ONTARIO POWER GENERATION

Allan Grace
Senior Vice President
Darlington Nuclear

1 Holt Road, Bowmanville ON L1C 3Z8 Tel: 905-260-1505 allan.grace@opg.com

OPG Proprietary

August 8, 2025

CD# NK38-CORR-00531-26277

Ms. C. Salmon
Commission Registrar
Canadian Nuclear Safety Commission
P.O. Box 1046
280 Slater Street
Ottawa, Ontario, K1P 5S9

Dear Ms. Salmon:

Darlington NGS – Amendment to the Licensing Basis of the Power Reactor Operating Licence 13.06/2025 for the Installation and Operation of Target Delivery Systems in Additional Units

The purpose of this letter is to provide a revision to the application for amendment to the Darlington Nuclear Generating Station (DNGS) Power Reactor Operating Licence (PROL) 13.06/2025 (Reference 1). Upon review of the application, CNSC staff indicated that the request did not meet the intent of a licence amendment but is a request to amend the licensing basis of the PROL. This letter also addresses the request in the Record of Decision (Reference 2) to provide information for public disclosure which demonstrates that the installation and operation of a TDS is a low-risk activity which can be executed safely.

While revising the package, the opportunity was also taken to reflect the current state of the project.

The TDS installation in Unit 3 is planned for D2631 outage window, which runs from March to November of 2026. Approval of this amendment to the licensing basis is requested by December 15, 2025, to align with outage planning milestones.

OPG will continue to meet Canada's international obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons*.

Should you require any further information, please contact Ms. Aditi Bhardwaj, Senior Manager, Darlington Regulatory Affairs, at 289-387-2110.

Sincerely,

Allan Grace
Senior Vice President
Darlington Nuclear
Ontario Power Generation Inc.

cc: CNSC Site Supervisor – Darlington
forms-formulaires@cnsc-ccsn.gc.ca

References:

1. OPG letter, A. Grace to S. Salmon, " Darlington NGS – Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.04/2025 to Approve Installation and Operation of Target Delivery Systems (TDS) on Additional Units", January 23, 2025, CD# NK38-CORR-00531-25802.

2 Canadian Nuclear Safety Commission, "Record of Decision – DEC 21-H107", https://www.nuclearsafety.gc.ca/eng/the-commission/pdf/Decision-OPG-Mo-99-CMD21-H107-e.pdf. October 26, 2021.

ATTACHMENT 1

OPG letter, A. Grace to C. Salmon, “Darlington NGS – Amendment to the Licensing Basis of the Power Reactor Operating Licence 13.06/2025 for the Installation and Operation of Target Delivery Systems in Additional Units”

CD# NK38-CORR-00531-26277

Licensing Impact Assessment in Support of Installation and Operation of Additional Target Delivery Systems at Darlington Nuclear Generating Station

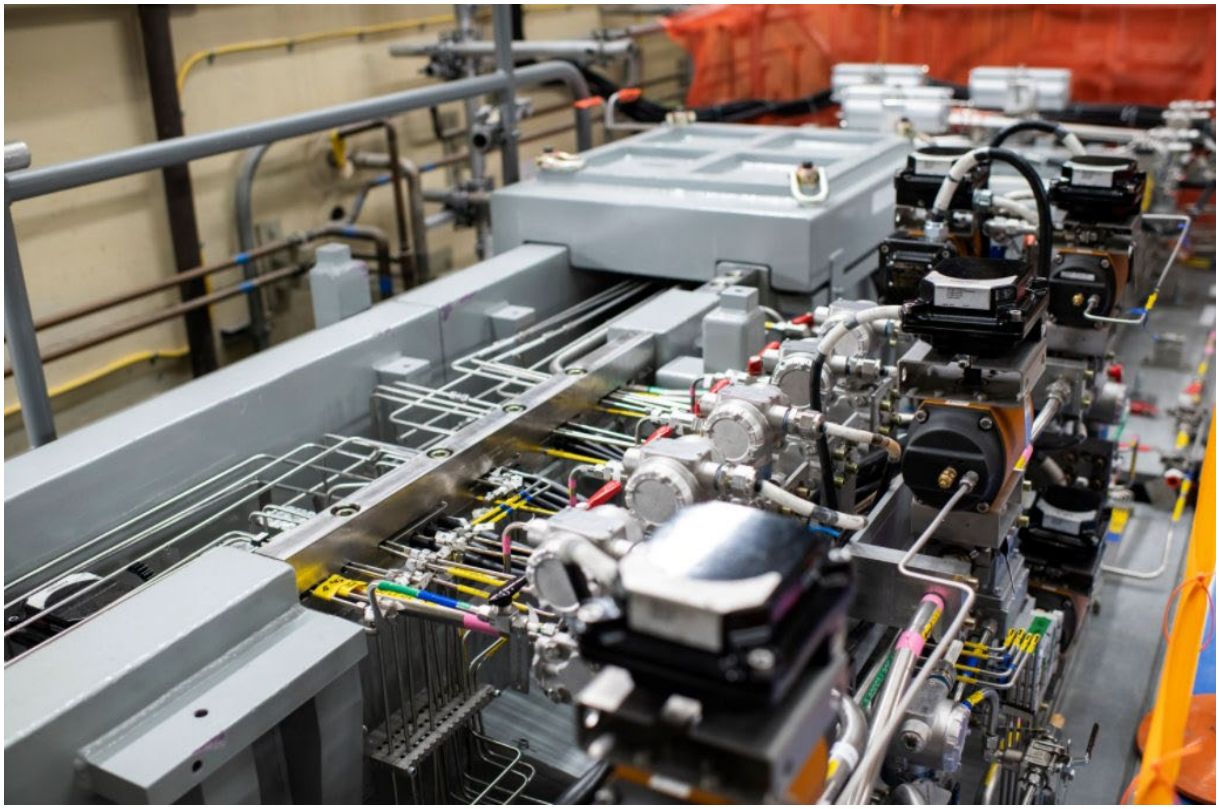
Prepared By: Carolyn Campbell

Checked By: Kirk Thompson

ATTACHMENT 1

ONTARIO POWER GENERATION | Electrifying life

Licence Impact Assessment in Support of Installation and Operation of Additional Target Delivery Systems at Darlington Nuclear Generating Station



Executive Summary

In December 2024, Ontario Power Generation (OPG) notified the CNSC staff of its intention to apply for a licence amendment to allow the installation and operation of Target Delivery Systems (TDS[1]) on all units at Darlington NGS (Reference 1). It has since been realized that the request to the CNSC is to approve an amendment to the licensing basis, rather than an amendment to the licence.

OPG's initial application for a PROL amendment to install a TDS at Darlington NGS (Reference 2) was not reactor unit specific and was considered a generic Darlington station amendment request. Given the similarities between the Darlington reactor units and that the safety assessments were predominantly unit independent, the amendment concluded that the safety case was expected to remain unchanged between units.

CNSC staff recommended, in CMD 21-H107 (Reference 3) that, if OPG were to plan to produce Molybdenum-99 (Mo-99) in a unit other than Unit 2, OPG must obtain concurrence from CNSC staff and demonstrate that it is a low-risk activity, which can be executed safely.

Following this application the Commission concluded that the use of the TDS to produce Mo-99 at Darlington NGS Unit 2 was a low-risk activity that would remain within the station's existing safe operating envelope. As such, a record of decision granting the approval of the license amendment was issued in October of 2021 (Reference 4). This record of decision also stated:

> *Paragraph 79: "CNSC staff recommended in CMD 21-H107 that, if OPG were to plan to produce Mo-99 in a unit other than Unit 2, OPG must obtain concurrence from CNSC staff and demonstrate that it is a low-risk activity, which can be executed safely. Due to the first-of-a-kind nature of the Mo-99 IIS design and to allow the public additional opportunity to participate, the Commission directs that OPG must obtain the approval of the Commission, rather than concurrence from CNSC staff, if it means to produce Mo-99 in a unit other than Unit 2."*
>
> *Paragraph 86: "The Commission directs, if OPG plans to produce Mo-99 in any reactor unit at the Darlington NGS other than Unit 2, that OPG must obtain approval of the Commission and demonstrate that the production of Mo-99 in any other unit is a low-risk activity that can be executed safely. Further, if OPG wishes to use the IIS to produce other types of radioisotopes at the Darlington NGS, the Commission directs that OPG must also obtain Commission approval."*

The existing licensing basis allows Darlington NGS to produce Mo-99, Lutetium-177 (Lu-177) and Yttrium-90 (Y-90) using the existing TDS. Any additionally installed TDS, like Unit 2, will be used to produce the entire inventory of approved isotopes.

This application focuses on providing evidence to the commission, in a public forum, to demonstrate that the installation of a TDS is a low-risk activity, which can be executed safely.

All installations of a TDS on additional units will be made through OPG's existing Engineering Change Control (ECC) program, N-PROG-MP-0001, "*Engineering Change Control*", confirming that all regulatory requirements are met, as well as ensuring the project is executed safely with

[1] TDS was referred to as Isotope Irradiation System (IIS) in previous submissions

high quality. OPG is currently working through this ECC program for the installation of the next TDS on Unit 3.

The safety case to demonstrate that the installation of a TDS on additional units is a low-risk activity, which can be executed safely is outlined below:

- **Design**: OPG will continue to follow its established N-PROC-MP-0090, "*Engineering Change Control Process*" for ensuring the design complies with applicable Darlington PROL 13.06/2025 regulatory requirements and that configuration management for the station is maintained.

- **Continued Safe Operations**: The nuclear safety case and operational assessments for the introduction of the Unit 2 TDS and production of Mo-99 was completed prior to the operation of the Unit 2 TDS. The complete comprehensive Mo-99 assessment N-REP-03500-0839983, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" demonstrated the relatively small impact of producing Mo-99 in the Unit 2 TDS on the complete safety case and operation at Darlington NGS (Enclosure 5 of Reference 5).

  Commissioning results and analysis pertaining to reactor response during Mo-99 seed and harvesting activities concluded that the reactor responded as expected, validating the simulations modeling, and confirming safe reactor operation post installation of the Unit 2 TDS as well as during Mo-99 seed and harvesting activities. (Reference 8).

  In support of the installation of new TDS on additional units, NK38-EVAL-03600-00001, "*Nuclear Safety Review - Target Delivery System Installed on Multiple Units"* was performed (Enclosure 1). Based on this review, there are no additional safety analysis requirements necessary to support the installation of a TDS on other Darlington NGS units. The review concluded that the installation of a TDS on other units will have no impact on the safe operation of Darlington NGS. Systems, structures and components will continue to provide the required safety, protective and mitigating actions necessary to ensure the original design objectives are met.

- **Environmental Protection**: The operational tritium releases for the Darlington NGS Unit, with the Unit 2 TDS in place, remain comparable to the projected releases as defined in the ALARA assessments. Since the projected releases are within the ALARA assessment, the conclusions of the PEA were confirmed.

  A Predictive Environmental Risk Assessment, NK38-REP-30550-00051 "*Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3)"*, prepared in accordance with Canadian Standards Association (CSA) N288.6-12, "Environmental risk assessments at Class 1 nuclear facilities and uranium mines and mills", concluded that the cumulative effects from operating an additional TDS will continue to have a negligible impact on the environment. This assessment is included in Enclosure 2.

  The existing environmental risk assessment will be updated, or additional assessments performed if and when OPG moves forward with additional installations

- **Radiological Protection**: An ALARA assessment was completed for the initial installation of the Unit 2 TDS (Reference 6) and has been updated as per the ECC program, N-PROG-MP-0001, "*Engineering Change Control*" [Enclosure 3 of Reference 7].

  A memo has been prepared to highlight the updates required to this ALARA assessment to account for the installation of TDS in additional units and is presented in Enclosure 3. This updated ALARA assessment is in progress and will be provided to the CNSC upon completion

- **Licensing Basis:** This LIA documents that there will be no negative impact to Darlington's licensing basis governance, programs, and processes resulting from the installation and operation of TDS on additional units

OPG is committed to the continued safe operation of Darlington NGS and confirms that the installation and operation of TDS on additional units will be implemented based on a robust safety case and in accordance with OPG's ECC program, which is supported by safety assessments that demonstrate continued safe reactor operation, public safety, and environmental protection.

TABLE OF CONTENTS

LAND ACKNOWLEDGEMENT

The lands and waters on which the Darlington Nuclear Generating Station (NGS) is situated are within the traditional and treaty territory of the Williams Treaties First Nations, which includes Curve Lake First Nation, Hiawatha First Nation, Alderville First Nation, Chippewas of Beausoleil First Nation, Chippewas of Georgina Island First Nation, Chippewas of Rama First Nation, and the Mississaugas of Scugog Island First Nation.

The Darlington NGS is within the territory of the Gunshot Treaty and the Williams Treaties of 1923. The Gunshot Treaty Rights were reaffirmed in 2018 in a settlement with Canada and the Province of Ontario.

To acknowledge the treaty and traditional territories is to recognize the rights of the First Nations. It is to recognize the history of the land, predating the establishment of the earliest European colonies. It is also to acknowledge the significance for the Indigenous peoples who lived and continue to live upon it, to acknowledge the people whose practices and spiritualties are tied to the land and water and continue to develop in relation to the territory and its other inhabitants today.

1.0 INTRODUCTION

1.1 Background

The purpose of this submission is to provide information in support of OPG's request for approval to install and operate additional Target Delivery Systems (TDS) under the Darlington NGS Power Reactor Operating Licence (PROL) 13.06/2025.

The key attributes, safety, and benefits associated with the proposed addition of TDS on additional units on the Darlington NGS is summarized in this document. The information provided in this Attachment is provided as follows:

Section 1: Provides background information on the existing Unit 2 TDS installed and operational at Darlington NGS; specific details on the licensing basis amendment request; a summary of the design changes for TDS installations on subsequent units; and an overview of responsibilities by organization.

Section 2: Summarizes regulatory compliance for the installation and operation of TDS on additional units, and impact on OPG's governance, programs, and processes for each of Darlington NGS PROL fourteen (14) Safety Control Areas (SCA).

Section 3: Summarizes public and Indigenous Nations engagement related to the application for a licensing basis amendment.

OPG is responsible for continued safe operation of the Darlington NGS and confirms that the modifications associated with the installation and operation of a TDS on additional units will be implemented based on a robust safety case and proven engineering methods.

OPG is confident that the activities necessary to support the installation of operation of a TDS on additional units will not compromise continued safe reactor operation. OPG has and will continue to follow the ECC program, N-PROG-MP-0001, "*Engineering Change Control*", to validate preliminary conclusions.

The global demand for diagnostic and therapeutic treatments has grown, and with hundreds of therapeutic radiopharmaceuticals in the pipeline, and many expected to reach the market in the coming years, demand is expected to rapidly increase. As such, OPG's proposed increased capacity of isotope production within Canada has significant importance to the nuclear industry and medical community. OPGs generation of these radioisotopes will have a significant positive impact on human health across Canada and the globe, expanding Canada's leadership role in the global community by supporting new and innovative approaches to cancer diagnosis and treatment.

1.2 Target Delivery System and Isotope Production

1.2.1 Target Delivery System Overview

The TDS utilizes a combination of mechanical, pneumatic, and hydraulic methods of propulsion to transfer target capsules into and out of the reactor core for the

purpose of irradiating the target capsules to produce medical isotopes. Strings of eight target capsules are inserted into the reactor in four out-of-service Adjuster Assembly (AA) locations, renamed as Target Elevators (TEL). TDS equipment is in each of the modified AA ports on the Reactivity Mechanisms Deck (RMD).

Target capsules are received and then, using pneumatic flight tubes, connected to the New Target Loader. The target capsules are then transferred through the Target Airlock (TAL), and from the TAL into a basket in a TEL using a hydraulic propulsion system. The target capsules are transferred into a locked basket in a “home” position. Target capsules are lowered in a target basket into the reactor core inside of a TEL. The drive mechanism at the top of the AA port moves the target basket using a winch and cable. The cable is unwound relying on the weight of the basket and targets to lower them to the proper location in the reactor core. The target basket and the guide tube are perforated so that the targets are in direct contact with the moderator, resulting in effective heat removal from target capsules because of thermal heating during irradiation and activation of the isotopes.

The target capsules will remain in-core, at approximately the reactor vertical centre line, during the irradiation period. After the necessary irradiation period, the targets are harvested by raising the target basket from the core with the drive mechanism. The target basket is initially raised to a dwell position in the guide tube extension below the RMD but out of the reactor core (out of the neutron flux) to allow short-lived activation products to decay. The dwell period is determined based on the isotope being irradiated but cannot be less than two hours due to procedural and associated dwell time requirements. Once the irradiated targets have completed the dwell period the targets are returned to the home position in the TEL. They are then transferred out of the basket to the TAL and then to the flask loader and finally into the shipping flask using both hydraulic and pneumatic systems.

The system operates based on the need to produce medical isotopes with the reactor operating at high power. The target strings reside in the core for the necessary irradiation period before being harvested and replaced. The typical time to harvest and then re-seed a target string is two to three hours.

1.2.2 TDS Installation on Unit 2 and Mo-99 Production

OPG has a strong history of safely producing isotopes for the medical industry demonstrated through the harvest of Cobalt-60 (Co-60) at Pickering NGS for over five decades. In 2021, the Commission amended the Darlington NGS PROL to allow OPG to possess, transfer, produce, package, manage, and store Mo-99 and its associated decay products at Darlington NGS and authorized the installation and safe operation of a TDS to produce Mo-99 in Unit 2. The TDS enables target capsules to be inserted (or “seeded”) in the reactor core, irradiates the target capsule in the reactor neutron flux for a defined period and then removes (or “harvests”) the target capsules for post processing. An overview of the TDS system is provided in Section 1.2.1.

In 2024, following OPG’s ECC program, N-PROG-MP-0001, “*Engineering Change Control*”, OPG successfully completed the installation and commissioning of the TDS in Unit 2 at Darlington NGS and irradiated natural Molybdenum target

capsules to produce Mo-99. Following harvesting of the target capsules, the target capsules were processed at the BWXT Medical Kanata Facility, successfully validating the radiochemical and radiopharmaceutical process and properties.

Through commissioning and operation of the Unit 2 TDS, OPG has demonstrated the following:

- **Unit 2 TDS operates as designed.** The design requirements pertaining to the Unit 2 TDS have been met as outlined in the system design requirements and detailed commissioning specifications defined in accordance with the ECC program.

- **Containment integrity is maintained.** Containment integrity has been maintained throughout the installation and commissioning phases and Unit 2 TDS containment boundary valves have been tested and turned over to operations.

- **Reactor physics and continued safe reactor operation have been confirmed.** Commissioning results and analysis pertaining to reactor response during Mo-99 seed and harvesting activities conclude that the reactor responded as expected, validating the simulations modeling, and confirming safe reactor operation post installation of the Unit 2 TDS as well as during Mo-99 seed and harvesting activities.

- **Unit 2 TDS and flask shielding protection to workers is as predicted in the As Low As Reasonably Achievable (ALARA) Assessment.** The radiation field measurement conducted during the installation of Unit 2 TDS, commissioning of Unit 2 TDS and reactor physics response have confirmed that the radiation fields are within the range as predicted. Sufficient shielding to ensure workers' protection is in place.

- **Emissions during Unit 2 TDS operations are within Predictive Effects Assessment (PEA) predictions.** The operational tritium releases for the Darlington NGS Unit, with the Unit 2 TDS in place, remain comparable to the projected releases as defined in the ALARA assessments. Since the projected releases are within the ALARA assessment, the conclusions of the PEA were confirmed.

OPG concludes that the Unit 2 TDS is safe and operating the Unit 2 TDS is a low-risk activity based on N-REP-03500-0839983, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" (Enclosure 5 of Reference 5] and Commissioning Report (Reference 8).

1.2.2 Additional Isotopes

In February 2024, OPG applied to the CNSC for an amendment to the PROL to use the existing TDS on Darlington NGS Unit 2 to produce two additional isotopes, Y-90 and Lu-177.

CNSC staff proposed that the Commission establish a Regulatory Hold Point (RHP) prior to OPG declaring the production of the new isotopes available for

service. Prior to removal of a RHP, OPG shall submit, and CNSC staff shall verify, that all required actions have been completed.

In May of 2025, the Commission amended the Darlington NGS to allow OPG to possess, transfer, produce, package, manage, and store Y-90 and Lu-177 and their associated decay products at Darlington NGS. This amended licence included the RHP recommended by the CNSC staff.

1.3 Description of Project Scope

This application focuses on providing evidence to the commission, in a public forum, to demonstrate that the installation of the TDS is a low-risk activity, which can be executed safely, and to thereby obtain approval to install the TDS on additional units.

Prior to the installation and operation of a TDS on additional units, any changes will be made through OPG's existing ECC program, N-PROG-MP-0001, "*Engineering Change Control*", confirming that all regulatory requirements are met, as well as ensuring the project is executed safely with high quality. OPG is currently working through this ECC program for the installation of the next TDS on Unit 3.

1.4 Design Changes

There are changes in the design to the TDS on additional units that are being implemented primarily to address interferences and obsolescence. Some changes are also being made in support of personnel safety, access control and to allow for easier installation. These changes do not impact on the overall assumptions or analysis completed in support of the Nuclear Safety Deterministic or Probabilistic analyses and assessments.

All changes will be managed in accordance with N-PROC-MP-0090, "*Engineering Change Control Process*", with all the necessary provisions to ensure that all aspects of safety and regulatory requirements are considered accordingly.

A summary of the current planned changes is provided below. It should be noted that as the detailed design progresses N-PROC-MP-0090, "*Engineering Change Control Process"* will continue to be followed to incorporate any changes required.

Pressure Boundary discovery issues on the TDS on Unit 2 will be resolved using existing OPG processes. This process will require a review of lessons learned and may trigger changes in subsequent units.

1.4.1 Bolted Joint and Seismic Brace

During the supply and installation of the Unit 2 TDS airlock platform and seismic braces, it was identified that some of the connections used bolts into threaded holes. Though it was shown that this was acceptable from a strength and seismic perspective, TDS on additional units will utilize bolt and nut connections where applicable. While changing the bolted connections on the seismic braces, the design will be modified to accommodate a design which will be more suitable for installation and fit-up at site.

These changes remain in compliance with the design requirements and comply with CSA S16-14, "*Design of Steel Structures – Welding Requirements* and CSA N291-19, *Requirements for Nuclear Safety-Related Structures"*.

1.4.2 Vertical Alignment

Design changes to TDS on additional units will be necessary to compensate for small elevation differences in some of the support surfaces of the frame assembly, due to differences in the location of the Reactivity Mechanism Decks (RMDs) on all units. This will allow the flight tubes and shielding to remain in the same location, which limits the changes to the rest of the transfer system and associated piping.

1.4.3 Target Elevator Cladding

Target elevator cladding will be changed on any TDS on additional units to a stainless-steel inner sleeve to isolate all tungsten from potentially wearing components. This change in the target elevator cladding will be at the top of the elevator and does not impact on the operation of the reactor in any way.

1.4.4 Target Transfer Deck Plate Optimization

The design for the target transfer deck plate on TDS on additional units will be changed to a split plate design that will allow for installation and removal without affecting target transfer assembly components.

1.4.5 Contaminated Exhaust Ducting

The scope includes providing a ductwork connection between TDS on additional units and the contaminated exhaust system. There is a Cobalt-60 positioner in Unit 3 that is not present in Unit 2. As a result, the design for this ductwork connection in Unit 3 will be slightly modified to account for this positioner.

1.4.6 Stairs and Handrails

Unit 3 has Cobalt-60 related components that are present in the same physical location as the TDS. As these Cobalt-60 components are not present near the Unit 2 TDS, the stairs and handrails for the additional TDS will be modified to accommodate for the presence of this equipment. There will also be an additional barrier on a hoist way gate installed for TDS on additional units for personnel safety and access control.

1.4.7 Obsolescence of Electrical Components

There are currently fourteen (14) electrical components that were used on the original TDS unit that are no longer available (obsolete). These components will be replaced with an equivalent component on any future TDS. The new components are similar in form, fit and function and will not impact on other aspects of the system.

1.4.8 Shut-off Rod Assembly (SAs)

Currently the station approved maintenance plans to remove adjuster absorber (AA) rods include steps to rotate shut-off rod assemblies (SA) and once maintenance is completed, rotate them back into place. There is a proposed engineering change to make that rotation permanent for the target elevators neighboring SAs to allow for future ease of maintenance for these SAs. These configuration changes have the potential to impact on the TDS piping geometry in TDS on additional units.

1.5 Safety Case

OPG is responsible for continued safe operation of Darlington NGS and confirms that the installation and operation of TDS on additional units will be implemented based on a robust safety case and in accordance with OPG's ECC program, which is supported by safety assessments that demonstrate continued safe reactor operation, public safety, and environmental protection.

The safety case to demonstrate that the installation of a TDS on additional units is a low-risk activity, which can be executed safely, is outlined below:

- **Design**: OPG will continue to follow its established N-PROC-MP-0090, *"Engineering Change Control Process*" for ensuring the design complies with applicable Darlington PROL 13.06/2025 regulatory requirements and that configuration management for the station is maintained.

- **Continued Safe Operations**: The nuclear safety case and operational assessments for the introduction of the Unit 2 TDS and production of Mo-99 was completed prior to the operation of the Unit 2 TDS. The complete comprehensive Mo-99 assessment N-REP-03500-0839983, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" demonstrated the relatively small impact of producing Mo-99 in the Unit 2 TDS on the complete safety case and operation at Darlington NGS (Enclosure 5 of Reference 5).

  Commissioning results and analysis pertaining to reactor response during Mo-99 seed and harvesting activities concluded that the reactor responded as expected, validating the simulations modeling, and confirming safe reactor operation post installation of the Unit 2 TDS as well as during Mo-99 seed and harvesting activities (Reference 8).

  In support of the installation of TDS on additional units, NK38-EVAL-03600-00001, *"Nuclear Safety Summary Review - Target Delivery System Installed on Multiple Units"* was performed (Enclosure 1). Based on this review, there are no additional safety analysis requirements necessary to support the installation of a TDS on other Darlington NGS units. The review concluded that the installation of a TDS on other units will have no impact on the safe operation of Darlington NGS. Systems, structures and components will continue to provide the required safety, protective and mitigating functions necessary to ensure the original design objectives are met.

- **Environmental Protection**: The operational tritium releases for the Darlington NGS Unit, with the Unit 2 TDS in place, remain comparable to the projected releases as defined in the ALARA assessments. Since the projected releases are

within the ALARA assessment, the conclusions of the TDS U2 Predictive Environmental Assessment (PEA) were confirmed.

A Predictive Environmental Risk Assessment, NK38-REP-30550-00051 "*Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3)"*, prepared in accordance with Canadian Standards Association (CSA) N288.6-12, "*Environmental risk assessments at Class 1 nuclear facilities and uranium mines and mills*", concluded that the cumulative effects from operating an additional TDS will continue to have a negligible impact on the environment. This assessment is included in Enclosure 2.

The existing environmental risk assessment will be updated, or additional assessments performed if and when OPG moves forward with additional installations

- **Radiological Protection**: An ALARA assessment was completed for the initial installation of the Unit 2 TDS (Reference 6) and has been updated as per the ECC program, N-PROG-MP-0001, "*Engineering Change Control*", (Enclosure 3 of Reference 7).

  A memo has been prepared to highlight the updates required to this ALARA assessment to account for the installation of TDS on additional units and is presented in Enclosure 3. This updated ALARA assessment is in progress and will be provided to the CNSC upon completion.

- **Licensing Basis:** This LIA documents that there will be no negative impact to Darlington's licensing basis governance, programs, and processes resulting from the installation and operation of TDS on additional units.

Overall, OPG does not expect any safety or operational issues to result from the installation of a TDS on additional units

1.6 Project Timeline

A high-level project timeline has been included as Enclosure 5.

To facilitate completion of the TDS installation in the desired outage window, certain work activities will be completed prior to approval and release of the Design Engineering Changes (EC) under a Work at Risk Release (WARR), in accordance with , "*Engineering Change Control Process"*. Work will be performed using approved and accepted Inspection and Test Plans (ITPs) based on approved and accepted design change papers.

The scope of work approved under this WARR is limited to the installation of anchors, base plates and cable tray supports and the temporary removal and replacement of a staircase. The is no pressure boundary work or tie-ins to station systems under this WARR. The project accepts the financial risk associated with reversing these installation activities, in the event ECs are not approved and released

OPG expects to be ready to install the TDS on Unit 3 reactor during the D2631 outage window, which runs from March to November of 2026.

The engineering and design activities will take place in accordance with N-PROC-MP-0090, "*Engineering Change Control Process"*.

1.7 Roles and Responsibilities by Organizations

All the companies for this project, listed below, have a long history of providing quality support to the Canadian nuclear industry.

1) Darlington NGS owned and operated by OPG, located in the Durham Region, will Operate the TDS.

2) Laurentis Energy Partners, a wholly owned subsidiary of OPG and located in the Greater Toronto Area, will provide strategic partnerships and project support.

3) BWXT-Nuclear Energy Company (NEC) located in Peterborough Ontario, designed the TDS and will also perform maintenance.

4) BWXT Canada Ltd. located in Cambridge, Ontario is the Engineer Procure Construct (EPC) Contractor / Constructor for this project.

Execution of this project, and the roles and responsibilities defined above, will be completed in accordance with OPG's nuclear management system described in N-CHAR-AS-0002, "*Nuclear Management System",* which governs how OPG executes work. OPG has an extensive supply chain and contractor management program as described in OPG-PROG-0009, "*Items And Services Management*". Figure 1 below depicts the contract structure, workflow, and accountabilities for this project.

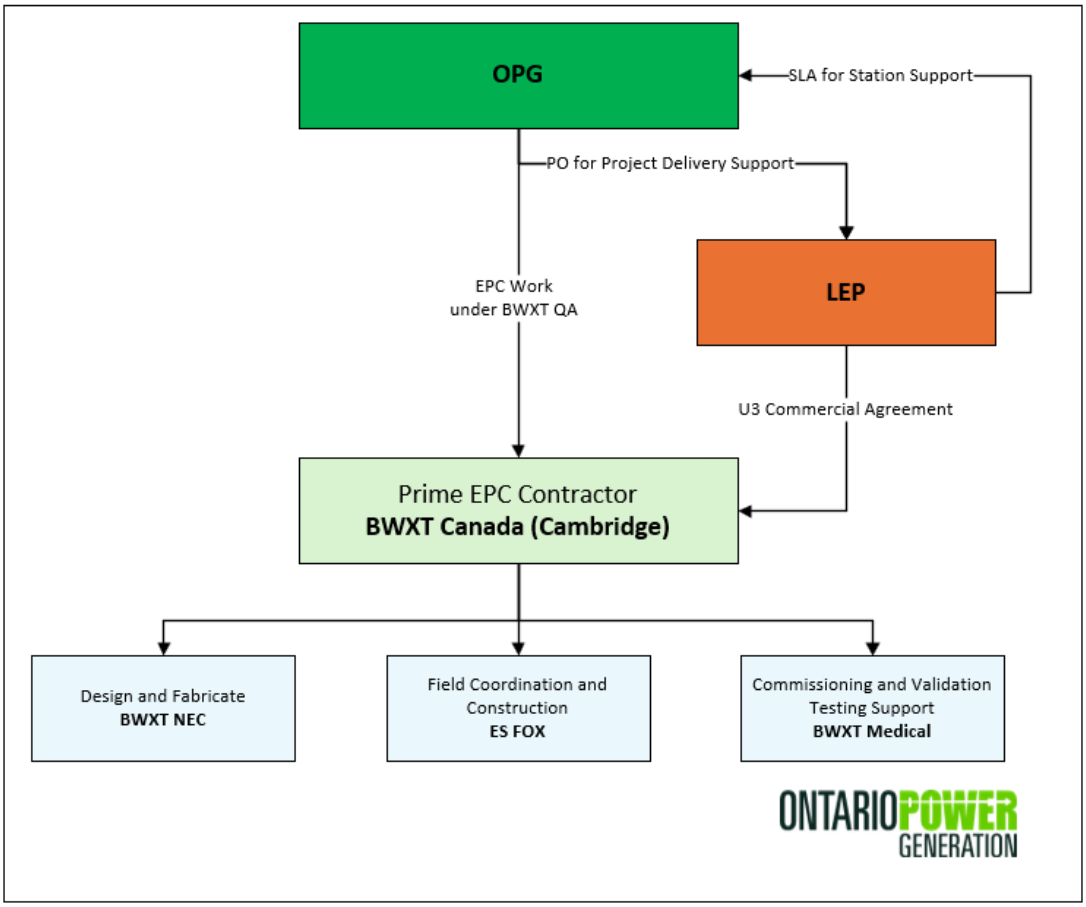


Figure 1: Strategic Partnership relationships between companies

2.0 SAFETY AND CONTROL AREAS

The purpose of this section is to document the impact of the installation and operation of a TDS on additional units at Darlington NGS on OPG's governance, programs and processes. A review of the impact on Darlington's NGS PROL fourteen (14) Safety Control Areas (SCA) was completed and is summarized in the following sections.

OPG is responsible for continued safe operation of Darlington NGS and confirms that the modifications associated with the installation and operation of TDS on additional units will be implemented based on a robust safety case and in accordance with OPG's ECC program and that is supported by safety assessments, which demonstrate continued safe reactor operation, public safety and environmental protection.

OPG confirms continued compliance with the applicable requirements and standards outlined in the current Darlington NGS Licence Condition Handbook (LCH), and correspondence between OPG and CNSC staff regarding the listed regulatory requirements and OPG governance, programs and processes that form the licensing basis.

2.1 Management System

OPG's proven Nuclear Management System provides a framework that establishes the processes and programs required to ensure OPG achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

Darlington NGS is compliant with CSA Standard N286-12, "*Management system requirements for nuclear facilities*". OPG's Nuclear Charter, N-CHAR-AS-0002, *"Nuclear Management System"*, establishes the Nuclear Management System for OPG Nuclear.

Vendors and contractors are qualified by OPG Supply Chain Quality Services under a process that ensures that the contractors have developed and implemented a management system that meets the applicable requirements outlined in the CSA Standard N286 series of standards.

Combining this with the long history of the contractors working in the Canadian nuclear industry and with OPG, provides verifiable confidence that the results of their work activities will satisfy all applicable standards.

The Management System SCA is comprised of the following Safety Performance Areas (SPAs):

- Management System
- Organization
- Performance Assessment, Improvement and Management Review
- Operating Experience (OPEX), Problem Identification and Resolution (PI&R)
- Change Management
- Safety Culture
- Configuration Management
- Records Management
- Supply Chain and Contractor Management
- Business Continuity

OPG has performed a thorough assessment of the project scope and has determined that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Management System SCA. This is further explained in Section 2.1.1 to 2.1.8.

Regulatory requirements that apply to the Management System SCA are listed in Table 2.1.a. Furthermore, Table 2.1.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Management System and identifies the impact from the installation and operation of TDS on additional units.

Table 2.1.a List of Management System Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Safety Culture	CNSC REGDOC - 2.1.2 (2018)	A healthy safety culture continues to remain OPG highest priority. The installation and operation of TDS on additional units will be consistent with this fundamental requirement.
Management System Requirements for Nuclear Facilities	CSA N286 (2012)	Continued compliance as applied to all aspects of operation, refurbishment and modifications at Darlington NGS.

Table 2.1.b Impact from installation and operation of TDS on additional units on Darlington's Management System Licensing Basis Documents

OPG Management System Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Nuclear Management System	N-CHAR-AS-0002	No Change
Nuclear Management Systems Administration	N-PROG-AS-0001	No Change
Information Management	OPG-PROG-0001	No Change
Project Management	OPG-PROG-0039	No Change
Construction Management	OPG-PROG-0046	No Change
Managing Change	OPG-STD-0140	No Change
Nuclear Organization	N-STD-AS-0020	No Change
Organization Design Change	OPG-PROC-0166	No Change
Nuclear Safety & Security Policy	N-POL-0001	No Change
Nuclear Safety Oversight	N-STD-AS-0023	No Change
Environment Health and Safety Managed Systems	OPG-PROG-0005	No Change
Nuclear Safety Culture Assessment	N-PROC-AS-0077	No Change
Independent Assessment	N-PROG-RA-0010	No Change
Contingency Guideline for Maintaining Staff in Key Positions When Normal Station Access is Impeded	N-GUID-09100- 10000	No Change
Business Continuity Program	OPG-PROG-0033	No Change

OPG Management System Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Items and Services Management	OPG-PROG-0009	No Change

2.1.1 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*". This document provides the pathways for compliance with Canadian Standards Association (CSA) N286-12 for all activities which take place at OPG stations. This compliance is established by the framework from which all processes and programs take authority.

OPG is responsible for the safe operation of the Darlington NGS and confirms that there will be no changes to the established Management System captured in OPG's Nuclear Management System. Compliance with OPG's ECC program will ensure quality, design basis compliance and configuration management. Safe reactor operation will take priority over medical isotope production and work executed by non-OPG staff will be through establish quality assurance programs verified by OPG through regularly completed audits.

There will be no change to the established licensing basis of the Management System SPA resulting from this amendment.

2.1.2 Organization

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".

Prior to declaring TDS on additional units available for service, resource planning activities will take place to ensure that the TDS are adequately resourced. If determined to be required, this increase will not result in organizational changes and there will be no changes to the established licensing basis of the Organization SPA.

The Darlington Operations Department will be continuing to be responsible for isotope production through regular, pre-established seed and harvest cycles. Both scheduled and non-scheduled TDS maintenance will be performed as already established under the Mo-99 project.

There will be no change to the established licensing basis of the Organization SPA resulting from this amendment.

2.1.3 Performance Assessment, Improvement and Management Review

OPG has an extensive performance improvement program and independent assessment described in N-PROG-RA-0003, "*Performance Improvement*", and N-PROG-RA-0010,

"*Independent Assessment*", respectively. OPG maintains this program as in accordance with its existing PROL and associated LCH.

There will be no change to the established licensing basis of the Performance Assessment, Improvement and Management Review SPA resulting from this amendment.

2.1.4 Operating Experience, Problem Identification and Resolution

OPG has an established comprehensive operating experience and process improvement & reliability procedures described in N-PROC-RA-0035, "O*perating Experience Process*", and N-PROC-RA-0022, "*Processing Station Condition Records*", respectively. OPG maintains these procedures in accordance with its existing PROL and associated LCH.

NK38-REP-30550-00005 "*OPEX Report - DNGS Target Delivery System Tie-In Modifications"* was issued during the initial phases of the Unit 2 TDS project, and this report has been credited for Unit 3 TDS (Reference 9).

There will be no change to the established licencing basis of the Operating Experience (OPEX), Problem Identification and Resolution (PI&R) SPA resulting from this amendment.

2.1.5 Change Management, Configuration Management, Records Management

Ensuring what is in the station matches OPG controlled documents (drawings, flowsheets, manuals and procedures) is key to configuration management. As part of OPG's modification process defined in OPG's procedure, N-PROC-MP-0090, "*Engineering Change Control Process",* the requirement to update station documentation will be identified and tracked to completion as part of the Available for Service (AFS) process.

Configuration Management is governed by PROG-AS-0001, "*Nuclear Management System Administration*".

Record Management is governed by OPG-PROG-0001, *"Information Management."*

Change Management is governed by N-PROG-MP-0001, "*Engineering Change Control"* and N-PROG-MP-0009, "*Design Management."*

There will be no change to the established licencing basis of the Change Management, Configuration Management, or Records Management SPAs resulting from this amendment.

2.1.6 Safety Culture

OPG's number one priority is, and will continue to be, the safety of its employees, the public, protection of the environment and continued safe unit operation. OPG's N-POL-0001, "*Nuclear Safety & Security Policy*" directs individuals at all levels of the organization to consider safety as the overriding priority (over schedule, cost and production).

OPG's approach to worker safety is governed by OPG-PROG-0005, "*Environment Health and Safety Managed Systems*", which defines the overall process for managing safety

and the responsibilities of the parties, specifically at the corporate level. In addition, 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”.

Continued safe reactor operation, compliance with operating limits and regulatory requirements will take priority over medical isotope production. Darlington Operating Manual, NK38-OM-30550, “*Target Delivery System Operating Manual”,* reinforces this requirement.

There will be no change to the established licencing basis of the Safety Culture SPA resulting from this amendment.

2.1.7 Supply Chain and Contractor Management

OPG has an extensive supply chain and contractor management program described in OPG-PROG-0009, "*Items And Services Management*". OPG maintains this program in accordance with its existing PROL and associated LCH.

OPG is ultimately responsible for ensuring that all on-site contractor activities comply with OPG’s safety requirements. OPG will provide oversight to BWXT employees who perform TDS installation, maintenance and testing work at Darlington NGS.

Figure 1 in Section 1.7 describes the contractor relationship between OPG, LEP and vendors partners

Oversight of contractors is described in OPG-PROG-0046, “*Construction Management”*, OPG-PROG-0038, “*Contract Management”*, OPG-PROC-0058, “*Procurement Activities”* and N-PROG-MP-0009, “*Design Management”.*

There will be no change to the established licencing basis of the Supply Chain and Contractor Management SPA resulting from this amendment.

2.1.8 Business Continuity

OPG’s program document OPG-PROG-0033, “*Business Continuity Program*” and guidance document N-GUID-09100-10000, “*Contingency Guideline for Maintaining Staff in Key Positions When Normal Station Access Is Impeded*”, will not require changes.

There will be no change to the established licencing basis of the Business Continuity SPA resulting from this amendment.

2.2 Human Performance Management

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.

The Human Performance program integrates site-wide proactive (prevention) and reactive (detection and correction) human performance initiatives.

The Human Performance SCA is comprised of the following SPAs:

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

OPG has performed a thorough assessment of the project scope and has determined that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Human Performance Management SCA.

As a result of this amendment, OPG will update and deliver the necessary training to staff working with TDS on additional units as per existing governance. This is further explained in Section 2.2.1 to 2.2.5.

Regulatory requirements that apply to the Human Performance Management SCA are listed in Table 2.2.a. Furthermore, Table 2.2.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Human Performance and identifies the impact from the installation and operation of TDS on additional units.

Table 2.2.a List of Human Performance Management Related Regulatory Requirement

OPG Human Performance Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Personnel Certification, Volume III: Certifications of Persons Working at Nuclear Power Plants	CNSC REGDOC-2.2.3 (2019)	Continued compliance, no impact from installation and operation of TDS on additional units.
Personnel Training	CNSC REGDOC-2.2.2 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units.
Fitness for Duty: Managing Worker Fatigue	CNSC REGDOC-2.2.4 (2017)	Continued compliance, no impact from installation and operation of TDS on additional units.
Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3	CNSC REGDOC- 2.2.4 (2021)	Continued compliance, no impact from installation and operation of TDS on additional units.
Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, Psychological Fitness	CNSC REGDOC-2.2.4 (2018)	Continued compliance, no impact from installation and operation of TDS on additional units.

Table 2.2.b Impact from installation and operation of TDS on additional units on Darlington's Management System Licensing Basis Documents

OPG Human Performance Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Limits of Hours of Work	N-PROC-OP-0047	No Change
Listing of Broad Population and Safety Sensitive Job Codes	N-LIST-09110-10005	No Change
Human Performance	N-PROG-AS-0002	No Change
Procedural Usage and Adherence	N-STD-AS-0002	No Change
Communications	N-STD-OP-0002	No Change
Self-Check	N-STD-OP-0004	No Change
Conservative Decision Making	N-STD-OP-0012	No Change
Second Party Verification	N-STD-RA-0014	No Change
Pre-Job Brief / Safe Work Plan and Post- Job Debriefing	N-PROC-OP-0005	No Change
Continuous Behaviour Observation Program (CBOP) – Participants Materials – Workbook Components	N-CMT-62808-00001	No Change
Training	N-PROG-TR-0005	No Change
Systematic Approach to Training	N-PROC-TR-0008	No Change
Written and Oral Initial Certification Examination for Shift Personnel	N-INS-08920-10004	No Change
Simulator-Based Initial Certification Examinations for Shift Personnel	N-INS-08920-10002	No Change
Requalification Testing of Certified Shift Personnel	N-INS-08920-10001	No Change
Responsible Health Physicist	N-MAN-08131-10000-CNSC-031	No Change
Shift Manager, Darlington Nuclear	N-MAN-08131-10000-CNSC-006	No Change
Control Room Shift Supervisor	N-MAN-08131-10000-CNSC-008	No Change
Authorized Nuclear Operators	N-MAN-08131-10000-CNSC-010	No Change
Unit 0 Control Room Operator	N-MAN-08131-10000-CNSC-025	No Change

2.2.1 Human Performance Program

The objective of Darlington's Human Performance program N-PROG-AS-0002, "*Human Performance*" is to reduce human performance events and errors by managing defences in pursuit of zero events of consequence.

Darlington NGS's N-PLAN-09030-10007, "*Darlington Human Performance Strategic Plan*" starts with awareness, understanding, and commitment by all levels of the organization. It involves driving line ownership and accountability regarding human performance best practices. The strategic plan involves multi-faceted initiatives from individual to leadership level.

The Human Performance program integrates site-wide proactive (prevention) and reactive (detection and correction) human performance initiatives, which includes the following:

- Providing oversight and mentoring of department human performance.
- Identifying emerging human performance issues and determining strategies for related improvement.
- Approving site-wide human performance improvement initiatives and measures and overseeing implementation progress.
- Use of the human performance toolbox, prevent event tools.
- Identifying and implementing human performance improvement communication, education, and training opportunities.

The site strategic plan provides guidance to the leadership team on the requirements for the development and implementation of an integrated site and department human performance strategic plan. Department managers and supervisors develop a human performance plan that sets clear direction and priorities to achieve common goals.

There will be no change to the established licencing basis of the Human Performance Program SPA resulting from this amendment.

2.2.1.1 Human Factors Engineering

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.

CNSC regulatory document REGDOC-2.2.1, "*Human Factors*" describes how CNSC staff will take human factors into account during its licensing, compliance and standards development activities.

NK38-PLAN-30550-00106, "*Darlington Target Delivery System Human Factors Engineering Program Plan"* (Enclosure 6) was created to define the scope of the HFE activities for the DNGS TDS Unit 3 project and describe the planned approach for the effective management of those activities and timely integration of HFE into the design.

2.2.2 Personnel Training

Staff operating a TDS are required to successfully complete the TDS training qualification that is compliant with OPG's training program N-PROG-TR-0005, "*Training*" and N-PROC-TR-0008 "*Systematic Approach to Training*".

All changes to training have been updated to include the operation of the Unit 2 TDS. As part of OPG's modification process defined in OPG's procedure, N-PROC-MP-0090, "*Engineering Change Control Process"*, the requirement to update station training for the installation and operation of TDS on additional units will be identified and tracked to completion

There will be no change to the established licencing basis of the Personnel Training SPA resulting from this amendment.

2.2.3 Personnel Certification

OPG's initial training for certified staff includes operation of a TDS. Only Operators who have completed the required qualifications will be permitted to operate a TDS.

There will be no change to the established licencing basis of the Personnel Certification SPA resulting from this amendment.

2.2.4 Work Organization and Job Design

OPG has an annual workforce planning process to manage its workforce.

There will be no change to the established licencing basis of the Work Organization and Job Design SPA resulting from this amendment.

2.2.5 Fitness for Duty

As part of OPG's fitness for duty program, OPG has a Continuous Behaviour Observation Program in place that trains supervisors and managers to monitor workers for signs of fatigue or other factors which could adversely impact worker performance.

OPG has hours of work requirements in place that are documented in N-PROC-OP-0047, "*Hours of Work Limits and Managing Worker Fatigue*" that sets limits for the number of hours within a specified period that station staff can work. The limits, which are in place to guard against fatigue in the workplace, are very strict in comparison to other jurisdictions.

There will be no change to the established licencing basis of the Fitness for Duty SPA resulting from this amendment.

2.3 Operating Performance

OPG's nuclear operations program, N-PROG-OP-0001, "*Nuclear Operations*", implements a series of standards and procedures in compliance with the regulatory requirements to ensure the safety of public, environment, station personnel, and station equipment. This program establishes safe, uniform, and efficient operating practices and processes within nuclear facilities that provide nuclear professionals the ability to ensure

facilities are operated in such a manner that the PROL, and other applicable regulations and standards are followed

.
The Operating Performance SCA is comprised of the following SPAs:

- Conduct of Licensed Activity
- Procedures
- Reporting and Trending
- Outage Management Performance
- Safe Operating Envelope
- Severe Accident Management and Recovery
- Accident Management and Recovery

OPG has performed a review of the project scope and anticipates that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Operating Performance SCA. This is further explained in Section 2.3.1 to 2.3.8

Regulatory requirements that apply to the Operating Performance SCA are listed in Table 2.3.a. Furthermore, Table 2.3.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Operating Performance and identifies the impact from installation and operation of TDS on additional units.

Table 2.3.a List of Operating Performance Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Accident Management: Severe Accident Management Programs for Nuclear Reactors	CNSC REGDOC-2.3.2 (2013)	Continued compliance, no impact from installation and operation of TDS on additional units.
Reporting Requirements for Nuclear Power Plants	CNSC REGDOC-3.1.1 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units.
Periodic Safety Reviews	CNSC REGDOC- 2.3.3 (2015)	Given TDS on additional units satisfy all applicable regulatory requirements, these systems will be factored into subsequent PSRs, after the PSR that was recently developed for renewal of the Darlington. PROL in 2025.
Requirements for the safe operating envelope for nuclear power plants	CSA N290.15 (2010)	Continued compliance, no impact from installation and operation of TDS on additional units.

Table 2.3.b Impact from installation and operation of TDS on additional units on Darlington's Management System Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Darlington Nuclear Operating Policies and Principles	NK38-OPP-03600	No Change
Safe Operating Envelope	N-STD-MP-0016	No Change
Heat Sink Management	N-STD-OP-0025	No Change
Nuclear Safety Configuration Management	N-STD-OP-0024	No Change
Operational Safety Requirements: Emergency Coolant Injection System	NK38-OSR-08131.02-10001	No Change
Operational Safety Requirements: Emergency Water System	NK38-OSR-08131.02-10002	No Change
Operational Safety Requirements: Fuel and Reactor Physics	NK38-OSR-08131.02-10003	No Change
Operational Safety Requirements: Shutdown Systems	NK38-OSR-08131.02-10004	No Change
Operational Safety Requirements: Main Steam Supply System	NK38-OSR-08131.02-10005	No Change
Operational Safety Requirements: Containment	NK38-OSR-08131.02-10006	No Change
Operational Safety Requirements: Steam Generator Emergency Cooling System	NK38-OSR-08131.02-10007	No Change
Operational Safety Requirements: Moderator System	NK38-OSR-08131.02-10008	No Change
Operational Safety Requirements: Powerhouse Steam Venting System	NK38-OSR-08131.02-10009	No Change
Operational Safety Requirements: Reactor Regulating System	NK38-OSR-08131.02-10010	No Change
Operational Safety Requirements: Group 1 Service Water Systems	NK38-OSR-08131.02-10011	No Change
Operational Safety Requirements: Emergency Power Supply System	NK38-OSR-08131.02-10012	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Operational Safety Requirements: Feedwater System	NK38-OSR-08131.02-10013	No Change
Operational Safety Requirements: Shutdown Cooling System	NK38-OSR-08131.02-10014	No Change
Operational Safety Requirements: Powerhouse Steam and Flooding Protective Provisions	NK38-OSR-08131.02-10019	No Change
Operational Safety Requirements: Annulus Gas System	NK38-OSR-08131.02-10020	No Change
Operational Safety Requirements: Critical Safety Parameter Monitoring Instrumentation	NK38-OSR-08131.02-10021	No Change
Operational Safety Requirements: Shield Cooling System	NK38-OSR-08131.02-10022	No Change
Conduct of Operations/Nuclear Operations	N-PROG-OP-0001	No Change
Chemistry	N-PROG-OP-0004	No Change
Conservative Decision Making	N-STD-OP-0012	No Change
Operational Decision Making	N-STD-OP-0036	No Change
Beyond Design Basis Accident Management	N-STD-MP-0019	No Change
Operations Performance Monitoring	N-STD-OP-0011	No Change
Operating Experience Process	N-PROC-RA-0035	No Change
Processing Station Conditions Records	N-PROC-RA-0022	No Change
Performance Improvement	N-PROG-RA-0003	No Change
Response to Transients	N-STD-OP-0017	No Change
Reactor Safety Program	N-PROG-MP-0014	No Change
Control of Fueling Operations	N-STD-OP-0021	No Change
Written Reporting to Regulatory Agencies	N-PROC-RA-0005	No Change
Preliminary Event Notifications	N-PROC-RA-0020	No Change

2.3.1 Conduct of Licensed Activity

OPG's nuclear operations program, N-PROG-OP-0001, "*Nuclear Operations*", implements a series of standards and procedures in compliance with the regulatory requirements to ensure the safety of public, environment, station personnel, and station equipment.

This program establishes safe, uniform, and efficient operating practices and processes within nuclear facilities that provide nuclear professionals the ability to ensure facilities are operated in such a manner that the PROL, and other applicable regulations and standards are followed. The installation and operation of TDS on additional units does not change this approach.

There will be no change to the established licencing basis of the Conduct of Licensed Activity SPA resulting from this amendment.

2.3.2 Procedures

The operating manual NK38-OM-30550, "*Target Delivery System*" and maintenance procedure NK38-MMP-30550-13, " *Target Delivery System Transport Package Flasking*" will be updated to incorporate TDS on additional units in accordance with OPG governance.

As per licence condition 15.6, "*Molybedenum-99 Isotope Irradiation Program",* in the Darlington NGS LCH, CNSC staff's notification will take place following completion of updates to these documents.

2.3.4 Reporting and Trending

Reporting will be performed in compliance with CNSC regulatory document REGDOC-3.1.1 "*Reporting Requirements for Nuclear Power Plants*" as applicable.

There will be no change to the established licencing basis of the Reporting and Trending SPA resulting from this amendment.

2.3.5 Outage Management Performance

As a prerequisite to a planned outage, the targets will be harvested from the core.
During planned outages where work activities are planned to occur on the RMD, TDS Elevator baskets will be lowered to the dwell position if required to reduce radiation exposure from the activated basket cable.

During planned outages, various inspections and maintenance activities on a TDS will be scheduled and planned in accordance with N-PROC-MA-0013, "*Planned Outage Management*".

There will be no change to the established licencing basis of the Outage Performance Management SPA resulting from this amendment.

2.3.6 Safe Operating Envelope (SOE)

The objective of OPG's SOE program, as defined in N-STD-MP-0016, "*Safe Operating Envelope*", is to specify information required to ensure that station operation is in conformance with Safety Analysis for which the station is licensed to operate.

TDS have very few interfaces with other station systems., They do not produce volatile fission products, and the design complies with applicable regulatory requirements. The installation of the Unit 2 TDS did not require any revision to the Operational Safety Requirements (OSRs).

Installation and operation of TDS on additional units at Darlington NGS reactors will not impact any of the SOE documents.

There will be no change to the established licencing basis of the SOE SPA resulting from this amendment.

2.3.7 Accident Management and Severe Accident Management and Recovery

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.

The impact from a TDS on accident management and recovery, and severe accident management and recovery is documented in section 2.10, Emergency Preparedness and Fire Protection.

2.4 Safety Analysis

The Safety Analysis SCA is comprised of the following SPAs:

- Deterministic Safety Analysis
- Hazard Analysis
- Probabilistic Safety Analysis
- Criticality Safety
- Severe Accident Analysis
- Management of Safety Issues (including R&D Programs)

Regulatory requirements that apply to the Operating Performance SCA are listed in Table 2.3.a. Furthermore, Table 2.3.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Operating Performance and identifies the impact from installation and operation of TDS on additional units.

Table 2.3.a List of Operating Performance Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Deterministic Safety Analysis	CNSC REGDOC-2.4.1 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units.
Probabilistic Safety Assessment (PSA) for Nuclear Power Plants	CNSC REGDOC-2.4.2 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units.
Quality assurance of analytical, scientific and design computer programs for nuclear power plants	CSA N286.7 (1999)	Continued compliance, no impact from installation and operation of TDS on additional units.

Table 2.3.b Impact from installation and operation of TDS on additional units on Darlington's Management System Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Darlington NGS Safety Report: Part 2 -System Descriptions	NK38-SR-03500-10001	A description of the TDS will be added during the next revision as part of OPG's ECC program
DN 1-4 Safety Report: Part 3 – Accident Analysis	NK38-SR-03500-10002	The Analysis of Record process will be followed for inclusion of applicable safety assessments
Darlington Analysis of Record	NK38-REP-00531.7-10001	The Analysis of Record process will be followed for inclusion of applicable safety assessments
Beyond Design Basis Accident Management	N-STD-MP-0019	No Change
Reactor Safety Program	N-PROG-MP-0014	No Change
Safety Analysis Basis and Safety Report	N-PROC-MP-0086	No Change
Risk and Reliability Program	N-PROG-RA-0016	No Change
Preparation, Maintenance and Application of Probabilistic Risk Assessment	N-STD-RA-0034	No Change
Software	N-PROG-MP-0006	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
RWPB Safety Analysis Summary Report	NK38-REP-09701-10344	No Change
Darlington Retube Waste Processing Building - Safety Assessment	NK38-REP-09701-10326	No Change
RWPB Worker Dose During Normal Operation and Under Accident Conditions	NK38-CORR-09701-0597849	No Change

The nuclear safety case and operational assessments for the introduction of the Unit 2 TDS was completed prior to the operation of the Unit 2 TDS. The complete comprehensive TDS assessment, N-REP-03500-0839983, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" (Enclosure 5 of Reference 5) demonstrated the relatively small impact of producing Mo-99 in the TDS on the complete safety case and operation at Darlington NGS.

In support of the installation of TDS on additional units, NK38-EVAL-03600-00001, "*Nuclear Safety Review - Target Delivery System Installed on Multiple Units"* was performed (Enclosure 1).

The review concluded that no new analysis is required to install additional systems in other units but recognizes that there are some outstanding Probabilistic Safety Assessment (PSA) models that are currently being updated according to a planned update cycle. The review also concluded that the installation of TDS on additional units will have no significant impact on the safe operation of Darlington NGS. Systems, structures and components will continue to provide the required safety, protective and mitigating actions necessary to ensure the original design objectives are met.

OPG has performed a review of the project scope and anticipates that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Safety Analysis SCA.

2.4.1 Deterministic Safety Analysis

Deterministic safety assessments were performed for the Unit 2 TDS design in accordance with CNSC Regulatory Document 2.4.1, specifically:

- A detailed review of the existing Safety Report demonstrated that the introduction of the Unit 2 TDS will have no impact on existing accident progression or consequences.
- 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 Hydrogen deflagration event following a postulated loss of moderator inventory (LOMI)

- The effectiveness of the Neutron Overpower Protection (NOP) trip setpoint is not affected by the operation of the Unit 2 TDS.

NK38-EVAL-03600-00001, "*Nuclear Safety Review - Target Delivery System Installed on Multiple Units"* (Enclosure 1) focused on the applicability of current analysis and assessments to the installation and operation of TDS on additional units in other Darlington NGS units. It concluded that no new analysis is required to support the installation of TDS in other units.

There will be no change to the established licencing basis of the Deterministic Safety Analysis SPA resulting from this amendment.

2.4.2 Hazard Screening Analysis

A Hazard Screening for the Unit 2 TDS design, N-REP-03611-0764525 R01, "*Assessment of Target Delivery System for Molybdenum Irradiation on the Darlington Internal and External Screening*", was completed and submitted to CNSC staff to document internal postulated hazards associated using OPG's Internal and External Hazards Screening Guides, N-GUID-03611-10001 Volume 9 R003, "*OPG Probabilistic Safety Assessment (PSA) Guide – Internal Hazard Screening*" and N-GUID-03611-10001 Volume 8 R005, "*Probabilistic Safety Assessment (PSA) Guide – External Hazard Screening*".

Existing hazards in the Internal and External Hazards Screening Guides were reviewed for any impacts the Unit 2 TDS may have on the existing hazard screening, including new internal hazards introduced based on the existing hazards categories identified in the guides. A list of hazards was then generated based on the Darlington Hazards Screening Analysis and previous assessments performed as part of this project.

NK38-EVAL-03600-00001, "*Nuclear Safety Review - Target Delivery System Installed on Multiple Units"* (Enclosure 1) focused on the applicability of current analysis and assessments to the installation and operation of TDS on additional units. It concluded that no new analysis is required to support the installation of TDS in other units.

There will be no change to the established licencing basis of the Hazard Screening Analysis SPA resulting from this amendment.

2.4.3 Probabilistic Safety Assessment

OPG's N-PROG-RA-0016, "*Risk and Reliability Program*" establishes the framework for the development and use of probabilistic risk assessment to manage radiological risks and to contribute to safe operation of nuclear reactors.

An assessment of the impacts on the existing Darlington PSA elements was completed (Reference 10) in accordance with CNSC's REGDOC-2.4.2, confirming that the Unit 2 TDS will have a negligible or low impact on Darlington Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF), and safety goals continue to be met. This result was expected as the TDS will have few interfaces with other station systems, does not produce volatile fission products and the design complies with applicable regulatory requirements.

In addition, the installation of the TDS does not constitute a “major change” requiring an update to the Darlington PSA models outside of the normal five-year PSA update cycle.

NK38-EVAL-03600-00001, “*Nuclear Safety Review - Target Delivery System Installed on Multiple Units”* (Enclosure 1) focused on the applicability of current analysis and assessments to the installation and operation of TDS on additional units. It concluded that no new analysis is required to support the installation of TDS in other units.

There will be no change to the established licencing basis of the Probabilistic Safety Assessment SPA resulting from this amendment.

2.4.4 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. The TDS will not impact the procedures for accident and severe accident management.

NK38-EVAL-03600-00001, “*Nuclear Safety Review - Target Delivery System Installed on Multiple Units”* (Enclosure 1) focused on the applicability of current analysis and assessments to the installation and operation of TDS on additional units. It concluded that no new analysis is required to support the installation of TDS in other units.
.

There will be no change to the established licencing basis of the Severe Accident Management SPA resulting from this amendment.

2.4.5 Management of Safety issues (including R&D programs)

The TDS will have no impact on the management of safety issues and OPG’s Research and Development programs.

There will be no change to the established licencing basis of the Management of Safety Issues SPA resulting from this amendment.

2.5 Physical Design

The Physical Design SCA is comprised of the following SPAs:

- Design Governance
- Site Characterization
- Facility Design
- Structure Design
- System Design
- Component Design

OPG has performed a review of the project scope and has determined that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Physical Design SCA. This is further explained in Section 2.5.1 to 2.5.6.

Regulatory requirements that apply to the Design Program SCA are listed in Table 2.5.a. Furthermore, Table 2.5.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Design Program and identifies the impact installation and operation of TDS on additional units.

Table 2.5.a List of Design Program Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Requirements for safety related structures for CANDU nuclear power plants	CSA N291 (2008)	Continued compliance, no impact from installation and operation of TDS on additional units.
General requirements for safety systems of nuclear power plants	CSA N290.0 (2011)	Continued compliance, no impact from installation and operation of TDS on additional units.
Human Factors in Design for Nuclear Power Plants Compliance Assessment Summary	CSA N290.12 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units.
General requirements for pressure- retaining systems and components in CANDU nuclear power plants	CSA N285.0 (2008 and Update No. 2)	Continued compliance, no impact from installation and operation of TDS on additional units.
Environmental qualification of equipment for CANDU nuclear powerplants	CSA N290.13 (2005 and Update No. 1)	Continued compliance, no impact from installation and operation of TDS on additional units.
General requirements for seismic design and qualification of CANDU nuclear power plants	CSA N289.1 (2008)	Continued compliance, no impact from installation and operation of TDS on additional units.

Table 2.5.b Impact from installation and operation of TDS on additional units on Darlington's Design Program Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Conduct of Engineering	N-STD-MP-0028	No Change
Engineering Change Control	N-PROG-MP-0001	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Configuration Management	N-STD-MP-0027	No Change
Design Management	N-PROG-MP-0009	No Change
Fuel	N-PROG-MA-0016	No Change
Procurement from Licensed Canadian Nuclear Utilities	N-INS-08173-10050	No Change
Engineering Change Control Process	N-PROC-MP-0090	No Change
Pressure Boundary Program	N-PROG-MP-0004	No Change
System and Item Classification	N-PROC-MP-0040	No Change
Design Registration	N-PROC-MP-0082	No Change
Pressure Boundary Program Manual	N-MAN-01913.11-10000	No Change
Index to OPG Pressure Boundary Program Elements	N-LIST-00531-10003	No Change
Authorized Inspection Agency for Pressure Boundary Inspection and Registration Services	N-CORR-00531-19076	No Change
Environmental Qualification	N-PROG-RA-0006	No Change

2.5.1 Design Governance

Design changes are performed in accordance with OPG's engineering change control program, N-PROG-MP-0001, "*Engineering Change Control*", to ensure design changes to each OPG Nuclear facility (including systems, structures, or components, software, and engineered tooling) are planned, designed, installed, commissioned and placed into or removed from service such that the facility configuration is managed in accordance with the design and the licensing basis, and remains within the SOE.

There will be no change to the established licencing basis of the Design Governance SPA resulting from this amendment.

2.5.2 Site Characterizations

There are no changes to Site Characterizations.

There will be no change to the established licencing basis of the Site Characterization SPA resulting from this amendment.

2.5.3 Facility Design

There are no changes to Facility Design.

There will be no change to the established licencing basis of the Facility Design SPA resulting from this amendment.

2.5.4 Structure Design

The TDS will require installation of a platform in Room 302 of each unit where the target airlock, diverters and new target loader will be installed. Section 1.4 outlines the changes in design for additional units from the previous installation on Unit 2

There will be no change to the established licencing basis of the Structure Design SPA resulting from this amendment.

2.5.5 System Design

2.5.5.1 Seismic Qualification

The TDS design for additional units will comply with seismic requirements in CSA Standard N289.1-08, *"General requirements for seismic design and qualification of CANDU nuclear power plants*" and CSA Standard N291-08 *"Requirements for safety-related structures for CANDU nuclear power plants*", Update No. 1.

2.5.5.2 Environmental Qualification

The Environmental Qualification (EQ) program is defined in document N-PROG-RA-0006, "*Environmental Qualification*".

The objective of the program is to ensure that all required systems, equipment, components, protective barriers, and structures are qualified to perform their safety functions under the environmental conditions defined by the Darlington design-basis accidents, such as a steam-line break which will likely lead to a harsh environment in terms of temperature and water vapour.

The program includes the procedures and processes to systematically identify the equipment to be environmentally qualified, the environmental conditions to be used for qualification and the required documentation.

The additional TDS designs will consider two EQ elements, the impact from increased radiation fields from the TDS during target harvesting on components and systems in the vicinity of the TDS, and EQ of the TDS components to withstand harsh environments caused by design basis events (example, a main steam-line break).

The additional TDS designs will comply with CSA Standard N290.13 "*Environmental qualification of equipment for CANDU nuclear power plants".* The EQ requirements are documented in NK38-REP-03651-10006, *Technical Basis Document for Environmental Qualification of Containment* and NK38-REP-03651-10010, *Technical Basis Documents for Environmental Qualification of Post Accident Monitoring.*

2.5.5.3 Over-Pressure Protection

The TDS on additional units will be designed for various operating design pressures and include pressure relief valves for overpressure protection. The design will comply with CSA Standard N285.0 "*General requirements for pressure-retaining systems and components in CANDU nuclear power plants*". The TDS relief valves will be tested at BWXT-NEC to confirm proper setpoint before installation at Darlington NGS.

Pressure Boundary discovery issues on the TDS on Unit 2 will be resolved using existing OPG processes. This process will require a review of lessons learned and may trigger changes on subsequent units

The calculations for the relief valve capacity and setpoints for various plausible overpressure scenarios is documented in NK38-CALC-30552-00001, "Darlington Nuclear Target Delivery System Relief Valve Capacity Assessment Design Calculation" and will be summarized in an overpressure protection report NK38-OPR-30550-00003, "*TDS Overpressure Protection Report*".

2.5.5.4 Software

Operation of the TDS on additional units for target harvesting and seeding will be automated and documented in NK38-DDD-63055-00008, "*Target Delivery Control System Control Sequences*" requiring few Operator actions.

Once the ANO in the MCR authorizes target harvesting/seeding, a Field Operator will initiate the harvesting and reseeding of a selected target site at the local control console. The software, which will be Category II, for the automated control sequence will be contained in two Programmable Logic Controllers.

The TDS on additional units will include provisions for verifying the completed movements of all targets in the string (eight targets) for tracking purposes.

2.5.5.5 Cyber Security

The additional TDS design will comply with OPG's cyber security requirements. Cyber Security is addressed during the design scoping phase of the modification process and issues are tracked through to the in-service declaration.

OPG's cyber security program is documented in OPG-PROG-0042, "*Cyber Security*". The program defines organizational responsibilities, processes and overall requirements for an effective Cyber Security Program, the purpose of which is assurance of protection of the confidentiality, integrity, and availability of OPG's assets.

OPG's N-PROC-RA-0135, "*Cyber Security*" takes authority from OPG-PROG-0042 and defines processes for the identification, classification, and protection of cyber assets (CAs) in OPG Nuclear. This procedure also ensures those nuclear CAs that are cyber essential assets (CEAs) are protected and meet the requirements of CSA Standard N290.7-14, "*Cyber Security for nuclear power plants and small reactor facilities*". These documents interface respectively with N-

PROG-MP-0009, "*Design Management*", and N-PROC-MP-0090 *Engineering Change Control Process"*.

There will be no change to the established licencing basis of the System Design SPA resulting from this amendment.

2.5.6 Component Design

2.5.6.1 Containment Integrity

The TDS on additional units will result in a change to the existing containment boundary from the Adjuster Rod mechanisms to the target elevators, target flight tubing, target airlock, DRS Unit, and the Target Propulsion System. As per NK38-DBD-34280-00001, "*Containment Boundary Manual*", a qualified (Class 2) containment boundary will be always maintained. Hardware interlocks (relays) will be used to ensure that only one set of dual containment isolation valves are open at the same time.

CNSC staff acceptance of the containment boundary for the initial TDS design was provided in (Reference 11). The TDS design is expected to remain unchanged for the other units from a containment integrity perspective.

2.5.6.2 TDS Code Classification

As accepted by CNSC staff (Reference 12, Reference 13) the TDS components are classified as Class 2, Class 3, Class 6 and Class Exempt as shown on NK38-DRAW-30550-10001-U3 depending on the safety function and size of the piping design. The Unit 3 TDS Code Classification complies with CSA Standard N285.0.

There will be no change to the established licencing basis of the Component Design SPA resulting from this amendment.

2.6 Fitness for Service

Darlington NGS, under its current PROL (13.06/2025), is required to have in place a fitness for service program in accordance with the CNSC regulatory documents and CSA Standards as specified in the PROL.

The Fitness for Service SCA is comprised of the following SPAs:

- Equipment Fitness for Service/Equipment Performance
- Maintenance
- Structural Integrity
- Aging Management
- Chemistry Control
- Periodic Inspection and Testing

OPG has performed a thorough assessment of the project scope and has determined that installation and operation of TDS on additional units will not require any changes to the

licensing basis of the Fitness for Service SCA. This is further explained in Section 2.6.1 to 2.6.6.

Regulatory requirements that apply to the Fitness for Service SCA are listed in Table 2.6.a. Furthermore, Table 2.6.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Fitness for Service and identifies the impact from the installation and operation of TDS on additional units.

Table 2.6.a List of Fitness for Service-Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Periodic inspection of CANDU nuclear power plant components	CSA N285.4 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units.
Periodic inspection of CANDU nuclear power plant containment components	CSA N285.5 (2008 and Update No.1)	Continued compliance, no impact from installation and operation of TDS on additional units.
Technical requirements for in-service inspection evaluation of zirconium alloy in pressure tubes in CANDU reactors	CSA N285.8 (2015)	Continued compliance, no impact from installation and operation of TDS on additional units.
In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plant components	CSA N287.7 (2008)	Continued compliance, no impact from installation and operation of TDS on additional units.
Reliability Programs for Nuclear Power Plants	CNSC REGDOC-2.6.1 (2017)	Continued compliance, no impact from installation and operation of TDS on additional units.
Maintenance Programs for Nuclear Power Plants	CNSC REGDOC-2.6.2 (2017)	Continued compliance, no impact from installation and operation of TDS on additional units.
Aging Management	CNSC REGDOC-2.6.3 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units.

Table 2.6.b Impact from installation and operation of TDS on additional units on Darlington's Management System Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Conduct of Maintenance	N-PROG-MA-0004	No Change
Component and Equipment Surveillance	N-PROG-MA-0017	No Change
Production Work Management	N-PROG-MA-0019	No Change
Integrated Aging Management	N-PROG-MP-0008	No Change
Planned Outage Management	N-PROC-MA-0013	No Change
Forced Outage Maintenance	N-PROC-MA-0049	No Change
Equipment Reliability	N-PROG-MA-0026	No Change
Risk and Reliability Program	N-PROG-RA-0016	No Change
Reliability and Monitoring of Systems Important to Safety	N-STD-RA-0033	No Change
List of Safety Related Systems and Functions	NK38-LIST-06937-10001	No Change
Major Components	N-PROG-MA-0025	No Change
Feeders Life Cycle Management Plan	N-PLAN-01060-10001	No Change
Darlington Nuclear Unit 1 Fuel Channel Feeder Pipes Periodic Inspection Program Plan	NK38-PIP-33160-10001	No Change
Darlington Nuclear Unit 2 Fuel Channel Feeder Pipes Periodic Inspection Program Plan	NK38-PIP-33160-10002	No Change
Darlington Nuclear Unit 3 Fuel Channel Feeder Pipes Periodic Inspection Program Plan	NK38-PIP-33160-10003	No Change
Darlington Nuclear Unit 4 Fuel Channel Feeder Pipes Periodic Inspection Program Plan	NK38-PIP-33160-10004	No Change
Fitness-for-Service Guidelines (FFSG) for Feeders in CANDU Reactors	COG-JP-4107-V06-R03	No Change
Steam Generators Life Cycle Management Plan	N-PLAN-33110-10009	No Change
Darlington Units 1-4 Steam Generator Life Cycle Management Plan	NK38-PLAN-33110-00001	No Change
Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes	COG-07-4089–R01	No Change
Fuel Channels Life Cycle Management Plan	N-PLAN-01060-10002	No Change
Darlington Nuclear 1-4, Unit 1 Fuel Channel Pressure Tubes	NK38-PIP-31100-10001	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Periodic Inspection Program Plan		
Darlington Nuclear 1-4, Unit 2 Fuel Channel Pressure Tubes Periodic Inspection Program Plan	NK38-PIP-31100-10002	No Change
Darlington Nuclear 1-4, Unit 3 Fuel Channel Pressure Tubes Periodic Inspection Program Plan	NK38-PIP-31100-10003	No Change
Darlington Nuclear 1-4, Unit 4 Fuel Channel Pressure Tubes Periodic Inspection Program Plan	NK38-PIP-31100-10004	No Change
Reactor Components and Structures Life Cycle Management Plan	N-PLAN-01060-10003	No Change
Long Term Darlington Life Management Plan for Inconel X-750 Spacers	NK38-PLAN-31160-10000	No Change
Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 1	NK38-PIP-03641.2-10001	No Change
Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 2	NK38-PIP-03641.2-10002	No Change
Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 3	NK38-PIP-03641.2-10003	No Change
Darlington Nuclear Generating Station Periodic Inspection Plan for Unit 4	NK38-PIP-03641.2-10004	No Change
Darlington Nuclear Generating Station – Periodic Inspection Program for Unit 0 and Units 1 to 4 Containment Components	NK38-PIP-03642.2-10001	No Change
Darlington Nuclear – Unit 0 Containment Periodic Inspection Program	NK38-PIP-03643.2-10002	No Change
Aging Management Plan for Containment Structures	N-PLAN-01060-10004	No Change
Darlington Nuclear – Reactor Building Periodic Inspection Program	NK38-PIP-03643.2-10001	No Change
Darlington Nuclear – Vacuum Building Periodic Inspection	NK38-PIP-03643.2-10003	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Program		
Inspection of Post Tensioning Tendons on Darlington NGS Vacuum Building	NK38-TS-03643-10001	No Change
Administrative Requirements for In- Service Examination and Testing for Concrete Containment Structures	N-PROC-MA-0066	No Change
Aging Management Plan for Darlington NGS Non-Containment Building Structures	NK38-PLAN-01060-10010	No Change
Darlington NGS Main Containment Structure In-Service Leakage Rate Test Requirements in Accordance with CSA N287.7-08	NK38-REP-34200-10066	No Change
Darlington NGS Vacuum Structure In- Service Leakage Rate Test Requirements in Accordance with CSA N287.7-08	NK38-REP-26100-10005	No Change

2.6.1 Equipment Fitness for Service/Equipment Performance

There will be no change to the established licencing basis of the Equipment Fitness for Service/Equipment Performance SPA resulting from this amendment.

2.6.2 Maintenance

Maintenance activities for all TDS will be scheduled and conducted in accordance with N-PROG-MA-0019, "*Production Work Management*". This program specifies the requirements for identifying, prioritizing, planning, scheduling, and executing work in support of the operation, maintenance and modification of the station. The program also establishes safe, uniform and efficient station work control practices.

The objective of OPG's maintenance program, N-PROG-MA-0004, "*Conduct of Maintenance",* is to ensure that safety systems remain available to satisfy their design intent as described in the station's supporting safety analysis and minimize equipment failures. This is accomplished by completion of corrective and preventative maintenance activities along with routine inspections on system components to ensure that they remain in good operating condition.

Corrective maintenance on all TDS will be performed by a combination of OPG and BWXT-NEC maintenance staff, depending on the severity of the required work activities. OPG

maintenance staff will address minor corrective maintenance, while BWXT-NEC will undertake more extensive repairs (replacement of TDS major components).

There will be no change to the established licencing basis of the Maintenance SPA resulting from this amendment.

2.6.3 Structural Integrity

The TDS on additional units will result in an extension to the containment boundary but will not impact containment structural integrity. A qualified containment boundary will be always maintained, as per section 2.5.6.1

There will be no change to the established licencing basis of the Structural Integrity SPA resulting from this amendment.

2.6.4 Aging Management

The objective of OPG's aging management program, N-PROG-MP-0008, *"Integrated Aging Management*", is 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.

There will be no change to the established licencing basis of the Aging Management SPA resulting from this amendment.

2.6.5 Chemistry Control

The impact from a TDS on reactor chemistry was assessed and determined to have minimal impact on Moderator system chemistry (Reference 14). Addition of chemicals to support TDS operation are not expected.

There will be no changes to the established licensing basis of the Chemistry Control SPA resulting from this request.

2.6.6 TDS Preventative Maintenance, Testing and Periodic Inspections

All TDS equipment will be included under the existing Preventive Maintenance identification numbers. The Mechanical Maintenance Procedures and Control Maintenance Procedures will also be updated to include the necessary TDS equipment.

There will be no changes to the established licensing basis of the Preventative Maintenance, Testing and Periodic Inspections SPA resulting from this request.

2.7 Radiation Protection

As per OPG's N-PROG-RA-0013, "*Radiation Protection*", the overriding objective of the Radiation Protection program at Darlington is the control of occupational and public exposure to radiation. For the purposes of controlling radiation doses to workers and the public, this program has five implementing objectives:

- Keeping individual radiation doses below regulatory limits
- Avoiding unplanned radiation exposures
- Keeping individual risk from lifetime radiation exposure to an acceptable level
- Keeping collective radiation doses ALARA, social and economic factors taken into account
- Keeping public exposure to radiation well within regulatory limits.

The Radiation Protection SCA is comprised of the following SPAs:

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

OPG has performed a thorough assessment of the project scope and has determined that installation and operation of TDS on additional units will not require any changes to the licensing basis of the Radiation Protection SCA. This is further explained in Section 2.7.1 to 2.7.5.

Regulatory requirements that apply to the Radiation Protection SCA are listed in Table 2.7.a. Furthermore, Table 2.7.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Radiation Protection and identifies the impact from the installation and operation of additional TDS.

Table 2.7.a List of Radiation Protection Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Radiation Protection Regulations	SOR/2000-203	Continued compliance, no impact from installation and operation of TDS on additional units.
Nuclear Substance and Radiation Device Regulations	SOR/2008-119	Continued compliance, no impact from installation and operation of TDS on additional units.

Table 2.7.b Impact from installation and operation of TDS on additional units on Darlington's Radiation Protection Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Radiation Protection	N-PROG-RA-0013	No Change
Controlling Exposure As Low As Reasonably Achievable	N-STD-RA-0018	No Change
Occupational Radiation Protection Action Levels for Power Reactor Operating Licences	N-REP-03420-10001	No Change
Dose Limits and Exposure Control	N-PROC-RA-0019	No Change
Radioactive Work Planning, Execution and Close Out	N-PROC-RA-0027	No Change
Radiation Dosimetry Program – General Requirements	N-MAN-03416-10000	No Change
Radiation Dosimetry Program – External Dosimetry	N-MAN-03416.1-10000	No Change
Radiation Dosimetry Program – Internal Dosimetry	N-MAN-03416.2-10000	No Change
Respiratory Protection	OPG-PROC-0132	No Change

2.7.1 Application of ALARA

The ALARA guide NK38-GUID-30550-00001, "*Darlington NGS Target Delivery System Alara Design Guide*" is the driving document that establishes the design targets and limits for radiological safety (radiation dose, dose rate, airborne and surface contamination, etc.).

Other factors for controlling and managing radiation exposure and ALARA principles applied during the Mo-99 TDS designs are documented in their respective design plan, NK38-PLAN-30550-00008, "*Darlington Nuclear Target Delivery System ALARA Design Plan*" (Reference 15) and ALARA Assessment, NK38-REP-30550-00012, "*Design ALARA Assessment*" (Reference 6).

As part of the ECC program for this modification, it has been identified that the TDS ALARA Assessment will require revision to account for design changes to the Target Elevator (TEL) upper guide tubes. The radiological hazard profile associated with the TDS design changes will be quantified and assessed against the existing TDS ALARA Assessment and the design criteria stated within the ALARA Design Guide. A summary of the planned updates to the TDS ALARA assessment is included in Enclosure 3.

While the TDS on additional units will largely be replicated from the U2 design, there is one planned TEL design change to replace the upper guide tube from a fully tungsten part to a tungsten part with stainless steel internal parts. The reduction in TEL shielding is justified as reasonable as the increase in radiological hazard is expected to be low and

replacement of the upper guide tube internals with stainless steel provides additional protection of tungsten surfaces and reduces expected inspection and maintenance efforts. There are no expected changes to existing ALARA design controls, the TDS exclusions zones, or TDS Operations.

There will be no changes to the established licensing basis of the Application of ALARA SPA resulting from this request.

2.7.2 Worker Dose Control

Individual worker radiation doses, including those for contractors and visitors, are managed to Exposure Control Levels that are below Administrative Dose Limits (ADLs) that are in turn below the regulatory limits. This process ensures planned exposures keep individuals within the regulatory dose limits.

The Design ALARA Assessment, NK38-REP-30550-00012 (Reference 6), documents the estimated accumulated whole-body dose increase to station personnel from Unit 2 TDS operation. Dose estimates during normal and maintenance TDS operations considering the design changes to the Target Elevator (TEL) upper guide tubes are expected to remain unchanged.

All existing radiation protection (RP) programs for all TDS managed by OPG RP will remain as they have been proven to be sufficient and preliminary analysis has shown that normal operation of all TDS is bounded by analysis. Further, existing dosimetry, rubber areas, and all radiation monitoring equipment (tritium, gamma) are still applicable

2.7.3 Radiation Protection Program Performance

There will be no changes to the established licensing basis of the RP Program Performance SPA resulting from this request.

2.7.4 Radiological Hazard Control

Key elements to controlling the radiological hazards from the irradiated target capsules and propulsion heavy water from the TDS are discussed in subsections 2.7.4.1 to 2.7.4.5

2.7.4.1 Source Term

In addition to the irradiated molybdenum within the target capsules, the capsule sheath, basket and cable represent a radiation source to workers requiring innovative design considerations. To lower the radiation source term, low magnesium content (zirconium-4) was selected for the target capsule sheath material to reduce radiation fields from the sheath. Titanium was selected for the basket cable to reduce long-lived activation. The inboard target propulsion will use low curie D2O.

2.7.4.2 Time

During target harvesting, the targets will be held in the dwell position to allow decay of high-energy short-lived activation products. The RMD will provide the required shielding. The design allows for the dwell time to be changed if required to ensure radiation fields during harvesting are within the limits of the TDS shielding.

2.7.4.3 Distance

Access gates at the entry points to Rooms 301 and 302 will be installed as a barrier to assist in preventing personnel from entering these rooms during target harvesting, until the target capsules are safely stored in the flask in the flask loader. To prevent radiation fields from changing, the new access gates provide a logic to stop target movement if either gate is opened during target harvesting. This will also cause an alarm on the local control console and a main control room (MCR) generic TDS trouble alarm.

As documented in NK38-REP-30550-00012 (Reference 6), the local control console for TDS will be located outside of the access doors which will be approximately 10 meters from the target airlock and outboard flight tubing.

2.7.4.4 Shielding

The irradiated targets represent a significant radiation risk to workers requiring innovative shielding. As documented in NK38-CALC-30552-00002, "*TDS Shielding Design Calculation*" innovative shielding design was incorporated in the design of the TDS to reduce radiation levels during target harvesting. A combination of lead, tungsten and steel will be used for shielding. Stainless steel will be used for the majority of the TDS components, target elevator housing, flight tubing, target airlock, D2O reservoir, and valves.

The radiation field measurement conducted during the installation of the Unit 2 TDS, commissioning of the Unit 2 TDS and reactor physics response have confirmed that the radiation fields are within the range as predicted. Sufficient shielding to ensure workers' protection is in place

2.7.4.5 Radiological Monitoring and Other Controls

Gamma monitoring on the RMD and at any TDS filter location will aid workers as they approach the TDS equipment to unexpected radiation fields and to abnormal TDS conditions.

There will be no changes to the established licensing basis of the Radiological Hazard Control SPA resulting from this request.

2.7.5 Estimated Dose to Public

Operations and maintenance of the TDS will be conducted in accordance with OPG's RP program to prevent uncontrolled releases of contamination or radioactive materials through established controls and monitoring of people and materials leaving the station.

For tritium and particulates emissions, NK38-REP-30550-0051 "*Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3)"* (Enclosure 2), estimates that the highest potential dose to a member of the public from TDS operation would not exceed 0.009 µSv/year. Considering the current Darlington emissions, the additional dose to a member of the public from TDS operation is estimated as an additional 1.2% dose above the current dose estimate. This would constitute 0.0009% of the regulatory dose limit of 1 mSv/year for a member of the public.

2.8 Conventional Health and Safety

The Conventional Health and SCA is comprised of the following SPAs:

- Performance
- Practices
- Awareness

The goal of OPG's Conventional Health and Safety Program is to ensure workers continue to work safely in a healthy and injury-free workplace by managing risks associated with activities, products, and services of OPG's nuclear operations. Risk reduction is primarily achieved through compliance with operational controls, developed through risk assessment and safe work planning.

OPG has performed a thorough assessment of the project scope and has determined that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Conventional Health and Safety SCA.

Regulatory requirements that apply to the Conventional Health and Safety SCA are listed in Table 2.8.a. Furthermore, Table 2.8.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Conventional Health and Safety and identifies from the installation and operation of TDS on additional units.

Table 2.8.a List of Conventional Health and Safety Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
General Nuclear Safety and Control Regulations	SOR/2000-202	Continued compliance, no Impact from installation and operation of TDS on additional units

Table 2.8.b Impact from installation and operation of TDS on additional units on Darlington's Conventional Health and Safety Program Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Health and Safety Policy	OPG-POL-0001	No Change
Environment Safety Managed Systems	OPG-PROG-0005	No Change
Work Protection	N-PROG-MA-0015	No Change
Respiratory Protection	OPG-PROC-0132	No Change
Fire Protection	N-PROG-RA-0012	No Change
Application of CSA Standard N293-7 to Structures, System and Components for Darlington Nuclear	NK38-LIST-78000-10001	No Change

2.8.1 Ensuring Conventional Safety Performance

The foundation of OPG's Health and Safety Management System is OPG-POL-0001, "*Employee Health and Safety Policy*" which describes the approach and commitments to conventional health and safety for the organization, and the requirements and accountabilities of all employees.

OPG's program document OPG-PROG-0005 "*Environment Health And Safety Managed Systems"* puts the Health and Safety Policy into action. The Health and Safety Management System program and supporting governing documents establish process requirements that protect employees by ensuring they are working safely in a healthy and injury-free workplace. It also outlines the responsibilities of various levels in the organization to ensure activities are performed to meet the requirements of OPG's Health and Safety Policy.

Installation of TDS on additional units will be performed by BWXT-Canada staff, with OPG oversight. BWXT-Canada has a proven health and safety program, and experience.

With respect to EPC contractors, BWXT-Canada will be the "constructor" and its contractors will be the "employer", as defined in the Ontario Occupational Health and Safety Act and are governed by the requirements set therein.

2.8.2 TDS Conventional Safety Provisions

Conventional safety principles were assessed during the TDS design process to protect personnel from injury during TDS operation. The results of this assessment are documented in NK38-REP-30550-00007 R000, "*Darlington Nuclear Target Delivery System Personnel Safety Analysis Report*" (Reference 11).

2.8.3 Awareness

OPG is ultimately responsible for safety, which cannot be delegated or contracted to other organizations. BWXT-Canada will be informed of their roles and responsibilities related to

conventional health and safety and will be working under OPG's health and safety program with oversight from OPG staff while working at Darlington NGS

2.9 Environmental Protection

The Environmental Protection SCA is comprised of the following SPAs:

- Effluent and Emissions Control (releases)
- Environmental Management System (EMS)
- Assessment and Monitoring
- Protection of People
- Environmental Risk Assessment

In accordance with Darlington NGS Licence Condition 9.1, "The licensee shall implement and maintain an environmental protection program, which includes a set of action levels". OPG will remain in compliance with this licence condition during installation and operation of TDS on additional units.

OPG has performed a thorough assessment of the project scope and has determined that the installation and operations of TDS on additional units will not require any changes to the licensing basis of the Environmental Protection SCA. This is further explained in Section 2.9.1 to 2.9.5.

Regulatory requirements that apply to the Environmental Protection SCA are listed in Table 2.9.a. Furthermore, Table 2.9.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Environmental Protection and identifies the impact from the installation and operation of TDS on additional units.

Table 2.9.a List of Environmental Protection Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	CSA N288.1 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units
Environmental monitoring program at class I nuclear facilities and uranium mines and mills	CSA N288.4 (2010)	Continued compliance, no impact from installation and operation of TDS on additional units
Effluent monitoring programs at class I nuclear facilities and uranium mines and mills	CSA N288.5 (2011)	Continued compliance, no impact from installation and operation of TDS on additional units
Environmental risk assessments at class I nuclear facilities and uranium mines and mills	CSA 288.6 (2012)	Continued compliance, no impact from installation and operation of TDS on additional units

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Performance Testing of Nuclear Air- Cleaning Systems at Nuclear Facilities	CSA N288.3.4 (2013)	Continued compliance, no impact from installation and operation of TDS on additional units
Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	CSA N288.7 (2015)	Continued compliance, no impact from installation and operation of TDS on additional units
Environmental Protection Policies, Programs and Procedures	REGDOC-2.9.1 (2013)	Continued compliance, no impact from installation and operation of TDS on additional units

Table 2.9.b Impact from installation and operation of TDS on additional units on Darlington's Environmental Protection Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation TDS on additional units
Monitoring of Nuclear and Hazardous Substances in Effluents	N-STD-OP-0031	No Change
Environment Manual	NK38-MAN-03480-10001	No Change
Derived Release Limits and Environmental Action Levels for Darlington Nuclear Generating Station	NK38-REP-03482-10001	No Change
Environmental Approvals	N-PROC-OP-0037	No Change
Environmental Policy	OPG-POL-0021	No Change
Environment Health and Safety Managed Systems	OPG-PROG-0005	No Change
Contaminated Lands and Groundwater Management	N-PROC-OP-0044	No Change
Hazardous Material Management	OPG-PROC-0126	No Change
Abnormal Waterborne Tritium Emission Response	N-PROC-OP-0038	No Change
Management of the Environmental Monitoring Programs	N-PROC-OP-0025	No Change
Darlington Environmental Monitoring Program	NK38-MAN-03443-10002	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation TDS on additional units
Darlington Nuclear Environmental Risk Assessment	NK38-REP-07701-00001	Emissions from TDS will be included in future ERA updates.

2.9.1 Effluent and Emissions Control (Releases)

OPG is committed to complying with the requirements of the CSA Standard N288 series documents, as required in Darlington's LCH.

Darlington NGS reports against approved Derived Release Limits (DRLs), which are defined in CSA Standard N288.1 as the release rate that would cause an individual of the most highly exposed group to receive and be committed to a dose equal to the regulatory annual dose limit, due to release of a given radionuclide to air or surface water during normal operation of a nuclear facility over the period of a calendar year.

Because radiological releases are very small in comparison with the DRLs and Action Levels, lower Internal Investigation Levels (IILs) are used to demonstrate and maintain adherence to the ALARA principle.

There will be no changes to the DRLs, Action Levels or IILs as a result of TDS on additional units. Consistent with current performance, the cumulative public dose resulting from Darlington NGS will remain well below 1% of the regulatory public dose limit of 1,000 µSv per year and the dose from background in the vicinity of Darlington NGS of approximately 1,400 µSv per year.

2.9.1.1 ALARA Principles Used in TDS Design

Protecting the environment and ensuring that emissions from Darlington NGS remain well below the DRLs was a consideration during the design of the TDS. All DRLs and Action Levels will be maintained as per the licensing basis throughout the operation of the TDS.

2.9.1.2 Venting to Contaminated Exhaust

The target airlock, D_2O reservoir, flask loader and D_2O fill station will connect to the unitized contaminated exhaust system through a HEPA filter to capture and reduce particulate emissions. To improve the longevity of the HEPA filter, a cyclone separator is installed upstream of the filter to separate particulates.

The contaminated exhaust on all units is continually monitored and there will be no changes in this area.

2.9.1.3 Low Curie Heavy Water

Moderator grade heavy water is used to propel the target capsules on the inboard side of the TDS. Venting of the target airlock and D2O reservoir to the

contaminated exhaust occurs periodically during TDS operation. To minimize emissions, low curie heavy water from the Tritium Removal Facility is used for inboard target propulsion. While the curie content of this water is expected to be in the 0.7 Ci/kg range, NK38-REP-30550-0051 "*Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3)"* [Enclosure 2] conservatively assumed 2 Ci/kg heavy water will be used for estimating emissions.

The constraints section of the TDS operating manual, NK38-OM-30550, *Target Delivery System Operating Manual,* also restrict the use of higher than 2 Ci/kg heavy water.

To control the spread of heavy water in the event of an unintentional heavy water release, a berm is installed on the floor around the D2O reservoir and Unit 2 TDS equipment to contain any release of TDS propulsion system D2O. This design will remain the same for TDS on additional units.

There will be no changes to the established licensing basis of the Effluent and Emissions Control SPA resulting from this request.

2.9.2 Environmental Management System (EMS)

OPG's OPG-POL-0021, "*Environmental Policy*" requires that OPG maintain an Environmental Management System (EMS) consistent with the ISO 14001, "Environmental Management System Standard".

Operation of all TDS will be in accordance with OPG's EMS program as described in OPG-PROG-0005, "*Environment Health And Safety Managed Systems*" and OPG-POL-0021. The EMS provides specific directions on how the Environmental Policy is implemented while meeting the expectations of OPG-POL-0032, "*Safe Operations Policy*" and N-POL-0001, "*Nuclear Safety & Security Policy*".

There will be no changes to the established licensing basis of the Environmental Management System SPA resulting from this request.

2.9.3 Assessment and Monitoring

The Darlington NGS Environmental Monitoring Program (EMP) complies with CSA Standard N288.4-10 "*Environmental monitoring programs at Class 1 nuclear facilities and uranium mines and mills*". The EMP also complies with any applicable statutes, regulations, licences, or permits that govern the operation of the facility including, but not limited to, section 3 (h) of CNSC's "Class I Nuclear Facilities Regulations" and section 3.5 of REGDOC-3.1.1. *Reporting Requirements for Nuclear Power Plants.*

The EMP is in place at Darlington NGS to monitor radioactive and non-radioactive contaminants, physical stressors, or environmental effects within the environment on and surrounding the OPG site, inclusive of those resulting from the installation and operation of all TDS. Additionally, environmental sampling and analyses for the EMPs support the calculation of annual public dose resulting from operation of Darlington NGS, as required by REGDOC-3.1.1, "*Reporting Requirements for Nuclear Power Plants".*

OPG submits the annual EMP report to CNSC staff as required by the Darlington PROL. The results are also made available to the public on the OPG website.

The Effluent Monitoring Program at Darlington NGS is in accordance with the N-STD-OP-0031 "*Monitoring of Nuclear and Hazardous Substances in Effluents*" and complies with CSA Standard N288.5-11, "*Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills*". This monitoring program ensures that releases are below regulatory limits and complies with principles of ALARA. OPG provides the results of the airborne and waterborne radioactive effluent monitoring program to CNSC staff quarterly and these results are also made available to the public on the OPG website.

There will be no changes to the established licensing basis of the Assessment and Monitoring SPA resulting from this request

2.9.4 Environmental Risk Assessment

A Predictive Environmental Risk Assessment, NK38-REP-30550-00051 "*Predictive Effects Assessment For Unit 3 Target Delivery System"* concluded that the cumulative effects from operating an additional TDS will continue to have a negligible impact on the environment. This assessment is included in Enclosure 2. The PEA demonstrates that the TDS on additional units will not create an unacceptable environmental impact from a human health and ecological risk assessment perspective.

The PEA is a Predictive Environmental Risk Assessment (ERA) as defined in CSA Standard N288.6-12, "*Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*", which estimates, prior to its release into the environment, the effects a contaminant or stressor would have on an existing environment resulting from a new facility or process.

For tritium and particulate emissions, the PEA estimates that the highest potential dose to a member of the public from all TDS operation would not exceed 0.009 µSv/year based on normal operations. This would constitute 0.0009% of the regulatory dose limit of 1 mSv/year for a member of the public. The incremental dose a member of the public would receive from TDS operation is estimated to be an additional 1% above the current dose estimate. Overall dose to the public would remain a very small fraction of the regulatory dose limit.

Emissions during TDS operations for Unit 2 were within the predictions in the Unit 2 PEA. The operational tritium releases for the Darlington NGS Unit, with the TDS in place, remained comparable to the projected releases as defined in the ALARA assessments. Since the projected releases were within the ALARA assessment, the conclusions of the PEA were confirmed

OPG submission of D-REP-07701-00002, "*2024 Environmental Risk Assessment Addendum for the Darlington Nuclear Site*" (Reference 16) concluded that releases from TDS to overall Darlington NGS site emissions are negligible.

There will be no changes to the established licensing basis of the Environmental Risk Assessment SPA resulting from this request.

2.9.5 Conventional Releases

The TDS will not result in increased non-radiological releases or emissions from Darlington NGS. Chemicals will not be used to support TDS operations, and the molybdenum target capsules, consisting of the molybdenum metal encased in a zirconium outer sheath, will not dissolve in the moderator water nor interact with the reactor components (Reference 14).

2.10 Emergency Management and Fire Protection

The Emergency Management and Fire Protection SCA is comprised of the following SPAs:

- Conventional Emergency Preparedness and Response
- Nuclear Emergency Preparedness and Response
- Fire Emergency Preparedness and Response

Under its current PROL, Darlington NGS is required to maintain an emergency preparedness program in accordance with CNSC regulatory documents REGDOC-2.10.1, "*Nuclear Emergency Preparedness and Response*" and REGDOC-2.3.2 "*Accident Management: Severe Accident Management Programs for Nuclear Reactors*", as well as a fire protection program in accordance with CSA Standard N293-12, "*Fire protection for CANDU nuclear power plants*".

OPG has performed a thorough assessment of the project scope and has determined that installation and operation of TDS on additional units will not require any changes to the licensing basis of the Emergency Management and Fire Protection SCA. This is further explained in Section 2.10.1 to 2.10.5.

Regulatory requirements that apply to the Emergency Management and Fire Protection SCA are listed in Table 2.10.a. Furthermore, Table 2.10.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Fire Emergency Preparedness and Response and identifies the impact from installation and operation of TDS on additional units.

Table 2.10.a List of Emergency Management and Fire Protection Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Fire protection for CANDU nuclear power plants	CSA N293 (2012)	Continued compliance, no impact from installation and operation of TDS on additional units
Nuclear Emergency Preparedness and Response, Version 2	CNSC REGDOC-2.10.1 (2016)	Continued compliance, no impact from installation and operation of TDS on additional units

Table 2.10.b Impact from installation and operation of TDS on additional units on Darlington's Emergency Management and Fire Protection Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Consolidated Nuclear Emergency Plan	N-PROG-RA-0001	No Change
Emergency Preparedness Drills and Exercises	N-PROC-RA-0045	No Change
Fire Protection	N-PROG-RA-0012	No Change
Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB)	NK38-REP-09701-10338	No Change

2.10.1 Conventional Emergency Preparedness and Response

The operation of TDS on additional units will not introduce new conventional emergency response requirements. Conventional chemicals will not be used to support its operation.

There will be no changes to the established licensing basis of the Conventional Emergency Preparedness and Response SPA resulting from this request

2.10.2 Nuclear Emergency Preparedness and Response

OPG's Emergency Preparedness program N-PROG-RA-0001, "*Consolidated Nuclear Emergency Plan*", requires OPG staff to implement and maintain its emergency response capability to protect the public, employees, and the environment in the event of a nuclear emergency."

There will be no changes to the established licensing basis of the Nuclear Emergency Preparedness and Response SPA resulting from this request.

2.10.2.1 Station Minimum Shift Complement

The Minimum Shift Complement (MSC) is the minimum number of qualified staff who are required to be present to ensure the safe continued operation of the Darlington NGS, to respond to all credible postulated DBA and to ensure adequate emergency response capability is available for the most resource intensive conditions.

Over the course of the Unit 2 TDS design phase, Human Factors Engineering took a systematic approach to MSC impact assessments and considered inputs from the safety analysis, as well as physical design considerations, staffing decisions and procedure changes.

Safety assessments of the impact of the Unit 2 TDS on postulated DBAs analysed in the Safety Report, including the six MSC determining DBAs, was completed and is documented in the N-CORR-03500-0764524, "*Disposition of Existing Analyses*

in Support of the Safety Case" (Qualitative Assessment SA04-07) (Reference 17). This assessment concluded that operation of the TDS will have no material impacts on most of the existing safety analyses with the presence of the system being bounded by existing analyses. This conclusion is due, in a large part, to the minimal interactions between the TDS, and other process and safety systems.

NK38-EVAL-03600-00001, "*Nuclear Safety Review - Target Delivery System Installed on Multiple Units"* (Enclosure 1) focused on the applicability of current analysis and assessments to the installation and operation of TDS on additional units. It concluded that no new analysis is required to support the installation of TDS in other units.

During operation of any TDS, in response to a unit transient on any Darlington unit requiring staff assembly and accounting, the Field Operator at the local TDS console will leave the TDS in the "idle" state and report to the designated assembly location. The Operator response to unit transients is covered in Section 5 of the TDS operating manual. Operation of the TDS will not prevent an Operator from fulfilling a MSC role.

The MSC for Darlington NGS, documented in D-PROC-OP-0009, "*Station Shift Complement*", documents the minimum staff numbers and their associated qualifications based on the following six DBAs:

1. Loss of Instrument Air
2. Main Steam Line Break
3. Common Mode – Design Basis Earthquake (DBE)
4. Primary Heat Transport (PHT) Liquid Relief Valve Fail Open
5. PHT Pump Seal Failure (all seals) and Motor Fire
6. Loss of Coolant Accident with Failure of Emergency Coolant Injection System)

2.10.2.2 Loss of Instrument Air

Following a Design Basis Loss of Instrument Air, Operator action will not be required within the first eight hours to address the status of any TDS. At all times, a qualified containment boundary will be maintained through Class II containment isolation valves and qualified TDS piping.

2.10.2.3 Main Steam Line Break

Following a Design Basis Main Steam Line Break, Operator action will not be required within the first eight hours to address the status of any TDS. As documented in (Reference 12), the containment isolation valves will be environmentally qualified to ensure containment is maintained in the event of a harsh environment event.

2.10.2.4 Common Mode Design Basis Earthquake (DBE)

Following a DBE, Operator action will not be required within the first eight hours to address the status of any TDS. As documented in (Reference 11), components and supporting structures for all TDS will be seismically qualified.

2.10.2.5 Other MSC Determining DBAs

The TDS will not adversely impact the progression or response to the remaining three MSC determining DBAs, specifically Primary Heat Transport (PHT) Liquid Relief Valve Fail Open, PHT Pump Seal Failure (all seals) and Motor Fire, and Loss of Coolant Accident (LOCA) with Failure of Emergency Coolant Injection System

Safety assessments for TDS operation were submitted to CNSC staff for the following non-MSC determining DBAs.

2.10.2.6 Slow Loss of Reactor Power Regulation

The impact of the TDS on a slow loss of reactivity event is documented in Reference 18. The conclusion was that the TDS will not impact the progression of this DBA.

2.10.2.7 Postulated TDS Piping Failure

The radiological impact from a postulated TDS piping failure leading to the release of heavy water propulsion fluid and Moderator Cover Gas into the open area of the Darlington station is addressed in Reference 19. The conclusion was that the radiological consequences would be well below the relevant public dose limits. This assessment did not identify any new operating limits or required Operator actions.

In addition, the TDS will not introduce new DBAs for which a response from Darlington staff will be required within the first eight hours of the postulated event. On the basis that no new or revised OPG staff actions will be required to respond to a postulated DBA, for which MSC is determined, there is no change required to the existing MSC for Darlington NGS as defined in D-PROC-OP-0009, "*Station Shift Complement*".

2.10.3 Emergency Field Operations

Although not identified through safety assessments, two section in NK38-OM-09013F, "*Abnormal Incidents Manual Part F, Emergency Field Operations (EFOs)"* did require updates to incorporate the TDS:

- LOCA (EFO 75 – LOCA – Establish Containment Boundary)
- Common Mode Event (EFO 46 - Unit Field Negative Pressure Containment (NPC) Actions for Closure of Containment Boundary Valves Following Seismic Event)

Each EFO is requested to be completed by the associated Abnormal Incident Manual (AIM), 3.3 "*LOCA*" and 8.0 "*Common Mode Event"*, with an approximate 24-hour timeframe for completion.

The EFOs were updated to select the DRS blowers to "OFF" and to select the DRS manual containment isolation valves to the "CLOSED" position.

Neither of the EFOs require any of the manual valves on the TDS to be manually closed. The rationale for this is the double isolation, inboard/outboard, operation of the TDS pneumatic valves in that system and the seismic qualification of the TDS.

2.10.4 Emergency Preparedness Drills and Exercises

To respond effectively to an emergency, the staff at Darlington NGS practices and conducts routine emergency preparedness drills and exercises in accordance with N-PROC-RA-0045, "*OPG Nuclear Emergency Response Organization Drills And Exercises*" through simulated events.

TDS operations will not impact existing or introduce new drills or exercises.

2.10.5 Fire Emergency Preparedness and Response

OPG's Fire Protection program N-PROG-RA-0012, "*Fire Protection*" establishes provisions to prevent, mitigate and respond to fires such that fire risk to OPG Nuclear workers, public, environment, nuclear physical assets, and power generation, is acceptably low and controlled.

There will be no changes to this program due to the installation and operation of TDS on additional units.

2.10.5.1 TDS Fire Protection and Compliance with CSA Standard N293-12

The Unit 2 TDS design and installation complies with CSA Standard N293-12, "*Fire protection for CANDU nuclear power plants"*. NK38-REP-30550-00018, "*DNGS U2 Target Delivery System Fire Protection Assessment"* is the third-party review for the Unit 2 TDS design that was completed by Jensen Hughes Consulting Company and reviewed by BWXT-NEC to determine the potential impact on fire safety. The review concluded that the Unit 2 TDS and associated modifications meet the fire protection goals and criteria of CSA N293 Clauses 5.2 to 5.5 and the requirements of the National Building Code of Canada and National Fire Code of Canada.

The existing facility Code Compliance Review (CCR), Fire Hazard Assessment (FHA), and Fire Safe Shutdown Analysis (FSSA) were not negatively impacted by the Unit 2 TDS. Therefore, as per Clauses 5.6.2 and 11.2.2 of CSA N293, the current Darlington NGS FHA and FSSA did not need to be revised. Darlington NGS continues to follow their ECC program to ensure that the TDS modifications are tracked and that modifications are included in the next (5 yearly) revisions of the FHA and FSSA as required by Clause 11.2.3 of CSA N293.

As TDS Unit 3 is a replication of TDS Unit 2, except in the case of design changes, the Fire Protection Assessment for TDS U2, NK38-REP-30550-00018, was reviewed for its applicability to TDS Unit 3 (Enclosure 7). Due to the similarity in TDS system design, and in physical layout between Unit 2 and Unit 3, it is not expected that the design changes being implemented for TDS Unit 3 will impact the results of the assessment, and that Unit 3 TDS and associated modifications will continue to meet the fire protection goals and criteria of CSA N293 Clauses 5.2 to 5.5 and the requirements of the National Building Code of Canada and National

Fire Code of Canada. There are also not any anticipated changes to the FHA or FSSA because of this installation.

2.11 Waste Management

Under the current PROL, Darlington NGS is required to have in place a program that covers internal waste programs related to the operation of the station and preliminary plans for decommissioning. OPG's waste management standard OPG-STD-0156, "*Management of Waste and Other Environmentally Regulated Materials*", documents how waste is managed and responsibilities for ensuring that all waste at Darlington NGS is processed in accordance with federal, provincial, and municipal regulations.

The Waste Management SCA is comprised of the following SPAs:

- Waste Characterization
- Waste Minimization
- Waste Management Practices
- Decommissioning Plans

OPG has performed a thorough assessment of the project scope and has determined that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Waste Management SCA.

Regulatory requirements listed in Table 2.11.a apply to the Waste Management SCA. Table 2.11.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Waste Management and identifies the impact of the installation and operation of TDS on additional units on these programs and processes.

Table 2.11.a List of Waste Management Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Management of low and intermediate- level radioactive waste	CSA N292.3 (2008)	Continued compliance, no impact from installation and operation of TDS on additional units
Decommissioning of facilities containing nuclear substances	CSA N294 (2019)	Continued compliance, no impact from installation and operation of TDS on additional units

Table 2.11.b Impact from installation and operation of TDS on additional units on Darlington's Waste Management Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Environment Health And Safety	N-PROG-OP-0005	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Managed Systems		
Management of Waste and Other Environmentally Regulated Materials	OPG-STD-0156	No Change
Segregation and Handling of Radioactive Wastes	N-PROC-RA-0017	No Change
Operations & Maintenance Plan –Retube Waste Processing Building	NK38-PLAN-09701-10293	No Change
RWPB Safety Analysis Summary Report	NK38-REP-09701-10344	No Change
Darlington Retube Waste Processing Building - Safety Assessment	NK38-REP-09701-10326	No Change
RWPB Worker Dose During Normal Operation and Under Accident Conditions	NK38-CORR-09701-0597849	No Change
Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB)	NK38-REP-09701-10338	No Change
Decommissioning Program	W-PROG-WM-0003	No Change
Preliminary Decommissioning Plan – Darlington Nuclear Generating Station	NK38-PLAN-00960-0001	No Change

2.11.1 Waste Characterization

2.11.1.1 Low Level Nuclear Waste

Low level waste generated through TDS maintenance activities will be managed in accordance with W-PROG-WM-0001, "*Nuclear Waste Management Program"*.

The operation of the TDS for the production of Mo-99 will not generate waste. Once the irradiated targets are shipped to BWXT- Medical, waste products during the processing of Tc-99m will not be returned to Darlington NGS. All waste associated with target processing will remain at vendor's facility.

2.11.1.2 Conventional Waste

Conventional waste generated through all TDS maintenance activities will be processed in accordance with OPG-STD-0156, *Management Of Waste And Other Environmentally Regulated Materials.*

2.11.1.3 Chemical and Hazardous Waste

Chemicals will not be used during any TDS operations. Therefore, TDS operations will not generate chemical or hazardous waste.

There will be no changes to the established licensing basis of the Waste Characterization SPA resulting from this request.

2.11.2 Waste Minimization and Waste Management Practices

The operation and maintenance of TDS will not impact OPG's waste management practices and Darlington will remain in compliance with CSA Standard N292.3-08, "*Management of low and intermediate-level radioactive waste"*.

To minimize waste generated, Darlington unpackages materials and equipment before they enter the station, thereby reducing the risk of contaminating items that would eventually become low level radioactive waste.

There will be no changes to the established licensing basis of the Waste Minimization and Waste Management Practices SPAs resulting from this request.

2.11.3 Decommissioning Plans

"*Preliminary Decommissioning Plan – Darlington Nuclear Generating Station*" describes the activities that will be required to decommission and restore the Darlington site for other OPG uses.

TDS on additional units, being a relatively small and removable system, will have minimal effect on future decommissioning activities

There will be no changes to the established licensing basis of the Decommissioning Plans SPAs resulting from this request.

2.12 Security

The targets, manufactured by BWXT-NEC, will be received periodically at Darlington NGS to meet medical demand for the isotopes to be irradiated. Once irradiated, the targets will be shipped from Darlington NGS to BWXT-Medical processing facility, using BWXT transportation packaging and equipment, for medical processing.

The Security SCA is comprised of the following SPAs:

- Facilities and Equipment
- Response Arrangements
- Security Practices
- Drills and Exercises
- Cyber Security

OPG has performed a thorough assessment of the project scope and has determined that the installation and operations of TDS on additional units will not require any changes to the licensing basis of the Security SCA. This is further explained in Section 2.12.1 to 2.12.4.

Regulatory requirements that apply to the Security SCA are listed in Table 2.12.a. Furthermore, Table 2.12.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Security and identifies the impact from installation and operation of TDS on additional units.

Table 2.12.a List of Security Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Nuclear Security Regulations	SOR/2000-209	Continued compliance, no impact from installation and operation of TDS on additional units
Cyber security for nuclear power plants and small reactor facilities	CSA N290.7 (2014)	Continued compliance, no impact from installation and operation of TDS on additional units
High-Security Sites, Volume II: Criteria for Nuclear Security Systems and Devices	REGDOC-2.12.1, Volume II (2018)	Continued compliance, no impact from installation and operation of TDS on additional units
High Security Facilities, Volume I: Nuclear Response Force, Version 2	CNSC REGDOC-2.12.1, Volume I (2018)	Continued compliance, no impact from installation and operation of TDS on additional units
Site Access Security Clearance	CNSC REGDOC- 2.12.2 (2013)	Continued compliance, no impact from installation and operation of TDS on additional units
Security of Nuclear Substances: Sealed Sources	REGDOC-2.12.3 (2.12.3)	Continued compliance, no impact from installation and operation of TDS on additional units
Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical, Psychological Fitness	CNSC REGDOC-2.2.4 (2018)	Continued compliance, no impact from installation and operation of TDS on additional units.

Table 2.12.b Impact from installation and operation of TDS on additional units on Darlington's Security Program Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Darlington Nuclear Generating Station Security Report	8300-REP-61400-10003	No Change
Darlington Nuclear	8300-PLAN-61400-10012	No Change

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Security Tactical Plan		
Nuclear Security	N-PROG-RA-0011	No Change
Transport Security Plan	TRAN-PLAN-03450- 10000	No Change
Threat and Risk Assessment	NK38-REP-08160.3- 00001	No Change
Cyber Security	N-PROC-RA-0135	No Change
Cyber Essential Asset Identification and Classification	N-STI-08161-10017	No Change
Cyber Security Controls for Cyber Essential Assets	N-INS-08161-10011	No Change
Significant Cyber Assets	NK38-LIST-69000-10001	No Change

2.12.1 Facilities and Equipment

The installation and operation of TDS on additional units will not require changes to security related facilities, equipment or staffing levels. The incoming and outgoing transportation vehicles will be processed by Darlington security staff in accordance with N-INS-61400-10016, "*Security Process of Vehicle Ingress and Egress to the Controlled and Protected Areas".*

There will be no changes to the established licensing basis of the Facilities and Equipment SPA resulting from this request.

2.12.2 Response Arrangements

There will be no changes to the established licensing basis of Response Arrangements SPA resulting from this request.

2.12.3 Security Practices, Drills and Exercises

There will be no changes to the established licensing basis of the Security Practices, Drills and Exercises SPA resulting from this request.

2.12.4 Cyber Security

There will be no changes to the established licensing basis of the Cyber Security SPA resulting from this request.

2.13 Safeguards and Non-Proliferation

The Safeguards and Non-Proliferation SCA is comprised of the following SPAs:

- Nuclear Material Accountancy and Control
- Access and Assistance to the IAEA

- Operational and Design Information
- Safeguards Equipment, Containment and Surveillance
- Import and Export

Darlington NGS will continue to meet Canada's international obligations under the Treaty on the Non-Proliferation of nuclear weapons. This project will not interface with the fuel cycle or with the Irradiated Fuel Bays and does not involve nuclear material as defined by IAEA regulations (Uranium, Thorium or Plutonium).

OPG has performed a thorough assessment of the project scope and has determined that the installation and operation of TDS on additional units will not require any changes to the licensing basis of the Safeguards and Non-Proliferation SCA. This is further explained in Section 2.13.1 to 2.13.5.

Regulatory requirements that apply to the Safeguards and Non-Proliferation SCA are listed in Table 2.13.a. Furthermore, Table 2.13.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Safeguards and Non-Proliferation and identifies the impact from the installation and operation of TDS on additional units.

Table 2.13.a List of Safeguards and Non-Proliferation Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from installation and operation of TDS on additional units
Nuclear Non-proliferation Import and Export Control Regulations	SOR/2000-210	Continued compliance, no impact from installation and operation of TDS on additional units
Safeguards and Nuclear Material Accountancy	CNSC REGDOC-2.13.1 (2018)	Continued compliance, no impact from installation and operation of TDS on additional units

Table 2.13.b Impact from installation and operation of TDS on additional units on Darlington's Safeguards and Non- Proliferation Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from installation and operation of TDS on additional units
Nuclear Safeguards	N-PROG-RA-0015	No Change
Nuclear Safeguards Implementation	N-STD-RA-0024	No Change
OPG Safeguards and Nuclear Material Accountancy Requirements	N-PROC-RA-0136	No Change

2.13.1 Nuclear Material Accountancy and Control

All reports and information necessary for safeguards implementation and compliance will continue to be provided on a timely basis.

Darlington completes an annual Physical Inventory Taking (PIT) as part of Licence Condition 13.1. TDS on additional units will not impact OPG's compliance with non-fuel reporting requirements documented in REGDOC-2.13.1, "*Safeguards and Nuclear Material Accountancy*".

2.13.2 Access and Assistance to the IAEA

Canadian facilities are selected at random by the IAEA for physical inspections to confirm compliance with international non-proliferation requirements. TDS on additional units will have no impact on IAEA inspections or access to IAEA equipment.

2.13.3 Operational and Design Information

The design description of the U2 TDS has been provided to CNSC staff for transmittal to the IAEA under the Mo-99 TDS submission (Reference 20). Should the design changes referenced in section 1.4 require an additional transmittal to the IAEA, OPG will support the CNSC with the details required for that transmittal.

2.13.4 Safeguards Equipment, Containment and Surveillance

TDS on additional units will not interfere with existing IAEA safeguards surveillance monitoring equipment.

2.13.5 Import and Export

There will be no requirement to import nuclear material for the irradiation of isotopes in any TDS. BWXT-Medical will be responsible for obtaining the required export licenses for exporting the processed isotopes outside of Canada.

2.14 Packaging And Transport

The Packaging and Transport SCA is comprised of the following SPAs:

- Package Design and Maintenance
- Packaging and Transport
- Registration for Use

The targets, manufactured by BWXT-NEC, will be received periodically at Darlington NGS to meet medical demand for the isotopes. Once irradiated, the targets will be shipped from Darlington NGS to BWXT-Medical for medical processing.

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the Unit 2 TDS will not require any changes to the licensing basis of the Packaging and Transport SCA. This is further explained in Section 2.14.1 to 2.14.3.

Regulatory requirements that apply to the Packaging and Transport SCA are listed in Table 2.14.a. Furthermore, Table 2.14.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Packaging and Transport and identifies the impact from the installation and operation of TDS on additional units.

Table 2.14a List of Packaging and Transport Related Regulatory Requirements

OPG Licensing Basis Document Title	Document Number	Impact from the installation and operation of TDS on additional units
Transportation of Dangerous Goods Regulations	SOR/2001-286	Continued compliance, no impact from the installation and operation of TDS on additional units.
Packaging and Transport of Nuclear Substances Regulations	SOR/2015-145 (2015)	Continued compliance, no impact from the installation and operation of TDS on additional units

Table 2.14.b Impact from the installation and operation of a TDS on additional units on Darlington's Packaging and Transport Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from the installation and operation of TDS on additional units
Radioactive Material Transportation	W-PROG-WM-0002	No Change
Radioactive Materials Transportation Emergency Response Plan	N-STD-RA-0036	No Change

2.14.1 Package Design and Maintenance

BWXT-Medical, having ownership of the transportation packaging, will be responsible for the packaging design and maintenance.

At the applicable Darlington NGS unit, the irradiated targets will be loaded into a certified radioactive material transportation package for shipment to BWXT-Medical in Kanata, Ontario, using the flask loader.

2.14.2 Packaging and Transport

The Radioactive Material Transportation (RMT) program W-PROG-WM-0002, "*Radioactive Material Transportation*", establishes the necessary controls for safe, regulatory compliant and efficient transportation of radioactive material at OPG. The RMT program establishes procedures for the handling, packaging, shipment, carriage, and

receipt of radioactive materials. The program also addresses emergency responses to transportation accidents.

In accordance with this program and the regulatory requirements, OPG staff will package the irradiated targets for shipment in CNSC certified transportation packaging and will prepare the shipping paperwork for receipt at a facility licensed by the CNSC to receive the specific material.

Flasking, hoisting, managing, and storing isotopes follow NK38-MMP-30550-13, "*Target Delivery System Transport Package Flasking."*

2.14.2.1 Response to Transportation Accidents

OPG's response to transportation accidents involving radioactive material is documented in N-STD-RA-0036, "*Radioactive Material Transportation Emergency Response Plan*". There will be no change required to this plan as a result of TDS on additional units.

BWXT-Medical, being the shipper, would be the primary contact for the police in the event of a transportation accident. BWXT-Medical may request OPG's assistance depending on the proximity of the accident to OPG's nuclear facilities. Both BWXT-Medical and OPG have emergency response capability.

2.14.3 Registration for Use

OPG has procedures in place for the registration for use of certified design transportation packages, and there will be no changes due to the installation of a TDS on additional units.

3.0 OTHER MATTERS OF REGULATORY INTEREST

3.1 Public Information and Engagement

OPG believes in timely open and transparent communication to maintain positive and supportive relationships and confidence of key stakeholders. OPG's Corporate Relations and Communications organization adheres to the principles and process for external communications as governed by the Nuclear Public Information and Disclosure standard.

OPG provides responses to issues and questions raised by stakeholders and the public, and tracks issues and questions to identify trends to further refine proactive communications. Two-way dialogue with community stakeholders and residents is facilitated through personal contact, community newsletters, speaking engagements, advertising, and educational outreach.

Through this regular outreach of an on-going nature, OPG continues to provide members of the public and interested parties with information regarding the production and transportation of isotopes.

3.2 Community Committees

The Darlington Community Advisory Council (CAC) meets to exchange information and provide advice to senior station management on station activities as they relate to the adjacent community and public use of the waterfront trail and adjacent lands.

OPG also has a representative on the Durham Nuclear Health Committee (DNHC). OPG Nuclear staff make regular presentations to the DNHC on a variety of environmental, community outreach and operational issues. The committee is chaired by the Durham Region Medical Officer of Health.

These forums provide opportunity for public engagement, and information exchange regarding the installation and operation of TDS on additional units.

3.3 Indigenous Community Engagement

OPG is committed to engaging with identified Indigenous Nations and communities and those having an interest in its current nuclear operations and future nuclear projects, including the production of the medical isotopes described herein. OPG's Indigenous Relations Policy, OPG-POL-0027, "*Indigenous Relations Policy*", provides a framework for engaging with Indigenous Nations and communities and providing support of community programs and initiatives. As part of its Indigenous Relations policy, OPG maintains and Indigenous Relations program for its nuclear operations with the goals of:

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

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

As recommended in the CNSC REGDOC 3.2.2, "*Indigenous Engagement"*, an Indigenous Engagement Plan has been prepared to document the engagement scope and activities regarding these medical isotope projects, NK38-PLAN-00120-00027, "*Target Delivery System Engagement and Communications Plan with Indigenous Nations and Communities*", (Enclosure 4).

4.0 CONCLUSION

This application focuses on providing evidence to the Canadian Nuclear Safety Commission, in a public forum, to demonstrate that the installation of a TDS is a low-risk activity, which can be executed safely, and to thereby obtain approval to install a TDS on additional units. Prior to the installation and operation of a TDS on additional units, any changes will be made through OPG's existing ECC program, confirming that all regulatory requirements are met, as well as ensuring the project is executed safely with high quality.

OPG is responsible for continued safe operation of Darlington NGS and confirms that the installation and operation of TDS on additional units will be implemented based on a robust safety case and in accordance with OPG's ECC program, which is supported by safety assessments that demonstrate continued safe reactor operation, public safety, and environmental protection.

The safety case to demonstrate that the installation of a TDS on additional units is a low-risk activity, which can be executed safely is outlined below:

- **Design**: OPG will continue to follow its established N-PROC-MP-0090, *"Engineering Change Control Process*" for ensuring the design complies with applicable Darlington PROL 13.06/2025 regulatory requirements and that configuration management for the station is maintained.

- **Continued Safe Operations**: The nuclear safety case and operational assessments for the introduction of the Unit 2 TDS and production of Mo-99 was completed prior to the operation of the Unit 2 TDS. The complete comprehensive Mo-99 assessment N-REP-03500-0839983, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" demonstrated the relatively small impact of producing Mo-99 in the Unit 2 TDS on the complete safety case and operation at Darlington NGS (Enclosure 5 of Reference 5).

  Commissioning results and analysis pertaining to reactor response during Mo-99 seed and harvesting activities concluded that the reactor responded as expected, validating the simulations modeling, and confirming safe reactor operation post installation of the Unit 2 TDS as well as during Mo-99 seed and harvesting activities (Reference 8).

  In support of the installation of new TDS on additional units NK38-EVAL-03600-00001, "*Nuclear Safety Review - Target Delivery System Installed on Multiple Units"* was performed (Enclosure 1). Based on this review, there are no additional safety analysis requirements necessary to support the installation of a TDS on other Darlington NGS units. The review concluded that the installation of a TDS on other units will have no impact on the safe operation of Darlington NGS. Systems, structures and components will continue to provide the required safety, protective and mitigating actions necessary to ensure the original design objectives are met.

- **Environmental Protection**: The operational tritium releases for the Darlington NGS Unit, with the Unit 2 TDS in place, remain comparable to the projected releases as defined in the ALARA assessments. Since the projected releases are within the ALARA assessment, the conclusions of the TDS U2 Predictive Environmental Assessment (PEA) were confirmed.

  A Predictive Environmental Risk Assessment, NK38-REP-30550-00051 "*Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3)"*, prepared in accordance with Canadian Standards Association (CSA) N288.6-12, "Environmental risk assessments at Class 1 nuclear facilities and uranium mines and mills", concluded that the cumulative effects from operating an additional TDS will continue to have a negligible impact on the environment. This assessment is included in Enclosure 2.

  The existing environmental risk assessment will be updated, or additional assessments performed if and when OPG moves forward with additional installations

- **Radiological Protection**: An ALARA assessment was completed for the initial installation of the Unit 2 TDS (Reference 6) and has been updated as per the ECC program, N-PROG-MP-0001, "*Engineering Change Control*", (Enclosure 3 of Reference 7).

  A memo has been prepared to highlight the updates required to this ALARA assessment to account for the installation of TDS in additional units and is presented in Enclosure 3. This updated ALARA assessment is in progress and will be provided to the CNSC upon completion.

- **Licensing Basis:** This LIA documents that there will be no negative impact to Darlington's licensing basis governance, programs, and processes resulting from the installation and operation of TDS on additional units.

Overall, OPG does not expect any safety or operational issues to result from the installation of a TDS on additional units.

OPG will continue to meet Canada's international obligations under the *Treaty on the Non-Proliferation of Nuclear Weapons.*

REFERENCES

1. OPG letter, A. Grace to A. Mathai, “Darlington NGS – Letter of Intent for Approval to Install additional Target Delivery Systems (TDSs)” December 9, 2024, CD# NK38-CORR-00531-25801.

2. OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS -Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment", December 5, 2018, CD# NK38-CORR-00531-20359.

3. Canadian Nuclear Safety Commission, "Commission Member Document: 21-H107”, https://www.nuclearsafety.gc.ca/eng/the-commission/hearings/cmd/pdf/cmd21/cmd21-h107.pdf. June 23, 2021.

4. Canadian Nuclear Safety Commission, "Record of Decision – DEC 21-H107”, https://www.nuclearsafety.gc.ca/eng/the-commission/pdf/Decision-OPG-Mo-99-CMD21-H107-e.pdf. October 26, 2021.

5. 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)", March 9, 2021, CD# NK38-CORR-00531-22385.

6. OPG email, A. Bhardwaj to S. Baskey, “Darlington NGS – System Design ALARA Assessment: Mo-99 IIS – Response to CNSC Staff Request - 6CE6”, September 7, 2022, CD# NK38-CORR-00531-23735.

7. OPG email, C. Bédard to A. Mathai, **“**Darlington NGS – Submission of Deliverables for the Regulatory Hold Point for Additional Isotope Production”, June 25, 2025, CD# NK-CORR-00531-26215.

8. OPG letter, R. Geofroy to A. Mathai, “Darlington NGS – Molybdenum Isotope Irradiation System / Target Delivery System: Submission of TDS Commissioning Report and Associated Documentation”, November 22, 2023, CD# NK38-CORR-00531-25033.

9. BWXT Letter, M. Trudel to D. Rogalski, “Approach and Deviations for Unit 3 TDS, PR-16-87897”, August 28, 2024, CD# NK38-CORR-30550-1342488.

10. OPG letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Revised Assessment of Target Delivery System for Molybdenum Irradiation on the Darlington Probabilistic Safety Assessments (SA05-02 R1)”, June 30, 2020, CD# NK38-CORR-00531-21764.

11. 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)”, July 22, 2020, CD# NK38-CORR-00531-21808.

12. CNSC letter, J. Burta to S. Gregoris, “Darlington NGS - Molybdenum-99 Isotope Irradiation System – CNSC Staff Review of OPG Updated Request for CNSC Staff’s Code Classification Consent for the Target Delivery System and Written Notification for Permanent Changes to the Containment Boundary”, March 30, 2020, e-Doc# 6267477, CD# NK38-CORR-00531-21684.

13. CNSC letter, A. Mathai to S. Gregoris, “Darlington NGS – Unit 3 Target Delivery System – Code Classification and Containment Boundary Requests for Consent and Containment Boundary Prior Notifications”, May 12, 2025, e-Doc# 7517483, CD# NK38-CORR-00531-26161.

14. 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)” August 31, 2020, CD# NK38-CORR-00531-21845.

15. OPG letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Preliminary Engineering Design Documents (D02-01)”, March 5, 2020, CD# NK38-CORR-00531-21389.

16. OPG letter, A. Grace to A. Mathai and S. Watt, “Darlington NGS – 2024 Environmental Risk Assessment Addendum for the Darlington Nuclear Site”, September 24, 2024, CD# NK38-CORR-00531-25312.

17. 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)”, June 4, 2019, CD# NK38-CORR-00531-20764.

18. OPG letter, S. Gregoris to N. Riendeau, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Impact of Target Delivery System on NOP Coverage for Slow Loss of Regulation (SA04-08)”, September 11, 2019, CD# NK38-CORR-00531-21018.

19. 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)”, May 28, 2020, CD# NK38-CORR-00531-21628.

20. OPG e-mail, L. Moraru to J. Burta, “Darlington NGS – Molybdenum 99 Isotope Irradiation System: IAEA Safeguards Update”, September 16, 2020, CD# NK38-CORR-00531-21952.

ENCLOSURES TO ATTACHMENT 1

OPG letter, A. Grace to C. Salmon, “Darlington NGS – Amendment to the Licensing Basis of the Power Reactor Operating Licence 13.06/2025 for the Installation and Operation of Target Delivery Systems in Additional Units”

CD# NK38-CORR-00531-26277

Enclosure 1: NK38-EVAL-03600-00001-R001, *Nuclear Safety Review - Target Delivery System Installed on Multiple Units*
(53 pages)

Enclosure 2: NK38-REP-30550-00051-R000, *Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3)*
(110 pages)

Enclosure 3: NK38-CORR-30550-1412375-R000, *Summary of Planned Updates to the Target Delivery System ALARA Assessment to Account for Target Delivery System Installation in Additional Units*
(4 pages)

Enclosure 4: NK38-PLAN-00120-00027, *Targeted Delivery System Engagement and Communications Plan with Indigenous Nations and Communities*
(17 pages)

Enclosure 5: *L1 Project Schedule: Darlington Target Delivery System (TDS) Project - Unit 3*
(1 page)

Enclosure 6: NK38-PLAN-30550-00106-R000, *Darlington Target Delivery System Human Factors Engineering Program Plan*
(23 pages)

Enclosure 7: NK38-CORR-30550-1417529, *Fire Protection Memo for Unit 3 TDS, PR-16-8 7897, Master EC 166617*
(3 pages)

Enclosure 8: *Summary of Design Changes*
(1 page)

Summary of Regulatory Commitments, Regulatory Obligations and Regulatory Management Actions Made/Concurrence Requested

CD# NK38-CORR-00531-26277

Submission Title: **Darlington NGS – Amendment to the Licensing Basis of the Power Reactor Operating Licence 13.06/2025 for the Installation and Operation of Target Delivery Systems in Additional Units**

Regulatory Commitments (REGC):

No.	Description	Date to be Completed
	None	

Regulatory Management Action (REGM):

No.	Description	Date to be Completed
	None	

Regulatory Obligation Action (REGO):

No.	Description	Date to be Completed
	None	

Concurrence Requested: Approval of this amendment to the licensing basis is requested by November 1, 2025, to align with outage planning milestones.