ONTARIO POWER GENERATION

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NK38-00531 P
NK38-CORR-00531-22275 P

Mr. M. Leblanc
Commission Secretary
Canadian Nuclear Safety Commission
P.O. Box 1046
280 Slater Street
Ottawa, Ontario
K1P 5S9

Dear Mr. Leblanc:

Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025

The purpose of this letter is to submit to the Canadian Nuclear Safety Commission, referred as "the Commission", an addendum to the request for Darlington NGS Power Reactor Operating Licence (PROL) 13.02/2025 to add, as a new activity, Molybdenum-99 (Mo-99) medical isotope production.

As presented in References 1 and 2, OPG's request for an amendment to Darlington NGS Power Reactor Operating Licence (PROL) 13.02/2025 to add a new licensed activity to possess, transfer, produce, package, manage and store Mo-99 radioisotope, and its associated decay isotopes, remains unchanged.

The Mo-99 medical isotope project is an important initiative for the nuclear industry and medical community. Approximately 80% of nuclear medical diagnostic procedures rely on Technetium-99m (Tc-99m), the decay isotope of the Mo-99 radioisotope. This translates into over 30 million heart, cancer and bone diagnostic scans, which are performed annually using Tc-99m.

Over the past two years, submissions to the Commission have been limited to high-level updates as OPG and the Mo-99 project vendor partners focused on completion of the design and required safety assessments for submission to CNSC staff.

Attachment 1 describes how the licensing basis for the proposed activity, as defined in OPG's application, will accommodate the pertinent clauses of relevant legislation.

Attachment 2 provides a description and key attributes of the Mo-99 Isotope Irradiation System (IIS) and documents the licensing impact assessment of the Mo-99 IIS on all 14 Safety and Control Areas of Darlington's PROL.

The design of the Mo-99 IIS complies with all applicable regulatory requirements. The safety assessment, which is referred as the "safety case", demonstrates that installation and operation of the Mo-99 IIS will have no significant impact on continued safe reactor operation, and on public, employee and environmental safety, as is defined in the following elements:

- **Design:** OPG has and will continue to follow its established Engineering Change Control (ECC) process for ensuring the design complies with applicable regulatory requirements and that configuration management for the station will be maintained.

- **Continued Safe Reactor Operation:** Safety analysis submitted to CNSC staff demonstrates that operation of the Mo-99 IIS will have negligible effect on safe reactor operation, and on public safety.

- **Environmental Protection**: A predictive environmental effects assessment, prepared in accordance with Canadian Standards Association (CSA) N288.6-12, "*Environmental risk assessments at Class 1 nuclear facilities and uranium mines and mills*", concludes that operation of the Mo-99 IIS will have negligible impact on the environment.

- **Licensing Basis**: As documented in Attachments 1 and 2, operation of the Mo-99 IIS will have negligible impact on Darlington's licensing basis, governance, and well established programs and processes.

OPG is targeting to start Mo-99 non-reactor system equipment installation in the second half of 2021 and expects to be ready to install the Mo-99 IIS on Unit 2 reactor in the first quarter of 2022.

OPG understands that CNSC staff are considering the use of Regulatory Hold Points. OPG supports this approach should it be deemed required, and will work with CNSC staff for the development of release criteria by a CNSC designated officer.

In summary, OPG remains committed to safe operation of the Darlington NGS units, and re-affirms that the Mo-99 system can be implemented as presented in the robust safety case. Assessments submitted to CNSC staff conclude that the proposed activities to support production of Mo-99 will not compromise continued safe reactor operation, environmental protection and public safety.

OPG staff has the required competence and skills to operate the proposed Mo-99 IIS and will continue to follow the robust and well established ECC process. OPG will continue to meet Canada's international obligations under the Treaty on the Non-Proliferation of Nuclear Weapons.

If you have any questions, please contact Paulina Herrera, Manager, Darlington Regulatory Affairs, at (905) 623-6670 extension 703 0219.

Sincerely,

for

Steve Gregoris
Senior Vice President
Darlington Nuclear
Ontario Power Generation Inc.

Attach.

cc: Mr. J. Burta – CNSC (Ottawa)
Ms. K. Hazelton - CNSC (Darlington)
cnsc.forms-formulaires.ccsn@canada.ca

References:

1. 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.

2. OPG letter, S. Gregoris to M. Leblanc and G. Frappier, “Darlington NGS – Molybdenum-99: Updated Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025”, June 23, 2020, CD# NK38-CORR-00531-21744.

ATTACHMENT 1

OPG letter S. Gregoris to M. Leblanc, “Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025”

CD# NK38-CORR-00531-22275

Licence Amendment Matrix - Applicable Regulations

Prepared by: **R. MacEacheron**

Checked by: **J. Chapin**

ATTACHMENT 1

Licence Amendment Matrix - Applicable Regulations

This Attachment, along with the accompanying letter and Attachment 2 of this submission, provides the information required by the Nuclear Safety and Control Act and the applicable Nuclear Regulations made pursuant to the Act, and constitutes an application by OPG to amend the current Darlington NGS Power Reactor Operating Licence (PROL) 13.02/2025.

In References [1] and [2], OPG staff requested an amendment to the Darlington PROL to authorize, as a licensed activity, the possession, transfer, production, packaging, management and storage of Molybdenum-99 (Mo-99) and its associated decay products.

The tables below are divided by applicable Regulation and demonstrate how OPG has addressed each the applicable regulatory requirements of the subject Regulation.

Nuclear Safety and Control Act		
Section	**Requirement**	**OPG Response**
	Licences	
24(2)	***Application*** *The Commission may issue, renew, suspend in whole or in part, amend, revoke, or replace a licence, or authorize its transfer on receipt of an application:* *(a) in the prescribed form;*	The request for licence amendment (Reference [1]) combined with this submission (letter and attachments) provide the information required by the Nuclear Safety and Control Act (referred to as the Act) and the Regulations made pursuant to the Act, and provides supplemental information in support of OPG's application for licence amendment. This requirement has been met.
	(b) containing the prescribed information and undertakings and accompanied by the prescribed documents; and	See response above under clause 24 (2) (a).
	(c) accompanied by the prescribed fee.	OPG is in good standing with respect to the provision of CNSC licensing fees and will provide any additional fees associated with this PROL amendment request, if requested.
24(4)	***Conditions for issuance, etc.*** *No licence may be issued, renewed, amended or replaced - and no authorization to transfer one given - unless, in the opinion of the Commission, the applicant:*	OPG understands that qualification will be determined through consideration by the Commission of this application and the associated supporting material, as well as deliberation through the Commission decision-making process.

Nuclear Safety and Control Act		
Section	**Requirement**	**OPG Response**
	(a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and	OPG is qualified to safely undertake the additional activities associated with the production on Mo-99 medical isotope at Darlington NGS.
	(b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.	Attachment 2 of this submission documents the assessments and provisions in support of the licence amendment request. Specifically: Section 2.8 documents worker health and safety provisions. Section 2.9 documents assessments and impact on environmental protection. Section 2.12 documents the security considerations. Section 2.13 documents the impact on Canada's international obligations related to safeguards and non-proliferation.
25	***Renewal, etc.*** *The Commission may, on its own motion, renew, suspend in whole or in part, amend, revoke or replace a licence under the prescribed conditions.*	OPG understands this requirement and will continue to comply.

Nuclear Safety and Control Act		
Section	**Requirement**	**OPG Response**
26	***Prohibitions*** *Subject to the regulations, no person shall, except in accordance with a licence:* *(a) possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information;* *(b) mine, produce, refine, convert, enrich, process, reprocess, package, transport, manage, store or dispose of a nuclear substance;* *(c) produce or service prescribed equipment;* *(d) operate a dosimetry service for the purposes of this Act;* *(e) prepare a site for, construct, operate, modify, decommission or abandon a nuclear facility; or* *(f) construct, operate, decommission or abandon a nuclear-powered vehicle or bring a nuclear-powered vehicle into Canada.*	OPG staff understand these requirements and will continue to comply.

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
Licences - General Application Requirements		
3 (1)	*An application for a licence shall contain the following information:* *(a) the applicant's name and business address;*	Applicant's name and business address: **Ontario Power Generation, Inc** **P.O Box 4000, Bowmanville,** **Ontario, L1C 3Z8** Official Language: **English** Contact person, signing authority and licence holder: **Steve Gregoris** **Senior Vice President** **Darlington Nuclear, Ontario Power Generation** **Telephone: 905-623-6670, extension 0099**
	(b) the activity to be licensed and its purpose;	OPG requests an amendment to the Darlington PROL 13.02/2025 to authorize the production of Molydendum-99 and its associated decay products for the medical community.
	(c) the name, maximum quantity and form of any nuclear substance to be encompassed by the licence;	The quantity of activated Mo-99 will not exceed 8766 TBq. The quantity of activated Zirconium target cladding will not exceed 369 TBq.
	(d) a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence;	A description of the required reactor modifications and Molybdenum Isotope Irradiation System are provided in Section 1 of Attachment 2 of this submission.
	(e) the proposed measures to ensure compliance with the Radiation Protection Regulations, the Nuclear Security Regulations and the Packaging and Transport of Nuclear Substances Regulations, 2015;	OPG understands this requirement and will remain in compliance with the current licence conditions documented in the PROL 13.02/2025 and with the Radiation Protection Regulations, the Nuclear

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
		Security Regulations, and the Packaging and Transport of Nuclear Substances Regulations as described in Attachment 2 of this submission.
	(f) any proposed action level for the purpose of section 6 of the Radiation Protection Regulations;	The requested PROL amendment will not require changes to the radiation protection action levels.
	(g) the proposed measures to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information;	The requested PROL amendment will not require changes to the measures to control Darlington site access, the nuclear substance, prescribed equipment or prescribed information.
	(h) the proposed measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information;	The requested PROL amendment will not require changes to the measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information.
	(i) a description and the results of any test, analysis or calculation performed to substantiate the information included in the application;	The requested PROL amendment to authorize the production of Molybdenum-99 at Darlington NGS is supported by a robust safety case that has been submitted to CNSC staff and is summarized in Attachment 2 of this submission.
	(j) the name, quantity, form, origin and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including waste that may be stored, managed, processed or disposed of at the site of the activity to be licensed, and the proposed method for managing and disposing of that waste;	As documented in Section 2.11 of Attachment 2 of this submission, minimal volume of radioactive waste will be generated from Mo-99 IIS operation. This waste will be managed in accordance with OPG's current programs and processes. No hazardous waste will be generated from Mo-99 IIS operation.
	(k) the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the	The organizational management structure will not change as a result of the requested licence amendment.

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
	Act and the regulations made under the Act, including the internal allocation of functions, responsibilities and authority;	
	(l) a description of any proposed financial guarantee relating to the activity to be licensed; and	OPG understands the regulatory requirements for a financial guarantee. The financial guarantee documented in Reference [3] will not change as a result of the requested PROL amendment.
	(m) any other information required by the Act or the regulations made under the Act for the activity to be licensed and the nuclear substance, nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.	OPG understands this requirement and will continue to comply.
(1.1)	*The Commission or a designated officer authorized under paragraph 37(2)(c) of the Act, may require any other information that is necessary to enable the Commission or the designated officer to determine whether the applicant* *(a) is qualified to carry on the activity to be licensed;* *(b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.*	OPG understands this requirement and will continue to comply.
Application for Amendment, Revocation or Replacement of Licence		
6	*An application for the amendment, revocation or replacement of a licence shall contain the following information:* *(a) a description of the amendment, revocation or replacement and of the measures that will be taken and the methods and procedures that will be used to implement it;*	Description of requested PROL amendment is provided in References [1] and [2], and in the enclosed letter

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
	(b) a statement identifying the changes in the information contained in the most recent application for the licence; *(c) a description of the nuclear substances, land, areas, buildings, structures, components, equipment and systems that will be affected by the amendment, revocation or replacement and of the manner in which they will be affected; and* *(d) the proposed starting date and the expected completion date of any modification encompassed by the application.*	and Attachment 2 of this submission documents the changes that will be required to permit the Darlington reactors to produce the Mo-99 medical isotope.
Incorporation of Material in Application		
7	*An application for a licence or for the renewal, suspension in whole or in part, amendment, revocation or replacement of a licence may incorporate by reference any information that is included in a valid, expired or revoked licence.*	OPG understands and has provided applicable references to information contained in the existing licence and Licence Conditions Handbook.
Obligations		
12 (1)	***Obligations of Licensees*** *Every licensee shall*	OPG understands the requirements and will continue to comply. Specifically:
	(*a) ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the regulations made under the Act and the licence;*	The regulatory requirement of Darlington NGS, Station Minimum Shift Complement, will not change as a result to the requested licence amendment. Refer to section 2.10 of Attachment 2 of this submission for further details.
	(b) train the workers to carry on the licensed activity in accordance with the Act, the regulations made under the Act and the licence;	OPG staff will be trained on operation and maintenance activities associated with the requested licence amendment. Refer to section 2.2 in Attachment 2 of this submission for further details.

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
	(c) take all reasonable precautions to protect the environment and the health and safety of persons and to maintain the security of nuclear facilities and of nuclear substances;	Refer to section 2.9 in Attachment 2 of this submission for details on environmental protection. Refer to section 2.13 in Attachment 2 of this submission for further details on the impact to security.
	(d) provide the devices required by the Act, the regulations made under the Act and the licence and maintain them within the manufacturer's specifications;	OPG understands this requirement and will continue to comply.
	(e) require that every person at the site of the licensed activity use equipment, devices, clothing and procedures in accordance with the Act, the regulations made under the Act and the licence;	OPG understands this requirement and will continue to comply.
	(f) take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances within the site of the *licensed activity and into the environment as a result of the licensed activity;*	OPG understand this requirement and will continue to comply. Refer to section 2.13 in Attachment 2 for further details on security.
	(g*) implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, prescribed equipment or prescribed information, or the illegal use of a nuclear facility;*	OPG understands this requirement and will continue to comply. Refer to section 2.13 in Attachment 2 of this submission for further details on security.
	(h) implement measures for alerting the licensee to acts of sabotage or attempted sabotage anywhere at the site of the licensed activity;	OPG understands this requirement and will continue to comply.
	(i) take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement;	OPG understands this requirement and will continue to comply. Refer to section 2.13 in Attachment 2 of this submission for further details on safeguards.
	(j) instruct the workers on the physical security program at the site of the licensed	OPG understands this requirement and will continue to comply.

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
	activity and on their obligations under that program;	Refer to section 2.12 in Attachment 2 of this submission for further details on security.
	(k) keep a copy of the Act and the regulations made under the Act that apply to the licensed activity readily available for consultation by the workers.	OPG understands this requirement and will continue to comply.
12 (2)	*Every licensee who receives a request from the Commission or a person who is authorized by the Commission for the purpose of this subsection, to conduct a test, analysis, inventory or inspection in respect of the licensed activity or to review or to modify a design, to modify equipment, to modify procedures or to install a new system or new equipment shall file, within the time specified in the request, a report with the Commission that contains the following information:* *(a) confirmation that the request will or will not be carried out or will be carried out in part;* *(b) any action that the licensee has taken to carry out the request or any part of it;* *(c) any reasons why the request or any part of it will not be carried out;* *(d) any proposed alternative means to achieve the objectives of the request; and* *(e) any proposed alternative period within which the licensee proposes to carry out the request.*	OPG understand this requirement and will continue to comply. Installation, testing and commissioning procedures and reports associated with the Mo-99 IIS will be made available to facilitate the regulatory role of CNSC staff.
Transfers		
13	*No licensee shall transfer a nuclear substance, prescribed equipment or prescribed information to a person who does not hold the licence, if any, that is required to possess the nuclear substance,*	OPG understands this requirement and will continue to comply. The irradiated Mo-99 targets will be transported to a CNSC licensed

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
	prescribed equipment or prescribed information by the Act and the regulations made under the Act.	facility for processing in compliance with the Packaging and Transportation of Nuclear Substances Regulations.
	Notice of Licence	
14	*(1) Every licensee other than a licensee who is conducting field operations shall post, at the location specified in the licence or, if no location is specified in the licence, in a conspicuous place at the site of the licensed activity,* *(a) a copy of the licence, with or without the licence number, and a notice indicating the place where any record referred to in the licence may be consulted; or* *(b) a notice containing* *(i) the name of the licensee,* *(ii) a description of the licensed activity,* *(iii) a description of the nuclear substance, nuclear facility or prescribed equipment encompassed by the licence, and* *(iv) a statement of the location of the licence and any record referred to in it*. *(2) Every licensee who is conducting field operations shall keep a copy of the licence at the place where the field operations are being conducted.* *(3) Subsections (1) and (2) do not apply to a licensee in respect of* *(a) a licence to import or export a nuclear substance, prescribed equipment or prescribed information;* *(b) a licence to transport a nuclear substance; or* *(c) a licence to abandon a nuclear substance, a nuclear facility,*	OPG understands this requirement and will continue to comply with this requirement.

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
	prescribed equipment or prescribed information.	
Publication of Health and Safety Information		
16	*(1) Every licensee shall make available to all workers the health and safety information with respect to their workplace that has been collected by the licensee in accordance with the Act, the regulations made under the Act and the licence.* *(2) Subsection (1) does not apply in respect of personal dose records and prescribed information.*	OPG understand this requirement and will continue to comply. OPG's Health and Safety Policy is posted on the OPG intranet website.
Obligations of Workers		
17	*Every worker shall:* *(a) use equipment, devices, facilities and clothing for protecting the environment or the health and safety of persons, or for determining doses of radiation, dose rates or concentrations of radioactive nuclear substances, in a responsible and reasonable manner and in accordance with the Act, the regulations made under the Act and the licence;* *(b) comply with the measures established by the licensee to protect the environment and the health and safety of persons, maintain security, control the levels and doses of radiation, and control releases of radioactive nuclear substances and hazardous substances into the environment;* (*c) promptly inform the licensee or the worker's supervisor of any situation in which the worker believes there may be* *(i) a significant increase in the risk to the environment or the health and safety of persons,*	OPG understands this requirement and will continue to comply.

General Nuclear Safety and Control Regulations		
Section	**Requirement**	**OPG Response**
	(ii) a threat to the maintenance of the security of nuclear facilities and of nuclear substances or an incident with respect to such security, *(iii) a failure to comply with the Act, the regulations made under the Act or the licence,* *(iv) an act of sabotage, theft, loss or illegal use or possession of a nuclear substance, prescribed equipment or prescribed information, or* *(v) a release into the environment of a quantity of a radioactive nuclear substance or hazardous substance that has not been authorized by the licensee;* *(d) observe and obey all notices and warning signs posted by the licensee in accordance with the Radiation Protection Regulations; and* *(e) take all reasonable precautions to ensure the worker's own safety, the safety of the other persons at the site of the licensed activity, the protection of the environment, the protection of the public and the maintenance of the security of nuclear facilities and of nuclear substances.*	

Class I Nuclear Facility Regulations
Applicable items in the Class I Nuclear Facility Regulations have been addressed in the above General Nuclear Safety and Control Regulations section.

Radiation Protection Regulations		
Section	**Requirement**	**OPG Response**
4	*Every licensee must implement a radiation protection program and must, as part of that program,* *(a) keep the effective dose and equivalent dose received by and committed to persons as low as reasonably achievable, taking into account social and economic factors, through the implementation of* *(i) management control over work practices,* *(ii) personnel qualification and training,* *(iii) control of occupational and public exposure to radiation, and* *(iv) planning for unusual situations; and* *(b) ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity* *(i) by direct measurement as a result of monitoring, or* *(ii) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the quantity and concentration using that method, by estimating them.*	OPG has a well established radiation protection program that complies with all elements of the Radiation Protection Regulations. Information on the radiation protection provisions and considerations during the design and operation of the Mo-99 IIS are documented in section 2.7 of Attachment 2 of this submission. OPG staff operating the proposed Mo-99 Isotope Irradiation System receive training and will have the appropriate radiation protection qualification. The Radiation Protection program at Darlington NGS has recently undergone an independent third party review and has recently been strengthened to take into account findings of this assessment with particular emphasis on alpha contamination. The Radiation Protection program will thus be able to manage any extra efforts required for possessing, producing, transferring, managing, and storing Mo-99.

Nuclear Security Regulations
The production of Mo-99 and its associated decay products does not involve Category I, II or III Nuclear Material as defined in the Nuclear Security Regulations. The security considerations for the Mo-99 IIS are documented in section 2.12 of Attachment 2 of this submission.

Nuclear Substance and Radiation Device Regulations		
Section	**Requirement**	**OPG Response**
Licence Applications		
3	***General Requirements*** *(1) An application for a licence in respect of a nuclear substance or a radiation device, other than a licence to service a radiation device, shall contain the following information in addition to the information required by section 3 of the General Nuclear Safety and Control Regulations:* *(a) the methods, procedures and equipment that will be used to carry on the activity to be licensed;* (b) *the methods, procedures and equipment that will be used while carrying on the activity to be licensed, or during and following an accident, to* *(i) monitor the release of any radioactive nuclear substance from the site of the activity to be licensed,* *(ii) detect the presence of and record the radiation dose rate and quantity in Becquerels of radioactive nuclear substances at the site of the activity to be licensed,* *(iii) limit the spread of radioactive contamination within and from the site of the activity to be licensed, and* *(iv) decontaminate any person, site or equipment contaminated as a result of the activity to be licensed;* *(c) a description of the circumstances in which the decontamination referred to in subparagraph (b)(iv) will be carried out;* *(d) the proposed location of the activity to be licensed, including a description of the site;*	Procedures for operation and maintenance of the Mo-99 IIS are currently under development and are expected to be finalized following completion of Factory Acceptance Testing of the assembled system at BWXT-NEC. OPG has committed to provide copies of these procedures to CNSC staff prior to installation of the Mo-99 IIS on the reactor. As documented in section 2.10 of Attachment 2 of this submission, there will be no Operator actions in the event of a Reactor transient. As documented in section 2.9 of Attachment 2 of this submission, emissions from operation of the Mo-99 IIS will be monitored. OPG will follow established procedures for responding to elevated emissions and contamination. Refer section 2.10 of Attachment 2 of this submission for further information on emergency response. Refer to section of 2.7 of Attachment 2 of this submission for further information on radiation protection. The production of Mo-99 and its associated decay products does not involve Category I, II or III Nuclear Material as defined in the Nuclear Security Regulations.

Nuclear Substance and Radiation Device Regulations		
Section	**Requirement**	**OPG Response**
	(e) the roles, responsibilities, duties, qualifications and experience of workers; *(f) the proposed training program for workers;* *(g) the proposed instructions for dealing with accidents, including fires and spills, in which the nuclear substance may be involved;* *(h) the proposed inspection program for the equipment and systems that will be used to carry on the activity to be licensed;* *(i) the methods, procedures and equipment that will be used to calibrate radiation survey meters in accordance with these Regulations;* *(j) the methods, procedures and equipment that will be used to calibrate and verify the calibration of dosimeters referred to in paragraphs 30(3)(d) and (e);* *(k) the methods, procedures and equipment that will be used to conduct the leak tests and surveys required by these Regulations;* *(l) where the application is in respect of a nuclear substance that is an unsealed source and that is to be used in a room, the proposed design of the room;* *(m) if the application is in respect of a nuclear substance that is contained in a radiation device, the brand name and model number of the radiation device, and the quantity of the devices;* *(n) where the application is in respect of Category I, II or III nuclear material, as defined in section 1 of the Nuclear Security Regulations,* *(i) the measures that will be taken to prevent nuclear criticality, and*	

Nuclear Substance and Radiation Device Regulations		
Section	**Requirement**	**OPG Response**
	(ii) the information required by section 3 or 4 of the Nuclear Security Regulations, as applicable; *(o) if the applicant will be manufacturing or distributing radiation devices referred to in paragraph 5(1)(c) or section 6 or 7, or check sources mentioned in section 8.1, the proposed procedure for the disposal of each radiation device or check source or for its return to the manufacturer.*	

Packaging and Transport of Nuclear Substances Regulations and Transportation of Dangerous Goods Regulations
The production of Mo-99 and its associated decay products does not involve Category I, II or III Nuclear Material as defined in the Nuclear Security Regulations. Packaging and transportation considerations for the Mo-99 IIS are documented in Section 2.14 of Attachment 2 of this submission.

References

[1] 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.

[2] OPG letter, S. Gregoris to M. Leblanc and G. Frappier, “Darlington NGS – Molybdenum-99: Updated Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025”, June 23, 2020, CD# NK38-CORR-00531-21744.

[3] OPG letter, J. Mauti to M. Leblanc, “Request for Acceptance of OPG’s Financial Guarantee”, August 4, 2017, CD# N-CORR-00531-18741.

ATTACHMENT 2

OPG letter S. Gregoris to M. Leblanc, “Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025”

CD# NK38-CORR-00531-22275

Molybdenum-99 Isotope Irradiation System Project: CNSC Commission Update in Support of the Darlington Power Reactor Licence Amendment

Prepared by: **R. MacEacheron**

Checked by: **J. Chapin**

ATTACHMENT 2

Molybdenum-99 Isotope Irradiation System Project: CNSC Commission Update in Support of the Darlington Power Reactor Operating Licence Amendment

ONTARIO POWER GENERATION

DARLINGTON
NUCLEAR GENERATING STATION

LICENCE AMENDMENT UPDATE FOR MOLYBDENUM-99

Table of Contents

1. Introduction

1.1 Background

The purpose of this attachment is to provide information in support of OPG's request for amendment to the Darlington Power Reactor Operating Licence (PROL) 13.02/2025.

The key attributes, safety and benefits of the proposed Molybdenum-99 Isotope Irradiation System (Mo-99 IIS) on Darlington Nuclear Generating Station (NGS) licensing basis is summarized in this document. The information provided in this Attachment is divided into three sections as follows:

Section 1: Provides background information on Mo-99 medical isotope, advantages of CANDU production of Mo-99 over traditional production methods, and a summary of the Mo-99 IIS design.

Section 2: Summarizes regulatory compliance for the Mo-99 IIS design and impact on OPG's governance, programs and processes for each of Darlington's Power Reactor Operating Licence (PROL) 14 Safety and Control Areas (SCA).

Section 3: Summarizes public, Indigenous and Metis engagement related to the application of licence amendment.

OPG is responsible for continued safe operation of the Darlington NGS, and confirms that the Mo-99 IIS modifications will be implemented based on a robust safety case and proven engineering methods.

OPG has concluded that the proposed activities to support production of Mo-99 in selected Darlington NGS CANDU reactors will not compromise continued safe reactor operation. OPG has and will continue to follow a robust and well established Engineering Change Control (ECC) process, and will continue to provide information to CNSC staff to assist in fulfillment of their regulatory oversight role.

In References 1.1 and 1.2, OPG submitted an application for amendment to the Darlington PROL 13.01/2025 to authorize a new licensed activity to possess, transfer, produce, package, manage and store the Mo-99 radioisotope and its associated decay isotopes. Subsequent to this request, the Darlington PROL was amended from 13.01/2025 to 13.02/2025 (Reference 1.3).

The Mo-99 medical isotope project is an important initiative for the nuclear industry and medical community. Approximately 80% of nuclear medical procedures rely on Technetium-99m (Tc-99m), the decay isotope of the Mo-99 radioisotope. This translates into over 30 million heart, cancer and bone diagnostic scans, which are performed annually using Tc-99m.

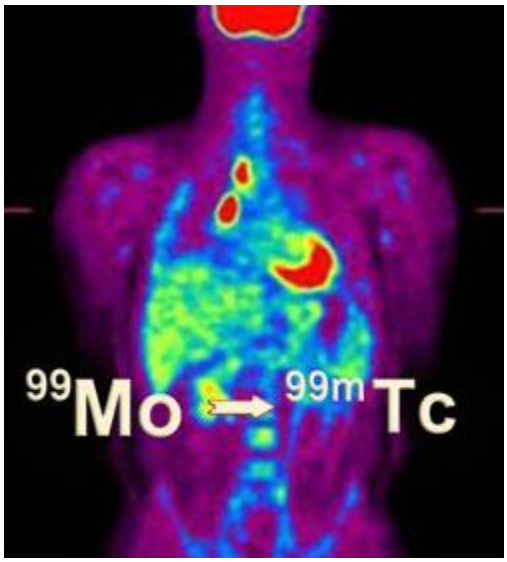
Over the past two years, since the licence amendment was requested (Reference 1.1), OPG has submitted to CNSC staff the design documents for Unit 4 and recently for Unit 2 (References 1.3 and 1.4), along with safety assessments and analysis for the proposed Mo-99 IIS demonstrating that public and environmental safety will be maintained.

1.2 Molybdenum-99 Medical Isotope

The Mo-99 isotope does not occur naturally. Rather, it is commonly man-made in a nuclear reactor or in an accelerator for the purposes of disease diagnosis and treatment management for a large number of medical conditions primarily related to cardiology and oncology. Virtually all major hospitals in Canada have a nuclear medicine department where Mo-99, and its daughter isotope Tc-99m, are used daily by doctors and clinicians to diagnose patients. Almost one-third of hospital admissions will involve nuclear medicine in the patient's diagnosis or treatment.

Of all the isotopes used in nuclear medicine none are more important than Tc-99^{m}. It has been estimated by the Organization for Economic Co-operation and Development High-Level Group on the Security of Supply of Medical Isotopes that over 80% of all nuclear medicine diagnostic procedures performed globally require Tc-99m.

Figure 1.1 Tc-99m Medical Isotope



Source: photochemistry.com

Reliable supply of Mo-99 is therefore critical to Canada and Internationally. Because Mo-99 and Tc-99m have relatively short half-lives, 66 hours and 6 hours respectively, this material must be supplied frequently to the network of nuclear medicine practitioners located in Canada and around the world.

1.3 Molybdenum-99 Darlington Production versus National Research Reactor Universal (NRU) Method

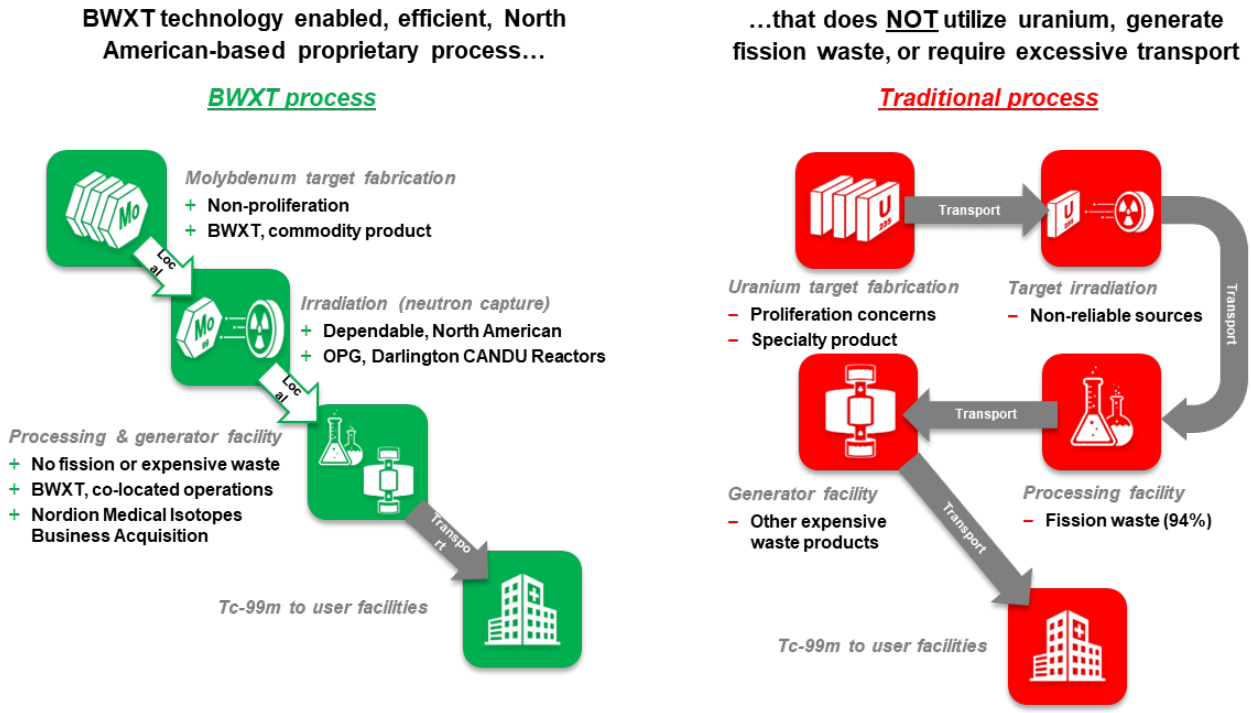
Conventional production methods of Mo-99 require targets enriched in U-235, so called Highly Enriched Uranium (HEU). The higher the enrichment, the higher the Mo-99 yield that can be extracted from the targets after they are irradiated in a high-flux experimental reactor. In Canada, the only reactor that was capable of irradiating HEU was the National Research Universal (NRU) located at Chalk River, Ontario. For decades, Canada was a world leader in medical isotope technology and was by far the largest global supplier of Mo-99, which was made from HEU targets irradiated at NRU and processed into Mo-99 by Nordion Inc. in Kanata, Ontario.

Although very efficient, Mo-99 production based on HEU gives rise to long-lived nuclear waste, and HEU is subject to international safeguards as a dual use defence material. Additionally, when the decision was made to shut down and decommission NRU in 2016, all Mo-99 production in Canada ceased. Since that time Mo-99 is imported into Canada from reactor sites in Belgium, South Africa, Australia, and Netherlands. Numerous shortages have occurred since 2016 due to aging nuclear infrastructure in those countries or the inability of Canada to import sufficient supplies of Mo-99 when global stocks are low.

To solve these strategic supply problems, BWX-Technologies (BWXT) developed a novel, breakthrough Mo-99 technology that does not require the use of either HEU or high-flux experimental reactors such as NRU. Rather, the BWXT method uses naturally occurring Molybdenum metal as the target material for irradiation in the CANDU reactors owned and operated by OPG at the Darlington NGS. The design of CANDU reactors, having a relatively low Moderator operating temperature and pressure is well suited for target irradiation.

The resulting irradiated targets will not give rise to the fission-product nuclear waste that HEU targets produce. The Tc-99m generators store Mo-99 and allow its decay product, Tc-99m to be recovered for use. The Tc-99m generators manufactured for this new technology will work seamlessly as replacements for the imported Tc-99m generators now in use throughout Canada. The differences between the BWXT natural Molybdenum irradiation process and the traditional Mo-99 production process illustrated in Figure 1.2.

Figure 1.2: BWXT Mo-99 Production versus Traditional Mo-99 Production



1.4 Made in Ontario Solution

The proposed production of this important medical isotope at Darlington NGS has been a collaboration of several Ontario based companies illustrated in Figure 1.3.

All of the vendor partner companies for the Darlington Mo-99 IIS project, listed below, have a long history of providing quality support to the Canadian Nuclear industry.

1) Darlington NGS owned and operated by OPG, will be used to irradiate the Mo-99 targets.

2) BWXT-Nuclear Energy Company (NEC), located in Peterborough, Ontario, designed the Mo-99 IIS and manufactures the unique Mo-99 IIS components. The target zirconium sheath will be manufactured at BWXT's facility in Arnpior, Ontario, and assembly of the target capsules with natural Molybdenum will occur at the Peterborough facility.

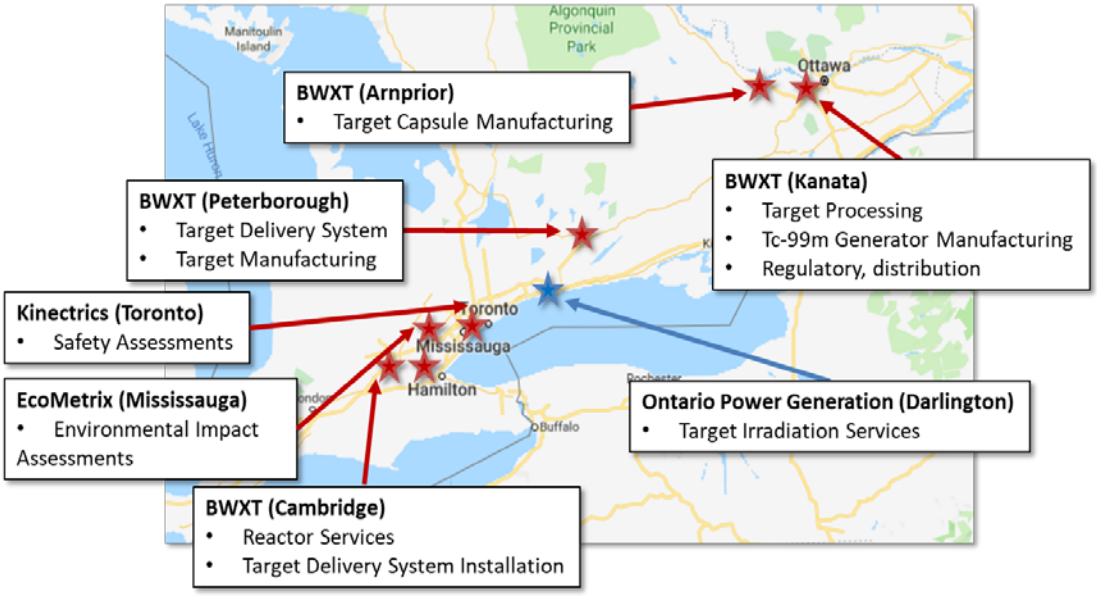
3) BWXT Canada Ltd., located in Cambridge, Ontario, is the Engineer Procure Construct (EPC) Contractor / Constructor for this project. BWXT Canada Ltd has over 60 years of expertise and experience in the design, manufacturing, commissioning and service of nuclear power generation equipment. This includes steam generators, nuclear fuel and fuel components, critical plant components, parts and related plant services

4) BWXT-Medical (formerly named BWXT-ITG (Isotope Technologies Group)), located in Kanata, Ontario, owns and operates the processing facility for generators that convert Mo-99 into Tc-99m for the medical community.

5) Kinectrics, located in Toronto, Ontario, prepared the safety analysis and assessments that demonstrate the Mo-99 IIS will have minimal impact on continued safe reactor operation.

6) EcoMetrix Inc., located in Mississauga, Ontario, prepared the environmental Predictive Effects Assessment for operation of the Mo-99 IIS. EcoMetrix provides support to the nuclear industry is the area of environmental assessments.

Figure 1.3: Contributing Companies to the Proposed Mo-99 Production at Darlington NGS



1.5 Description of the Mo-99 IIS Design

The BWXT system for irradiating natural Molybdenum, which is predominately Mo-98, to form Mo-99 through a process called irradiation or neutron capture, is referred to as the Mo-99 IIS.

The Mo-99 IIS will use modified, out-of-service, Adjuster Rod Ports for insertion and removal of Molybdenum targets from the reactor.

1.5.1 Molybdenum Targets

The Molybdenum targets capsules will be comprised of natural Molybdenum encased in a Zirconium sheath, the same material that is used in CANDU nuclear fuel, shown in Figure 1.4. Target manufacturing by BWXT-NEC will follow a similar process and quality control processes that BWXT-NEC currently uses for manufacturing of CANDU nuclear fuel used at Darlington NGS.

Figure 1.4: Molybdenum Target Capsule

New targets will arrive at Darlington station from BWXT-NEC enclosed in a protective sleeve to ensure cleanliness. The sleeve, containing up to eight target capsules, will be manually loaded into a new target loader for insertion into the reactor for irradiation. The activity of inserting new targets into the reactor is referred to as “target-seeding”.

After approximately seven days of irradiation inside of the reactor, the targets will be removed during a process referred to as “target-harvesting”. Through neutron capture, the irradiated targets will be radioactive requiring shielding and provisions, which are outlined in section 2.7 for ensuring worker radiation exposure is kept As Low As Reasonably Achievable (ALARA).

Following target-harvesting, target-seeding will occur replacing the removed targets where the irradiation process starts over again. This process of target-harvesting followed by target-seeding is expected to occur on a routine basis as determined by medical demand.

1.5.2 Key Attributes of the Mo-99 IIS

The target capsules will be transferred to and from the reactor through shielded piping, referred to a ‘flight-tubing”, using a combination of pneumatics and hydraulics.

An important nuclear safety requirement is that there must always be in place a qualified containment boundary capable of operating under normal and abnormal reactor operation. Containment will be achieved through a combination of qualified sets of redundant containment isolation valves and qualified components and flight-tubing.

A target airlock will act as the transfer point between the pneumatic and hydraulic propulsion systems. Pneumatic propulsion is used on the outboard side, between the target airlock and both the new target loader and flask loader. Hydraulic propulsion will be used on the inboard side, between the target airlock and the target elevator.

A series of diverters will be used on the inboard side to direct the targets between the single target airlock and the four target elevators. A single diverter is used on the outboard side to direct targets from the new target loader to the target airlock, or from the target airlock to the flask loader.

The Mo-99 IIS equipment will be located on the Reactivity Mechanisms Deck (RMD), and adjacent rooms, as well as the Main Control Room (MCR).

The Mo-99 IIS will be controlled and monitored using a combination of a Local Control Panel located in the vicinity of the Mo-99 IIS, along with the MCR. Permission to operate the system must be granted from the MCR, and remain active to allow the local control panel to operate the system.

1.6 Target Transportation

The harvested irradiated targets will be loaded into a CNSC certified transportation package (shielded flask and overpack) by OPG staff and loaded onto a truck for transport to BWXT-Medical for medical isotope processing. BWXT staff will be responsible for transportation from Darlington station to BWXT-Medical in Kanata, Ontario. OPG will be responsible for packaging the radioactive material and preparing the shipping documents.

Figure 1.5: Mo-99 Transportation Flask (Left) and Overpack (Right)

1.7 Safety Case

Safety is OPG's number one priority, proven over many years of reactor operation. OPG is responsible for continued safe operation of Darlington NGS and confirms that the Mo-99 IIS modifications will be implemented based on a robust safety case and in accordance with OPG's Engineering Change Control process, which is supported by safety assessments that demonstrate continued safe reactor operation, public safety and environmental protection.

The Mo-99 IIS safety case can be defined based on the following elements:

1) Mo-99 IIS Design: OPG has and will continue to follow its Engineering Change Control process, as described in N-PROG-MP-0001, "*Engineering Change Control*", for ensuring the design complies with applicable Darlington PROL 13.02/2025 regulatory requirements and that configuration management for the station is maintained. Further explanation is provided in section 2.5.

2) Continued Safe Reactor Operation: Safety analysis submitted to CNSC staff demonstrates that operation of the Mo-99 IIS will have negligible effect on safe reactor operation, and on public safety. Further explanation is provided in section 2.4.

3) Environmental Protection: A predictive environmental effects assessment, prepared in accordance with Canadian Standards Association (CSA) N288.6-12, "*Environmental risk assessments at Class 1 nuclear facilities and uranium mines and mills*" concludes that operation of the Mo-99 IIS will have negligible impact on the environment. Further explanation is provided in section 2.9.

4) Licensing Basis: As documented in sections 2.1 to 2.14, operation of the Mo-99 IIS will have negligible impact on Darlington's licensing basis, governance, programs and processes. Attachment 1 documents the impact on the "*Nuclear Safety Control Act*" and applicable regulations.

Overall there are no notable safety or operational issues that result from introducing Mo-99 irradiation at Darlington NGS and there are significant benefits to the wellbeing of Canadians.

1.8 Schedule

In May 2020, OPG submitted the design documents for installation of the Mo-99 IIS on Unit 4 followed by the "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" (Reference 1.4) in August 2020.

OPG recently submitted the design documents for Mo-99 IIS installation on Unit 2 (Reference 1.5), the majority of which are similar to the design package that was submitted for Unit 4.

OPG is targeting to start Mo-99 IIS non-reactor installation in the second half of 2021 and reactor installation in in the first quarter of 2022, pending Commission approval of the operating licence amendment. Routine Mo-99 production is expected to occur in second half of 2022. At the time of this submission, a decision on Mo-99 IIS installation on units other than Unit 2 had not been made. The requested PROL amendment, is not unit specific, relying on the Licence Condition Handbook to document the requirements for installation on other units.

1.9 Quality Control

OPG plans to use Quality Release Holdpoints (QRHPs) for ensuring quality during Mo-99 IIS installation. The two proposed QRHPs are:

QRHP#1: Prior to reactor modifications, installation of target elevators and modification to the existing containment boundary.

QRHP#2: Prior to "on-power" commissioning of the Mo-99 IIS (first time insertion of targets into an operating reactor).

OPG understands that CNSC staff are considering the use of Regulatory Hold Points (RHPs). OPG supports this approach should it be deemed required, and will work with CNSC staff for the development of release criteria by a CNSC designated officer.

References 1.1 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.

1.2 OPG letter, S. Gregoris to M. Leblanc and G. Frappier, "Darlington NGS – Molybdenum-99: Updated Request for Amendment to the Darlington Nuclear Generating Power Reactor Operation Licence 13.02/2025", June 23, 2020, CD# NK38-CORR-00531-21744.

1.3 CNSC letter, “Application for Nuclear Power Reactor Operating Licenses to reference REGDOC-2.2.3 Personnel Certification Volume III Certification of Persons Working at Nuclear Power Plants”, April 9, 2020, CD# NK38-CORR-00531-21645.

1.4 OPG Confidential 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.

1.5 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Unit 2 Design Documents for Target Delivery System and Plant Modifications (D04-02-U2 and D06-01-U2)”, January 29, 2021, CD# NK38-CORR-00531-22277.

2. Safety Control Areas

The purpose of this section is to document the impact of Darlington Mo-99 IIS on OPG’s governance, programs and processes. A review of the Mo-99 IIS impact on Darlington’s PROL 14 SCA was completed and is summarized in the following sections. Key attributes of the Mo-99 IIS design and safety assessments that make up the “safety case” are also summarized.

OPG is responsible for continued safe operation of Darlington NGS and confirms that the Mo-99 IIS modifications will be implemented based on a robust safety case and in accordance with OPG’s ECC process and that is supported by safety assessments, which demonstrate continued safe reactor operation, public safety and environmental protection.

2.1 Management System

Darlington NGS remains in compliance with Canadian Standards Association (CSA) Standard N286-12

- ✓ ***OPG’s ECC process ensures quality, design basis compliance and configuration management.***
- ✓ ***Continued safe reactor operation will always take priority over medical isotope production.***
- ✓ ***Qualified vendors follow their own quality assurance programs and OPG confirms compliance through audits.***

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.

2.1.1 Regulatory Requirements Related to Management System

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.1.1 apply to the Management System SCA.

Table 2.1.1 List of Management System Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Safety Culture	CNSC REGDOC - 2.1.2	A healthy safety culture continues to remain OPG highest priority. The Mo-99 IIS will be installed and operated consistent with this fundamental requirement. OPG includes any vendor working on OPG systems to be a partner in Safety Culture monitoring process
Management System Requirements for Nuclear Facilities	CSA N286 (2012)	Continued compliance as applied to all aspects of operation, refurbishment and modifications at Darlington NGS.

2.1.2 OPG Submissions to CNSC Staff Related to Management System

OPG's management system related document, listed in Table 2.1.2, was submitted to CNSC staff (Reference 2.1.2).

Table 2.1.2 List of Management System Related Mo-99 IIS Documents Submitted to CNSC Staff

Document Title	Document Number
Engineering Oversight Plan for Alpha Project Preliminary Engineering	NK38-PLAN-30550-00001

2.1.3 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 R04, "*Nuclear Safety & Security Policy*" directs individuals at all levels of the organization to consider safety as the overriding priority (over schedule, cost and production).

There will be no change to this Nuclear Safety Policy as a result of the Mo-99 IIS. Continued safe reactor operation, compliance with operating limits and regulatory requirements will take priority over medical isotope production. The Mo-99 IIS operating manual will reinforce this requirement.

2.1.4 Quality Assurance, CSA Standard N286-12 Compliance

Darlington NGS is compliant with CSA Standard N286-12, "*Management system requirements for nuclear facilities*". The Nuclear Charter, N-CHAR-AS-0002, "*Nuclear Management System*", establishes the Nuclear Management System for OPG Nuclear. The Nuclear Management System will not change as a result of the proposed installation and operation of the Mo-99 IIS on one or multiple Darlington reactor units.

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 in particular with OPG, provides verifiable confidence that the results of their work activities will satisfy all applicable standards.

2.1.5 Management of Contractors

OPG is ultimately responsible for ensuring that all on-site contractor activities comply with OPG's safety requirements. OPG will provide oversight of BWXT employees who perform Mo-99 IIS installation and testing work at Darlington NGS.

2.1.5.1 Vendor and Engineering Oversight

OPG uses EPC process for obtaining design and safety assessments products from qualified vendors. BWXT-Canada Ltd is the EPC contractor for the Mo-99 project while BWXT-NEC is the qualified vendor for the Mo-99 IIS and Molybdenum target capsules.

Similar to other projects implemented at OPG facilities, OPG provides vendor and contractor oversight during on-site and off-site activities to ensure compliance with quality and safety requirements, and continued safe reactor operation. Specifically, OPG ensures:

- Engineering deliverables submitted by BWXT-NEC meet design quality and procedural requirements
- Early detection of potential issues so that corrective measures can be taken at the appropriate time
- Approved design is constructible, operable and maintainable safely without any adverse impact on station's design basis

2.1.6 Organization

Operation of the Mo-99 IIS may result in an increase to staffing level, but will not require organizational changes. As outlined in section 2.3, the Darlington Operations Department will be responsible for Mo-99 IIS operation, while scheduled and non-scheduled maintenance will be performed by a combination of the OPG Maintenance Department and by BWXT-NEC staff.

2.1.7 Operating Experience (OPEX)

An OPEX review was conducted during various stages of the Mo-99 IIS project to identify previous applicable experience and lessons learned identified within OPG's Station Condition Records database and for external events documented in the CANDU Owners Group (COG) database. The results of the OPEX reviews were documented in Conceptual Design Report NK38-REP-31710-10002 R000, "*Project Alpha Target Delivery System*" and N-REP-03500-0715868 R000, "*Project Execution Plan: Project Alpha Nuclear Safety Assessment*" (Reference 2.1.2) and used as part of the design process.

2.1.8 Change Management, Configuration Management and Records Management

Ensuring what is in the station matches OPG controlled documents (drawings, flowsheets, manuals and procedures) is key to configuration management. The Mo-99 IIS will be no exception. As part of OPG's modification process defined in OPG's procedure, N-PROC-MP-0090, "*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.

2.1.9 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 for Mo-99 IIS installation and operation.

2.1.10 Unit Installation Applicability

The Management System licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.1.11 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.1.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Management System and identifies the impact of Mo-99 IIS on these programs and processes.

Table 2.1.3: Impact of Mo-99 IIS on Darlington's Management System Licensing Basis Documents

OPG Management System Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Nuclear Management System	N-CHAR-AS-0002	No Change
Managed Systems	N-PROG-AS-0001	No Change
Information Management	OPG-PROG-0001	No Change
Project Management Program	OPG-PROG-0039	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 Policy	N-POL-0001	No Change
Nuclear Safety Oversight	N-STD-AS-0023	No Change
Health and Safety Management System Program	OPG-PROG-0010	No Change
Nuclear Safety Culture Assessment	N-PROC-AS-0077	No Change

OPG Management System Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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
Items and Services Management	OPG-PROG-0009	No Change

References 2.1.2 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum-99 Isotope Irradiation System: Submission of Conceptual Design Report Revision, Safety Analysis Project Execution Plan and Engineering Oversight Plan", November 14, 2018, NK38-CORR-00531-20289.

2.2 Human Performance Management

Reduction of the potential for human errors was an important consideration during the Mo-99 IIS design process.

- ✓ ***Compliance with CNSC regulatory document REGDOC-2.2.1, "Human Factors"***
- ✓ ***Human Factors Engineering principles were applied***
- ✓ ***Systematic Approach to Training (SAT) based training will be completed prior to operation of the Mo-99 IIS.***

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.

2.2.1 Regulatory Requirements Related to Human Performance Management

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.2.1 apply to the Human Performance Management SCA.

Table 2.2.1 List of Human Performance Management Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Personnel Certification, Volume III: Certifications of Persons Working at Nuclear Power Plants	CNSC REGDOC-2.2.3	Continued compliance, no impact from Mo-99 IIS
Personnel Training	CNSC REGDOC-2.2.2 (2014)	Continued compliance, no impact from Mo-99 IIS
Fitness for Duty: Managing Worker Fatigue	CNSC REGDOC-2.2.4 (2017)	Continued compliance, no impact from Mo-99 IIS

Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 2	CNSC REGDOC-2.2.4 (2017)	Continued compliance, no impact from Mo-99 IIS

2.2.2 OPG Submissions to CNSC Staff Related to Human Performance Management

Table 2.2.2 provides the list of Mo-99 IIS Human Performance Management related documents that were included in the design submissions (References 2.2.1 and 2.2.2).

Table 2.2.2 List of Human Performance Management Documents Submitted to CNSC Staff

Title of Documents Submitted to CNSC Staff	Document Number
Engineering Oversight Plan for Alpha Project Preliminary Engineering	NK38-PLAN-30550-00001 R000
Darlington Target Delivery System Human Factors Engineering Program Plan MECs 143544, 143546, 143646	NK38-PLAN-30550-00002 R001
Darlington Target Delivery System Human Factors Engineering Verification and Validation Plan	NK38-PLAN-30550-00003 R000
40% Human Factors Engineering	NK38-PLAN-0763175 R000

2.2.3 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 NK38-PLAN-09030.2-10001 R008, "*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 the common goals. This rigorous program will be applied to Mo-99 IIS as a prerequisite to operation with Mo-99 system.

2.2.3.1 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.

Human factors engineering principles were applied during the design of the Mo-99 IIS by BWXT-NEC to reduce the probability of human errors. Oversight and guidance was also provided by OPG Human Factors Engineering specialists. The following Human Factors Engineering documents were included in the detailed design submission (Reference 2.2.2):

- NK38-PLAN-30550-00002 R01, "*Darlington Target Delivery System Human Factors Engineering Program Plan MECs 143544, 143546, 143646*"
- NK38-PLAN-30550-00003 R000, "*Darlington Target Delivery System Human Factors Engineering Verification and Validation Plan*"
- NK38-PLAN-0763175 R000, "*40% HFE Report*"

2.2.4 Personnel Training

As a prerequisite for Mo-99 IIS operation, OPG staff operating the Mo-99 IIS will be required to successfully complete a Mo-99 IIS training qualification that is compliant with OPG's training program, N-PROG-TR-0005 R018, "*Training"* and N-PROC-TR-0008 "*Systematic Approach to Training"*.

Portions of the Mo-99 IIS have been assembled for proof-of-concept testing which has been witnessed by OPG and CNSC staff. A mock-up of the Mo-99 IIS will be assembled for Factory Acceptance Testing (FAT). The assembled FAT mock-up will be used to facilitate training and finalization of the operating procedures. A Mo-99 IIS simulator will also be used for personnel training.

OPG is targeting to complete the Mo-99 IIS training material by the fourth quarter of 2021.

2.2.5 Personnel Certification

After confirming that unit conditions are acceptable as defined in the Mo-99 IIS operating manual (which is under development), the ANO in the MCR of the associated unit will authorize the Field Operator to initiate target-harvesting and reseeding. During target movement, unit conditions will be monitored to ensure the expected reactivity response and to ensure compliance with reactor operating limits.

The applicable ANOs will be required to successfully complete a Mo-99 IIS training qualification as a prerequisite for Mo-99 IIS operation. OPG is targeting to have the Mo-99 IIS training material ready for staff training by the fourth quarter of 2021.

2.2.6 Initial Certification Examinations and Requalification Tests

OPG's initial training for certified staff will include operation of the Mo-99 IIS. Only Operators who have completed the required qualifications will be permitted to operate the Mo-99 IIS.

2.2.7 Fitness for Duty

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

OPG has in place hours of work requirements 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 time 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.

Installation and operation of the Mo-99 IIS will not impact OPG's fitness for duty program or compliance to hours-of-work requirements.

2.2.8 Unit Installation Applicability

The Human Performance Management licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.2.9 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.2.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Human Performance and identifies the impact of Mo-99 IIS on these programs and processes.

Table 2.2.3: Impact of Mo-99 IIS on Darlington's Human Performance Management Licensing Basis Documents

OPG Human Performance Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Limits of Hours of Work	N-PROC-OP-0047	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
Leadership and Management Training and Qualification Description	N-TQD-601-00001	No Change

OPG Human Performance Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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

References

2.2.1 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum-99 Isotope Irradiation System: Submission of Conceptual Design Report Revision, Safety Analysis Project Execution Plan and Engineering Oversight Plan”, November 14, 2018, NK38-CORR-00531-20289.

2.2.2 OPG Confidential 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.

2.3 Operating Performance

Operation of the Mo-99 IIS will not adversely affect continued safe reactor operation

- ✓ ***Safe reactor operation takes priority over Mo-99 isotope production***
- ✓ ***The Safe Operating Envelope (SOE) and the licensing basis remains unchanged***
- ✓ ***Mo-99 IIS operation will not impact safety limits, special safety system trip setpoints, or accident management***
- ✓ ***OPG staff will follow approved procedures and will receive training prior to Mo-99 IIS operation.***

Licence Condition 3.1 states "*the licensee shall implement and maintain an operating program, which includes a set of operating limits*" and the details in the Darlington NGS Licence Conditions Handbook (LCH) outline the regulatory requirements.

2.3.1 Regulatory Requirements Related to Operating Performance

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.3.1 apply to the Operating Performance SCA.

Table 2.3.1 List of Operating Performance Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Accident Management: Severe Accident Management Programs for Nuclear Reactors	CNSC REGDOC-2.3.2 (2013)	Continued compliance, no impact from Mo-99 IIS
Reporting Requirements for Nuclear Power Plants	CNSC REGDOC-3.1.1 (2014)	Continued compliance, no impact from Mo-99 IIS
Periodic Safety Reviews	CNSC REGDOC- 2.3.3 (2015)	Given the Mo-99 IIS is a new design that satisfies all applicable regulatory requirements, this system will be factored into subsequent PSRs after the PSR that is currently under development for renewal of the Darlington PROL in 2025.
Requirements for the safe operating envelope for nuclear power plants	CSA N290.15	Continued compliance, no impact from Mo-99 IIS

2.3.2 OPG Submissions to CNSC Staff Related to Operating Performance

The following operating performance related documents listed in Table 2.3.2 were submitted to CNSC staff (References 2.3.1, 2.3.2 and 2.3.3).

Table 2.3.2 List of Operating Performance Related Mo-99 IIS Documents Submitted to CNSC Staff

Document Title	Document Number
Darlington Nuclear Target Delivery System Concept of Operations	NK38-PLAN-30550-00010 R00
Darlington Nuclear Target Delivery System Control Sequences	NK38-DDD-63055-00008 R00
Operational Assessment of the TDS Installation in Darlington (SA04-10)	NK38-REP-03100-0838344 R00
Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington (SA06-01)	N-REP-03500-083998

2.3.2 Conduct of Licensed Activities

To address the potential operational impacts, an operational assessment NK38-REP-03100-0838344 R00, "*Operational Assessment of the TDS Installation in Darlington*" was completed and submitted to CNSC staff, (Reference 2.3.1). This assessment was used to evaluate the operational impact from the Mo-99 IIS. The simulations covered normal operating modes, as well as conditions which bound non-standard and highly unlikely scenarios.

The overall findings of this report are summarized in the Integrated Safety Assessment N-REP-03500-083998, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" (Reference 2.3.2). This assessment confirms that Mo-99 IIS will have only minor impact on unit operation described in further detail in subsequent sections. The operation of the Mo-99 IIS and production of isotopes will have no significant impact on the normal operation of the station and potential Anticipated Operational Occurrences. The SOE and the licensing basis remains unchanged. The Mo-99 IIS has no impact on safe operation, power limits, special safety system trip setpoints, or on accident management.

The safe operating limits as defined in the licensing envelope, conditions of operability of the reactor, action and action times remain unchanged.

OPG's nuclear operations program, N-PROG-OP-0001, "*Conduct of 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 addition of the Mo-99 IIS does not change this approach and is no different than any other Engineering Change carried out during station operations.

2.3.3 Mo-99 IIS Operation Impact on Reactor Unit Operation

2.3.3.1 Reactivity Management

Insertion (seeding) and removal (harvesting) of target capsules will result in a minor reactivity change within the reactor.

All station operations and maintenance activities with potential to impact core reactivity must be performed in a safe, controlled, conservative manner, following approved procedures. Planned changes to core reactivity are not executed until the expected response is understood. Any deviations from the expected response must be immediately investigated.

Mo-99 IIS harvesting and reseeding will be incorporated into the associated unit's reactivity management plan to predict and ensure that the reactivity effects match the analysis predictions and reactivity returns to steady state following target movement.

2.3.3.2 Impact on Fuelling

As documented in Reference 2.3.1, the Mo-99 IIS will require some changes to existing fuelling practices in order to comply with existing administrative limits during target-harvesting/reseeding operations.

The target capsules represents a negative reactivity presence in the reactor. As a result, operation of the Mo-99 IIS is expected to increase the reactor fuelling rate by approximately 18 bundles per year due to the negative reactivity impact on fuel burnup. This is a cost and production issue, and not a safety issue.

2.3.3.3 Chemistry

As documented in Reference 2.3.2, under normal operating conditions for the moderator, molybdenum will not disperse by a dissolution mechanism. Molybdenum will not cause the precipitation of chemicals in the moderator, such as the gadolinium poison (gadolinium nitrate) or the boron poison (boric acid) under normal operating conditions, and hence there is no risk from a chemical reaction.

2.3.2.3 Response to Reactor Unit Transients

Operator response to unit transients will be documented in the Mo-99 IIS operating manual that is currently under development.

There will be no automatic Mo-99 IIS operations or actions in response to a unit transient (activation of Setback, Stepback, Shutdown System 1 (SDS1), SDS2, and Containment Isolation). In response to a transient on any Darlington unit requiring staff assembly and accounting, the Mo-99 IIS Operator at the local Mo-99 IIS console will place the Mo-99 IIS in the “idle” state and report to the designated assembly location.

There will be no additional risk in leaving the Mo-99 IIS in the idle state for an indefinite period of time.

2.3.4 Procedures Overview

The following Mo-99 IIS operation procedures will be developed in accordance with OPG governance and will be finalized following FAT mock-up activities:

1) Mo-99 IIS operating manual

2) Mo-99 flask hoisting and handling procedure

2.3.5 Mo-99 IIS Installation and Commissioning

As documented in Reference 2.3.4 (Installation and Commissioning Strategy), the plan is to install non-reactor modifications of the Mo-99 IIS that do not affect continued safe reactor operation in second half of 2021.

Reactor modifications, pending successful licence amendment, will require the reactor to be in the Guaranteed Shutdown State (GSS). Portions of the Mo-99 IIS will be tested to the maximum extent possible before reactor restart.

Commissioning of the Mo-99 IIS will be completed in accordance with approved commissioning plans, which will be submitted to CNSC staff. Commissioning will confirm Mo-99 IIS operation is consistent with design and safety assessments.

As documented in section 1.9, OPG plans to use QRHPs for ensuring quality during Mo-99 IIS installation. The two QRHPs are:

QRHP#1: Prior to reactor modifications (removal of the unused Adjuster Assemblies), installation of target elevators and modification to the existing containment boundary.

QRHP#2: Prior to "on-power" commissioning of the Mo-99 IIS (first time insertion of targets into an operating reactor).

OPG understands that CNSC staff are considering the use of RHPs. OPG supports this approach, should it be deemed required, and will work with CNSC staff for the development of release criteria by a CNSC designated officer.

2.3.6 Handover to Darlington NGS Operations

In accordance with N-PROC-MP-0090, following installation by BWXT Canada Ltd, the Mo-99 IIS will be turned-over to Darlington NGS Operations following the AFS process. This process is identical to that used extensively during refurbishment of Unit 2 and hence it is a "tried and tested" proven process.

2.3.7 Storage of Targets

Prior to target harvesting, the Mo-99 IIS Operator will obtain up to eight targets contained in a protective Foreign Material Exclusion sleeve for reseeding following harvesting. Sufficient quantities of new Molybdenum target capsules will be stored in an approved location at Darlington NGS to meet medical demands.

Given the short half-life of Mo-99 and Tc-99m, storage of irradiated targets at Darlington NGS is not expected. Therefore, a dedicated storage area for irradiated targets will not be established. In the event of shipment delays, irradiated targets can be safely left in the shielded transportation package or within the Mo-99 IIS. Both the transportation package and the Mo-99 IIS provide shielding for the irradiated targets.

2.3.8 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.

2.3.9 Safe Operating Envelope

The objective of the 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.

Because the Mo-99 IIS will have few interfaces with other station systems, it does not produce volatile fission products and the design complies with applicable regulatory requirements, the Mo-99 IIS will not impact the SOE documents listed in Table 2.3.3.

2.3.10 Outage Management Performance

During planned outages, various inspections and maintenance activities on the Mo-99 IIS will be scheduled and planned in accordance with N-PROC-MA-0013, "*Planned Outage Management*".

2.3.10.1 Guaranteed Shutdown States

The three Guaranteed Shutdown States (GSS) used at Darlington NGS are Overpoisoned (OPGSS), Rod-Based (RBGSS) and Moderator Drained GSS.

Assessments have concluded that the Mo-99 IIS will not adversely affect the integrity of these three Guaranteed Shutdown States.

2.3.11 Accident Management and Recovery, and Severe Accident Management and Recovery

The impact from the Mo-99 IIS on accident management and recovery, and severe accident management and recovery is documented in section 2.10.

2.3.12 Unit Installation Applicability

Due to the similarities between units, the Mo-99 IIS licensing impact for the Operating Performance will not to change between Darlington units.

2.3.13 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.3.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Operating Performance, and identifies the impact of Mo-99 IIS installation and operation on these programs.

Table 2.3.3: Impact of Mo-99 IIS on Darlington's Operating Performance Related Licensing Basis Documents

OPG Document Title	OPG Document Number	Impact from Mo-99 IIS
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
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
Corrective Action	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 Fuelling Operations	N-STD-OP-0021	No Change

References

2.3.1 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Operational Assessment of the Target Delivery System Installation (SA04-10)”, July 24, 2020, CD# NK38-CORR-00531-21814.

2.3.2 OPG Confidential 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, NK38-CORR-00531-21845.

2.3.3 OPG Confidential 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.

2.3.4 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Request for CNSC Staff’s Concurrence of the Installation and Commissioning Strategy”, February 21, 2020, CD# NK38-CORR-00531-21387.

2.4 Safety Analysis

Safety assessments completed in compliance with REGDOC-2.4.1, “Deterministic Safety Analysis” and REGDOC-2.4.2, “Probabilistic Safety Assessment (PSA) for Nuclear Power Plants” demonstrate:

- ✓ ***Continued safe reactor operation***
- ✓ ***No reduction in margins of safety and changes to safety system setpoints are not required***
- ✓ ***Public safety will be maintained***

In accordance with the Darlington NGS Licence Condition 4.1, the licensee shall implement and maintain a safety analysis program.

The safety case of the facility will not be altered by the introduction of the Mo-99 IIS. The frequency of the Design Basis Accidents (DBAs) and Beyond Design Basis Accidents (BDBAs) is not affected by the introduction of this system. The ability to control power, cool the fuel, and contain radioactivity is also not affected. The following outline demonstrates the measures taken to show Darlington NGS remains within the safety analysis envelope.

2.4.1 Regulatory Requirements Related to Safety Analysis Program

In addition to compliance with the “*Nuclear Safety and Control Act*” and the “*General Nuclear Safety Control Regulations*” as outlined in Attachment 1, the regulatory requirements listed in Table 2.4.1 apply to the Safety Analysis SCA.

Table 2.4.1 List of Safety Analysis Program Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Deterministic Safety Analysis	CNSC REGDOC-2.4.1 (2014)	Mo-99 IIS safety assessments were conducted in compliance with applicable requirements
Probabilistic Safety Assessment (PSA) for Nuclear Power Plants	CNSC REGDOC-2.4.2 (2014)	Mo-99 IIS safety assessments were conducted in compliance with applicable requirements
Quality assurance of analytical, scientific and design computer programs for nuclear power plants	CSA N286.7 (1999 Reaffirmed 2012)	Mo-99 IIS safety assessments were conducted in compliance with applicable requirements

2.4.2 OPG Submissions to CNSC Staff Related to Safety Analysis

In accordance with N-REP-03500-0715868 R000, "*Safety Analysis Project Execution Plan*" (Reference 2.4.1), 20 safety assessments documented in Table 2.4.2 were submitted to CNSC staff and are summarized in Reference 2.4.2 and 2.4.3 in support of the Mo-99 IIS project.

Table 2.4.2 List of Mo-99 IIS Safety Analysis Documents Submitted to CNSC Staff

Document Title	Document Number
Project Execution Plan: Project Alpha Nuclear Safety Assessment	N-REP-03500-0715868 R000
Project Alpha Operational Analysis Plan	N-PLAN-03550-0731244 R00
Darlington RFSP RDS Update and Steady State for Project Alpha	N-REP-03550-0731239 R00
Project Alpha Initiating Event Identification and Classification (Revision) Note 1	N-REP-03500-0735634 R02
Thermalhydraulics Analysis to Assess the Impact of the Target Delivery System	N-CORR-03500-0759869 R00
Assessment of TDS Target Gamma on In-Core Detector Signals	N-CORR-03500-0759870 R00
Reactor Physics Assessments for the Target Delivery System	N-CORR-03500-0760363 R00
Analysis Plan for Target Delivery System Out of Core Events (Revision) Note 1	N-PLAN-03500-0765097 R01
Moderator Temperature Fluctuations Impacts on Liquid Zone Controller Level and Implications for the Target Delivery System	N-CORR-03500-0764523 R00
Disposition of Existing Analyses in Support of the Safety Case (Qualitative Assessment)	N-CORR-03500-0764524 R00
Assessment of Target Delivery System for Molybdenum Irradiation on the Darlington Internal and External Screening (Revision) Note 1	N-REP-03611-0764525 R01

Document Title	Document Number
Loss of Moderator Inventory: Impact of Installation of Target Delivery System	N-PLAN-03500-0778356 R00
Assessment of Target Delivery System for Molybdenum Irradiation on the Darlington Probabilistic Safety Assessment (PSA) (Revision) Note 1	N-REP-03611-0778355 R01
Darlington Unit 4 Target Delivery Systems Fuel Management Study	NK38-REP-03160-0784032 R00
Radiological Consequences of Out of Core Events for the Darlington Target Delivery System (Revision) Note 1	N-REP-03500-0780839 R01
Impact of Target Delivery System on NOP Coverage for Slow LORs	N-REP-03500-0786223 R00
Impact of the Target Delivery System on Normal System Operational	NK38-CORR-03160-0817763 R00
Impact of TDS Installation on the Potential for Deflagration following a Loss of Moderator Inventory Event	N-REP-03500-0817764 R00
Operational Assessment of the TDS Installation in Darlington	NK38-REP-03100-0838344 R00
Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington	N-REP-03500-0839983 R00

Note: 1. Five safety assessments were subsequently revised and resubmitted to CNSC staff as a result of a design change to the inboard target propulsion.

The analyses performed to meet the objectives consisted of three parts:

1. Operational analyses and assessments
2. Analyses and assessments of DBA and Anticipated Operational Occurrences (AOOs)
3. Assessment of the impact on Probabilistic Safety Analyses

The final two safety assessment reports submitted to CNSC staff, NK38-REP-03100-0838344 R00, "*Operational Assessment of the TDS Installation in Darlington*" (Reference 2.4.2) and N-REP-03500-0839983 R00, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" (Reference 2.4.3) are based on the final OPG accepted Mo-99 IIS design information.

These reports summarize the operational impact and integrated collection of conclusions and evidence from the individual safety assessments to demonstrate the continued safe and reliable operation of the Darlington NGS, specifically:

1. All applicable regulatory requirements from the Darlington PROL 13.02/2025 will continue to be satisfied.

2. Operation of the Mo-99 IIS and production of the Mo-99 isotope will have no significant impact on the normal operation of the station and potential AOO.

3. Systems, structures and components important to nuclear safety and security will continue to meet their design basis in all operational states and DBA.

4. The ability of protective systems and emergency mitigating equipment to adequately control reactor power, cool the fuel and contain or limit any radioactivity that could be released from the station, is demonstrated to be acceptable for DBAs and BDBAs events.

The Darlington PROL 13.02/2025 requires design modifications be "controlled such that the station is maintained and modified within the limits prescribed by the design and licensing basis". Accordingly, OPG ensures that modifications made to the facility are in accordance with OPG's ECC process and CSA Standards N291, "*Requirements for safety-related structures for CANDU nuclear power plants*" and N290.0 "*General requirements for safety systems of nuclear power plants*". This process ensures that the modification is accurately reflected in the safety analysis, is in compliance with the requirements set out in the PROL, including CNSC regulatory documents REGDOC-2.4.1 "*Deterministic Safety Analysis*" and REGDOC-2.4.2 "*Probabilistic Safety Assessments*", and all applicable CSA Standards in the N286 series.

The safety assessment performed to support the installation and operation of the Mo-99 IIS included detailed assessments of potential new initiating events, the potential for impact on the existing safety analyses, impacts on the PSA elements, and operational impacts.

2.4.3 Deterministic Safety Analysis

Deterministic safety assessments were performed for the Mo-99 IIS in accordance with CNSC regulatory document REGDOC-2.4.1, specifically:

- A detailed review of the existing Safety Report demonstrated that the introduction of the Mo-99 IIS 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.
- The effectiveness of the Neutron Overpower Protection (NOP) trip setpoint is not affected by the operation of the Mo-99 IIS. No changes to any safety system setpoints will be required.

2.4.4 Hazard Screening Analysis

A Hazard Screening for the Mo-99 IIS, 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 impacts that the Mo-99 IIS 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.

2.4.5 Probabilistic Safety Assessment

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

An assessment of the impacts on the existing Darlington PSA elements was completed (Reference 2.4.4) in accordance with CNSC's REGDOC-2.4.2, confirming that the Mo-99 IIS will have a negligible effect 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 Mo-99 IIS 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 Mo-99 IIS does not constitute a "major change" requiring an update to the Darlington PSA models outside of the normal five-year PSA update cycle.

2.4.6 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 Mo-99 IIS will not impact the procedures for accident and severe accident management.

2.4.7 Management of Safety Issues (including Research & Development programs)

The Mo-99 IIS will have no impact on the management of safety issues and OPG's Research and Development programs.

2.4.8 Unit Installation Applicability

Given the similarities between the Darlington reactor units, and fact that the safety assessments were predominantly unit independent, the design and safety case will not change between units.

2.4.9 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.4.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Safety Analysis and identifies the impact of Mo-99 IIS on these programs and processes.

Table 2.4.3: Impact on Mo-99 IIS on Darlington's Safety Analysis Licensing Basis Documents

OPG Safety Analysis Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Darlington NGS Safety Report: Part 2 - System Descriptions	NK38-SR-03500-10001	A description of the Mo-99 IIS will be added during the next revision as part of OPG's ECC process

OPG Safety Analysis Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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
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

References

2.4.1 OPG Confidential letter, S. Gregoris to N. Riendeau, “Darlington NGS - Molybdenum-99 Isotope Irradiation System: Submission of Conceptual Design Report Revision, Safety Analysis Project Execution Plan and Engineering Oversight Plan”, November 14, 2018, CD# NK38-CORR-00531-20289.

2.4.2 OPG Confidential letter, S. Gregoris to J. Burta, Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Operational Assessment of the Target Delivery System (SA04-10)”, July 24, 2020, CD# NK38-CORR-00531-21814.

2.4.3 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Integrated Nuclear Safety and Operational Assessment of the Target Delivery System SA06-01)”, August 31, 2020, CD# NK38-CORR-00531-21845.

2.4.4 OPG Confidential 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.

2.4.5 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Unit 2 Design

Documents for Target Delivery System and Plant Modifications (D04-02-U2 and D06-01-U2)", January 28, 2021, CD# NK38-CORR-00531-22277.

2.5 Physical Design

Unit 2 Mo-99 IIS submitted design complies with all applicable regulatory requirements.

- ✓ ***Unit 2 Mo-99 IIS design is the same as Unit 4 design with minor enhancements***
- ✓ ***OPG staff provides oversight to vendors and follows the Engineering Change Control Program***

Darlington's PROL 13.02/2025 requires that plant modifications be controlled such that the station is maintained and modified within the limits prescribed by the design and licensing basis.

2.5.2 Regulatory Requirements Related to Design Program

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.5.1 apply to the Design Program SCA.

Table 2.5.2 List of Design Program Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Requirements for safety related structures for CANDU nuclear power plants	CSA N291 (2008)	Mo-99-IIS design complies with the requirements in this CSA Standard
General requirements for safety systems of nuclear power plants	CSA N290.0 (2011)	Mo-99-IIS design complies with the requirements in this CSA Standard
General requirements for pressure-retaining systems and components in CANDU nuclear power plants	CSA N285.0 (2008 and Update No. 2)	Mo-99-IIS design complies with the requirements in this CSA Standard
Environmental qualification of equipment for CANDU nuclear power plants	CSA N290.13 (2005 and Update No. 1)	Mo-99-IIS design complies with the requirements in this CSA Standard
General requirements for seismic design and qualification of CANDU nuclear power plants	CSA N289.1 (2008)	Mo-99-IIS design complies with the requirements in this CSA Standard

2.5.1 OPG Submissions to CNSC Staff Related to Physical Design

Unit 4 Mo-99 IIS design documents were submitted to CNSC staff in References 2.5.1 and 2.5.2. Unit 2 Mo-99 IIS design documents were submitted to CNSC staff in Reference 2.5.3.

2.5.2 Design Governance

Design changes are performed in accordance with OPG's program N-PROG-MP-0001 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. This is confirmed in the case of Mo-99 IIS.

During the Mo-99 IIS design process, OPG staff provided input and oversight to ensure compliance with N-PROG-MP-0001.

2.5.3 Site Characterizations

The Mo-99 IIS will not change Darlington NGS site characterization.

2.5.4 Facility Design

The Mo-99 IIS will not result in the installation of new facilities at Darlington NGS.

2.5.5 Structure Design

The Mo-99 IIS will require installation of a platform where the Mo-99 IIS components will be installed as detailed in the design package documents submission (Reference 2.5.3).

2.5.6 Mo-99 IIS System Design

2.5.6.1 Seismic Qualification

The Mo-99 IIS design complies with seismic requirements in CSA Standards N289.1-08, *"General requirements for seismic design and qualification of CANDU nuclear power plants*" and N291-08 *"Requirements for safety-related structures for CANDU nuclear power plants*", Update No. 1.

2.5.6.2 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 Mo-99 IIS design considered two EQ elements, the impact on components and systems in the vicinity of the Mo-99 IIS from increased radiation fields during Mo-99 IIS target-harvesting, and qualification of the Mo-99 IIS components to withstand harsh environments caused by design basis events (example, a main steam-line break).

The Mo-99 IIS design (Reference 2.5.2) complies with CSA Standard N290.13 "*Environmental qualification of equipment for CANDU nuclear power plants".* The EQ requirements are documented in NK38-MAN-03651-10001, "*Environmental Qualification Room Conditions - Darlington*".

2.5.6.3 Over-Pressure Protection

The Mo-99 IIS design complies with CSA Standard N285.0 "*General requirements for pressure-retaining systems and components in CANDU nuclear power plants*".

The Mo-99 IIS was designed for various operating design pressures which are shown on NK38-DRAW-30550-10001-U2 "*Target Delivery System Flow Diagram*" (Reference 2.5.3) and includes pressure relief valves for overpressure protection.

The calculations for the relief valve capacity and setpoints for various plausible overpressure scenarios are documented in NK38-CALC-30552-00001 R000, "*Relief Valve Capacity Assessment*" and are summarized in an overpressure protection report NK38-OPR-30550-00001, R000 "*IIS Overpressure Protection Report*" both submitted in Reference 2.5.2. The Mo-99 IIS relief valves will be tested at BWXT-NEC to confirm proper setpoint before installation at Darlington NGS.

2.5.6.4 Software

Operation of the Mo-99 IIS for target-harvesting and seeding will be automated as documented in NK38-DDD-63055-00008 R000, "*Target Delivery Control System Control Sequences*" (Reference 2.5.2) requiring few Operator actions.

Once the Authorized Nuclear Operator 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 Mo-99 IIS will include provisions for verifying the completed movements of all targets in the string (up to eight targets) for tracking purposes.

2.5.6.5 Cyber Security

The Mo-99 IIS design complies with OPG's cyber security requirements. Cyber Security was 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 in OPG Nuclear. This procedure also ensures that cyber essential assets 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.

2.5.7 Components Design

2.5.7.1 Containment Integrity

The Mo-99 IIS will result in a change to the existing containment boundary from the Adjuster Rod mechanisms to the Mo-99 IIS components. As per NK38-DBD-34280-00001, "*Containment Boundary Manual*", a qualified (Class 2) containment boundary will be maintained at all times.

CNSC staff acceptance of the containment boundary change was received for Unit 4 Mo-99 IIS design in Reference 2.5.5. Review by CNSC staff of Unit 2's Mo-99 IIS design was in progress at the time of this submission.

2.5.7.2 Mo-99 IIS Code Classification

OPG has submitted a request for CNSC staff acceptance for Unit 2 Mo-99 design code classification which complies with applicable regulatory requirements (Reference 2.5.5). As accepted by CNSC staff for Unit 4 design in Reference 2.5.4, the Mo-99 IIS components will be classified as Class 2, Class 3, Class 6 and Class Exempt as shown in NK38-DRAW-30550-10001-U2, depending on the safety function and size of the piping. The Mo-99 IIS Code Classification complies with CSA Standard N285.0.

2.5.8 Unit Installation Applicability

Given the similarities between the Darlington reactor units, the design is not expected to change significantly. As part of OPG's ECC Process, safety culture and drive for continuous improvements, enhancements were included in Unit 2 design. These enhancements will be considered for future units and managed through OPG's robust ECC process.

2.5.9 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.5.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Design Program and identifies the impact of Mo-99 IIS on these programs and processes.

Table 2.5.3: Impact of Mo-99 IIS on Darlington's Design Program Licensing Basis Documents

OPG Physical Design Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Conduct of Engineering	N-STD-MP-0028	No Change
Engineering Change Control	N-PROG-MP-0001	No Change
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
Software	N-PROG-MP-0006	No Change
Pressure Boundary Program	N-PROG-MP-0004	No Change
System and Item Classification	N-PROC-MP-0040	No Change

OPG Physical Design Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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

References

2.5.1 OPG Confidential 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.

2.5.2 OPG Confidential 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.

2.5.3 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Target Delivery System Design Packages (D04-02-U2 and D06-01-U2)”, January 28, 2021, CD# NK38-CORR-00531-22277.

2.5.4 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.

2.5.5 OPG Confidential letter, S. Gregoris to J. Burta, “Darlington NGS – Molybdenum Isotope Irradiation System: Request for Code Classification Consent for Unit 2 Target Delivery System and Prior Written Notification for Permanent Change to Containment Boundary (D03-01-U2)”, December 2, 2020, CD# NK38-CORR-00531-22139.

2.6 Fitness for Service

The Mo-99 IIS was designed to allow removal of components for fitness for service inspections and preventative maintenance.

- ✓ ***Preventative maintenance plans, testing and periodic inspections in accordance OPG’s governance are under development.***

Darlington NGS, under its current PROL (13.02/2025), 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.

2.6.1 Regulatory Requirements Related to Fitness for Service

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.6.1 apply to the Fitness for Service SCA.

Table 2.6.1 List of Fitness for Service Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Periodic inspection of CANDU nuclear power plant components	CSA N285.4 (2014)	Mo-99-IIS design complies
Periodic inspection of CANDU nuclear power plant containment components	CSA N285.5 (2008 and Update No. 1)	Mo-99-IIS design complies
In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plant components	CSA N287.7 (2008)	Not applicable
Maintenance Programs for Nuclear Power Plants	CNSC RD/GD-210 (2012)	Mo-99-IIS design complies
Reliability Programs for Nuclear Power Plants	CNSC REGDOC-2.6.1 (2017)	Mo-99-IIS design complies
Maintenance Programs for Nuclear Power Plants	CNSC REGDOC-2.6.2 (2014)	Mo-99-IIS design complies
Aging Management	CNSC REGDOC-2.6.3	The Mo-99 IIS will be incorporated into the aging management program as applicable as part of the ECC process.

2.6.1 OPG Submissions to CNSC Staff Related to Fitness for Service

OPG is following the robust and proven ECC process which includes the development of fitness for service and maintenance strategies. At this stage in the ECC process, Fitness for Service documents are under development. Per process, issuance of these strategies and documents is being tracked internally and will be provided to CNSC staff when available.

2.6.2 Equipment Fitness for Service / Equipment Performance

OPG's, N-PROG-MA-0025, "*Major Components Program*" establishes a formal and systematic process in OPG Nuclear for managing information related to four major component areas: feeders, steam generators, fuel channels, and reactor components and structures.

The Mo-99 IIS will not impact the fitness for service and periodic inspections of the major components.

2.6.3 Maintenance

Maintenance activities for the Mo-99 IIS will be scheduled and conducted in accordance with N-PROG-MA-0019, "*Production Work Management Program*". 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.

2.6.3.1 Mo-99 IIS Corrective Maintenance

Corrective maintenance on the Mo-99 IIS will be performed predominately by BWXT-NEC maintenance staff with oversight being provided by OPG staff.

2.6.3.2 Mo-99 IIS Preventative Maintenance, Testing and Periodic Inspections

The development of preventative maintenance, testing and periodic inspection plans are requirements of the ECC process, for which OPG is following. It is anticipated that critical equipment inspections will be performed during unit planned outages in accordance with OPG work management processes. The details of these plans will be provided to CNSC staff once the project's ECC process has reach that stage. The development of these plans is being tracked internally in accordance with OPG's established processes.

2.6.4 Structural Integrity

The Mo-99 IIS will result in an extension to the containment boundary, but will not impact containment structural integrity. A qualified containment boundary will be maintained at all times as documented in the Unit 2 design documents submission (Reference 2.6.2).

2.6.5 Aging Management

The objective of OPG's aging management program, N-PROG-MP-0008, *"Integrated Aging Management Program*", 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. The Mo-99 IIS will be incorporated into the aging management program as applicable as part of the ECC process.

2.6.6 Chemistry Control

As documented in Reference 2.6.1, the impact form the Mo-99 IIS on reactor chemistry was assessed and determined to have minimal impact on Moderator system chemistry. Addition of chemicals to support Mo-99 IIS operation is not expected.

2.6.7 Unit Installation Applicability

Due to the similarities between units, the licensing impact to Fitness for Service will be applicable to any Darlington unit.

2.6.8 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.6.2 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 of Mo-99 IIS on these programs and processes.

Table 2.6.2: Impact of Mo-99 IIS on Darlington's Fitness for Service Licensing Basis Documents

OPG Fitness for Service Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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 Program	N-PROG-MA-0025	No Change
Feeders Life Cycle Management	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

OPG Fitness for Service Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Fuel Channels Life Cycle Management Plan	N-PLAN-01060-10002	No Change
Darlington Nuclear 1-4, Unit 1 Fuel Channel Pressure Tubes Periodic Inspection Program Plan	NK38-PIP-31100-10001	No Change
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 Program	NK38-PIP-03643.2-10003	No Change
Inspection of Post Tensioning Tendons on DNGS 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

OPG Fitness for Service Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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

References

2.6.1 OPG Confidential 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.

2.6.2 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of Unit 2 Design Documents for Target Delivery System and Plant Modifications (D04-02-U2 and D06-01-U2)", January 29, 2021, CD# NK38-CORR-00531-22277.

2.7 Radiation Protection

The Mo-99 IIS design and operation will comply with OPG's Radiation Protection program.

- ✓ ***As Low As Reasonably Achievable (ALARA) principles were applied during Mo-99 IIS design***
- ✓ ***Worker and public dose during Mo-99 IIS operation is expected to be low***

As per OPG's N-PROG-RA-0013, "*Radiation Protection*", the overriding objective of the Radiation Protection (RP) 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.

2.7.1 Regulatory Requirements Related to Radiation Protection

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.7.1 apply to the Radiation Protection SCA.

Table 2.7.1 List of Radiation Protection Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Radiation Protection Regulations	SOR/2000-203	Continued compliance as documented in Attachment 1
Nuclear Substance and Radiation Device Regulations	SOR/2008-119	Continued compliance as documented in Attachment 1

2.7.2 OPG Submissions to CNSC Staff Related to Radiation Protection and ALARA

The following radiation protection and ALARA related documents listed in Table 2.7.2 were submitted to CNSC staff as part of the preliminary and detailed design package submissions (References 2.7.1, 2.7.2 and 2.7.3).

Table 2.7.2 List of Radiation Protection and ALARA Related Mo-99 IIS Documents Submitted to CNSC Staff

Document Title	Document Number
Darlington Nuclear Target Delivery System ALARA Design Plan	NK38-PLAN-30550-00008 R000
Darlington NGS Target Delivery System ALARA Design Guide	NK38-GUID-30550-00001 R01
TDS Shielding Design Calculation	NK38-CALC-30552-00002 R000
Design ALARA Assessment	NK38-REP-30550-00012 R01

2.7.3 Application of ALARA

CNSC guidance document G-129, "*Keeping Radiation Exposures and Doses As-Low-As Reasonably-Achievable (ALARA)*', was used as guidance during the Mo-99 IIS design process to ensure that radiation exposures to station personnel will be kept well within regulatory dose limits and as low a reasonably achievable.

The ALARA guide, NK38-GUID-30550-00001 R01, "*Darlington Nuclear 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.) (Reference 2.7.3). Satisfying these inputs required evaluating various options and stepping through an iterative process to optimize the system.

Other factors for controlling and managing radiation exposure and ALARA principles applied during the Mo-99 IIS designs are documented in NK38-PLAN-30550-00008, "*Darlington*

Nuclear Target Delivery System ALARA Design Plan" (Reference 2.7.1) and NK38-REP-30550-00012, "*Design ALARA Assessment"* (Reference 2.7.3).

2.7.4 Worker Radiation Dose Control

Individual worker radiation doses, including those for contractors and visitors, are managed to Exposure Control Levels that are below Administrative Dose Limits that are in turn below the regulatory limits.

As documented in the Design ALARA Assessment (NK38-REP-30550-00012), the estimated accumulated whole body dose increase to station personnel from Mo-99 IIS operation will be maintained well below the Exposure Control Levels.

2.7.5 Radiological Hazard Control

The Mo-99 IIS will represent a radiation hazard that will need to be managed to ensure compliance with OPG's RP program. Key elements to controlling the Mo-99 IIS radiological hazards from the irradiated target capsules are discussed in subsections 2.7.4.1 to 2.7.4.5.

2.7.5.1 Source Term

In addition to the irradiated Molybdenum within the target capsules, the capsule sheath represents 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.

2.7.5.2 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 Mo-99 IIS shielding.

2.7.5.3 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 MCR generic Mo-99 IIS trouble alarm.

As documented in NK38-REP-30550-00012, the Mo-99 IIS local control console will be located outside of the access doors which will be approximately 10 meters from the target airlock and outboard flight tubing.

2.7.5.4 Shielding

The irradiated targets represents an increased radiation risk to workers requiring an innovative shielding design.

As documented (Reference 2.7.2) in NK38-CALC-30552-00002, "*TDS Shielding Design Calculation*" innovative shielding design was incorporated in the design of the IIS to reduce radiation levels during target-harvesting. A combination of lead, tungsten and steel will be used for shielding.

2.7.5.5 Radiological Monitoring and Other Controls

The Mo-99 IIS design includes the installation of a radiation and Tritium monitor in the vicinity of the Mo-99 IIS equipment to provide warning to workers in the event of higher than expected radiation fields and airborne Tritium levels.

2.7.6 Estimated Public Dose

Mo-99 IIS operations and maintenance will be conducted in accordance with OPG's Radiation Protection 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, N-REP-30550-00035 R000, "*Predictive Effects Assessment for the DN Molybdenum Isotope Irradiation System*" (ERA01-01-U2) (Reference 2.7.5) estimates that the highest potential dose to a member of the public from Mo-99 IIS operation would not exceed 0.006 µSv/year. Taking into account the current Darlington emissions, the additional dose to a member of the public from Mo-99 IIS operation is estimated as an additional 1% dose above the current dose estimate. This would constitute 0.0006% of the regulatory dose limit of 1 mSv/year for a member of the public.

2.7.7 Unit Installation Applicability

Due to the similarities between Darlington reactor units, the results documented in the RP and ALARA assessments submitted for the Unit 4 and Unit 2 detailed design (References 2.7.1 and 2.7.3) will be applicable to any Darlington NGS unit.

2.7.8 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.7.7 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Radiation Protection and identifies the impact of Mo-99 IIS on these programs.

Table 2.7.3: Impact of Mo-99 IIS on Darlington's Radiation Protection and ALARA Licensing Basis Documents

OPG Radiation Protection Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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

OPG Radiation Protection Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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

References

2.7.1 OPG Confidential 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.

2.7.2 OPG Confidential 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.

2.7.3 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Target Delivery System Design Packages (D04-02-U2 and D06-01-U2)", January 28, 2021, CD# NK38-CORR-00531-22277.

2.7.4 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Predictive Effects Assessment (ERA01-01)", June 11, 2020, CD# NK38-CORR-00531-21626.

2.7.5 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Unit 2 Predictive Effects Assessment (ERA01-01-U2)", November 24, 2020, CD# NK38-CORR-00531-22155.

2.8 Conventional Health and Safety

OPG staff remains committed to preventing workplace injuries and to continuous improvement in employee health and safety performance.

- ✓ ***Conventional safety principles were assessed during the Mo-99 IIS design process to protect personnel from injury***

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 to operational controls, developed through risk assessment and safe work planning.

2.8.1 Regulatory Requirements Related to Conventional Health and Safety

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.8.1 apply to the Conventional Health and Safety SCA.

Table 2.8.1 List of Conventional Health and Safety Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
General Nuclear Safety and Control Regulations	SOR/2000-202	Continued compliance as documented in Attachment 1

2.8.2 OPG Submissions to CNSC Staff Related to Conventional Safety

Personnel conventional safety principles were assessed during the Mo-99 IIS design process to protect personnel from injury during Mo-99 IIS operation. This assessment, listed in Table 2.8.2, was submitted to CNSC staff as part of the Unit 4 and Unit 2 detailed design submissions (Reference 2.8.1 and 2.8.2).

Table 2.8.2: List of Conventional Safety Related Mo-99 IIS Documents CNSC Submissions

Document Title	Document Number
Darlington Nuclear Target Delivery System Personnel Safety Analysis Report	NK38-REP-30550-00007

2.8.2 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-0010, "*Health and Safety Management System Program*" 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 the Mo-99 IIS will be performed by BWXT Canada Ltd staff, with OPG staff providing oversight. BWXT-Canada Ltd has an experienced and proven health and safety program.

With respect to on-site contractors, BWXT Canada Ltd 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. In accordance with OPG governance, all contractors are expected to comply with OPG's conventional health and safety protocols while on sit.

2.8.3 Mo-99 IIS Conventional Safety Provisions

Conventional safety principles were assessed during the Mo-99 IIS design process to protect personnel from injury during Mo-99 IIS installation and operation. The results of this assessment are documented in NK38-REP-30550-00007, "*Darlington Nuclear Target Delivery System Personnel Safety Analysis Report"* (Reference 2.8.1 and 2.8.2).

2.8.4 Awareness

OPG is ultimately responsible for safety, which cannot be delegated or contracted to other organizations. BWXT Canada Ltd 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 while working at Darlington NGS. This approach is similar to other projects (Darlington Unit 2 refurbishment) involving on-site contractors.

2.8.5 Unit Installation Applicability

Due to the similarities between units, the Conventional Health and Safety licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.8.6 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.8.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Conventional Safety and identifies the impact of Mo-99 IIS on these programs and processes.

Table 2.8.3: Impact of Mo-99 on Darlington's Conventional Safety Program Licensing Basis Documents

OPG Conventional Safety Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Health and Safety Policy	OPG-POL-0001	No Change
Health and Safety Management System Program	OPG-PROG-0010	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

References 2.8.1. OPG Confidential 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.

2.8.2 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Target Delivery System Design Packages (D04-02-U2 and D06-01-U2)", January 28, 2021, CD# NK38-CORR-00531-22277.

2.9. Environmental Protection

Installation and operation of the Mo-99 IIS is predicted to cause negligible environmental impact:

- ✓ ***ALARA principles applied***
- ✓ ***Public dose will remain well below 1% of the regulatory public dose limit***
- ✓ ***Compliance with CSA N288 Standard series and applicable sections of REGDOC-2.9.1, "Environmental Protection: Environmental Principles, Assessments and Protection Measures"***

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 the Mo-99 IIS.

2.9.1 Regulatory Requirements Related to Environmental Protection

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.9.1 apply to the Environmental Protection SCA.

Table 2.9.1 List of Environmental Protection Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	CSA N288.1 (2008 Update No. 1)	Mo-99 IIS environmental assessments were conducted in accordance with requirements
Environmental monitoring program at class I nuclear facilities and uranium mines and mills	CSA N288.4 (2010)	Mo-99 IIS environmental assessments were conducted in accordance with requirements
Effluent monitoring programs at class I nuclear facilities and uranium mines and mills	CSA N288.5 (2011)	Mo-99 IIS environmental assessments were conducted in accordance with requirements
Environmental risk assessments at class I nuclear facilities and uranium mines and mills	CSA 288.6 (2012)	Mo-99 IIS environmental assessments were conducted in accordance with requirements
Performance Testing of Nuclear Air-Cleaning Systems at Nuclear Facilities	CSA N288.3.4 (2013)	Mo-99 IIS environmental assessments were conducted in accordance with requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	CSA N288.7 (2015)	Mo-99 IIS environmental assessments were conducted in accordance with requirements

2.9.2 OPG Submissions to CNSC Staff Related to Environmental Protection

The following environmental protection related documents (Table 2.9.1) were submitted to CNSC staff in References 2.9.1 and 2.9.2 and are described in section 2.9.3.

Table 2.9.2 List of Environmental Protection Related Mo-99 IIS Design Documents Submitted to CNSC Staff

Document Title	Document Number
Predictive Effects Assessment for the DN Molybdenum Isotope Irradiation System (Unit 4)	NK38-REP-30550-00029
Predictive Effects Assessment for the DN Molybdenum Isotope Irradiation System (Unit 2)	NK38-REP-30550-00035

2.9.2 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.

The licensee shall control radiological releases to ALARA, thereby minimizing dose to the public resulting from Darlington NGS operation.

Darlington NGS reports against approved 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 Derived Release Limits (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 the Mo-99 IIS. Consistent with current performance, the cumulative public dose resulting from Darlington NGS and Mo-99 IIS operation 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.

2.9.2.1 ALARA Principles Used in Mo-99 IIS Design

Protecting the environment and ensuring that emissions from Darlington NGS remain well below the DRLs was a consideration during the design of the Mo-99 IIS. All DRLs and Action Levels will be maintained as per the licensing basis throughout the operation of Mo-99 IIS.

2.9.2.1.1 Venting to Contaminated Exhaust

The Mo-99 IIS will connect to the unitized contaminated exhaust system through a High Efficiency Particulate Air (HEPA) filter to capture and reduce particulate emissions.

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

2.9.3 Predictive Effects Assessment

In support of the Mo-99 IIS, an environmental Predictive Effects Assessment (PEA) for Units 4 and 2, N-REP-30550-00029 R000 and N-REP-30550-00035 were completed and submitted to CNSC staff (References 2.9.1 and 2.9.2 respectively).

The PEA for Unit 2 demonstrates that the Mo-99 IIS 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, 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. The last issued Darlington ERA, NK38-REP-07701-00001 R001, "*Darlington Nuclear Environmental Risk Assessment*" has not considered the potential for effects from the Mo-99 IIS, as it was prepared as a retrospective ERA. As defined in CSA Standard N288.6-12, a retrospective ERA is an ERA that attempts to estimate the effect that a contaminant or stressor has already had on the environment.

For tritium and particulate emissions, the PEA estimates that the highest potential dose to a member of the public from Mo-99 IIS operation would not exceed 0.006 µSv/year based on normal operations. This would constitute 0.0006% of the regulatory dose limit of 1 mSv/year for a member of the public, which is extremely low. Considering the 2019 Darlington NGS emissions resulted in a public dose of 0.006 µSv/year, the incremental dose a member of the public would receive from Mo-99 IIS 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.

Confirmation of emissions from Mo-99 IIS operation will be performed during commissioning of the Mo-99 IIS. The actual emissions will be compared against the PEA projections and provided to CNSC staff in the commissioning report.

As documented in Reference 2.9.2, Darlington NGS operates in compliance with REGDOC-2.9.1, "*Environmental Protection - Environmental Principles, Assessments and Protection Measures Version 1.1"*, with the exception of section 4.5 dealing with groundwater protection and monitoring. Given the Mo-99 IIS project will not impact ground water protection and monitoring, operation of the Mo-99 IIS will be in compliance with the applicable sections of REGDOC-2.9.1.

The Darlington ERA is required to be periodically updated as per REGDOC-2.9.1 and REGDOC-3.1.1, and the Darlington LCH. After the Mo-99 IIS is operational, its environmental impact will be included in the Darlington Environmental Risk Assessment (ERA).

2.9.4 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 the Mo-99 IIS will be in accordance with OPG's EMS as described in OPG-PROG-0005, "*Environmental Management Systems*" and OPG-POL-0021. The EMS provides specific direction on how the Environmental Policy is implemented while meeting the expectations of OPG-POL-0032, "*Safe Operations Policy*", N-POL-0001, "*Nuclear Safety & Security Policy"*, and N-CHAR-AS-0002, "*Nuclear Management System*".

2.9.5 Monitoring Programs

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. 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 the Mo-99 IIS. 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. 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.

2.9.6 Conventional Releases

The Mo-99 IIS will not result in increased non-radiological releases or emissions from Darlington NGS. Chemicals will not be used to support Mo-99 IIS operation and the molybdenum target capsules, consisting of the molybdenum metal encased in a zirconium outer sheath, will not dissolve in the heavy water nor interact with the reactor components (Reference 2.9.3).

2.9.7 Unit Installation Applicability

Based on unit similarities, the conclusions of the environmental PEA are expected to remain consistent across all units.

2.9.8 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.9.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Environmental Protection and identifies the impact of Mo-99 IIS on these programs and processes.

Table 2.9.3: Impact of Mo-99 IIS on Darlington's Environmental Protection Licensing Basis Documents

OPG Environmental Protection Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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
Environmental Management 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
Darlington Nuclear Environmental Risk Assessment	NK38-REP-07701-00001	Emissions from Mo-99 IIS will be included in future ERA updates when the Mo-99 IIS is operational

References

2.9.1 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Predictive Effects Assessment (ERA01-01)", June 11, 2020, CD# NK38-CORR-00531-21626.

2.9.2 OPG Confidential letter, S. Gregoris to J. Burta, "Darlington NGS – Molybdenum Isotope Irradiation System: Submission of the Unit 2 Predictive Effects Assessment (ERA01-01-U2)", November 24, 2020, CD# NK38-CORR-00531-22155.

2.9.3 OPG Confidential 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.

2.10 Emergency Management and Fire Protection

Operation of the Mo-99 IIS will have an acceptable impact on Darlington's Emergency Management and Fire Protection

- ✓ ***Mo-99 IIS design complies with CSA Standard N293-12, "Fire protection for nuclear power plants"***
- ✓ ***Mo-99 IIS does not introduce a new fire hazard***
- ✓ ***No impact on Station Minimum Shift Complement***
- ✓ ***No new operating limits or Operator actions within first eight hours***

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.

2.10.1 Regulatory Requirements Related to Emergency Management and Fire Protection

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.10.1 apply to the Emergency Management and Fire Protection SCA.

Table 2.10.1 List of Emergency Management and Fire Protection Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Fire protection for CANDU nuclear power plants	CSA N293 (2012)	Mo-99 IIS design and operation complies with the requirements in this CSA Standard
Nuclear Emergency Preparedness and Response	CNSC REGDOC-2.10.1 (2014)	Mo-99 IIS will have no impact, continued compliance

2.10.2 OPG Submissions to CNSC Staff Related to Emergency Preparedness and Fire Protection

The submissions that impact Emergency Preparedness and Fire Protection were submitted to CNSC staff in References 2.10.1 to 2.10.4.

2.10.3 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."

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 Design basis Accidents (DBA) and to ensure adequate emergency response capability is available for the most resource intensive conditions.

Over the course of the Mo-99 IIS 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 Mo-99 IIS on postulated DBAs in the Safety Report, including the six MSC determining DBAs, were completed and are documented in the N-CORR-03500-0764524, "*Disposition of Existing Analyses in Support of the Safety Case*" (Reference 2.10.1). This assessment concludes that operation of the Mo-99 IIS 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 large part, to minimal interactions between the Mo-99 IIS with other processes and safety systems.

During Mo-99 IIS operation, in response to a unit transient on any Darlington unit requiring staff assembly and accounting, the Field Operator at the local Mo-99 IIS console will leave the Mo-99 IIS in the "idle" state and report to the designated assembly location. The Operator response to unit transients will be contained in the Mo-99 IIS operating manual. Operation of the Mo-99 IIS will not prevent an Operator from fulfilling a MSC role.

2.10.2.6 Slow Loss of Reactor Power Regulation

Reference 2.10.3 documents the impact of the Mo-99 IIS on a slow loss of reactivity event. The assessment determined that the Mo-99 IIS will not impact the progression of this DBA.

2.10.2.7 Postulated Mo-99 IIS Piping Failure

Reference 2.10.4 documents the radiological impact from a postulated Mo-99 IIS piping failure and concludes that the radiological consequences would be well below the relevant public dose limits, and did not identify any new operating limits or required Operator actions.

In addition, the Mo-99 IIS 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.

2.10.3 Emergency Preparedness Drills and Exercises

In order 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, "*Emergency Preparedness Drills and Exercises*" through simulated events. Mo-99 IIS operation will not impact existing exercises, or introduce new drills or exercises.

2.10.4 Conventional Emergency Preparedness and Response

The Mo-99 IIS will not introduce new conventional emergency response requirements. Conventional chemicals will not be used to support Mo-99 IIS operation.

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 N-PROG-RA-0012 as a result of the Mo-99 IIS.

2.10.5.1 Mo-99 IIS Fire Protection and Compliance with CSA Standard N293-12

The Mo-99 IIS design and installation complies with CSA Standard N293-12, "*Fire protection for CANDU nuclear power plants*".

In addition, the installation of the Mo-99 IIS should not constitute a "major change" requiring an update to the Darlington Fire Hazard Assessment, and Fire Safe Shutdown Assessments outside of the normal five-year update cycle (Reference 2.10.5).

2.10.6 Unit Installation Applicability

The Emergency Preparedness and Fire Protection licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.10.7 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.10.3 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Emergency Management and Fire Protection, and identifies the impact of the Mo-99 IIS on these programs and processes.

Table 2.10.3 Impact of Mo-99 IIS on Darlington's Emergency Management and Fire Protection Licensing Basis Documents

OPG Emergency Management and Fire Protection Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Consolidated Nuclear Emergency Plan	N-PROG-RA-0001	No Change

OPG Emergency Management and Fire Protection Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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

References

2.10.1 OPG Confidential 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.

2.10.2 OPG Confidential 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.

2.10.3 OPG Confidential 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.

2.10.4 OPG Confidential 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.

2.10.5 OPG Confidential letter, B. Duncan to M. Santini, "Darlington NGS – Submission of the 2016 Fire Hazard Assessment (FHA) and Fire Safe Shutdown Analysis Reports (FSSA)", December 22, 2016, CD# NK38-CORR-00531-18179.

2.11 Waste Management

A minimal amount of waste is expected to be generated from Mo-99 IIS operation and maintenance.

- ✓ ***No waste will be shipped from BWXT back to Darlington NGS***
- ✓ ***Waste generated will be managed in accordance with existing waste management processes***

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.

2.11.1 Regulatory Requirements Related to Waste Management

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.11.1 apply to the Waste Management SCA.

Table 2.11.1 List of Emergency Management and Fire Protection Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Management of low and intermediate-level radioactive waste	CSA N292.3 (2008)	Mo-99 IIS design and operation complies with the requirements in this CSA Standard

2.11.2 Waste Characterization

2.11.2.1 Low Level Nuclear Waste

Operation of the Mo-99 IIS, which includes routine target-harvesting and reseeding, will not generate waste. The irradiated targets are shipped to BWXT- Medical and waste products during the processing of $Tc\text{-}99^{m}$ will not be returned to Darlington NGS. All waste associated with target processing will remain at vendor's facility.

The only waste expected to be generated from Mo-99 IIS operation is from Mo-99 IIS maintenance activities. This waste will be managed in accordance with N-PROC-RA-0017, "*Segregation and Handling of Radioactive Waste*", ensuring that radiological waste is properly handled, segregated and characterized.

2.11.2.2 Conventional Waste

Conventional waste generated through Mo-99 IIS maintenance activities, confirmed to be free of contamination, is expected to be minimal and processed in accordance with OPG-STD-0156.

2.11.2.3 Chemical and Hazardous Waste

Chemicals will not be used during Mo-99 IIS operation. Therefore, Mo-99 IIS operation will not generate chemical or hazardous waste.

2.11.3 Waste Minimization and Waste Management Practices

Mo-99 IIS operation and maintenance 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.

To ensure cleanliness and to prevent foreign material from entering the Mo-99 IIS, new target capsules will be contained within a stainless steel sleeve with removable caps that will be loaded into the new target loader. Once emptied of targets, the sleeve will be returned to BWXT-NEC for reuse.

2.11.4 Decommissioning Plans

The Darlington NGS preliminary decommissioning plan NK38-PLAN-00960-10001*,* "*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 (Reference 2.11.1).

The Mo-99 IIS, being a relatively small and removable system, will have minimal effect on future decommissioning activities.

2.11.5 Unit Installation Applicability

The Waste Management licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.11.6 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.11.1 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 Mo-99 IIS on these programs and processes.

Table 2.11.1: Impact of Mo-99 IIS on Darlington's Waste Management Licensing Basis Documents

OPG Waste Management Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Environmental Management System	N-PROG-OP-0005	No Change
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

OPG Waste Management Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
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

Reference 2.11.1 OPG Confidential letter, S. Granville to A. Viktorov, M. Santini, and K. Glenn, "Submission of Preliminary Decommissioning Plans", January 30, 2017, CD# N-CORR-00531-18384.

2.12 Security

Operation of the Mo-99 IIS will not require changes to OPG security provisions or processes.

- ✓ ***Incoming and outgoing shipments of targets will follow existing security processes***

The natural molybdenum targets, manufactured by BWXT-NEC, will be received periodically at Darlington NGS to meet medical demand for the Tc-99m. Once irradiated, the targets will be shipped from Darlington NGS to BWXT-Medical processing facility, using BWXT transportation packaging and equipment, for medical processing.

2.12.1 Regulatory Requirements Related to Security

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.12.1 apply to the Security SCA.

Table 2.12.1 List of Security Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Nuclear Security Regulations	SOR/2000-209	Compliance documented in Attachment 1
Cyber security for nuclear power plants and small reactor facilities	CSA N290.7 (2014)	Mo-99 IIS design complies with cyber security requirements
High Security Sites: Nuclear Response Force	CNSC REGDOC-2.12.1 (2013)	Continued compliance, Mo-99 II will have no impact
Site Access Security Clearance	CNSC REGDOC- 2.12.2 (2013)	Continued compliance, Mo-99 II will have no impact

Nuclear Security Officer Medical, Physical and Psychological Fitness	CNSC RD-363 (2010)	Continued compliance, Mo-99 II will have no impact
Criteria for Physical Protection Systems and Devices at High Security Sites	CNSC RD-321 (2010)	Continued compliance, Mo-99 II will have no impact
Criteria for Explosive Substance Detection, X-Ray Imaging and Metal Detection at High Security Sites	CNSC RD-361 (2010)	Continued compliance, Mo-99 II will have no impact

2.12.2 Facilities and Equipment

The Mo-99 IIS will not require changes to security related facilities, equipment or staffing levels. The incoming and outgoing BWXT-Medical 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*".

2.12.3 Response Arrangements

The installation and operation of the Mo-99 IIS will not require changes to security response arrangements or processes.

2.13.4 Security Practices, Drills and Exercises

The installation and operation of the Mo-99 IIS will not require changes security practices, drills or exercises.

2.12.5 Unit Installation Applicability

The Security licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.12.6 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.12.1 provides the list of OPG governance, programs and processes that form the licensing basis for Darlington's Security and identifies the impact of Mo-99 IIS on these programs and processes.

Table 2.12.1: Impact of Mo-99 IIS on Darlington's Security Program Licensing Basis Documents

OPG Security Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Darlington Nuclear Generating Station Security Report	8300-REP-61400-10003	No Change
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

OPG Security Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Cyber Security Controls for Cyber Essential Assets	N-INS-08161-10011	No Change
Significant Cyber Assets	NK38-LIST-69000-10001	No Change

2.13 Safeguards and Non-Proliferation

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

- ✓ ***As a result of the Mo-99 IIS design descriptions provided to CNSC staff, no safeguard provisions have been identified by the International Atomic Energy Agency (IAEA).***
- ✓ ***OPG will comply with any changes or new IAEA requirements***
- ✓ ***Newly installed Mo-99 IIS equipment will not interfere will IAEA safeguards requirements.***
- ✓ ***All reports and information necessary for safeguards implementation and compliance will continue to be provided on a timely basis.***

Darlington will continue to meet Canada's international obligations under the Treaty on the Non-Proliferation of Nuclear Weapons. The Mo-99 IIS 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).

2.13.1 Regulatory Requirements Related to Safeguards and Non-Proliferation

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.13.1 apply to the Safeguards and Non-Proliferation SCA.

Table 2.13.1 List of Safeguards and Non-Proliferation Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Nuclear Non-proliferation Import and Export Control Regulations	SOR/2000-210	Compliance documented in Attachment 1
Safeguards and Nuclear Material Accountancy	CNSC REGDOC-2.13.1 (2018)	Continued compliance
Accounting and Reporting of Nuclear Material	CNSC RD-336 (2010)	Continued compliance

2.13.2 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. The Mo-99 IIS will not impact OPG's compliance with non-fuel reporting requirements documented in REGDOC-2.13.1, "*Safeguards and Nuclear Material Accountancy*".

2.13.3 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. The Mo-99 IIS will have no impact on IAEA inspections or access to IAEA equipment. Newly installed Mo-99 IIS equipment will not interfere with OPG's obligations.

2.13.4 Operational and Design Information

The Mo-99 IIS design description has been provided to CNSC staff for transmittal to the IAEA.

2.13.5 Safeguards Equipment, Containment and Surveillance

The Mo-99 IIS will not interfere with existing IAEA safeguards surveillance monitoring equipment.

2.13.6 Import and Export

There will be no requirement to import nuclear material for Mo-99 IIS installation and operation. BWXT-Medical will be responsible for obtaining the required export licenses for exporting the processed Tc-99m outside of Canada.

2.13.7 Unit Installation Applicability

The Safeguards and Non-Proliferation licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.13.8 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.13.2 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 of Mo-99 IIS installation and operation on these programs and processes.

Table 2.13.1: Impact of Mo-99 IIS on Darlington's Safeguards and Non-Proliferation Program Licensing Basis Documents

OPG Safeguards and Non-Proliferation Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Nuclear Safeguards	N-PROG-RA-0015	No Change
Nuclear Safeguards Implementation	N-STD-RA-0024	No Change

2.14 Packaging and Transport

OPG will comply with applicable transportation regulations:

- ✓ ***Mo-99 irradiated targets will be transported in CNSC certified radioactive material transportation packages***
- ✓ ***Both OPG and BWXT-Medical have the capability and plans for responding to transportation accidents***
- ✓ ***There will be no change to OPG's response to transportation accidents***
- ✓ ***The recipients of Mo-99 targets will be a licensed facility***

The natural Molybdenum targets, manufactured by BWXT-NEC, will be periodically received periodically at Darlington NGS to meet medical demand for the $Tc\text{-}99^{m}$.

Once irradiated, the targets will be shipped from Darlington NGS to BWXT-Medical for medical processing.

2.14.1 Regulatory Requirements Related to Packaging and Transport

In addition to compliance with the "*Nuclear Safety and Control Act*" and the "*General Nuclear Safety Control Regulations*" as outlined in Attachment 1, the regulatory requirements listed in Table 2.14.1 apply to the Packaging and Transport SCA.

Table 2.14.1 List of Packaging and Transport Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Mo-99 IIS Impact
Transportation of Dangerous Goods Regulations	SOR/2001-286	Compliance with requirements as documented in Attachment 1.
Packaging and Transport of Nuclear Substances Regulations	SOR/2015-145 (2015)	Compliance with requirements as documented in Attachment 1.

BWXT-Medical, having responsibility for the radioactive material transportation of the irradiated targets to the BWXT-Medical processing facility and ownership of the transportation packaging, has made CNSC submissions related to package certification. As these activities are the responsibility of BWXT-Medical, they are outside the bounds of OPG's application for Darlington PROL amendment.

2.14.2 Package Design and Maintenance

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

At the applicable Darlington unit, the irradiated targets will be loaded into a certified radioactive material transportation package for shipment to BWXT-Medical in Kanata, Ontario, using the Mo-99 flask loader.

2.14.2.1 Mo-99 Transportation Packaging Certification

BWXT-Medical has submitted information to CNSC staff in support of the Mo-99 transportation packaging certification. OPG understands that the transportation packaging, which is undergoing certification testing by BWXT-Medical, will be similar to the packaging used for transportation of irradiated targets from NRU to Nordion for Tc-99m processing. OPG understands that minor modifications have been made by BWXT-Medical to the packaging for the Darlington NGS Mo-99 IIS project, requiring packaging re-certification by CNSC staff.

2.14.3 Packaging and Transport

The program document, W-PROG-WM-0002, "*Radioactive Material Transportation*" (RMT), establishes the program and 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 response to transportation accidents.

In accordance with W-PROG-WM-0002 and the regulatory requirements, OPG staff will package the irradiated targets for shipment in the CNSC certified transportation packaging, and will prepare the shipping paperwork for receipt at a facility licensed by the CNSC to receive the specific material.

2.14.3.1 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 the Mo-99 IIS project.

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 transportation response capability.

2.14.4 Transportation Packaging CNSC Registration for Use

In accordance with the CNCS' "*Packaging and Transportation of Nuclear Substances Regulations*", OPG will apply for and obtain CNSC confirmation to use the Mo-99 certified transportation packaging prior to the first shipment. OPG has procedures in place for the registration for use of certified design transportation packages. There will be no changes as a result of the Mo-99 IIS project.

2.14.5 Unit Installation Applicability

The Packaging and Transport licensing requirements, being unit neutral, will be applicable to any Darlington NGS unit.

2.14.6 Impact of Mo-99 IIS on OPG Governance, Programs and Processes

Table 2.14.1 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 of Mo-99 IIS on these programs and processes.

Table 2.14.1: Impact of Mo-99 IIS on Darlington's Packaging and Transport Licensing Basis Documents

OPG Transportation and Packaging Licensing Basis Document Title	OPG Document Number	Impact from Mo-99 IIS
Radioactive Material Transportation	W-PROG-WM-0002	No Change
Radioactive Materials Transportation Emergency Response Plan	N-STD-RA-0036	No Change

3. 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 standard N-STD-AS -0013, "*Nuclear Public Information and Disclosure*".

OPG provides responses to issues and questions raised by stakeholders and the public, and tracks issues and questions to identify trends in order 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 the medical isotope Mo-99.

3.1.1 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 Mo-99 IIS project.

3.2 Indigenous Community Engagement

OPG acknowledges the Aboriginal and Treaty Rights of Indigenous communities as recognized in the *Constitution Act, 1982*. Under its Indigenous Relations Policy, OPG regularly undertakes engagement with Indigenous communities with established or asserted rights and/or interests. In the case of the Mo-99 IIS project, and its vendor partners, engage with the Indigenous communities listed below. The planned production of the isotope at Darlington NGS and Mo-99 transportation along highways 401 and 417, crosses multiple treaty and traditional territories.

- Williams Treaties First Nations
    - Beausoleil First Nation
    - Chippewas of Rama First Nation
    - Chippewas of Georgina Island
    - Mississaugas of Scugog Island
    - Hiawatha First Nation
    - Curve Lake First Nation
    - Alderville First Nation
- Mohawks of the Bay of Quinte
- Métis Nation of Ontario, Regions 5, 6 and 8
- Algonquins of Ontario
- Algonquins of Pikwakanagan
- Algonquin Anishinabeg Nation Tribal Council (Quebec)

OPG has engaged with these Indigenous communities throughout 2019 and 2020 in order to provide them with information regarding the production and transportation of the medical isotope, and to discuss any identified issues and concerns.

As a part of its engagement plan, the partners have offered additional updates/meetings with the identified Indigenous communities during 2020 and 2021, leading up to hearing to further discuss the project. OPG has made available baseline capacity support to the engaged Indigenous communities in line with its Indigenous Policy and the scope of the engagement required.

In preparation for hearings regarding the production and transportation of Mo-99, OPG will proactively engage the identified Indigenous communities through activities of their choice, such as staff briefings, community information sessions and/or workshops, etc. The specific objective is to ensure that Indigenous peoples and communities in the production area around Darlington NGS and along the transportation route to the BWXT-Medical facility in Kanata, Ontario are provided with a forum to discuss key topics of Indigenous interest related to the application. Although the application does not require compliance with CNSC's REGDOC-3.2.2, "*Indigenous Engagement*", the activities undertaken will meet those requirements as a matter of preferred practice by OPG.

4. Conclusion

The Mo-99 medical isotope project is an important initiative for the nuclear industry and medical community. Approximately 80% of nuclear medical procedures rely on Tc-99m, the decay isotope of the Mo-99 radioisotope. This translates into over 30 million heart, cancer and bone diagnostic scans, performed annually using Tc-99m.

OPG's request for amendment of the Darlington NGS PROL to add a new licensed activity to possess, transfer, produce, package, manage and store Mo-99 radioisotope and its associated decay isotopes remains unchanged.

OPG is responsible for continued safe operation of the Darlington NGS, and confirms that the Mo-99 IIS modifications will be implemented based on a robust safety case. CNSC staff have been kept informed of the progress and safety conclusions. Assessments submitted to CNSC staff conclude that the proposed activities to support production of Mo-99 in selected Darlington NGS CANDU reactors will not compromise continued safe reactor operation, public and employee safety, and environmental protection.

The safety case for this project can be summarized as follows:

- Design: OPG will continue to follow its established Engineering Change Control process for ensuring the design complies with applicable regulatory requirements and that configuration management for the station will be maintained.

- Continued Safe Reactor Operation: Safety analysis submitted to CNSC staff demonstrates that operation of the Mo-99 IIS will have negligible effect on safe reactor operation, and on public safety.

- Environmental Protection: A predictive environmental effects assessment, prepared in accordance with CSA Standards N288, concludes that operation of the Mo-99 IIS will have negligible impact on the environment.

- Licensing Basis: Operation of the Mo-99 IIS will have negligible impact on Darlington's licensing basis, governance, programs and processes.

Prior to operating the Mo-99 IIS, the new system will be fully tested and commissioned following detailed procedures to demonstrate continued reactor safety. Once installed and fully commissioned, OPG staff will be qualified to operate and maintain the Mo-99 IIS.

OPG will continue to provide information to CNSC staff to assist in fulfillment of their regulatory role.

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

5. Acronyms

The following is a list of acronyms used throughout this Attachment.

Acronym	Definition
ALARA	As Low As Reasonably Achievable
BDBE	Beyond Design Basis Event
CBOP	Continuous Behaviour Observation Program
CNSC	Canadian Nuclear Safety Commission
COG	CANDU Owners' Group
CSA	Canadian Standards Association
CNEP	Consolidated Nuclear Emergency Plan
DARA	Darlington 'A' Risk Assessment
DBE	Design Basis Event
DNGS	Darlington Nuclear Generating Station
EA	Environmental Assessment
ECC	Engineering Change Control
EMS	Environmental Management System
EMP	Environmental Monitoring Program
EPC	Engineer, Procure and Construct
ERA	Environmental Risk Assessment
ERO	Emergency Response Organization
ERT	Emergency Response Team
FAT	Factory Acceptance Testing
FHA	Fire Hazard Assessment
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
LRF	Large Release Frequency
NGS	Nuclear Generating Station
NOP	Neutron Overpower Protection
OHSA	Ontario Occupational Health and Safety Act
OPEX	Operating Experience
OPG	Ontario Power Generation
OP&P	Operating Policies and Principles
PNERP	Provincial Nuclear Emergency Response Plan
PIT	Physical Inventory Taking
PROL	Power Reactor Operating Licence
PSA	Probabilistic Safety Assessment
QRHP	Quality Release Hold Point
R&D	Research and Development
SCA	Safety and Control Area
SCDF	Severe Core Damage Frequency
SAT	Systematic Approach to Training
SOE	Safe Operating Envelope

6. Glossary of Terms

Beyond Design Basis Event (BDBE) – An extemely unlikely event for which the station has not been specifically designed.

Design Basis Events (DBE) – The set of nonstandard internal and external events for which the station has been designed for and for which the safety analysis must demonstrate acceptable public safety impact.

Engineering Change Control (ECC) – A rigorous process that ensures all plant modifications are designed and installed in a thorough and complete manner.

Quality Release Hold Point – HoldPoints are established an key project milestones to ensure qualilty and readiness to proceed to the next milestone.

Large Release Frequency (LRF) – The sum of the mean frequencies of events that can lead to the release of greater than 1% of the core inventory of Caesium-137 (Cs-137) to the environment due to the operation of a nuclear reactor when averaged over a one year period. Large Release requires Severe Core Damage with coincident failure of containment.

Licensing Basis – Defined in Darlington's Licence Condition Handbook as the set of requirements for which the station has been licensed (i.e., the basis upon which the station has received an operating licence).

Probabilistic Safety Assessment (PSA) – PSA is a comprehensive set of models of plant systems, components and Operator actions in response to abnormal internal and external plant events. The PSA for Darlington (DARA) updated in 2015, followed by 2020, in accordance with S-294, demonstrates that the public risk from Darlington operation remains very low.

Safe Operating Envelope (SOE) – Defines the safety analysis bounds (limits, component and system requirements) for safe plant operation.

Safety Goals – In PSA, safety goal refers to a set of numerical values, expressed in terms of the frequency of Severe Core Damage or Large Release Events, which establish targets and limits for station design and operation. These goals represent the high standards of safety and reliability for nuclear power plant operations.

Severe Core Damage Frequency (SCDF) – The sum of the mean frequencies of events due to operation of a nuclear reactor that can lead to failure of both fuel and fuel channels when averaged over one year.

Target Harvesting – The activitiy of removing irradiated target capsules from the reactor core to flask and shipment the medical isotope off-site for processing.

Target Seeding – The activity of inserting target capsules into the reactor core for irradiation.

7. List of Organizations

The following is a list of organizations referenced in this Attachment.

BWXT-Nuclear Energy Company (NEC) – located in Peterborough, Ontario, designed the Mo-99 IIS and manufactures the unique Mo-99 IIS components. The target zirconium sheath will be manufactured at BWXT's facility in Arnpior, Ontario, and assembly of the target capsules with natural Molybdenum will occur at the Peterborough facility.

BWXT Canada Ltd. – located in Cambridge, Ontario, is the EPC Contractor / Constructor for this project. BWXT Canada Ltd has over 60 years of expertise and experience in the design, manufacturing, commissioning and service of nuclear power generation equipment. This includes steam generators, nuclear fuel and fuel components, critical plant components, parts and related plant services

BWXT-Medical (formerly named BWXT-ITG (Isotope Technologies Group)) – located in Kanata, Ontario, owns and operates the processing facility for generators that convert Mo-99 into Tc-99m for the medical community.

Canadian Nuclear Safety Commission (CNSC) – Established under the Nuclear Safety and Control Act, the CNSC regulates the use of nuclear power and material in Canada. The CNSC issues operating licences and confirms compliance with regulatory requirements through ongoing inspections.

Canadian Standards Association (CSA) – The CSA Group is a membership association, serving industry, government and consumers. OPG is a CSA member and participates in the development of industry codes and standards. Many of CSA's energy standards are cited in both federal and provincial regulations. CSA also helps to promote a safe and reliable nuclear power industry in Canada through the creation of specific nuclear industry standards.

CANDU Owners' Group (COG) – The CANDU Owners Group Inc. (COG) is an affiliation of CANDU Nuclear Power Plant Operators and the original CANDU designer Atomic Energy of Canada Limited (AECL), that provides a framework for co-operation, mutual assistance and exchange of information for the successful support, development, operation, maintenance and economics of CANDU technology. OPG is an ongoing partner in COG initiatives.

Ecometrics Inc. - located in Mississauga, Ontario, prepared the environmental Predictive Effects Assessment for operation of the Mo-99 IIS. EcoMetrix provides support to the nuclear industry is the area of environmental assessments.

International Organization for Standardization (ISO) – ISO is an independent, non-governmental membership organization and the world's largest developer of voluntary International Standards. ISO has published more than 19,500 International Standards covering almost every industry including technology, agriculture, and healthcare.

International Atomic Energy Agency (IAEA) – The IAEA is widely known as the world's "Atoms for Peace" organization within the United Nations family. Set up in 1957 as the world's centre for cooperation in the nuclear field, the Agency works with its

Member States and multiple partners worldwide to promote the safe, secure and peaceful use of nuclear technologies.

Kinectrics - located in Toronto, Ontario, prepared the safety analysis and assessments that demonstrate the Mo-99 IIS will have minimal impact on continued safe reactor operation.

National Fire Protection Association (NFPA) – Founded in 1896, NFPA is a global, nonprofit organization devoted to eliminating death, injury, property and economic loss due to fire, electrical and related hazards. The association delivers information and knowledge through more than 300 consensus codes and standards, research, training, education, outreach and advocacy.

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

NK38-CORR-00531-22275

Submission Title: **Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025**

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: None