Record of Decision

DEC 21-H107

In the Matter of

Applicant	Ontario Power Generation Inc.
Subject	Application to Amend Power Reactor Operating Licence PROL 13.02/2025 to Authorize the Production of Molybdenum-99 at the Darlington Nuclear Generating Station
Date of Decision	October 26, 2021

RECORD OF DECISION – DEC 21-H107

Applicant:	Ontario Power Generation Inc.
Address/Location:	700 University Avenue, Toronto, Ontario, M5G 1X6
Purpose:	Application to Amend Power Reactor Operating Licence PROL 13.02/2025 to Authorize the Production of Molybdenum-99 at the Darlington Nuclear Generating Station
Application received:	December 5, 2018
Hearing:	Public Hearing in Writing – Notice of Hearing in Writing published on May 4, 2021
Date of decision:	October 25, 2021
Panel of Commission:	S. Demeter, Presiding Member

Licence: Amended

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1.0 INTRODUCTION

1. Ontario Power Generation Inc. (OPG) has applied to the Canadian Nuclear Safety Commission[1] (CNSC), under subsection 24(2) of the *Nuclear Safety and Control Act* (NSCA), for an amendment to the Power Reactor Operating Licence (PROL) for its Darlington Nuclear Generating Station (NGS), located in the Municipality of Clarington, Ontario. OPG has requested an amendment to its licence to authorize the production of Molybdenum-99 (Mo-99). The decay isotope of Mo-99, Technetium-99^{m} (Tc-99^{m}), is a diagnostic imaging agent used in nuclear medicine. OPG's current licence for the Darlington NGS, PROL 13.02/2025, does not authorize the deliberate production of any medical isotopes. PROL 13.02/2025 expires on November 30, 2025.

2. OPG, in partnership with BWXT Nuclear Energy Company (NEC) and BWXT Canada Ltd., plans to install an Isotope Irradiation System (IIS) at Darlington Unit 2 to produce Mo-99. OPG will be responsible for the irradiation of natural molybdenum targets and the subsequent packaging of irradiated molybdenum. All other aspects of the supply chain downstream of OPG's production of Mo-99 will be handled by qualified parties with the necessary CNSC nuclear facility and/or nuclear substances and radiation devices licences. In particular, BWXT Medical Ltd. and the hospital end users will be responsible for wastes associated with the processing and use of Mo-99 and Tc-99^{m}.

Issues

3. The Commission is required to determine whether and what requirements the *Impact Assessment Act* (IAA) imposes in relation to the activities sought to be authorized in OPG's licence amendment application.

4. The Commission must determine, under paragraph 24(4)(*a*) and (*b*) of the NSCA, whether it is satisfied that:

    a) OPG is qualified to carry on the activities that the amended licence would authorize; and

    b) in carrying on that activity, 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.

5. As an agent of the Crown, the CNSC 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

[1] 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.

which may adversely impact potential or established Indigenous or treaty rights.[2] As such, the Commission must determine what engagement and consultation steps and accommodation measures are called for, respecting Indigenous interests.

Panel

6. Pursuant to section 22 of the NSCA, the President of the Commission established Dr. Sandor Demeter as a Panel of the Commission to consider the licence amendment application. A notice of hearing in writing and participant funding was published on May 4, 2021. The Commission, in conducting a public hearing based on written materials, considered written submissions from OPG (CMD 21-H107.1, CMD 21-H107.1A, CMD 21-H107.1B), CNSC staff (CMD 21-H107, CMD 21-H107.A) and ten intervenors.[3]

CNSC Participant Funding Program

7. Pursuant to paragraph 21(1)(b.1) of the NSCA, the Commission has established a Participant Funding Program (PFP) to facilitate the participation of Indigenous peoples, members of the public and stakeholders in Commission proceedings. In May 2021, up to $30,000 in funding to participate in this licence amendment process was made available through the CNSC's PFP. A Funding Review Committee (FRC), independent of the CNSC, reviewed the funding applications received and made recommendations on the allocation of funds. Based on the recommendations from the FRC, the CNSC awarded a total of $20,600 to five applicants. The applicants were required, by virtue of being awarded participant funding, to submit a written intervention respecting OPG's application.

2.0 DECISION

8. The Commission is satisfied that an impact assessment under the IAA was not required for the licence amendment.

9. The Commission is satisfied that CNSC staff's efforts to engage with Indigenous groups who may have interest in the proposed licence amendment have fulfilled the Commission's responsibility with respect to engagement respecting this licensing action. The efforts made by CNSC staff are key to the important work of the Commission toward reconciliation and relationship building with Canada's Indigenous peoples.

10. Based on its consideration of the matter, as described in more detail in the following sections of this Record of Decision, the Commission concludes that OPG satisfies the conditions of subsection 24(4) of the NSCA. Therefore,

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[2] *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

[3] See Appendix A for a list of interventions

The Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the Power Reactor Operating Licence issued to Ontario Power Generation Inc. for its Darlington Nuclear Generating Station located in the Municipality of Clarington, Ontario. The amended licence, PROL 13.03/2025, remains valid until November 30, 2025.

11. The Commission amends the licence to authorize the activities related to the production of Mo-99 and includes in the licence the amendment to condition 15.6 as recommended by CNSC staff in CMD 21-H107. The Commission also delegates its authority to remove the regulatory hold points associated with Licence Condition 15.6 to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch, as recommended by CNSC staff.

12. This licence amendment authorizes OPG to produce Mo-99 in Unit 2 of the Darlington NGS. If OPG plans to produce Mo-99 in any other reactor unit at the Darlington NGS, it must obtain approval of the Commission, and demonstrate that the production of Mo-99 in any other unit is a low risk activity that can be executed safely. Further, if OPG wishes to use the IIS to produce other types of radioisotopes at the Darlington NGS, Commission approval would also be required.

3.0 APPLICABILITY OF THE IMPACT ASSESSMENT ACT

13. In coming to its decision, the Commission was first required to determine whether the IAA had requirements to be met, including whether an impact assessment of the proposal was required. CNSC staff determined the proposed activities are not captured in the IAA's *Physical Activities Regulations* nor are they considered a project on federal lands. Based on the information provided for this hearing, the Commission is satisfied that an impact assessment under the IAA is not required.

4.0 ISSUES AND COMMISSION FINDINGS

14. OPG first notified the CNSC of its intention to apply for a licence amendment to allow for the production of Mo-99 at the Darlington NGS in May 2018. In December 2018, OPG applied to amend its PROL for the Darlington NGS to authorize the production and possession of Mo-99. OPG's original intention was to host the first Mo-99 IIS at Unit 4; however, in June 2020, OPG submitted an update to the licence amendment application and notified the CNSC that OPG would be pursuing a Mo-99 IIS at Darlington NGS Unit 2. In February 2021, OPG provided an application addendum focusing on the impacts of the Mo-99 IIS on existing programs and procedures set out in the licensing basis reflected in the Licence Conditions Handbook.

15. In its consideration of this matter, the Commission examined the completeness of the application and the adequacy of the information submitted by OPG, as required by the NSCA, the *General Nuclear Safety and Control Regulations* (GNSCR), and other applicable regulations made under the NSCA. The GNSCR calls on a licence amendment applicant to provide information regarding any changes in information to the CNSC as part of its application. Section 6 provides:

> An application for the amendment, revocation or replacement of a licence shall contain the following information:
>
> (a) a description of the amendment, revocation or replacement and of the measures that will be taken and the methods and procedures that will be used to implement it;
>
> (b) a statement identifying the changes in the information contained in the most recent application for the licence;
>
> (c) a description of the nuclear substances, land, areas, buildings, structures, components, equipment and systems that will be affected by the amendment, revocation or replacement and of the manner in which they will be affected; and
>
> (d) the proposed starting date and the expected completion date of any modification encompassed by the application.

16. The intervention from the Canadian Environmental Law Association (CELA, CMD 21-H107.7) raised concerns regarding the completeness of OPG's licence amendment application. CELA submitted that OPG had not provided sufficient information regarding changes from previous licence amendment applications, nor had OPG provided schematics explaining the Mo-99 IIS design. On the topic of CELA's concerns, the Commission finds that Attachment 1 of OPG's CMD 21-H107.1 includes a description of how OPG's application satisfies Section 6 of the GNSCR. After the deadline for interventions, OPG also submitted CMD 21-H107.1A to provide additional details on the design of the Mo-99 IIS. The Commission is satisfied that OPG has provided sufficient information to address the requirements for a licence amendment application.

17. The Commission considered a number of issues and submissions relating to OPG's qualification to carry out the activity the amended licence would authorize. The Commission 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. The Commission also examined CNSC staff's assessment of the impact of Mo-99 production on all 14 safety and control areas (SCAs), Indigenous engagement, and several other matters of regulatory interest.

18. Intervenors provided the Commission with information and views about the economic impact of Mo-99 production at the Darlington NGS. The NSCA provides the extent of the Commission's statutory authority, which does not include an economic mandate, and the Commission's decisions do not weigh economic impact.

19. CNSC staff proposed the use of two regulatory hold points to verify operational readiness of the Mo-99 IIS prior to commercial production. Due to the nature of the execution of the Mo-99 project, OPG can only finalize a number of documents closer to time of commissioning the Mo-99 IIS. CNSC staff propose that the two hold points will ensure that specific activities associated with the installation and commissioning of the IIS are satisfied prior to progressing the project. CNSC staff will verify that the requirements of each regulatory hold point are met. The use of regulatory hold points is further discussed in Section 4.3 of this Record of Decision.

20. In making its decision, the Commission sent questions to OPG and CNSC staff, through CMD 21-H107Q, seeking further information. A key consideration by the Commission was why OPG chose a design for the Mo-99 IIS that is first-of-a-kind in a CANDU reactor. The Commission is satisfied with the completeness of the responses provided by OPG (CMD 21-H107.1B) and CNSC staff (CMD 21-H107.A).

4.1 Safety and Control Areas

4.1.1 Physical Design

21. OPG proposes to use a first-of-a-kind IIS design to produce Mo-99 via the irradiation of natural molybdenum (predominantly Molybdenum-98) targets. The targets, manufactured by BWXT-NEC, will be comprised of zirconium capsules containing natural molybdenum metal. As described in detail in CMD 21-H107.1A, a combination of pneumatic and hydraulic systems will insert and remove targets from out-of-service adjuster rod ports in the reactor core.[4] New targets will be loaded into the IIS outside of containment and pneumatic propulsion will carry targets along shielded "flight tubes" to the target airlock, which acts as the transfer point between the pneumatic and hydraulic propulsion systems. Hydraulic propulsion will carry the targets from the airlock to the target elevator, which will move targets into the reactor core. After approximately seven days of irradiation inside of the reactor core, the targets will be harvested, travelling back through the described systems to the flask loader to be packaged for transportation offsite. The Mo-99 IIS equipment will be located on and around the reactivity mechanism deck, as well as in the Main Control Room (MCR). The Mo-99 IIS will be controlled and monitored both via a local control panel and from the MCR.

22. CNSC staff evaluated the IIS design against the regulatory requirements and technical standards detailed in the Darlington Licence Conditions Handbook for the following areas: mechanical and process systems, instrumentation and control, electrical power systems, environmental qualification, human factors in design, pressure boundary, containment boundary, civil structure design, seismic qualification, and core neutronics.

[4] The reactor units at Darlington NGS were designed with 24 vertical neutron-absorbing adjuster rods, which are normally positioned in the core. Early in operation of the Darlington NGS, OPG determined that eight of these adjuster rods were not required and they were permanently removed from service. OPG proposes to modify four of the out-of-service adjuster rod ports for the purposes of the Mo-99 IIS project.

CNSC staff reported that OPG had demonstrated that the IIS design meets all applicable regulatory requirements. CNSC staff will confirm that the IIS has met design requirements and operates as expected by reviewing OPG's factory acceptance testing (FAT) report, as well as verifying OPG's testing, during the installation and commissioning phases.

23. OPG submitted that the Mo-99 IIS will form part of the reactor containment boundary. Containment integrity will be maintained through a combination of qualified sets of redundant containment isolation valves, and qualified components and flight-tubing. The Mo-99 IIS control system will utilize a hardware interlock circuit to ensure that at least one set of containment valves remains closed at all times. CNSC staff assessed OPG's submissions and reported that the design of the Mo-99 IIS would ensure that the containment boundary is maintained during normal operations and accident scenarios. CNSC staff reviewed the proposed permanent changes to the Unit 2 containment boundary and accepted the changes on February 12, 2021.

24. The Commission considered the impact of the operation of the Mo-99 IIS on reactor core neutronics. OPG submitted that the reactivity impact of the operation of the Mo-99 IIS will remain within the capabilities of the reactor regulating system. CNSC staff assessed OPG's analyses and reported that OPG had adequately considered the impact of operation of the Mo-99 IIS on the reactor core. OPG will validate its analyses during commissioning of the IIS and provide the results to the CNSC in the final commissioning report.

25. Interventions from D. J. Winfield and J. W. Hilborn (CMD 21-H107.2) and CELA (CMD 21-H107.7) raised concerns regarding the complexity of the first-of-a-kind Mo-99 IIS design. The Commission enquired about why a first-of-a-kind design was chosen over a design with real-world operating experience. OPG submitted that the basic concept of irradiating material in a reactor is well understood and that each component of the IIS is based on proven principles. CNSC staff stated that there are no requirements for the CNSC to preferentially treat one design option over another, as long as all regulatory requirements are met. The Commission is satisfied with the information provided by OPG and CNSC staff in response to this concern.

26. The Commission, as well as the intervention from D.J Winfield and J.W Hilborn (CMD 21-H107.2), questioned how OPG determined the impact of irradiation on the molybdenum targets. OPG submitted that demonstrations of target irradiation were performed in the University of Missouri Research Reactor (MURR), which provided confirmatory information to proceed to full production at Darlington NGS.

27. The Commission is satisfied that the design of the Mo-99 IIS meets regulatory requirements and that, through planned oversight, CNSC staff will verify that regulatory requirements are met when detailed documents become available closer to the installation and commissioning phases of the project.

4.1.2 Management Systems and Human Performance

28. The Commission examined OPG's management system and human performance programs related to the Mo-99 project. Specific areas included change management, contractor management, problem identification and resolution, and training.

29. CNSC staff assessed OPG's existing management system, in the context of the Mo-99 IIS project, against regulatory requirements, including CSA Group standard N286-12, *Management System Requirements for Nuclear Facilities* and REGDOC-2.1.2, *Safety Culture*. OPG submitted that its existing management system and nuclear safety policy contain the necessary processes for change management, self-assessment, corrective action implementation, and records management and do not need to be changed to accommodate the proposed activities associated with the operation of the Mo-99 IIS. CNSC staff confirmed that OPG's management system and nuclear safety policy comply with N286-12 and REGDOC 2.1.2, respectively. CNSC staff intend to verify that OPG continues to meet the requirements of CSA N286-12 during the various stages of the Mo-99 project, including development of isotope irradiation program documentation that will govern the production of Mo-99. The Commission is satisfied that staff will do the verification and will report to the Commission any information that merits Commission attention in this regard.

30. As the licence holder, OPG is ultimately responsible for the safety of all on-site contractor activities. OPG is utilizing multiple experienced vendors to provide services in support of the design, construction, and installation of the Mo-99 IIS. Laurentis Energy Partners (LEP), a wholly owned subsidiary of OPG, is the Mo-99 Project Owner. OPG and LEP have joint oversight of the project's execution. BWXT-NEC designed the Mo-99 IIS and will be responsible for the assembly of the natural molybdenum targets. BWXT-Canada Ltd. will be responsible for installation of the IIS. Kinectrics and Ecometrix prepared safety and environmental analyses, respectively. Through compliance verification activities such as inspections, CNSC staff have confirmed that OPG's contractor management program meets regulatory requirements.

31. The Mo-99 IIS is a first-of-a-kind design; as such, there are no comparable irradiation systems operating in a CANDU reactor. OPG submitted that, despite the first-of-a-kind nature of the IIS, it has considered operating experience (OPEX) from internal and external sources relevant to the irradiation of isotopes, modification of a nuclear power plant, the design process for first-of-a-kind projects. OPG also considered CANDU-specific OPEX related to fuel power ramping, moderator cover gas composition, and deflagration. CNSC staff's view is that OPG has satisfied the regulatory requirements related to problem identification and OPEX.

32. CNSC staff reported that OPG has a well-established systematic approach to training (SAT) system in place. OPG's training program meets the requirements of REGDOC-2.2.2, *Personnel Training* and includes a training-change control process. OPG submitted that it had completed preliminary training assessments and training needs analyses for groups impacted by the Mo-99 IIS. Through these assessments, OPG identified additional

training needs for specific work groups. OPG plans to use a Mo-99 IIS simulator, along with a Mo-99 IIS mock-up produced by BWXT, to train staff. CNSC staff reported that OPG demonstrated use of their SAT-based training system to conduct preliminary analyses of training impacts for Mo-99 production. CNSC staff will verify detailed training documentation as part of its planned regulatory oversight.

33. The Commission is satisfied that OPG has adequate management system and human performance programs in place to manage changes, manage contractors, identify and resolve problems, and train staff to ensure the effective installation and operation of the Mo-99 IIS.

4.1.3 Operating Performance

34. OPG is required to implement and maintain operations programs in compliance with REGDOC-2.3.2, *Accident Management: Severe Accident Management Programs for Nuclear Reactors* and CSA Group standard N290.15, *Requirements for the safe operating envelope for nuclear power plants*.[5] OPG asserted that the operation of the Mo-99 IIS would not require any changes to safety limits, special safety system trip set points, accident management procedures, or other aspects of its safe operating envelope (SOE) program. CNSC staff reported that OPG has a mature SOE program that is compliant with CSA N290.15. CNSC staff assessed OPG's submitted documentation and determined that OPG sufficiently demonstrated that the Mo-99 IIS will not invalidate the current SOE. The Commission directs CNSC staff to verify this determination through its review of OPG's final IIS commissioning report.

35. OPG submitted that it is producing new procedures, and revising all applicable existing procedures, to include maintenance and operation of the Mo-99 IIS. OPG submitted that approximately 50 procedures will be revised and up to 40 new maintenance procedures will be created in accordance with established OPG processes. CNSC staff reported that OPG's nuclear operations program, which includes processes for the development and revision of technical procedures, meets regulatory requirements. OPG will submit necessary procedures, including the new IIS operating manual, and the Commission directs CNSC staff to verify prior to the operation of the Mo-99 IIS.

36. The interventions by D. J. Winfield and J.W Hilborn (CMD 21-H107.2) and by A. Tilman (CMD 21-H107.10) raised the issue of the potential consequences of a molybdenum target becoming stuck in the reactor core. The Commission enquired about such a scenario. OPG submitted that a target stuck in the core could be left in place to be retrieved during a future planned outage. OPG's analysis found that a target stuck in the core for 7 years would have no effect on reactor operation. The ultimate fate of a target that has been stuck inside the core for an extended period, once retrieved, would be disposal as radioactive waste in accordance with waste handling procedures. The Commission is satisfied that, should a molybdenum target become stuck in the reactor core, it would not adversely affect the safe operation of the reactor.

[5] N290.15, Requirements for the safe operating envelope for nuclear power plants, CSA Group, 2010

37. The Commission concludes that the installation and operation of the Mo-99 IIS will remain within the existing SOE for the Darlington NGS and that OPG has sufficiently considered the scenario of a stuck target. The Commission is satisfied that OPG is following its management system process in the development of new procedures for the Mo-99 IIS and directs CNSC staff to check the completion of these documents under planned regulatory oversight.

4.1.4 Safety Analysis

38. The Commission considered the impact of the Mo-99 IIS on the safety case for the Darlington NGS, including the probabilistic safety analysis, deterministic safety analysis, hazard analysis, severe accident analysis, and the management of CANDU safety issues. OPG submitted that it identified and assessed new hazards associated with the Mo-99 IIS as part of the Darlington Hazards Screening Analysis. OPG reported that the introduction of the Mo-99 IIS will have a negligible effect on severe core damage frequency and large release frequency. OPG also reported that the Mo-99 IIS will have no impact on:

- the existing accident progressions detailed in the Darlington Safety Report
- severe accident management and recovery
- the management of CANDU safety issues

CNSC staff verified that OPG completed its Mo-99 IIS project safety assessments in accordance with REGDOC-2.4.1, *Deterministic Safety Analysis* and REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*. The Commission directs OPG to verify the safety analysis inputs during the commissioning of the Mo-99 IIS and submit them to CNSC staff for review.

39. The intervention by H. Ragheb (CMD 21-H107.5) raised concerns regarding the applicability of safety analysis models and computer codes to the Mo-99 IIS. OPG performed an assessment, as required by REGDOC-2.4.1 and CSA Group standard N286.7 *Quality assurance of analytical, scientific and design computer programs for nuclear power plants,*[6] to confirm the applicability and accuracy of the suite of codes used in the analysis to support the installation and operation of the Mo-99 IIS. As a result of the assessment, OPG recognized that a change was needed to modify the core representation and material properties to account for the Mo-99 IIS. CNSC staff determined this change to be technically reasonable and assessed that the modelling methodology utilized by OPG is acceptable. The Commission directs OPG to validate the models during commissioning and provide the results to CNSC staff for review.

40. On the topic of hydrogen deflagration – combustion caused by the interaction of specific concentrations of hydrogen and oxygen – OPG submitted that the Mo-99 IIS would not introduce any new potential for hydrogen deflagration following a postulated loss of moderator inventory (LOMI) event. A support system called the deuterium recombination system will limit the amount of deuterium gas that accumulates in the target elevators and

[6] N286.7, Quality assurance of analytical, scientific and design computer programs for nuclear power plants, CSA Group, 2012

IIS components inside of containment by recombining deuterium and oxygen back into deuterium oxide (D_2O). OPG also submitted that the surface temperatures of in-core IIS components will remain below the surface ignition temperature following a postulated LOMI. CNSC staff reviewed OPG's assessment of the LOMI event and are of the view that installation and operation of the Mo-99 IIS will not introduce the potential for a hydrogen deflagration event following a postulated LOMI.

41. The intervention by Curve Lake First Nation (CMD 21-H107.6) questioned if climate change-related extreme weather events were considered as part of the Mo-99 IIS safety analysis. The Commission notes that REGDOC 2.4.1 and REGDOC 2.4.2, which specify regulatory requirements for safety analyses at the Darlington NGS, provide guidance on incorporating severe weather considerations into safety analyses. During the 2015 renewal hearing for the Darlington NGS, CNSC staff also stated that its licensing and compliance assessments at the Darlington NGS incorporate climate change considerations. The Commission is satisfied that the impacts of severe weather are adequately considered in safety analyses at the Darlington NGS.

42. The Commission concludes that the installation and operation of the Mo-99 IIS will not alter the existing safety case for the Darlington NGS. The Commission directs CNSC staff to assess OPG's validation of the safety case following OPG's completion of the final Mo-99 IIS commissioning reports.

4.1.5 Fitness for Service

43. The Commission considered OPG's maintenance, aging management, and chemistry control programs as they apply to the Mo-99 IIS fitness for service. Fitness for service covers activities that affect the physical condition of equipment to ensure that they remain effective over time. This area includes programs that ensure the Mo-99 IIS equipment is available to perform its intended design function.

44. OPG submitted that maintenance on the Mo-99 IIS would be performed by OPG and BWXT staff. CNSC staff assessed OPG's high-level maintenance strategy for the Mo-99 IIS and determined that it complies with the regulatory requirements outlined in REGDOC 2.6.1, *Reliability Programs for Nuclear Power Plants* and REGDOC 2.6.2, *Maintenance Programs for Nuclear Power Plants*. At the time of CNSC staff's submission of CMD 21-H107, detailed Mo-99 IIS preventive maintenance and aging management documentation was still in development. The Commission directs CNSC staff to verify that the detailed Mo-99 IIS maintenance plans meet regulatory requirements prior to operation of the IIS.

45. With respect to chemistry control, OPG submitted that chemicals will not be used during operation of the Mo-99 IIS and that the Mo-99 IIS components located within the reactor core will not generate undesirable chemical interactions within reactor systems. CNSC staff reported that OPG's assessment of the impact of the Mo-99 IIS on system chemistry meets regulatory requirements. CNSC staff determined that the proposed installation and operation of the Mo-99 IIS will have negligible impact on chemistry control in reactor systems.

46. The Commission is satisfied that OPG has adequate programs in place to manage the maintenance, aging management and chemistry control of the IIS. The Commission directs CNSC staff to verify that OPG's detailed preventive maintenance plans and aging management strategy continue to meet regulatory requirements.

4.1.6 Radiation Protection

47. The *Radiation Protection Regulations* require licensees to establish a radiation protection program to keep exposures as low as reasonably achievable (ALARA), taking economic and social factors into account. CNSC staff reported that OPG has an effective radiation protection program in place at the Darlington NGS that meets regulatory requirements. OPG submitted that it will utilize its existing radiation protection program to manage radiological hazards involved with the installation, operation and maintenance of the Mo-99 IIS.

48. On the topic of worker dose control, OPG submitted that it applied ALARA principles to the design of the Mo-99 IIS including shielding, a dwell period[7], and installing equipment that requires personnel access in areas with low background radiation. OPG submitted that the incremental increase to an individual worker's whole body dose from activities related to Mo-99 production, together with all other occupational exposures at Darlington NGS in the course of the year, would be below OPG's exposure control levels (10 millisieverts/year (mSv/y), administrative control levels (20 mSv/y), and the regulatory dose limit (50 mSv/y).[8] CNSC staff determined that OPG sufficiently applied ALARA principles to the Mo-99 IIS design and is satisfied that the design will control doses to workers.

49. With respect to doses to the public, OPG's analysis of predicted emissions of tritium and particulates estimated that the highest potential dose to a member of the public from Mo-99 IIS operation would not exceed 0.006 microsieverts (μSv)/y. Considered in context with the current Darlington emissions, OPG estimates that the additional dose to a member of the public from Mo-99 IIS operation is an additional 1% dose above the current dose estimate of 0.4 μSv. This additional dose for a member of the public represents 0.0006% of the regulatory dose limit of 1 mSv/y. CNSC staff's assessment is that the predicted releases associated with the Mo-99 IIS do not pose additional risk to public health.

50. The interventions from CELA (CMD 21-H107.7) and A. Tilman (CMD 21-H107.10) raised concerns regarding the creation of additional radioactive isotopes as a byproduct of Mo-99 production. The Commission requested further information on the radiation hazard associated with these non-Mo-99 isotopes. OPG explained that, in addition to Mo-99, the irradiation of the molybdenum targets would produce Mo-101 (from the targets) and Manganese-56, Zirconium-97 and Sodium-24 (from the zirconium capsule). OPG

[7] The dwell period is the time for which the target basket is raised to just above reactor level to allow high energy, short-lived radioisotopes time to decay.

[8] Sievert (Sv) is a unit of equivalent dose and effective dose, equal to 1 joule/kilogram. A millisievert is one-thousandth of a sievert. A microsievert is one millionth of a sievert.

determined that a dwell period of 2 hours was appropriate based on the 15-minute half-life of Mo-101 and the 2.6-hour half-life of Manganese-56. OPG explained that, after the dwell period, 70 Curie/capsule would remain, with 95% of that dose attributed to Mo-99 and Mo-101.[9] OPG confirmed that it will follow all established radiation protection procedures to ensure personnel are protected from any radiation hazards associated with the production of Mo-99.

51. The Commission is satisfied that OPG has a sufficient radiation protection program in place at the Darlington NGS that will keep doses ALARA and ensure the protection of workers and members of the public from radiological hazards associated with the production of Mo-99.

4.1.7 Environmental Protection

52. 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. With respect to the Mo-99 project, CNSC staff evaluated the impact of Mo-99 production on OPG's environmental management system (EMS), environmental risk assessment (ERA), effluent and emissions control, environmental assessment and monitoring, and the protection of the public.

53. OPG is required to have an EMS and Environmental Monitoring Program (EMP) in place that are compliant with REGDOC-2.9.1 *Environmental Protection: Environmental Principles, Assessments and Protection Measures* and CSA Standard N288.4-10 *Environmental monitoring programs at Class 1 nuclear facilities and uranium mines and mills*, respectively.[10] CNSC staff assessed that OPG's EMS and EMP meet regulatory requirements and will continue to do so during the construction and the operation of the Mo-99 IIS.

54. OPG is required to implement and maintain an Environmental Risk Assessment (ERA) that complies with CSA Group standard N288.6-12 *Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*.[11] OPG's latest (2020) ERA for the Darlington NGS is currently under review by CNSC staff and does not incorporate Mo-99 production. OPG completed an environmental Predictive Effects Assessment (PEA) as a gap analysis against the current ERA to evaluate the impact of the Mo-99 IIS on emissions to the environment and on public dose. Per CSA Group standard N288.6-12, OPG is required to revise its ERA at least every five years. OPG plans to revise the ERA in 2025, in line with its five-year revision cycle. The revision will contain the results of the PEA, including information on station releases associated with the Mo-99 IIS.

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[9] Curie (Ci) is a non-SI unit of radioactivity. Radioactivity describes the rate at which a radioactive material emits radiation.

[10] N288.4, Environmental monitoring programs at Class 1 nuclear facilities and uranium mines and mills, CSA Group, 2010

[11] N288.6, Environmental risk assessments at Class I nuclear facilities and uranium mines and mills, CSA Group, 2012

55. In its PEA, OPG determined that the total tritium emission from the operation of the Mo-99 IIS would constitute 0.001% of the current Derived Release Limits (DRL) for the Darlington NGS. Therefore, DRLs and internal action levels are not expected to change as a result of the installation and operation of the Mo-99 IIS. The Mo-99 IIS also will not result in increased non-radiological emissions from the Darlington NGS. OPG will confirm the emissions from Mo-99 IIS operation during commissioning and provide the results to CNSC staff in the commissioning report. CNSC staff assessed OPG's PEA and is of the view that the existing DRLs will be maintained because emissions from the installation and operation of the Mo-99 IIS will be minimal.

56. OPG is required to implement and maintain an effluent monitoring program that complies with CSA Group standard N288.5-11, *Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills*.[12] OPG submitted that emissions from the Mo-99 IIS will pass through a cyclone separator and a High Efficiency Particulate Air Filter (HEPA), which will capture Mo-99 IIS related emissions prior to entering the reactor unit's existing contaminated exhaust system. The interventions by CELA (CMD 21-H107.7) and A. Tilman (CMD 21-H107.10) requested information on the types of particulate emissions that operation of the Mo-99 IIS will produce. The PEA details that the particulate emissions with the highest dose contribution expected from Mo-99 IIS operation include Zirconium-95 and its decay product, Niobium-95. OPG continuously monitors contaminated exhaust stack emissions and reports the emissions to the CNSC via quarterly and annual compliance monitoring reports.

57. CNSC staff also conducted an Environmental Protection Review for this licence amendment application. CNSC staff determined that the information provided by OPG regarding environmental protection is adequate to meet the applicable regulatory requirements under the NSCA and associated regulations.

58. The Commission concludes that, relative to the existing releases from the Darlington NGS, the environmental releases predicted in OPG's PEA for the proposed Mo-99 production activities are negligible. The Commission is satisfied that OPG has made, and will continue to make, adequate provision for the protection of the environment and the public in relation to the Mo-99 production activities that the amended licence will authorize.

4.1.8 Emergency Management and Fire Protection

59. CNSC staff submitted that OPG's existing emergency response and fire protection programs meet the regulatory requirements outlined in REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response* and CSA Group standard N293 *Fire protection for nuclear power plants*.[13] OPG submitted that the installation and operation of the Mo-99 IIS will not add additional requirements to its existing emergency management and fire protection programs. CNSC staff's view is that OPG has adequate programs and

[12] N288.5, Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills, CSA Group, 2011
[13] N293, Fire protection for CANDU nuclear power plants, CSA Group, 2012

provisions in place to mitigate and manage any potential emergency event that may arise during any of the proposed activities associated with the operation of the Mo-99 IIS.

60. The Commission concludes that OPG has sufficient response capabilities and emergency preparedness provisions in place at the Darlington NGS to protect the health and safety of persons and the environment in the case of an emergency related to the production of Mo-99.

4.1.9 Waste Management

61. OPG submitted that, aside from the used fuel waste generated through routine operations, the operation of the Mo-99 IIS will not generate waste at the Darlington NGS. The irradiated targets will be shipped to BWXT Medical, and any waste produced during the processing of $Tc\text{-}99^{m}$ will not be returned to the Darlington NGS.[14] OPG expects to generate a minimal amount of waste from Mo-99 IIS installation and maintenance activities, which OPG will process in accordance with its existing waste management program. CNSC staff confirmed that OPG's waste management program is compliant with CSA Group standard N292.3 *Management of low and intermediate-level radioactive waste*[15], and that OPG has the processes in place to safely manage waste related to the Mo-99 IIS.

62. The Commission is satisfied that the production of Mo-99 will have minimal impact on the amount of radioactive waste produced at the Darlington NGS site. The Commission concludes that OPG's existing waste management program is sufficient to safely manage any radioactive waste associated with the Mo-99 IIS.

4.1.10 Packaging and Transport

63. For the Mo-99 project, OPG is responsible for loading the irradiated Mo-99 targets into certified transport packages. BWXT Medical is responsible for the package design, certification and maintenance, as well as transportation. In accordance with the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR 2015), OPG must apply for and obtain CNSC approval to use the certified transport package prior to the first shipment. In accordance with Transport Canada's *Transportation of Dangerous Goods Regulations* (TDGR), OPG is also required to have appropriate training for personnel involved in the handling and transport of dangerous goods and to issue a training certificate to those workers. CNSC staff verified that OPG's existing packaging and transport program meets the requirements of the PTNSR and TDGR, and reported that OPG is qualified to ensure continued compliance with those requirements.

64. The Commission sought confirmation that CNSC staff had validated BWXT's compliance with relevant regulations, as it relates to their role in the transportation of Mo-99 targets. CNSC staff explained that, at the time of the hearing, BWXT had two

[14] Waste management at BWXT Medical is discussed in the Record of Decision for BWXT's Application for the Issuance of a Class IB Nuclear Substance Processing Facility Operating Licence, issued October 2021.
[15] N292.3, Management of low and intermediate-level radioactive waste, CSA Group, 2008

related applications under review with the CNSC: BWXT's application for certification of the transport package design, which CNSC staff certified as of September 20, 2021, and BWXT Medical's application for a nuclear substance processing facility licence, which the Commission issued in October 2021.

65. The Commission sought clarification on who would bear responsibility in the event of a transport incident. OPG submitted that BWXT Medical, being the shipper, would be the responsible party in the event of a transportation incident off site. CNSC staff explained that, under its site licence, OPG would be responsible should an incident occur during the loading of the package on the Darlington NGS site. Both BWXT Medical and OPG have emergency transportation response capability.

66. The Commission is satisfied that OPG has an adequate program in place to safely manage the packaging and transport of radioactive material associated with the production of Mo-99, and to ensure compliance with the PTNSR 2015 and TDGR. Recognizing that BWXT Medical is responsible for the package design, certification and maintenance, as well as transportation, and that these matters are not under consideration for this application, the Commission is nonetheless satisfied that the CNSC's regulatory regime encompasses these elements.

4.1.11 Security, Safeguards, and Conventional Health and Safety

67. CNSC staff determined that the existing security, safeguards, and conventional health and safety programs in place at the Darlington NGS meet regulatory requirements and are sufficient to accommodate the proposed activities associated with the Mo-99 IIS project. Given the scope of the project and the information presented, the Commission finds this assessment to be reasonable, as the Mo-99 project would not substantively affect those programs. The Commission is satisfied that OPG has the security, safeguards, and conventional health and safety programs in place to ensure the safe production of Mo-99.

68. CNSC staff submitted that OPG's safeguards program conforms to the measures required to meet Canada's international safeguards obligations, including Canada's obligations to the Comprehensive Safeguards Agreement and an Additional Protocol it has entered into with the International Atomic Energy Agency (IAEA). OPG is required, as set out in REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*, to provide information and access to IAEA inspectors for the completion of safeguards activities. OPG submitted that it will provide access and information related to the production of Mo-99 to the IAEA in a timely manner, and that the Mo-99 IIS will not interfere with existing IAEA safeguards surveillance monitoring equipment at the Darlington NGS. The Commission is satisfied that the production of Mo-99 at the Darlington NGS will have no impact on Canadian compliance with the safeguards agreements entered into with the IAEA.

4.2 Indigenous Engagement and Public Information

69. The common law duty to consult with Indigenous peoples applies when the Crown contemplates action that may adversely affect established or potential Indigenous and/or treaty rights. The CNSC, as an agent of the Crown and as Canada's nuclear regulator, recognizes and understands the importance of building relationships and engaging with Canada's Indigenous peoples. The CNSC ensures that its licensing decisions under the NSCA uphold the honour of the Crown and considers Indigenous peoples' potential or established Indigenous and/or treaty rights pursuant to section 35 of the *Constitution Act, 1982*.[16]

70. The duty to consult is engaged wherever the Crown has "knowledge, real or constructive, of the potential existence of an Indigenous right or title and contemplates conduct that might adversely affect it".[17] Licensing decisions of the Commission, where Indigenous interests may be adversely impacted by its decision, will therefore engage the duty to consult, and the Commission must be satisfied that the duty has been met prior to making the relevant decision.

71. The proposed physical modifications associated with this licence amendment are confined within the existing footprint of the Darlington NGS and environmental impacts beyond the limits of the Darlington site are expected to be negligible. CNSC staff submitted that this licence amendment would not cause adverse impacts to any potential or established Indigenous and/or treaty rights.

72. OPG submitted that the Darlington NGS and the planned Mo-99 transport route along highways 401, 416 and 417 traverse the treaty and traditional territories of multiple Indigenous communities. In co-operation with CNSC staff, OPG identified that the following Indigenous groups may have an interest in the proposed licence amendment:

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

OPG reported that it has engaged with the identified Indigenous communities to provide

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[16] *Constitution Act, 1982*, Schedule B to the *Canada Act 1982*, 1982, c. 11 (U.K.).
[17] *Haida Nation v. British Columbia (Minister of Forests),* 2004 SCC 73 at para 35.

information on the Mo-99 project and answer questions since 2019. Asked for further information regarding Indigenous engagement activities related to the proposed Mo-99 transport route, OPG submitted that LEP (wholly owned by OPG) and BWXT jointly engaged with Indigenous communities in the vicinity of the Darlington NGS and the transportation route. Engagement activities included phone calls, emails and both virtual and in-person presentations.

73. CNSC staff identified the First Nation and Métis groups who may have an interest in the proposed licence amendment due to the proximity of their communities, treaty areas and/or traditional territories to the Darlington NGS, or due to their previously expressed interest. CNSC staff informed the Commission that it sent letters to the identified Indigenous groups in May 2019 to notify them of the proposed licence amendment application and of their opportunity to participate in the hearing process. CNSC staff held meetings with the Métis Nation of Ontario, the Mohawks of the Bay of Quinte, Curve Lake First Nation, Hiawatha First Nation, the Mississaugas of Scugog Island First Nation, and the Chippewas of Rama First Nation in December 2018 and Spring 2019 to provide information and answer questions regarding the application. In May 2021, CNSC staff sent follow-up letters to each Indigenous group, and subsequently followed up with each group by email or phone. CNSC staff reported that no specific concerns about the licence amendment application were expressed to CNSC staff.

74. In its intervention (CMD 21-H107.6), Curve Lake First Nation (CLFN) provided recommendations to promote further meaningful consultation between CLFN, OPG and CNSC staff regarding the Mo-99 project. CLFN's recommendations included having more detailed discussions on environmental protection and safety analysis topics during their ongoing engagement meetings with OPG and CNSC staff. The Commission greatly values and appreciates the input and perspectives of the CLFN in relation to this matter.

75. The Commission is satisfied that this licence amendment would not cause adverse impacts to any potential or established Indigenous and/or treaty rights. The Commission is also satisfied with CNSC staff's efforts to engage with Indigenous groups who may have an interest in the Mo-99 IIS project. The efforts made by CNSC staff in this regard are key to the important work of the Commission toward reconciliation and relationship-building with Canada's Indigenous peoples, and for the purposes of this licence amendment, have satisfied the Commission's responsibility in this regard. The Commission expects CNSC staff to continue to build meaningful long-term relationships with Indigenous communities as part of the CNSC's reconciliation efforts.

4.3 Licence Conditions and Delegation of Authority

76. CNSC staff proposed the addition of the following text to PROL 13.02/2025 Part IV licensed activity (vi):

"*(vi) possess, transfer, process, package, manage and store Molybdenum-99 radioisotope and its associated decay isotopes.*"

and licence condition 15.6:

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

CNSC staff's CMD 21-H107 included a draft of the proposed amended licence.

77. CNSC staff proposed the use of two regulatory hold points (RHPs) to track the completion and verification of identified actions prior to the installation and commissioning of the Mo-99 IIS:

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

The proposed hold points will be used to confirm the operational readiness of the IIS prior to the start of Mo-99 commercial production. Section 4.5 of CNSC staff's CMD 21-H107 described the details of each hold point, including the completion of factory acceptance testing and commissioning plans. CNSC staff recommended that the Commission delegate its authority for the consent to remove the two regulatory hold points to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

78. The interventions from the CELA (CMD 21-H107.7) and A. Tilman (CMD 21-H107.10) raised concerns regarding the use of regulatory hold points and the delegation of authority for the removal of the hold points to CNSC staff. The Commission clarifies that the use of regulatory hold points does not leave the responsibility of defining the licensing basis to CNSC staff, but rather delegates to CNSC staff the authority to verify that the licensing basis approved by the Commission has been upheld. The Commission directs CNSC staff not to authorize OPG to commence installation or commissioning of the Mo-99 IIS until OPG has satisfied the pre-requisites for the release of each respective hold point. CNSC staff will perform compliance verification activities to confirm that OPG has completed the identified actions.

79. The Commission includes in the licence the conditions and licensed activity as recommended by CNSC staff in CMD 21-H107 and concludes that the production of Mo-99 at Darlington NGS Unit 2 is a low risk activity that will remain within the station's existing safe operating envelope. CNSC staff recommended in CMD 21-H107 that, if

OPG were to plan to produce Mo-99 in a unit other than Unit 2, OPG must obtain concurrence from CNSC staff and demonstrate that it is a low risk activity, which can be executed safely. Due to the first-of-a-kind nature of the Mo-99 IIS design and to allow the public additional opportunity to participate, the Commission directs that OPG must obtain the approval of the Commission, rather than concurrence from CNSC staff, if it means to produce Mo-99 in a unit other than Unit 2.

80. The Commission is satisfied with the delegation of authority for removal, of the two regulatory hold points. The Commission recognizes the benefit of using regulatory hold points to verify the operational readiness of the Mo-99 IIS, prior to the start of commercial production. The CNSC has successfully used hold points in larger projects such as the Darlington Unit 2 Refurbishment.

5.0 CONCLUSION

81. The Commission has considered OPG's application for a licence amendment to authorize the production of Mo-99. Based on its consideration of the information submitted, the Commission is satisfied that the application submitted by OPG meets the requirements of the NSCA, the GNSCR and other applicable regulations made under the NSCA.

82. The Commission has also considered the submissions of OPG, CNSC staff and all participants as set out in the material available for reference on the record, as well as the written interventions provided by intervenors for the hearing.

83. The Commission is satisfied that an impact assessment under the IAA was not required for OPG's licence amendment application and notes that the NSCA provides a strong regulatory framework for environmental protection. Further, the Commission is satisfied that, in conducting the activities that the amended licence authorizes, OPG will make adequate provision for the protection of the environment and the health of persons.

84. The Commission is satisfied with CNSC staff's efforts to engage with Indigenous groups who may have interest in OPG's licence amendment application. The efforts made by CNSC staff in this regard are key to the important work of the Commission toward reconciliation and relationship-building with Canada's Indigenous peoples, and for the purposes of this licensing action these efforts have satisfied the Commission's responsibility in this regard.

85. The Commission is satisfied that OPG meets the test for a licence amendment set out in subsection 24(4) of the *Nuclear Safety and Control Act*. That is, the Commission is of the opinion that OPG is qualified to carry on the activity that the proposed amended licence will authorize and that it 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.

86. The Commission directs, if OPG plans to produce Mo-99 in any reactor unit at the Darlington NGS other than Unit 2, that OPG must obtain approval of the Commission and demonstrate that the production of Mo-99 in any other unit is a low risk activity that can be executed safely. Further, if OPG wishes to use the IIS to produce other types of radioisotopes at the Darlington NGS, the Commission directs that OPG must also obtain Commission approval.

87. Therefore, the Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the power reactor operating licence issued to OPG for the Darlington Nuclear Generating Station located on the Municipality of Clarington, Ontario. The amended licence, PROL 13.03/2025, is valid until November 30, 2025. The Commission includes in the amended licence the condition and licensed activities as recommended by CNSC staff in CMD 21-H107. In the administration of licence condition 15.6, the Commission also authorizes the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch to release the two regulatory hold points, related to the installation and commissioning of the Mo-99 IIS, upon verifying that the prerequisite steps for release have been taken by the licensee.

Dr. Sandor Demeter Digitally signed by Dr. Sandor Demeter Date: 2021.10.26 10:01:54 -05'00'

Sandor Demeter
Member,
Canadian Nuclear Safety Commission

October 26, 2021
Date

Appendix A – Intervenors

Intervenors –Written Submission	Document Number
David Winfield	CMD 21-H107.2
North American Young Generation in Nuclear (NAYGN)	CMD 21-H107.3
Canadian Nuclear Association	CMD 21-H107.4
Helmy Ragheb	CMD 21-H107.5
Curve Lake First Nation	CMD 21-H107.6
Canadian Environmental Law Association	CMD 21-H107.7
The Society of United Professionals	CMD 21-H107.8
Canadian Nuclear Workers'Council	CMD 21-H107.9
Anna Tilman	CMD 21-H107.10
North American Young Generation in Nuclear (NAYGN) – Durham Chapter	CMD 21-H107.11