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SUPPLEMENTAL/COMPLÉMENTAIRE

CMD : 21-H107.A

Date signed/Signé le : 23 SEPTEMBER 2021

Reference CMD(s)/CMD(s) de référence : 21-H107 & 21-H107Q

A Licence Amendment

Une modification de permis

**Ontario Power
Generation Inc.**

**Ontario Power
Generation Inc.**

**Darlington Nuclear
Generating Station**

**Centrale nucléaire de
Darlington**

Hearing in writing based solely on
written submissions

Audience fondée uniquement sur des
mémoires

Scheduled for:
September 2021

Prévue le :
Septembre 2021

Submitted by:
CNSC Staff

Soumise par :
Le personnel de la CCSN

e-Doc 6638917 (Word)
e-Doc 6643677 (PDF)

Summary

This supplemental Commission Member Document (CMD) provides CNSC staff's response to questions raised by the Commission panel members in CMD 21-H107Q.

Résumé

Ce document à l'intention des commissaires (CMD) supplémentaire apporte les réponses du personnel de la CCSN aux questions posées par les membres de la formation de la Commission dans le CMD 21-H107Q.

Signed/signé le
23 September 2021

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EXECUTIVE SUMMARY

Pursuant to paragraphs 24(4)(a) and (b) of the *Nuclear Safety and Control Act*, a panel of the Commission has been established to consider Ontario Power Generation's (OPG) application for an amendment to the Darlington Power Reactor Operating Licence (PROL), in the matter of the production of molybdenum-99 (Mo-99) radionuclides at the Darlington Nuclear Generating Station (NGS). In conducting this hearing in writing, the panel of the Commission has considered the written submissions (Commission Member Documents [CMDs]) provided by CNSC staff, OPG, and 10 Intervenors. During its considerations, the panel of the Commission requested additional information with respect to CNSC staff's CMD. The current submission, provides responses to the four (4) questions directed to CNSC staff. CNSC staff conclusions remain unchanged and continue to recommend that the Commission amend the Darlington PROL to include a new authorized activity and licence condition related to the installation and operation of a Mo-99 Isotope Irradiation System at Darlington NGS.

1 OVERVIEW

Pursuant to paragraphs 24(4)(a) and (b) of the [Nuclear Safety and Control Act](#),¹ a panel of the Commission has been established to consider Ontario Power Generation's (OPG) application for an amendment to the Darlington Power Reactor Operating Licence (PROL) 13.02/2025, in the matter of the production of molybdenum-99 (Mo-99) radionuclides at the Darlington Nuclear Generating Station (NGS) [1]. In conducting this hearing in writing, the panel of the Commission has considered the written submissions (Commission Member Documents [CMDs]) provided by:

- ❖ OPG, specifically:
 - the Application [[21-H107.1](#)]
 - Supplementary technical information [[21-H107.1A](#)]
- ❖ CNSC staff [[CMD 21-H107](#)]
- ❖ 10 Intervenors [21-H107.2 – 21-H107.11].

As part of the hearing in writing, the panel of the Commission requested additional information with respect to CMD 21-H107; the request being documented in CMD 21-H107Q [2]. The current submission (CMD 21-H107.A) provides responses to four (4) questions raised in CMD 21-H107Q [2] that were directed to CNSC staff.

2 CNSC STAFF RESPONSES TO QUESTIONS RAISED BY THE PANEL OF THE COMMISSION IN CMD 21-H107

Via CMD 21-H107Q [2], the panel of the Commission requested CNSC staff respond to four (4) questions. CNSC staff's responses are presented throughout the remainder of this section. CNSC staff's current submission does not provide responses to the questions in CMD 21-H107Q [2] that were directed to the applicant, OPG; nor does it address the interventions beyond the questions raised by the panel of the Commission.

The Commission's questions, including repeated extracts, have been reproduced below in the shaded boxes to provide suitable context for CNSC staff's responses. When included, annotations ahead of the question provide clarity if the Commission Panel's questions have been separated to facilitate CNSC staff's response. Lastly, CNSC staff note that aside from a question being broken up, none of the original wording was changed in anyway.

¹ *Nuclear Safety Control Act (NSCA) [S.C. 1997, c. 9]*

2.1 CNSC staff reply to CMD 21-107Q Question # 1

Some interveners have raised the point that this proposal [i.e. first-of-a-kind (FOAK) initiative], relatively speaking, is more technically complicated than other extant neutron irradiation [i.e. 98 Mo (n, gamma) 99 Mo] systems. The point has also been raised that there is no operational experience (OPEX) with this design. Relative to striving to use “best available technology” (BAT), and lack of OPEX for this process, the Panel would suspect that the confidence margins on the safety case are much broader than on other existing similar technologies/processes. What is the role of the regulator when there are multiple applicable options relative to preferentially supporting the safest approach?

The CNSC’s regulatory framework is established such that any application that meets all pertinent regulatory requirements has the potential to be implemented safely. There is no direction in the NSCA to only choose the safest, most conservative option. The CNSC regulatory framework is risk informed and already requires provisions be in place for an applicant to defend manageable levels of uncertainty and risk. The approach preferred by the applicant may also be informed by aspects related to economics, synergies with other activities or projects, and requirements of other regulatory bodies, which do not fall within the CNSC's (nuclear) safety oriented mandate. As long as all regulatory requirements are met, there are no requirements to preferentially treat one option over the other.

For the amendment requested by OPG only one complete design, including a comprehensive safety case, is fulsomely presented to the CNSC for consideration. As only one mature design is presented, a determination that there may have been safer alternatives based only high level descriptions of the fundamentals to other conceptual designs is not a determination CNSC staff can make.

The role of the CNSC staff is to review the applicant's proposal and ensure that the licensee is qualified to safely conduct the activities that will be authorized by the licence. To inform its recommendations to the Commission, CNSC staff conduct a complete review of OPG’s application and its supporting documentation in accordance with Section 6 of CNSC’s [General Nuclear Safety and Control Regulations](#)². As stated in CNSC staff CMD 21-H107 [3], the purpose of CNSC staff’s review, is to perform

a comprehensive review of OPG’s submissions against each of the 14 SCAs to determine whether: (1) the production and possession of Mo-99 would have any impacts to the existing safety case; (2) the design has addressed all regulatory requirements; and (3) OPG’s existing programs are sufficient to ensure the safe installation, commissioning, and operation of a Mo-99 IIS [isotope irradiation system, also referred to as the Target Delivery System (TDS)] in Darlington NGS Unit 2.

To clarify the preamble of the Commissioner Member's question concerning the lack of OPEX for this process:

² [General Nuclear Safety and Control Regulations](#) (GNSCR) [SOR/2000-202]

[...] The point has also been raised that there is no operational experience (OPEX) with this design. Relative to striving to use “best available technology” (BAT), and lack of OPEX for this process [...]

CNSC staff's review considers all pertinent regulatory requirements associated with the safety and control areas (SCAs); including, under the management system review, OPEX. It is the position of CNSC staff that OPG met the regulatory requirements to consider OPEX during the Mo-99 IIS design process. This information was reviewed by CNSC staff and reported in the CMD 21-H107 Section B.1 *Management System*, Subsection: *Problem identification and operating experience (OPEX)* [3]:

For design and safety analysis, OPG demonstrated that they have identified and considered OPEX from numerous sources including OPG's SCR database, CANDU Owners Group (COG) database, and international experience relevant to the irradiation of isotopes, modification of a nuclear power plant, and the design process for first-of-a-kind projects [...]. OPG also identified and considered CANDU-specific OPEX related to fuel power ramping, moderator cover gas compositions, and deflagration [...].

During its review of the material supporting OPG's application [1], CNSC staff reviewed OPG's Conceptual Design Report [4], which describes the OPEX gathered from cobalt processing activities at other CANDU stations as well as international facilities running hydraulic, pneumatic and hybrid mechanical systems. Further, this report documents the provisions in which OPEX was gathered and applied in the evaluation of alternative design approaches, risk assessments, and failure mode identification exercises for the major equipment and modifications required for the implementation the Mo-99 IIS.

Specific categories of the OPEX considered in this report [4] include:

- ❖ General OPEX,
- ❖ Hydraulic Transfer OPEX,
- ❖ Pneumatic Transfer OPEX,
- ❖ Cobalt Removal/Gantry Positioner and Flask System, and
- ❖ Mechanical Pneumatic System.

2.2 **CNSC staff reply to CMD 21-107Q Question # 2**

An intervener (CMD 21-H107.2) raised the question of why an empiric, real-world demonstration of how the proposed target apparatus will respond to irradiation, e.g. in a research reactor setting, is not required versus a more theoretical “proof of principle” approach. Please respond.

As a non-prescriptive regulator, the CNSC has not established explicit requirements concerning when “proof of principle” testing is required. It is the

licensee's responsibility to compile a valid safety case sufficient to demonstrate that all operating states and operational risks have been considered. Further, the licensee must demonstrate that they have adequate provisions in place to conduct the activities under their licence safely. CNSC staff note that the use of theoretical models, developed and validated on the best available empirical evidence derived from commercial operations and research are the cornerstone for analyses in nuclear safety, particularly concerning accident progression, hazard analysis, fitness for service, and radiation protection.

As documented in CMD 21-H107 [3], CNSC staff have reviewed OPG's design and safety analyses, and have concluded that OPG has submitted an acceptable safety case to establish the licensing basis for the operation of new equipment related to the proposed production of Mo-99 with an Isotope Irradiation System (IIS).

CNSC staff were made aware of the previous models, and tests conducted in research reactors to validate the concept, of natural molybdenum neutron capture ($\text{Mo-98} + \text{Neutron} \rightarrow \text{Mo-99} \rightarrow \text{Tc-99}^m$). These tests, however were not crucial to CNSC staff's review of OPG's safety case as CNSC staff's review focused on the predicted impacts of the Mo-99 IIS on the operation of Darlington NGS Unit 2.

Further, the interactions within the reactor core of the primary components of the proposed target apparatus (*e.g.* zirconium alloys) have been the subject of extensive industry study and use in CANDU reactors. CNSC staff also note that the interactions of molybdenum within the reactor core were discussed in CNSC staff CMD 21-H107 [3] (section B.6) in great detail from a chemistry perspective. The methodologies OPG used to justify the conclusions in the consolidated safety analysis were found to be well supported, consistent with CNSC staff's expectations, and acceptable to demonstrate the continued safe operation of Darlington NGS Unit 2, during normal operations, as well as during accident scenarios.

Further, as documented in the CNSC staff CMD [3], a compliance activity has been planned to review the commissioning results and assess OPG's validation of the safety case. CNSC staff note that this is consistent with planned regulatory oversight CNSC staff perform during other large scale nuclear projects such as the Darlington Unit 2 refurbishment. Lastly, CNSC staff have sufficient enforcement tools at their disposal to ensure the licensee operates their plant in an analyzed state consistent with the licensing basis established in support of the application for amendment.

2.3 **CNSC staff reply to CMD 21-107Q Question # 3**

It is the Panel's understanding, from CNSC staff CMD 21-H107, that the recommendation to allow installation of additional 98 Mo target units on other NPP units would depend on the safety case of the first install and CNSC staff would make a decision as to whether or not to refer the issue to the Commission. Is this correct?

CNSC staff confirm that the Commission Member's understanding is essentially correct. There are additional nuances found in CNSC staff CMD 21-H107 [3] that will be reiterated below to provide additional clarity:

- ❖ The current proposal for licence condition 15.6 is unit-agnostic (non-unit-specific) and thus does not explicitly limit the activities associated with a Mo-99 IIS at Darlington NGS to Unit 2.
- ❖ The proposed Licence Conditions Handbook (LCH), however, is explicit to Unit 2, as the other unit specific information has not yet been submitted, reviewed, and accepted by the Commission or a person authorized by the Commission.
- ❖ Compliance Verification Criteria proposed in the LCH are sufficient to ensure adequate regulatory oversight is in place and the units with the Mo-99 ISS operate safely and within its licensing basis.
- ❖ In accordance with the regulatory requirements specified in CSA standard N290.15, *Requirements for the safe operating envelope for nuclear power plants* and the Darlington NGS LCH, OPG must operate their plant in a fully analyzed state, so a complete design, safety analysis, and licensing impact assessment are all required for units that OPG wishes to introduce a Mo-99 IIS to.
 - Note: CSA N290.15 is part of OPG's licensing basis for Darlington NGS to ensure that all regulations under the NSCA (e.g. the [GNSCR](#) and [Class I Nuclear Facilities Regulations](#))³ are adhered to.
- ❖ The proposed Regulatory Hold Points (RHPs), including their removal by *Delegation of the Commission's Authority*, apply to the installation and commissioning of a Mo-99 IIS on any unit (current and future) at Darlington NGS.
 - CNSC staff have proposed that the CNSC's *Executive Vice-President and Chief Regulatory Operations Officer* be the position the Commission Delegate its authority to for the removal of the RHPs.

If the proposed licence amendment, pertaining to the production of Mo-99 at Darlington NGS, is accepted by the Commission, OPG, in order to introduce a Mo-99 IIS to another unit at Darlington NGS, would need to provide written notification to CNSC staff in accordance with licence condition G.2. Specifically, OPG must provide technical information for CNSC staff's consideration demonstrating that the additional target unit(s) remain within the established licensing basis. CNSC staff expect that OPG's submission would:

³ *Class I Nuclear Facilities Regulations [SOR/2000-204]*

- ❖ Provide all the necessary technical information demonstrating that the design, safety case, and impacts to governance are consistent with the established licensing basis.
- ❖ Demonstrate that OPEX from the existing system(s) have been considered.

Upon receipt of this application, CNSC staff would review OPG's documentation, in accordance with the scope and objectives of the RHPs as established in section 4.5.1 and 4.5.4 of CNSC staff's CMD 21-H107 [3]. Lastly, in accordance with licence condition G.1, if changes to the licensing basis were required to introduce a Mo-99 IIS to any subsequent unit(s) at Darlington NGS, the matter would be referred to the Commission.

2.4 **CNSC staff reply to CMD 21-107Q Question # 4**

Please note that CNSC staff have broken the Commission's question into two sub questions to facilitate the clarity of the response.

Please confirm that BWXT is the shipper, transporter, and receiver of the product and that they hold ultimate accountability to manage such in a manner prescribed by applicable regulations and that they are also responsible to respond and mitigate any transport accidents or incidents.

OPG will be the consignor (shipper) for the shipments of irradiated Mo-99 in the certified package and will be responsible for loading the contents and preparing the package for shipment at their Darlington site in accordance with the package design certificate issued by the CNSC. As identified in appendix B.14 of CNSC staff's CMD 21-H107 [3], prior to OPG's use of BWXT's certified package, OPG is required to register the use of this package with the CNSC in compliance with regulatory requirements specified in the CNSC's [Packaging and Transport of Nuclear Substances Regulations, 2015](#) (PTNSR 2015). OPG is required to confirm that it possesses the instructions necessary to prepare the package for shipment as set out in the certificate for the package design. OPG will be responsible should an incident occur during the loading of the package under their site license.

According to BWXT Medical's class IB licence application (CMD 21-H5) [5], once the package is loaded on the conveyance (shipping vehicle) by OPG, BWXT Medical will take the responsibility of shipping the package from OPG, Darlington to BWXT Medical, Kanata. Transport will be done by a qualified carrier contracted by BWXT. BWXT Medical's 24-hour emergency phone number will be specified on the Transport Document and BWXT Medical will hold the ultimate responsibility to respond and mitigate any transport accidents or incidents. BWXT Medical is also the consignee (receiver) of the package.

Has BWXT presented information to CNSC to inform the opinion that they are in compliance with all packaging and transportation regulations?

OPG's proposed activities are dependent on having a certified package to load the irradiated targets into. In addition, as the consignor to the package, OPG has responsibilities under the applicable packaging and transport regulations, for example: to ensure that the package is properly prepared and loaded, marked and labelled, and that a properly completed transport document accompanies the shipment. As discussed in CNSC staff's CMD, OPG's application was reviewed and CNSC staff concluded that OPG is qualified to ensure compliance with the requirements of both the PTNSR 2015 and the [Transportation of Dangerous Goods Regulations](#).

Also as mentioned in CNSC staff's CMD – there are two related applications with the CNSC at this time.

1. BWXT's application for certification of the design of BWXT Model F-522 (Type B (U) transport package
 - a. Needed to transport Mo-99 targets from Darlington site to BWXT
 - b. Certified as of 2021-09-20
2. BWXT Medical's application for a nuclear substances processing facility licence.
 - a. Pending Commission Decision

BWXT's application for the certification of the transport package

At the time of CNSC staff's CMD 21-H107, BWXT had submitted the package design information for BWXT Model F-522 that will be used to transport irradiated Mo-99 targets from OPG Darlington site to BWXT, Kanata. CNSC staff have assessed the information provided by BWXT and conclude that the BWXT Model F-522 transport package meets the regulatory requirements prescribed for Type B (U) packages as described in PTNSR 2015 and the [IAEA's Regulations for the Safe Transport of Radioactive Material, 2012](#). As of September 20th 2021, the CNSC has certified the BWXT Model F-522 for use.

BWXT Medical's application for a class 1B nuclear processing facility licence

BWXT Medical submitted Packaging & Transport policies and procedures to the CNSC as part of their class IB licence application (CMD 21-H5) [5]. These policies and procedures were reviewed during the technical assessment by CNSC staff and found to meet all necessary regulatory requirements.

In March 2019, CNSC staff conducted a Type II compliance inspection at the Nordion facility, which is now leased by BWXT Medical. The findings noted by CNSC staff were minor in nature and did not represent any risks to the health and safety of the persons or the environment.

While BWXT Medical's compliance with all packaging and transportation requirements were not explicitly discussed in CNSC staff's CMD 21-H107, they are fulsomely considered in CNSC staff's recommendations to the Commission in CMD 21-H5.

3 CONCLUSIONS

In this CMD, CNSC staff provided responses to questions from a panel of the Commission (CMD 21-H107Q) in respect of the hearing in writing CMD 21-H107 concerning OPG's request for an amendment to the Darlington PROL.

CNSC staff's conclusion remains unchanged; CNSC staff determined that OPG has adequate provisions in place to ensure the safe production and packaging of Mo-99. The installation and operation of the Mo-99 Isotope Irradiation System will not result in significant doses to workers or members of the public, and will not result in significant releases to the environment. In addition, the existing security and safeguards program in place is sufficient for the production of Mo-99. OPG will continue to protect the health and safety of the public, as well as the environment. CNSC staff recommend that the Commission amend the Darlington PROL to include a new authorized activity and licence condition related to the installation and operation of a Mo-99 IIS at Darlington NGS.

REFERENCES

- [1] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS – Molybdenum-99: Addendum to the Request for Amendment to the Darlington Nuclear Generating Station Power Reactor Operating Licence 13.02/2025," 2021-02-12. [NK38-CORR-00531-22275 P, e-Doc [6489932](#)]
- [2] Commission Panel Questions CMD, "Questions from Commission Panel Members in the Matter of Application for a licence amendment to authorize activities related to the production and possession of Mo-99 at the Darlington Nuclear Generating Station," CMD 21-H107Q, 2021-09-09. [e-Doc [6637962](#)]
- [3] CNSC staff CMD, "Request for licence amendment for the production of Mo-99 at the Darlington Nuclear Generating Station," CMD 21-H107, 2021-06-23. [e-Doc [5682560](#)]
- [4] OPG report, "Conceptual Design Report - Project Alpha Target Delivery System," NK38-REP-31710-10002 R01, 2018-11-09. [e-Doc [5715229](#), [6481816](#)]
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- [5] CNSC staff CMD, "Application from BWXT Medical Ltd. for a Class IB nuclear substance processing facility operating licence," CMD 21-H5, 2021-03-10. [e-Doc [6428772](#)]