDU nuclear power plants*.

N-PROG-MA-0017, *Components and Equipment Surveillance*, includes a comprehensive set of activities to evaluate, inspect, test and report on the health of specific safety-significant BOP component groups which forms part of the pressure-retaining system and components.

N-PROG-MP-0008, *Integrated Aging Management*, defines and provides the requirements for the establishment of the aging management scope related to safety-related BOP civil structures.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Maintenance | | |
| Conduct of Maintenance | N-PROG-MA-0004 | No |
| Component and Equipment Surveillance | N-PROG-MA-0017 | No |
| Production Work Management | N-PROG-MA-0019 | No |
| Integrated Aging Management | N-PROG-MP-0008 | No |
| Planned Outage Management | N-PROC-MA-0013 | No |
| Forced Outage Management | N-PROC-MA-0049 | No |
| Reliability | | |
| Equipment Reliability | N-PROG-MA-0026 | No |
| Risk and Reliability Program | N-PROG-RA-0016 | No |
| Reliability and Monitoring of Systems Important to Safety | N-STD-RA-0033 | No |
| List of Safety Related Systems and Functions | NK38-LIST-06937-10001 | Yes |

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Aging Management | | |
| Major Components | N-PROG-MA-0025 | No |
| Feeders Life Cycle Management Plan | N-PLAN-01060-10001 | Yes* |
| Feeders | | |
| Darlington Nuclear Unit 1 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | NK38-PIP-33160-10001 | Yes |
| Darlington Nuclear Unit 2 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | NK38-PIP-33160-10002 | Yes |
| Darlington Nuclear Unit 3 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | NK38-PIP-33160-10003 | Yes |
| Darlington Nuclear Unit 4 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | NK38-PIP-33160-10004 | Yes |
| Fitness-for-Service Guidelines (FFSG) for Feeders in CANDU Reactors | COG-JP-4107-V06-R03 | Yes |
| Pressure Boundary | | |
| Steam Generators Life Cycle Management Plan | N-PLAN-33110-10009 | Yes* |
| Steam Generators | | |
| Darlington Units 1-4 Steam Generator Life Cycle Management Plan | NK38-PLAN-33110-00001 | Yes* |
| Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes | COG-07-4089–R02 | Yes** |
| Fuel Channels | | |
| Fuel Channels Life Cycle Management Plan | N-PLAN-01060-10002 | Yes* |
| Darlington Nuclear 1-4, Unit 1 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | NK38-PIP-31100-10001 | Yes |
| Darlington Nuclear 1-4, Unit 2 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | NK38-PIP-31100-10002 | Yes |
| Darlington Nuclear 1-4, Unit 3 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | NK38-PIP-31100-10003 | Yes |
| Darlington Nuclear 1-4, Unit 4 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | NK38-PIP-31100-10004 | Yes |
| Reactor Components and Structures Life Cycle Management Plan | N-PLAN-01060-10003 | Yes |
| Long Term Darlington Life Management Plan for Inconel X-750 Spacers | NK38-PLAN-31160-10000 | Yes |
| Periodic Inspection Plans | | |
| Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 1 | NK38-PIP-03641.2-10001 | Yes |

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 2 | NK38-PIP-03641.2-10002 | Yes |
| Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 3 | NK38-PIP-03641.2-10003 | Yes |
| Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 4 | NK38-PIP-03641.2-10004 | Yes |
| Darlington Nuclear Generating Station – Periodic Inspection Program for Unit 0 and Units 1 To 4 Containment Components | NK38-PIP-03642.2-10001 | Yes |
| Darlington Nuclear – Unit 0 Containment Periodic Inspection Program | NK38-PIP-03643.2-10002 | Yes |
| Aging Management Plan for Containment Structures | N-PLAN-01060-10004 | Yes |
| Darlington Nuclear – Reactor Building Periodic Inspection Program | NK38-PIP-03643.2-10001 | Yes |
| Darlington Nuclear – Vacuum Building Periodic Inspection Program | NK38-PIP-03643.2-10003 | Yes |
| Inspection of Post Tensioning Tendons on DNGS Vacuum Building | NK38-TS-03643-10001 | Yes |
| Administrative Requirements for In-Service Examination and Testing for Concrete Containment Structures | N-PROC-MA-0066 | Yes |
| Aging Management Plan for Darlington NGS Non-Containment Building Structures | NK38-PLAN-01060-10010 | Yes |
| Balance of Plant | | |
| Darlington NGS Main Containment Structure In-Service Leakage Rate Test Requirements in Accordance with CSA N287.7-08 | NK38-REP-34200-10066 | Yes |
| Darlington NGS Vacuum Structure In-Service Leakage Rate Test Requirements in Accordance with CSA N287.7-08 | NK38-REP-26100-10005 | Yes |

**Prior notification is only required when changes to the document result in changes to the PIP that has received regulatory acceptance.*
***With the exceptions listed under the CVC for steam generator tubes.*

## Recommendations and Guidance

### Maintenance

The range of maintenance activities includes monitoring, inspecting, testing, assessing, calibrating, servicing, overhauling, repairing, and parts replacing. The type of maintenance activity and frequency applied to each SSC should be commensurate with importance to safety, design function and required performance.

**Outage Management**

The outage program should have designated criteria that the licensee will follow to confirm that planned and discovery work has been satisfactorily completed during the planned outage, and that all safety-significant SSCs are available to ensure the continued safe operation of the facility.

CNSC staff located at the site offices should be invited to the restart meetings in order to verify that all appropriate reviews for restart of the reactor have occurred.

**Management of Planned Outages**

Outage completion assurance statement should include the status of planned work that was identified in the notification of regulatory undertakings but not completed.

**Inspection Programs for Balance of Plant**

The licensee should document the current status of all of the safety-significant pressure-retaining components and develop aging management or LCMPs following the regulatory requirements of CNSC regulatory document REGDOC-2.6.3, *Aging Management*. The licensee may elect to use alternative approaches, provided the elements identified in REGDOC-2.6.3 are addressed in an equivalent manner, and are demonstrated to be effective in managing aging. The plans should apply a systematic and integrated approach to establish, implement and improve programs to manage aging and obsolescence of SSCs. SSC-specific LCMPs and AMPs should be implemented in accordance with the licensee's overall integrated AMP framework.

Non-destructive examination (NDE) procedures used in the Components and Equipment Surveillance sub-program should be developed and implemented using a level of rigour consistent with the safety significance of systems and components and the nature of the degradation. For NDE procedures necessary to carry out inspections in the BOP programs, guidance may be obtained from NDE requirements for the PIP program addressed in CSA standard N285.4, *Periodic inspection of CANDU nuclear power plant components*.

**Aging Management**

Whenever a revision to the AMP, SSC-specific AMP or LCMP is submitted to CNSC for review, the licensee should identify whether the revision(s), affects the previously planned inspection and maintenance activities, with supporting technical basis for the change.

The licensee should maintain a roadmap outlining the programs and procedures that ensure a well-documented overall integrated aging management framework exists.

# 7 SCA – RADIATION PROTECTION

The safety and control area "Radiation Protection" covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. This program must ensure that contamination and radiation doses received are monitored and controlled, and maintained as low as reasonably achievable (ALARA).

Performance Objective(s)

The health and safety of persons inside the facility are protected through the implementation of a radiation protection program that ensures that occupational exposures are below regulatory dose limits and are optimized and maintained ALARA.

## 7.1 *Radiation Protection Program and Action Levels*

**Licence Condition 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.**

**Preamble**

The *Radiation Protection Regulations* require that the licensee implement a radiation protection program and also ascertain and record doses for each person who perform any duties in connection with any activity that is authorized by the *Nuclear Safety and Control Act* or is present at a place where that activity is carried on. This program must ensure that doses to workers do not exceed prescribed dose limits and are kept As Low As Reasonably Achievable (the ALARA principle), social and economic factors being taken into account.

Note that the regulatory dose limits are explicitly provided in the *Radiation Protection Regulations*.

Action Levels (ALs) are designed to alert licensees before regulatory dose limits are reached. By definition, if an action level referred to in a licence is reached, a loss of control of some part of the associated radiation protection program may have occurred, and specific action is required, as defined in the *Radiation Protection Regulations* and the licence. ALs are not intended to be static and are to reflect operating conditions in the station.

Administrative Dose Limits (ADLs) are the licensee's internal dose limits designed to ensure individuals do not exceed regulatory dose limits. Certain ADLs that are exceeded without prior approval from the designated licensee authority are considered AL exceedances, as defined in the *Radiation Protection Regulations*.

**Compliance Verification Criteria**

**Radiation Protection Program**

Provisions for respiratory protection are captured in OPG-PROC- 0132, *Respiratory Protection*, identified as a document requiring written notification under LC 8.1.

Additionally, the radiation protection program shall ensure that occupational exposures are ascertained and recorded in accordance with the *Radiation Protection Regulations*, through the establishment of dosimetry requirements.

**Radiation Protection Action Levels**

The ALs and ADLs are considered part of the licensing basis. Changes to these limits are subject to LC G.1. The current ALs and ADLs for this facility are extracted from N-REP-03420-10001, *Occupational Radiation Protection Action Levels for Power Reactor Operating Licenses*, and N-PROC-RA-0019, *Dose Limits and Exposure Control*, summarized in the table below. In the event of a discrepancy between these tables below and the licensee documentation upon which they are based, the licensee documentation shall be considered the authoritative source (assuming that the licensee has followed its own change control process).

Action Levels: Worker Dose

| Field of application | Value | Action Level |
|---|---|---|
| DOSE TO WORKERS: Individual worker external radiation dose received on a job greater than planned | 2mSv (200 mrem) | A person receives an external whole body dose that equals or exceeds 2 mSv (200 mrem) above the Electronic Personal Dosimeter (EPD) dose alarm set point. |
| DOSE TO WORKERS: Individual worker internal exposures greater than planned | 2400 kBq/L (65 µCi/L) [2 mSv or (200 mrem)] | A person receives a single intake of tritium oxide (tritiated water) in which the unplanned component of the initial concentration immediately after intake is estimated to equal or exceed 2400 kBq/L (65 µCi/L) (representing an unplanned exposure of 2 mSv (200 mrem)). |
| DOSE TO WORKERS: Individual worker internal exposure to radionuclides (other than tritium as tritium oxide) greater than planned | 0.1 ALI for a radionuclide other than tritium (tritium oxide). [2 mSv or (200 mrem)] | A person receives an intake of a radionuclide other than tritium (in the form of tritium oxide) attributable to a single event that equals or exceeds an unplanned exposure of 2 mSv [200 mrem] |
| DOSE TO WORKERS: Cumulative annual Individual radiation dose exceeds annual administrative dose limits without approval. | The Administrative Dose Limits (ADLs) are shown in the Table below. | An individual's total whole body radiation dose accumulated over a calendar year exceeds his annual Administrative Dose Limit (ADL) without approval. Doses that are to be compared with the ADLs include doses received at all places of employment during the year. |

Administrative Dose Limits:

| **Whole Body Dose (Effective) limits (**one calendar year) | | | |
|---|---|---|---|
| **Category of Worker** | **Nuclear Part D&G Employees** | **Other Ontario Power Generation Employees** | **Contract and Building Trades Union Employees** |
| Nuclear Energy Workers (NEW) | 20 mSv (2 rem) | 20 mSv (2 rem) | 40 mSv (4 rem) |
| NEW with a lifetime whole body dose greater than 500 mSv (50 rem) | 10 mSv (1 rem) | 10 mSv (1 rem) | Not applicable |
| Non-New | 0.5 mSv (0.050 rem) | 0.5 mSv (0.05 rem) | 0.5 mSv (0.050 rem) |
| **Whole Body Dose (Effective) limits** (rolling 5 calendar years) | | | |
| NEW | 50 mSv (5 rem) | 90 mSv (9 rem) | 90 mSv (9 rem) |

Action Levels: Surface Contamination Levels

| **Field of application** | **Action Level** | **Observations** |
|---|---|---|
| CONTAMINATION CONTROL: Alpha or Beta-gamma surface contamination levels beyond limits in Zone 1. | 37 kBq/$m^2$ (1 µCi/$m^2$) (beta-gamma); 0.5 kBq/$m^2$ (0.01 µCi/$m^2$) (alpha); 7.4 kBq (200 nCi) Cs-137-equivalent (for a DRP) | Total (fixed and loose) surface contamination levels greater than 37 kBq/$m^2$ (1 µCi/$m^2$) (beta-gamma) or 0.5 kBq/$m^2$ (0.01 µCi/$m^2$) (alpha) are found in Zone 1 or a Discrete Radioactive Particle (DRP) of 7400 Bq Cs137 equivalent activity found in Zone 1. |

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Radiation Protection | N-PROG-RA-0013 | Yes |
| Controlling Exposure As Low As Reasonably Achievable | N-STD-RA-0018 | No |
| Occupational Radiation Protection Action Levels for Power Reactor Operating Licenses | N-REP-03420-10001 | Yes |
| Dose Limits and Exposure Control | N-PROC-RA-0019 | Yes |
| Radioactive Work Planning, Execution and Close Out | N-PROC-RA-0027 | No |
| Radiation Dosimetry Program – General Requirements | N-MAN-03416-10000 | No |

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Radiation Dosimetry Program – External Dosimetry | N-MAN-03416.1-10000 | No |
| Radiation Dosimetry Program – Internal Dosimetry | N-MAN-03416.2-10000 | No |
| Respiratory Protection | OPG-PROC-0132 | No |

**Recommendations and Guidance**

CNSC guidance document G-129, *Keeping Radiation Exposures and Doses As Low As Reasonably Achievable (ALARA)*, provides the licensee guidance for developing, implementing and maintaining a radiation protection program to ensure that exposures will be ALARA.

CNSC guidance document G-228, *Developing and Using Action Levels* provides the licensees guidance for developing ALs in accordance with the *General Nuclear Safety and Control Regulations* and section 6 of the *Radiation Protection Regulations*.

The licensee should conduct a documented review and, if necessary, revise the ALs specified above at least once every five years in order to validate their effectiveness. The results of such reviews should be provided to CNSC staff.

# 8 SCA – CONVENTIONAL HEALTH AND SAFETY

The Safety and Control Area "Conventional Health and Safety" covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.

Performance Objective(s)

Conventional health and safety work practices and conditions achieve a high degree of personnel safety.

## 8.1 *Conventional Health and Safety Program*

**Licence Condition 8.1:**

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

**Preamble**

The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed worker health and safety policies and procedures.

NPPs in Ontario are regulated by the *Ontario Occupational Health and Safety Act* and the *Labour Relations Act*.

**Compliance Verification Criteria**

The licensee has the prime responsibility for safety at all times. This responsibility cannot be delegated or contracted to another organization or entity. The licensee shall ensure that contractors and other organizations present on site are informed of and uphold their roles and responsibilities related to conventional health and safety.

N-PROG-RA-0012, *Fire Protection*, and NK38-LIST-78000-10001, *Application of CSA N293-07 to Structures, System and Components for Darlington Nuclear*, may identify specific SSCs in the protected area or exclusion zone to which the requirements of CSA standard N293, *Fire protection for CANDU nuclear power plants*, are not applied, in which case the requirements of the 2010 edition of the *National Building Code of Canada* and the 2010 edition of the *National Fire Code* shall be applied. See LC 10.2 for version control of CSA N293.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Work Protection | N-PROG-MA-0015 | No |
| Health and Safety Policy | OPG-POL-0001 | No |
| Health and Safety Management System Program | OPG-PROG-0010 | No |

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Respiratory Protection | OPG-PROC- 0132 | No |
| Fire Protection | N-PROG-RA-0012 | Yes |
| Application of CSA N293-07 to Structures, System and Components for Darlington Nuclear | NK38-LIST-78000-10001 | No |

**Recommendations and Guidance**

It is expected that OPG will apply the Ontario Building and Fire Codes to SSCs within the exclusion zone but external to the protected area. For fire protection, N-PROG-RA-0012, *Fire Protection,* and NK-38-LIST-78000-10001, *Application of CSA N293 to Structures, Systems and Components for Darlington Nuclear,* may identify specific SSCs in the exclusion zone to which the requirements of CSA N293 are applied.

Additional information can be found in CNSC regulatory document REGDOC-2.8.1, *Conventional Health and Safety*.

# 9 SCA – ENVIRONMENTAL PROTECTION

The safety and control area "Environmental Protection" covers programs that identify, control, and monitor all releases of radioactive and hazardous substances and the effects on the environment from facilities or as the result of licensed activities.

Performance Objective(s)

The environment and the health and safety of persons are protected by the licensee taking all reasonable precautions, including identifying, controlling and monitoring the release of nuclear substances and hazardous substances to the environment.

## 9.1 *Environmental Protection Program*

**Licence Condition 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 7 days.**

**Preamble**

The *Class I Nuclear Facilities Regulations* set out requirements related to environmental protection that must be met by the applicant.

The *General Nuclear Safety and Control Regulations* require every licensee to take all reasonable precautions to protect the environment and to control the release of radioactive nuclear substances or hazardous substances within the site of the licensed activity and into the environment as a result of the licensed activity.

The *Radiation Protection Regulations* prescribe the radiation dose limits for the general public of 1 mSv per calendar year.

CNSC regulatory policy P-223, *Protection of the Environment* and CNSC regulatory document REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures, Version 1.1*, 2017, describes the principles and factors that guide the CNSC in regulating the development, production and use of nuclear energy and the production, procession and use of nuclear substances, prescribed equipment and prescribed information in order to prevent unreasonable risk to the environment in a manner that is consistent with Canadian environmental policies, acts and regulations and with Canada's international obligations.

The release of hazardous substances is regulated by the Province of Ontario and Environment and Climate Change Canada (ECCC) through various acts and regulations, as well as the CNSC.

**Derived Release Limits**

Derived Release Limits (DRLs) are calculated or derived using environmental transfer modeling that describes transfer of radioactive materials through environmental pathways to humans. DRLs are required for the purpose of protecting members of the public from unreasonable risk resulting from releases of radionuclides into the environment from the normal operation of the licensed facility.

The release of hazardous substances is regulated by the CNSC as well as both the Ontario Ministry of Environment, Conservation and Parks (MECP) and Environment and Climate Change Canada (ECCC) through various acts and regulations.

**Action Levels**

OPG has set Environmental Action Levels (EAL) and related parameters, to provide early warnings of any actual or potential losses of control of the Environmental Protection Program. EALs are precautionary levels and are set far below the actual DRLs. EALs are designed to alert licensees before DRLs are reached. They are required by regulations to be specific doses of radiation or other parameter that, if reached, may indicate a loss of control of the licensee's Environmental Protection Program.

## Compliance Verification Criteria

The licensee shall implement and maintain programs to ensure environmental protection as set out in the licensing basis (LCH Section G.1). These programs shall comply with the requirements set out in:

- CNSC regulatory document REGDOC-2.9.1, *Environmental Protection Policies, Programs and Procedures*;
- CSA standard N288.1, *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities*;
- CSA standard N288.4, *Environmental monitoring program at class I nuclear facilities and uranium mines and mills*;
- CSA standard N288.5, *Effluent monitoring programs at class I nuclear facilities and uranium mines and mills*; and
- CSA standard N288.6, *Environmental risk assessments at class I nuclear facilities and uranium mines and mills.*

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| Effluent and Emissions Control (Releases) | | | | |
| CSA | Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills | N288.5 | 2011 | 2015-12-31 |
| CSA | Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities | N288.1 | 2014 | 2019-01-01 |

| | | | | |
|---|---|---|---|---|
| CSA | Performance Testing of Nuclear Air-Cleaning Systems at Nuclear Facilities | N288.3.4 | 2013 | 2017-12-14 |
| Environmental Management System (EMS) | | | | |
| CNSC | Environmental Protection Policies, Programs and Procedures | REGDOC-2.9.1* | 2013 | 2016-01-01 |
| Assessment and Monitoring | | | | |
| CSA | Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills | N288.4 | 2010 | 2016-01-01 |
| CSA | Groundwater protection programs at Class I nuclear facilities and uranium mines and mills | N288.7 | 2015 | 2022-12-31 |
| Environmental Risk Assessment (ERA) | | | | |
| CSA | Environmental risk assessments at Class I nuclear facilities and uranium mines and mills | N288.6 | 2012 | 2016-12-01 |

**REGDOC-2.9.1 Version 1.1, Environmental Protection: Environmental Principles, Assessments and Protection Measures was published in April 2017. As described in OPG letter N-CORR-00531-22251 (e-doc 6355265), OPG has developed a plan to implement REGDOC-2.9.1 Version 1.1 by December 31, 2022. CNSC staff consider the implementation date of the REGDOC to be effective as of December 31, 2022.*

OPG-POL-0021, *Environmental Policy*, and OPG-PROG-0005, *Environmental Management System*, are key documents of the "Environmental Protection" program. CSA N286-12 defines additional requirements needed to adequately address environmental protection. Refer to LCH Section 1.1 for version details regarding the implementation of N286.

**Effluent and Emissions Control (Releases)**

The licensee shall ensure effluent monitoring for nuclear and hazardous substances is designed, implemented and managed to respect applicable laws and to incorporate best practices. The effluent monitoring program shall incorporate airborne and waterborne effluents. Effluent monitoring is a risk-informed activity which assures quantifying of the important releases of the nuclear and hazardous substances into the environment.

OPG Darlington's Effluent Monitoring Program shall be compliant with CSA N288.5-2011 Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills.

**Measures to Control Releases of Nuclear and Hazardous Substances**

Nuclear Substances – Derived Release Limits

The licensee shall control radiological releases to ALARA, within the DRLs, and take action to investigate cause(s) and correct the cause(s) of increased releases. The licensee shall also monitor and report these releases.

The licensee shall establish the DRLs in accordance with CSA N288.1. If any of the individual radionuclide DRLs are exceeded, or if the sum of individual releases (expressed as a fraction of the relevant DRL) exceeds unity, it indicates that the licensee is in non-compliance with the public dose limit of 1mSv/year as per the CNSC *Radiation Protection Regulations*.

The DRLs are considered part of the licensing basis. Changes to these limits are subject to LC G.1. The DRLs for this facility are summarized in the table below. In the event of a discrepancy between these tables below and the licensee documentation upon which they are based, the licensee documentation shall be considered the authoritative source (assuming that the licensee has followed its own change control process).

| Release Category | Radionuclide | DRL(Becquerel/year) |
|---|---|---|
| Air | Tritium (HTO) | 4.94E+16 |
| | Elemental Tritium (HT) | 8.23E+17 |
| | Iodine (mixed fission products) | 1.77E+12 |
| | Carbon-14 | 1.21E+15 |
| | Noble Gases | 3.80E+16 |
| | Particulate – Gross Beta-Gamma | 6.06E+11 |
| | Particulate – Gross Alpha | 1.08E+11 |
| Water | Tritium | 6.43.E+18 |
| | Carbon-14 | 6.97E+14 |
| | Gross Alpha | 4.39E+11 |
| | Gross Beta-Gamma | 3.47E+13 |

These DRLs for radionuclides and radionuclide groups account for the most significant releases and are the focus of monitoring and reporting requirements.

Note: During refurbishment of Darlington NPP, OPG is reporting % of DRL as % of Flow Adjusted Release Limits (FARLS) for liquid releases in the Safety Performance Indicator reports.

Nuclear Substances – Environmental Action Levels (EAL)

For the licensee, the established EALs are ~10% of the DRLs for respective radionuclides released via airborne, waterborne or sewage discharge pathways.

The EALs are considered part of the licensing basis. Changes to these limits are subject to LC G.1. The EALs for this facility are summarized in the table below. In the event of a discrepancy between these tables below and the licensee documentation upon which they are based, the licensee documentation shall be considered the authoritative source (assuming that the licensee has followed its own change control process).

Further to the requirements of LC 3.3 that cites CNSC REGDOC-3.1.1, OPG shall notify the Commission within seven days of becoming aware that an action level has been reached.

The current EALs for Darlington NGS are given in the following table:

| Release Category | Radionuclide | Action Levels: Gaseous releases (Becquerel/week) |
|---|---|---|
| Air | Tritium (HTO) | 9.88E+13 |
| | Elemental Tritium (HT) | 1.65E+15 |
| | Iodine (mixed fission products) | 3.53E+9 |
| | Carbon-14 | 2.42E+12 |
| | Noble Gases* | 7.60E+13 |
| | Particulate | 1.21E+09 |
| Release Category | Radionuclide | Action Levels: Liquid releases (Becquerel/month) |
| Water | Tritium (HTO) | 5.14E+16 |
| | Carbon-14 | 5.58E+12 |
| | Gross Beta-Gamma | 2.77E+11 |

** Units for noble gas action level are Bq-MeV/week*

Hazardous Substances

The licensee shall control hazardous substances releases according to the limits defined in the licensing basis in accordance with the applicable environmental compliance approvals, provincial and other federal legislation and take action to investigate and correct the cause(s) of increased releases.

**Environmental Management System (EMS)**

The objective of the environmental protection policies, programs and procedures is to establish adequate provisions for protection of the environment. This shall be accomplished through an integrated set of documented activities of an environmental management system (EMS).

OPG shall implement and maintain an environmental management program to assess environmental risks associated with its nuclear activities, and to ensure these activities are conducted in such a way that adverse environmental effects are prevented or mitigated. OPG environmental management program shall be compliant with REGDOC-2.9.1, *Environmental Protection Policies, Programs and Procedures*, version 2013.

OPG shall ensure that all aspects of its environmental management program are effectively implemented in order to assure compliance with environmental regulatory requirements and expectations, including those set in the International Organization for Standardization 14001, *Environmental Management Systems*. OPG's EMS is registered to the ISO-14001. Having the ISO-14001certification is not part of the CNSC requirement; however it shows that a third party recognized OPG's Environmental Management System as being in accordance with the standard.

**Assessment and Monitoring**

An environmental monitoring program consists of a risk-informed set of integrated and documented activities to sample, measure, analyze, interpret, and report the following:

- the concentration of hazardous and/or nuclear substances in environmental media to assess one or both of
  - exposure of receptors to those substances; and
  - the potential effects on human health, safety, and the environment;
- the intensity of physical stressors and/or their potential effect on human health and the environment; and
- the physical, chemical, and biological parameters of the environment normally considered in design of the EMP.

OPG Darlington's Environmental Monitoring Program shall be compliant with CSA N288.4-2010 Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills.

Groundwater monitoring

OPG shall implement CSA N288.7, *Groundwater Protection Programs at Class I Nuclear Facilities and Uranium Mines and Mills* by December 31, 2022 (e-Doc: 5420088).

**Protection of the public**

This aspect relates to the assessment of predicted human health effects measured and potential quantities of hazardous substance in the environment (abiotic and biotic) of the Darlington NPPs. This aspect is link to the Dose to the public SPA as well as the Environmental Risk Assessment SPA.

**Environmental Risk Assessment**

In accordance with CSA N288.4 and N288.5, the ERA establishes the basis for both the environmental monitoring program and the effluent monitoring program. The ERA shall be updated periodically with the results from the environmental and effluent monitoring programs in order to confirm the effectiveness of any additional mitigation measures needed.

OPG Darlington's ERA shall be compliant with CSA N288.6- 2012 Environmental risk assessments at Class I nuclear facilities and uranium mines and mills

The following documents require written notification of change:

| Document Title | Document Number | Prior Notification |
|---|---|---|
| Effluent and Emissions Control (Releases) | | |
| Monitoring of Nuclear and Hazardous Substances in Effluents | N-STD-OP-0031 | No |
| Environment Manual | NK38-MAN-03480-10001 | No |

| | | |
|---|---|---|
| Derived Release Limits and Environmental Action Levels for Darlington Nuclear Generating Station | NK38-REP-03482-10001 | Yes |
| Environmental Approvals | N-PROC-OP-0037 | No |
| Environmental Management System (EMS) | | |
| Environmental Policy | OPG-POL-0021 | No |
| Environmental Management Systems | OPG-PROG-0005 | No |
| Contaminated Lands and Groundwater Management | N-PROC-OP-0044 | No |
| Hazardous Material Management | OPG-PROC-0126 | No |
| Abnormal Waterborne Tritium Emission Response | N-PROC-OP-0038 | No |
| Assessment and Monitoring | | |
| Management of the Environmental Monitoring Programs | N-PROC-OP-0025 | No |
| Darlington Environmental Monitoring Program | NK38-MAN-03443-10002 | No |
| Environmental Risk Assessment (ERA) | | |
| Darlington Nuclear Environmental Risk Assessment | NK38-REP-07701-00001-R001 | No |

**Recommendations and Guidance**

Guiding principles and factors for CNSC staff consideration are also given in CNSC Regulatory policy P-223, *Protection of the Environment* and CNSC regulatory document REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures, Version 1.1*, 2017.

It is recommended that the licensee provide to the CNSC a copy of the reports sent to the Ministry of the Environment and Environment Canada on hazardous releases.

The licensee should review and, if necessary, revise and reissue the DRLs & EALs specified above at least once every five years, in accordance with

- CSA N288.2, *Guidelines for Calculating the Radiological Consequences to the Public of a Release of Airborne Radioactive Material for Nuclear Reactor Accidents*, 2014; and
- CSA N288.8, *Establishing and implementing action levels for releases to the environment from nuclear facilities*, 2017.

CNSC staff use the criteria set out in the CNSC guidance document G-129, *Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)",* 2004, as guidance to help assess the adequacy of DRLs established by the licensee.

CNSC staff use the criteria set out in the CNSC guidance document G-228, *Developing and Using Action Levels*, as guidance to help assess the adequacy of EALs established by the licensee.

# 10 SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION

The safety and control area "Emergency Management and Fire Protection" covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.

Performance Objective(s)

The licensee is ready to respond effectively to any fire or emergency situation.

## 10.1 *Emergency Preparedness Program*

**Licence Condition 10.1:**

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

**Preamble**

The *Class I Nuclear Facilities Regulations* require that a licence application contain information on the licensee's proposed mitigating measures for on-site and off-site events. This includes measures to prevent or mitigate the effects of accidental releases of nuclear and hazardous substances to the environment, to protect the health and safety of persons, to ensure the maintenance of national security, as well as measures to assist off-site planning authorities regarding an accidental release for:

- Planning and preparing to limit the effects;
- Notification;
- Reporting of information during and after;
- Assisting off-site authorities with dealing with effects; and
- Testing the implementation of the measures to prevent or mitigate the effects.

As part of the emergency preparedness program, the licensee shall have a public information program consistent with CNSC regulatory document REGDOC-3.2.1, *Public Information and Disclosure*. This is addressed in licence condition G.6.

The licensee also has processes in place to ensure business continuity in the event of an emergency (see LC 2.1).

In addition to the nuclear emergency plan, the licensee maintains a set of emergency operating procedures and abnormal plant operating procedures. This aspect is covered under licence condition 3.1.

A security response to malevolent acts is governed by a separate plan under OPG's nuclear security program (LC 12.1) but provisions of the licensee's site security report apply to any associated potential threat of release of radioactive material - for example, the need for off-site notification, situation updates and confirmation of any radioactive releases.

Liquid release response and radioactive materials transportation emergency response plan are also governed by separate plans (LCs 9.1 and 14.1, respectively).

**Compliance Verification Criteria**

The licensee shall implement and maintain programs to ensure emergency preparedness. These programs shall comply with the requirements set out in CNSC regulatory document REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Nuclear Emergency Preparedness and Response | REGDOC-2.10.1* | 2014 | 2017-09-29 |

**REGDOC-2.10.1 Version 2, Nuclear Emergency Preparedness and Response was published in February 2016. OPG has been requested to provide implementation plans by September 24, 2021 (e-Doc 6505636).*

The emergency program consists of a description to cope with accidental releases. This program encompasses both emergency preparedness and emergency response measures. It ensures that appropriate emergency response capabilities are developed and maintained available for use.

The emergency preparedness program consists of:

- Basis for emergency planning;
- Personnel selection and qualification;
- Emergency preparedness and response organizations;
- Staffing levels;
- Emergency training, drills and exercises;
- Emergency facilities and equipment;
- Emergency procedures;
- Assessment of emergency response capability;
- Assessment of accidents;
- Activation and termination of emergency responses;
- Protection of facility personnel and equipment,
- Interface with off-site organizations;
- Recovery program;
- Public information program; and
- Public education program.

The licensee's Consolidated Nuclear Emergency Plan (CNEP) deals with emergency situations that could endanger the safety of on-site staff, the environment and the public. It is predominantly conceived to deal with releases of radioactive materials from fixed facilities and to outline interfaces with the Provincial Nuclear Emergency Response Plan (PNERP). The licensee shall maintain equipment, procedures and

staff to support off- site response activities for an accidental release. Infrastructures defined within the PNERP may be used in planning and response to virtually all emergencies. The licensee's Nuclear Emergency Plan also represents a basis for controlling changes and modifications to the licensee's nuclear emergency preparedness program.

OPG is required to conduct Emergency Exercises and Drills as described in the CNEP. Drills and/or exercises are required at least annually in most areas. The drill and exercise program details the requirements for corporate exercises, testing of drill and exercise objectives, and coordination with non-OPG facilities. Participation by municipal and provincial emergency response groups is scheduled by mutual agreement.

The licensee implements and maintains a "Business Continuity Program", to support minimum shift complement staffing and makes provisions should a labour dispute arise by implementing and maintaining strike contingency documentation, "Contingency Guideline for Maintaining Staff in Key Positions When Normal Station Access is Impeded" (refer to LC 1.1).

The licensee shall provide the necessary resources and support to provincial and municipal authorities in implementing the provincial and municipal plans to do the following, or the licensee shall do the following:

- Ensure that a sufficient quantity of iodine thyroid blocking (ITB) agents are pre-distributed, to all residences, businesses and institutions within the primary zone, together with instructions on their proper administration;
- Ensure that a sufficient quantity of ITB agent is pre-stocked and available within the secondary zone to the extent practicable. This pre-stocked inventory of ITB agents shall be located so that it can be promptly and efficiently obtained by, or provided to, members of the public with particular consideration to sensitive populations such as children and pregnant women;
- Ensure that pre-distributed and pre-stocked ITB agents are maintained within their expiry date;
- Ensure that pre-distribution plans are supported by a robust, ongoing, and cyclical public education program; and
- Ensure that public emergency preparedness information is provided to all residences, businesses and institutions within the primary zone and readily available to the general public, including online.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Consolidated Nuclear Emergency Plan | N-PROG-RA-0001 | Yes |
| Emergency Preparedness Drills and Exercises | N-PROC-RA-0045 | No |

**Recommendations and Guidance**

The licensee should provide emergency communications outlining what surrounding community residents need to know and do before, during and after a nuclear emergency. Information should be in plain language, readily accessible and include the following:

- How the public is notified of an emergency;
- What protective actions may be required during an emergency;
- What the public is expected to do, and why, when directed to take protective actions;
- What the public can do now to be better prepared for an emergency; and
- Where can the public get more information on emergency plans.

Regarding the distribution of ITB agents, recognizable locations with credible persons within the community, such as fire stations, police stations and pharmacies should be considered in the selection of pre-stocking locations.

## 10.2 *Fire Protection Program*

**Licence Condition 10.2:**

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

**Preamble**

Licensees require a comprehensive Fire Protection Program (FPP) to ensure the licensed activities do not result in unreasonable risk to the health and safety of persons and to the environment due to fire and to ensure that the licensee is able to efficiently and effectively respond to emergency fire situations.

Fire protection provisions, including response, are required for the design, construction, commissioning, operation, and maintenance nuclear facilities, including structures, systems, and components (SSCs) that directly support the plant and the protected area. External events such as an aircraft crash or threats are addressed by LC 12.1.

**Compliance Verification Criteria**

The licensee shall implement and maintain programs to ensure fire protection. These programs shall comply with the requirements set out in CSA standard N293, *Fire protection for CANDU nuclear power plants*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | Fire protection for CANDU nuclear power plants | N293* | 2012 | 2016-01-01 |

**N293-12 (R2017), Fire Protection for Nuclear Power Plants was published in November 2017. OPG has been requested to provide implementation plans by September 24, 2021 (e-Doc 6505636).*

**Fire Protection**

The licensee shall assess the Fire Hazard Assessment and Fire Safe Shutdown Analysis revisions against the requirements of CSA N293 and provide a justification of any non-conformances found and development a plan for the execution of corrective actions to address the identified gaps.

As required by CSA N293, the licensee shall ensure that a qualified third party performs a plant condition inspection annually and an FPP audit every three years. The resulting inspection and audit reports shall be submitted to CNSC staff.

As per the Integrated Safety Review (ISR) process and as permitted by CSA N293, CNSC staff concurred with OPG's request for Fire Protection Acceptable Deviations and Alternate Compliances related to the Refurbishment project in July of 2015 (e-Doc 4806897). Per CSA N293, CNSC staff have subsequently provided concurrence to additional fire protection related alternate compliances (e-Doc 5296647, 4996509, 4995266, 4994520, 4982486, 4950896, 4940772).

**Fire Response**

In accordance with CSA N293, the licensee shall arrange for third party audits of one industrial fire brigade fire drill once every two years. The purpose of a Third Party Audit is to provide an in-depth analysis of the Industrial Fire Brigade's (IFB) fire response performance against applicable regulatory criteria. A fire response is a planned, coordinated and controlled activity to provide emergency response to a fire.

An independent third party auditor is required to be an expert in their discipline, normally firefighting and qualified through specific education and relevant experience. The third party auditor is required to be independent or at "arm's length" from the facility to ensure total impartiality. The review shall be of sufficient depth and detail that the reviewer can attest with reasonable confidence on the competencies of the IFB at the facility.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Fire Protection | N-PROG-RA-0012 | Yes |
| Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB) | NK38-REP-09701-10338 | Yes |

**Recommendations and Guidance**

The Nuclear Energy Institute in NEI 00-01, *Guidance for Post Fire Safe Shutdown Circuit Analysis*, is used by CNSC staff to help determine the adequacy of safe shutdown electrical circuit analysis.

The results of the Third Party Audit report will typically consist of a report which compares the requirements of the applicable codes and standards against the implementation of the FPP or the Fire Response exercised (based on the scope of the audit). The report should identify any non-compliance and formulate a conclusion if the licensee's FPP or IFB meets the requirements of CSA N293.

As a guideline the report should provide sufficient detail to support the conclusion and to convey that the requirements of CSA N293 are met. As a minimum, the documentation for a Third Party Audit should include:

- Scope and objective of the review;
- A list of applicable codes and standards;
- Summary of the review methodology, including areas and documents reviewed;
- Detailed observations or issues that have been identified;
- Conclusion should identify whether the FPP or the IFB response meets applicable requirements, achieves the FPP or IFB response objectives;
- Summary of any non-compliance, recommendations (if any) and the corrective action plan; and
- The report to be signed by the person taking responsibility for the review

# 11 SCA – WASTE MANAGEMENT

The safety and control area "Waste Management" covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.

Performance Objective(s)

There is full development, implementation and auditing of a facility- and waste stream- specific waste management program to control and minimize the volume of nuclear waste generated by the licensed activity; waste management is included as a key component of licensee's corporate and safety culture; and a decommissioning plan is maintained.

## 11.1 *Waste Management Program*

**Licence Condition 11.1:**

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

**Preamble:**

The *General Nuclear Safety and Control Regulations* require that a licence application contain information related to the in-plant management of radioactive waste or hazardous waste resulting from the licensed activities.

The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.

**Compliance Verification Criteria:**

The licensee shall implement and maintain a program for waste management that includes strategies for waste minimization. Low and intermediate level waste shall be managed in accordance with CSA standard N292.3, *Management of low and intermediate-level radioactive waste*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | Management of low and intermediate-level radioactive waste | N292.3 | 2008 | 2016-01-01 |

The licensee shall:

- Characterize its waste streams and minimize the production of all wastes taking into consideration the health and safety of workers and the environment;
- Integrate waste management programs as a key element of the facility's safety culture; and
- Audit on a regular basis its program to maximize its efficiency.

OPG shall ensure that the Retube Waste Processing Building (RWPB) is operated in accordance with the Darlington Nuclear Generating Station PROL and the applicable documents included below as requiring written notification of change:

- Operations & Maintenance Plan - Retube Waste Processing Building
- RWPB Safety Analysis Summary Report (see LC 4.1)
- Darlington Retube Waste Processing Building – Safety Assessment (see LC 4.1)
- RWPB Worker Dose During Normal Operation and Under Accident Conditions (see LC 4.1)
- Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB) (see LC 10.2)

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Environmental Management System | OPG-PROG-0005 | No |
| Waste Management | N-PROC-OP-0043 | No |
| Segregation and Handling of Radioactive Wastes | N-PROC-RA-0017 | No |
| Operations & Maintenance Plan - Retube Waste Processing Building | NK38-PLAN-09701-10293 | Yes |
| RWPB Safety Analysis Summary Report | NK38-REP-09701-10344 | Yes |
| Darlington Retube Waste Processing Building - Safety Assessment | NK38-REP-09701-10326 | Yes |
| RWPB Worker Dose During Normal Operation and Under Accident Conditions | NK38-CORR-09701-0597849 | Yes |
| Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB) | NK38-REP-09701-10338 | Yes |

**Recommendations and Guidance:**

Additional guidance related to this LC can be found in CSA standard N292.2, *Interim dry storage of irradiated fuel*.

With respect to the storage and management of spent nuclear fuel, the waste management practices should reflect the fundamental safety concerns related to criticality, exposure, heat control, containment and retrievability. Namely, the systems that are designed and operated should assure subcriticality, control radiation exposure, assure heat removal, assure containment and allow retrievability.

## 11.2 *Program for Planning the Decommissioning of the Nuclear Facility*

**Licence Condition 11.2:**

**The licensee shall implement and maintain a decommissioning strategy.**

**Preamble:**

The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed plan for decommissioning of the nuclear facility.

The decommissioning plan includes strategies for the management of low and intermediate level waste, reactor and waste storage facility decommissioning, and the used fuel arising from the operation of the nuclear facility.

**Compliance Verification Criteria:**

CSA standard N294, *Decommissioning of facilities containing nuclear substances,* provides direction on the decommissioning of licensed facilities and specifies requirements for the planning, preparation, execution and completion of decommissioning.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CSA | Decommissioning of facilities containing nuclear substances | N294 | 2009* | 2016-01-01 |

** CSA N294:19 was published in November 2019. As detailed in OPG letter N-CORR-00531-22454 (e-Doc 6445579), OPG will complete its implementation of the revised standard by December 31, 2021.*

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Decommissioning Program | W-PROG-WM-0003 | Yes |
| Preliminary Decommissioning Plan - Darlington Nuclear Generating Station | NK38-PLAN-00960-10001 | Yes |

The decommissioning plan shall be kept current to reflect any changes in the site or nuclear facility. The decommissioning plan shall be revised at a minimum every five years, unless specified otherwise by the Commission. NK38-PLAN-00960-10001, *Preliminary Decommissioning Plan – Darlington Nuclear Generating Station*, will be revised and submitted to the CNSC by January 31, 2022.

**Recommendations and Guidance:**

CNSC guidance document G-219, *Decommissioning Planning for Licensed Activities*, provides guidance regarding the preparation of decommissioning plans for activities licensed by the CNSC. It also provides the basis for calculating the financial guarantees discussed in the CNSC guidance document G-206, *Financial Guarantees for the Decommissioning of Licensed Activities* (further discussed under LC G.5)

# 12 SCA – SECURITY

The safety and control area "Security" covers the programs required to implement and support the security requirements stipulated in the *Nuclear Security Regulations*, the licence, orders, or expectations for the facility or activity.

Performance Objective(s)

Loss, theft or sabotage of nuclear material or sabotage of the licensed facility are prevented.

## 12.1 *Nuclear Security Program*

**Licence Condition 12.1:**

**The licensee shall implement and maintain a security program.**

**Preamble**

The *General Nuclear Safety and Control Regulations* require that a licence application contain information related to site access control and measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information.

The *Class I Nuclear Facilities Regulations* require that a licence application contain the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility.

The *Nuclear Security Regulations* require that a licence application contain specific information related to nuclear security, stipulates the requirements for High-Security Sites, and contains specific requirements pertaining to the transportation of Category I, II or III nuclear material.

The *Nuclear Security Regulations* require that a licensee of a high security site:

- Maintain at all times a qualified onsite nuclear response force;
- Obtain the applicable certifications, before issuing an authorization to a nuclear security officer;
- Prevent unauthorized removal of nuclear material;
- Prevent and detect unauthorized entry into a protected area or inner area; and
- Prevent unauthorized entry of weapons and explosive substances into a protected area or inner area.

The *Nuclear Security Regulations* require every licensee to: conduct, at least once every 12 months, a threat and risk assessment specific to a facility where it carries on licensed activities in order to determine the adequacy of its physical protection system; make modifications to its physical protection system, as necessary, to counter any credible threat identified as a result of the threat and risk assessment; keep a written record of each threat and risk assessment that it conducts and provide a copy of the written record,

together with a statement of actions taken as a result of the threat and risk assessment, to the Commission upon request (within 60 days) after completion of the assessment.

CNSC regulatory document REGDOC-2.12.1, *High Security Sites: Nuclear Response Force*, describes how, when required by a CNSC licence or order, a trained and equipped on-site nuclear response force shall be established and deployed at a nuclear facility.

**Compliance Verification Criteria**

The licensee shall implement and maintain programs to ensure security of the nuclear facility. These programs shall comply with the requirements set out in CNSC regulatory documents:

- CNSC regulatory document REGDOC-2.12.1, *High Security Sites: Nuclear Response Force*;
- CNSC regulatory document REGDOC-2.12.2, *Site Access Security Clearance*;
- CNSC regulatory document RD-321, *Criteria for Physical Protection Systems and Devices at High-Security Sites*;
- CNSC regulatory document RD-361, *Criteria for Explosive Substance Detection, X-Ray Imaging and Metal Detection Devices at High-Security*; and
- CNSC regulatory document RD-363, *Nuclear Security Officer Medical, Physical, and Psychological Fitness*.
- CNSC regulatory document REGDOC-2.2.4, *Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, and Psychological Fitness*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | High Security Sites: Nuclear Response Force | REGDOC-2.12.1 | 2013 | 2016-01-01 |
| CNSC | ***High Security Facilities, Volume I: Nuclear Response Force*, Version 2** | **REGDOC-2.12.1** | 2018 | 2020-12-31* |
| CNSC | Site Access Security Clearance | REGDOC-2.12.2 | 2013 | 2016-01-01 |
| CNSC | *Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, and Psychological Fitness* | REGDOC-2.2.4 | 2018 | 2020-12-31 |
| CNSC | Nuclear Security Officer Medical, Physical, and Psychological Fitness | RD-363 | 2008 | 2016-01-01 |
| CNSC | Criteria for Physical Protection Systems and Devices at High-Security Sites | RD-321 | 2010 | 2016-01-01 |
| CNSC | Criteria for Explosive Substance Detection, X-Ray Imaging and Metal Detection Devices at High-Security Sites | RD-361 | 2010 | 2016-01-01 |
| CSA | Cyber security for nuclear power plants and small reactor facilities | N290.7 | 2014 | 2019-11-30 |

**REGDOC-2.12.1 High-Security Sites, Volume I: Nuclear Response Force, Version 2 was published in September 2018. As described in OPG letter N-CORR-00531-07110 (e-doc 6061256), OPG has developed a plan to implement Appendix C of REGDOC-2.12.1 Volume I, Version 2 by December 31, 2020. CNSC staff consider the implementation date of the REGDOC to be effective as of December 31, 2020.*

The licensee shall ensure the identified vital areas within the nuclear facility are protected against design basis threats and any other credible threat identified in their Threat and Risk Assessment documentation. The prime functions that must be maintained to prevent unacceptable radiological consequences are those of control, cool, and contain.

The licensee shall maintain the operation, design and analysis provisions credited in the above assessments as required to ensure adequate engineered safety barriers for the protection against malevolent acts. The provisions for the protection against malevolent acts shall be documented as part of a managed sub-program or process within the management system. The licensee shall summarize changes in design, analysis or operational procedures that are credited for the protection against malevolent acts in the annual threat and risk assessment, and submit a copy to the Commission upon request.

All detection devices shall be installed, operated and maintained in accordance with manufacturers' specifications and meet the criteria in RD-321 and RD-361.

The licensee shall, in accordance with REGDOC-2.2.4, ensure that the required documentation and necessary medical, physical, and psychological certification of a person is obtained before authorizing that person to act as a nuclear security officer.

The licensee shall implement measures for the purpose of preventing and detecting unauthorized entry into a protected area or inner area at a high-security site, including:

- Vehicle barriers and vehicle access control points;
- Perimeter intrusion detection systems and devices;
- Closed-circuit video systems/ devices for applications in a protected area or inner area;
- Security monitoring rooms; and
- Security monitoring room systems and devices.

**Cyber Security**

The licensee's cyber security program shall be designed, implemented, and maintained to protect the cyber essential assets (CEAs) that perform or impact nuclear safety, nuclear security, emergency preparedness, or safeguard functions from cyber attacks.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington Nuclear Generating Station Security Report | 8300-REP-61400-10003 | Yes |
| Nuclear Security | N-PROG-RA-0011 | Yes |
| Transport Security Plan | TRAN-PLAN-03450-10000 | No |
| Threat and Risk Assessment | NK38-REP-08160.3-00001 | No |
| Cyber Security | N-PROC-RA-0135 | No |
| Cyber Essential Asset Identification and Classification | N-STI-08161-10017 | No |
| Cyber Security Controls for Cyber Essential Assets | N-INS-08161-10011 | No |
| Significant Cyber Assets | NK38-LIST-69000-10001 | No |

**Recommendations and Guidance**

CNSC regulatory document REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources*, provides security measures to prevent the loss, sabotage, illegal use, illegal possession or illegal removal of sealed sources. It also provides the same regarding transportation activities. OPG should provide a transition plan to meet the documents requirements and guidance.

CNSC guidance document G-274, *Security Programs for Category I or II Nuclear Material or Certain Nuclear Facilities*, provides guidance for preparing, submitting and revising the Station Security Report.

CNSC guidance document G-208, *Transportation Security Plans for Category I, II, or III Nuclear Material*, provides guidance to the licensee on how to prepare and submit a "written transportation security plan".

Guidance may be obtained in the IAEA Nuclear Security Series No. 4, *Technical Guidance: Engineering Safety Aspects of the Protection of Nuclear Power Plants Against Sabotage*, IAEA Nuclear Security Series No.13, *Recommendations: Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5)*, and IAEA Nuclear Security Series No. 17, *Technical Guidance: Computer Security at Nuclear Facilities*.

# 13 SCA – SAFEGUARDS AND NON-PROLIFERATION

The safety and control area "Safeguards and Non-Proliferation" covers the programs required for the successful implementation of the obligations arising from the Canada/IAEA Safeguards Agreement, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

Performance Objective(s)

Conformity with measures required by the facility to meet Canada's international safeguards obligations through:

- Timely provision of accurate reports and information;
- Provision of access and assistance to IAEA inspectors for verification activities;
- Submission of annual operational information and accurate design information of plant structures, processes and procedures;
- Development and satisfactory implementation of appropriate facility safeguards procedures; and
- Demonstration of capability, as confirmed through CNSC onsite evaluations, to meet all requirements in support of physical inventory verifications of nuclear material by the IAEA.

## 13.1 *Safeguards Program*

**Licence Condition 13.1:**

**The licensee shall implement and maintain a safeguards program.**

**Preamble**

Safeguards is a system of inspection and other verification activities undertaken by the IAEA in order to evaluate a Member State's compliance with its obligations pursuant to its safeguards agreements with the IAEA.

The *General Nuclear Safety and Control Regulations* require the licensee to take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement, and defines reporting requirements for safeguards events.

The *Class I Nuclear Facilities Regulations* require that a licence application contain information on the licensee's proposed measures to facilitate Canada's compliance with any applicable safeguards agreement.

Canada has entered into a Safeguards Agreement and an Additional Protocol (hereafter referred to as "safeguards agreements") with the IAEA pursuant to its obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons* (INFCIRC/140). The objective of the Canada-IAEA safeguards agreements is for the IAEA to provide assurance on an annual basis to Canada and to the international community that all declared nuclear materials are in peaceful, non-explosive uses and that there is no

indication of undeclared nuclear materials or activities. This conclusion confirms that Canada is in compliance with its obligations under the following Canada-IAEA safeguards agreements:

- *Agreement Between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons; and*
- *Protocol Additional to the Agreement Between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons.*

These are reproduced in information circulars INFCIRC/164, and INFCIRC/164/Add. 1.

The scope of non-proliferation activities carried out under this licence is limited to tracking and reporting of foreign obligations and origins of nuclear material. Additionally, the import and export of controlled nuclear substances, equipment and information identified in the *Nuclear Non-proliferation Import and Export Control Regulations* require separate authorization from the CNSC, consistent with the *General Nuclear Safety and Control Regulations*.

**Compliance Verification Criteria**

The licensee shall ensure that accounting and reporting of nuclear materials is carried out in accordance with CNSC regulatory document REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*.

Relevant documents that require version control:

| Source | Document Title | Document # | Revision # | Effective Date |
|---|---|---|---|---|
| CNSC | Safeguards and Nuclear Material Accountancy | REGDOC-2.13.1 | 2018 | 2020-03-31*<br>2021-10-29** |

* *except for non-fuel nuclear material inventory requirements*
** *for non-fuel nuclear material inventory requirements*

REGDOC-2.13.1, *Safeguards and Nuclear material Accountancy*, was published in February 2018. As detailed in OPG letter N-CORR-00531-20127 (e-doc 6288999), OPG has implemented REGDOC-2.13.1 requirements, except for requirements to non-fuel nuclear material inventory. OPG will implement the requirements for non-fuel nuclear material inventory by October 29, 2021.

To avoid a potential non-compliance with REGDOC-2.13.1, section 8.1.1, when the Nuclear Material Accountancy Reporting (NMAR) e-business system is not available, OPG is to contact the CNSC International Safeguards Division (cnsc.sg.official.ccsn@canada.ca) to inform them of the issue and to seek guidance on how to fulfill reporting requirements. When OPG inventory change documents and physical-key measurement point inventory summaries are submitted using an alternative method, OPG will still be required to re-submit using the NMAR e-business system once the NMAR system becomes available. For additional information see CNSC letter e-Doc 6032545.

The licensee shall not make changes to operation, equipment or procedures that would affect the implementation of safeguards measures, except with the prior written approval of the Commission or CNSC staff as follows:

- Director, International Safeguards Division;
- Director General, Directorate of Security and Safeguards;
- Vice-President, Technical Support Branch; and
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

With respect to the implementation of safeguards measures, changes made by the licensee to operation, equipment or procedures as of the result of agreement between the licensee, the CNSC and the IAEA are considered routine.

If a requested change would adversely impact Canada's compliance its safeguards agreements, CNSC staff does not have the authority to give approval, as this would violate the obligations arising from the Canada-IAEA safeguards agreement.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Nuclear Safeguards | N-PROG-RA-0015 | Yes |
| Nuclear Safeguards Implementation | N-STD-RA-0024 | Yes |
| OPG Safeguards and Nuclear Material Accountancy Requirements | N-PROC-RA-0136 | No |

**Recommendations and Guidance**

None

# 14 SCA – PACKAGING AND TRANSPORT

The safety and control area "Packaging and Transport" covers programs for the safe packaging and transport of nuclear substances to and from the licensed facility.

Performance Objective(s)

All radioactive shipments leaving the site adhere to the *Packaging and Transport of Nuclear Substances Regulations* and the *Transportation of Dangerous Goods Regulations*.

## 14.1 *Packaging and Transport Program*

**Licence Condition 14.1:**

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

**Preamble**

The *Class I Nuclear Facilities Regulations* require that a licence application contain information on the proposed procedures for transporting nuclear substances.

Every person who transports radioactive material, or requires it to be transported, shall act in accordance with the requirements of the *Transportation of Dangerous Goods Regulations* (TDGR) and the *Packaging and Transport of Nuclear Substances Regulations*, *2015* (PTNSR 2015).

The *PTNSR* and the *TDGR* provide specific requirements for the design of transport packages, the packaging, marking and labeling of packages and the handling and transport of nuclear substances.

**Compliance Verification Criteria**

The licensee shall implement and maintain a packaging and transport program that will ensure compliance with the requirements of the TDGR and the PTNSR.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Radioactive Material Transportation | W-PROG-WM-0002 | No |
| Radioactive Materials Transportation Emergency Response Plan | N-STD-RA-0036 | No |

**Recommendations and Guidance**

Not applicable to this LC.

# 15 NUCLEAR FACILITY-SPECIFIC

## 15.1 *Tritium Removal Facility Operations*

**Licence Condition:**

**The licensee shall implement and maintain an operations program for the Tritium Removal Facility including a set of operating limits.**

**Preamble**

The Darlington NGS PROL authorizes OPG to operate the Tritium Removal Facility (TRF) housed in the Heavy Water Management Building on the site. Tritium is produced in the moderator and primary heat transport circuit of CANadian Deuterium Uranium (CANDU) reactors. The TRF is designed to reduce levels of radioactive tritium from these heavy water (deuterium oxide, $D_2O$) inventories. This in turn reduces the potential radiation exposure of licensee staff and reduces releases to the environment. The systems of the TRF have been designed to perform three primary functions: tritium extraction, tritium immobilization/storage and tritium clean up.

In addition to reducing tritium levels in Darlington NGS heavy water inventories, the TRF is also used to reduce tritium levels in heavy water inventories from the other Canadian NPPs.

**Compliance Verification Criteria**

The licensee shall ensure that the operation of the TRF is addressed in the operating policies and principles (OP&Ps).

The licensee shall ensure that the concentration of tritium in any tritiated deuterium oxide feedstock to be treated in the Darlington TRF does not exceed 1.26 TBq/kg $D_2O$ (34 Ci/kg $D_2O$).

D-INS-39000-10003, *TRF Planned Outage Management* is specific to managing outages in the TRF. While this document takes its authority from N-PROC-MA-0013, *Planned Outage Management* (listed under LC 6.1), the document also takes into account the specific nature and timing of TRF outages, allowing OPG to achieve a higher degree compliance with their own documentation.

Condition assessments of the TRF conducted by the OPG indicate that detritiation capacity may be extended to 2055 to match the end of extended life of Darlington NGS, instead of the currently expected end of design life in 2025. The decision to extend TRF life is under assessment by OPG, the status of which was communicated to CNSC staff in December 2017. An update on the decision regarding TRF life extension is expected by October 30, 2018.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington Nuclear Operating Policies and Principles | NK38-OPP-03600 | Yes |
| TRF Planned Outage Management | D-INS-39000-10003 | No |
| Heavy Water Management Plan | N-PROG-AS-0008 | No |

**Recommendations and Guidance**

Not applicable to this LC.

## 15.2 *Refurbishment - Return to Service*

**Licence Condition:**

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

**Preamble**

Reactor units will be removed from service for replacement of internal reactor components and other activities that can only be accomplished in a "refurbishment" outage. Refurbishment outages differ from planned maintenance outages in that the duration is longer, work activities are more complex, and the configuration of the unit is significantly altered to allow work to proceed.

Return to service (RTS) involves returning the reactor and associated nuclear and non-nuclear systems to commercial operation. The licensee must demonstrate that all regulatory requirements have been met and that the associated work has been done to the satisfaction of the CNSC.

**Compliance Verification Criteria**

The licensee's Return to Service Program Management Plan describes the processes, procedures, and organization that will be used during the Darlington Refurbishment Project to manage the modification and restart activities.

This plan identifies OPG internal restart control hold points (RCHPs) that will be the focus of the run-up activities leading up to full power and unit availability for commercial operation. For each RCHP, the licensee will produce a Completion Assurance Document (CAD) which provides confirmation that all pre-requisites, modification commissioning, testing, system restart activities and commitments have been addressed to the allow OPG's release of the specific hold point. The CAD will include references to the following reports with detail applicable to the specific activities associated with the RCHP:

- Construction Completion Declarations:
  - Confirm that construction and installation activities are sufficiently complete and that it is safe to proceed with modification commissioning and re-start testing on the affected SSCs.
- Modification Commissioning Reports:
  - Confirm that new or modified SSCs meets the design specifications and performance criteria.
- System Available for Service Packages:
  - Confirm that individual systems, or a group of systems, can be credited to safety and reliability perform their design functions.
- Re-start Reports:
  - Confirm that non-modified SSCs are ready to return to normal operation after the refurbishment outage.
- Unit Readiness for Service Packages:
  - Confirm that each unit is returned to service in a manner which demonstrates that new and existing plant SSCs conform to the defined physical, function, performance, safety and control requirements.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington Refurbishment Return to Service Program Management Plan | NK38-NR-PLAN-09701-10001, Sheet: 0003 | No |
| Engineering Change Control Process | N-PROC-MP-0090 | Yes |

**Recommendations and Guidance**

OPG should apply the concepts described in REGDOC-2.3.1, *Conduct of Licensed Activities: Construction and Commissioning Programs*, to the extent practicable, when commissioning and returning SSCs to service. CNSC staff will consider pertinent sections of REGDOC-2.3.1 when evaluating OPG's commissioning and return to service activities related to the refurbishment.

OPG and CNSC staff have bilaterally issued Return to Service (RTS) protocols intended to manage prerequisites for Regulatory Hold Point (RHP) removal and for production of certain deliverables by both parties, to obtain certainty around the schedule and scope and management of anticipated changes to deliverables associated to a refurbished Unit's RTS.

The scope of work specified in the RTS protocols have been based on this Licence Conditions Handbook and agreed to with CNSC staff for implementation for refurbished Units' RTS.

The RTS protocols detail the administrative process to be used between the CNSC and OPG to manage the regulatory interaction for the listed deliverables in Appendix B of the protocols that comprise the assurance CNSC seeks as defined in this LCH for removal of the RHPs referenced in License Condition 15.4 of the Darlington PROL.

## 15.3 *Integrated Implementation Plan*

**Licence Condition:**

**The licensee shall implement the Integrated Implementation Plan.**

**Preamble**

The Integrated Implementation Plan (IIP) contains commitments, including the timeframes for implementation, resulting from the Environmental Assessment (EA) for Darlington Refurbishment and Continued Operations as well as the Darlington Integrated Safety Review (ISR). These commitments include, but are not limited to:

- Replacement of fuel channels, feeders, calandria tubes, and end fittings;
- Installation of two auxiliary shutdown cooling pumps per unit;
- Installation of a containment filtered venting system;
- Provision of shield tank overpressure protection;
- Enhancements to the powerhouse steam venting system;
- Installation of a 3rd emergency power generator;
- Provision of an alternate, independent supply of water as an emergency heat sink;
- Implementation of safety related recommendations from component condition assessments; and
- Implementation of mitigation and follow up activities stemming from the Environmental Assessment conducted under the *Canadian Environmental Assessment Act, 1992*.

**Compliance Verification Criteria**

In implementing the commitments identified in the IIP, NK38-REP-03680-10185 R002, *Darlington NGS Integrated Implementation Plan*, OPG committed to submitting to CNSC staff formal progress reports on the status of all IIP commitments on an annual basis by March 31st of each year during the licence period. Any proposed non-intent changes to the IIP shall be subject to the licensee's IIP Change Control Process Principles (e-Doc 4575922), as further developed in N-INS-03680-10001, *Darlington NGS Integrated Implementation Plan (IIP) Change Control and Closeout Process*.

On July 18, 2019, the Commission issued a Record of Decision approving OPG's request to revise the IIP (e-Doc 5948260). With this decision, the IIP commitments associated to the following IIP items have been modified:

- IIP-EA 009
- IIP-OI 002
- IIP-OI 023
- IIP-OI 024
- IIP-CC 023
- IIP-CC 026
- IIP-CC 034

OPG is currently in the process of revising the IIP. Once issued and accepted by CNSC staff, the new revision of the IIP will be referenced in this LCH and will form part of the Licensing Basis for the Darlington NGS.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Darlington NGS Integrated Implementation Plan (IIP) Change Control and Closeout Process | N-INS-03680-10001 | No |

**Recommendations and Guidance**

Not applicable to this LC.

## 15.4 *Regulatory Hold Points for Return to Service and Continued Operations*

**Licence Condition:**

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

**Preamble**

CNSC selected four (4) regulatory hold points for which CNSC approval will be sought prior to proceeding to the subsequent commissioning phase. These hold points require regulatory verification to confirm operational readiness of the plant safety systems to satisfy regulatory requirements for staged progress through the commissioning phases up to full power operation. These regulatory hold points are consistent with the regulatory approach described in CNSC regulatory document RD-360, *Life Extension of Nuclear Power Plants*.

**Compliance Verification Criteria**

The licensee shall seek approval of the Commission or consent of a person authorized by the Commission prior to the removal of the following regulatory hold points for the return to service of each unit. The regulatory hold points that mark the completion of the commissioning phases are as follows:

1. Prior to **Fuel Load - Phase A**
2. Prior to removal of **Guaranteed Shutdown State - Phase B**
3. Prior to exceeding **1% Full Power - Phase C**
4. Prior to exceeding **35% Full Power - Phase D**

For each of the regulatory hold points, the licensee shall submit Completion Assurance Documents (CAD). In addition to these CAD's, the licensee shall submit CADs following sustained operation at 100% full power that will specify activities that were completed between 35% and 100% full power. Each CAD shall present evidence that all pre-established conditions for removal have been met.

Prior to GSS removal, all plant personnel who work on the refurbished reactor shall have completed update training appropriate to the knowledge and skill requirements of the applicable position covering the changes to facility systems, equipment and procedures made during refurbishment.

For each ANO, CRSS and SM this includes, at a minimum:

- Principles of reactor operation with new fuel;
- Principles of nuclear safety relevant to the operation of the reactor unit with new fuel;
- Operating constraints and limits associated with the operation of the reactor unit with new fuel;
- The initial approach to criticality and power increase until control by the reactor regulating system is established, including the systems and equipment required and their operation; and
- Changes in fuel composition and core reactivity until reaching equilibrium fuel conditions.

This training shall include formal knowledge and performance evaluations that confirm and document that, at the time of GSS removal, the person has the required knowledge and skills to perform the duties of the applicable position.

Low power testing (Phase C) shall be carried out at the lowest possible power level, with a maximum of 1% of full power.

**Pre-requisites for Removal of Hold Points:**

Pre-requisites for Fuel Load

1. All IIP commitments required prior to fuel load are complete;
2. All SSCs required for safe operation beyond fuel load are available for service;
3. Staffing levels to safety operate the unit are adequate;
4. Specified operating procedures for fuel load have been formally validated;
5. Specified training for fuel load is complete and staff qualified;
6. Specified SSCs meet the quality and completion requirements of CSA standard N286, *Management system requirements for nuclear facilities*;
7. All non-conformances and open items identified leading up to the fuel load are addressed; and
8. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to fuel load have been successfully completed.

With respect to pre-requisite #3: Staffing levels refers to a sufficient number of qualified workers present at all times to ensure the safe operation of the nuclear facility and to ensure adequate emergency response capability. The licensee should have adequate staff available such that absences due to vacation, sick leave and training do not cause violations of the minimum shift complement levels.

Pre-requisites for GSS Removal

1. All IIP commitments required prior to GSS removal are complete;
2. All SSCs required for safe operation beyond GSS removal are available for service;
3. Specified operating procedures for GSS removal have been formally validated;
4. Specified training for GSS removal is complete and staff qualified;
5. All non-conformances and open items identified leading up to GSS removal are addressed;
6. Specified SSCs meet the quality and completion requirements of CSA N286; and
7. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to GSS removal have been successfully completed.

Pre-requisites for Reactor Power Increases Prior to exceeding 1% Full Power

1. All IIP commitments required prior to increasing reactor power are complete;

2. All SSCs required for safe operation are available for service;
3. Specified operating procedures have been formally validated;
4. Specified training is complete and staff qualified;
5. All non-conformances and open items identified leading up to reactor power increases are addressed;
6. Specified SSCs meet the quality and completion requirements of CSA N286; and
7. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to increasing reactor power have been successfully completed.

Pre-requisites for Reactor Power Increases Prior to exceeding 35 % Full Power

1. All IIP commitments required prior to normal operation are complete;
2. All SSCs required for safe operation are available for service;
3. Specified operating procedures have been formally validated;
4. Specified training is complete and staff qualified;
5. All non-conformances and open items identified leading up to reactor power increases are addressed;
6. Specified SSCs meet the quality and completion requirements of CSA N286; and
7. Verification by CNSC staff that all construction, commissioning, re-start, and available for service activities required prior to increasing reactor power have been successfully completed.

The licensee's criteria for the removal of hold points are contained in NK38-INS-09701-10006, *Nuclear Refurbishment Unit Readiness for Service*.

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Nuclear Refurbishment Unit Readiness for Service | NK38-INS-09701-10006 | Yes |

**Recommendations and Guidance**

OPG and CNSC staff have bilaterally issued Return to Service (RTS) protocols intended to manage prerequisites for Regulatory Hold Point (RHP) removal and for production of certain deliverables by both parties, to obtain certainty around the schedule and scope and management of anticipated changes to deliverables associated to a refurbished Unit's RTS.

The scope of work specified in the RTS protocols have been based on this License Conditions Handbook and agreed to with CNSC staff for implementation for a refurbished Unit's RTS.

The RTS protocols detail the administrative process to be used between the CNSC and OPG to manage the regulatory interaction for the listed deliverables in Appendix B of the protocol that comprise the assurance CNSC seeks as defined in this LCH for removal of the RHPs referenced in License Condition 15.4 of the Darlington PROL.

## 15.5 *Import and Export of Nuclear Substances*

**Licence Condition:**

**The licensee shall limit the activities of import and export of nuclear substances occurring as contaminants in laundry, packaging, shielding or equipment.**

**Preamble**

OPG is authorized to import and export nuclear substances other than controlled nuclear substances as defined in the *Nuclear Non-Proliferation Import and Export Control Regulations*. The nuclear substances are materials consisting primarily of contaminated laundry originating from Darlington NGS. In addition to contaminated laundry, the licence condition allows for import and export of packaging, shielding or equipment with low levels of contamination similar to laundry.

**Compliance Verification Criteria**

The following documents require written notification of change:

| Document Title | Document # | Prior Notification? |
|---|---|---|
| Radioactive Material Transportation | W-PROG-WM-0002 | No |
| Radiation Protection | N-PROG-RA-0013 | Yes |

The licensee shall limit the activities of import and export of nuclear substances to the isotopes and quantities listed in Table 1 as follows:

**Table 1: Nuclear Substances and Quantity Limits for Import and Export**

| **Nuclear Substance** | **Maximum Total Quantity** |
|---|---|
| Americium 241 | 10 MBq |
| Antimony 122 | 10 GBq |
| Antimony 124 | 50 GBq |
| Antimony 125 | 20 GBq |
| Carbon 14 | 10 GBq |
| Cerium 141 | 1 GBq |
| Cerium 144 | 1 GBq |
| Cesium 134 | 1 GBq |
| Cesium 137 | 5 GBq |

| Nuclear Substance | Maximum Total Quantity |
|---|---|
| Chromium 51 | 50 GBq |
| Cobalt 57 | 10 MBq |
| Cobalt 58 | 100 MBq |
| Cobalt 60 | 50 GBq |
| Curium 242 | 1 MBq |
| Curium 244 | 100 kBq |
| Deuterium | 350 mg |
| Europium 154 | 50 MBq |
| Europium 155 | 50 MBq |
| Gadolinium 153 | 100 MBq |
| Gadolinium 159 | 500 MBq |
| Hafnium 181 | 10 MBq |
| Hydrogen 3 | 10 GBq |
| Iodine 129 | 200 kBq |
| Iodine 131 | 2 MBq |
| Iodine 133 | 2 MBq |
| Iron 55 | 10 GBq |
| Iron 59 | 50 GBq |
| Lanthanum 140 | 1 MBq |
| Manganese 54 | 5 GBq |
| Manganese 56 | 5 GBq |
| Molybdenum 99 | 1 MBq |
| Neptunium 237 | 1 kBq |
| Neptunium 239 | 500 kBq |
| Nickel 59 | 200 MBq |
| Nickel 63 | 500 MBq |
| Niobium 94 | 10 MBq |
| Niobium 95 | 5 GBq |
| Plutonium 238 | 1 MBq |
| Plutonium 239 | 50 MBq |

| Nuclear Substance | Maximum Total Quantity |
|---|---|
| Plutonium 240 | 1 MBq |
| Plutonium 241 | 58 MBq |
| Promethium 147 | 50 MBq |
| Ruthenium 103 | 1 GBq |
| Ruthenium 106 | 1 GBq |
| Scandium 46 | 50 MBq |
| Silver 108m | 100 kBq |
| Silver 110m | 10 MBq |
| Strontium 89 | 5 MBq |
| Strontium 90 | 10 MBq |
| Tantalum 182 | 50 kBq |
| Tin 113 | 50 MBq |
| Tungsten 187 | 1 MBq |
| Uranium 234 | 1 kBq |
| Uranium 235 | 1 kBq |
| Uranium 238 | 10 kBq |
| Zinc 65 | 5 MBq |
| Zirconium 93 | 100 GBq |
| Zirconium 95 | 100 GBq |

The licensee is not authorized, subject to any restrictions or exemptions under the regulation, to import or export the items described in Parts A and B of the Schedule to the *Nuclear Non-Proliferation Import and Export Control Regulations*, such as:

(1) Special fissionable material, as described in paragraph A.1.1:

(i) Plutonium;

(ii) Uranium 233;

(iii) Uranium enriched in Uranium 233 or Uranium 235.

(2) Source material, as described in paragraph A.1.2:

(i) Uranium, containing the mixture of isotopes that occurs in nature;

(ii) Uranium, depleted in the isotope Uranium 235; and

(iii) Thorium.

(3) Deuterium and heavy water, as described in paragraph A.1.3.

(4) Tritium, as described in paragraph A.1.5.

(5) Alpha-emitting nuclear substances, as described in paragraph B.1.1.1, including but not limited to:

(i) Actinium 225, 227;

(ii) Californium 248, 250, 252, 253, 254;

(iii) Curium 240, 241, 242, 243, 244;

(iv) Einsteinium 252, 253, 254, 255;

(v) Fermium 257;

(vi) Gadolinium 148;

(vii) Mendelevium 258, 260;

(viii) Neptunium 235;

(ix) Polonium 208, 209, 210;

(x) Radium 223; and

(6) Radium-226, as described in paragraph B.1.1.16.

# APPENDIX A – Administrative Processes

This appendix describes the administrative process necessary for managing the LCH, such as delegation of authority, change control, reporting to Commission, document version control, record-keeping and dispute resolution.

## A.1 Delegation of Authority

Throughout the licence, the statement "or consent of a person authorized by the Commission" reflects to whom the Commission may delegate certain authority (hence "consent") to CNSC staff. Unless otherwise specified, the delegation of authority by the Commission to act as a "person authorized by the Commission" is only applied to the incumbents of the following positions:

- DPRR Regulatory Program Directors;
- Director General (DG), Directorate of Power Reactor Regulation (DPRR); and
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

Delegations of authority are recorded in the Commission "Record of Proceedings, Including Reasons for Decision", but they may be documented elsewhere by the Commission.

## A.2 LCH Change Control

The CNSC will apply a change control process, with clear procedures to the LCH in accordance with the CNSC Management System to ensure that:

- Preparation and use of the LCH is properly controlled;
- All referenced documents are correctly identified and maintained;
- Changes are conducted in accordance with CNSC regulatory policy P-299, *Regulatory Fundamentals*; and
- Procedures for modifying the LCH are followed.

The licensing basis is defined at licence issuance/renewal. The principles for achieving compliance with the licensing basis will not change greatly during the licence period. However, changes to the LCH may be requested by either CNSC staff or the licensee, which impact the specific details of these principles in order to achieve greater clarity and achieve an equivalent level of safety. Whenever CNSC staff request a change to the LCH the licensee will be consulted.

The following are examples of LCH change requests:

- Operating experience with the LCH may reveal instances where the Compliance Verification Criteria text may leave room for varying interpretation between the licensee and CNSC staff, Such instances would require further clarity.
- The transitional provisions for new codes, standards and regulatory documents, which are documented in the compliance verification criteria, may be revised. Assuming that the implementation plan was part of the licence application (and hence part of the licensing basis), such a development would result in a LC non-compliance (reportable in CNSC regulatory document REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*, as such) and CNSC staff modifying the date and taking any necessary other actions, including possible enforcement action, based on the time at risk.
- As a result of a licensing decision being issued by the Commission. (i.e., amendment to the licence). One example is the inclusion of, or revision to, regulatory documents, codes and standards. These amendments may involve amending the CVC in the LCH.
- An Environmental Assessment relevant to the licensed facility may lead to licensee commitments that should be recorded as CVC in the LCH.
- Changes to recommendations and guidance, such as the inclusion or amendment of CNSC regulatory guidance documents or recommendations.

For licensee-requested changes to the LCH, that include the licensee's alternative cost effective approach where applicable, CNSC staff will review the proposed changes, as required by CNSC regulatory policy P-242, *Considering Cost-benefit Information,* and decide if the LCH should be modified. The CNSC document, *Risk Informed Approach for the CNSC Power Reactor Regulatory Program – Basis Document*, contains information on how to consider cost benefit information in licensee submissions.

The Director General, Directorate of Power Reactor Regulation, has the authority to approve changes to the LCH.

In order to effect a modification to the LCH, the CNSC Regulatory Program Officer will:

- Initiate a request using the Document Change Request (DCR) Form;
- Liaise with the Power Reactor Licensing and Compliance Integration Division (PRLCID);
- Coordinate the review by the identified Subject Matter Expert;
- Consult licensee, as required;
- Obtain endorsement from the Regulatory Program Director;
- Obtain approval and signature from the DG of DPRR;
- Update the LCH; and
- Distribute the updated version of the LCH.

If the change involves the revision of a WN document, the Regulatory Program Division will also update the registry it uses to track the version history and e-Doc number of the WN documents.

The Power Reactor Licensing and Compliance Integration Division (PRLCID) will:

- assess if the request is generic to the Power Reactor Regulatory Program;
- endorsement of the change by the PRLCID Director; and
- update the generic LCH, if required.

## A.3 Reporting to the Commission

Changes to the LCH will be tracked through the DCR. CNSC staff will summarize all the changes made to the LCH and report them to the Commission for information in the CNSC staff's annual report entitled "Integrated Safety Assessment of Canadian Nuclear Power Plants". This report is presented annually in a public proceeding of the Commission at a scheduled date. The report should emphasize instances where the CVC were relaxed (such as modifying target dates as discussed above).

CNSC staff will review the content of the LCH annually to ensure that the collective changes made to the document did not result in an unauthorized change of scope. For example, CNSC staff will ensure that the LCH continues to maintain a clearly-documented set of compliance verification criteria and that any changes remain within the licensing basis. The results of this review should also be reported to the Commission annually.

## A.4 Document Control and Approval/Consent

### A.4.1 Document Control and Oversight

Whenever proposed changes to version control documents are accepted by the CNSC, the compliance verification criteria in the LCH must be updated (per the LCH change control process described in Appendix A.2). The Director General, Directorate of Power Reactor Regulation, has the authority to make the changes to the compliance verification criteria as long as the changes remain within the licensing basis.

The CNSC uses a risk-informed process to determine the type of regulatory oversight that is appropriate for each licensee document in the licensing basis. WN documents do not require prior Commission approval or CNSC staff consent of changes, but the changes are still reviewed by CNSC staff. Changes to WN documents are not tracked through the LCH; they are tracked by the CNSC licensing division using the registry described in Section A.2.

### A.4.2 Approval/Consent of Changes (other than document changes)

CNSC facility operating licences may include LCs that address situations where the licensee has to apply to make, or at least provide notification before making, a change that is not linked to a specific document. The LCH may also specify similar mechanisms. These situations could include potential design, organizational, or operational changes. The LC or LCH could indicate that the change must be approved by the Commission.

Alternately, the LC or LCH may indicate the circumstances under which consent for the change can be granted by a delegated authority. In some cases, the associated compliance verification criteria in the LCH may indicate specific criteria that the Commission and/or delegated authority would assess when considering the request for approval/consent.

A.4.3 CNSC Review Criteria Related to Document Changes and Approvals/Consent

For the approvals of document changes or other changes described above in Sections A.4.1 and A.4.2, the CNSC checks that the licensee submission includes the appropriate level of information with regards to the proposed changes or action, to the extent relevant:

- A summary description;
- An indication of the duration (temporary or permanent);
- A justification;
- Any relevant supporting documentation;
- An evaluation of the impact on health, safety, security, the environment and Canada's international obligations; and
- An evaluation to determine if the resultant effects remain within the limits defined by the licensing basis.

The CNSC then assesses whether the following general criteria would be met for the proposed change/action:

- The proposed change or action will be made or done in accordance with licensee's quality assurance and change control processes, applicable design guides, design requirements, standards, operating documentation, regulatory documents, applicable safety principles and applicable safeguards agreement.
- Following the proposed change or action, the licensee remains in compliance with the requirements set out in the applicable laws, regulations and licence conditions, including appendices of the licence.
- The proposed change or action is in the safe direction.
- Following the proposed change or action:
  - The licensee remains qualified to carry out the licensed activity;
  - The licensee has adequate provision for the protection of the health and safety of persons, protection of the environment, maintenance of national security and measures required to implement international obligations to which Canada has agreed; and
  - The licensed activity remains within the limits defined by the licensing basis.

(The above criteria can also apply when CNSC staff review a notification of a licensee change that was already made.)

If the licensee's request is being assessed by a delegated authority and it is found that the request for change or action does not meet all of the above criteria, the delegated authority will address the situation with the licensee to determine if adjustments to the proposal can satisfy all the criteria. If not, consideration of the change must be turned from the delegated authority back to the Commission.

## A.5 Record Keeping

A.5.1 Records Management

The DCR and accompanying documentation will be archived in Records and referenced in the Revision History section of the LCH. Marked-up documents by the reviewers and any other supporting information will be kept in Records Office (File No. 2.01). Electronic communication related to the change, such as comments from reviewers will be stored in the CNSC's "e-Access."

### A.5.2 Distribution

A copy of the updated version of the LCH will be provided to the following:

- Responsible Regulatory Program Director;
- Responsible Site Office;
- Responsible Administrative Assistant; and
- Licensee's single point of contact.

## A.6 Dispute Resolution

In the event of disagreement on a proposed change to the LCH, staff and the licensee will attempt to resolve the issue. The following steps will be followed:

- A meeting with the appropriate parties, including Directors, will be scheduled by the Regulatory Program Officer;
- The rationale supporting the decision and the decision will be documented; and
- If any party is not satisfied with the decision, the disagreement will be brought to the next level of authority, Directors General or Vice-Presidents, as required.

Any unresolved issue will be referred to the Commission.

# APPENDIX B – Glossary of Terms

## B.1 – Acronyms

The following is the list of acronyms used in the LCH:

| | |
|---|---|
| ADL | Administrative Dose limits |
| AIA | Authorized Inspection Agency |
| AL | Action Levels |
| ALARA | As Low As Reasonably Achievable |
| ASME | American Society of Mechanical Engineers |
| CANDU | Canadian Deuterium Uranium |
| CMD | Commission Member Document |
| CNSC | Canadian Nuclear Safety Commission |
| COG | CANDU Owners Group |
| CSA | Canadian Standards Association |
| CVC | Compliance Verification Criteria |
| DBA | Design Basis Accident |
| DCR | Document Change Request |
| DG | Director General |
| DPRR | Directorate of Power Reactor Regulation |
| DRL | Derived Release Limits |
| EAL | Environmental Action Levels |
| EQ | Environmental Qualification |
| GSS | Guaranteed Shutdown State |
| IAEA | International Atomic Energy Agency |
| LCH | Licence Conditions Handbook |
| LCMP | Life Cycle Management Plans |
| NDE | Non-destructive Examination |
| NEW | Nuclear Energy Worker |
| NFPA | National Fire Protection Association |
| NGS | Nuclear Generating Station |
| NPP | Nuclear Power Plant |
| OP&P | Operating Policies and Principles |
| OPEX | Operating Experience |
| OSR | Operational Safety Requirements |
| PCB | Polychlorinated Biphenyls |
| PIP | Periodic Inspection Program |
| PRA | Probabilistic Risk Assessment |
| PROL | Nuclear Power Reactor Operating Licence |
| PSA | Probabilistic Safety Assessment |
| RPD | Regulatory Program Division |
| SAT | Systematic Approach to Training |
| SCA | Safety and Control Area |
| SOE | Safe Operating Envelope |
| SSCs | Systems, structures and components |
| WN | Written Notification |

**B.2 – Definitions**

The following is a list of definitions of words or expressions used in the LCH that may need clarification. Unless a reference source is provided in parenthesis, the words or expressions have been defined for the purpose of the LCH.

**Accept/ed/able/ance**
Meet regulatory requirements, which mean it is in compliance with regulatory documents or technical standards referenced in the licence.

**Approval**
Commission's permission to proceed, for situations or changes where the licensee would be:

- Not compliant with a regulatory requirements set out in applicable laws and regulations;
- Not compliant with a licence condition; and
- Not in the safe direction but the objective of the licensing basis is met.

**Boundary conditions**
Procedural, administrative rules and operating limits for ensuring safe operation of the facility based on safety analysis. It also includes any applicable regulatory requirements.

**Certified Staff**
Trained licensee staff, certified by the Commission to be competent in completing tasks identified in their respective roles.

**Compliance verification criteria**
Criteria used to verify compliance with a licence condition. CVC provides the licensee and CNSC staff with detailed information to clarify regulatory requirements for compliance purposes.

**Consent**
Written permission to proceed, given by CNSC delegated authority, for situations or changes where the licensee would:

- Comply with a regulatory requirements set out in applicable laws and regulations;
- Comply with a licence condition; and
- Not adversely impact the licensing basis.

**Defense-in-depth**
The application of more than one protective measure for a given safety objective, such that the objective is achieved even if one of the protective measures fails.

**Design basis**
The range of conditions and events taken into account in the design of the facility, according to established criteria, such that the facility can withstand them without exceeding authorized limits for the planned operation of safety systems.

[CNSC regulatory document RD-360, *Life Extension of Nuclear Power Plants*]

**Design basis accident**
Accident conditions against which an NPP is designed according to established design criteria, and for which the damage to the fuel and the release of radioactive material are kept within authorized limits.

[CNSC regulatory document RD-310, *Safety Analysis for Nuclear Power Plants*]

**Effective Date**
The date that a given document becomes effective within the licensing period. The effective date is either set to the licence issue date or to a future date when the given document becomes effective.

**Extent of condition**
An evaluation to determine if an issue has potential or actual applicability to other activities, processes, equipment, programs, facilities, operations or organizations.

**Graduated enforcement**
A process for escalating enforcement action. If initial enforcement action does not result in timely compliance, gradually more severe enforcement actions may need to be used. It takes into account such things as:

- The risk significance of the non-compliance with respect to health, safety, security, the environment and international obligations;
- The circumstances that lead to the non-compliance (including acts of willfulness);
- Previous compliance record;
- Operational and legal constraints (for example, Directive on the Health of Canadians); and
- Industry specific strategies.

[CNSC process document, *Assure Compliance: Select and Apply Enforcement Tools*]

**Human factors engineering**
Is the application of knowledge about human capabilities and limitations to plant or facility, system, and equipment design. Human factors engineering ensures that the plant or facility, system, or equipment design, human tasks, and work environment, are compatible with the sensory, perceptual, cognitive, and physical attributes of the personnel who operate, maintain, and support it.

[CNSC guidance document G-276, *Human Factors Engineering Program Plans*]

**Important to safety**
Items important to safety include, but are not limited to:

- Structures, Systems or Components (SSC) whose malfunction or failure could lead to undue radiation exposure of the facility/site personnel, or members of the public;
- SSCs that prevent anticipated operational occurrences from leading to accident conditions;
- Those features that are provided to mitigate the consequences of malfunctions or failures of SSCs; and
- Tasks, duties, activities, aging mechanisms, findings, or any work that improperly performed could lead to radiation exposure of the facility/site personnel, or members of the public.

**Levels 1 and 2 Outage Plans** A level 1 outage plan is a schedule which identifies the key components of the finalized critical path, major projects and programs. A level 2 outage plan is a schedule which identifies the system windows with durations.

**Licensee documents requiring notification of change**
As determined by CNSC staff, these are documents needed to support the licence application which contain the necessary safety and control measures. Depending on the risk significance of the document, changes may require either a "notification" or a "notification prior to implementation".

**Program(s)**
A documented group of planned activities, procedures, processes, standards and instructions coordinated to meet a specific purpose.

**Programmatic failure**
A programmatic failure (or programmatic non-compliance), arises under one or more of the following circumstances:

- Failure to establish a required program or program element;
- Failure of a program or program element to meet a mandated standard;
- Failure to comply with a specific, objective provision of a program; and
- Aggravated or systemic failure(s) to adhere to applicable procedures.

[*OPG governance Regulatory Interpretation* CNSC-024]

**Probabilistic safety assessment (PSA)**
For a NPP or nuclear fission reactor, a comprehensive and integrated assessment of the safety of the plant or reactor. The safety assessment considers the probability, progression and consequences of equipment failures or transient conditions to derive numerical estimates that provide a consistent measure of the safety of the plant or reactor, as follows:

(i) A Level 1 PSA identifies and quantifies the sequences of events that may lead to the loss of core structural integrity and massive fuel failures.
(ii) A Level 2 PSA starts from Level 1 results, and analyses the containment behaviour, evaluates the radionuclides released from the failed fuel and quantifies the releases to the environment.
(iii) A Level 3 PSA starts from the Level 2 results, and analyses the distribution of radionuclides in the environment and evaluates the resulting effect on public health.

A PSA may also be referred to as a Probabilistic Risk Assessment (PRA).

[CNSC standard document S-294, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*]

**Qualified Staff**
Trained licensee staff, deemed competent and qualified to carry out tasks associated to their respective positions.

**Recommendation and Guidance**
Non-mandatory suggestions on how to comply with the licence condition. Recommendations and guidance may include regulatory advice and/or recommended industry best practices to guide the licensee towards a higher level of safety and/or fully satisfactory performance/implementation of its programs.

**Regulatory undertakings**
Refers to high level commitments that ensure safety, not component work orders or regulatory predefined maintenance tasks. The licensee's deferral and Station Condition Record process focus on these lower level commitments.

**Restart of the reactor**
Removal of the Guaranteed Shutdown State (GSS).

**Safe direction**
Changes in plant safety levels which would not result in:

- A reduction in safety margins;
- A breakdown of barrier;
- An increase (in certain parameters) above accepted limits;
- An increase in risk;
- Impairment(s) of special safety systems;
- An increase in the risk of radioactive releases or spills of hazardous substances;
- Injuries to workers or members of the public;
- Introduction of a new hazard;
- Reduction of the defense-in-depth provisions;
- Reducing the capability to control, cool and contain the reactor while retaining the adequacy thereof; and
- Causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility.

**Safety and control measures**
Measures or provisions that demonstrate that the applicant:

(i) Is qualified to carry on the licensed activities; and
(ii) Has made adequate provision for the protection of the environment, the health and safety of persons, the maintenance of national security and any measures required to implement international obligations to which Canada has agreed.

**Safety-related system(s)**
A system, including its components and structures that, by failing to perform in accordance with the design intent, has the potential to impact on the radiological safety of the public or plant staff. Safety-related systems are associated with:

(i) The regulation (including controlled startup and shutdown) and cooling of the reactor core under all normal operating and shutdown conditions;
(ii) The regulation, shutdown, and cooling of the reactor core under anticipated transient conditions and accident conditions, and the maintenance of the reactor core in a safe shutdown state for an extended period following such conditions; and
(iii) Limiting the release of radioactive material and the radiation exposure of plant staff and/or the public in accordance with the criteria established by the regulatory/licensing authority during and following normal, anticipated transient, and accident conditions.

[CSA standard N291-08, *Requirements for safety-related structures for CANDU nuclear power plants*]

**Safety significance**
Refers to the significance of a discovery/issue with respect to the impact on meeting the fundamental nuclear safety objectives as defined by the IAEA.

In general, a discovery/event has safety significance if it denotes a deviation away from the safety case accepted in the licence, in the direction detrimental to safety, such as:

- Reducing margins to, or exceeding the accepted limits;
- Increasing risk;
- Impairments (various degrees) of the special safety systems or of the safety functions for accident mitigation;
- Human factor issues; and
- Events causing radioactive releases and spills of hazardous substances, injuries to workers**,** public, etc.

[CNSC internal document, *Risk-Informing CNSC Planning, Licensing, and Compliance Activities*]

**Serious process failure**
Means a failure of a process system, a component or a structure that:

(i) Leads to a systematic fuel failure or to a significant release from the nuclear power plant, or
(ii) Could lead to a systematic fuel failure or a significant release in the absence of action by any special safety system.

[CNSC regulatory document REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*]

**Version-controlled documents**
Refers to documents which require a certain type of CNSC control and are captured in the Document Version Control subsection of the LCH. Such documents include regulatory/industry standards as referenced in the licence (may include regulatory/industry standards which require transition).

**Worker**
Any person adequately trained to work at the facility covered under the associated operating licence.

**Written notification**
A physical or electronic communication between a CNSC delegated authority and a person authorized to act on behalf of the licensee.

**Written notification prior to implementation**
CNSC must receive the WN for the proposed changes within a reasonable time (based on the extent of the proposed changes and the potential impact on safe operation of the facility) prior to the implementation. This will allow sufficient time for CNSC staff to review the submission and determine the acceptability.

# APPENDIX C – List of All Version-Controlled Documents

### C.1 – All Canadian Standards Association (CSA) documents referenced in the LCH

| Document # | Document Title | Version | L.C. | E-Doc # |
|---|---|---|---|---|
| N286 | Management system requirements for nuclear facilities | 2012 | 1.1<br>9.1 | 4021509 |
| N290.15 | Requirements for the safe operating envelope for nuclear power plants | 2010 | 3.1 | 4022031 |
| N286.7 | Quality assurance of analytical, scientific and design computer programs for nuclear power plants | 1999<br>reaffirmed 2012 | 4.1 | 4021695 |
| N291 | Requirements for safety related structures for CANDU nuclear power plants | 2008 | 5.1 | 4022067 |
| N290.0 | General requirements for safety systems of nuclear power plants | 2011 | 5.1 | 5049437 |
| N285.0 | General requirements for pressure-retaining systems and components in CANDU nuclear power plants | 2008<br>and<br>update no. 2 | 5.2 | 4021486 |
| N290.13 | Environmental qualification of equipment for CANDU nuclear power plants | 2005<br>and<br>update no. 1 | 5.3 | 4022005 |
| N289.1 | General requirements for seismic design and qualification of CANDU nuclear power plants | 2008 | 5.3 | 4021720 |
| N285.4 | Periodic inspection of CANDU nuclear power plant components | 2014<br>(2019†) | 6.1 | 4506027 |
| N285.5 | Periodic inspection of CANDU nuclear power plant containment components | 2008 and update no. 1 (January 2011)<br>2018** | 6.1 | 4021501 |
| N285.8 | Technical requirements for in-service inspection evaluation of zirconium alloy in pressure tubes in CANDU reactors | 2015 | 6.1 | |
| N287.7 | In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plant components | 2008 | 6.1 | 4021715 |
| N288.1 | Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities | 2008<br>and<br>update no. 1 | 9.1 | 4021717 |
| N288.4 | Environmental monitoring program at class I nuclear facilities and uranium mines and mills | 2010 | 9.1 | 4117824 |
| N288.5 | Effluent monitoring programs at class I nuclear facilities and uranium mines and mills | 2011 | 9.1 | 4021719 |
| N288.6 | Environmental risk assessments at class I nuclear facilities and uranium mines and mills | 2012 | 9.1 | 4117816 |
| N293 | Fire protection for CANDU nuclear power plants | 2012 | 10.2 | 4138035 |

| Document # | Document Title | Version | L.C. | E-Doc # |
|---|---|---|---|---|
| N292.3 | Management of low and intermediate-level radioactive waste | 2008 | 11.1 | 4022079 |
| N294 | Decommissioning of facilities containing nuclear substances | 2009 | 11.2 | 4022713 |
| N290.7 | Cyber security for nuclear power plants and small reactor facilities | 2014 | 12.1 | 4671282 |
| N288.3.4 | Performance Testing of Nuclear Air-Cleaning Systems at Nuclear Facilities | 2013 | 9.1 | 4961349 |
| N288.7 | Groundwater protection programs at Class I nuclear facilities and uranium mines and mills | 2015 | 9.1 | 4961360 |

*** Compliance with the 2018 edition of CSA N285.5 is only for the clauses specified under "CVC related to CSA N285.5" in this LCH.*
*† Compliance with the 2019 edition is only for the clauses specified under "CVC related to CSA N285.4" in this LCH.*

**C.2 – All Canadian Nuclear Safety Commission (CNSC) documents referenced in the LCH**

| Document # | Document Title | Version | L.C. | e-Doc # |
|---|---|---|---|---|
| REGDOC-2.1.2 | Safety Culture | 2018 | 1.1 | CNSC Website |
| N/A | CNSC Financial Security and ONFA Access Agreement and Provincial Guarantee Agreement, effective January 1, 2013 | 2013 | G.5 | 3501509 |
| REGDOC-3.2.1 | Public Information and Disclosure | 2018 | G.6 | CNSC Website |
| REGDOC-2.2.2 | Personnel Training | 2014 | 2.3 | CNSC Website |
| REGDOC-2.2.3 | Personnel Certification, Volume III: Certification of Persons Working at Nuclear Power Plants | 2019 | 2.3 | CNSC Website |
| REGDOC-2.2.4 | Fitness for Duty: Managing Worker Fatigue | 2017 | 2.1 | CNSC Website |
| REGDOC-2.2.4 | Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3 | 2021 | 2.1 | CNSC Website |
| REGDOC-2.2.4 | Fitness for Duty, Volume III Nuclear Security Officer Medical, Physical, Psychological Fitness | 2018 | 2.1<br>12.1 | CNSC Website |
| REGDOC-2.3.2 | Accident Management: Severe Accident Management Programs for Nuclear Reactors | 2013 | 3.1 | CNSC Website |
| REGDOC-3.1.1 | Reporting Requirements for Nuclear Power Plants | 2014 | 3.3 | CNSC Website |
| REGDOC-2.3.3 | Periodic Safety Reviews | 2015 | 3.4 | CNSC Website |
| REGDOC-2.4.1 | Deterministic Safety Analysis | 2014 | 4.1 | CNSC Website |
| REGDOC-2.4.2 | Probabilistic Safety Assessment (PSA) for Nuclear Power Plants | 2014 | 4.1 | CNSC Website |
| RD/GD-210 | Maintenance Programs for Nuclear Power Plants | 2012 | 6.1 | CNSC Website |
| RD/GD-98 | Reliability Programs for Nuclear Power Plants | 2012 | 6.1 | CNSC Website |
| REGDOC-2.6.1 | Reliability Programs for Nuclear Power Plants | 2017 | 6.1 | CNSC Website |
| REGDOC-2.6.2 | Maintenance Programs for Nuclear Power Plants | 2017 | 6.1 | CNSC Website |
| REGDOC-2.6.3 | Aging Management | 2014 | 6.1 | CNSC Website |
| REGDOC-2.9.1 | Environmental Protection: Environmental Principles, Assessments and Protection Measures | 2013 | 9.1 | CNSC Website |

| Document # | Document Title | Version | L.C. | e-Doc # |
|---|---|---|---|---|
| REGDOC-2.10.1 | Nuclear Emergency Preparedness and Response | 2014 | 10.1 | CNSC Website |
| REGDOC-2.12.1 | High Security Sites: Nuclear Response Force | 2013 | 12.1 | N/A |
| REGDOC-2.12.1 | **REGDOC-2.12.1, *High Security Facilities, Volume I: Nuclear Response Force*, Version 2** | 2018 | 12.1 | Document contains prescribed information |
| REGDOC-2.12.2 | Site Access Security Clearance | 2013 | 12.1 | CNSC Website |
| REGDOC-2.13.1 | Safeguards and Nuclear Material Accountancy | 2018 | 13.1 | CNSC Website |
| RD-363 | Nuclear Security Officer Medical, Physical and Psychological Fitness | 2008 | 12.1 | CNSC Website |
| RD-321 | Criteria for Physical Protection Systems and Devices at High Security Sites | 2010 | 12.1 | N/A |
| RD-361 | Criteria for Explosive Substance Detection, X-Ray Imaging and Metal Detection at High Security Sites. | 2010 | 12.1 | N/A |
| RD-336 | Accounting and Reporting of Nuclear Material | 2010 | 13.1 | CNSC Website |

# APPENDIX D – List of Licensee Documents that Require Notification of Change

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| **GENERAL** | | | |
| OPG-PROG-0001 | Information Management | When implemented | G.2<br>1.1 |
| NK38-SR-03500-10001 | Darlington NGS Safety Report:<br>Part 1 – Plant/Site Description | When implemented | G.3 |
| NK38-D0H-10220-1001 | Ontario Hydro layout drawing, Rev. 9, November 1981 | When implemented | G.3 |
| NK38-D0H-10220-1002 | Ontario Hydro layout drawing, Rev. 4, March 1982. | When implemented | G.3 |
| LO4254-DZS-10162-0531 | Darlington NGS-A Plant Survey June 7, 1999 | PRIOR to implementation | G.3 |
| N-STD-AS-0013 | Nuclear Public Information Disclosure | When implemented | G.6 |
| **MANAGEMENT SYSTEM** | | | |
| N-CHAR-AS-0002 | Nuclear Management System | PRIOR to implementation | 1.1 |
| N-PROG-AS-0001 | Nuclear Management System Administration | When implemented | 1.1 |
| OPG-PROG-0001 | Information Management | When implemented | 1.1<br>G.2 |
| OPG-PROG-0039 | Project Management Program | When implemented | 1.1 |
| OPG-STD-0140 | Managing Change | When implemented | 1.1 |
| N-STD-AS-0020 | Nuclear Management Systems Organization | When implemented | 1.1 |
| OPG-PROC-0166 | Organization Design Change | When implemented | 1.1 |
| N-POL-0001 | Nuclear Safety & Security Policy | When implemented | 1.1 |
| N-STD-AS-0023 | Nuclear Safety Oversight | When implemented | 1.1 |
| OPG-PROG-0010 | Health and Safety Management System Program | When implemented | 1.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| N-PROC-AS-0077 | Nuclear Safety & Security Culture Assessment | When implemented | 1.1 |
| N-PROG-RA-0010 | Independent Assessment | When implemented | 1.1 |
| N-GUID-09100-10000 | Contingency Guideline for Maintaining Staff in Key Positions When Normal Station Access is Impeded | When implemented | 1.1 |
| OPG-PROG-0033 | Business Continuity Program | When implemented | 1.1 |
| OPG-PROG-0009 | Items and Services Management | When implemented | 1.1 |
| **HUMAN PERFORMANCE MANAGEMENT** | | | |
| N-PROC-OP-0047 | Limits of Hours of Work | PRIOR to implementation | 2.1 |
| N-LIST-09110-10005 | Listing of Broad Population and Safety Sensitive Job Codes | PRIOR to implementation | 2.1 |
| N-PROG-AS-0002 | Human Performance | When implemented | 2.1 |
| N-STD-AS-0002 | Procedure Use and Adherence | When implemented | 2.1 |
| N-STD-OP-0002 | Communications | When implemented | 2.1 |
| N-STD-OP-0004 | Self-Check | When implemented | 2.1 |
| N-STD-OP-0012 | Conservative Decision Making | When implemented | 2.1 |
| N-STD-RA-0014 | Second Party Verification | When implemented | 2.1 |
| N-PROC-OP-0005 | Pre-Job Brief / Safe Work Plan and Post-Job Debriefing | When implemented | 2.1 |
| N-CMT-62808-00001 | Continuous Behaviour Observation Program (CBOP) – Participants Materials – Workbook Components | When implemented | 2.1 |
| N-TQD-601-00001 | Leadership and Management Training and Qualification Description | When implemented | 2.1 |
| D-PROC-OP-0009 | Station Shift Complement | PRIOR to implementation | 2.2 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| D-INS-09260-10001 | Duty Crew Minimum Complement Assurance | PRIOR to implementation | 2.2 |
| N-PROG-TR-0005 | Training | When implemented | 2.3 |
| N-PROC-TR-0008 | Systematic Approach to Training | When implemented | 2.3 |
| N-INS-08920-10004 | Written and Oral Initial Certification Examination for Shift Personnel | PRIOR to implementation | 2.3 |
| N-INS-08920-10002 | Simulator-Based Initial Certification Examinations for Shift Personnel | When implemented | 2.3 |
| N-INS-08920-10001 | Requalification Testing of Certified Shift Personnel | When implemented | 2.3 |
| N-MAN-08131-10000-CNSC-031 | Responsible Health Physicist | PRIOR to implementation | 2.3 |
| N-MAN-08131-10000-CNSC-006 | Shift Manager, Darlington Nuclear | PRIOR to implementation | 2.3 |
| N-MAN-08131-10000-CNSC-010 | Authorized Nuclear Operators | PRIOR to implementation | 2.3 |
| N-MAN-08131-10000-CNSC-008 | Control Room Shift Supervisor | PRIOR to implementation | 2.3 |
| N-MAN-08131-10000-CNSC-025 | Unit 0 Control Room Operator | PRIOR to implementation | 2.3 |
| **OPERATING PERFORMANCE** | | | |
| NK38-OPP-03600 | Darlington Nuclear Operating Policies and Principles | PRIOR to implementation | 3.1<br>15.1 |
| N-STD-MP-0016 | Safe Operating Envelope | PRIOR to implementation | 3.1 |
| N-STD-OP-0025 | Heat Sink Management | When implemented | 3.1 |
| N-STD-OP-0024 | Nuclear Safety Configuration Management | When implemented | 3.1 |
| N-PROG-OP-0001 | Conduct of Operations/Nuclear Operations | When implemented | 3.1 |
| N-PROG-OP-0004 | Chemistry | When implemented | 3.1 |
| N-STD-OP-0012 | Conservative Decision-Making | When implemented | 3.1 |
| N-STD-OP-0036 | Operational Decision Making | When implemented | 3.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| N-STD-MP-0019 | Beyond Design Basis Accident Management | When implemented | 3.1<br>4.1 |
| N-STD-OP-0011 | Operations Performance Monitoring | When implemented | 3.1 |
| N-PROC-RA-0035 | Operating Experience Process | When implemented | 3.1 |
| N-PROC-RA-0022 | Processing Station Conditions Records | When implemented | 3.1 |
| N-PROG-RA-0003 | Performance Improvement | When implemented | 3.1 |
| N-STD-OP-0017 | Response to Transients | When implemented | 3.1<br>3.2 |
| N-PROG-MP-0014 | Reactor Safety Program | When implemented | 3.1<br>3.2<br>4.1 |
| N-STD-OP-0009 | Reactivity Management | When implemented | 3.1 |
| N-STD-OP-0021 | Control of Fuelling Operations | When implemented | 3.1 |
| N-PROG-MP-0014 | Reactor Safety Program | When implemented | 3.2<br>3.1 |
| N-STD-OP-0017 | Response to Transients | When implemented | 3.2<br>3.1 |
| N-PROC-RA-0005 | Written Reporting to Regulatory Agencies | When implemented | 3.3 |
| N-PROC-RA-0020 | Preliminary Event Notifications | When implemented | 3.3 |
| **SAFETY ANALYSIS** | | | |
| NK38-SR-03500-10001 | Darlington NGS Safety Report: Part 2 – System Descriptions | When implemented | 4.1 |
| NK38-SR-03500-10002 | DN 1-4 Safety Report: Part 3- Accident Analysis | When implemented | 4.1 |
| NK38-REP-00531.7-10001 | Darlington Analysis of Record | When implemented | 4.1 |
| N-STD-MP-0019 | Beyond Design Basis Accident Management | When implemented | 4.1<br>3.1 |
| N-PROG-MP-0014 | Reactor Safety Program | When implemented | 4.1<br>3.1<br>3.2 |
| N-PROC-MP-0086 | Safety Analysis Basis and Safety Report | When implemented | 4.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| N-PROG-RA-0016 | Risk and Reliability Program | When implemented | 4.1<br>6.1 |
| N-STD-RA-0034 | Preparation, Maintenance and Application of Probabilistic Safety Assessment | When implemented | 4.1 |
| N-PROG-MP-0006 | Software | When implemented | 4.1 |
| NK38-REP-09701-10344 | RWPB Safety Analysis Summary Report | PRIOR to implementation | 4.1<br>11.1 |
| NK38-REP-09701-10326 | Darlington Retube Waste Processing Building -Safety Assessment | PRIOR to implementation | 4.1<br>11.1 |
| NK38-CORR-09701-0597849 | RWPB Worker Dose During Normal Operation and Under Accident Conditions | PRIOR to implementation | 4.1<br>11.1 |
| **PHYSICAL DESIGN** | | | |
| N-STD-MP-0028 | Conduct of Engineering | When implemented | 5.1 |
| N-PROG-MP-0001 | Engineering Change Control | When implemented | 5.1 |
| N-STD-MP-0027 | Configuration Management | When implemented | 5.1 |
| N-PROG-MP-0009 | Design Management | When implemented | 5.1 |
| N-PROG-MA-0016 | Fuel | When implemented | 5.1 |
| N-INS-08173-10050 | Procurement from Licensed Canadian Nuclear Utilities | When implemented | 5.1 |
| N-PROC-MP-0090 | Engineering Change Control Process | PRIOR to implementation | 5.1<br>15.2 |
| N-PROG-MP-0004 | Pressure Boundary Program | PRIOR to implementation | 5.2 |
| N-PROC-MP-0040 | System and Item Classification | PRIOR to implementation | 5.2 |
| N-PROC-MP-0082 | Design Registration | PRIOR to implementation | 5.2 |
| N-MAN-01913.11-10000 | Pressure Boundary Program Manual | When implemented | 5.2 |
| N-LIST-00531-10003 | Index to OPG Pressure Boundary Program Elements | When implemented | 5.2 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| N-CORR-00531-19076 | Authorized Inspection Agency for Pressure Boundary Inspection and Registration Services | PRIOR to implementation | 5.2 |
| N-PROG-RA-0006 | Environmental Qualification | When implemented | 5.3 |
| | **FITNESS FOR SERVICE** | | |
| N-PROG-MA-0004 | Conduct of Maintenance | When implemented | 6.1 |
| N-PROG-MA-0017 | Component and Equipment Surveillance | When implemented | 6.1 |
| N-PROG-MA-0019 | Production Work Management | When implemented | 6.1 |
| N-PROG-MP-0008 | Integrated Aging Management | When implemented | 6.1 |
| N-PROC-MA-0013 | Planned Outage Management | When implemented | 6.1 |
| N-PROC-MA-0049 | Forced Outage Management | When implemented | 6.1 |
| N-PROG-MA-0026 | Equipment Reliability | When implemented | 6.1 |
| N-PROG-RA-0016 | Risk and Reliability Program | When implemented | 6.1<br>4.1 |
| N-STD-RA-0033 | Reliability and Monitoring of Systems Important to Safety | When implemented | 6.1 |
| NK38-LIST-06937-10001 | List of Safety Related Systems and Functions | PRIOR to implementation | 6.1 |
| N-PROG-MA-0025 | Major Components | When implemented | 6.1 |
| N-PLAN-01060-10001 | Feeders Life Cycle Management Plan | PRIOR to implementation** | 6.1 |
| NK38-PIP-33160-10001 | Darlington Nuclear Unit 1 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |
| NK38-PIP-33160-10002 | Darlington Nuclear Unit 2 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |
| NK38-PIP-33160-10003 | Darlington Nuclear Unit 3 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| NK38-PIP-33160-10004 | Darlington Nuclear Unit 4 Fuel Channel Feeder Pipes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |
| N-PLAN-33110-10009 | Steam Generators Life Cycle Management Plan | PRIOR to implementation** | 6.1 |
| NK38-PLAN-33110-00001 | Darlington Units 1-4 Steam Generator Life Cycle Management Plan | PRIOR to implementation** | 6.1 |
| N-PLAN-01060-10002 | Fuel Channels Life Cycle Management Plan | PRIOR to implementation** | 6.1 |
| NK38-PIP-31100-10001 | Darlington Nuclear 1-4, Unit 1 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |
| NK38-PIP-31100-10002 | Darlington Nuclear 1-4, Unit 2 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |
| NK38-PIP-31100-10003 | Darlington Nuclear 1-4, Unit 3 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |
| NK38-PIP-31100-10004 | Darlington Nuclear 1-4, Unit 4 Fuel Channel Pressure Tubes Periodic Inspection Program Plan | PRIOR to implementation | 6.1 |
| N-PLAN-01060-10003 | Reactor Components and Structures Life Cycle Management Plan | PRIOR to implementation | 6.1 |
| NK38-PLAN-31160-10000 | Long Term Darlington Life Management Plan for Inconel X-750 Spacers | PRIOR to implementation | 6.1 |
| NK38-PIP-03641.2-10001 | Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 1 | PRIOR to implementation | 6.1 |
| NK38-PIP-03641.2-10002 | Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 2 | PRIOR to implementation | 6.1 |
| NK38-PIP-03641.2-10003 | Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 3 | PRIOR to implementation | 6.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| NK38-PIP-03641.2-10004 | Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 4 | PRIOR to implementation | 6.1 |
| NK38-PIP-03642.2-10001 | Darlington Nuclear Generating Station - Periodic Inspection Program for Unit 0 and Units 1 to 4 Containment Components | PRIOR to implementation | 6.1 |
| NK38-PIP-03643.2-10002 | Darlington Nuclear - Unit 0 Containment Periodic Inspection Program | PRIOR to implementation | 6.1 |
| N-PLAN-01060-10004 | Aging Management Plan for Containment Structures | PRIOR to implementation | 6.1 |
| NK38-PIP-03643.2-10001 | Darlington Nuclear – Reactor Building Periodic Inspection Program | PRIOR to implementation | 6.1 |
| NK38-PIP-03643.2-10003 | Darlington Nuclear - Vacuum Building Periodic Inspection Program | PRIOR to implementation | 6.1 |
| NK38-TS-03643-10001 | Inspection of Post Tensioning Tendons on DNGS Vacuum Building | PRIOR to implementation | 6.1 |
| N-PROC-MA-0066 | Administrative Requirements for In-Service Examination and Testing for Concrete Containment Structures | PRIOR to implementation | 6.1 |
| NK38-PLAN-01060-10010 | Aging Management Plan for Darlington NGS Non-Containment Building Structures | PRIOR to implementation | 6.1 |
| NK38-REP-34200-10066 | Darlington NGS Main Containment Structure In-Service Leakage Rate Test Requirements In Accordance With CSA N287.7-08 | PRIOR to implementation | 6.1 |
| NK38-REP-26100-10005 | Darlington NGS Vacuum Structure In-Service Leakage Rate Test Requirements In Accordance With CSA N287.7-08 | PRIOR to implementation | 6.1 |
| **RADIATION PROTECTION** | | | |
| N-PROG-RA-0013 | Radiation Protection | PRIOR to implementation | 7.1<br>15.5 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| N-STD-RA-0018 | Controlling Exposure As Low As Reasonably Achievable | When implemented | 7.1 |
| N-REP-03420-10001 | Occupational Radiation Protection Action Levels for Power Reactor Operating Licenses | PRIOR to implementation | 7.1 |
| N-PROC-RA-0019 | Dose Limits and Exposure Control | PRIOR to implementation | 7.1 |
| N-PROC-RA-0027 | Radioactive Work Planning, Execution and Close Out | When implemented | 7.1 |
| N-MAN-03416-10000 | Radiation Dosimetry Program – General Requirements | When implemented | 7.1 |
| N-MAN-03416.1-10000 | Radiation Dosimetry Program – External Dosimetry | When implemented | 7.1 |
| N-MAN-03416.2-10000 | Radiation Dosimetry Program – Internal Dosimetry | When implemented | 7.1 |
| OPG-PROC-0132 | Respiratory Protection | When implemented | 7.1 |
| **CONVENTIONAL HEALTH AND SAFETY** | | | |
| N-PROG-MA-0015 | Work Protection | When implemented | 8.1 |
| OPG-POL-0001 | Health and Safety Policy | When implemented | 8.1 |
| OPG-PROG-0010 | Health and Safety Management System Program | When implemented | 8.1 |
| OPG-PROC-0132 | Respiratory Protection | When implemented | 8.1 |
| N-PROG-RA-0012 | Fire Protection | PRIOR to implementation | 8.1<br>10.2 |
| NK-38-LIST-78000-10001 | Application of CSA N293-7 to Structures, System and Components for Darlington Nuclear | When implemented | 8.1 |
| **ENVIRONMENTAL PROTECTION** | | | |
| OPG-POL-0021 | Environmental Policy | When implemented | 9.1 |
| OPG-PROG-0005 | Environmental Management System | When implemented | 9.1<br>11.1 |
| NK38-MAN-03480-10001 | Environment Manual | When implemented | 9.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| N-PROC-OP-0025 | Environmental Monitoring Programs | When implemented | 9.1 |
| OPG-PROC-0126 | Hazardous Material Management | When implemented | 9.1 |
| N-STD-OP-0031 | Monitoring of Nuclear and Hazardous Substances in Effluents | When implemented | 9.1 |
| N-PROC-OP-0044 | Contaminated Lands and Groundwater Management | When implemented | 9.1 |
| NK38-REP-03482-10001 | Derived Release Limits and Environmental Action Levels for Darlington Nuclear Generating Station | PRIOR to implementation | 9.1 |
| N-PROC-OP-0037 | Environmental Approvals | When implemented | 9.1 |
| N-PROC-OP-0038 | Abnormal Waterborne Tritium Emission Response | When implemented | 9.1 |
| NK38-MAN-03443-10002 | Darlington Environmental Monitoring Program | When implemented | 9.1 |
| NK38-REP-07701-00001-R001 | Darlington Nuclear Environmental Risk Assessment | When implemented | 9.1 |
| **EMERGENCY MANAGEMENT AND FIRE PROTECTION** | | | |
| N-PROG-RA-0001 | Consolidated Nuclear Emergency Plan | PRIOR to implementation | 10.1 |
| N-PROC-RA-0045 | Emergency Preparedness Drills and Exercises | When implemented | 10.1 |
| N-PROG-RA-0012 | Fire Protection | PRIOR to implementation | 10.2<br>8.1 |
| NK38-REP-09701-10338 | Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB) | PRIOR to implementation | 10.2<br>11.1 |
| **WASTE MANAGEMENT** | | | |
| OPG-PROG-0005 | Environmental Management System | When implemented | 11.1<br>9.1 |
| N-PROC-OP-0043 | Waste Management | When implemented | 11.1 |
| N-PROC-RA-0017 | Segregation and Handling of Radioactive Wastes | When implemented | 11.1 |
| NK38-PLAN-09701-10293 | Operations & Maintenance Plan - Retube Waste Processing Building | PRIOR to implementation | 11.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| NK38-REP-09701-10344 | RWPB Safety Analysis Summary Report | PRIOR to implementation | 11.1<br>4.1 |
| NK38-REP-09701-10326 | Darlington Retube Waste Processing Building -Safety Assessment | PRIOR to implementation | 11.1<br>4.1 |
| NK38-CORR-09701-0597849 | RWPB Worker Dose During Normal Operation and Under Accident Conditions | PRIOR to implementation | 11.1<br>4.1 |
| NK38-REP-09701-10338 | Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB) | PRIOR to implementation | 11.1<br>10.2 |
| W-PROG-WM-0003 | Decommissioning Program | PRIOR to implementation | 11.2 |
| NK38-PLAN-00960-10001 | Preliminary Decommissioning Plan - Darlington Nuclear Generating Station | PRIOR to implementation | 11.2 |
| **SECURITY** | | | |
| 8300-REP-61400-10003 | Darlington Nuclear Generating Station Security Report | PRIOR to implementation | 12.1 |
| N-PROG-RA-0011 | Nuclear Security | PRIOR to implementation | 12.1 |
| TRAN-PLAN-03450-10000 | Transport Security Plan | When implemented | 12.1 |
| NK38-REP-08160.3-00001 | Threat and Risk Assessment | When implemented | 12.1 |
| N-PROC-RA-0135 | Cyber Security | When implemented | 12.1 |
| N-STI-08161-10017 | Cyber Essential Asset Identification and Classification | When implemented | 12.1 |
| N-INS-08161-10011 | Cyber Security Controls for Cyber Essential Assets | When implemented | 12.1 |
| NK38-LIST-69000-10001 | Significant Cyber Assets | When implemented | 12.1 |
| **SAFEGUARDS** | | | |
| N-PROG-RA-0015 | Nuclear Safeguards | PRIOR to implementation | 13.1 |
| N-STD-RA-0024 | Nuclear Safeguards Implementation | PRIOR to implementation | 13.1 |
| N-PROC-RA-0136 | OPG Safeguards and Nuclear Material Accountancy Requirements | When implemented | 13.1 |

| Document # | Document Title | Notification Requirements | L.C. |
|---|---|---|---|
| **PACKAGING AND TRANSPORT** | | | |
| W-PROG-WM-0002 | Radioactive Material Transportation | When implemented | 14.1<br>15.5 |
| N-STD-RA-0036 | Radioactive Materials Transportation Emergency Response Plan | When implemented | 14.1 |
| **SITE SPECIFIC** | | | |
| NK38-OPP-03600 | Darlington Nuclear Operating Policies and Principles | PRIOR to implementation | 15.1<br>3.1 |
| D-INS-39000-10003 | TRF Planned Outage Management | When implemented | 15.1 |
| N-PROG-AS-0008 | Heavy Water Management Plan | When implemented | 15.1 |
| NK38-NR-PLAN-09701-10001, Sheet: 0003 | Darlington Refurbishment Return to Service Program Management Plan | When implemented | 15.2 |
| N-PROC-MP-0090 | Engineering Change Control Process | PRIOR to implementation | 15.2<br>5.1 |
| N-INS-03680-10001 | Darlington NGS Integrated Implementation Plan (IIP) Change Control and Closeout Process | When implemented | 15.3 |
| NK38-INS-09701-10006 | Nuclear Refurbishment Unit Readiness for Service | PRIOR to implementation | 15.4 |
| W-PROG-WM-0002 | Radioactive Material Transportation | When implemented | 15.5<br>14.1 |
| N-PROG-RA-0013 | Radiation Protection | PRIOR to implementation | 15.5<br>7.1 |

**Should a document listed as a WN document within this LCH also require submission for approval/acceptance per a standard referenced in the associated Nuclear Power Reactor Operating Licence (PROL), the licensee shall submit that document for approval/acceptance to comply with the governing standard and the associated LC.*
***Prior notification is only required when changes to the document result in changes to the PIP that has received regulatory acceptance.*

# APPENDIX E – List of Documents used as Guidance or Criteria

### E.1 – Other Codes or Standards referenced in the LCH

| Document # | Document Title | L.C. | e-Doc # |
|---|---|---|---|
| CSA N290.11 | Requirements for heat sink removal capability during outage of nuclear power plants | 3.1 | 4345687 |
| COG-13-9035-R00 | Derived Acceptance Criteria for Deterministic Safety Analysis | 4.1 | 4982290 |
| COG-09-9030-R02 | Principles & Guidelines for Deterministic Safety Analysis | 4.1 | 4398701 |
| COG-11-9023-R00 | Guidelines for Application of the Limit of Operating Envelope Methodology to Deterministic Safety Analysis | 4.1 | 3966049 |
| COG-06-9012-R01 | Guidelines for Application of the Best Estimate Analysis and Uncertainty (BEAU) Methodology to Licensing Analysis | 4.1 | 3367467 |
| COG-08-2078-R00 | Principles and Guidelines for NOP/ROP Trip Setpoint Analysis for CANDU Reactors | 4.1 | 4251741 |
| CSA N287.1 | General requirements for concrete containment structures for CANDU nuclear power plants | 5.1 | 4021701 |
| CSA N287.2 | Material requirements for concrete containment structures for CANDU nuclear power plants | 5.1 | 4021702 |
| CSA N287.3 | Design requirements for concrete containment structures for CANDU nuclear power plants | 5.1 | 4477203 |
| CSA N287.4 | Construction, fabrication, and installation requirements for concrete containment structures for CANDU nuclear power plants | 5.1 | 4021708 |
| CSA N287.5 | Examination and testing requirements for concrete containment structures for CANDU nuclear power plants | 5.1 | 4021711 |
| CSA N287.6 | Re-operational proof and leakage rate testing requirements for concrete containment structures for CANDU nuclear power plants | 5.1 | 4021713 |
| CSA N289.2 | Ground motion determination for seismic qualification of CANDU nuclear power plants | 5.1<br>5.2<br>5.3 | 4021722 |
| CSA N289.3 | Design procedures for seismic qualification of CANDU nuclear power plants | 5.1<br>5.2<br>5.3 | 4021725 |
| CSA N289.4 | Testing procedures for seismic qualification of CANDU nuclear power plants | 5.1<br>5.2<br>5.3 | 4021728 |
| CSA N289.5 | Seismic instrumentation requirements for CANDU nuclear power plants | 5.1<br>5.2<br>5.3 | 4021978 |

| Document # | Document Title | L.C. | e-Doc # |
|---|---|---|---|
| CSA N290.1 | Requirements for the shutdown systems of nuclear power plants | 5.1 | 4021894 |
| CSA N290.2 | General requirements for emergency core cooling systems for nuclear power plants | 5.1 | 4477280 |
| CSA N290.3 | Requirements for containment system of nuclear power plants | 5.1 | 4021988 |
| CSA N290.4 | Requirements for reactor control systems of nuclear power plants | 5.1 | 4022038 |
| CSA N290.5 | Requirements for electrical power and instrument air systems of CANDU nuclear power plants | 5.1 | 4102370 |
| CSA N290.6 | Requirements for monitoring and display of nuclear power plant safety functions in the event of an accident | 5.1 | 4022059 |
| CSA N290.14 | Qualification of pre-developed software | 5.1 | 4022010 |
| UFC 3-340-02 | Structures to Resist the Effects of Accidental Explosions | 5.1 | N/A |
| CSA N290.12 | Human factors in design for nuclear power plants | 5.1 | 4671284 |
| ASME B31.1 | Power Piping | 5.2 | N/A |
| ASME B31.3 | Process Piping Code | 5.2 | N/A |
| ASME B31.5 | Refrigeration Piping and Heat Transfer Component Code | 5.2 | N/A |
| ASME | Boiler and Pressure Vessel Code | 5.2<br>6.1 | N/A |
| CSA B51 | Boiler, Pressure Vessel and Piping | 5.2 | N/A |
| NFPA 20 | Standard for the Installation of Stationary Pumps for Fire Protection | 5.2 | N/A |
| NFPA 24 | Standard for the Installation of Private Fire Service Mains and Their Appurtenances | 5.2 | N/A |
| CSA N285.6 Series | General requirements for pressure-retaining systems and components in CANDU nuclear power plants/material standards for reactor components for CANDU nuclear power plants | 5.2 | 4021486 |
| CSA N288.2 | Guidelines for Calculating the Radiological Consequences to the Public of a Release of Airborne Radioactive Material for Nuclear Reactor Accidents | 9.1 | 4961342 |
| CSA N288.8 | Establishing and implementing action levels for releases to the environment from nuclear facilities | 9.1 | 5204135 |
| COG-JP-4107-V06-R03 | Fitness-for-Service Guidelines (FFSG) for Feeders in CANDU Reactors | 6.1 | 3926409 |
| COG-07-4089-R02 | Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes | 6.1 | N/A |
| COG-JP-4107-V06-R03 | Fitness-for-Service Guidelines (FFSG) for Feeders in CANDU Reactors | 6.1 | N/A |
| COG-07-4089–R02 | Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes | 6.1 | N/A |
| NEI 00-01 | Guidance for Post Fire Safe Shutdown Circuit Analysis | 10.2 | N/A |

| Document # | Document Title | L.C. | e-Doc # |
|---|---|---|---|
| CSA N292.2 | Interim dry storage of irradiated fuel | 11.1 | 4413183 |
| IAEA | Nuclear Security Series No. 4, Technical Guidance: Engineering Safety Aspects of the Protection of Nuclear Power Plants Against Sabotage | 12.1 | IAEA Website |
| IAEA | Nuclear Security Series No. 13, Recommendations: Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5) | 12.1 | IAEA Website |
| IAEA | Nuclear Security Series No. 17, Technical Guidance: Computer Security at Nuclear Facilities | 12.1 | IAEA Website |

**E.2 – Other CNSC documents referenced in the LCH**

| Document # | Document Title | L.C. | e-Doc # |
|---|---|---|---|
| REGDOC-3.5.3 | Regulatory Fundamentals (2018) | G.1 | CNSC Website |
| G-206 | Financial Guarantees for the Decommissioning of Licensed Activities | G.5<br>11.2 | CNSC Website |
| REGDOC-2.1.1 | Management System | 1.1 | CNSC Website |
| REGDOC-2.2.1 | Human Factors | 2.1 | CNSC Website |
| REGDOC-2.2.4 | Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical and Psychological Fitness | 2.1 | CNSC Website |
| REGDOC-2.5.1 | General Design Considerations: Human Factors | 2.1<br>5.1<br>B.2 | CNSC Website |
| REGDOC-2.2.5 | Minimum Shift Compliment | 2.2 | CNSC Website |
| REGDOC-2.2.3 | Personnel Certification Volume III: Certification of Persons Working at Nuclear Power Plants | 2.3 | CNSC Website |
| CNSC-EG1, Rev.0 | Requirements and Guidelines for Written and Oral Certification Examinations for Shift Personnel at Nuclear Power Plants | 2.3 | 3402702 |
| CNSC-EG2, Rev.0 | Requirements and Guidelines for Simulator-Based Certification Examinations for Shift Personnel at Nuclear Power Plants | 2.3 | 3402705 |
| N/A | Requirements for the Requalification Testing of Certified Shift Personnel at Nuclear Power Plants, Revision 2 | 2.3 | 3436327 |
| REGDOC-2.3.2 (2014) | Accident Management | 3.1 | CNSC Website |
| N/A | Interpretation of REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants | 3.3 | 4525925 |
| RD-360 | Life Extension of Nuclear Power Plants | 3.4<br>15.4<br>B.2 | CNSC Website |
| REGDOC-1.1.3 | Licence Application Guide: Licence to Operate a Nuclear Power Plant | 3.4 | CNSC Website |
| REGDOC-2.5.2 | Design of Reactor Facilities: Nuclear Power Plants | 5.1 | CNSC Website |
| REGDOC-2.8.1 | Conventional Health and Safety | 8.1 | CNSC Website |
| G-129 | Keeping Radiation Exposures and Doses “As Low As Reasonably Achievable (ALARA)” | 7.1 | CNSC Website |

| Document # | Document Title | L.C. | e-Doc # |
|---|---|---|---|
| G-228 | Developing and Using Action Levels | 7.1<br>9.1 | CNSC Website |
| P-223 | Protection of the Environment | 9.1 | CNSC Website |
| G-219 | Decommissioning Planning for Licensed Activities | 11.2 | CNSC Website |
| REGDOC-2.12.1 | High Security Facilities, Volume I: Nuclear Response Force | 12.1 | CNSC Website |
| REGDOC-2.12.3 | Security of Nuclear Substances: Sealed Sources | 12.1 | CNSC Website |
| G-274 | Security Programs for Category I or II Nuclear Material or Certain Nuclear Facilities | 12.1 | CNSC Website |
| G-208 | Transportation Security Plans for Category I, II or III Nuclear Material | 12.1 | CNSC Website |
| REGDOC-2.3.1 | Conduct of Licensed Activities: Construction and Commissioning Programs | 15.2 | CNSC Website |
| P-299 | Regulatory Fundamentals | A.2 | CNSC Website |
| P-242 | Considering Cost-benefit Information | A.2 | CNSC Website |
| N/A | Risk Informed Approach for the CNSC Power Reactor Regulatory Program – Basis Document | A.2 | 3466324 |
| RD-310 | Safety Analysis for Nuclear Power Plants | B.2 | CNSC Website |
| N/A | Select and Apply Enforcement Tools | B.2 | 3320246 |
| S-294 | Probabilistic Safety Assessment (PSA) for Nuclear Power Plants | B.2 | CNSC Website |
| N/A | Risk-Informing CNSC Planning, Licensing and Compliance Activities | B.2 | N/A |

# APPENDIX F – Approvals pursuant to a PROL LC granted by the Commission

| L.C | Subject of the Approval | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
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# APPENDIX G – Consents pursuant to a PROL LC

| L.C | Subject of the Consent | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
|---|---|---|---|---|---|
| 2.3 | Initial general written certification examinations | 6352433 | NK38-CORR-00531-21655 | 2020-08-04 | N/A |
| 3.1 | Implementation of Rod-Based Guaranteed Shutdown State | 4192803 | NK38-CORR-00531-16479 | 2013-09-06 | N/A |
| 3.1 | Concurrence to Extend the Applicability of Rod-Based Guaranteed Shutdown State to Outages up to 375 Days in Duration | 5979625 | NK38-CORR-00531-21056 | 2019-08-28 | N/A |
| 4.1 | Request to Load Modified 37 Element Fuel Bundles for Demonstration Irradiation | 3538424 | NK38-CORR-00531-15080 | 2010-05-04 | N/A |
| 4.1 | Darlington NGS - Request for a Licence Amendment to Darlington PROL 13.00/2015 to Implement New Regulatory Documents REGDOC-2.4.1 and REGDOC-2.4.2 | 4572122 | NK38-CORR-00531-17057 | 2015-01-01 | N/A |
| 4.1 | Darlington NGS - Additional Information to Support Darlington Request for Licence Amendment to Incorporate REGDOC- 2.4.2 on Probabilistic Safety Assessment | 4596974 | NK38-CORR-00531-17143 | 2015-01-01 | N/A |
| 5.1 | Concurrence to Use the Municipality of Clarington as the AHJ to Process and Approve Building Permits for Future Modifications for the OSB | 4018888 | NK38-CORR-00531-16233 | 2013-02-13 | N/A |
| 5.1 | Approval for Full Core Implementation of Modified 37 Element Fuel Bundles | 3945360 | NK38-CORR-00531-15967 | Upon completion of OPG EC activities | N/A |
| 5.1<br>5.3 | Design Codes and Standards Effective Dates for OPG Nuclear Fleet | 3947068 | N-CORR-00531-05758 | Refurb. design 2012-06-22<br>Other design 2013-10-31 | 2024-12-31 |
| 5.1<br>5.3 | Design Codes and Standards Effective Dates for OPG Nuclear Fleet - Clarification | 4058619 | N-CORR-00531-05995 | Refurb. design 2012-06-22<br>Other design 2013-10-31 | 2024-12-31 |

| L.C | Subject of the Consent | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
|---|---|---|---|---|---|
| 5.2 | Temporary Leak Suppression | 982959 | NK38-CORR-00531-12896 | 2005-08-24 | N/A |
| 5.2 | CNSC Agreement for Use of Class 6 Valves for Repair and Replacement in Instrument Lines – Darlington, Pickering NGS-A and Pickering NGS-B | 4027215 | N-CORR-00531-05935 | 2010-07-30 | N/A |
| 5.2 | Units 1-4: Request for Generic Ice Plug Approval | 983146 | NK38-CORR-00531-13572 | 2007-02-23 | N/A |
| 5.2 | CNSC Approval for a Variance to Table 3 of CSA Standard N285.0-08 | 3560743 | N-CORR-00531-04928 | 2010-06-30<br>2010-06-03 | N/A |
| 5.2 | Approval of a Variance to ASME B31.1 Para. 104.1.2 (C.3) – Copper Tubing | 3693058 | N-CORR-00531-05256 | 2011-03-18 | N/A |
| 5.2 | for Acceptance of Legacy Pressure Boundary (PB) Systems' List – Class 6 | 3796306 | N-CORR-00531-05427 | 2011-09-13 | N/A |
| 5.2 | Concurrence to Complete Installation and Commissioning of Primary Heat Transport System Liquid Relief Valves (LRV) in Refurbishment Outages | 3737115 | NK38-CORR-00531-15651 | 2011-08-17 | Last unit refurbishment outage 2021 |
| 5.2 | Federal/Provincial Requirements Applicable to Operations Support Building | 1017001 | NK38-CORR-00531-12379 | 2004-07-11 | N/A |
| 5.2 | CNSC Acceptance of Transition Plan for Repair/Replacement Process for Pressure Boundary Legacy Systems | 4067642 | N-CORR-00531-06072 | 2012-12-15 | N/A |
| 5.2 | Concession Request to use ASME BPVC SEC IIII and section XI APPL L Methodology for the LRV replacement Project | 3954028 | NK38-CORR-00531-15982 | 2012-06-15 | N/A |
| 5.2 | Request to Reinstate the agreement for Welded Joints in Small Diameter Tubing | 4108186 | N-CORR-00531-06102 | 2013-03-20 | N/A |
| 5.2 | CNSC Acceptance of Process for Submission of Variances for Replacement of Non-Registered Items in Pressure Boundary Legacy Systems | 4123087 | N-CORR-00531-06139 | 2013-04-23 | N/A |
| 5.2 | CNSC Acceptance for OPG Use of ASME OM Code Case OMN-20 | 4213198 | N-CORR-00531-06315 | 2013-10-09 | N/A |

| L.C | Subject of the Consent | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
|---|---|---|---|---|---|
| 5.2 | CNSC acceptance for OPG to use a variance to CSA N285.0-08 and Update No 2 clause 3 and clause 14.2.7 to perform external weld overlay repairs | 5635890 | N-CORR-00531-19208 | 2018-10-01 | N/A |
| 6.1 | OPG Compliance with CSA Standard N285.4 – Periodic Inspection of CANDU Nuclear Power Plant Components – Request for Acceptance of Alternative Requirements | 6067846 | N-CORR-00531-20029 | 2019-12-13 | N/A |
| 6.1 | Summary Record of Proceedings and Decision - Darlington Licence Renewal 2015 | 4908897 | | 2015-12-23 | N/A |
| 6.1 | Darlington and Pickering NGS – Uncertainty Analysis to the Cohesive-Zone Fracture Toughness Model for CANDU Pressure Tubes | 6366701 | N-CORR-00531-22348 | 2020-09-17 | N/A |
| 6.1 | Pickering and Darlington NGS – Response to OPG's Closure Request of the Probabilistic Core Assessment (PCA) Flaw Removal Issue | 6415008 | N-CORR-00531-22440 | 2020-11-13 | N/A |
| 6.1 | Darlington NGS - Request for CNSC Staffs Acceptance of Revised Periodic Inspection Program Plans for Major Components and Plant Components - CSA N285.4-14 | 5853238 | | 2019-03-21 | N/A |
| 6.1 | Pickering and Darlington NGS - Revised CSA N285.8 Compliance Plan | 6441842 | | 2020-12-15 | N/A |
| 6.1 | Darlington and Pickering NGS – CNSC Staff Acceptance to Extend Use of the Two-Tiered Approach for HROL Evaluation | 6555785 | N-CORR-00531-22693 | 2021-05-07 | 2022-08-31 |
| 6.1 | Updated Acceptance Criteria and Evaluation Procedures for Material Surveillance Pressure Tube - Action Item 20101306, Item No. 4 | 3895468 | | 2012-03-16 | N/A |

| L.C | Subject of the Consent | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
|---|---|---|---|---|---|
| 6.1 | Darlington and Pickering NGS - Extension of the Acceptance Criterion for Method 1 Probabilistic Leak-Before-Break, closure of Action Item 2015-OPG-7000 | 5421207 | | 2019-02-06 | 2021-02-28 |
| 6.1 | Pickering and Darlington NGS – CNSC staff Review of Interim Acceptance Criterion for Method 1 Probabilistic Leak-Before-Break | 6543544 | N-CORR-00531-22678 | 2021-04-27 | N/A |
| 6.1 | Darlington and Pickering NGS – CNSC Conditional Acceptance of OPG Proposed Probabilistic Fracture Protection Acceptance Criteria | 6264964 | N-CORR-00531-20176 | 2020-04-09 | 2021-12-31 |
| 6.1 | Darlington NGS - CNSC Staff's Acceptance of Spacer Location Inspection Results, PT-CT Gap Results, and Degradation Assessment Results Associated with the Long Term Darlington Life Management Plan for Inconel X-750 Spacers | 6270657 | | 2020-04-01 | N/A |
| 6.1 | Darlington NGS 'A' – Request for CNSC Acceptance of the DNGS Outlet Feeder Dissimilar Metal Weld Leak-Before-Break Assessment | 3689595 | NK38-CORR-00531-15466 | 2011-03-11 | N/A |
| 6.1 | Submission of Fitness-for-Service Guidelines tor Feeders in CANDU Reactors COG-JP-4107-V06 Revision 03 | 3922168 | N-CORR-00531-05590 | 2012-04-17 | N/A |
| 6.1 | Submission of Fitness-for-Service Guidelines for Feeders in CANDU Reactors COG-JP-4107-V06 Revision 03 | 4001054 | N-CORR-00531-05856 | 2012-09-10 | N/A |
| 6.1 | Darlington NGS and Pickering NGS Units 1 to 8: CNSC Conditional Acceptance of Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes | 4298097 | N-CORR-00531-06445 | 2014-01-30 | N/A |
| 6.1 | Vacuum Building Test and Inspection Frequency | 967920 | NK38-CORR-00531-11060 | 2002-03-22 | N/A |

| L.C | Subject of the Consent | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
|---|---|---|---|---|---|
| 6.1 | Darlington NGS – Request for Approval to Change the Main Containment System Positive Pressure Test Frequency | 4429280 | NK38-CORR-00531-16817 | 2014-05-05 | N/A |
| 6.1 | Darlington Feeder PIP, with an exemption from periodic inspection in place for outlet feeder dissimilar metal welds | 3689595 | NK38-CORR-00531-15466 | 2011-03-11 | N/A |
| 6.1 | OPG's request to use COG-JP-4107-V06 Rev. 03 "Fitness-for-Service Guidelines (FFSG) for Feeders in CANDU Reactors" | 4001054 | N-CORR-00531-05856 | 2012-09-10 | N/A |
| 6.1 | *CNSC staff acceptance of performance based disposition process*" for steam generator inspections and dispositions | 3615950 | N-CORR-00531-05174 | 2010-10-07 | N/A |
| 6.1 | CNSC staff acceptance of OPG's request to use COG Report 07-4089-R2 "*Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes, Section I: Evaluation Procedures and Acceptance Criteria*" | 5503070 | N-CORR-00531-18337 | 2018-04-11 | N/A |
| 6.1 | Deferral of repairs to Vacuum Building caulking until VBO | 4068270 | NK38-CORR-00531-16234 | 2013-02-11 | VBO/2015 |
| 6.1 | OPG Transition to 2008 Edition of CSA Standard N285.5 Update No.1 – Periodic Inspection of CANDU Nuclear Power Plant Containment Components | 4042937 | NK38-CORR-00531-16158 | 2012-11-22 | N/A |
| 6.1 | Acceptance of OPG's 287.7 PIP except for two areas: leakage rate testing of the concrete containment structures and inspection of the post tensioning system | 3745275 | NK38-CORR-00531-15603 | 2011-07-07 | N/A |
| 6.1 | Letter accepting OPG request to use a new approach for the evaluation of crevice corrosion flaws | 3915570 | N-CORR-00531-05660 | 2012-04-12 | N/A |
| 6.1 | Darlington NGS: Submission of Leakage Rate Testing Requirements and Post-tensioning System Inspection Documents | 4788314 | NK38-CORR-00531-17486 | 2015-07-23 | N/A |

| L.C | Subject of the Consent | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
|---|---|---|---|---|---|
| 10.2 | Request for Acceptance to change the inspection and testing frequency of Deluge and Turbine Generator sprinkler System Check | 3767391 | NK38-CORR-00531-15627 | 2011-07-28 | N/A |
| 10.2 | Concurrence to Fire Protection Acceptable Deviations and Alternate Compliances Related to the Refurbishment Integrated Safety Review (ISR) | 4806897 | N/A | 2015-07-28 | N/A |
| 10.2 | Consent for Alternate Compliance to Code-of-Records Deviations for Means of Egress | 4940772 | NK38-CORR-00531-17788 | 2016-02-18 | N/A |
| 10.2 | Consent for an Alternate Compliance to the Requirements of NBCC 2010 to Allow Occupancy of the Retube and Feeder Replacement Island Support Annex (RFRISA) | 4950896 | NK38-CORR-00531-17805 | 2016-03-04 | N/A |
| 10.2 | Consent for Alternate Compliance with CSA N293, NBCC, NFPA 14 and NFPA 24, as part of the Retube and Feeder Replacement - Retube Waste Processing Building Project | 4982486 | NK38-CORR-00531-17870 | 2016-04-28 | N/A |
| 10.2 | Consent for Alternate Compliance with CSA N293-07 and NFPA 14, as part of a Modification to the DNGS Transformer Fire Protection Features (MEC #126981/Design EC #127317) | 4994520 | NK38-CORR-00531-17885 | 2016-05-05 | N/A |
| 10.2 | Consent for Alternate Compliance with CSA N293 as a Modification to the DNGS Fire Protection Design Features of the Powerhouse Fire Alarm System (MEC #126981/Design EC#l27316 | 4995266 | NK38-CORR-00531-17892 | 2016-05-06 | N/A |
| 10.2 | Consent for Alternate Compliance with CSA N293-07 and ULC S524-06, as Part of the Retube and Feeder Replacement Project - Retube Waste Processing Building Fire Detection and Public Address Systems | 4996509 | NK38-CORR-00531-17894 | 2016-05-09 | N/A |

| L.C | Subject of the Consent | e-Doc # | Licensee's reference # | Effective Date | Expiry Date |
|---|---|---|---|---|---|
| 10.2 | Consent for Alternate Compliance with CSA N293-07, as part of the Retube and Feeder Replacement Project - Retube Waste Processing Building Fire Detection System - Acceptance | 5296647 | NK38-CORR-00531-18694 | 2017-07-12 | N/A |
| 13.1 | Clarification on requirements for reporting nuclear material inventory listings to the CNSC | 3932320/ 4055469 | NK38-CORR-00531-16014 | 2013-07-13 | TBD |
| 15.3 | Darlington NGS - Integrated Implementation Plan (llP) Change Control Process Principles | 4575922 | NK38-CORR-00531-16991 | 2014-11-14 | N/A |

# APPENDIX H – Resolution of Inconsistencies

| L.C. | Subject of Conflict or Inconsistency | e-Doc # | Licensee's reference # | Identifier | Approved Date |
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