



# Record of Decision

DEC 25-H107

In the Matter of

Applicant Ontario Power Generation Inc.

Subject Application to Amend the Licensing Basis for the Darlington Nuclear Generating Station to Install and Operate a Target Delivery System on Additional Units

Summary Record of Decision Date December 19, 2025

Detailed Record of Decision Date April 10, 2026

**RECORD OF DECISION – DEC 25-H107**

Applicant: Ontario Power Generation Inc.

Address/Location: 700 University Avenue, Toronto, Ontario, M5G 1X6

Purpose: Application to amend the licensing basis for the Darlington Nuclear Generating Station to install and operate a Target Delivery System on additional units

Application received: August 8, 2025

Hearing: *Notice of Hearing in Writing* published on September 29, 2025

Summary Record of Decision Date: December 19, 2025

Detailed Record of Decision Date: April 10, 2026

Panel of Commission: P. Tremblay

**Licensing Basis: Amended**

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## 1.0 INTRODUCTION

1. On [August 8, 2025](#), Ontario Power Generation Inc. (OPG) submitted an application to the Canadian Nuclear Safety Commission<sup>1</sup> (CNSC) to amend the licensing basis<sup>2</sup> for the power reactor operating licence (PROL) for its [Darlington Nuclear Generating Station](#) (Darlington NGS) located in the Municipality of Clarington, Ontario. The Darlington NGS is located on the traditional lands and waters of the Michi Saagiig Anishinaabeg, the Gunshot Treaty (1787-88), the Williams Treaties (1923), and the Williams Treaties Settlement Agreement (2018).
2. The Darlington NGS includes 4 CANDU<sup>3</sup> reactors and their associated equipment.<sup>4</sup> The current licence, PROL 13.00/2045, [was issued in September 2025](#),<sup>5</sup> and is valid until November 30, 2045.
3. The licensing basis authorized OPG to produce Molybdenum-99 (Mo-99), Lutetium-177 (Lu-177) and Yttrium-90 (Y-90) using the isotope Target Delivery System<sup>6</sup> (TDS) installed on Darlington NGS Unit 2. OPG applied for an amendment to its licensing basis to authorize the installation and operation of a TDS on additional reactor units<sup>7</sup> for the production of any radionuclides authorized by its licence. On December 19, 2025, the Commission amended the licensing basis for the Darlington NGS and issued a [Summary Record of Decision](#).<sup>8</sup> This detailed *Record of Decision* does not replace that decision but provides the reasons for that decision.

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<sup>1</sup> The *Canadian Nuclear Safety Commission* is referred to as the “CNSC” when referring to the organization and its staff in general, and as the “Commission” when referring to the tribunal component.

<sup>2</sup> The licensing basis is a set of requirements and documents for a regulated facility or activity comprising:

- the regulatory requirements set out in the applicable laws and regulations
- the conditions and safety and control measures described in the facility’s or activity’s licence and the documents directly referenced in that licence
- the safety and control measures described in the licence application and the documents needed to support that licence application

<sup>3</sup> All operating nuclear power reactors in Canada are CANDU (Canadian Deuterium-Uranium) reactors. CANDU reactors are pressurized heavy water reactors that use natural uranium as fuel and heavy water as a coolant and moderator.

<sup>4</sup> Each of the reactors corresponds to a unit and are known as: Unit 1, Unit 2, Unit 3 and Unit 4.

<sup>5</sup> Record of Decision DEC 25-H2, *Application to Renew the Power Reactor Operating Licence for the Darlington Nuclear Generating Station*, September 24, 2025.

<sup>6</sup> The TDS was referred to as the Mo-99 Isotope Irradiation System (Mo-99 IIS) in CNSC Record of Decision DEC 21-H107. Following a subsequent licence amendment decision (DEC 25-H100), the system will no longer be used exclusively to produce Mo-99.

<sup>7</sup> “Additional units” correspond to only Unit 3 in CMD 25-H107, whereas in OPG’s Letter and Application, this term corresponds to Units 1, 3, and 4.

<sup>8</sup> Summary Record of Decision DEC 25-H107, *Application to Amend the Licensing Basis for the Darlington Nuclear Generating Station to Install and Operate a Target Delivery System on Additional Units*, December 19, 2025.

4. The Commission previously authorized the production of radionuclides using the TDS on Unit 2 in 2 decisions:
  - In [October 2021](#),<sup>9</sup> the Commission amended the Darlington NGS PROL to authorize the construction of a TDS to produce Mo-99 on Darlington NGS Unit 2 (DEC 21-H107).
  - In [May 2025](#),<sup>10</sup> the Commission amended the Darlington NGS PROL to authorize the production of two additional radionuclides, Y-90 and Lu-177, and established a regulatory hold point (RHP) prior to permitting full scale production of those radionuclides (DEC 25-H100). This authorization was contingent on OPG validating and demonstrating that operation of the TDS associated with the production and handling of Mo-99 remains the bounding case for the other radionuclides (Y-90 and Lu-177) on Unit 2.
5. In DEC 21-H107, the Commission required that OPG obtain authorization from the Commission prior to installing a TDS on additional reactor units, and demonstrate that the production of Mo-99 in any other unit is a low-risk activity that can be executed safely.<sup>11</sup> OPG is now seeking authorization to install and operate an isotope TDS on the remaining units at the Darlington NGS for the production of any radionuclides already authorized by the Commission on Unit 2. OPG's application included documentation to support a specific TDS installation and operation on Unit 3, which is planned for a 2026 outage window. OPG proposed that this application can serve as a basis for authorization to install and operate a TDS on the remaining Units 1 and 4 at the Darlington NGS.

### Issues

6. The licence, PROL 13.00/2045, authorizes OPG to operate the Darlington NGS, including equipment for the production of Y-90, Mo-99 and Lu-177, including the associated decay radionuclides.<sup>12</sup> Licence condition 15.6 of the licence requires OPG to implement and maintain an operations program for the use of the TDS to produce the radionuclides described in section IV (vi) (2).
7. Licence condition G.1, *Licensed Activities*, of PROL 13.00/2045 requires that:

*The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:*

*(i) the regulatory requirements set out in the applicable laws and regulations*

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<sup>9</sup> CNSC Record of Decision, *Application to Amend Power Reactor Operating Licence PROL 13.02/2025 to Authorize the Production of Molybdenum-99 at the Darlington Nuclear Generating Station*, DEC 21-H107, October 26, 2021.

<sup>10</sup> CNSC Record of Decision, *Application to Amend Darlington Nuclear Generating Station Power Reactor Operating Licence 13.05/2025 for the Production of Additional Isotopes using the Target Delivery System*, DEC 25-H100, May 23, 2025.

<sup>11</sup> DEC 25-H107, Paragraphs 12, 79, and 86.

<sup>12</sup> PROL 13.00/2045, section IV (vi) (2)

- (ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence
- (iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC, hereinafter "the Commission").

8. OPG's application does not call for a licensing decision that is specifically contemplated under section 24 of the [Nuclear Safety and Control Act](#)<sup>13</sup> (NSCA), as a change to the licensing basis does not necessarily amend the terms of a licence and would not in this case. What is requested would not change the licensed activities authorized in the current licence. The Commission has considered:
- whether any requirements under the [Impact Assessment Act](#)<sup>14</sup> (IAA) apply to this application
  - whether OPG is qualified to carry on the activity that the licence, including the proposed changes to the licensing basis, would authorize
  - whether, in carrying on that activity in the changed manner contemplated, OPG will 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
9. As an agent of the Crown, the Commission recognizes its role in fulfilling the Crown's constitutional obligations, along with advancing reconciliation with Canada's Indigenous peoples. The Commission's responsibilities include the duty to consult and, where appropriate, accommodate Indigenous interests where the Crown contemplates conduct which may adversely impact potential or established Aboriginal<sup>15</sup> or treaty rights.<sup>16</sup> As such, the Commission must determine what engagement and consultation steps and accommodation measures are called for, and whether what has been done satisfies the obligation of consultation and, where appropriate, accommodation of implicated Aboriginal or treaty rights. A determination of what the duty to consult and accommodate requires is informed by the principles and provisions of the [United Nations Declaration on the Rights of Indigenous Peoples](#)<sup>17</sup> (UNDRIP), as a result of its adoption into Canadian law via the [United Nations Declaration on the Rights of Indigenous Peoples Act](#)<sup>18</sup> (UNDA).<sup>19</sup> Where the duty to consult is triggered, the Commission must be satisfied that the duty to consult has been met prior to making its licensing decision.

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<sup>13</sup> S.C. 1997, c. 9.

<sup>14</sup> S.C. 2019, c. 28, s. 1.

<sup>15</sup> "Aboriginal" is the term used in this document when referring to the Crown's duty to consult as that is the term used in section 35 of the *Constitution Act, 1982*. In all other cases, "Indigenous" is the preferred terminology and used accordingly.

<sup>16</sup> *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73; *Taku River Tlingit First Nation v. British Columbia (Project Assessment Director)*, 2004 SCC 74.

<sup>17</sup> *United Nations Declaration on the Rights of Indigenous Peoples*, United Nations, September 2007.

<sup>18</sup> S.C. 2021, c. 14.

<sup>19</sup> *Kebaowek First Nation v. Canadian Nuclear Laboratories*, 2025 FC 319.

### Public Hearing in Writing

10. On September 29, 2025, the Commission published [Notice of Hearing in Writing](#)<sup>20</sup> for this matter, which invited requests to intervene by November 27, 2025.
11. The President of the Commission established himself as a Panel of the Commission to consider the application.<sup>21</sup> The Commission, in conducting a public hearing based on written materials, considered written submissions from OPG ([Letter](#), [Application](#)) and CNSC staff ([CMD 25-H107](#)). The Commission also considered a written submission from 1 intervenor (see Appendix A). A [Summary Record of Decision](#) was issued on December 19, 2025.
12. In making its decision, the Commission sent questions to OPG through [CMD 25-H107-Q](#). OPG staff provided responses to the Commission's questions in [CMD 25-H107.1](#). The Commission is satisfied with the responses provided by OPG.
13. In determining whether a public hearing will be an oral hearing or a hearing in writing, the Commission is guided by the direction of the NSCA that "all proceedings before the Commission must be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit", and it considers such things as whether the proposed licensing action would authorize new or different activities or take novel or controversial approaches, the complexity of the matter under consideration, the proposed timing and steps in the lifecycle of the facility or operation, and the anticipated level of interest from intervenors. For this matter, given the low safety significance of the application, the Commission determined that a hearing in writing was appropriate.

### Mandate of the Commission

An intervention addressed the economic benefits of producing medical isotopes. The Commission notes that, as the regulatory authority over nuclear matters in Canada, it has no economic mandate and does not base its decisions on the economic impact of a facility. The Commission's mandate is found in section 9 of the NSCA and includes the Commission's object to regulate the production and use of nuclear energy to prevent unreasonable risk to national security, the environment, and the health and safety of people, and to implement the international obligations to which Canada has agreed.

## **2.0 DECISION**

14. The Commission is satisfied that OPG has demonstrated that the installation of a TDS on Unit 3 at the Darlington NGS is a low-risk activity that can be executed by OPG. Therefore, the Commission amends the licensing basis for OPG's Darlington NGS located in the Municipality of Clarington, Ontario. OPG is authorized to install and

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<sup>20</sup> *Notice of Hearing in Writing*, CNSC, September 29, 2025.

<sup>21</sup> See section 22 of the NSCA.

operate a TDS on Unit 3 at the Darlington NGS for the production of any radionuclides authorized in PROL 13.00/2045 (i.e. Y-90, Mo-99, and Lu-177), subject to verification by CNSC staff.<sup>22</sup> The terms and conditions of the current licence for the Darlington NGS, PROL 13.00/2045, remain unchanged.

15. The decision by the Commission was made based on its consideration of this matter and the following conclusions:
  - the Commission is satisfied that an impact assessment under the IAA is not required
  - the contemplated licensing basis amendment does not present any adverse impact to the exercise of established or potential Indigenous and/or treaty rights as continued operations will not change the Darlington NGS site characterization
  - the Commission's responsibility to uphold the honour of the Crown and its constitutional obligations with regard to engagement and consultation respecting Indigenous interests have been satisfied
  - OPG is qualified to carry on the activities that the amended licensing basis will authorize
  - OPG, in carrying on these activities, will 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
16. The Commission further authorizes the installation and operation of a TDS on Units 1 and 4, subject to the same RHP previously established by the Commission in DEC 25-H100 for Unit 2. The authority delegated to CNSC staff for the release of that RHP remains unchanged and continues to apply. To be clear, with this decision, the RHP established under DEC 25-H100 for licence condition 15.4 ("The licensee shall obtain the approval of the Commission, or consent of a person authorized by the Commission, prior to the removal of established regulatory hold points.") shall be applied to the TDS on all other reactor units. In administering the RHP, CNSC staff will confirm that the installation and operation of a TDS on units at the Darlington NGS remains a low-risk activity, within the licensing basis and safety case previously accepted by the Commission.
17. The Commission delegates authority to the following CNSC staff to accept future TDS installations and operations on Units 1 and 4 at the Darlington NGS:
  - Executive Vice President/Chief Operations Officer (EVP/COO)
  - Director General of the Directorate of Power Reactor Regulation (DG-DPRR)
18. In carrying out its delegated authority, the Commission expects CNSC staff to verify that OPG's installation, commissioning and operation of a TDS on any unit at the Darlington NGS remains within the safety case previously established for Unit 2, and within the

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<sup>22</sup> CNSC staff verification is conducted as required by the RHP established in DEC 25-H100 for Unit 2.

licensing basis, as established in DEC 21-H107 and DEC 25-H100 and this *Record of Decision*. In conducting this verification, CNSC staff shall confirm that OPG has followed its Engineering Change Control (ECC) process, that the resulting design is consistent with all applicable regulatory requirements, and that an adequate safety case has been prepared demonstrating that TDS operations remain a low-risk activity. Should CNSC staff determine that any TDS installation or operation falls outside the authorized safety case or licensing basis, OPG will be required to return to the Commission for authorization.

19. The Commission emphasizes that any proposal by OPG to produce radioisotopes other than those currently authorized (i.e. Y-90, Mo-99, and Lu-177) would require a licence amendment. Any such application would be subject to a public hearing of the Commission.
20. With this decision, the Commission directs CNSC staff to update the licence conditions handbook (LCH) for the Darlington NGS as described in CMD 25-H107,<sup>23</sup> and in a manner consistent with the Commission's delegation of authority described above.

### **3.0 ISSUES AND COMMISSION FINDINGS**

21. In making its decision, the Commission considered a number of relevant issues and submissions relating to OPG's qualification to carry out the activities the amended licensing basis would authorize. The Commission also considered the adequacy of OPG's proposed measures for protecting the environment, the health and safety of persons, national security and international obligations to which Canada has agreed.
22. The Commission's analyses for its decision in this matter are set out within the following sections of this *Record of Decision*:
  - Section 3.1 Overview of the Target Delivery System
  - Section 3.2 Applicability of the *Impact Assessment Act*
  - Section 3.3 Summary of Views of Hearing Participants
  - Section 3.4 OPG's Safety and Control Measures with Respect to the Safety and Control Areas
  - Section 3.5 Indigenous Engagement and Consultation
  - Section 3.6 Other Matters of Regulatory Importance
  - Section 3.7 Licensing Basis Amendment

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<sup>23</sup> CMD 25-H107, Section 1.4 and Appendix A.

### 3.1 Overview of the Target Delivery System

23. 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. Fresh targets are manually loaded into a target loading device, from where they are propelled via a pneumatic/hydraulic system into one of four baskets located above the reactor core. The baskets are lowered by a cable into the reactor core to expose the targets to the reactor's neutron flux, where the targets are irradiated. Following irradiation, the basket is raised out of the core and held above the reactor for a predefined dwell-time.<sup>24</sup> The targets are then propelled via a pneumatic/hydraulic system to a flask loading device where they are packaged in a shielded flask to be transported off-site for processing.<sup>25</sup>
24. OPG has declared that the Unit 2 TDS is available for Mo-99 operations. The Unit 2 TDS is subject to the CNSC's ongoing regulatory oversight for the Darlington NGS. Before Unit 2 can begin producing additional isotopes (i.e. Y-90 and Lu-177), CNSC staff must verify that all required conditions have been met, including the release of the existing RHPs under Licence Condition 15.4.<sup>26</sup>

### 3.2 Applicability of the *Impact Assessment Act*

25. In coming to its decision, the Commission is first required to determine whether any requirements under the IAA apply to the application and whether an impact assessment is required.
26. Under the IAA and its [\*Physical Activities Regulations\*](#),<sup>27</sup> impact assessments are required for projects with significant potential for adverse environmental effects in areas of federal jurisdiction. The proposed licensing basis amendment to the PROL licence does not involve activities listed in the Regulations or meet the definition of a project on federal lands.
27. The Commission concludes that there is no requirement under the IAA for an impact assessment to be completed. The Commission is also satisfied that there are no other applicable requirements of the IAA to be addressed in this matter.<sup>28</sup>

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<sup>24</sup> Dwell-time is the period of time when the targets are held above the reactor core but below the reactivity mechanism deck to reduce the radiological hazard associated with short-lived high-energy activation products prior to harvesting and shipment.

<sup>25</sup> The activity of inserting unirradiated target capsules into the reactor is referred to as "target-seeding" and the activity of removing the target capsules from the reactor after the required irradiation period is referred to as "target-harvesting".

<sup>26</sup> CMD 25-H107, Section 3.1.2, page 11.

<sup>27</sup> SOR/2019-285.

<sup>28</sup> The IAA can impose other requirements on federal authorities in respect of authorizing projects that are not designated as requiring an impact assessment, including projects that are to be carried out on federal lands, or projects outside of Canada. This licensing basis amendment does not engage any such applicable IAA requirements.

### 3.3 Summary of Views of Hearing Participants

28. In its consideration of this application, the Commission carefully considered all submissions and perspectives received, in accordance with its mandate and the scope of this public hearing in writing. The Commission appreciates the efforts and contributions of all participants.
29. OPG provided a summary of its position with respect to its application, including that:<sup>29</sup>
- OPG does not expect any safety or operational issues to result from the installation of TDSs on additional units
  - installation and operation of TDSs on additional units would not impact the Darlington NGS's licensing basis governance, programs, and processes
  - modifications for installing and operating TDSs on additional units would be carried out in accordance with OPG's ECC program, supported by a robust safety case and safety assessments that confirm safe reactor operation, public safety, and environmental protection
  - the cumulative effects from operating additional TDSs would have a negligible impact on the environment
  - OPG will continue to meet Canada's international obligations under the [\*Treaty on the Non-Proliferation of Nuclear Weapons\*](#)<sup>30</sup>
30. OPG submitted that the complete comprehensive Unit 2 TDS assessment, *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 the Darlington NGS. OPG added that the commissioning and operation of the Unit 2 TDS at the Darlington NGS demonstrated that:<sup>31</sup>
- the Unit 2 TDS operates as designed
  - containment integrity is maintained
  - reactor physics and continued safe reactor operation have been confirmed
  - the radiation fields around the Unit 2 TDS are within the range predicted in the As Low As Reasonably Achievable (ALARA) Assessment
  - emissions during Unit 2 TDS operations are within those predicted in the Predictive Effects Assessment
31. In its submission,<sup>32</sup> CNSC staff provided an update on directives from DEC 21-H107 and DEC 25-H100 related to the Unit 2 TDS and associated commitments. CNSC staff addressed those directives in evaluating OPG's performance and readiness to install and commission a TDS on Unit 3 and future units.

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<sup>29</sup> OPG's Application, Attachment 1, Section 4.0.

<sup>30</sup> INFCIRC/140.

<sup>31</sup> OPG's Application, Attachment 1, Section 1.2.2.

<sup>32</sup> CMD 25-H107, Section 3, page 7.

32. CNSC staff recommended that the Commission authorize the installation and operation of a TDS on Unit 3 for the production of any radionuclides authorized by the Commission. CNSC staff assessed the following:<sup>33</sup>
- OPG's request would not change any of the currently authorized activities and conditions of the PROL, nor any of the accompanying licence-related accountabilities and responsibilities<sup>34</sup>
  - OPG remains qualified and competent in implementing its licensed activities
  - OPG would make adequate provision for the protection of the environment and the health of persons<sup>35</sup>
  - OPG has met the criteria of the Commission's directives regarding the expansion of the TDS to additional units at Darlington NGS as required by DEC 21-H107<sup>36</sup>
  - installation and operation of additional TDSs on additional units at the Darlington NGS for the purposes of producing Mo-99, Lu-177, and Y-90 is a low-risk activity that can be conducted safely and within the established licensing basis
  - review of OPG's submissions did not raise concerns with the evolutionary and unit specific differences in the next iteration of the TDS design and safety case<sup>37</sup>
  - OPG's supporting case confirms that any required design changes to the TDS were being managed within OPG's approved ECC process and do not have an adverse impact on the safety case
  - OPG has made adequate efforts to engage with Indigenous Nations and communities, and the public, as required by its licence
33. The Commission received 1 intervention for this hearing. The Society of United Professionals ([CMD 25-H107.2](#)) expressed support for OPG's Application.

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<sup>33</sup> CMD 25-H107, Section 1.3, page 5.

<sup>34</sup> CMD 25-H107, Section 1.1.1, page 4.

<sup>35</sup> CMD 25-H107, Section 2, page 7.

<sup>36</sup> CMD 25-H107, Section 3.2, page 14.

<sup>37</sup> CMD 25-H107, page 1.

### 3.4 OPG's Safety and Control Measures with Respect to the Safety and Control Areas

34. The Commission examined OPG's proposed safety and control measures with respect to the CNSC's [safety and control area](#)<sup>38</sup> (SCA) framework, for the purpose of evaluating OPG's licensing basis amendment application. The Commission's evaluation includes consideration of the proposed safety and control measures of relevance to the application, including with respect to:

- Management System
- Operating Performance
- Safety Analysis
- Physical Design
- Fitness for Service
- Environmental Protection

35. With respect to the remaining SCAs, OPG submitted that:

- a plan was created to define the scope of the Human Factors Engineering (HFE) activities for the Darlington NGS TDS Unit 3 project and describe the planned approach for the effective management of those activities and timely integration of HFE into the design<sup>39</sup>
- training has been updated to include Unit 2 TDS operations, and updates to station training for TDS installation and operation on additional units would be identified and tracked to completion<sup>40</sup>
- a memo outlining the required updates to the ALARA Assessment to account for the installation of TDS on additional units had been prepared, and the revised assessment would be submitted to CNSC staff once completed<sup>41</sup>
- since the Unit 3 TDS design closely mirrors that of Unit 2, the Unit 2 Fire Protection Assessment remains applicable, and the component and physical differences do not affect compliance with CSA N293<sup>42</sup> and the National Building Code of Canada or require changes to the Fire Hazard Assessment or Fire Safe Shutdown Analysis<sup>43</sup>
- the additional dose to a member of the public from TDS operation was estimated as an additional 1.2% dose above the current dose estimate constituting 0.0009%

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<sup>38</sup> SCAs are the technical topics used by CNSC staff across all regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance.

<sup>39</sup> OPG's Application, Attachment 1, Section 2.2.1.1, and *Darlington Target Delivery System Human Factors Engineering Program Plan*, Enclosure 6 of OPG's Application, NK38-PLAN-30550-00106-R000, August 8, 2025.

<sup>40</sup> OPG's Application, Attachment 1, Section 2.2.

<sup>41</sup> OPG's Application, Attachment 1, Section 4.0 and *Summary of Planned Updates to the Target Delivery System ALARA Assessment to Account for Target Delivery System Installation in Additional Units*, Enclosure 3 of OPG's Application, NK38-CORR-30550-1412375-R000, August 8, 2025.

<sup>42</sup> CSA Group Standard, CSA N293, *Fire protection for CANDU nuclear power plants*, 2012 (R2022).

<sup>43</sup> *Fire Protection Memo for Unit 3 TDS, PR-16-8 7897, Master EC 166617*, Enclosure 7 of OPG's Application, NK38-CORR-30550-1417529, August 8, 2025, and OPG's Application, Attachment 1, Section 2.10.5.1.

of the regulatory dose limit of 1 millisievert per year (mSv/year) for a member of the public, and approximately 0.0007% of the dose from background radiation in the vicinity of the Darlington NGS, which is 1.4 mSv/year<sup>44</sup>

36. CNSC staff provided an overview and assessment of OPG's application. CNSC staff submitted the following:
- experience obtained through regulatory oversight of the Unit 2 TDS would be applied to the oversight of the Unit 3 TDS and any subsequent installations<sup>45</sup>
  - OPG had completed all activities related to the updated design, installation and commissioning of the TDS for Unit 2 through its ECC process<sup>46</sup>
  - additional installations of TDS beyond Unit 3, would be handled in accordance with processes in place, both for OPG and CNSC staff, regarding plant modifications to confirm that they remain within OPG's licensing basis<sup>47</sup>
  - CNSC staff would continue to provide appropriate oversight of OPG's ECC process and the turnover to operations, and it would verify selections of project governance and ECC deliverables as the project progresses<sup>48</sup>

#### 3.4.1 Management System

37. The management system SCA covers the framework that establishes the processes and programs required to ensure that OPG achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture. Licence condition 1.1 of PROL 13.00/2045 requires OPG to implement and maintain a management system for the Darlington NGS.
38. The [\*Class I Nuclear Facilities Regulations\*](#)<sup>49</sup> (CINFR) state that a licence application for a Class I nuclear facility shall contain "the proposed management system for the activity to be licensed, including measures to promote and support safety culture."<sup>50</sup> The [\*General Nuclear Safety and Control Regulations\*](#)<sup>51</sup> (GNSCR) contain requirements that form the basis of a management system.<sup>52</sup>
39. CSA N286, *Management System Requirements for Nuclear Facilities*<sup>53</sup> provides an overall management framework and direction to develop and implement sound management practices and controls for the licensing basis. CNSC regulatory document<sup>54</sup>

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<sup>44</sup> OPG's Application, Attachment 1, Section 2.7.5.

<sup>45</sup> CDM 25-H107, Section 3.1.2, page 10.

<sup>46</sup> CDM 25-H107, Section 3.1.2, page 9.

<sup>47</sup> CDM 25-H107, Section 1.1, page 4.

<sup>48</sup> CMD 25-H107, Section 3.1.2, page 9.

<sup>49</sup> SOR/2000-204.

<sup>50</sup> Paragraph 3(d) of the CINFR.

<sup>51</sup> SOR/2000-202.

<sup>52</sup> Section 3 of the GNSCR.

<sup>53</sup> CSA Group Standard, CSA N286-12, *Management System Requirements for Nuclear Facilities*, 2012 (R2022).

<sup>54</sup> CNSC [regulatory documents](#) are typically referred to as REGDOCs.

[REGDOC-2.1.2, \*Safety Culture\*](#)<sup>55</sup> sets out requirements and guidance for fostering a healthy safety culture and conducting safety culture assessments.

40. OPG provided the Commission with information on how its management system applies to the proposed licensing basis amendment, including in the following performance areas:<sup>56</sup>

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

41. OPG submitted that:

- the installation and operation of TDSs on additional units would not require any changes to the licensing basis of the management system SCA
- continued safe reactor operation, compliance with operating limits and regulatory requirements would take priority over medical isotope production
- a strong safety culture remains OPG's top priority, and the installation and operation of TDSs on additional units would be carried out in line with this commitment
- before declaring additional TDS units in service, resource planning would ensure adequate staffing without changing the organization or its licensing basis
- OPG is responsible for ensuring all on-site contractor activities meet its safety requirements and would oversee contracted workers performing TDS work at the Darlington NGS
- work performed by contractors would follow established quality assurance programs, which are regularly audited and verified by OPG

42. OPG submitted that its Supply Chain Quality Services qualifies vendors and contractors through a process that ensures their management systems comply with the relevant CSA N286 standards. OPG provided information on the following contracted vendors involved in the project:<sup>57</sup>

1. Laurentis Energy Partners, a wholly owned subsidiary of OPG, will provide strategic partnerships and project support

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<sup>55</sup> CNSC Regulatory Document, REGDOC-2.1.2, *Safety Culture*, April 2018.

<sup>56</sup> OPG's Application, Attachment 1, Section 2.1.

<sup>57</sup> OPG's Application, Attachment 1, Section 1.7.

2. BWXT-Nuclear Energy Canada (NEC) designed the TDS and will also perform maintenance
  3. BWXT Canada Ltd. is the Engineer Procure Construct Contractor / Constructor for the project
43. CNSC staff reported that OPG's nuclear operations program provides adequate governance for developing and revising technical procedures, ensuring proper management of documentation changes related to Unit 3 TDS.<sup>58</sup> CNSC staff submitted that it would verify that:<sup>59</sup>
- the updated operational procedures for the Unit 3 TDS are implemented in a manner consistent with those for Unit 2
  - OPEX from Unit 2 is properly documented and applied to Unit 3 and any future installations, as applicable
  - OPG continues to meet regulatory requirements throughout the TDS project, including the development of isotope irradiation program documentation; these documents would be subject to regulatory oversight to ensure OPG continues to operate within its licensing basis
44. CNSC staff noted that, at the time of submission of CMD 25-H107, there was an open inspection finding that was elevated to "medium" against OPG concerning the oversight of contractors to support isotope-related activities.<sup>60</sup> CNSC staff reported that a specific contractor had been used for types of work for which they were not formally qualified. CNSC staff submitted that, through follow-up actions to date, OPG was developing and implementing adequate corrective actions and would apply operational experience to current and future isotope projects at the Darlington NGS. CNSC staff submitted that it expected these issues to be fully resolved by OPG prior to commencing any further installation of a TDS, including on Unit 3.
45. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate management system in place to carry on the activities that would be authorized by the proposed licensing basis amendment. The Commission bases its conclusion on the following:
- OPG has implemented and maintained a management system in compliance with regulatory requirements, including CSA N286-12 and REGDOC-2.1.2
  - OPG's existing management system is adequate to support the installation and operation of a TDS on Darlington NGS Unit 3
  - compliance with OPG's ECC program would ensure quality, design basis compliance and configuration management
  - OPG's nuclear operations program includes governance for the development and revision of technical procedures

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<sup>58</sup> CMD 25-H107, Section 3.1.2, page 11.

<sup>59</sup> CMD 25-H107, Section 3.1.2, pages 11-12.

<sup>60</sup> CMD 25-H107, Section 5.

- CNSC staff will continue to provide enhanced regulatory oversight of the OPG supply chain and contractor management processes, including monitoring OPG's implementation of effective corrective actions
46. The Commission notes that OPG is required to address the outstanding actions established in CNSC staff's warning letter, to CNSC staff's satisfaction, and that CNSC staff may take additional compliance enforcement measures, if necessary.

#### 3.4.2 *Operating Performance*

47. The operating performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.
48. OPG's current licence includes 4 licence conditions related to the operating performance SCA:
- Licence condition 3.1 requires OPG to implement and maintain an operations program, which includes a set of operating limits
  - Licence condition 3.2, which states that OPG shall not restart a reactor after a serious process failure without the prior written approval of the Commission, or the prior written consent of a person authorized by the Commission
  - Licence condition 3.3, which requires OPG to notify and report in accordance with [REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants](#)<sup>61</sup>
  - Licence condition 3.4, which requires OPG to implement a periodic safety review (PSR) in support of its subsequent power reactor operating licence application
49. The CINFR provide that an application for a licence to operate a Class I nuclear facility must include information on the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.<sup>62</sup>
50. The following CNSC REGDOCs include requirements and guidance relevant to the operating performance SCA:
- [REGDOC-2.3.2, Accident Management, Version 2](#)<sup>63</sup> sets out the requirements and guidance of the CNSC for the development, implementation and validation of integrated accident management for reactor facilities
  - [REGDOC-2.3.3, Periodic Safety Reviews](#)<sup>64</sup> sets out the CNSC's requirements for the conduct of a PSR for a nuclear power plant
  - REGDOC-3.1.1 sets out requirements and guidance for reports and notifications that licensees of nuclear power plants must submit to the CNSC

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<sup>61</sup> CNSC Regulatory Document, REGDOC-3.1.1, *Reporting Requirements for Nuclear Power Plants*, Version 3, CNSC, May 2024.

<sup>62</sup> Paragraph 6(d) of the CINFR.

<sup>63</sup> CNSC Regulatory Document, REGDOC-2.3.2, *Accident Management*, Version 2, CNSC, September 2015.

<sup>64</sup> CNSC Regulatory Document, REGDOC-2.3.3, *Periodic Safety Reviews*, CNSC, April 2015.

51. In addition, CSA N290.15, *Requirements for the Safe Operating Envelope of Nuclear Power Plants*<sup>65</sup> sets out requirements and guidance for the Safe Operating Envelope (SOE) of Nuclear Power Plants (NPPs).
52. OPG provided the Commission with information on how its operating performance program applies to the proposed licensing basis amendment, including in the following performance areas:<sup>66</sup>
- Conduct of Licensed Activity
  - Procedures
  - Reporting and Trending
  - Outage Management Performance
  - Safe Operating Envelope
  - Severe Accident Management and Recovery
  - Accident Management and Recovery
53. OPG submitted that:
- the installation and operation of TDSs on additional units would not require any changes to the licensing basis of the operating performance SCA
  - OPG is committed to updating both the operating manual and maintenance procedure to include TDS on additional units, in line with OPG's governance
  - CNSC staff would be notified of the updates upon completion, as required by Licence Condition 15.6 of the Darlington NGS LCH
  - installation and operation of TDSs on additional units at the Darlington NGS reactors would not impact any of the SOE documents
54. CNSC staff submitted that:<sup>67</sup>
- OPG had submitted two TDS Commissioning Reports for Unit 2 to CNSC staff in November 2023
  - CNSC staff undertook additional verification activities to confirm the implementation of an SOE program by OPG to ensure station operations align with licensed safety analysis and accident response procedures
  - OPG confirmed that the installation of the Mo-99 TDS did not require revisions to the Operational Safety Requirements, which define the specific technical requirements for operating the plant within the SOE
  - the continued validity of the existing SOE would be confirmed through a review of the detailed nuclear safety analysis as outlined in the RHP included by the Commission in DEC 25-H100

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<sup>65</sup> CSA Group Standard, CSA N290.15, *Requirements for the safe operating envelope of nuclear power plants*, 2010 (R2024).

<sup>66</sup> OPGs Application, Attachment 1, Section 2.3.

<sup>67</sup> CMD 25-H107, Section 3.1.2, page 10.

55. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate operating performance program in place to carry on the activities that would be authorized by the proposed licensing basis amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained an operating performance program in compliance with regulatory requirements, including CSA N290.15, and REGDOCs 2.3.2, 2.3.3, and 3.1.1
- OPG's existing operating performance program is adequate to support the activities that the amended licensing basis would authorize
- OPG's existing processes are adequate to support the installation and operation of a TDS on the Darlington NGS Unit 3

### 3.4.3 Safety Analysis

56. The safety analysis SCA, which supports the overall safety case for a facility, includes a systematic evaluation of the potential hazards associated with the conduct of the licensed activity or the operation of a facility. Safety analysis also considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards. Licence condition 4.1 of PROL 13.00/2045 requires OPG to implement and maintain a safety analysis program.

57. The CINFR provide that an application for a licence to operate a Class I nuclear facility must include a final safety analysis report demonstrating the adequacy of the design of the nuclear facility.<sup>68</sup>

58. The following CNSC REGDOCs include requirements and guidance relevant to the safety analysis SCA:

- [REGDOC-2.4.1, \*Deterministic Safety Analysis\*](#)<sup>69</sup> sets out requirements and guidance for the preparation and presentation of a safety analysis that demonstrates the safety of a nuclear facility
- [REGDOC-2.4.2, \*Probabilistic Safety Assessment \(PSA\) for Nuclear Power Plants\*](#)<sup>70</sup> sets out requirements for a licensee to conduct a PSA<sup>71</sup> for a Nuclear Power Plant
- REGDOC-3.1.1 sets out reporting requirements for NPPs, including providing updated safety reports at least every 5 years, or when directed by the CNSC

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<sup>68</sup> Paragraph 6(i) of the CINFR.

<sup>69</sup> CNSC Regulatory Document, CNSC Regulatory Document, REGDOC-2.4.1, *Deterministic Safety Analysis*, May 2014.

<sup>70</sup> CNSC Regulatory Document, CNSC Regulatory Document, REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*, May 2014.

<sup>71</sup> A probabilistic safety assessment is a comprehensive and integrated assessment of the safety of a facility. The PSA considers the probability, progression and consequences of equipment failures or transient conditions to derive numerical estimates that provide a consistent measure of the safety of the facility.

In addition, CSA N286.7, *Quality assurance of analytical, scientific and design computer programs for nuclear power plants*<sup>72</sup> specifies expectations applicable to the development, modification, maintenance, and use of computer programs in analytical, scientific, and design applications during any phase of the nuclear plant lifecycle.

59. OPG provided the Commission with information on how its safety analysis program applies to the proposed licensing basis amendment, including in the following performance areas:<sup>73</sup>

- Deterministic Safety Analysis
- Hazard Analysis
- Probabilistic Safety Analysis
- Criticality Safety
- Severe Accident Analysis
- Management of Safety Issues (including Research and Development Programs)

60. OPG submitted that:<sup>74</sup>

- the installation and operation of TDSs on additional units would not require any changes to the licensing basis of the safety analysis SCA
- a description of the Unit 3 TDS would be added during the next revision of OPG's document *Darlington NGS Safety Report: Part 2 -System Descriptions* as part of its ECC program
- the Analysis of Record process would be followed for inclusion of applicable safety assessments into OPG's documents *DN 1-4 Safety Report: Part 3 – Accident Analysis* and *Darlington Analysis of Record*
- the TDS installation is not considered a “major change” and does not require updates to the Darlington PSA models beyond the regular five-year update cycle
- some outstanding PSA models are currently being updated according to a planned update cycle
- the TDS would not impact the procedures for accident and severe accident management

61. Accompanying its application, OPG submitted a *Nuclear Safety Review – Target Delivery System Installed on Multiple Units*,<sup>75</sup> which evaluated the applicability of key safety analyses performed for the Unit 2 TDS to TDS installation on additional Darlington NGS units. Based on these assessments, OPG determined that a new analysis was not required to support installing TDSs on additional units at the Darlington NGS. OPG confirmed that:<sup>76</sup>

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<sup>72</sup> CSA Group Standard, CSA N286.7, *Quality assurance of analytical, scientific and design computer programs for nuclear power plants*, 1999 (R2021).

<sup>73</sup> OPGs Application, Attachment 1, Section 2.4.

<sup>74</sup> OPGs Application, Attachment 1, Section 2.4.

<sup>75</sup> *Nuclear Safety Review – Target Delivery System Installed on Multiple Units*, Enclosure 1 of OPG's Application, NK38-EVAL-03600-00001, August 8, 2025.

<sup>76</sup> OPGs Application, Attachment 1, Section 2.4.

- the deterministic safety assessments for the Unit 2 TDS design remain applicable to additional units
- the Hazard Screening Analysis for Unit 2 is also valid for other units
- the assessment of Unit 2 TDS impacts on existing Darlington NGS PSA elements applies to further installations
- the Severe Accident Analysis remains applicable without requiring further updates

62. CNSC staff submitted that:

- the design, methodology and conclusions in OPG's summary safety case were consistent with those previously submitted to the Commission for Unit 2 in DEC 21-H107 and DEC 25-H100
- based on CNSC staff's broader range of oversight activities, it is satisfied that OPG ensured the safe installation and commissioning of the TDS in Unit 2 through the verification of the critical parameters of the safety case
- CNSC staff's review of OPG's safety case and commissioning documentation in support of the additional isotopes authorized by the Commission in DEC 25-H100, would provide another opportunity for it to confirm that TDS operations remain within SOE limits and pose no new risks to safe TDS or station operations

63. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate safety analysis program in place to carry on the activities that would be authorized by the proposed licensing basis amendment. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a safety analysis program in compliance with regulatory requirements, including REGDOCs 2.4.1 and 2.4.2, and CSA N286.7
- OPG's existing safety analysis program is adequate to support the activities that the licensing basis amendment would authorize
- the Commission is satisfied that the evidence provided by OPG and CNSC staff sufficiently demonstrates that the safety analysis of the Darlington NGS continues to be adequate for the proposed licensing basis amendment
- the scope of proposed work is in alignment with that the Commission authorized for Unit 2, as previously presented to the Commission in DEC 21-H107

#### *3.4.4 Physical Design*

64. The physical design SCA relates to activities that impact the ability of structures, systems and components (SSCs) to meet and maintain their design basis, given new information arising over time and taking changes in the external environment into account. The design basis is the range of conditions and events taken explicitly into account in the design of a

nuclear facility, according to established criteria, such that the facility can withstand this range without exceeding authorized limits.

65. OPG's licence includes 3 licence conditions related to the physical design SCA:
- Licence condition 5.1, which requires OPG to implement and maintain a design program
  - Licence condition 5.2, which requires OPG to implement and maintain a pressure boundary program and have in place a formal agreement with an Authorized Inspection Agency
  - Licence condition 5.3, which requires OPG to implement and maintain an equipment and structure qualification program
66. The GNSCR require that a licence application contain a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.<sup>77</sup> The CINFR indicate that a licence application for a Class I nuclear facility must include a description of the site of the activity to be licensed, as well as plans showing the location, perimeter, areas, structures and systems of the nuclear facility.<sup>78</sup> The CINFR provide that an application for a licence to operate a Class I nuclear facility includes a description of the structures, systems and equipment at the nuclear facility, including their design and their design operating conditions.<sup>79</sup>
67. OPG provided the Commission with information on how its physical design program applies to the proposed licensing basis amendment, including in the following performance areas:<sup>80</sup>
- Design Governance
  - Site Characterization
  - Design of the facility and SSCs
68. In its submission, OPG outlined the changes in TDS design for additional units from the previous installation on Unit 2.<sup>81</sup> OPG submitted that:
- the installation and operation of TDSs on additional units would not require any changes to the licensing basis of the physical design SCA
  - the changes are being implemented to address interferences, obsolescence, safety, access, and installation, without affecting nuclear safety analyses or assumptions
  - all changes would be managed in accordance with OPG's ECC process to ensure that the design complies with applicable regulatory requirements and that configuration management for the station is maintained

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<sup>77</sup> Paragraph 3(1)(d) of the GNSCR.

<sup>78</sup> Paragraphs 3(a) and 3(b) of the CINFR.

<sup>79</sup> Paragraphs 6(a) and 6(b) of the CINFR.

<sup>80</sup> OPG's Application, Attachment 1, Section 2.5.

<sup>81</sup> OPG's Application, Attachment 1, Section 1.4. OPG also submitted a *Summary of Design Changes*, Enclosure 8 of OPG's Application.

- the additional TDS designs would consider two Environmental Qualification (EQ) elements: impact of increased radiation fields on nearby components and systems during target harvesting, and EQ of the TDS components to withstand harsh design-basis event environments
  - the TDS design for additional units would comply with applicable requirements for the physical design SCA<sup>82</sup>
  - Pressure Boundary issues on Unit 2 TDS would be addressed through existing OPG processes, with lessons learned reviewed and potential changes applied to later units
69. CNSC staff noted that the TDS design for Unit 3 is consistent with that of Unit 2. CNSC staff submitted that it is satisfied that the changes have negligible or positive safety impacts and represent foreseeable design evolutions that either:<sup>83</sup>
- are informed on OPEX considered from Unit 2 while maintaining adequate worker protection; or
  - account for inherent inter-unit differences that do not necessitate changes to the design basis
70. Based on the information on record for this hearing, the Commission concludes that OPG has an adequate physical design program in place to carry on the activities that would be authorized by the proposed licensing basis amendment. The Commission bases its conclusion on the following:
- OPG has implemented and maintained a physical design program in compliance with regulatory requirements
  - OPG's existing physical design program is adequate to support the activities that the amended licensing basis would authorize
  - OPG's existing ECC process is adequate to manage any required changes to the TDS

#### 3.4.5 *Fitness for Service*

71. The fitness for service SCA covers activities that are performed to ensure that SSCs remain effective over time and are available to perform their intended design functions

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<sup>82</sup> Regulatory requirements for the physical design SCA include:

- CSA Group Standard, CSA N285.0, *General requirements for pressure-retaining systems and components in CANDU nuclear power plants*, 2008 (and update No. 2)
- CSA Group Standard, CSA N289.1, *General requirements for seismic design and qualification of CANDU nuclear power plants*, 2008 (R2013)
- CSA Group Standard, CSA N290.13, *Environmental qualification of equipment for CANDU nuclear power plants*, 2005 (and update No. 1) (R2015)
- CSA Group Standard, CSA N291, *Requirements for safety related structures for CANDU nuclear power plants*, 2008 (R2013)

<sup>83</sup> CMD 25-H107, page 9.

upon request. Licence condition 6.1 of PROL 13.00/2045 requires OPG to implement and maintain a fitness-for-service program.

72. The CINFR require that an application for a licence to operate a Class I nuclear facility contains the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.<sup>84</sup>
73. The following CNSC REGDOCs include requirements and guidance relevant to the fitness for service SCA:
  - [REGDOC-2.6.1, Reliability Programs for Nuclear Power Plants](#)<sup>85</sup> sets out the requirements for the development and implementation of a reliability program for a nuclear power plant in Canada
  - [REGDOC-2.6.2, Maintenance Programs for Nuclear Power Plants](#)<sup>86</sup> sets out guidance and requirements for maintaining an effective maintenance program for a nuclear power plant
  - [REGDOC-2.6.3, Aging Management](#)<sup>87</sup> sets out guidance and the requirements for managing aging of SSCs for reactor facilities
74. OPG provided the Commission with information on how its fitness-for-service program applies to the proposed licensing basis amendment, including in the following performance areas:<sup>88</sup>
  - Equipment Fitness for Service/Equipment Performance
  - Maintenance
  - Structural Integrity
  - Aging Management
  - Chemistry Control
  - Periodic Inspection and Testing
75. OPG submitted that:
  - the installation and operation of TDSs on additional units would not require any changes to the licensing basis of the fitness for service SCA
  - OPG would continue to comply with the relevant regulatory requirements<sup>89</sup>

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<sup>84</sup> Paragraph 6(d) of the CINFR.

<sup>85</sup> CNSC Regulatory Document, REGDOC-2.6.1, *Reliability Programs for Nuclear Power Plants*, August 2017.

<sup>86</sup> CNSC Regulatory Document, REGDOC-2.6.2, *Maintenance Programs for Nuclear Power Plants*, August 2017.

<sup>87</sup> CNSC Regulatory Document, REGDOC-2.6.3, *Aging Management*, March 2014.

<sup>88</sup> OPG's Application, Attachment 1, Section 2.6.

<sup>89</sup> Regulatory requirements for the fitness for service SCA include:

- CSA Group Standard, CSA N285.4, *Periodic inspection of CANDU nuclear power plant components* (2014)
- CSA Group Standard, CSA N285.5, *Periodic inspection of CANDU nuclear power plant containment components*, 2018

- OPG and BWXT NEC maintenance staff would perform corrective maintenance on all TDSs
- OPG maintenance staff would address minor corrective maintenance, while BWXT NEC would undertake more extensive repairs
- the TDSs on additional units would result in an extension to the containment boundary without impacting the containment structural integrity
- the impact from a TDS on reactor chemistry was determined to have minimal impact on moderator system chemistry and the addition of chemicals to support TDS operation is not expected
- all TDS equipment would be added under current Preventive Maintenance IDs, and both Mechanical and Control Maintenance Procedures would be updated to cover this equipment

76. CNSC staff submitted that:<sup>90</sup>

- OPG's maintenance program meets regulatory requirements
- maintenance documentation for the Unit 2 TDS, which was declared commercially available in November 2024, will be subject to CNSC regulatory oversight as it becomes available
- CNSC staff will confirm that maintenance procedures for the Unit 3 TDS align with those used for Unit 2, and that operating experience from Unit 2 is properly documented and applied to Unit 3 and future installations

77. The Commission concludes that OPG continues to implement and maintain an effective fitness for service program at the Darlington NGS that meets regulatory requirements. The Commission bases its conclusion on the following:

- OPG has implemented and maintained a fitness-for-service program in compliance with regulatory requirements, including REGDOCs 2.6.1, 2.6.2, and 2.6.3 and applicable CSA standards
- OPG's existing fitness-for-service program is adequate to support the activities that the licensing basis amendment would authorize

#### 3.4.6 Environmental Protection

78. The Environmental Protection SCA covers programs that identify, control, and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities. These programs include effluent and emission control, environmental monitoring, and estimated doses to the public. Licence

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- CSA Group Standard, CSA N285.8, *Technical requirements for inservice inspection evaluation of zirconium alloy in pressure tubes in CANDU reactors*, 2023
  - CSA Group Standard, CSA N287.7, *In-service examination and testing requirements for concrete containment structures for CANDU nuclear power plant components*, 2008 (R2013)

<sup>90</sup> CMD 25-H107, Section 3.1.2, page 13.

condition 9.1 of PROL 13.00/2045 requires OPG to implement and maintain an environmental protection program, including a set of action levels.

79. In accordance with the NSCA, licensees are required to make adequate provision for the protection of the environment. The GNSCR require each licensee to take all reasonable precautions to protect the environment and the health and safety of persons, and to control the release of radioactive nuclear substances and hazardous substances within the site of the licensed activity and into the environment.<sup>91</sup> The *Radiation Protection Regulations* prescribe dose limits for the public, which are 1 mSv per calendar year.<sup>92</sup>
80. [REGDOC-2.9.1, Environmental Principles, Assessments, and Protection Measures](#)<sup>93</sup> describes the CNSC's principles of environmental protection, the scope of an environmental review, the roles and responsibilities associated with an environmental review, as well as the CNSC's requirements and guidance for developing environmental protection measures, including an environmental risk assessment where required.
81. OPG provided the Commission with information on how its environmental protection program applies to the proposed licensing basis amendment, including in the following performance areas:<sup>94</sup>
- Effluent and emissions control (releases)
  - Environmental Management System (EMS)
  - Assessment and monitoring
  - Protection of people
  - Environmental Risk Assessment
82. OPG submitted that:
- the installation and operation of TDSs on additional units would not require any changes to the licensing basis of the environmental protection SCA
  - OPG is committed to complying with the requirements of the CSA Standard N288 series documents<sup>95</sup>

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<sup>91</sup> Paragraphs 12(1)(c) and (f) of the GNSCR.

<sup>92</sup> Pursuant to subsection 1(3) of the *Radiation Protection Regulations*.

<sup>93</sup> CNSC Regulatory Document, REGDOC-2.9.1, *Environmental Principles, Assessments and Protection Measures*, September 2020.

<sup>94</sup> OPG's Application, Attachment 1, Section 2.9.

<sup>95</sup> Regulatory requirements for the environmental protection SCA include:

- CSA Group Standard, CSA N288.1, *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities*, 2014 (R2019)
- CSA Group Standard, CSA N288.3.4, *Performance testing of nuclear air-cleaning systems at nuclear facilities*, 2013 (R2022)
- CSA Group Standard, CSA N288.4, *Environmental monitoring programs at nuclear facilities and uranium mines and mills*, 2019
- CSA Group Standard, CSA N288.5, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills*, 2011 (R2021)

- the installation and operation of TDSs on additional units would not impact the derived release limits, action levels, or internal investigation levels for the Darlington NGS
- OPG's Environmental Policy requires that OPG maintain an EMS consistent with the ISO 14001 *Environmental Management System Standard*
- operation of the TDS to produce isotopes would adhere to OPG's existing EMS
- OPG has an Effluent Monitoring Program in place to ensure that environmental releases remain below regulatory limits and comply with the principles of ALARA
- the TDS will not result in increased non-radiological releases or emissions from the Darlington NGS
- chemicals would not be used to support TDS operations, and the molybdenum target capsules, consisting of the molybdenum metal encased in a zirconium outer sheath, would not dissolve in the moderator water nor interact with the reactor components
- the existing environmental risk assessment will be updated, or additional assessments performed if and when OPG moves forward with additional installations<sup>96</sup>

83. In accordance with CSA N288.6-22 and REGDOC-2.9.1, OPG submitted a Predictive Environmental Risk Assessment (PERA) to support its request to construct and operate a Molybdenum TDS for Unit 3 at the Darlington NGS.<sup>97</sup> The PERA found that:

- no additional mitigation or environmental monitoring as a result of the TDS project was identified
- non-radiological contaminants of potential concerns would not be expected to arise due to the TDS operation
- the total tritium emission and particulate emissions from the operation of the TDS would constitute 0.002% and 0.0005%, respectively, of the current facility derived release limits<sup>98</sup>
- OPG is committing that TDS emissions would not exceed the maximum emissions assessed in the PERA, and the monitoring and control measures would be designed accordingly
- the TDS includes design features to minimize emissions of tritium and particulates, and keep them below the established action levels

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- CSA Group Standard, CSA N288.6, *Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*, 2012 (R2017)
  - CSA Group Standard, CSA N288.7, *Groundwater protection programs at Class I nuclear facilities and uranium mines and mills*, 2015 (R2020)

<sup>96</sup> OPG's Application, Attachment 1, Section 4.0.

<sup>97</sup> *Predictive Environmental Risk Assessment for the DNGS Target Delivery System (Unit 3)*, Enclosure 2 of OPG's Application, NK38-REP-30550-0051, August 8, 2025.

<sup>98</sup> OPG's Application, Enclosure 2, Section 4.2.

- the cumulative public dose estimated from Darlington NGS operations for the critical group with the highest exposure, Farm Adult, is 0.078% of the regulatory public dose limit of 1 mSv/year and 0.056% of the dose from background radiation of 1.4 mSv/year in the vicinity of the Darlington NGS (excluding medical doses)<sup>99,100</sup>
  - the total radiological doses received by indicator species as a result of emission from the TDS project are well below the radiation dose benchmark values given in CSA N288.6-22<sup>101,102</sup>
84. CNSC staff submitted that it conducted an Environmental Protection Review for OPG's application, which determined that the installation and operation of additional TDSs for the production of an increased volume of medical radionuclides are minimal and that OPG's programs are sufficient to protect the environment and the public.<sup>103</sup> CNSC staff added that the information provided by OPG regarding environmental protection was adequate to demonstrate that it met CNSC regulatory requirements.
85. The Commission concludes that OPG has an adequate environmental protection program in place to carry on the activities that would be authorized by the proposed licensing basis amendment. The Commission bases its conclusion on the following:
- OPG has implemented and maintained an environmental protection program in compliance with regulatory requirements, including REGDOC-2.9.1 and the CSA N288 series documents
  - OPG's existing environmental protection program is adequate to support the activities that the licensing basis amendment would authorize
  - CNSC staff will maintain oversight to ensure ongoing protection of the environment and public health through continuous licensing and compliance reviews

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<sup>99</sup> Darlington NGS operations include existing Darlington NGS operations, operation of the Co-60 Production System, Unit 2 and Unit 3 TDS, and the Darlington New Nuclear Project. OPG's Application, Enclosure 2, Section 8.1, Table 8-2.

<sup>100</sup> OPG's Application, Enclosure 2, Section 8.1.

<sup>101</sup> OPG's Application, Enclosure 2, Section 8.2

<sup>102</sup> Radiation dose benchmarks of 400 µGy/h (9.6 mGy/d) and 100 µGy/h (2.4 mGy/d) were selected for the assessment of effects on aquatic biota and terrestrial biota, respectively, as recommended in the CSA N288.6-22 standard. OPG's Application, Enclosure 2, Section 12.2.1.

<sup>103</sup> CMD 25-H107, Section 2.

### 3.4.7 Conclusion on OPG's Safety and Control Measures with Respect to the SCAs

86. Based on its analysis of the information provided and discussed above, the Commission is satisfied that OPG is qualified to carry on the licensed activities that the amended licensing basis would authorize. In addition, the Commission finds that OPG has adequate programs and measures in place with respect to the 14 SCAs to ensure that the health and safety of workers, the public and the environment will be protected. The Commission further concludes that OPG has adequate measures in place to provide for the maintenance of national security and to implement international obligations to which Canada has agreed.
87. OPG is required to submit updated documentation to CNSC staff to verify continued compliance with regulatory requirements, specifically within the Radiation Protection, Emergency Management and Fire Protection, and Operating Performance SCAs. This includes providing the updated ALARA Assessment and Fire Protection currently in progress to support the Unit 3 TDS installation, alongside revised operating manuals and procedures. Furthermore, in accordance with OPG's ECC process and the LCH, OPG must confirm that the activity remains within the licensing basis prior to installing a TDS on Units 1 and 4. OPG is required to submit a unit-specific safety case and design documentation to the CNSC for verification. This verification is further discussed in Section 3.7.2 of this *Record of Decision*.

## 3.5 Indigenous Engagement and Consultation

88. The Commission considered the information provided by CNSC staff and OPG regarding Indigenous consultation and engagement activities in respect of this application to amend the licensing basis for the PROL. Indigenous consultation refers to the common law duty to consult with Indigenous Nations and communities pursuant to section 35 of the [Constitution Act, 1982](#).<sup>104</sup>
89. The common law duty to consult is grounded in the key principle of the honour of the Crown. The foundation of the duty and the goal of reconciliation mean that the duty arises when the Crown has knowledge, real or constructive, of the potential existence of an Aboriginal right or title and contemplates conduct that might adversely affect it.<sup>105</sup> Licensing decisions of the Commission, where Indigenous interests may be adversely impacted, can engage the duty to consult, and the Commission must be satisfied that if the duty is engaged, it has met the duty prior to making the relevant licensing decision. The duty to consult is not triggered by historical impacts and is not meant to address past grievances but rather is designed to address potential impacts flowing from a current proposed amendment.<sup>106</sup>

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<sup>104</sup> *Constitution Act, 1982*, Schedule B to the *Canada Act 1982* (UK), 1982, c 11.

<sup>105</sup> *Haida Nation v. British Columbia (Minister of Forests)*, 2004 SCC 73 at para 35.

<sup>106</sup> *Rio Tinto Alcan Inc. v. Carrier Sekani Tribal Council*, 2010 SCC 43 at para 49; *Chippewas of the Thames First Nation v. Enbridge Pipelines Inc.*, 2017 SCC 41 at para. 41.

90. The determination of what the duty to consult and accommodate requires is informed by the principles and the provisions of the UNDRIP as a result of its adoption into Canadian law via the UNDA. The content of the UNDRIP is to be used as a lens to interpret the Crown's duty to consult and accommodate.<sup>107</sup>
91. CNSC staff submitted that, based on the information in OPG's application, the installation and operation of TDSs on additional units at the Darlington NGS is unlikely to cause new adverse impacts to the exercise of potential or established Indigenous and/or Treaty rights as continued operations will not change the Darlington NGS site characterization.<sup>108</sup> The Commission notes that OPG has programs in place to actively monitor and assess its operations to confirm that there are no unforeseen effects on the environment.

### *3.5.1 Indigenous Engagement by CNSC Staff*

92. CNSC staff provided the Commission with information about its engagement activities with the Indigenous Nations and communities that were identified as having a potential interest in OPG's licensing basis amendment application.<sup>109</sup> CNSC staff identified that Williams Treaties First Nations have established Indigenous and treaty rights to the lands and waters surrounding and inclusive of the Pickering NGS site. Williams Treaties First Nations are:
- Alderville First Nation (AFN)
  - Curve Lake First Nation (CLFN)
  - Hiawatha First Nation (HFN)
  - Mississaugas of Scugog Island First Nation (MSIFN)
  - Chippewas of Beausoleil First Nation (CBFN)
  - Georgina Island First Nation (GIFN)
  - Chippewas of Rama First Nation (CRFN)
93. CNSC staff identified the following Indigenous Nations and communities with interests in the Darlington NGS and the lands and waters surrounding and inclusive of the Darlington NGS:
- Mohawks of the Bay of Quinte (MBQ)
  - Métis Nation of Ontario (MNO)
  - Six Nations of the Grand River (SNGR)
  - Mississaugas of the Credit First Nation (MCFN)
  - Saugeen Ojibway Nation (SON)

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<sup>107</sup> *Kebaowek First Nation v. Canadian Nuclear Laboratories*, 2025 FC 319.

<sup>108</sup> CMD 25-H107, Section 4.1.1, page 17.

<sup>109</sup> CMD 25-H101, Section 4.1.1.

94. CNSC staff reported that it:<sup>110</sup>
- sent letters of notification to the identified Indigenous Nations and communities on May 23, 2025, to inform them of OPG's application, and opportunities to participate in the hearing process through written interventions
  - encouraged all identified Indigenous Nations and communities to participate in the Commission hearing through written interventions to advise the Commission directly of any concerns they may have in relation to OPG's request to install TDSs on additional units at the Darlington NGS
95. CNSC staff expressed its willingness to continue to offer to meet with all identified Indigenous Nations and communities to discuss OPG's request and plan to raise OPG's request in regular meetings under Terms of Reference (ToR) for long-term engagement arrangements with CLFN, HFN and MSIFN.<sup>111</sup> CNSC staff further submitted that the CNSC is open to developing ToR for long-term engagement with other interested Indigenous Nations and communities as appropriate.
96. CNSC staff acknowledged Algonquins of Pikwàkanagàn First Nation's (AOPFN) interest in isotope projects at the Darlington NGS and reaffirmed its commitment to ongoing engagement with AOPFN, particularly regarding the transportation of nuclear materials through AOPFN territory,<sup>112</sup> even if the current application does not involve that territory.<sup>113</sup>
97. CNSC staff submitted that it is committed to building long-term relationships with Indigenous Nations and communities who have interest in CNSC-regulated facilities within their traditional and/or treaty territories.<sup>114</sup>

### 3.5.2 *Indigenous Engagement by OPG*

98. OPG reported that it has implemented its Indigenous Relations Policy to provide a framework for engaging with, and providing support to, Indigenous Nations and communities.<sup>115</sup> Under this policy, OPG maintains an Indigenous relations program for its nuclear operations with the goals of:
- informing proximate Indigenous Nations and communities of OPG's nuclear operations and projects
  - seeking input from Indigenous Nations and communities
  - addressing identified concerns as applicable

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<sup>110</sup> CMD 25-H107, Section 4.1.1, pages 15-16.

<sup>111</sup> CMD 25-H107, Section 4.1.1, page 16.

<sup>112</sup> DEC 25-H100, paragraph 178.

<sup>113</sup> CMD 25-H107, Section 4.1.1, page 16.

<sup>114</sup> CMD 25-H107, Section 4.1, page 15.

<sup>115</sup> *Target Delivery System Engagement and Communications Plan with Indigenous Nations and Communities*, (Enclosure 4 of OPG's Application), NK38-PLAN-00120-00027, November 15, 2024, Section 2.0, page 5.

99. OPG's submission, *Target Delivery System Engagement and Communications Plan with Indigenous Nations and Communities*,<sup>116</sup> documents the scope and activities OPG will conduct with the identified Indigenous Nations and communities through all phases of the TDS project.<sup>117</sup> The plans were prepared in accordance with [REGDOC 3.2.2, \*Indigenous Engagement\*](#),<sup>118</sup> which sets out requirements and guidance for licensees on Indigenous engagement.
100. OPG submitted that it is committed to respecting Aboriginal and treaty rights and OPG's commitment to developing positive relationships with Indigenous communities remains integral to its operations. OPG also reported that it has a Reconciliation Action Plan that sets measurable goals to advance reconciliation with Indigenous Nations, communities, and organizations.<sup>119</sup>
101. CNSC staff noted that it reviewed OPG's *Target Delivery System Engagement and Communications Plan with Indigenous Nations and Communities*. CNSC staff submitted that OPG had sufficiently engaged Indigenous communities with respect to the application.<sup>120</sup>
102. The Commission asked OPG to provide information on the specific engagement activities that it had undertaken relative to this application ([CMD 25-H107-Q](#)). In its response, OPG submitted an Isotope engagement log detailing the specific Indigenous engagement activities it completed in relation to its TDS and isotope projects at the Darlington NGS between January 2025 and December 2025.<sup>121</sup> OPG reported that it engaged with the following Indigenous Nations and communities:
- MSIFN
  - CLFN
  - HFN
  - AFN
  - BFN
  - GIFN
  - Kawartha Nishnawbe
  - SNGR
  - MBQ
  - MNO
  - AOPFN
  - CRFN

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<sup>116</sup> Enclosure 4 of OPG's Application.

<sup>117</sup> Enclosure 4 of OPG's Application, Sections 2.0 and 3.0.

<sup>118</sup> REGDOC-3.2.2, *Indigenous Engagement*, Version 1.2, CNSC, February 2022.

<sup>119</sup> Enclosure 4 of OPG's Application, Section 2.0.

<sup>120</sup> CMD 25-H107, Section 4.3.1, page 19.

<sup>121</sup> CMD 25-H107.1, Attachment 1, Table 1.

### 3.5.3 Conclusion on Indigenous Engagement and Consultation

103. The Commission recognizes that the Darlington NGS is located on Michi Saagiig Anishinaabeg lands and waters, within the Williams Treaties territory. The Commission recognizes the individual rights of AFN, CLFN, HFN, MSIFN, CBFN, GIFN, and CRFN as independent Williams Treaties First Nations and the Crown's responsibility to discharge the duty to consult and, where appropriate, accommodate with respect to each individual Nation. The Commission did not receive any submissions from any Indigenous Nations or communities in this hearing.
104. Based on the evidence on the record for this hearing in writing and described above, the Commission is satisfied with CNSC staff's efforts to engage with Indigenous Nations and communities who have established or asserted rights and/or interests regarding the Darlington NGS on matters relevant to the licensing basis amendment application before the Commission. The Commission also recognizes the engagement activities undertaken by OPG with each Indigenous Nation and community. These engagement efforts included email and information exchanges, and other activities including meetings, reflected in the submission by OPG ([CMD 25-H107.1](#)). The Commission is satisfied with the evidence it has received in this regard to render its decision on OPG's application.
105. Recent jurisprudence confirms that the UNDA incorporates the UNDRIP into Canada's positive legal framework. Accordingly, the Commission considered, in making its determination on the fulfillment of section 35 rights and of the duty to consult and accommodate, how the UNDRIP and its articles may impact the fulfillment of such rights.<sup>122</sup> The Commission has assessed the application of the duty to consult and accommodate in relation to the licencing basis amendment within the context of and with acknowledgement of the UNDA.
106. The Commission finds that the proposed licensing basis amendment will not cause any new adverse impacts to any potential or established Indigenous and/or treaty rights.<sup>123</sup> The licensing basis amendment requested by OPG does not include any new licensed activities that could cause new impacts to the environment or changes in the ongoing licensed activities at the Darlington NGS. The Commission is further satisfied that Indigenous Nations and communities were informed of OPG's application, and that they were provided with an opportunity to participate in the hearing process.
107. The Commission therefore concludes that its responsibility to uphold the honour of the Crown has been satisfied.
108. The Commission notes that, in renewing the licence for the Darlington NGS, the Commission included licence condition G.7, which requires OPG to implement and maintain an Indigenous engagement program. The Commission expects that OPG's engagement will include with respect to the TDS, as appropriate.

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<sup>122</sup> *Kebaowek First Nation v. Canadian Nuclear Laboratories*, 2025 FC 319.

<sup>123</sup> *Rio Tinto Alcan v. Carrier Sekani Tribal Council*, 2010 SCC 43 at paras 45 and 49.

### 3.6 Other Matters of Regulatory Importance

#### 3.6.1 Public Engagement

109. A public information and disclosure program (PIDP) is a regulatory requirement for licence applicants and licensed operators of Class I nuclear facilities. Licence condition G.6 of PROL 13.00/2045 requires OPG to implement and maintain a public information and disclosure program. [REGDOC-3.2.1, Public Information and Disclosure](#)<sup>124</sup> sets out requirements for public information programs, disclosure protocols, and related documentation as they relate to licensed activities.
110. OPG provided information on its public engagement<sup>125</sup> and submitted that it adheres to REGDOC-3.2.1. OPG noted that it uses personal contact, community newsletters, speaking engagements, advertising, and educational outreach to facilitate two-way dialogue with community stakeholders and residents. OPG submitted that it engages with the public and local stakeholders through established committees to share information, receive advice, and discuss environmental, community, and operational issues. OPG noted that its engagement has included information on the installation and operation of TDSs on additional units.
111. CNSC staff submitted that OPG has consistently and appropriately communicated with the public regarding events and activities of interest at Darlington NGS, including on the application.<sup>126</sup>
112. Based on the information on record as described above, the Commission concludes that OPG has a PIDP in place to communicate to the public information about the health, safety and security of persons and the environment, including information relevant to the installation and operation of a TDS on Unit 3 at the Darlington NGS.

#### 3.6.2 Decommissioning Plans and Financial Guarantee

113. The NSCA and its regulations require licensees to make adequate provision for the safe decommissioning of their facilities and for the long-term management of waste produced during the life of a facility. To ensure that adequate resources are available for the safe and secure future decommissioning of the Darlington NGS, the Commission requires that an adequate financial guarantee (FG) for the realization of planned activities be put in place and maintained in a form acceptable to the Commission throughout the licence period. Licence condition 11.2 requires OPG to implement and maintain a decommissioning strategy. Licence condition G.5 requires OPG to maintain a financial guarantee for decommissioning that is acceptable to the Commission.

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<sup>124</sup> CNSC REGDOC-3.2.1, *Public Information and Disclosure*, May 2018.

<sup>125</sup> OPG's Application, Attachment 1, Sections 3.1 and 3.2.

<sup>126</sup> CMD 25-H107, Section 4.3.1, page 19.

114. OPG submitted that:<sup>127</sup>
- OPG’s “*Preliminary Decommissioning Plan – Darlington Nuclear Generating Station*” outlines the activities that will be required to decommission and restore the Darlington site for other OPG uses<sup>128</sup>
  - the TDS can be dismantled and removed without negative impacts on the Darlington NGS decommissioning strategy
  - any emissions due to dismantling and removal of the TDS are anticipated to be minimal
  - no changes from the established licensing basis for the decommissioning plan are required<sup>129</sup>
115. The Commission is satisfied that OPG’s existing Preliminary Decommissioning Plan and FG for the Darlington NGS are adequate to account for the installation and operation of a TDS on Unit 3 at the Darlington NGS.

### **3.7 Licensing Basis Amendment**

116. The Commission considered OPG’s application for a licensing basis amendment for the Darlington NGS PROL 13.00/2045, to authorize the installation and operation of a TDS on Units 1, 3, and 4 at the Darlington NGS for the production of any radionuclides authorized in PROL 13.00/2045 (i.e. Y-90, Mo-99, and Lu-177). OPG is not seeking a change to the licensed activities authorized by the licence.
117. A change to the licensing basis does not necessarily amend the terms of a licence and would not in this case. OPG did not apply for a licence amendment, nor did CNSC staff recommend one.

#### *3.7.1 Proposed Licensing Basis Amendment*

118. OPG applied for an amendment to its licensing basis to authorize the installation and operation of a TDS on additional reactor units. OPG’s application included documentation to support a specific TDS installation and operation on Unit 3, which is planned for a 2026 outage window. OPG proposed that this application can serve as a basis for authorization to install and operate a TDS on the remaining Units 1 and 4 at the Darlington NGS.
119. In the Appendix of CMD 25-H107,<sup>130</sup> CNSC staff described how OPG’s LCH would be updated to identify the units for which a completed design and safety case have been

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<sup>127</sup> OPG’s Application, Enclosure 2, Section 2.0.

<sup>128</sup> OPG’s Application, Attachment 1, Section 2.11.3.

<sup>129</sup> OPG’s Application, Attachment 1, Section 2.11.3.

<sup>130</sup> CMD 25-H107, Appendix, Section entitled *Draft Licence Condition Handbook Section*.

accepted, and for which TDS installation and operations have been authorized.<sup>131</sup> CNSC staff noted that, following the Commission's decision on this application, it would update the LCH to reflect that OPG can produce any radionuclides authorized by the Commission at Darlington NGS Unit 2 and Unit 3.

120. CNSC staff further proposed that, if OPG wishes to install a TDS on either Unit 1 or 4, OPG must submit design documentation and a safety case for a TDS designed for the units to the CNSC, to demonstrate that the additional unit will remain within the licensing basis for Darlington NGS. CNSC staff recommended that the acceptance of these submissions be delegated to certain CNSC staff.
121. As described in Section 3.4 of this *Record of Decision*, the Commission is satisfied that OPG is qualified and has adequate measures in place to safely install and operate a TDS on Unit 3. The Commission is satisfied that OPG has demonstrated that the installation of a TDS on Unit 3 at the Darlington NGS is a low-risk activity. The Commission is further satisfied that the established safety case for this installation can serve as a basis for the installation of a TDS on other units.
122. Therefore, the Commission amends the licensing basis for OPG's Darlington NGS. OPG is authorized to install and operate a TDS on Unit 3 at the Darlington NGS for the production of any radionuclides authorized in PROL 13.00/2045 (i.e. Y-90, Mo-99, and Lu-177), subject to verification by CNSC staff. The Commission further authorizes the installation and operation of a TDS on Units 1 and 4, subject to the RHP previously established by the Commission in DEC 25-H100 for Unit 2. The terms and conditions of the licence for the Darlington NGS, PROL 13.00/2045, remain unchanged. The authority delegated to CNSC staff for the release of that RHP is discussed below.

### 3.7.2 Delegation of Authority

123. CNSC staff recommended that the Commission delegate authority for the authorization of future installations and operations of TDS on additional units at Darlington NGS to CNSC staff, specifically the:
  - EVP/COO
  - DG-DPRR and/or
  - Regulatory Program Director of the Darlington Regulatory Program Division
124. The Commission notes that, with its decision above, OPG is authorized to install and operate a TDS on Unit 3, as well as Units 1 and 4, subject to verification by CNSC staff. With this decision, the RHP established under the Commission's previous decision, DEC 25-H100, shall be applied to the TDS on all other reactor units. In administering the RHP, CNSC staff will confirm that the installation and operation of a TDS on units at the Darlington NGS remains a low-risk activity, within the licensing basis and safety case previously accepted by the Commission.

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<sup>131</sup> CMD 25-H107, Section 6, page 22.


125. The Commission delegates its authority for the purpose of accepting future TDS installations and operations on Units 1 and 4 at the Darlington NGS to the following CNSC staff:

- EVP/COO
- DG-DPRR

126. The Commission notes that this delegation is strictly for the administration of matters already within the established safety case and licensing basis. In delegating this authority, the Commission is authorizing designated CNSC staff to verify that OPG's installation, commissioning, and operation of a TDS on any unit remain consistent with the safety case previously accepted for Unit 2 and within the licensing basis set out in DEC 21-H107, DEC 25-H100, and this *Record of Decision*. This delegated authority is limited to confirming that OPG's submissions conform to the established regulatory framework; it does not extend to authorizing any activity that would fall outside the approved safety case or licensing basis. Any such matters remain solely within the Commission's purview. The Commission is satisfied that this approach is reasonable.

#### 4.0 CONCLUSION

127. The Commission has considered the information and submissions of OPG, and CNSC staff, as well as a written intervention submitted for the hearing. Based on its consideration of the evidence on the record, the Commission amends the licensing basis to authorize OPG to install and operate a TDS on Unit 3 at the Darlington NGS for the production of any radionuclides authorized in PROL 13.00/2045 (i.e. Y-90, Mo-99, and Lu-177), subject to verification by CNSC staff.<sup>132</sup> The terms and conditions of the licence for the Darlington NGS, PROL 13.00/2045, remain unchanged. The Commission also authorizes OPG to install and operate TDSs on Units 1 and 4, subject to the same RHP previously established by the Commission in DEC 25-H100 for Unit 2. The authority delegated to CNSC staff for the release of that RHP remains unchanged and continues to apply.

  
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Pierre F. Tremblay  
President  
Canadian Nuclear Safety Commission

April 10, 2026  
Date

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<sup>132</sup> CNSC staff verification is conducted as required by the RHP established in DEC 25-H100 for Unit 2.

**Appendix A – Intervenors**

<b>Intervenors</b>	<b>Document Number</b>
Society of United Professionals	<a href="#">CMD 25-H107.2</a>