ONTARIO POWER GENERATION

Allan Grace
Senior Vice President
Darlington Nuclear

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

OPG Proprietary

January 24, 2025

CD# NK38-CORR-00531-25810 P

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

Dear Ms. C. Salmon:

Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production

The purpose of this letter is to submit to the Canadian Nuclear Safety Commission (CNSC) a revised redacted application for amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for additional isotope production.

In February of 2024, OPG submitted an application to amend the Darlington NGS Power Reactor Operating Licence 13.03/2025 for additional isotope production (Reference 1). A request for confidentiality was submitted to request that the application, including all attachments and enclosures, be kept confidential for financial, commercial, scientific and technical reasons.

The Commission Registry requested that OPG provide a summary or redacted version of the application to be posted on the CNSC website. In May of 2024, OPG submitted a redacted version of the application (Reference 2). A request for confidentiality was submitted to request that the redacted information, the nuclear safety impact assessment report, and select reference documents be kept confidential. The redacted application and request for confidentiality were posted on the CNSC website.

Information related to Lutetium-177 and BWXT-Medical is no longer considered to be commercially sensitive information and can now be disclosed to the public. This revised redacted application removes the redactions regarding Lutetium-177 and

BWXT-Medical and is intended to replace the redacted application provided under Reference 2. This revised redacted application does not provide any new information beyond the information provided in Reference 2 and its attachments and enclosures.

OPG is requesting an amendment to PROL 13.03/2025 to:

- Modify activity (vi) in part IV of the Darlington NGS PROL to state: "possess, transfer, process, package, manage and store Molybdenum-99, **Lutetium-177 and Yttrium-90** radioisotopes and **their** associated decay isotopes."

OPG is seeking to expand its irradiation capacity by leveraging the existing Darlington NGS Target Delivery System (TDS) also referred to as the Isotope Irradiation System, and associated infrastructure and expertise, to produce two additional isotopes, Lutetium-177 (Lu-177) and Yttrium-90 (Y-90). OPG currently uses the TDS to irradiate target capsules to produce the medical isotope Molybdenum-99 (Mo-99). By loading different material contained within each target capsule, OPG can use the existing TDS to generate these new radioisotopes which will have a significant positive impact on human health across Canada and the globe, expanding Canada's leadership role in the global community by supporting new and innovative approaches to cancer diagnosis and treatment.

OPG is committed to the safe and reliable operation of Darlington NGS and confirms that the changes to the TDS required to accommodate production of these two new isotopes 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 safety case for this project can be summarized as follows:

- **Design:** OPG will continue to follow its established N-PROC-MP-0090, "*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:** OPG will complete a comprehensive safety assessment to confirm that the operation of the TDS using Lu-177 and Y-90 target capsules will have negligible effects on safe reactor operation, and on public safety. Attachment 4 provides a technical summary of the confidential preliminary nuclear safety assessment NK38-REP-03600-10014-000, "*Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System*". Based on this report, OPG is confident that the activities necessary to support production of Lu-177 and Y-90 using the existing TDS will not compromise continued safe reactor operation.

- **Environmental Protection:** A predictive environmental effects assessment, prepared in accordance with Canadian Standards Association N288.6-12, "*Environmental risk assessments at Class 1 nuclear facilities and uranium mines and mills*" concludes that operation of the TDS is safe and continues to be applicable for Lu-177 and Y-90.

- **Licensing Basis:** Operation of the TDS using Lu-177 and Y-90 target capsules will have minimal impact on Darlington NGS's licensing basis, governance, programs and processes.

Attachment 1 provides the proposed amendment to Darlington NGS's PROL 13.03/2025.

Attachment 2 provides the compliance matrix for the *Nuclear Safety and Control Act*, and the associated regulations required for the amendment of the Darlington NGS PROL to add the proposed new licensed activity.

Attachment 3 provides the licence impact assessment of the proposed new licensed activity on Darlington's licensing bases for each of the 14 PROL Safety and Control Areas and Nuclear Facility Specific licence conditions, to support the application for PROL amendment and summarizes public, Indigenous and Metis engagement related to the application of licence amendment.

Attachment 4 provides a technical summary of NK38-REP-03600-10014-000, Nuclear Safety Impact Assessment for the introduction of new isotopes in the Target Delivery System (TDS) at Darlington NGS (Enclosure 1 of Reference 1).

OPG is committed to engaging with identified Indigenous Nations and communities and those having an interest in its current nuclear operations and future nuclear projects, including the production of the medical isotopes described herein. OPG will engage with identified Indigenous Nations and communities which have inherent and/or Aboriginal and treaty rights or interests regarding the project in accordance with NK38-PLAN-00120-00018-R000, "*Isotope Engagement and Communications Plan with Indigenous Communities*" provided in Enclosure 1 (previously Enclosure 2 of Reference 1).

In summary, OPG is requesting the Commission to grant the amendment to Darlington NGS PROL 13.03/2025 to add a new licensed activity to possess, transfer, process, package, manage and store Lu-177 and Y-90 radioisotopes and their associated decay isotopes.

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

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

Sincerely,

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

cc: CNSC Site Supervisor – Darlington
A. Viktorov - Ottawa
A. Baig - Ottawa
forms-formulaires@cnsc-ccsn.gc.ca
registry-greffe@cnsc-ccsn.gc.ca

References:

1. OPG letter, A. Grace to D. Saumure, “Darlington NGS – Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”, February 26, 2024. CD# NK38-CORR-00531-25141.

2. OPG letter, A. Grace to D. Saumure, “Darlington NGS – Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”, CD# NK38-CORR-00531-25215.

ATTACHMENT 1

OPG letter, A. Grace to C. Salmon, “Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”

CD# NK38-CORR-00531-25810 P

Proposed Amendment to Darlington NGS PROL 13.03/2025

Prepared By:	**K. Lynchahon**
Checked By:	**L. Moraru**

ATTACHMENT 1

Proposed Amendment to Darlington NGS PROL 13.03/2025

Current PROL 13.03/2025	Requested Amendment to PROL 13.03/2025 (Revised proposed amendment in bold and italic)
IV) LICENSED ACTIVITIES:	**IV) LICENSED ACTIVITIES:**
This licence authorizes the licensee to:	This licence authorizes the licensee to:
(i) operate the Darlington Nuclear Generating Station which includes the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter "the nuclear facility") at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario;	(i) operate the Darlington Nuclear Generating Station which includes the Darlington Tritium Removal Facility housed within the Heavy Water Management Building (hereinafter "the nuclear facility") at a site located in the Municipality of Clarington, in the Regional Municipality of Durham, in the Province of Ontario;
(ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i);	(ii) possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the activities described in (i);
(iii) import and export nuclear substances, except controlled nuclear substances, that are required for, associated with, or arise from the activities described in (i);	(iii) import and export nuclear substances, except controlled nuclear substances, that are required for, associated with, or arise from the activities described in (i);
(iv) possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the activities described in (i);	(iv) possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the activities described in (i);
(v) possess, transfer, process, package, manage and store the nuclear substances associated with the operation of the Darlington Tritium Removal Facility;	(v) possess, transfer, process, package, manage and store the nuclear substances associated with the operation of the Darlington Tritium Removal Facility;
(vi) possess, transfer, process, package, manage and store Molybdenum-99 radioisotope and its associated decay isotopes.	(vi) possess, transfer, process, package, manage and store Molybdenum-99, **Lutetium-177 and Yttrium-90 radioisotopes** and **their** associated decay isotopes.

ATTACHMENT 2

OPG letter, A. Grace to C. Salmon, “Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”

CD# NK38-CORR-00531-25810 P

Licence Amendment Matrix – Nuclear Safety and Control Act and Applicable Regulations

Prepared By:	**H. Overton**
Checked By:	**K. Thompson**

ATTACHMENT 2

Licence Amendment Matrix - Nuclear Safety and Control Act and Applicable Regulations

This Attachment, along with Attachment 3 of this submission, provide the information required by the *Nuclear Safety and Control Act* and the applicable Nuclear Regulations made pursuant to the Act, to support an application by OPG to amend the current Darlington NGS Power Reactor Operating Licence (PROL) 13.03/2025.

OPG staff is requesting an amendment to the Darlington NGS PROL to authorize OPG to possess, transfer, process, package, manage, and store Lutetium-177 (Lu-177) radioisotope and the Yttrium-90 (Y-90) radioisotope and their associated decay isotopes.

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

Nuclear Safety and Control Act		
Section	**Regulatory Requirement**	**OPG Response**
Licences		
24	***Licences*** *(1) The Commission may establish classes of licences authorizing the licensee to carry on any activity described in any of paragraphs 26(a) to (f) that is specified in the licence for the period that is specified in the licence.* ***Application*** *(2) 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;*	This submission (letter and attachments) provides the information required by the *Nuclear Safety and Control Act* (referred to as the Act) and the Regulations made pursuant to the Act. 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. The requirements under clause 24(2) have been met.

Nuclear Safety and Control Act		
Section	**Regulatory Requirement**	**OPG Response**
	(b) containing the prescribed information and undertakings and accompanied by the prescribed documents; and *(c) accompanied by the prescribed fee*	
	Conditions for issuance, etc. *(4) No licence shall be issued, renewed, amended or replaced — and no authorization to transfer one given — unless, in the opinion of the Commission, the applicant or, in the case of an application for an authorization to transfer the licence, the transferee* *(a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and* *(b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.*	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. OPG is qualified to safely undertake the additional activities associated with producing Lu-177 and Y-90 medical isotopes at Darlington NGS. Attachment 3 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.

Nuclear Safety and Control Act		
Section	**Regulatory Requirement**	**OPG Response**
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 these requirements and will continue to comply.
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 understands these requirements and will continue to comply.

Nuclear Safety and Control Act		
Section	**Regulatory Requirement**	**OPG Response**
Records and Reports		
27	***Records and reports*** *Every licensee and every prescribed person shall* *(a) keep the prescribed records, including a record of the dose of radiation received by or committed to each person who performs duties in connection with any activity that is authorized by this Act or who is present at a place where that activity is carried on, retain those records for the prescribed time and disclose them under the prescribed circumstances; and* *(b) make the prescribed reports and file them in the prescribed manner, including a report on* *(i) any theft or loss of a nuclear substance, prescribed equipment or prescribed information that is used in carrying on any activity that is authorized by this Act, and* *(ii) any contravention of this Act in relation to an activity that is authorized by this Act and any measure that has been taken in respect of the contravention.*	OPG understands these requirements and will continue to comply in accordance with provisions/requirements stated in Darlington's Licence Conditions Handbook section A.5, *"Record Keeping"* and applied through OPG program N-PROG-AS-0001, *"Nuclear Management System Administration"*.

Nuclear Safety and Control Act		
Section	**Regulatory Requirement**	**OPG Response**
Procedures for Decisions and Orders		
40	***Public hearings*** *(5) The Commission shall, subject to any by-laws made under section 15 and any regulations made under section 44, hold a public hearing with respect to* *(a) the proposed exercise by the Commission, or by a panel established under section 22, of the power under subsection 24(2) to issue, renew, suspend, amend, revoke or replace a licence; and* *(b) any other matter within its jurisdiction under this Act, if the Commission is satisfied that it would be in the public interest to do so.*	OPG understands these requirements regarding the Commission decision-making process.

General Nuclear Safety and Control Regulations		
Section	**Regulatory 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**

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
		Official Language: **English** Contact person, signing authority and licence holder: **Allan Grace** **Senior Vice President Darlington Nuclear,** **Ontario Power Generation** **Telephone: 905-260-1505**
	(b) the activity to be licensed and its purpose;	OPG requests the Darlington NGS PROL 13.03/2025 be amended to authorize OPG to the possess, transfer, process, package, manage, and store Lu-177 and Y-90 and their associated decay isotopes for the purpose of supporting the medical community.
	(c) the name, maximum quantity and form of any nuclear substance to be encompassed by the licence;	The form of each isotope is as per Section 1.4.1 of Attachment 3 of this submission. The maximum quantity of activated Lu-177 will not exceed 445.20 TBq. The maximum quantity of activated Y-90 will not exceed 97.50 TBq.
	(d) a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence;	The requested PROL amendment will not require any physical design changes to the Target Delivery System (TDS) used to irradiate Molybdenum-99 (Mo-99), or changes to prescribed equipment or prescribed information.
	(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 13.03/2025 and with the *Radiation Protection Regulations*, the *Nuclear Security Regulations*, and the *Packaging and Transport of Nuclear Substances Regulations* as described in Sections 2.7, 2.12 and 2.14 of Attachment 3 of this submission.

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
	(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 or environmental 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 NGS site access, the nuclear substances, 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 substances, 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 Lu-177 and Y-90 at Darlington NGS is supported by the safety case summarized in Attachment 4 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 3, some low level waste will be generated from Lu-177 production. This waste will be managed in accordance with OPG's current programs and processes.
	(k) the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the Act and the regulations made under the Act, including the internal allocation of functions, responsibilities and authority;	The organizational management structure will not change as a result of the requested licence amendment.

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
	(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 [2-1] 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;* *or* *(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.

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
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* *(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.*	Attachment 3 provides a description of the requested PROL amendment and the changes that will be required to permit the production of the Lu-177 and Y-90 medical isotopes. There will be no effect on land, areas, buildings, structures, components, equipment and systems as a result of this amendment.
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.*	Attachment 3 includes applicable references to information contained in the existing Darlington NGS PROL and Licence Conditions Handbook.

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
Obligations – Obligations of Licensees		
12(1)	*Every licensee shall* *(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 irradiation of two new medical isotopes may result in an increase to staffing level at Darlington NGS. Refer to section 2.1.2 of Attachment 3 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 will develop and deliver the necessary training to staff working with the TDS as per existing OPG governance. Refer to section 2.2 in Attachment 3 for further details.
	(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 sections 2.8 and 2.9 in Attachment 3 for details on health and safety of persons and on environmental protection. Refer to section 2.12 in Attachment 3 for security considerations.
	(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	OPG understands this requirement and will continue to comply.

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
	the site of the licensed activity and into the environment as a result of the licensed activity;	Refer to section 2.9 in Attachment 3 for details on environmental protection.
	(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 2.12 in Attachment 3 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 3 for further details on safeguards.
	(j) instruct the workers on the physical security program at the site of the licensed activity *and on their obligations under that program; and*	OPG understands this requirement and will continue to comply. Refer to section 2.12 in Attachment 3 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.
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 Lu-177 and Y-90 targets will be transported to a CNSC licensed facility for processing in compliance with the

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
	prescribed equipment or prescribed information by the Act and the regulations made under the Act.	*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.*	OPG understands this requirement and will continue to comply with this requirement.

General Nuclear Safety and Control Regulations		
Section	**Regulatory Requirement**	**OPG Response**
	(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, prescribed equipment or prescribed information.*	

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	**Regulatory Requirement**	**OPG Response**
Radiation Protection Program		
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*. See section 2.7 of Attachment 3 for information on the radiation protection provisions and considerations associated with this amendment request.

Nuclear Security Regulations
The production of Lu-177 and Y-90 and their associated decay products does not involve Category I, II or III Nuclear Material as defined in the *Nuclear Security Regulations*. Refer to section 2.12 of Attachment 3 for discussion of security considerations.

Nuclear Substance and Radiation Device Regulations		
Section	**Regulatory Requirement**	**OPG Response**
Licence Applications – General Requirements		
3(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 Becquerel's 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*	As detailed in Attachment 3, OPG intends to use the existing TDS installed in the Darlington NGS to produce two new isotopes in the same manner that Mo-99 is produced. The TDS and production of Mo-99 is already part of the Darlington NGS licensing basis. Based on preliminary assessments, these two new isotopes are bounded by the safety assessment that was completed for Mo-99 and presents no greater risk than the production of Mo-99 using the TDS. As described in section 2.2 of Attachment 3, OPG will update and deliver the necessary training to staff working with the TDS as per existing governance. As documented in section 2.9 of Attachment 3, emissions from operation of the TDS will be monitored. OPG will follow established procedures for responding to elevated emissions and contamination.

Nuclear Substance and Radiation Device Regulations		
Section	**Regulatory Requirement**	**OPG Response**
	(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;* *(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*	Refer section 2.10 of Attachment 3 for further information on emergency response. Details related to the inspection and maintenance of the TDS were provided to CNSC staff in [redacted], under the scope of the Mo-99 program and will be updated to incorporate the irradiation of Lu-177 and Y-90. Refer to section 2.7 of Attachment 3 for further information on radiation protection. The production of Lu-177, Y-90 and their 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	**Regulatory Requirement**	**OPG Response**
	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,* *(v) the measures that will be taken to prevent nuclear criticality, and* *(vi) 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
OPG will continue to comply with the requirements of the *Packaging and Transport of Nuclear Substances Regulations,* and *Transportation of Dangerous Goods Regulations.* Refer to section 2.14 of Attachment 3 for packaging and transport considerations.

References:

[2-1] "Record of Decision – OPG's Consolidated Financial Guarantee – DEC 22-H104", December 6, 2022, e-Doc# 6930798, CD# N-CORR-00531-23514.

[redacted]

ATTACHMENT 3

OPG letter, A. Grace to C. Salmon, “Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”

CD# NK38-CORR-00531-25810 P

Licensing Impact Assessment in Support of the Lutetium-177 and Yttrium-90 Isotope Production Project at the Darlington Nuclear Generating Station using the Target Delivery System

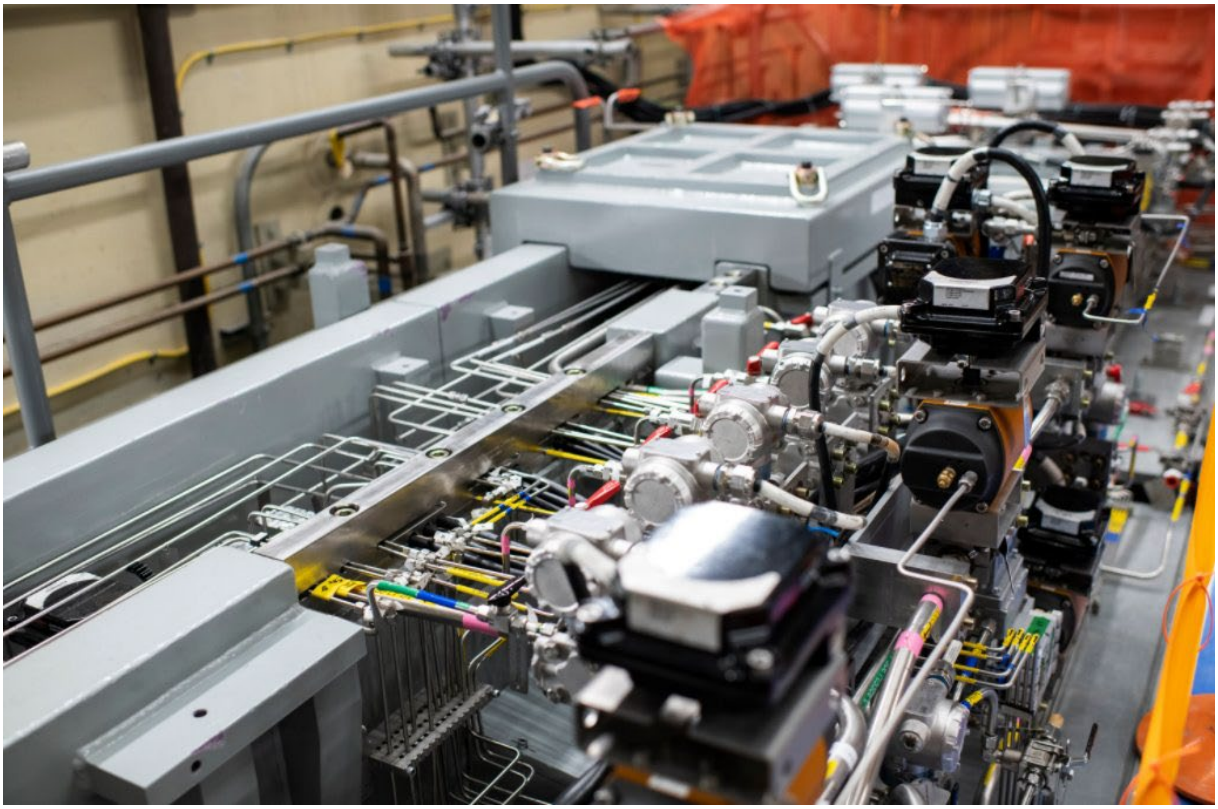
Prepared By: **S. Rajadurai**

Checked By: **K. Thompson**

ATTACHMENT 3
CD# NK38-CORR-00531-25810

ONTARIO POWER GENERATION | Electrifying life

Licence Impact Assessment in Support of Lutetium-177 and Yttrium-90 Isotope Production at Darlington Nuclear Generating Station using the Target Delivery System



Executive Summary

In December 2023, Ontario Power Generation (OPG) notified CNSC staff of its intention to apply for a licence amendment to allow for the production of two new medical radioisotopes: Lutetium-177 (Lu-177) and Yttrium-90 (Y-90) at the Darlington Nuclear Generating Station (NGS) [redacted].

Both isotopes will be produced using the existing Target Delivery System (TDS) also referred to as the Isotope Irradiation System, installed at Darlington NGS Unit 2.

The current licensed activities under Part IV of the Darlington NGS Power Reactor Operator Licence (PROL) 13.02/2025 allow production of the medical isotope Molybdenum-99 (Mo-99) using the installed TDS. In 2021, the Commission amended the Darlington NGS PROL to allow OPG to possess, transfer, process, package, manage, and store Mo-99 and its associated decay products at Darlington NGS. Therefore, the production of Mo-99 and the use of the TDS is not described in this application.

OPG is requesting the Commission's approval to produce two new isotopes at Darlington NGS using the already installed TDS on Darlington NGS Unit 2. All changes will be made through OPG's existing Engineering Change Control (ECC) program, confirming that all regulatory requirements are met, as well as ensuring the project is executed safely with high quality.

In this amendment application OPG is seeking the following:

- Modify activity (vi) in part IV of the Darlington NGS PROL to state: "possess, transfer, process, package, manage and store Molybdenum-99, **Lutetium-177 and Yttrium-90 radioisotopes** and **their** associated decay isotopes."

OPG intends to use the existing TDS currently installed on Darlington NGS Unit 2 to produce two new isotopes in the same manner Mo-99 is produced. The TDS and production of Mo-99 is part of the existing Darlington NGS licensing basis, and this amendment application is an expansion of the inventory of isotopes which can be produced by using same already authorized equipment.

Preliminary analysis of the new isotopes production, Lu-177 and Y-90, demonstrates that there will be negligible impact on safe reactor operations. This application demonstrates that the production of the new isotopes is bounded by Mo-99 safety and operational assessments.

OPG remains committed to safe operation of the Darlington NGS and re-affirms that the production of two new medical isotopes Lu-177 and Y-90 will be implemented in accordance with Darlington NGS licensing basis and will not compromise continued safe reactor operation, environment protection, or public safety.

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LAND ACKNOWLEDGEMENT

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

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

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

1.0 INTRODUCTION

1.1 Background

The purpose of this amendment application is to provide information in support of OPG's request for amendment to the Darlington NGS PROL 13.03/2025.

The key attributes, safety, and benefits associated with the proposed addition of Lu-177 and Y-90 production capacity on the Darlington NGS is summarized in this document. The information provided in this Attachment is provided into three sections as follows:

Section 1: Provides background information on the existing TDS installed at Darlington NGS and the approved production of the Mo-99 medical isotope; information on the proposed Lu-177 and Y-90 medical isotopes; specific details on the amendment request; a summary of the design changes necessary to produce Lu-177 and Y-90; and an overview of responsibilities by organization.

Section 2: Summarizes regulatory compliance for the design changes associated with Lu-177 and Y-90 production and impact on OPG's governance, programs, and processes for each of Darlington NGS PROL fourteen (14) Safety Control Areas (SCA).

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

OPG is responsible for continued safe operation of the Darlington NGS and confirms that the modifications associated with Lu-177 and Y-90 production will be implemented based on a robust safety case and proven engineering methods.

Based on a preliminary nuclear safety assessment, OPG is confident that the activities necessary to support production of Lu-177 and Y-90 using the existing TDS will not compromise continued safe reactor operation. OPG has and will continue to follow ECC process, as described in N-PROG-MP-0001, "*Engineering Change Control*", to validate preliminary conclusions.

The global demand for diagnostic and therapeutic treatments has grown, and with hundreds of therapeutic radiopharmaceuticals in the pipeline, and many expected to reach the market in the coming years, demand is expected to rapidly increase. As such, OPG's proposed production of Lu-177 and Y-90 within Canada has significant importance to the nuclear industry and medical community. OPGs generation of these new radioisotopes will have a significant positive impact on human health across Canada and the globe, expanding Canada's leadership role in the global community by supporting new and innovative approaches to cancer diagnosis and treatment.

1.2 Target Delivery System and Molybdenum-99 Production

OPG has a strong history of safely producing isotopes for the medical industry demonstrated through the harvest of Cobalt-60 (Co-60) at Pickering NGS for over five decades. More recently, in 2021, the Commission amended the Darlington NGS PROL to allow OPG to possess, transfer, process, package, manage, and store Mo-99 and its

associated decay products at Darlington NGS and authorized the installation and safe operation of a TDS to produce Mo-99. The TDS enables target capsules to be inserted (or "seeded") in the reactor core, irradiates the target capsule in the reactor neutron flux for a defined period, and then removes (or "harvests") the target capsules for post processing. An overview of the TDS system is provided in Section 1.2.1.

In 2023, following OPG's ECC process, as described in N-PROG-MP-0001, OPG successfully completed the installation and commissioning of the TDS at Darlington NGS and irradiated natural Molybdenum target capsules to produce Mo-99 [redacted]. Following harvesting of the target capsules, the target capsules were processed at the BWXT Medical Kanata Facility, successfully validating the radiochemical and radiopharmaceutical process and properties.

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

- **TDS operates as designed.** The design requirements pertaining to the TDS have been met as outlined in the system design requirements and detailed commissioning specifications defined in accordance with the ECC process.
- **Containment integrity is maintained.** Containment integrity has been maintained throughout the installation and commissioning phases and TDS containment boundary valves have been tested and turned over to operations.
- **Reactor physics and continued safe reactor operation have been confirmed.** Commissioning results and analysis pertaining to reactor response during Mo-99 seed and harvesting activities conclude that the reactor responded as expected, validating the simulations modeling, and confirming safe reactor operation post installation of the TDS as well as during Mo-99 seed and harvesting activities.
- **TDS and flask shielding protection to workers is as predicted in the As Low As Reasonably Achievable (ALARA) Assessment.** The radiation field measurement conducted during the installation of TDS, commissioning of TDS and reactor physics response have confirmed that the radiation fields are within the range as predicted. Sufficient shielding to ensure workers' protection is in place.
- **Emissions during TDS operations are within Predictive Effects Assessment (PEA) predictions.** The operational tritium releases for Darlington NGS Unit 2, with the TDS in place, remain comparable to the projected releases as defined in the ALARA assessments. Since the projected releases are within the ALARA assessment, it is expected that the conclusions of the PEA are still applicable. This will be reviewed as per OPG ECC process (see Section 1.6)

OPG concludes that the TDS is safe, and operating the TDS is a low-risk activity based on N-REP-03500-0839983, "*Integrated Nuclear Safety and Operational Assessment of the Target Delivery System in Darlington*" [redacted] and the Commissioning Report [redacted].

1.2.1 Target Delivery System Overview

The TDS utilizes a combination of mechanical, pneumatic, and hydraulic methods of propulsion to transfer target capsules into and out of the reactor core for the purpose of irradiating the target capsules to produce medical isotopes. Strings of eight target capsules are inserted into the reactor in four out-of-service Adjuster Assembly (AA) locations, renamed as Target Elevators (TEL). TDS equipment is in each of the modified AA ports on the Reactivity Mechanisms Deck (RMD).

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

The target capsules will remain in-core, at approximately the reactor vertical centre line, during the irradiation period. For Mo-99 production, the target capsules are harvested after approximately seven days of irradiation at or near full power. The irradiation period for Lu-177 and Y-90 are estimated to be 7 days and 3 days, respectively. The exact durations will be determined after the completion of the Nuclear Safety and Operational Feasibility Assessment. After the necessary irradiation period, the targets are harvested by raising the target basket from the core with the drive mechanism. The target basket is initially raised to a dwell position in the guide tube extension below the RMD but out of the reactor core (out of the neutron flux) to allow short-lived activation products to decay. The dwell period is determined based on the isotope being irradiated but cannot be less than two hours due to procedural and associated dwell time requirements. Once the irradiated targets have completed the dwell period the targets are returned to the home position in the TEL. They are then transferred out of the basket to the TAL and then to the flask loader and finally into the shipping flask using both hydraulic and pneumatic systems.

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

The TDS is excluded from this licence amendment application as the system installed on Unit 2 is already part of Darlington NGS's current licensing basis.

1.3 Lutetium-177 and Yttrium-90 Medical Isotopes

This licence amendment will allow OPG to produce Lu-177 and Y-90, in addition to Mo-99, at Darlington NGS. These isotopes are to be used for radiation therapy and are proven to provide significant results in the treatment of specific cancers.

Lu-177 is a radioisotope with significant applications in the field of nuclear medicine, particularly for therapeutic purposes. One prominent medical use of Lu-177 is in targeted radionuclide therapy for certain types of cancer. Lu-177 is employed in the development of radiopharmaceuticals for the treatment of neuroendocrine tumors, including gastro-entero-pancreatic neuroendocrine tumors. Therapy using Lu-177 has shown promising results in clinical trials, demonstrating improved patient outcomes and prolonged survival rates in neuroendocrine tumor and prostate cancer patients. The isotope's unique characteristics, including its beta-emitting properties and relatively short half-life, make it well-suited for precision cancer treatment. Lu-177 therapy involves the systemic administration of radiolabeled compounds that selectively bind to tumor cells, delivering localized radiation and minimizing damage to surrounding healthy tissues. This targeted medical approach has shown promise in improving therapeutic outcomes and quality of life for patients with certain cancers. Ongoing research continues to explore and expand the applications of Lu-177 in addressing various types of malignancies, contributing to advancements in personalized and effective cancer treatments. Lu-177 would be produced through irradiation of the stable isotope Ytterbium-176 using the TDS.

Similarly, Y-90 is another radioisotope widely utilized in the medical field, primarily for therapeutic purposes. One of its key medical applications is in targeted radionuclide therapy for the treatment of liver cancer, particularly Hepatocellular Carcinoma and metastatic liver tumors. Y-90 is incorporated into microspheres or radiopharmaceuticals, which are administered directly into the liver's blood vessels. The high-energy beta radiation emitted by Y-90 selectively targets cancerous cells in the liver, leading to localized radiation and minimizing damage to healthy surrounding tissues. This approach is particularly beneficial for patients who may not be suitable candidates for surgery or other conventional treatments. Y-90 therapy has demonstrated efficacy in extending survival rates and improving the quality of life for individuals with liver cancer. Ongoing research continues to explore Y-90's potential applications in other types of cancer and further optimize its use in targeted cancer therapies. Y-90 would be produced through irradiation of the stable isotope Yttrium-89 using the TDS.

As global demand for these isotopes continues to increase, a reliable supply of these isotopes is critical to Canada and internationally. In addition, due to the relatively short half lives of these isotopes, this material must be supplied frequently to the network of nuclear medicine practitioners located in Canada and around the world.

1.4 Description of Project Scope

To accommodate the production of these new isotopes using the TDS, three critical project components are to be completed:

- Development of new isotope targets appropriate for irradiation in the TDS
- Supporting Nuclear Safety Assessment
- Minor TDS Software Changes and associated document updates and revisions required in accordance with N-PROC-MP-0090, “*Engineering Change Control Process*”

Each component is described further in Sections 1.4.1 to 1.4.3. OPG will finalize these deliverables in accordance with OPG’s ECC process, leveraging the existing Mo-99

target capsule design, impact analysis, and operational infrastructure. OPG is committed to ensuring that all critical project elements have been completed in accordance with applicable governance and change control processes. The activities associated with these components will be tracked to completion under Regulatory Management Action Requests (REGM). This will enable OPG to progress the project with regulatory certainty and provide CNSC staff an opportunity to verify compliance with requirements prior to the irradiation of additional isotopes. Appendix A provides a consolidated list of OPG's pending regulatory commitments associated with this project.

1.4.1 New Isotope Targets (Lu-177 and Y-90)

To accommodate the production of Lu-177 and Y-90 within the existing TDS, new target capsules are required. Design of these targets has been proposed by BWXT-Nuclear Energy Company (NEC) and details are provided in Appendix B, *'Lu-177 Target Capsule Outline', and* Appendix C, '*Y-90 Target Capsule Outline'*. Acceptability via nuclear safety analysis and in accordance with OPG's ECC process will be demonstrated through a regulatory action as per Appendix A to provide CNSC staff the OPG accepted target drawings.

The new target capsules have been designed to replicate the Mo-99 target capsule, and have very similar characteristics in terms of geometry, physical properties, including mass and reactivity worth, combined with negligible differences in heating, radiation, and chemistry impacts.

The following description of target capsules is per the existing TDS design manual, NK38-DM-30550-MAN-00001, "*TDS Design Manual*", [redacted] and is applicable to the existing Mo-99 target capsules and the proposed target capsule designs for Lu-177 and Y-90. The target capsule is a streamlined container designed to operate within the TDS to allow the transport of a defined quantity of material for irradiation inside the TEL to produce the required isotopes. Target capsules are constructed of Zirconium with welded end caps and an aerodynamic shape to maximize flow performance through the transfer tubing.

Figure 1 shows the exterior of the Mo-99, Lu-177 and Y-90 target capsule. Bulges added to each end of the target capsules increase the cross-sectional area, improving the propulsion characteristic and reduce the contact area responsible for generating friction. The target capsules are helium filled and leak tested prior to being shipped to site for isotope production through irradiation. Joints, ends and the tubular section are designed to not loosen, stretch, or jam due to internal system pressures, forces encountered during transfer and planned impacts.

The target capsules for production of Mo-99 contain a series of natural molybdenum washers secured by a molybdenum pin encased in a Zirconium alloy. The preliminary design for the target capsules to produce Lu-177 and Y-90 contain both molybdenum metal and zirconium as a ballast material to ensure weight requirements are met to properly function with the existing TDS. In addition, they contain a quartz ampoule containing the source isotope material in the form of powder for Lu-177, and glass microspheres for Y-90. These target designs are being considered by OPG for the purposes of this project pending review and acceptance following OPG governance.

Lu-177 will be generated by neutron capture of the source material Ytterbium (III) Oxide (Yb_2O_3). A Lu-177 generating target contains Yb_2O_3 in powder form in a quartz ampoule, which is contained in an outer target assembly as per Appendix B which maintains the same form, fit and function as Mo-99 targets.

Y-90 will be generated by irradiation neutron capture of the source material Yttrium Aluminosilicate (YAS). A Y-90 generating target contains YAS glass microspheres in a quartz ampoule, this ampoule is contained in an outer target assembly as per Appendix C which maintains the same form, fit and function as Mo-99 targets.

A key element associated with the introduction of new isotopes is the associated impact on dynamic reactivity worth of the target capsules during the seeding and harvesting process. Preliminary analysis suggests that the new isotopes contribute very little to the overall reactivity worth of the target capsules based on the preliminary design material compositions. Additional details are provided in Section 1.4.2.

These target capsules are designed to be inserted into the Darlington NGS TDS using the same processes developed to produce Mo-99.

Target capsule manufacturing will be completed by BWXT-NEC and 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. Exterior of Mo-99, Lu-177, and Y-90 Target Capsule

Unirradiated target capsules will arrive at Darlington NGS from BWXT-NEC in pre-loaded New Target Magazines (NTMs), which are identical to the NTMs used for Mo-99. This will prevent any direct handling of the target capsules. The NTMs, containing up to eight target capsules, will be placed into the target loader for insertion into the reactor for irradiation. The activity of inserting unirradiated target capsules into the reactor is referred to as “target-seeding”. The process for inserting Lu-177 and Y-90 target capsules from the NTMs into the core will remain identical to that of Mo99, without any modifications. This approach will ensure consistency and adherence to established-protocols.

After the required irradiation period for each isotope, the target capsules will be removed during a process referred to as “target-harvesting”. The irradiation period for Lu-177 and

Y-90 are approximately 7 days and 3 days, respectively. The exact durations will be determined after the completion of a Nuclear Safety and Operational Feasibility Assessment. Through neutron capture, the irradiated targets will be radioactive and require shielding and provisions, which are outlined in Section 2.7.1 to ensure worker radiation exposure is kept 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 in accordance with existing TDS operating manual.

1.4.2 Nuclear Safety Assessment

A preliminary assessment NK38-REP-03600-10014-R000, "*Nuclear Safety Impact Assessmen*t *Report*" (Enclosure 1 of this submission), has been completed based on preliminary target capsule design/drawings provided in Appendix B and Appendix C. This preliminary assessment focuses on the introduction of new isotopes that will be irradiated in the Darlington NGS TDS utilizing target capsules that are very similar to those used currently to produce Mo-99. The new target capsules have very similar characteristics in terms of geometry, physical properties, including mass and reactivity worth, combined with negligible differences in heating, radiation, and chemistry impacts.

The assessment supports the introduction of new target capsules to produce new isotopes and includes a review of key documents completed in support of the installation and operation of the existing TDS, as well as the introduction of Cobalt Adjusters to Darlington NGS reactors (Reference [3-5] pending Commission's decision) should the TDS and Cobalt Adjuster Absorber Rods exist in the same Darlington NGS unit. Detailed assessments of potential new initiating events, the potential for impact on the existing safety analyses, impacts on the Probabilistic Safety Assessment (PSA) elements, and operational impacts were part of the review. The conclusions of the assessment are:

- While the event identification and classification identified 11 new events and potential impact on some existing systems, the introduction of new target capsules does not change the conclusions or introduce any new events;
- Parametric assessments indicated the TDS and production of isotopes has no detrimental impact on reactor safe and reliable operation and the introduction of new target capsules does not change the conclusions;
- Introduction of new target capsules does not impact the conclusion that the overall impact from the TDS on the quantification of Severe Core Damage Frequency and Large Release Frequency in the various PSA elements would be expected to be low;
- Operational assessments completed for the TDS are not impacted by the introduction of new target capsules;
- A review of safety analysis appendices and Cobalt Adjuster Rod interactions report did not identify any issues or challenges associated with the existing

accident progression or consequences with the introduction of new target capsules.

As part of the original design and installation of the TDS at Darlington NGS, a detailed Failure Mode and Effects analysis was completed and formed the basis for the subsequent planning and analysis of the associated safety cases. The Event identification and classification exercise identified a few new initiating events with only a small subset being associated with or impacted by the target capsule design. In addition to those initiating events considered in safety analysis, additional initiating events were screened for impact on the PSA. Again, only a subset of these being specific to the target capsule design.

Detailed analysis was performed in support of the TDS installation, not just for safety analysis implications but the overall impact on plant operations. Review of all Darlington NGS Safety Report Accident Analysis Appendices were completed and detailed in the Integrated Nuclear Safety and Operational Assessment of the TDS, as well as the Isotope Interactions Report submitted previously to CNSC staff [redacted]. Impact on the ability to comply with key safety parameters was assessed and documented in both the operational and the integrated safety and operational assessment reports.

The detailed assessments concluded the TDS system did not introduce any new initiating events or hazards that would impact the conclusions of the current safety analysis or PSAs. Further, the operational assessment confirmed that the introduction of the current target capsules for molybdenum is well within the capability of current systems and process to ensure plant operation remains consistent with the defined Safe Operating Envelope (SOE). The Nuclear Safety Impact Assessment report considered the relative reactivity worth of various device configurations.

Figure 2 shows the anticipated relative reactivity worth for the current target and the new target capsules. The new target capsule values (Lu-177 and Y-90) are based on estimated values based of the preliminary device composition using a mass extrapolation. The value for Mo-99 is the theoretical value that was confirmed during commissioning of the system. This is the reactivity worth of a single string of eight target capsules.

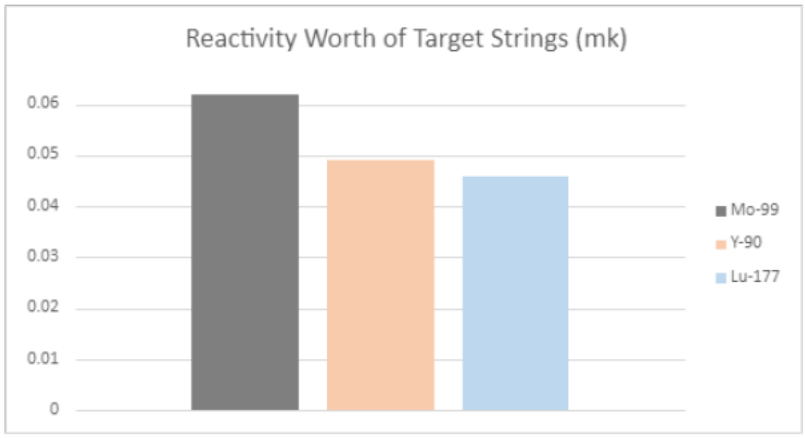


Figure 2. Target Capsule Reactivity Worth (mk)

Furthermore, this figure indicates that the reactivity worth of new target capsules for Y-90 and Lu-177 may be over 20% less than the existing Mo-99 target. It is noted that the calculated reactivity worth within the target capsules for Lu-177 and Y-90 is predominately a result of the use of Molybdenum metal and Zirconium to add ballast and fill space not occupied by the ampoules. Based on preliminary target capsule design and calculations, the YAS glass microspheres used in the Y-90 target capsules has a negligible effect on the overall reactivity worth for a string of Y-90 target capsules, and the Yb_2O_3 used in the Lu-177 target capsule accounts for ~2% of the total reactivity worth for a string of Lu-177 target capsules. The use of Molybdenum metal and Zirconium to add ballast and fill space has two contributing effects. First it adds ballast to the target capsule to ensure an appropriate target mass to allow for functionality of the TDS. Second, it increases the amount of neutron absorption which allows the targets to closely resemble the Mo-99 target capsules.

Figure 3 includes some additional operational device values for comparison with the single string of target capsules. The values represent the calculation of a one percent change in overall average liquid zone controller level and the removal of the first bank of Adjusters (Bank-A). The Reactor Regulating System can adequately control larger changes in reactivity as part of system design. The values shown from the Simulation of Reactor Operation were calculated based on the total change in reactivity from a single characteristic state, by comparing the initial state to the same state instantaneously moving the represented device(s).

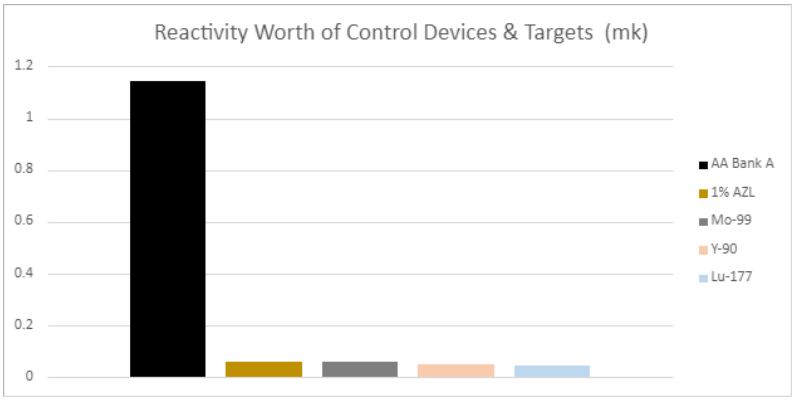


Figure 3. Comparison of Targets and Operational Changes During Normal Operation

Based on the completed impact assessment, introduction of new target capsules to produce new isotopes with the existing TDS will have no significant impact on the safe operation of Darlington NGS. This will be validated through the completion of a more detailed assessment of the final target capsule designs for the new isotopes, as per OPG's ECC process. It is expected that the current analysis that includes operation of the TDS with molybdenum being irradiated and with nothing in-core will bound new isotope production. Systems, structures, and components will continue to provide the required safety, protective and mitigating actions necessary to ensure the original design

objectives are met. Further, current operating practices and processes will ensure continued operation within the defined SOE.

A comprehensive safety assessment will be completed as per the commitments provided in Appendix A to confirm and validate the safety impacts in accordance with the ECC process.

1.4.3 Software Updates

To introduce Lu-177 and Y-90 target capsules into the TDS, minor software updates are required. These changes are expected to be minimal in nature, limited to updates to the irradiation durations, dwell times, and Human Machine Interface panel to indicate the new isotopes. TDS documentation will also be updated to refer to the new isotope as necessary to maintain correct station configuration. OPG has established and approved processes in place to update the TDS software and the existing license already permits software changes. These software updates, and any Human Factors considerations, will be completed in accordance with OPG's ECC process and will ensure compliance with regulatory requirements.

1.5 Target Transportation

The new Lu-177 and Y-90 target capsules will be transported using the same process as the Mo-99 target capsules. The harvested irradiated target capsules will be loaded into a transportation package of CNSC certified design (shielded flask and overpack) by OPG staff and loaded for transport to BWXT Medical for medical isotope processing. BWXT staff will be responsible for transportation from Darlington NGS to BWXT-Medical in Kanata, Ontario. OPG will be responsible for packaging the radioactive material and preparing the shipping documents per existing procedures established previously in NK38-MMP-30550-13, "*Target Delivery System Transport Package Flasking*" ([redacted]).

Figure 4. Lu-177 and Y-90 Transportation Flask (left) and Overpack (right)

1.6 Safety Case

OPG is responsible for continued safe operation of Darlington NGS and confirms that the changes to the TDS required to accommodate these two new targets will be implemented based on a robust safety case and in accordance with OPG's ECC process, which is supported by safety assessments that demonstrate continued safe reactor operation, public safety, and environmental protection.

The Lu-177 and Y-90 safety case can be defined based on the following elements:

- **OPG ECC Process:** The introduction of new Target Capsules to produce new isotopes in the TDS is being completed using approved OPG Governance. OPG has and will continue to follow its existing ECC process, for ensuring the design complies with applicable Darlington NGS PROL 13.02/2025 regulatory requirements and that configuration management for the station is maintained. This process is part of the Darlington NGS licensing basis.

    - **Target Design:** The target capsule preliminary designs for both Lu-177 and Y-90 have been developed in a manner that is consistent with the Mo-99 target capsule. The new target capsules have very similar characteristics in terms of geometry, physical properties, including mass and reactivity worth, combined with negligible differences in heating, radiation, and chemistry impacts. NK38-REP-03600-10014, "*Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System*" (Enclosure 1 of this submission) concludes that introduction of new target capsules to produce these new isotopes with the existing TDS will have negligible impact on the safe operation of Darlington NGS and is bounded by the Mo-99 safety analysis. A comprehensive assessment will be completed as per the commitments provided in Appendix A to confirm and validate the safety impacts during the detailed engineering phase of the project.

- **Continued Safe Reactor Operation**: The nuclear safety analysis for the production of Mo-99 describes the minimal impact that the production of Mo-99 has on reactor operations. Furthermore, NK38-REP-03600-10014, "*Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System"*, (Enclosure 1 of this submission) demonstrates that the two new isotopes have less impact, therefore there is no additional risk to reactor operations. Further explanation is provided in Section 2.4.

- **Environmental Protection**: A predictive environmental effects assessment, NK38-REP-30550-00029, "*Predictive Effects Assessment for The DN Molybdenum Isotope Irradiation System (Unit 4)*" [redacted], was prepared for the production of Mo-99. This assessment concluded the safe operation of the TDS, which was confirmed during TDS commissioning. As the number of seeding and harvesting cycles per year for the new isotopes remains unchanged, which was the primary factor considered in the Mo-99 PEA assessment, the introduction of the new

target capsules is not expected to have any additional environmental impact. This will be reviewed and validated as per OPG's ECC process.

- **Radiological Protection:** An ALARA assessment was completed for the production of Mo-99 under NK38-REP-30550-00012, "*Target Delivery System Design ALARA Assessment*" ([redacted]). Moreover, preliminary findings indicate that the new isotopes will have less radiological consequence than Mo-99 (see Section 2.7). The ALARA assessment will be updated per the ECC process and the revised ALARA assessment will be provided for CNSC staff review (Appendix A).

- **Licensing Basis**: As documented in Sections 6.1 to 6.14, the operation of the TDS with Lu-177 and Y-90 target capsules will be in accordance with Darlington NGS's licensing basis, governance, programs, and processes. TDS specific operating procedures prepared for the production of Mo-99 will be updated to include references to Lu-177 and Y-90 and provided to CNSC staff as per the written notification process in the Darlington LCH.

Overall, OPG does not expect any safety or operational issues to result from introducing Lu-177 and Y-90 production at Darlington NGS using the existing TDS, and this will be confirmed with the completion of the safety and operational assessments.

1.7 Project Timeline

Following the submission of Letter of Intent to CNSC staff [redacted], OPG is targeting to complete preliminary engineering for both isotopes in Q2 2024. Detailed engineering for the production of Lu-177 and Y-90 will be completed in Q1 2025 and Q2 2025 respectively. The nuclear safety assessment will be completed prior to the completion of preliminary engineering since a bounding case approach is used for the design of the targets. Commissioning for each isotope will take place following completion of detailed engineering.

The engineering and design activities associated with the Lu-177 and Y-90 Isotope Production projects will take place in accordance with N-PROC-MP-0090 as required per OPG Nuclear Management Systems. Final design of TDS software modifications required to support irradiation of new isotope targets will be completed in Q1 of 2025. Modification and reactor response commissioning activities will begin shortly after design completion.

1.8 Regulatory Commitments

The design documentation and safety analyses to be completed as part of the Lu-177 and Y-90 Isotope Production Projects are described in detail throughout previous sections of this submission. Some of the submissions and activities described are scheduled to occur after the date of this application. To provide confirmation that analysis and design has been completed as described throughout this submission, OPG has committed to REGMs to track completion of these deliverables. Appendix A provides a complete list of OPG's regulatory commitments to support this amendment request.

These REGMs will provide assurance to CNSC staff that the following project deliverables have been completed in accordance with approved OPG governance and OPG's ECC process:

- Final target capsule design for Lu-177
- Final target capsule design for Y-90
- Detailed Nuclear Safety Analysis
- Updated ALARA assessment (NK38-REP-30550-00012 ([redacted])
- Human Factors Assessment Report
- Commissioning Reports for Lu-177 and Y-90

1.9 Roles and Responsibilities by Organizations

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

1) Darlington NGS owned and operated by OPG, located in the Durham Region, will be used to irradiate the Lu-177 and Y-90 targets.
2) Laurentis Energy Partners, a wholly owned subsidiary of OPG and located in the Greater Toronto Area, will provide strategic partnerships and project support.
3) BWXT-NEC, located in Peterborough, Ontario, will design, manufacture, and assemble the Lu-177 and Y-90 targets.
4) BWXT-Medical located in Kanata, Ontario, owns and operates the processing facility for generators that convert Mo-99 into Tc-99m for the medical community and will be responsible for the transportation and processing of the irradiated Lu-177 and Y-90 targets
5) BTG PLC (Boston Scientific), located in Ottawa, Ontario, is a pharmaceutical company that will provide the target material to be irradiated.

Execution of this project, and the roles and responsibilities defined above, will be completed in accordance with OPG's nuclear management system described in N-CHAR-AS-0002, "*Nuclear Management System*", which governs how OPG executes work. OPG has an extensive supply chain and contractor management program as described in OPG-PROG-0009, "*Items And Services Management*", and ***Figure 5*** below depicts the contract structure, workflow, and accountabilities for this project.

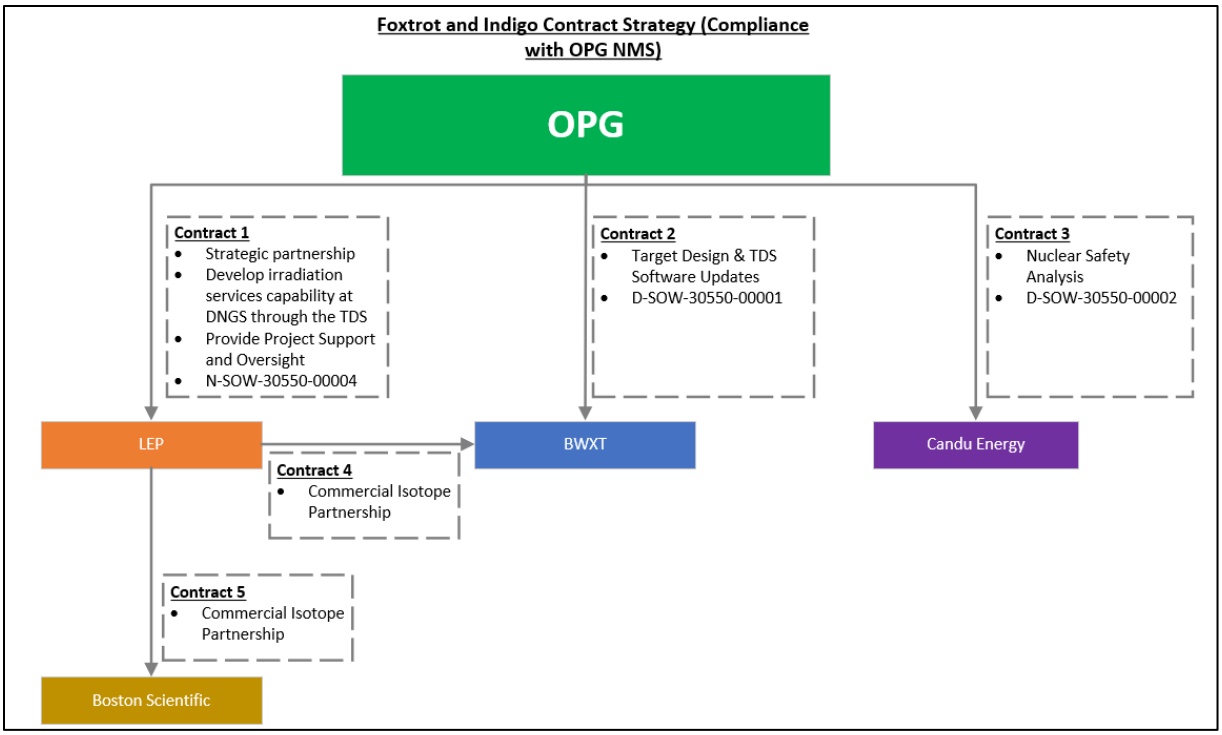


Figure 5. Strategic Partnership relationships between companies

2.0 SAFETY AND CONTROL AREAS

The purpose of this section is to document the impact of Lu-177 and Y-90 medical isotope production on OPG's governance, programs and processes. A review of the impact on Darlington NGS's PROL fourteen (14) SCAs was completed and is summarized in the following sections.

OPG is responsible for continued safe operation of Darlington NGS and confirms that the modifications associated with the production of Lu-177 and Y-90 medical isotopes 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.

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

2.1 Management System

OPG's proven Nuclear Management System provides a framework that establishes the processes and programs required to ensure OPG achieves its safety objectives,

continuously monitors its performance against these objectives, and fosters a healthy safety culture.

Darlington NGS is compliant with Canadian Standards Association (CSA) N286-12, "*Management system requirements for nuclear facilities*". OPG's Nuclear Charter, N-CHAR-AS-0002, *"Nuclear Management System"*, establishes the Nuclear Management System for OPG Nuclear. Vendors and contractors are qualified by OPG Supply Chain Quality Services under a process that ensures that the contractors have developed and implemented a management system that meets the applicable requirements outlined in the CSA N286 series of standards.

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

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

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Management System SCA. This is further explained in Section 2.1.1 to 2.1.8.

Regulatory requirements that apply to the Management System SCA are listed in Table 2.1.a. Furthermore, Table 2.1.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Management System and identifies the impact from Lu-177 and Y-90.

Table 2.1.a List of Management System Related Regulatory Requirements

Licensing Basis Document Title	Document Number	Impact from Lu-177 and Y-90
Safety Culture	CNSC REGDOC - 2.1.2	A healthy safety culture continues to remain OPG's highest priority. The production of Lu-177 and Y-90 will be consistent with this fundamental requirement.
Management System Requirements for Nuclear Facilities	CSA N286 (2012)	Continued compliance as applied to all aspects of operation, refurbishment and modifications at Darlington NGS.

Table 2.1.b Impact from Lu-177 and Y-90 on Darlington's Management System Licensing Basis Documents

OPG Management System Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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
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

2.1.1 Management System

The management and operation of OPG nuclear facilities is defined by the programs and associated nuclear governing documents as described in N-CHAR-AS-0002, "*Nuclear Management System*". This document provides the pathways for compliance with CSA N286-12 for all activities which take place at OPG stations. This compliance is established by the framework from which all processes and programs take authority.

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

As a result of this amendment there will be no change to the established licensing basis of the Management System SPA.

2.1.2 Organization

OPG's organization is defined by N-STD-AS-0020, "*Nuclear Management Systems Organization*", OPG's role documents for certified positions, and OPG correspondence "*Persons Authorized to Act on Behalf of OPG in Dealings with the CNSC*".

The irradiation of two new medical isotopes, in addition to irradiation of Mo-99 using the Darlington NGS TDS may result in an increase to staffing level at Darlington NGS. This will be determined as part of the ECC process. If determined to be required, this increase will not result in organizational changes and there will be no changes to the established licensing basis of the Organization SPA. Similar to operation for the purposes of Mo-99, the Darlington Operations Department will be responsible for Lu-177 and Y-90 production through regular, pre-established seed and harvest cycles. Both scheduled and non-scheduled TDS maintenance will be performed as already established under the Mo-99 project.

As a result of this amendment there will be no change to the established licensing basis of the Organization SPA.

2.1.3 Performance Assessment, Improvement and Management Review

OPG has an extensive performance improvement program and independent assessment described in N-PROG-RA-0003, "*Performance Improvement*", and N-PROG-RA-0010, "*Independent Assessment*", respectively. OPG maintains this program as in accordance with its existing PROL and associated LCH.

As a result of this amendment there will be no change to the established licensing basis of the Performance Assessment, Improvement and Management Review SPA.

2.1.4 Operating Experience, Problem Identification and Resolution

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

As a result of this amendment there will be no change to the established licensing basis of the OPEX, PI&R SPA.

Further, OPEX review will be conducted during the preliminary engineering phase 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 will be documented and incorporated into this project.

2.1.5 Change Management, Configuration Management, Records Management

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

As a result of this amendment there will be no change to the established licensing basis of the Change Management SPA

2.1.6 Safety Culture

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

OPG's approach to worker safety is governed by OPG-PROG-0005, "*Environment Health and Safety Managed Systems*", which defines the overall process for managing safety and the responsibilities of the parties, specifically at the corporate level. In addition, a safety culture self-assessment methodology is developed following a continuous improvement process, which is governed by N-PROC-AS 0077, "*Nuclear Safety & Security Culture Assessment*".

As a result of this amendment there will be no change to the established licencing basis of the Safety Culture SPA. Continued safe reactor operation, compliance with operating limits and regulatory requirements will take priority over medical isotope production.

2.1.7 Supply Chain and Contractor Management

OPG has an extensive supply chain and contractor management program described in OPG-PROG-0009, "*Items And Services Management*", OPG maintains this program in

accordance with its existing PROL and associated LCH. OPG is ultimately responsible for ensuring that all on-site contractor activities comply with OPG's safety requirements. OPG will provide oversight to BWXT employees who perform TDS maintenance and testing work at Darlington NGS. ***Figure 5*** Section 1.9 describes the contractor relationship between OPG, LEP and vendors partners.

As a result of this amendment there will be no change to the established licensing basis of the Supply Chain and Contractor Management SPA.

2.1.8 Business Continuity

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

As a result of this amendment there will be no change to the established licensing basis of the Business Continuity SPA.

2.2 Human Performance Management

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

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

The Human Performance SCA is comprised of the following SPAs:

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Human Performance Management SCA. As a result of this amendment, OPG will develop and deliver the necessary training to staff working with the TDS as per existing governance. This is further explained in Section 2.2.1 to 2.2.5.

Regulatory requirements that apply to the Human Performance Management SCA are listed in Table 2.2.a. Furthermore, Table 2.2.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Human Performance and identifies the impact from Lu-177 and Y-90.

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

OPG Human Performance Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Personnel Certification, Volume III: Certifications of Persons Working at Nuclear Power Plants	CNSC REGDOC-2.2.3	Continued compliance, no impact from Lu-177 and Y-90.
Personnel Training	CNSC REGDOC-2.2.2 (2014)	Continued compliance, no impact from Lu-177 and Y-90.
Fitness for Duty: Managing Worker Fatigue	CNSC REGDOC-2.2.4 (2017)	Continued compliance, no impact from Lu-177 and Y-90.
Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 2	CNSC REGDOC-2.2.4 (2017)	Continued compliance, no impact from Lu-177 and Y-90.

Table 2.2.b Impact from Lu-177 and Y-90 on Darlington's Human Performance Management Licensing Basis Documents

OPG Human Performance Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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
Training	N-PROG-TR-0005	No Change
Systematic Approach to Training	N-PROC-TR-0008	No Change

Written and Oral Initial Certification Examination for Shift Personnel	N-INS-08920-10004	No Change
Simulator-Based Initial Certification Examinations for Shift Personnel	N-INS-08920-10002	No Change
Requalification Testing of Certified Shift Personnel	N-INS-08920-10001	No Change
Responsible Health Physicist	N-MAN-08131-10000-CNSC-031	No Change
Shift Manager, Darlington Nuclear	N-MAN-08131-10000-CNSC-006	No Change
Control Room Shift Supervisor	N-MAN-08131-10000-CNSC-008	No Change
Authorized Nuclear Operators	N-MAN-08131-10000-CNSC-010	No Change
Unit 0 Control Room Operator	N-MAN-08131-10000-CNSC-025	No Change

2.2.1 Human Performance Program

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

Darlington NGS's 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 common goals.

A Human Factors Assessment will be completed as part of the detailed engineering phase following OPG's ECC process (Appendix A).

As a result of this amendment there will be no change to the established licensing basis of the Human Performance Program SPA.

2.2.2 Personnel Training

As a prerequisite for TDS operation, OPG staff are required to successfully complete the TDS training qualification that is compliant with OPG's training program N-PROG-TR-0005, "*Training*" and N-PROC-TR-0008 "*Systematic Approach to Training*" (and include irradiation of Lu-177 and Y-90). As a result of this amendment, changes to training will be updated according to OPG's governance. No changes are required to the Darlington NGS licensing basis; however, existing licensing basis programs will be used to ensure training is developed and delivered in accordance with requirements.

2.2.3 Personnel Certification

As a result of this amendment there will be no change to the established licensing basis of the Personnel Certification SPA.

2.2.4 Work Organization and Job Design

OPG has an annual workforce planning process to manage its workforce verified by station management prior to the TDS operation on Unit 2. There is no change to this performance area based on the introduction of the Lu-177 and Y-90.

As a result of this amendment there will be no change to the established licensing basis of the Work Organization and Job Design SPA.

2.2.5 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.

Production of Lu-177 and Y-90 using the TDS will not impact OPG's fitness for duty program or compliance to hours-of-work requirements.

2.3 Operating Performance

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 Lu-177 and Y-90 to the TDS operation does not impact station operations programs.

The Operating Performance SCA is comprised of the following SPAs:

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

OPG has performed a review of the project scope and anticipates that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Operating Performance SCA. This is further explained in Section 2.3.1 to 2.3.7.

Regulatory requirements that apply to the Operating Performance SCA are listed in Table 2.3.a. Furthermore, Table 2.3.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Operating Performance and identifies the impact from Lu-177 and Y-90.

Table 2.3.a List of Operating Performance Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Accident Management: Severe Accident Management Programs for Nuclear Reactors	CNSC REGDOC-2.3.2 (2013)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Reporting Requirements for Nuclear Power Plants	CNSC REGDOC-3.1.1 (2014)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Periodic Safety Reviews	CNSC REGDOC- 2.3.3 (2015)	Given the TDS satisfies all applicable regulatory requirements, this system will be factored into subsequent PSR~~s~~ 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 Lu-177 and Y-90 in the TDS.

Table 2.3.b Impact from Lu-177 and Y-90 on Darlington's Operating Performance Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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 Fueling Operations	N-STD-OP-0021	No Change

2.3.1 Conduct of Licensed Activity

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 Lu-177 and Y-90 to the TDS operation does not change this approach.

As a result of this amendment, the licenced activities will be updated accordingly to include the addition of Lu-177 & Y-90.

2.3.2 Procedures

The operating manual NK38-OM-30550, "*Target Delivery System Operating Manual*" and maintenance procedure NK38-MMP-30550-13, "*Mechanical Maintenance Procedure*" developed to support the production of Mo-99 will be updated to incorporate the irradiation of Lu-177 and Y-90 in accordance with OPG governance and will largely consist of minor configuration changes.

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

2.3.3 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.

2.3.4 Outage Management Performance

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

2.3.5 Safe Operating Envelope (SOE)

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

The TDS has very few interfaces with other station systems, it does not produce volatile fission products and the design complies with applicable regulatory requirements. The installation of the TDS did not require any revision to the Operational Safety Requirements (OSRs). The production of Mo-99, Lu-177, and Y-90 in Darlington NGS reactors will not impact any of the SOE documents.

2.3.6 Severe Accident Management and Recovery

There is no impact to severe accident management and recovery from the addition of these new medical isotopes.

2.3.7 Accident Management and Recovery

There is no impact to accident management and recovery from the addition of these new medical isotopes.

2.4 Safety Analysis

The Safety Analysis SCA is comprised of the following SPAs:

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

The nuclear safety case and operational assessments for the introduction of the TDS and production of Mo-99 was completed prior to the operation of the TDS. The complete comprehensive Mo-99 assessment N-REP-03500-0839983, "*Integrated Nuclear Safety*

and Operational Assessment of the Target Delivery System in Darlington" demonstrated the relatively small impact of producing Mo-99 in the TDS on the complete safety case and operation at Darlington NGS ([redacted]).

Similarly, NK38-REP-03600-10014, "*Nuclear Safety Impact Assessment Report*", was completed to determine the impact of introducing new isotopes into the TDS. This report reviewed the critical documents that were produced in support of the installation and operation of the existing TDS. The assessments concluded the TDS system did not introduce any new initiating events or hazards that would impact the conclusions of the current safety analysis or Probabilistic Safety Assessments (PSA).

Furthermore, the operational assessment confirmed that the introduction of the current target capsules for molybdenum is well within the capability of current systems and process to ensure plant operation remains consistent with the defined SOE. Introduction of new target capsules with new isotopes that have very similar characteristics in terms of reactivity worth and mass are not expected to change the conclusions made for the original TDS project.

The new target capsule design requirements will include a bounding requirement in terms of the existing Mo-99 safety analysis. This will be confirmed through detailed analysis of the two targets to confirm this design requirement and validated through detailed commissioning. This detailed safety assessment will be carried out as per OPG's Nuclear Safety Analysis governance and ECC process.

OPG has performed a review of the project scope and anticipates that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Safety Analysis SCA based on the completed Nuclear Safety Impact Assessment.

2.5 Physical Design

It is important to note that there have been no modifications made to the physical design of the TDS. While the physical system and configuration remains unchanged, a software update will be completed to accommodate the different dwell times for each isotope. The system will continue to operate as intended and maintains its established functionality without any alterations to its physical structure or components.

The Physical Design SCA is comprised of the following SPAs:

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

OPG has performed a review of the project scope and given that there is no change to the physical design has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Physical Design SCA. This is further explained in Section 2.5.1 to 2.5.6.

Regulatory requirements that apply to the Design Program SCA are listed in Table 2.5.a. Furthermore, Table 2.5.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Design Program and identifies the impact from Lu-177 and Y-90.

Table 2.5.a List of Design Program Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Requirements for safety related structures for CANDU nuclear power plants	CSA N291 (2008)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
General requirements for safety systems of nuclear power plants	CSA N290.0 (2011)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
General requirements for pressure- retaining systems and components in CANDU nuclear power plants	CSA N285.0 (2008 and Update No. 2)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Environmental qualification of equipment for CANDU nuclear power plants	CSA N290.13 (2005 and Update No. 1)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
General requirements for seismic design and qualification of CANDU nuclear power plants	CSA N289.1 (2008)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.5.b Impact from Lu-177 and Y-90 on Darlington's Design Program Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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
Design Registration	N-PROC-MP-0082	No Change
Pressure Boundary Program Manual	N-MAN-01913.11-10000	No Change
Index to OPG Pressure Boundary Program Elements	N-LIST-00531-10003	No Change
Authorized Inspection Agency for Pressure Boundary Inspection and Registration Services	N-CORR-00531-19076	No Change
Environmental Qualification	N-PROG-RA-0006	No Change

2.5.1 Design Governance

Design changes are performed in accordance with OPG's engineering change control program N-PROG-MP-0001 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.

2.5.2 Site Characterizations

There are no changes to Site Characterizations.

2.5.3 Facility Design

There are no changes to Facility Design.

2.5.4 Structure Design

There are no changes to Structure Design.

2.5.5 System Design

Minor software changes are anticipated prior to the introduction of Lu-177 and Y-90 into the TDS in order to accommodate the different dwell times for different isotopes. These modifications will be implemented in accordance with OPG's ECC process.

2.5.6 Component Design

As a result of introducing Lu-177 and Y-90 target capsules into the TDS, software changes will be completed to update the required dwell time as it is isotope specific. These changes will be done in accordance with OPG ECC process.

2.6 Fitness for Service

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.

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

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Fitness for Service SCA. This is further explained in Section 2.6.1 to 2.6.6.

Regulatory requirements that apply to the Fitness for Service SCA are listed in Table 2.6.a. Furthermore, Table 2.6.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Fitness for Service and identifies the impact from Lu-177 and Y-90.

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

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Periodic inspection of CANDU nuclear power plant components	CSA N285.4 (2014)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Periodic inspection of CANDU nuclear power plant containment components	CSA N285.5 (2008 and Update No. 1)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plant components	CSA N287.7 (2008)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Maintenance Programs for Nuclear Power Plants	CNSC RD/GD-210 (2012)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Reliability Programs for Nuclear Power Plants	CNSC REGDOC-2.6.1 (2017)	Continued compliance, no

		impact from Lu-177 and Y-90 in the TDS.
Maintenance Programs for Nuclear Power Plants	CNSC REGDOC-2.6.2 (2014)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Aging Management	CNSC REGDOC-2.6.3	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.6.b Impact from Lu-177 and Y-90 on Darlington's Fitness for Service Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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	COG-JP-4107-V06-	No Change

(FFSG) for Feeders in CANDU Reactors	R03	
Steam Generators Life Cycle Management Plan	N-PLAN-33110-10009	No Change
Darlington Units 1-4 Steam Generator Life Cycle Management Plan	NK38-PLAN-33110-00001	No Change
Fitness-for-Service Guidelines for Steam Generator and Preheater Tubes	COG-07-4089–R01	No Change
Fuel Channels Life Cycle Management Plan	N-PLAN-01060-10002	No Change
Darlington Nuclear 1-4, Unit 1 Fuel Channel Pressure Tubes 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 Darlington NGS Vacuum Building	NK38-TS-03643-10001	No Change
Administrative Requirements for In- Service Examination and Testing for Concrete Containment Structures	N-PROC-MA-0066	No Change
Aging Management Plan for Darlington NGS Non-Containment Building Structures	NK38-PLAN-01060-10010	No Change
Darlington NGS Main Containment Structure In-Service Leakage Rate Test Requirements in Accordance with CSA N287.7-08	NK38-REP-34200-10066	No Change
Darlington NGS Vacuum Structure In- Service Leakage Rate Test Requirements in Accordance with CSA N287.7-08	NK38-REP-26100-10005	No Change

2.6.1 Equipment Fitness for Service/Equipment Performance

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 operation of the TDS with Lu-177 and Y-90 target capsules will not impact the fitness for service and periodic inspections of the major components.

The TDS system will continue to be maintained in accordance with OPG procedures and the introduction of new target capsules and associated changes in system operating requirements due to differences in harvesting and seeding requirements will be reviewed and updated as per OPG's ECC process.

2.6.2 Maintenance

As a result of this amendment there will be no change to the established licensing basis of the Maintenance SPA.

2.6.3 Structural Integrity

As a result of this amendment there will be no change to the established licensing basis of the Structural Integrity SPA.

2.6.4 Aging Management

As a result of this amendment there will be no change to the established licensing basis of the Aging Management SPA.

2.6.5 Chemistry Control

As a result of this amendment there will be no change to the established licensing basis of the Chemistry Control SPA.

2.6.6 Periodic Inspection and Testing

As a result of this amendment there will be no change to the established licensing basis of the Periodic Inspection and Testing SPA.

2.7 Radiation Protection

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

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

The Radiation Protection SCA is comprised of the following SPAs:

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Radiation Protection SCA. This is further explained in Section 2.7.1 to 2.7.4.

Regulatory requirements that apply to the Radiation Protection SCA are listed in Table 2.7.a. Furthermore, Table 2.7.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Radiation Protection and identifies the impact from Lu-177 and Y-90.

Table 2.7.a List of Radiation Protection Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Radiation Protection Regulations	SOR/2000-203	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Nuclear Substance and Radiation Device Regulations	SOR/2008-119	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.7.b Impact from Lu-177 and Y-90 on Darlington's Radiation Protection Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Radiation Protection	N-PROG-RA-0013	No Change
Controlling Exposure As Low As Reasonably Achievable	N-STD-RA-0018	No Change
Occupational Radiation Protection for Power Reactor Operating Licences	N-REP-03420-10001	No Change
Dose Limits and Exposure Control	N-PROC-RA-0019	No Change
Radioactive Work Planning, Execution and Close Out	N-PROC-RA-0027	No Change
Radiation Dosimetry Program – General Requirements	N-MAN-03416-10000	No Change
Radiation Dosimetry Program – External Dosimetry	N-MAN-03416.1-10000	No Change
Radiation Dosimetry Program – Internal Dosimetry	N-MAN-03416.2-10000	No Change
Respiratory Protection	OPG-PROC-0132	No Change

2.7.1 Application of ALARA

CNSC guidance document G-129, "*Keeping Radiation Exposures and Doses As-Low-As-Reasonably-Achievable (ALARA)*", will be used as guidance during this project's 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 TDS ALARA guide NK38-GUID-30550-00001, "*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.)

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

OPG completed a preliminary Lu-177 and Y-90 ALARA analysis, where the objective was to estimate if external radiation hazards associated with the irradiated Lu-177 and Y-90 target capsules are bounded by the external radiation hazards of Mo-99 targets. The focus of the preliminary assessment was on the project specific target material and capsule design. The remaining TDS system components (Zirconium Basket, Titanium Winch Cable, etc.) were assumed to remain constant, and therefore, not considered in this assessment. The primary variables that affect external radiation hazards associated with unshielded irradiated target capsules are composition (target material, ballast, sheath), irradiation duration, and dwell time. In conclusion, the unshielded external radiation hazards documented in NK38-REP-30550-00012, were bounding. A complete ALARA assessment will be completed during the detailed engineering phase of the project and will be submitted to CNSC staff as per the commitments in Appendix A.

2.7.2 Worker Dose Control

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

The Design ALARA Assessment, NK38-REP-30550-00012, documents the estimated accumulated whole-body dose increase to station personnel from TDS operation. This will be maintained well below the Exposure Control Levels and will be confirmed through the completion of detailed design.

2.7.3 Radiation Protection Program Performance

As a result of this amendment there will be no change to the established licensing basis of the Radiation Protection Program Performance SPA.

2.7.4 Radiological Hazard Control

The radiological hazard of processing the Lu-177 and Y-90 is bounded by the processing of Mo-99. It represents a radiation hazard that can be managed to ensure compliance with OPG's RP program.

2.8 Conventional Health and Safety

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

- Performance
- Practices

- Awareness

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

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

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Conventional Health and Safety SCA.

Regulatory requirements that apply to the Conventional Health and Safety SCA are listed in Table 2.8.a. Furthermore, Table 2.8.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Conventional Health and Safety and identifies the impact from Lu-177 and Y-90.

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

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
General Nuclear Safety and Control Regulations	SOR/2000-202	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.8.b Impact from Lu-177 and Y-90 on Darlington's Conventional Health and Safety Program Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Health and Safety Policy	OPG-POL-0001	No Change
Health and Safety Management System	OPG-PROG-0010	No Change

Program		
Work Protection	N-PROG-MA-0015	No Change
Respiratory Protection	OPG-PROC-0132	No Change
Fire Protection	N-PROG-RA-0012	No Change
Application of CSA Standard N293-7 to Structures, System and Components for Darlington Nuclear	NK38-LIST-78000- 10001	No Change

2.9 Environmental Protection

The Environmental Protection SCA is comprised of the following SPAs:

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

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Environmental Protection SCA. This is further explained in Section 2.9.1 to 2.9.5.

Regulatory requirements that apply to the Environmental Protection SCA are listed in Table 2.9.a. Furthermore, Table 2.9.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Environmental Protection and identifies the impact from Lu-177 and Y-90.

Table 2.9.a List of Environmental Protection Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Environmental monitoring program at class I nuclear facilities and uranium	CSA N288.4 (2010)	Continued compliance, no impact from Lu-177

mines and mills		and Y-90 in the TDS.
Effluent monitoring programs at class I nuclear facilities and uranium mines and mills	CSA N288.5 (2011)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Environmental risk assessments at class I nuclear facilities and uranium mines and mills	CSA 288.6 (2012)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Performance Testing of Nuclear Air- Cleaning Systems at Nuclear Facilities	CSA N288.3.4 (2013)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Groundwater protection programs at Class I nuclear facilities and uranium mines and mills	CSA N288.7 (2015)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.9.b Impact from Lu-177 and Y-90 on Darlington's Environmental Protection Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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	N-PROC-OP-0025	No Change

Programs		
Darlington Environmental Monitoring Program	NK38-MAN-03443- 10002	No Change
Darlington Nuclear Environmental Risk Assessment	NK38-REP-07701- 00001	No Change

2.9.1 Effluent and Emissions Control (Releases)

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

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

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

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

There will be no changes to the DRLs, Action Levels, or IILs as a result of the Lu-177 and Y-90 introduction into the TDS. Consistent with current performance, the cumulative public dose resulting from Darlington NGS is bounded by the Mo-99 operation which 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 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 TDS with Lu-177 and Y-90 is bounded by Mo-99 operation and will be in accordance with OPG's EMS program as described in OPG-PROG-0005, "*Environmental Management Systems*" and OPG-POL-0021. The EMS provides specific directions on how the Environmental Policy is implemented while meeting the expectations of OPG-POL-0032, "*Safe Operations Policy*" and N-POL-0001, "*Nuclear Safety & Security Policy*".

2.9.3 Assessment and Monitoring

The Darlington NGS Environmental Monitoring Program (EMP) complies with CSA Standard N288.4-10 "*Environmental monitoring programs at Class 1 nuclear facilities and uranium mines and mills*".

The EMP also complies with any applicable statutes, regulations, licences, or permits that govern the operation of the facility including, but not limited to, section 3 (h) of CNSC's *Class I Nuclear Facilities Regulations* and section 3.5 of REGDOC-3.1.1. 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 TDS. Additionally, environmental sampling and analyses for the EMPs support the calculation of annual public dose resulting from operation of Darlington NGS, as required by REGDOC-3.1.1. 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.

2.9.4 Protection of People

There are no changes to Protection of People.

2.9.5 Environmental Risk Assessment

There are no changes to Environmental Risk Assessment.

2.10 Emergency Management and Fire Protection

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

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

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Emergency Management and Fire Protection SCA. This is further explained in Section 2.10.1 to 2.10.3.

Regulatory requirements that apply to the Emergency Management and Fire Protection SCA are listed in Table 2.10.a. Furthermore, Table 2.10.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's

Fire Emergency Preparedness and Response and identifies the impact from Lu-177 and Y-90.

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

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Fire protection for CANDU nuclear power plants	CSA N293 (2012)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Nuclear Emergency Preparedness and Response	CNSC REGDOC-2.10.1 (2014)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.10.b Impact from Lu-177 and Y-90 on Darlington's Emergency Management and Fire Protection Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Consolidated Nuclear Emergency Plan	N-PROG-RA-0001	No Change
Emergency Preparedness Drills and Exercises	N-PROC-RA-0045	No Change
Fire Protection	N-PROG-RA-0012	No Change
Fire Hazard Assessment of the DNGS Retube Waste Processing Building (RWPB)	NK38-REP-09701-10338	No Change

2.10.1 Conventional Emergency Preparedness and Response

Lu-177 and Y-90 will not introduce new conventional emergency response requirements. Conventional chemicals will not be used to support Lu-177 and Y-90 operation. As a result of this amendment there will be no change to the established licensing basis of the Conventional Emergency Preparedness and Response SPA.

2.10.2 Nuclear Emergency Preparedness and Response

OPG's Emergency Preparedness program N-PROG-RA-0001, "*Consolidated Nuclear Emergency Plan*", requires OPG staff to implement and maintain its emergency response capability to protect the public, employees, and the environment in the event of a nuclear emergency." As a result of this amendment there will be no change to the established licensing basis of the Nuclear Emergency Preparedness and Response SPA.

2.10.3 Fire Emergency Preparedness and Response

OPG's Fire Protection program N-PROG-RA-0012, "*Fire Protection*" establishes provisions to prevent, mitigate and respond to fires such that fire risk to OPG Nuclear workers, public, environment, nuclear physical assets, and power generation, is acceptably low and controlled. There will be no changes to this program due to the production of Lu-177 and Y-90.

2.11 Waste Management

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

The Waste Management SCA is comprised of the following SPAs:

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Waste Management SCA.

2.11.1 Lutetium-177 Waste

There is expected waste from the production of Lu-177. The empty target shells from Lu-177 production will be sent back to OPG once the isotope source material is removed at an external third-party site. This waste is considered Low Level Waste (LLW) and will be stored at an OPG Waste Facility under the Waste Facility Operating Licence (WFOL-W4-314.00/2027). This will be managed as described in Section 11.1 of the LCH.

Regulatory requirements listed in Table 2.11.a apply to the Waste Management SCA. Table 2.11.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Waste Management and identifies the impact of Lu-177 and Y-90 on these programs and processes.

Table 2.11.a List of Waste Management Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Management of low and intermediate- level radioactive waste	CSA N292.3 (2008)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.11.b Impact from Lu-177 and Y-90 on Darlington's Waste Management Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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
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

2.12 Security

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

The Security SCA is comprised of the following SPAs:

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Security SCA. This is further explained in Section 2.12.1 to 2.12.4.

Regulatory requirements that apply to the Security SCA are listed in Table 2.12.a. Furthermore, Table 2.12.b provides the list of OPG governance, programs and

processes that form the licensing basis for Darlington NGS's Security and identifies the impact from Lu-177 and Y-90.

Table 2.12.a List of Security Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Nuclear Security Regulations	SOR/2000-209	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Cyber security for nuclear power plants and small reactor facilities	CSA N290.7 (2014)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
High Security Sites: Nuclear Response Force	CNSC REGDOC-2.12.1 (2013)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Site Access Security Clearance	CNSC REGDOC- 2.12.2 (2013)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Nuclear Security Officer Medical, Physical and Psychological Fitness	CNSC RD-363 (2010)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Criteria for Physical Protection Systems and Devices at High Security Sites	CNSC RD-321 (2010)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Criteria for Explosive Substance Detection, X-Ray Imaging and Metal Detection at High Security Sites	CNSC RD-361 (2010)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.12.b Impact from Lu-177 and Y-90 on Darlington's Security Program Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
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
Cyber Security Controls for Cyber Essential	N-INS-08161-10011	No Change

Assets		
Significant Cyber Assets	NK38-LIST-69000-10001	No Change

2.12.1 Facilities and Equipment

The production of Lu-177 and Y-90 in the TDS 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*".

2.12.2 Response Arrangements

The installation and operation of the Lu-177 and Y-90 in the TDS will not require changes to security response arrangements or processes.

2.12.3 Security Practices, Drills and Exercises

The installation and operation of the Lu-177 and Y-90 in the TDS will not require changes security practices, drills, or exercises.

2.12.4 Cyber Security

The installation and operation of the Lu-177 and Y-90 in the TDS will not require changes to cyber security.

2.13 Safeguards and Non-Proliferation

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

- Nuclear Material Accountancy and Control
- Access and Assistance to the IAEA
- Operational and Design Information
- Safeguards Equipment, Containment and Surveillance
- Import and Export

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

OPG has performed a thorough assessment of the project scope and has determined that the production of new isotopes using the existing TDS will not require any changes to the licensing basis of the Safeguards and Non-Proliferation SCA. This is further explained in Section 2.13.1 to 2.13.5.

Regulatory requirements that apply to the Safeguards and Non-Proliferation SCA are listed in Table 2.13.a. Furthermore, Table 2.13.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Safeguards and Non-Proliferation and identifies the impact from Lu-177 and Y-90.

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

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Nuclear Non-proliferation Import and Export Control Regulations	SOR/2000-210	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Safeguards and Nuclear Material Accountancy	CNSC REGDOC-2.13.1 (2018)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Accounting and Reporting of Nuclear Material	CNSC RD-336 (2010)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.13.b Impact from Lu-177 and Y-90 on Darlington's Safeguards and Non- Proliferation Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Nuclear Safeguards	N-PROG-RA-0015	No Change
Nuclear Safeguards Implementation	N-STD-RA-0024	No Change

2.13.1 Nuclear Material Accountancy and Control

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

Darlington completes an annual Physical Inventory Taking (PIT) as part of Licence Condition 13.1. Lu-177 and Y-90 in the TDS will not impact OPG's compliance with non-fuel reporting requirements documented in REGDOC-2.13.1, "*Safeguards and Nuclear Material Accountancy*".

2.13.2 Access and Assistance to the IAEA

Canadian facilities are selected at random by the IAEA for physical inspections to confirm compliance with international non-proliferation requirements. Lu-177 and Y-90 in the TDS will have no impact on IAEA inspections or access to IAEA equipment. No changes from Mo-99 licence amendment submission have been made to the TDS.

2.13.3 Operational and Design Information

The design description of the TDS has been provided to CNSC staff for transmittal to the IAEA under the Mo-99 TDS submission. No other changes have been made.

2.13.4 Safeguards Equipment, Containment and Surveillance

Lu-177 and Y-90 being in the TDS will not interfere with existing IAEA safeguards surveillance monitoring equipment.

2.13.5 Import and Export

There will be no requirement to import nuclear material for the irradiation of Lu-177 and Y-90 in the TDS. BWXT-Medical will be responsible for obtaining the required export licenses for exporting the processed isotopes outside of Canada.

2.14 Packaging And Transport

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

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

The targets, manufactured by BWXT-NEC, will be received periodically at Darlington NGS to meet medical demand for the isotopes Lu-177 and Y-90. Once irradiated, the targets will be shipped from Darlington NGS to BWXT-Medical for medical processing.

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

Regulatory requirements that apply to the Packaging and Transport SCA are listed in Table 2.14.a. Furthermore, Table 2.14.b provides the list of OPG governance, programs and processes that form the licensing basis for Darlington NGS's Packaging and Transport and identifies the impact from Lu-177 and Y-90.

Table 2.14a List of Packaging and Transport Related Regulatory Requirements

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Transportation of Dangerous Goods Regulations	SOR/2001-286	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.
Packaging and Transport of Nuclear Substances Regulations	SOR/2015-145 (2015)	Continued compliance, no impact from Lu-177 and Y-90 in the TDS.

Table 2.14.b Impact from Lu-177 and Y-90 on Darlington's Packaging and Transport Licensing Basis Documents

OPG Licensing Basis Document Title	OPG Document Number	Impact from Lu-177 and Y-90
Radioactive Material Transportation	W-PROG-WM-0002	No Change
Radioactive Materials Transportation Emergency Response Plan	N-STD-RA-0036	No Change

2.14.1 Package Design and Maintenance

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

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

2.14.2 Packaging and Transport

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

In accordance with this program and the regulatory requirements, OPG staff will package the irradiated targets for shipment in 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 Registration for Use

In accordance with the CNCS's "*Packaging and Transportation of Nuclear Substances Regulations*", OPG will apply for and obtain CNSC confirmation to use the Lu-177 and Y-90 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 due to Lu-177 and Y-90.

3.0 OTHER MATTERS OF REGULATORY INTEREST

3.1 Public Information and Engagement

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

OPG provides responses to issues and questions raised by stakeholders and the public, and tracks issues and questions to identify trends 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 Lu-177 and Y-90.

3.2 Community Committees

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

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

These forums provide opportunity for public engagement, and information exchange regarding the expansion of the TDS to also produce Lu-177 and Y-90.

3.3 Indigenous Community Engagement

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

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

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

As recommended in the CNSC REGDOC 3.2.2, Indigenous Engagement, an Indigenous Engagement Plan has been prepared to document the engagement scope and activities regarding these medical isotope projects, NK38-PLAN-00120-00018, "*Isotope Engagement and Communications Plan with Indigenous Communities*", (Enclosure 2 of this submission).

4.0 CONCLUSION

The production of Lu-177 and Y-90 are an important initiative for the nuclear industry and the medical community. OPG's request for amendment of the Darlington NGS PROL to add a new licensed activity to possess, transfer, process, package, manage and store Lu-177 and Y-90 radioisotopes and their associated decay isotopes is presented in this application. Based on preliminary assessments, these two new isotopes are bounded by the safety assessment that was completed for Mo-99 and presents no greater risk than the production of Mo-99 using the TDS. Furthermore, the production of these medical isotopes will be implemented based on OPG'S Nuclear Management System. Overall, OPG is responsible for continued safe operation of the Darlington NGS and confirms that the production of Lu-177 and Y-90 at Darlington NGS using the TDS 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 design basis will be maintained.
- **Continued Safe Reactor Operation:** OPG will complete a comprehensive safety assessment to confirm that the operation of the TDS using Lu-177 and Y-90 target capsules will have negligible effects on safe reactor operation, and on public safety.
- **Environmental Protection:** A predictive environmental effects assessment, NK38-REP-30550-00029, "*Predictive Effects Assessment for The DN Molybdenum Isotope Irradiation System (Unit 4)*" [redacted] prepared in accordance with CSA Standards N288, concluded the safe operation of the TDS, which was confirmed during TDS commissioning. As the number of seeding and harvesting cycles per year for the new isotopes remains unchanged, which was the primary factor considered in the Mo-99 PEA assessment, the introduction of the new target capsules is not expected to have any additional environmental impact. This will be reviewed and validated as per OPG's ECC process.
- **Licensing Basis:** Operation of the TDS using Lu-177 and Y-90 target capsules will have minimal impact on Darlington's licensing basis, governance, programs and processes.

Prior to operating the TDS with Lu-177 and Y-90 target capsules, the insertion, seeding and harvesting will be fully tested following detailed procedures to demonstrate continued reactor safety. Once installed and fully commissioned, OPG staff will be qualified to operate and maintain the TDS to produce Mo-99, Lu-177 and Y-90.

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

5.0 REFERENCES

[3-5] OPG letter, R. Geofroy to M. Bacon Dussault, “Darlington NGS – Addendum to the Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.03/2025 Amendment for Production of the Cobalt-60 Radioisotope”, December 22, 2023, CD# NK38-CORR-00531-25073.

APPENDIX A

Lutetium-177 and Yttrium-90 Isotope Production Project Regulatory Commitments

The purpose of this appendix is to document a consolidated list (Table 1) of OPG's pending regulatory commitments for the Lutetium-177 and Yttrium-90 Production Projects. Some of the submissions and activities are scheduled to occur after the date of this application and, in some cases, after the licence amendment hearing. OPG has initiated Regulatory Management Action Requests (REGMs) for all regulatory commitments to track to completion the outstanding submissions and activities, in accordance with OPG's processes.

Should changes to the due date of these commitments be required, in recognition that there will be activities occurring over the course of the project, OPG will provide prior CNSC staff notification.

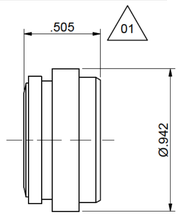
Table 1 – List of Lutetium-177 and Y-90 Isotope Production Project Regulatory Commitments

#	Description	REGM #	Target Completion Date
1	Submit the OPG accepted target capsule design for Lu-177 to CNSC staff.	28265351	August 30th, 2024
2	Submit the OPG accepted target capsule design for Y-90 to CNSC staff.	28265352	December 16th, 2024
3	Submit the detailed nuclear safety analysis that confirms and validates the safety impacts during the detailed engineering phase of the project for CNSC staff review.	28265354	August 30th, 2024
4	Submit the revised Target Delivery System Design ALARA Assessment report (NK38-REP-30550-00012,) which incorporates the production of Lu-177 and Y-90 for CNSC staff review.	28265355	August 30th, 2024
5	Submit the Human Factors Assessment completed as part of the detailed engineering phase for CNSC staff review	28265356	August 30th, 2024
6	Submit the commissioning report for Lu-177 for CNSC staff review	28265357	Feb 28th, 2025
7	Submit the commissioning report for Y-90 for CNSC staff review	28265358	June 30th, 2025

APPENDIX B

Lu-177 Target Capsule Outline

BWXT-TARG-00003-0001



5

Lu-177 CARRIER, LOWER DETAIL
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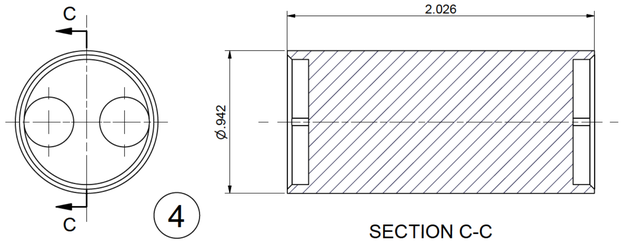

4

SECTION C-C

Lu-177 CARRIER, MIDDLE DETAIL
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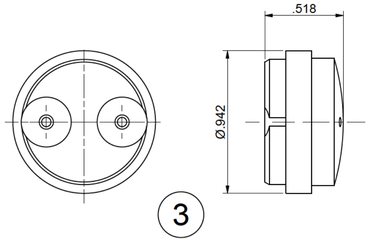
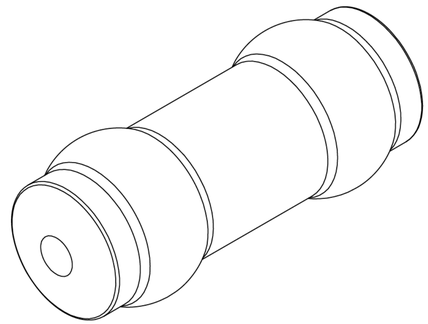


3

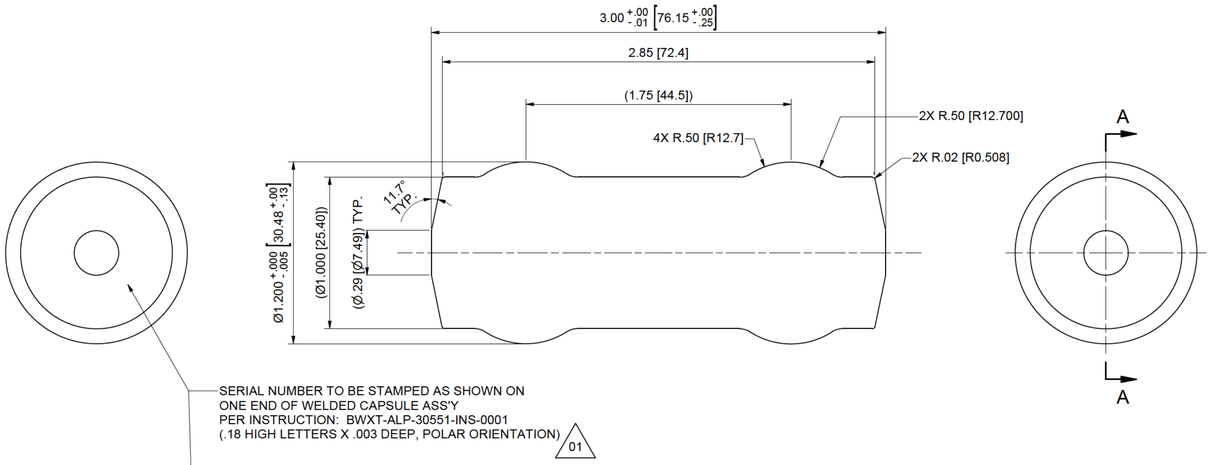
Lu-177 CARRIER, UPPER DETAIL
EST. WEIGHT = 41.4 g 01

PART. No.	QTY	DESCRIPTION	SIZE	MATERIAL
1	1	CAPSULE BODY	1.000 OD X .024 WALL TUBE	ZIRCALOY - 4 SPEC. B50QX202
2	2	ENDCAP	1.000 DIA. X .286 LG.	ZIRCALOY - 4 SPEC. B50QX203
3	1	Lu-177 CARRIER, UPPER	.942 OD X .518 LG	MOLYBDENUM ASTM B387
4	1	Lu-177 CARRIER, MIDDLE	.942 OD X 2.026 LG	ZIRCALOY - 4 SPEC. B50QX203
5	1	Lu-177 CARRIER, LOWER	.942 OD X .505 LG	MOLYBDENUM ASTM B387
6	2	IRRADIATION AMPOULE	8 mm OD x 50 mm LG	K129311-002, HERAEUS QUARTZ HLQ210
7	2	Yb-176 POWDER	UP TO 4 g PER AMPOULE	ENRICHED YTTERBIUM OXIDE POWDER
8	2	WOOL PACKING	UP TO 0.5 g PER AMPOULE	99.99% SiO2 WOOL

01



G1 TOTAL CAPSULE MASS = 240.4 g +11.7 / -2.6 g 01



SERIAL NUMBER TO BE STAMPED AS SHOWN ON
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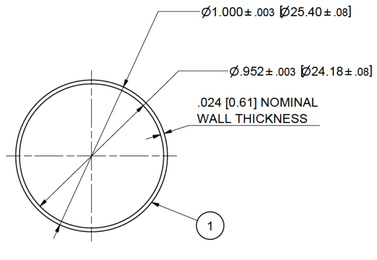
PER INSTRUCTION: BWXT-ALP-30551-INS-0001
(.18 HIGH LETTERS X .003 DEEP, POLAR ORIENTATION) 01



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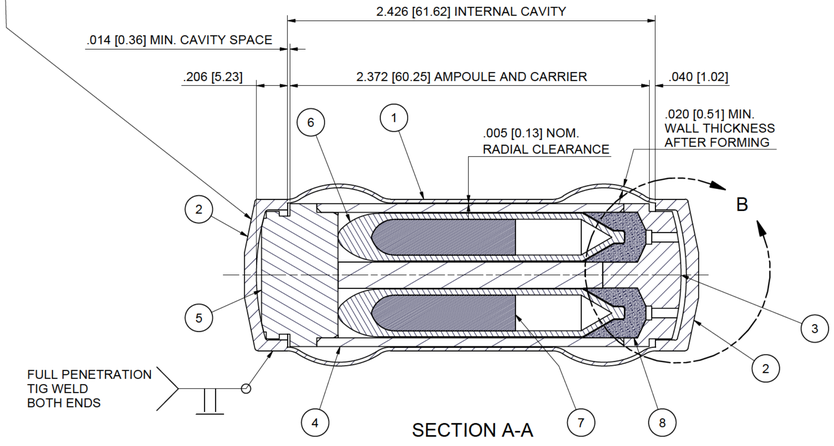
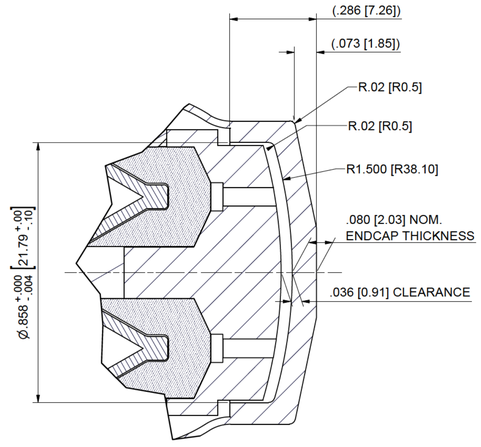
(BEFORE FORMING)



SECTION A-A



DETAIL B
SCALE 4 : 1

CAPSULE ASSEMBLY NOTES:

1. THIS DRAWING IS NOT A MANUFACTURING DRAWING, AND THE DETAILS SHOWN ARE FOR REFERENCE PURPOSES.
2. MANUFACTURED PER BWXT MANUFACTURING NUMBER:
   BWXT-TARG-00003-0002 SHT 0001
3. INTERNAL FILLING GAS SHALL CONSIST OF A MINIMUM OF 80% HELIUM BY VOLUME, A MAXIMUM OF 10% ARGON BY VOLUME AND SHALL CONTAIN LESS THAN 5000 PPM O2 BY VOLUME ON ASSAY OF COMPLETED CAPSULE (TARGET 4000 PPM). THE REMAINDER SHALL BE HELIUM. 01
4. HELIUM LEAK TEST REQUIREMENT < 1 X 10 $^{-7}$ ATM CC/SEC ON COMPLETED CAPSULE.
5. UNLESS OTHERWISE STATED, UNITS ARE GIVEN IN INCHES [millimeters], INCH UNITS GOVERN AND [millimeters] ARE FOR REFERENCE ONLY.
6. REFER TO BWXT-ALP-30551-SPEC-0004 FOR THE TARGET CAPSULE DESIGN SPECIFICATION.

LICENSED PROFESSIONAL ENGINEER
T. G. ONDERWATER
34781625
PROVINCE OF ONTARIO

BWXT-TARG-0003-0001 REV01

2024-01-30

Rev No.	Date	Description	Dwn	Chk	Dsgn	Vrfd	Appd	Manuf
01	2024 01-29	CHANGED PT8 SIZE AND MATERIAL. UPDATED PT3, 4, 5, AND G1 WEIGHTS. CHANGED NOTE 3. SERIAL NUMBER NOTE WAS ON OPPOSITE END. PICTORIAL UPDATES. .505 WAS .506.	JR	JB	NK	TGO	SMW	N/A
00	2023 12-08	INITIAL ISSUE	JR	JB	NK	TGO	SMW	N/A

DARLINGTON 1 2 3 4

TARGET DELIVERY SYSTEM
Lu-177 TARGET CAPSULE
OUTLINE

Designed By: BWXT Nuclear Energy Canada Inc.

SCALE APPLIES ONLY TO ORIGINAL PRINT

Drawn J. RIBEIRO	Third Angle Projection	Cad # NP0089665
Checked J. BLACK	F.C.F.	
Designed N. KORELL	BOM #	
Verified T.G. ONDERWATER	Lin. Meas. INCH [mm]	Scale 2 : 1
Approved S.M. WILSON	Size D	Sheet No. 0001 OF 0001
Drawing No. BWXT-TARG-00003-0001		Rev. 01

OPG ASSIGNED DRAWING NUMBER	
Drawing No.	Rev.
Sheet No. 0001 OF 0001	Sub-Type MAD

(OPG CONFIDENTIAL)

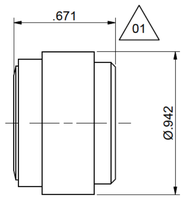
APPENDIX C

Y-90 Target Capsule Outline

BWXT-TARG-00004-0001

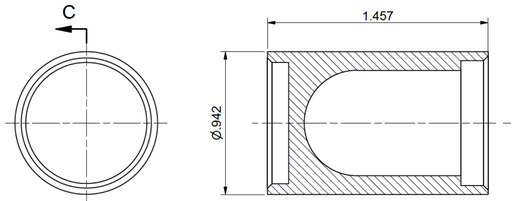
PART. No.	QTY	DESCRIPTION	SIZE	MATERIAL
1	1	CAPSULE BODY	1.000 OD X .024 WALL TUBE	ZIRCALOY - 4 SPEC. B50QX202
2	2	ENDCAP	1.000 DIA. X .286 LG.	ZIRCALOY - 4 SPEC. B50QX203
3	1	Y-90 CARRIER, UPPER	.942 OD X .961 LG	MOLYBDENUM ASTM B387
4	1	Y-90 CARRIER, MIDDLE	.942 OD X 1.457 LG	ZIRCALOY - 4 SPEC. B50QX203
5	1	Y-90 CARRIER, LOWER	.942 OD X .671 LG	MOLYBDENUM ASTM B387
6	1	IRRADIATION AMPOULE	17 mm OD X 45 mm LG	FUSED QUARTZ TUBE, GRADE SUP310
7	1	Y-89 POWDER	UP TO 4.5 g	GLASS MICROSPHERES; YTTRIA ALUMINOSILICATE (YAS) GLASS FRIT, OTT-00103
8	1	WOOL PACKING	UP TO 1.3 g	99.99% SiO2 WOOL

01



5

Y-90 CARRIER, LOWER
EST. WEIGHT = 68.2 g 01



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SECTION C-C

Y-90 CARRIER, MIDDLE
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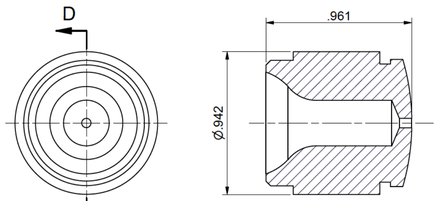

3

SECTION D-D

Y-90 CARRIER, UPPER
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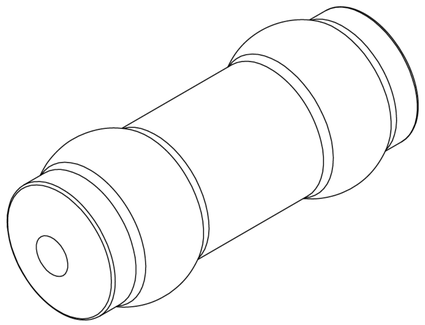
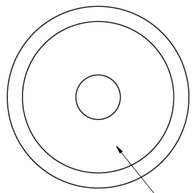


G1 TOTAL CAPSULE MASS = 249.4 g +8.8 / -2.8 g 01



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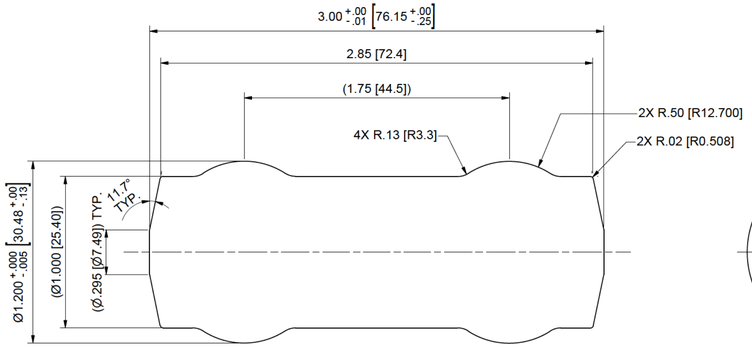
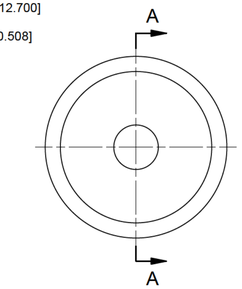
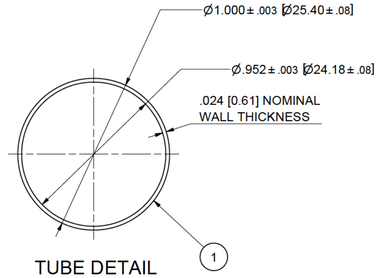
(.18 HIGH LETTERS X .003 DEEP, POLAR ORIENTATION) 01







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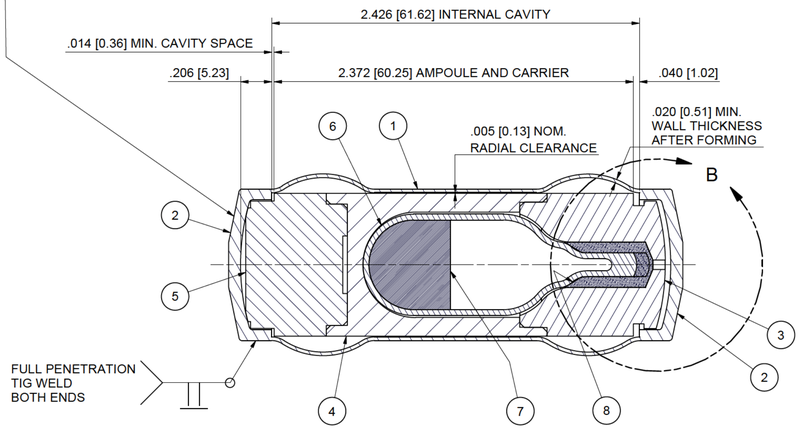
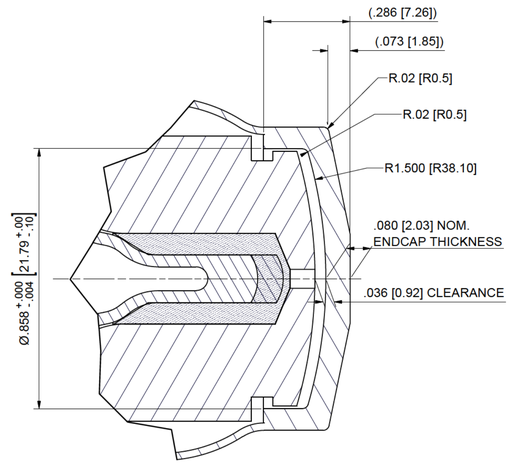
(BEFORE FORMING)



SECTION A-A



DETAIL B
SCALE 4 : 1

CAPSULE ASSEMBLY NOTES:

1. THIS DRAWING IS NOT A MANUFACTURING DRAWING, AND THE DETAILS SHOWN ARE FOR REFERENCE PURPOSES.
2. MANUFACTURED PER BWXT MANUFACTURING NUMBER:
   BWXT-TARG-00004-0002 SHT 0001
3. INTERNAL FILLING GAS SHALL CONSIST OF A MINIMUM OF 80% HELIUM BY VOLUME, A MAXIMUM OF 10% ARGON BY VOLUME AND SHALL CONTAIN LESS THAN 5000 PPM O2 BY VOLUME ON ASSAY OF COMPLETED CAPSULE (TARGET 4000 PPM). THE REMAINDER SHALL BE HELIUM. 01
4. HELIUM LEAK TEST REQUIREMENT < 1 X 10 $^{-7}$ ATM CC/SEC ON COMPLETED CAPSULE.
5. UNLESS OTHERWISE STATED, UNITS ARE GIVEN IN INCHES [millimeters], INCH UNITS GOVERN AND [millimeters] ARE FOR REFERENCE ONLY.
6. REFER TO BWXT-ALP-30551-SPEC-0003 FOR THE TARGET CAPSULE DESIGN SPECIFICATION.

LICENSED PROFESSIONAL ENGINEER
T. G. ONDERWATER
34781625
PROVINCE OF ONTARIO

BWXT-TARG-00004-00001 REV01

2024-01-30

Rev No.	Date	Description	Dwn	Chk	Dsgn	Vrfd	Appd	Manuf
01	2024 01-29	CHANGED PT8 SIZE AND MATERIAL. UPDATED PT3, 4, 5, AND G1 WEIGHTS. CHANGED NOTE 3. SERIAL NUMBER NOTE WAS ON OPPOSITE END. PICTORIAL UPDATES. .671 WAS .672.	JR	JB	NK	TGO	SMW	N/A
00	2023 12-08	INITIAL ISSUE	JR	JB	NK	TGO	SMW	N/A

DARLINGTON 1 2 3 4

TARGET DELIVERY SYSTEM
Y-90 TARGET CAPSULE
OUTLINE

Designed By: BWXT Nuclear Energy Canada Inc.

SCALE APPLIES ONLY TO ORIGINAL PRINT

Drawn J. RIBEIRO	Third Angle Projection	Cad # NP0089664
Checked J. BLACK	F.C.F.	
Designed N. KORELL	BOM #	
Verified T.G. ONDERWATER	Lin. Meas. INCH [mm]	Scale 2 : 1
Approved S.M. WILSON	Size D	Sheet No. 0001 OF 0001

Drawing No. BWXT-TARG-00004-0001 Rev. 01

OPG ASSIGNED DRAWING NUMBER
Drawing No. | Rev.
Sheet No. 0001 OF 0001 | Sub-Type MAD
(OPG CONFIDENTIAL)

ATTACHMENT 4

OPG letter, A. Grace to C. Salmon, “Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”

CD# NK38-CORR-00531-25810 P

Technical Summary of NK38-REP-03600-10014-000, Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System

Prepared By: **S. Goodchild**

Checked By: **E. Reynolds**

ATTACHMENT 4

Technical Summary of NK38-REP-03600-10014-000, Nuclear Safety Impact Assessment of New Isotope Irradiation in the Target Delivery System

The Nuclear Safety Impact Assessment conducted by Ontario Power Generation (OPG) focuses on the introduction of new isotopes in the Target Delivery System (TDS) at Darlington Nuclear Generating Station (DNGS). The assessment aims to evaluate the impact of using new target capsules to produce medical isotopes. The document provides an overview of the TDS system, target capsule design features, and the objectives of the assessment.

The assessment focuses on the introduction of new isotopes that will be irradiated in the DNGS TDS utilizing target capsules that are like those used currently to produce Mo-99. The new target capsules have the same characteristics in terms of geometry, physical properties, including mass and reactivity worth, combined with negligible differences in heating, radiation, and chemistry impacts.

The assessment included reviewing key documents completed supporting the installation and operation of the existing TDS. Several key reports and assessments were reviewed, including the Event Identification and Classification Report, the Internal and External Hazard Screening Assessment, the Probabilistic Safety Assessment, the Integrated Nuclear Safety and Operational Assessment, the Operational Assessment of the TDS Installation, and the Cobalt Adjuster and Molybdenum Target Delivery System Interaction report. These reports provide valuable information on the safety analysis, operational assessments, and interactions between the TDS and other systems.

Detailed assessments of potential new initiating events, the potential for impact on the existing safety analyses, impacts on the Probabilistic Safety Assessment (PSA) elements, and operational impacts were part of the review. The conclusions of the assessments are:

- While the event identification and classification for the TDS identified 11 new events and potential impact on some existing systems, the introduction of new target capsules does not change the conclusions or introduce any new events;
- Parametric assessments indicated the TDS and production of isotopes has no detrimental impact on reactor safe and reliable operation and the introduction of new target capsules does not change the conclusions;
- Introduction of new target capsules does not impact the conclusion that the overall impact from the TDS on the quantification of Severe Core Damage Frequency and Large Release Frequency in the various PSA elements would be expected to be low;
- Operational assessments completed for the TDS are not impacted by the introduction of new target capsules;
- A review of safety analysis appendices and Cobalt Adjuster Rod interactions report did not identify any issues or challenges associated with the existing accident progression or consequences with the introduction of new target capsules.

As part of the original design and installation of the TDS at DNGS a detailed Failure Mode and Effects analysis was completed and formed the basis for the subsequent planning and analysis of the associated safety cases. The Event identification and classification exercise identified a few new initiating events with only a small subset being associated with or impacted by the target capsule design. In addition to those initiating events considered in safety analysis, additional initiating events were screened for impact on the PSA. Again, only a subset of these being specific to the target capsule design.

Detailed analysis was performed in support of the TDS installation, not just for safety analysis implications but the overall impact on plant Operations. Review of all Darlington Safety Report Accident Analysis Appendices was completed and are detailed in the integrated safety and operational assessment and the Cobalt interactions report. Impact on the ability to comply with key safety parameters was assessed and documented in both the operational and the integrated safety and operational assessment reports.

The detailed assessments concluded the TDS system did not introduce any new initiating events or hazards that would impact the conclusions of the current safety analysis or PSAs. Further, the operational assessment confirmed that the introduction of the current target capsules for molybdenum is well within the capability of current systems and process to ensure plant operation remains consistent with the defined Safety Operating Envelope (SOE).

The Nuclear Safety Impact Assessment considered the relative reactivity worth of various device configurations. Figure 1 shows the anticipated relative reactivity worth for only the current target and the new target capsules. The new target capsule values (Iso XXX and Iso YYY) are based on estimated worth values based of the preliminary device composition using a mass extrapolation. The value for Mo-99 is the theoretical value that was confirmed during commissioning of the system. This is the reactivity worth of a single string of target capsules.

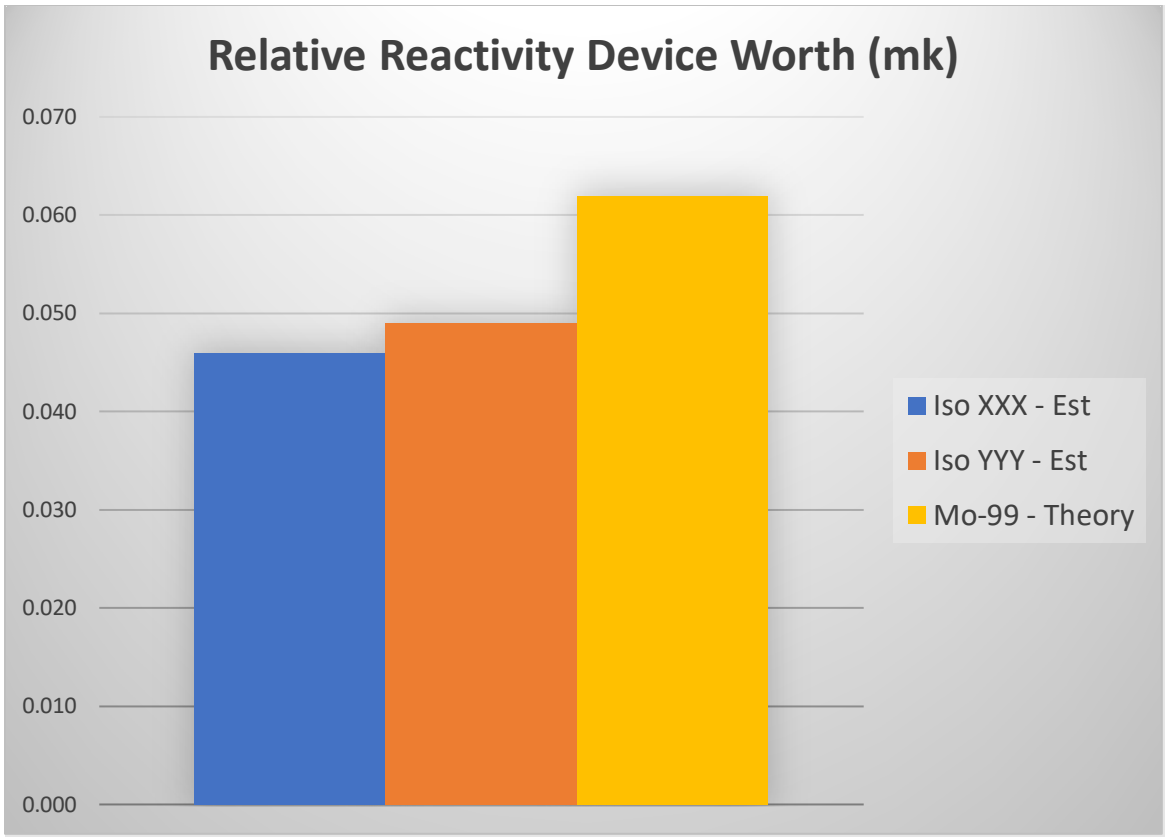


Figure 1, Target Capsule Reactivity Worth (mk)

Figure 2 includes some additional operational device values for comparison with the single string of target capsules. The values represent the calculation of a one percent change in overall average liquid zone controller level and the removal of the first bank of Adjusters (Bank-A). Adjuster Absorber rods are used during operation of the reactor to allow for poison override during changes in power and may be used for reactivity addition (shim) should on-power fuelling be interrupted. The Reactor Regulating System can adequately control larger changes in reactivity as part of system design. The values shown from the Simulation of Reactor Operation (SORO) were calculated based on the total change in reactivity from a single characteristic state, by comparing the initial state to the same state instantaneously moving the represented device(s).

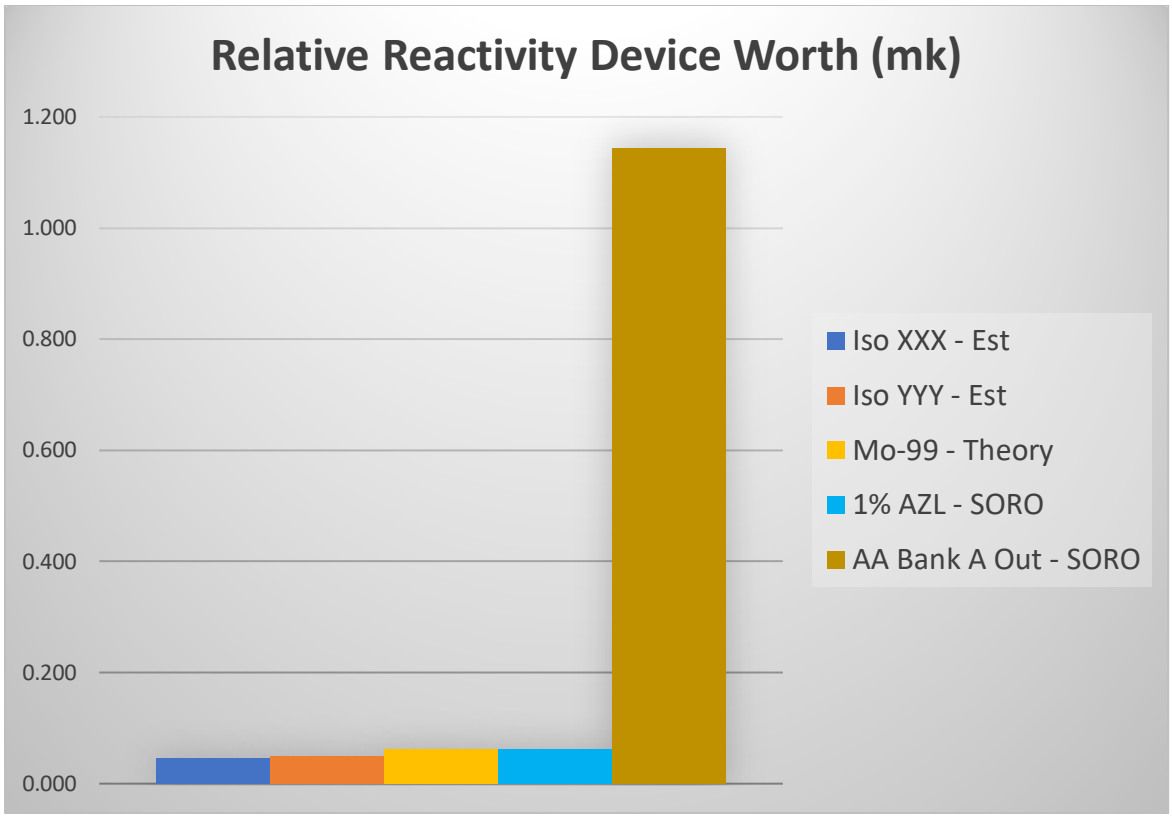


Figure 2, Comparison of Targets and Operational Changes During Normal Operation

Based on the completed impact assessment, introduction of new target capsules to produce new isotopes with the existing TDS will have no significant impact on the safe operation of DNGS. There is a requirement that the existing analysis for molybdenum targets will bound the new target capsule designs to produce both new isotopes. This requirement will need validation through a more detailed assessment of the final target capsule designs for the new isotopes. Systems, structures, and components will continue to provide the required safety, protective and mitigating actions necessary to ensure the original design objectives are met. Further, current operating practices and processes will ensure continued operation within the defined Safe Operating Envelope.

The document highlights the importance of previous assessments conducted for the TDS and the production of molybdenum. These assessments have demonstrated the small impact of the TDS on the overall safety case and operation at DNGS. The introduction of new isotopes in similar target capsules is expected to be bounded by the analysis and operational assessments conducted for molybdenum production.

In conclusion, the assessment is based on a thorough review of key documents and assessments related to the TDS and its interaction with other systems. The Nuclear Safety Impact Assessment affirms that introducing new target capsules to produce new isotopes in the TDS at DNGS will not impact safe operation.

Acronym	Definition
DNGS	Darlington Nuclear Generating Station
OPG	Ontario Power Generation
PSA	Probabilistic Safety Assessment
SORO	Simulation Of Reactor Operation
TDS	Target Delivery System

ENCLOSURE 1

OPG letter, A. Grace to C. Salmon, “Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production”

CD# NK38-CORR-00531-25810 P

Isotope Engagement and Communications Plan with Indigenous Communities

NK38-PLAN-00120-00018 R000

(18 total pages)

ONTARIO POWER GENERATION

Plan

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Document Number: NK38-PLAN-00120-00018	Usage Classification: INFORMATION
Sheet Number: N/A	Revision: R000

Title:
ISOTOPE ENGAGEMENT AND COMMUNICATIONS PLAN WITH INDIGENOUS COMMUNITIES

ISOTOPE ENGAGEMENT AND COMMUNICATIONS PLAN WITH INDIGENOUS COMMUNITIES

NK38-PLAN-00120-00018-R000
2023-11-09

Order Number: N/A
Other Reference Number: N/A

Internal Use Only

Prepared by: Kenn Ross Nov 27, 2023

Kenn Ross Date
Sr Manager, Indigenous Relations
OPG Indigenous Relations

Reviewed by: Nov 27, 2023

Katie Haddlesey Date
Director Indigenous Partnerships
OPG Indigenous Relations

Concurred by: 11/27/2023

Gillian Spinney Date
Manager, Projects
Laurentis Energy Partners

Approved by: Dec 1, 2023

Kirk Thompson Date
Manager, Projects
Ontario Power Generation

Table of Contents

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Revision Summary

Revision Number	Date	Comments
R000	2023-11-09	Initial Issue.

1.0 LAND ACKNOWLEDGEMENT

The sources of the isotopes described in this plan will originate on the lands and waters on which the Darlington Nuclear Generating Stations (DNGS) is situated. DNGS is located within the shared traditional and treaty territory of the Williams Treaties First Nations, which includes the Mississaugas of Scugog Island First Nation, Curve Lake First Nation, Hiawatha First Nation, Alderville First Nation, Chippewas of Beausoleil First Nation, Chippewas of Georgina Island First Nation, Chippewas of Rama First Nation.

Also, DNGS lies within the territory of the Gunshot Treaty and the Williams Treaties of 1923. These treaty rights were recognized in 2018 in a settlement with Canada and the Province of Ontario.

Additionally, OPG acknowledges the Aboriginal and treaty rights, interests and the traditional territories of Indigenous communities and peoples along the proposed isotope transportation route and whose practices, histories and spiritualties are tied to their lands and waters. These communities include Métis Nation of Ontario Regions 6 and 8, Mohawks of the Bay of Quinte and the unceded territory of the Algonquin Nation.

2.0 PROJECT DESCRIPTION AND RATIONALE

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

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

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

As recommended in the Canadian Nuclear Safety Commission (CNSC) REGDOC 3.2.2, Indigenous Engagement, this Indigenous Engagement Plan has been prepared to document the engagement scope and activities regarding the medical isotope project. This plan will provide the details and actions specific to this project.

The project will engage with identified Indigenous Nations and communities which have inherent and/or Aboriginal and treaty rights or interests regarding the project. The activities will include ongoing dialogue and project overview meetings, both general and technical. The engagement activities specified in this plan should support the goal of continuing dialogue and ensuring sufficient information is provided so Indigenous Nations and communities are informed and have ample opportunity to provide feedback and voice any questions and concerns.

Feedback from Indigenous Nations and concerns will be reviewed. This feedback may be collected during in-person/virtual meetings, correspondence or other methods as determined by OPG and the communities. Actionable feedback will be recorded and tracked in a project-specific Engagement Log.

BWXT Medical, a health science company based in Kanata (Ottawa), Ontario, is OPG's strategic partner in this project. The relationship between OPG, BWXT Medical and its predecessor companies is over 50 years old. OPG and BWXT Medical will work to collaboratively on Indigenous engagement. BWXT Medical owns and maintains the licensed transportation containers that will be used to transfer the medical isotopes to their facility and is accountable for arranging all transportation of

the isotopes. OPG is accountable for the irradiation, harvesting and processing of the medical isotopes at the Darlington site.

In response to the growing global demand for radioisotopes utilized in cancer treatment, OPG plans to produce two new isotopes, Lutetium-177 (Lu-177) and Yttrium-90 (Y-90), using the existing Target Delivery System (TDS) installed at Darlington Nuclear Generating Station (DNGS). This expansion will introduce two new isotopes into OPG's existing portfolio, further diversifying its capabilities, and enhancing its social licence contributions.

The production of these medical isotopes represents a significant opportunity through which nuclear science contributes to the well-being of Canadians. It offers innovative and alternate approaches to cancer diagnosis and treatment.

Lu-177 is a radioactive isotope with distinctive medical applications. Its primary purpose is for targeted cancer therapies, particularly for neuroendocrine tumors and prostate cancer. Lu-177 emits beta radiation, which allows it to effectively target and destroy cancer cells while minimizing damage to the surrounding healthy tissue.

Similarly, Y-90 is also a beta emitter. It is primarily utilized in a form known as Y-90 microspheres. These microspheres are used for targeted internal radiation therapy, particularly in the treatment of liver cancer, also known as hepatocellular carcinoma.

OPG is committed to respecting Aboriginal and treaty rights and interests and OPG's commitment to developing positive relationships with Indigenous communities remains integral to our operations. Our objective is to ensure that Indigenous peoples and communities are provided with a forum to discuss key topics related to this licence amendment application.

In summary, OPG remains committed to the safe operation of the Darlington Nuclear Generating Station units and re-affirms that the TDS activities relating to the production of these two new isotopes can be implemented safely. OPG's dedication to upholding rigorous safety and the proposed expansion will be executed in strict adherence to established nuclear safety protocols.

2.1 ROLES AND RESPONSIBILITIES

OPG Indigenous Engagement Lead will:

- Provide advice and counsel to the Project Manager and Project Team.
- Liaise with Indigenous communities and maintain an engagement log detailing contact with Indigenous communities including questions and comments which may require action.

- Organize and facilitate outreach with Indigenous Nations and communities (meetings, presentations, community events, etc.).

- Lead meaningful dialogue should impact to inherent, Aboriginal and Treaty rights be identified.

- Updates the Indigenous engagement plan as required.

- Identify Indigenous business contracting where appropriate and refer to OPG and Project member supply chains.

Note: OPG's Indigenous Engagement Lead will be supported by OPG Indigenous Partnership's group under Katie Haddlesey with Kenn Ross as the Primary Lead.

Laurentis Energy Partners Project Team will:

- Provide the OPG Indigenous Engagement Lead with the necessary support to execute engagement plan.

- Provide technical support during presentations to the Indigenous Communities.

- Provide as identified costs associated with engagement. (See 4.0)

3.0 INDIGENOUS ENGAGEMENT AND COMMUNICATIONS OVERVIEW

The Duty to Consult is a Crown responsibility, described and upheld in Supreme Court of Canada case law and grounded in the honour of the Crown. Duty to Consult is of paramount importance where an Environmental Assessment has been undertaken, and federal and provincial permits are required. Duty to Consult is covered in detail in the following document: OPG-STD-0087 Management of Indigenous Relations and OPG-MAN-08410.1-0001 Indigenous Relations Manual. Appendix A describes where this Plan resides in the context of OPG's Indigenous Relations governance.

For the purposes of this Plan, the Canadian Nuclear Safety Commission (CNSC) holds the Duty to Consult with aspects of this duty delegated to OPG and Project proponents. Should it be determined by the CNSC that the Duty is not triggered by this undertaking, as was the case with the amendment to the DNGS operating license for Molybdenum 99 production, OPG will still conduct its engagement with rigor as a matter of preferred practice.

In alignment with CNSC REGDOC 3.2.2, Indigenous Engagement, this Engagement and Communication Plan with Indigenous Communities was prepared to document the scope and activities OPG and the Project partners will conduct with the identified Indigenous communities through all phases of the project.

CNSC REGDOC 3.2.2, Indigenous Engagement is currently being updated by the Regulator in conjunction with Indigenous communities and organization as well as proponents. However, the updated REGDOC 3.2.2. will not be in place until late 2024 and will not impact this Plan.

Overall, engagement is a dialog between proponents and Indigenous communities to maintain two-way communication regarding a project as well as providing a record and disposition of questions, issues, and potential impacts of a project to Aboriginal and Treaty rights, if any.

3.1 IDENTIFIED INDIGENOUS COMMUNITIES

In collaboration with the CNSC, it had been determined that the following Indigenous communities have Aboriginal and treaty rights and/or interests along the transportation route from DNGS and the BWXT Medical facility and will be engaged. The primary transportation route is highway 401 east to 416, north on 416 to Ottawa and west on 417 to the BWXT Medical site. (See Table 1 below.)

Table 1: Identified Indigenous Communities

Indigenous Community	Cultural Affiliation	Political Representation
Mississaugas of Scugog Island First Nation	Mississauga	Williams Treaties First Nations (WTFN) & Anishinabek Nation (AN)
Curve Lake First Nation	Mississauga	Williams Treaties First Nations (WTFN) & Anishinabek Nation (AN)
Hiawatha First Nation	Mississauga	Williams Treaties First Nations (WTFN) & Association of Iroquois and Allied Indians (AIAI)
Alderville First Nation	Mississauga	Williams Treaties First Nations (WTFN) & Anishinabek Nation (AN)
Chippewas of Rama FN	Chippewa	Williams Treaties First Nations (WTFN) & Anishinabek Nation (AN)

Chippewas of Beausoleil First Nation	Chippewa	Williams Treaties First Nations (WTFN) & Anishinabek Nation (AN)
Chippewas of Georgina Island First Nation	Chippewa	Williams Treaties First Nations (WTFN) & Anishinabek Nation (AN)
Kawartha Nishnawbe	Mississauga	Independant
Mohawks of the Bay of Quinte	Haudenosaunee	Association of Iroquois and Allied Indians (AIAI)
Six Nations of the Grand River	Haudenosaunee	Six Nations of the Grand River (SNGR)
Métis Nation of Ontario Regions 6 & 8	Métis	Métis Nation of Ontario (MNO)
Algonquins of Ontario	Algonquin	Algonquins of Ontario (AOO)
Algonquins of Pikwakanagan	Algonquin	Anishinabek Nation (AN)
Kitigan Zibi First Nation	Algonquin	Algonquin Anishinabeg Nation Tribal Council (AANTC)

Table 2: Indigenous Community Contacts

Indigenous Community	Leadership	Consultation
Mississaugas of Scugog Island First Nation MSIFN Homepage (scugogfirstnation.com) 22521 Island Rd, Port Perry, ON L9L 1B6 905-985-3337	Chief Kelly LaRocca	Don Richardson (consultant) don.richardson@threefires.com

Curve Lake First Nation Curve Lake First Nation – Home to Mississaugas of the Great Anishinaabe Nation 22 Winookeedaa Road Curve Lake, Ontario K0L1R0 705-657-8045	Chief Keith Knott Keithk@curvelake.ca	Paige Williams, Coordinator paigew@curvelake.ca Francis Chua (consultant) francis@francischua.com relationships@4directions co nservation.com
Hiawatha First Nation Hiawatha First Nation 23 Paudash St, Hiawatha, ON K9J 0E6 705-295-4421	Chief Laurie Carr chiefcarr@hiawathafn.ca	Sean Davison, Coordinator sdavison@hiawathafn.ca
Alderville First Nation alderville.ca 11696 Line Rd 2, Roseneath, ON K0K 2X0 905-352-2011	Chief Taynar Simpson Tsimpson@alderville.ca	Julie Kapyrka, Coordinator jkapyrka@alderville.ca
Chippewas of Rama FN The Chippewas of Rama First Nation in Rama, Ontario	Chief Ted Williams tedw@ramafirstnation.ca	Ben Benson, Coordinator consultation@ramafirstnation.ca

5884 Rama Rd, Suite 200, Rama ON, L3V 6H6 1-866-854-2121		
Chippewas of Beausoleil First Nation http://chimnissing.ca/ 11 O'Gemaa Miikaan Christian Island, ON L9M 0A9 705-247-2251	Chief Joanne P. Sandy jsandy@chimnissing.ca	Dana Monague, Coordinator danamonague@chimnissing.ca
Chippewas of Georgina Island First Nation https://georginaisland.com/ R.R.#2 Box N-13 Sutton West, ON L0E 1R0 705-437-1337	Chief Donna Big Canoe Donna.bigcanoe@georginaisland.com	JL Porte. Coordinator jl.porte@georginaisland.com
Kawartha Nishnawbe First Nation Care of Christopher Reid, Solicitor 38 Nursewood Road Toronto, ON M4E 3R8 kawarthanishnawbecouncil@outlook.com lawreid@aol.com		Independent

Mohawks of the Bay of Quinte Mohawks of the Bay of Quinte | Mohawks of the Bay of Quinte (mbq-tmt.org) 24 Meadow Drive Tyendinaga Mohawk Territory, ON K0K 1X0 613-396-3424	Chief R. Donald Maracle rdonm@mbq-tmt.org	Lisa Maracle Director of Community Services lisam@mbq-tmt.org Cassie Thompsson, Coordinator consultation@mbq-tmt.org)
Six Nations of the Grand River 1695 Chiefswood Rd PO Box 5000 Ohsweken ON N0A 1M0 519-445.-201	Chief Mark Hill Election in early November 2023 (Chief Hill is not running.)	Peter Graham Land Use Officer Lands & Resources Six Nations of the Grand River petergraham@sixnations.ca
Métis Nation of Ontario Regions 6 https://www.Métisnation.org/community-councils/peterborough-and-district-wapiti-Métis-council/ Region 6 Suite 102 – 1054 Monaghan Road Peterborough, ON, K9J 5L3 Métis Nation of Ontario Regions 8 Oshawa and Durham Métis Council	President Christa Lemelin PWMC@Métisnation.org President Helen Giacchetta oshawadurhamMétiscouncil@gmail.com	Ethan Roy, Consultation Advisor ethanr@Métisnation.org

Region 8 Suite 101 – 74 Simcoe Street South Oshawa, ON, L1H 4G6		
Algonquins of Ontario https://www.tanakiwin.com/ 31 Riverside Drive, Suite 101 Pembroke, ON K8A 8R6 1.855.735.3759	Executive Director Jim Meness jmeness@tanakiwin.com	Melissa Knight, Senior Project Development Manager mknight@tanakiwin.com
Anamikàge (Welcome) - Algonquins of Pikwakanagan 1657A Mishomis Inamo Pikwakanagan, ON K0J 1X0 613-625-2800	Chief Greg Sarazin Chief.pik@pikwakanagan.ca	Amanda Two-Axe Kohoko consultation@pikwakanagan.ca Laura Sarazin Assistant.consultation@pikwakanagan.ca
Kitigan Zibi Anishinabeg Kitigan Zibi P.O. Box 309 1 Paganakomin Mikan Maniwaki, Quebec J9E 3C9 (819) 449-5593	Chief Dylan Whitedeck dylan.whiteduck@kza.qc.ca.	Valerie Brazeau Valerie.Brazeau@kza.qc.ca

3.2 COMMUNICATIONS AND ENGAGEMENT

In Q4 2023 a formal notification by letter via email will be shared with the identified Indigenous communities. The letter will briefly describe the isotopes and their

purposes, the process of their production, the necessity of a license amendment and other key facts. The notification letter will also state that communities will be contacted to arrange mutually agreeable times to hold an initial meeting in person and/or virtually. The goal will be to be hold the initial meetings by the end of Q2 2024 and additional meetings, presentations, community visits, etc., during the course of 2024.

OPG's Indigenous Relations and Partnerships Department (IRPD) will arrange for the delivery of the notification letter and the follow-up meetings. IRPD will support the Project, but Project meetings will require representation by Project team members to explain technical questions and disposition issues and questions. IRPD will also assist the Project Lead in meeting CNSC reporting requirements, e.g., the maintenance of an engagement log and required meetings.

The proposed roll out of communications and engagement with the Indigenous communities is proposed as follows.

Table 2: Communications and Engagement

Date	Item	Indigenous Community
November 2023	Notification Letter	Sent via email to all Indigenous community contacts.
December 2023	Notification Letter Follow-Up	Follow-up to secure initial presentation meetings.
January 2024	Presentation Meetings	-Williams Treaties First Nations -Kawartha Nishnawbe
February 2024	Presentation Meetings	Métis Nation of Ontario Regions 6 & 8 -Mohawks of the Bay of Quinte -Six Nations
March 2024	Follow-Up Meetings	-Algonquins of Ontario -Algonquins of Pikwakanagan -Kitigan Zibi
April 2024	Follow-Up Meetings	-As required.

May 2024	Follow-Up Meetings	-As required.
June 2024	Follow-Up Meetings	-As required.
July 2024	Follow-Up Meetings	-As required.
August 2024	Follow-Up Meetings	-As required.
September 2024	Follow-Up Meetings	-As required.
October 2024	Follow-Up Meetings	-As required.
November 2024	Follow-Up Meetings	-As required.
December 2024	Follow-Up Meetings	-As required.

3.3 COMMUNICATION AND ENGAGEMENT

The Communications and Engagement Log will be maintained by IRPD and will be available to Project partners, CNSC and other parties as deemed appropriate. An example of the format is below.

Table 4: Communications and Engagement Log (Format Example)

Date	OPG/Project Contacts	Contact Type	Indigenous Community	Comments, Questions, Issues	Disposition
Feb 5/2024	Kenn Ross, Project contacts.	Meeting	-Curve Lake FN -Hiawatha FN -Alderville FN - Mississaugas of Scugog Island	Transport safety. Purpose/use of isotopes.	Detailed safety case discussion re: containment packaging. Discussion on medical uses of isotopes and current needs in Canada.

3.4 REPORT ON ENGAGEMENT

The information collected through the Engagement Log will be used to generate a Report on Engagement as required by OPG, its partners and/or CNSC.

4.0 PROJECT ENGAGEMENT COSTS

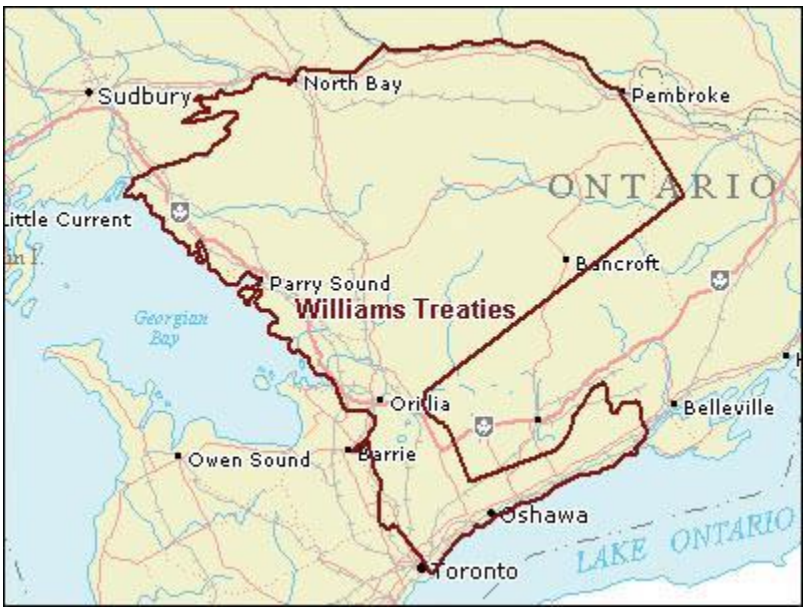
Any costs incurred as a result of engagement with Indigenous communities will be covered by the Project. These costs may include but not be limited to community honouraria and staff time, catering, room rentals, mileage, etc. Related costs are not expected to be onerous.

5.0 CO-ORDINATION WITH PUBLIC ENGAGEMENT

The Project team and the Indigenous Relations Lead will co-ordinate with the Public Engagement Lead to ensure that Project messaging is consistent and mutually supporting. It is expected that the respective Leads will share their outreach plans, products and feedback from the public and Indigenous communities.

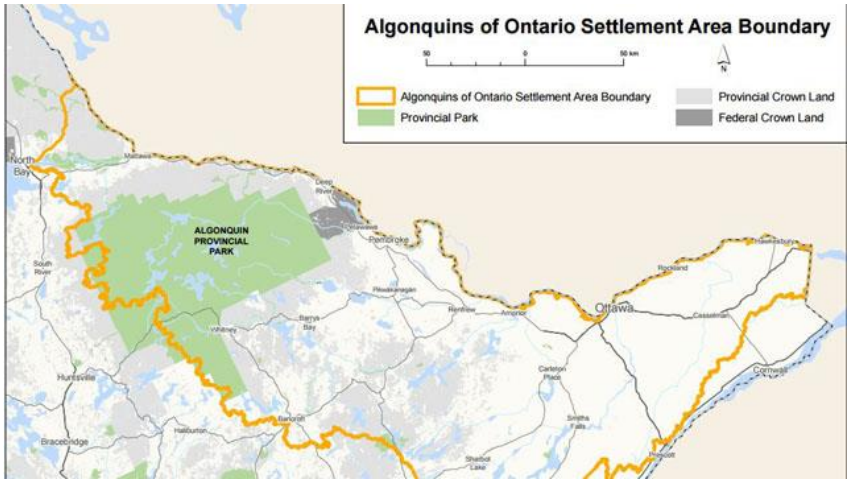
Appendix A: TERRITORIAL MAPS

Williams Treaties First Nations:



Mohawks of the Bay of Quinte:

Algonquins of Ontario Agreement in Principle



Métis Nation of Ontario Regions

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

CD# NK38-CORR-00531-25810 P

Submission Title: **Darlington NGS – Revised Redacted Application for Amendment to the Darlington NGS Power Reactor Operating Licence 13.03/2025 for Additional Isotope Production**

Regulatory Commitments (REGC):

No.	Description	Date to be Completed
	None.	

Regulatory Management Action (REGM): As per Appendix A, Attachment 3

No.	Description	Date to be Completed
	Various – Appendix A	

Regulatory Obligation Action (REGO):

No.	Description	Date to be Completed
	None.	

Concurrence Requested: OPG is requesting the Canadian Nuclear Safety Commission amend the Darlington NGS PROL 13.03/2025 to authorize OPG to possess, transfer, process, package, manage, and store the Lutetium-177 and Yttrium-90 radioisotopes and their associated decay isotopes.