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Written submission from the Canadian Environmental Law Association

Mémoire de l'Association canadienne du droit de l'environnement

In the Matter of

À l'égard de

Application for a licence amendment to authorize activities related to the production and possession of Molybdenum-99 (Mo-99) at the Darlington Nuclear Generating Station (NGS)

Demande de modification de permis en vue d'obtenir l'autorisation de produire du molybdène 99 (Mo-99) à la centrale nucléaire de Darlington

Public Hearing - Hearing in writing based on written submissions

Audience Publique - Audience fondée sur des mémoires

September 2021

Septembre 2021

Canada

August 17, 2021

Senior Tribunal Officer, Secretariat
Canadian Nuclear Safety Commission
280 Slater Street, P.O. Box 1046, Station B
Ottawa, Ontario K1P 5S9

Sent by email cnsc.interventions.ccsn@canada.ca

Dear Sir or Madam:

RE: APPLICATION FOR A LICENCE AMENDMENT TO AUTHORIZE ACTIVITIES RELATED TO THE PRODUCTION AND POSSESSION OF MOLYBDENUM-99 (MO-99) AT THE DARLINGTON NUCLEAR GENERATING STATION (NGS)

I. INTRODUCTION

The Canadian Environmental Law Association (CELA), submits this letter in response to the Canadian Nuclear Safety Commission's (CNSC) Revised Notice of Hearing in Writing dated May 4, 2021 requesting comments on an application from Ontario Power Generation Inc. (OPG) for a licence amendment to authorize activities related to the production and possession of Molybdenum-99 (Mo-99) at the Darlington Nuclear Generating Station (DNGS).[1] A hearing for this licence amendment application is scheduled for September 23, 2021. Our recommendations in response to the above noted matter are summarized in Section V of this letter**.**

II. INTEREST AND EXPERTISE OF THE INTERVENOR

CELA is a non-profit, public interest law organization. CELA is funded by Legal Aid Ontario as a speciality legal clinic to provide equitable access to justice to those otherwise unable to afford representation for environmental injustices. For nearly 50 years, CELA has used legal tools to advance the public interest, through advocacy and law reform, in order to increase environmental protection and safeguard communities across Canada. CELA has been involved in number of nuclear facility licensing and regulatory matters before the CNSC. CELA also has an extensive

[1] Canadian Nuclear Safety Commission, *Notice of Hearing in Writing and Participant Funding*, May 4, 2021 (Ref. 2021-H-107).

library of materials related to Canada's nuclear sector which is publicly available on their website.[2]

Supporting this intervention, is expert Dr. Ian Fairlie who CELA has retained to provide advice on the proposed licence in tandem with the recent licence granted to BWXT in Kanata, review the health and safety risks arising from the licence amendment requested by OPG for the manufacture of Mo-99, and analyze the cyclotron alternative for the safer means of providing Tc-99m by hospitals.

III. BACKGROUND

OPG's existing licence for the DNGS, which expires November 30, 2025, authorizes OPG to operate the DNGS as well as a wide range of associated activities, such as to possess, transfer, use, package, manage and store the nuclear substances that are required for, associated with, or arise from the operation of the DNGS, and to possess and use prescribed equipment and prescribed information that are required for, associated with, or arise from the operation of the DNGS.[3]

OPG now requests an amendment to its existing decommissioning licence in order to authorize it to add a new licensed activity to possess, transfer, produce, package, manage and store Mo-99 radioisotope, and its associated decay isotopes.[4]

CELA has reviewed OPG's licence application for the requested amendment[5] as well as the Commission Member Document (CMD) from OPG. CELA has also reviewed the CMD submitted by CNSC staff. [6] In response, CELA has prepared this letter containing a number of recommendations, accompanied by an Expert Report prepared by Dr. Ian Fairlie.

IV. SCOPE OF REVIEW

CELA received participant funding to review OPG's licence amendment application and related documentation, including OPG and CNSC Commission Member Documents (CMDs), with a

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[2] Canadian Environmental Law Association, online: www.cela.ca.
[3] Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025, page 1.
[4] Written submission from Ontario Power Generation Inc. In the Matter of Application for a licence amendment to authorize activities related to the production and possession of Molybdenum-99 (Mo-99) at the Darlington Nuclear Generating Station (NGS), CMD 21-H107.1, page 2 (page 3 of pdf). **[OPG CMD].**
[5] OPG letter, S. Gregoris to M. Leblanc, "Darlington NGS - Application for Darlington Nuclear Generating Station Power Reactor Operating Licence 13.01/2025 Amendment", December 5, 2018, CD# NK38-CORR-00531-20359 [**2018 Licence Application**].
[6] Canadian Nuclear Safety Commission (2021), "Ontario Power Generation Inc. Darlington Nuclear Generating Station" 21-H107 **[CNSC Staff CMD].**

focus on potential health and safety risks specific to OPG's proposed licence amendment application.

CELA also received funding to retain Dr. Ian Fairlie. Dr. Fairlie's expert report (see **Appendix A**) and CV (see **Appendix B**) are appended to this submission.

This intervention and expert report therefore considers the CNSC's jurisdiction per the *Nuclear Safety and Control Act* (NSCA) to ensure the adequate protection of the health and safety of persons.[7] In meeting this objective, per section 24(4) of the *NSCA*, CELA has compiled its findings from its review of CNSC staff and OPG Commission Member Documents (CMDs). Our recommendations to the Commission from this review, as well as those of Dr. Ian Fairlie, are summarized below.

V. RECOMMENDATIONS

For the reasons detailed in this submission, CELA finds that the requisite statutory and regulatory requirements have not been fulfilled. With this in mind, CELA makes the following recommendations to the Commission, which are further explored in the sections below:

(1) The Commission should ensure that OPG's design meets all regulatory requirements, including the Unit 2 containment boundary change, instead of leaving these issues to be determined by CNSC staff.

(2) The Commission should not delegate the authority to remove Regulatory Hold Points (RHP's) and should furthermore require that OPG submit a more fulsome licence application, in line with regulatory requirements, thus reducing the need to rely on RHP's.

(3) Given the key role played by BWX Technologies (BWXT) in the design of the system, the Commission should require that the division of maintenance responsibilities be made clear and preventative maintenance plans, testing and periodic inspections be completed.

(4) The Commission should require OPG to recognize and assess the impact of the Mo-99 IIS on both upstream and downstream waste generation to provide a more complete picture of the waste that the proposed activity will result in. OPG must also specify the number of fuel bundles currently being used by DNGS on an annual basis.

[7] *Nuclear Safety and Control Act*, SC 1997, c 9.

(5) The Commission should require OPG to properly consider the decommissioning aspect of the Mo-99 IIS.

(6) The Commission should require the inclusion of illustrations of the actual physical design of the Mo-99 IIS, including the Mo-99 IIS itself and the location where it will be installed.

(7) The Commission should require that OPG identify changes in the information contained in the most recent licence application.

(8) As the Mo-99 IIS constitutes a significant change, the Commission should require that the ERA be updated before proceeding with licensing to reflect the addition of the Mo-99 IIS.

(9) The Commission should require that the Mo-99 IIS be factored into the PSR that is currently under development.

(10) If the Commission decides to proceed with the licencing, it should require that the Mo-99 IIS be factored into the PSR currently under development.

(11) The Commission should require separate Action Levels for the Mo-99 IIS, instead of relying on the existing Action Levels for the DNGS as a whole.

(12) The Commission should clarify the degree to which the Mo-99 IIS will be tested after installation, but prior to operation, and should ensure that sufficient testing is carried out after installation as a requirement of licensing.

(13) The Commission should require more detailed information on the types and amounts of nuclear substances that are expected to be emitted as a result of the operation of the Mo-99 IIS, including any cumulative impacts over time.

(14) The Commission should not proceed with licensing given the deficiencies in OPG's Licence Application, in particular the lack of key details and the number of issues still to be determined or resolved. Instead, the Commission should wait until the recommendations above have been addressed.

We furthermore direct your attention to the findings and recommendations in the attached expert report by Dr. Ian Fairlie. The recommendations in the export are as follows:

(1) Given the close relationship between the licence amendment sought by OPG and the new licence sought by BWXT, the two matters should be heard together so that the public and Commission can best adjudicate this matter in the public interest.

(2) CNRC should ask OPG whether there is a supply issues with the importation of Mo-99 supplies.

(3) The CNSC should establish an expert committee to examine the efficacy of Canadian hospital cyclotrons to directly manufacture Tc-99m.

(4) CNSC should confirm with OPG that it is proposing to irradiate all the molybdenum isotopes in natural molybdenum.

(5) CNSC should request OPG to inform it which Mo isotopes (and in what percentages) would be created in their molybdenum targets.

(6) CNSC should request OPG to provide information regarding which *other* isotopes (i.e. apart from Mo isotopes) will result from the irradiation of the targets.

(7) CNSC should inform itself of the possible disadvantages to patients of using Tc-99m supplies contaminated with other Tc isotopes originating from using natural molybdenum.

i. Several key requirements remain outstanding

The CNSC Staff CMD suggests several so-called *regulatory* requirements associated with two proposed regulatory hold points, which need to be met before the Regulatory Hold Points (RHPs) can be removed:

Regulatory Requirements Associated with Installation (RHP-1)

- That OPG has a design that meets all regulatory requirements and has incorporated existing OPEX
- That OPG has conducted a thorough safety analysis that verifies the impact of the Mo-99 IIS is negligible and operation poses minimal additional risk to the operation of the unit
- That OPG has accepted the results of the factory acceptance tests demonstrating the Mo-99 IIS is functioning as intended and can safely be installed
- That OPG has prepared the necessary work plans in accordance with existing procedures, processes, and programs within its management system and is ready to install the Mo-99 IIS

Regulatory Requirements Associated with Commissioning (RHP-2)

- That OPG has prepared the necessary work plans, identified the relevant commissioning tests, acceptance criteria, and back-out conditions; and is ready to safely test and commission the Mo-99 IIS on an operating reactor[8]

CELA submits the direction on RHPs provided in the CNSC Staff CMD is unclear, as several of the proposed requirements associated with these two RHP's are very broadly worded. Additionally, these directions set out requirements which ought to be met, before granting a licence and not subsequent to its issuance.

As such, the Commission should not consider granting a licence permitting the operation of the Mo-99 IIS, without first ensuring that OPG has a design that meets all regulatory requirements. This is a fundamental requirement which flows from Section 24(4)(b) of the *NSCA.* As proposed, the CNSC is adopting a backwards approach, wherein it presumes a licence can be granted without first having studied and completed the requisite safety analysis.

While the use of RHP's may be warranted in some circumstances (i.e. once all licence application requirements set out in the NSCA and regulations have been met), they cannot offset requirements which must be met at the time of licensing. Further, RHP's must not be as broadly worded as these, but should be far more specific, to make it clear exactly what work has been completed and what remains to be done, before the RHP can be removed.

Furthermore, OPG notes that "*CNSC staff acceptance of the containment boundary change was received for Unit 4 Mo-99 IIS design in Reference 2.5.5. Review by CNSC staff of Unit 2's Mo-99 IIS design was in progress at the time of this submission.*"[9] CELA **requests** the Commission to confirm whether the CNSC has completed its review of the containment boundary change. If not, then CELA recommends it be completed before granting a licence.

RECOMMENDATION NO. 1: Before granting a licence, the Commission should ensure that OPG's design meets all regulatory requirements, including the Unit 2 containment boundary change, instead of leaving these issues to be determined at a later date by CNSC staff.

ii. Authority to remove RHP's should not be delegated

The authority to remove regulatory hold points (RHP's) should not be delegated from the Commission to CNSC staff, especially in this instance when much preparatory work remains to be done, before the Mo-99 IIS will be ready.

[8] CNSC Staff CMD, Part One, page 28.
[9] OPG CMD, Attachment 2, page 34.

Doing so would arguably result in the Commission handing over to much of its authority to grant licences as the project is still under development at the present time. This is also evidenced by the fragmented nature of this project, where multiple parties will be involved through various different licences, making it essential for the commission to track the project until completion.

It is, furthermore, a first of a kind (FOAK) design, which makes it particularly important for the Commission to retain some degree of oversight to ensure that the Commission can confirm whether the licenced activity will be carried out in a way that fully lives up to the requirements of the NSCA and its regulations.

CELA furthermore **requests** the Commission to confirm if CNSC staff or OPG have considered whether there are any alternative approaches that could be used, instead of the significant reliance on RHP's? For instance, are there other ways of preparing for this licence application that requires less preparation to take place after the licence has been granted? It appears as though this piecemeal approach has simply been accepted for sake of convenience and that there has been no consideration given to an approach that would provide the Commission, and the public, with a more complete picture of the proposed activity.

The suggested use of RHP's is furthermore emblematic of the many items left to be completed, and suggests that OPG is not, in fact, at a stage where they are actually ready to apply for a licence. The licence application thus appears premature and should be rejected, and OPG be required to submit an updated application that does not require the same use of RHP's covering core aspects of the proposed activity.

RECOMMENDATION NO. 2: The Commission should not delegate the authority to remove RHP's and should furthermore require that OPG submit a more fulsome licence application, in line with regulatory requirements, thus reducing the need to rely on RHP's.

iii. Division of maintenance responsibilities etc. is unclear

OPG notes that "*Corrective maintenance on the Mo-99 IIS will be performed predominately by BWXT-NEC maintenance staff with oversight being provided by OPG staff.*"[10]

This statement makes it unclear who is responsible for identifying the *need* for corrective maintenance. Is it BWXT or OPG? It also leaves unclear where the boundary is drawn, i.e. what does it mean that corrective maintenance will be performed *predominately* by BWXT, and how is it determined whether BWXT or OPG will carry out the maintenance.

[10] Ibid., page 37.

Furthermore, earlier in the OPG CMD it is stated that "*scheduled and non-scheduled maintenance will be performed by a combination of the OPG Maintenance Department and by BWXT-NEC staff.*"[11]

OPG then later states that "*OPG is ultimately responsible for safety, which cannot be delegated or contracted to other organizations*",[12] and finally concludes that "*OPG staff will be qualified to operate and maintain the Mo-99 IIS.*"[13]

All in all, there is a lack of clarity as to who is responsible for ensuring maintenance is carried out, and who is responsible for actually carrying out said maintenance. CELA presumes this is a result of the fact that BWXT has designed the Mo-99 IIS, while it will be installed at Darlington NGS.

With these varying statements in mind, CELA asks if the division of labour and responsibilities regarding maintenance has already been established. If *yes*, this is critical information that must be set out in the licence application and reviewable by the CNSC and the public. If *no*, it is a deficiency which must be remedied before proceeding with licensing. As proper maintenance is key to ensuring human health and safety in the long-term, it should be ensured that there is a clear delineation of responsibilities, to avoid situations where both parties believe the other party will assess the need for maintenance and carry out said maintenance. This must be considered up front as part of the licence application process.

OPG also notes that "*Human factors engineering principles were applied during the design of the Mo-99 IIS by BWXT-NEC to reduce the probability of human errors. Oversight and guidance was also provided by OPG Human Factors Engineering specialists.*"[14] With this in mind, as well as the above described lack of clarity regarding maintenance responsibilities, OPG should provide further information on its involvement during BWXT's design of the system. The purpose of this information is to confirm whether OPG is sufficiently informed as to the design and operation of the system and in turn fully equipped to assume maintenance responsibilities, or whether knowledge about the design and functioning of the system, which would be key to ensuring proper maintenance, still resides with BWXT to a significant extent.

Finally, OPG notes that *"Preventative maintenance plans, testing and periodic inspections in accordance OPG's governance are under development."*[15] In particular given the collaboration between OPG and BWXT and the uncertainty regarding maintenance responsibilities, this should be in place before a licence amendment is granted. Alternatively, the licence should specify that

[11] Ibid., page 13.
[12] Ibid., page 46.
[13] Ibid., page 66.
[14] Ibid., page 17.
[15] Ibid., page 35.

this must be completed prior to initiating production, and should be a RHP to be verified/released by the Commission.

RECOMMENDATION NO. 3: Given the key role played by BWXT in the design of the system, the Commission should require that the division of maintenance responsibilities be made clear and preventative maintenance plans, testing and periodic inspections be completed.

iv. Waste is not properly accounted for in the licence application

OPG claims that *"Operation of the Mo-99 IIS, which includes routine target-harvesting and reseeding, will not generate waste."*[16]

Arguably this statement is false or at best misleading, as it ignores the fact that the Mo-99 IIS is expected to increase the reactor fuelling rate. OPG itself estimates that "*operation of the Mo-99 IIS is expected to increase the reactor fuelling rate by approximately 18 bundles per year due to the negative reactivity impact on fuel burnup.*"[17] The production and disposal of these 18 bundles will inevitably produce waste, which is a direct result of the operation of the Mo-99 IIS. Without the operation of the Mo-99 IIS, 18 fewer fuels bundles would need to be used.

The Mo-99 IIS uses radiation from nuclear fuel to convert natural Mo into Mo-99. Without access to nuclear fuel, the Mo-99 IIS cannot carry out the conversion. By increasing the demand for nuclear fuel, the Mo-99 IIS thus contributes to the unresolved issue of how to dispose of spent nuclear fuel. This issue is, however, not addressed.

Even if the operation of the Mo-99 IIS may account for a small portion of the total nuclear fuel used at Darlington, it still does require the continued use of nuclear fuel, and thus increases the demand for such fuel, and provides an additional reason to keep the Darlington NGS in continued operation. This issue ought to be considered and addressed as part of this licence application and a determination should be made as to its impact on the use of nuclear fuel and the associated challenge of disposing of the spent fuel.

This application should include an assessment of the total environmental impact, from mining to storage of spent fuel, as a result of this activity. Doing this will provide a more complete picture of the total impact of the proposed licence amendment. As a lifecycle regulator, such assessment is directly within the purview of the Commission.

The consideration of waste should thus include not just downstream waste, but also upstream waste from the production of the raw-materials used to produce Mo-99. Upstream waste should

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[16] Ibid., page 56.
[17] Ibid., page 22.

include waste produced when making the required fuel bundles and Mo-targets, while downstream waste should include spent fuel used in the reactors. Failing to do so, provides an incomplete picture of the waste generated as a result of the proposed activity and the impact of operations on future decommissioning activities.

To further illuminate the share of the Mo-99 IIS's contribution to the nuclear waste problem, CELA also **requests** the Commission to confirm the total number of bundles currently being used by DNGS per year, in order to make it clear, how large an increase in fuel use the Mo-99 IIS would lead to.

RECOMMENDATION NO. 4: The Commission should require OPG to recognize and assess the impact of the Mo-99 IIS on both upstream and downstream waste generation to provide a more complete picture of the waste that the proposed activity will result in. OPG must also specify the number of fuel bundles currently being used by DNGS on an annual basis.

v. Decommissioning should be considered in reasonable detail

A critical gap in OPG's documents is their lack of consideration of decommissioning, for which they simply conclude that "*The Mo-99 IIS, being a relatively small and removable system, will have minimal effect on future decommissioning activities.*"[18]

CNSC staff also considers the issue of decommissioning, albeit very briefly, and concludes that:

> OPG's program document W-PROG-WM-0003, Decommissioning Program, documents how OPG meets the applicable standards and regulatory requirements for decommissioning Darlington NGS. CNSC staff have reviewed OPG's decommissioning program and have concluded that it meets the applicable requirements [40].[19]

To this, CNSC staff adds the following:

> OPG has identified that the Mo-99 IIS is a relatively small and removable system that will have minimal effect on future decommissioning activities [1]. OPG concluded that based on their assessment the Mo-99 IIS would have no impact and would require no changes to the current decommissioning plan [1, 41]. CNSC staff will review OPG's next submission of the decommissioning plan and financial guarantee due in 2022 that covers all of OPG's liabilities.[20]

CELA finds this summary consideration unsatisfactory and recommends the Commission require a more fulsome discussion of decommissioning be included before proceeding with licensing, i.e. what will happen with the components that make up the Mo-99 IIS? To the extent that they

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[18] Ibid., page 57.
[19] CNSC Staff CMD, Part One, page 81.
[20] Ibid., page 82.

are radioactive, will they be reused in some way or will they need to be placed into interim storage while awaiting future long-term storage, etc.?

RECOMMENDATION NO. 5: The Commission should require OPG to properly consider the decommissioning aspect of the Mo-99 IIS.

vi. Very limited number of illustrations included in the application

While photos of the transportation flask, overpack and the target capsule are provided,[21] the application does not contain schematics, drawings, illustrations, photos or other visual representations of the proposed design of the Mo-99 IIS itself.

The photos of the transportation flask, overpack and the target capsule provide valuable insight into the design of key components. Similarly, schematics, illustrations, drawings or even photos would make it much easier to understand the design of the proposed Mo-99 IIS.

The application should thus include, at a minimum, some basic illustrations of the actual physical design of the Mo-99 IIS. This should include drawings or plans of the facility as a whole and the location of the Mo-99 IIS within it, as well as reasonably detailed drawing(s) of the Mo-99 IIS, only to be limited by any competing interests, such as security precautions. The lack of any such visual aids begs the question whether this is the result of the incomplete design, and thus another reflection of a premature licence application.

RECOMMENDATION NO. 6: The Commission should require the inclusion of illustrations of the actual physical design of the Mo-99 IIS, including the Mo-99 IIS itself and the location where it will be installed.

vii. Changes in information contained in the most recent licence application should be identified

Section 6 of the *General Nuclear Safety and Control Regulations*[22], states what information shall be contained in an application for the amendment, revocation or replacement of a licence. This includes the requirement in Section 6(b) that the application must include "*a statement identifying the changes in the information contained in the most recent application for the licence.*"

OPG's response to this requirement is not contained in the OPG CMD, but is instead found in the 2018 Licence Application, where the following is said:

[21] OPG CMD, Attachment 2, pages 7 and 9.
[22] General Nuclear Safety and Control Regulations, SOR/2000-202.

> As this is a new activity for OPG and a new design, the latest application for Darlington NGS licence renewal did not include details of the Molybdenum Isotope Irradiation System.[23]

This reply fails to address what is actually requested in Section 6(b). Any change in the current application, compared to the most recent application should be provided here, not just information that deals exclusively with the Mo-99 IIS.

Any changes in the information provided in the current application when compared to the information provided in the most recent application should thus be provided in response to Section 6(b). It would indeed be curious if there had been no changes in the information, as the Mo-99 IIS will undoubtedly require changes to be made in the structure, components etc. of the existing NGS. In the unlikely event that OPG is of the opinion that there are no changes in information provided in the previous licence application when compared to the current application, then this should be explicitly stated in the application.

On a related note, CELA also notes that the 2018 Licence Application itself should have been included on the CNSC website as part of the documents provided for this hearing.

RECOMMENDATION NO. 7: The Commission should require that OPG identify changes in the information contained in the most recent licence application.

viii. The Mo-99 IIS constitutes a significant change – ERA should be updated now

CNSC staff notes that "*OPG updates its ERA every five years. OPG's latest (2020) ERA (e-Doc 6527728), was provided to CNSC staff in March 2021 and is presently under review.*"[24]

Furthermore, OPG appears to suggest that an update will be made after the Mo-99 IIs is operational, as part of the periodic updates required by REGDOC-2.9.1, which would mean that an update that reflects the proposed Mo-99 IIS will not be carried out for another 5 years.[25]

If the Commission chooses to proceed with the licence application, the Environmental Risk Assessment (ERA) should be updated in accordance with REGDOC-2.9.1, which requires that updates be made when a significant change occurs in either the facility of the activity. Adding a first of a kind activity and making changes to the very core of the facility is arguably a significant change as it involves first of a kind modifications to the reactor itself. The ERA should thus be updated now rather than in 5 years, to ensure compliance REGDOC-2.9.1.

[23] 2018 Licence Application, Attachment 1, page 1.
[24] CNSC Staff CMD, Part One, page 74 (footnote 6).
[25] OPG CMD, Attachment 2, page 49.

Alternatively, the Commission should explore what constitutes a significant change, including what factors were weighed/involved in making this determination regarding the Mo-99 IIS.

RECOMMENDATION NO. 8: As the Mo-99 IIS constitutes a significant change, the Commission should require that the ERA be updated before proceeding with licensing to reflect the addition of the Mo-99 IIS.

ix. The Mo-99 IIS should be factored into the PSR that is currently under development

Section 3(1)(a) of the *Nuclear Substance and Radiation Devices Regulations*[26] requires that a licence application include "*the methods, procedures and equipment that will be used to carry on the activity to be licensed* ".

OPG's response simply provides that *"Procedures for operation and maintenance of the Mo-99 IIS are currently under development and are expected to be finalized following completion of Factory Acceptance Testing of the assembled system at BWXT-NEC"*.[27] OPG also notes that the Mo-99 IIS operating manual is under development. [28]

In other words, the application does not fulfill the requirement in Section 3(1)(a). On this basis alone, CELA submits the Commission should not consider the licence application until the Mo-99 IIS has been factored into the PSR that is currently under development.

RECOMMENDATION NO. 9: The Commission should require that the Mo-99 IIS be factored into the PSR that is currently under development.

x. OPG assumes Mo-99 IIS satisfies regulatory requirements, suggests delaying inclusion in PSR

OPG claims that *"Given the Mo-99 IIS is a new design <u>that satisfies all applicable regulatory requirements</u>, this system will be factored into subsequent PSRs [periodic safety reviews] after the PSR that is currently under development for renewal of the Darlington PROL in 2025."*[29] (emphasis added)

CELA objects to this statement by OPG which assumes the role of the Commission in making a finding of regulatory compliance, and then relies upon this 'finding' to argue that the Mo-99 IIS does not need to be factored into the PSR currently under review. However, the question as to whether this new design satisfies all applicable regulatory requirements is not for OPG to

[26] Nuclear Substances and Radiation Devices Regulations (SOR/2000-207).
[27] OPG CMD, Attachment 1, page 14.
[28] OPG CMD, Attachment 2, page 17.
[29] Ibid., page 20.

determine, and should not be used as a reason to not factor the Mo-99 IIS into the PSR currently under development.

This type of statement furthermore suggests that OPG considers the licence application process as somewhat of a formality rather than an actual approval process. OPG may itself believe that the design satisfies all applicable regulatory requirements, but that has yet to be determined. By relying on this essentially self-serving statement OPG is arguably pre-empting the very purpose of the licence hearing, a key part of which is to determine if the Mo-99 IIS actually satisfies all regulatory requirements.

Additionally, the fact that the Mo-99 IIS is a first of a kind design should further support including the Mo-99 IIS in the PSR that is under development, rather than wait until a later time.

RECOMMENDATION NO. 10: If the Commission decides to proceed with the licencing, it should require that the Mo-99 IIS be factored into the PSR currently under development.

xi. OPG assumes no changes needed to Action Levels etc.

OPG concludes that "*There will be no changes to the DRLs, Action Levels or IILs as a result of the Mo-99 IIS.*"[30]

CELA submits Mo-99 IIS should have its own, sufficiently conservative and proportionate Action Levels etc., rather than simply be lumped together with the limits set for the DNGS as a whole. Alternatively, it should be determined in the licence, how large a percentage the Mo-99 IIS may contribute to the overall emissions from the site, before action must be taken.

RECOMMENDATION NO. 11: The Commission should require separate Action Levels for the Mo-99 IIS, instead of relying on the existing Action Levels for the DNGS as a whole.

xii. Testing and verification should take place after installation

The OPG CMD mentions various testing prior to installation, including the testing of the Mo-99 IIS relief valves at BWXT-NEC to confirm proper set-point before installation at Darlington NGS.[31] CELA **requests** the Commission to clarify if such testing will also be carried out after installation?

Furthermore, OPG notes that "*The irradiated targets represents an increased radiation risk to workers requiring an innovative shielding design"*, and that "*innovative shielding design was*

[30] Ibid., page 48.
[31] Ibid., page 33.

incorporated in the design of the IIS to reduce radiation levels during target-harvesting."[32] CELA **requests** the Commission to confirm whether the effectiveness of this design will be verified after installation but before operation?

In general, CELA recommends including further information on the testing and verification of the proper functioning of the Mo-99 IIS after installation. If such testing is not planned, it should be required as a licence condition.

RECOMMENDATION NO. 12: The Commission should clarify the degree to which the Mo-99 IIS will be tested after installation, but prior to operation, and should ensure that sufficient testing is carried out after installation as a requirement of licensing.

xiii. Negligible impact on Environment?

OPG concludes "*that operation of the Mo-99 IIS will have negligible impact on the environment*" and refers to Section 2.9 of the OPG CMD for further information.[33] In Section 2.9 OPG states that emissions will include tritium and particulate emissions,[34] but does not specify what the particulate emissions will consist of. CELA recommends the Commission require, in furtherance of its mandate to ensure adequate protection of the environment and human health under section 24(4) of the NSCA that OPG detail the substances, including nuclear substances, and their quantities that are anticipated to be emitted on an annual basis as a result of the operation of the Mo-99 IIS.

CELA also recommends that OPG detail precisely what exact nuclear substances are expected to be released as a result of the operation of the Mo-99 IIS. Before proceeding with licensing, OPG must demonstrate that the releases will not have direct, indirect or cumulative impacts on the environment over time.

RECOMMENDATION NO. 13: The Commission should require more detailed information on the types and amounts of nuclear substances that are expected to be emitted as a result of the operation of the Mo-99 IIS, including any cumulative impacts over time.

xiv. The Commission should not proceed with hearing, due to application deficiencies

CELA's comments and recommendations above support a finding that OPG's application is deficient and/or premature. In this regard, CELA relies mainly on Section 24(4) of the NSCA:

[32] Ibid., page 43.
[33] Ibid., page 9.
[34] Ibid., page 49.

> (4) No licence shall be issued, renewed, amended or replaced — and no authorization to transfer one given — unless, in the opinion of the Commission, the applicant or, in the case of an application for an authorization to transfer the licence, the transferee
> (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
> (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

First, the 2018 Licence Application and the OPG CMD both lack key information as to how OPG intends to carry out the proposed activities, or indeed what the final design will look like. As has been shown above, there are important issues that still need to be considered before a full assessment of the licence amendment application can be carried out. At present, the 2018 Licence Application and the OPG CMD fail to provide a sufficiently detailed evidentiary foundation to allow the Commission to determine whether OPG is indeed qualified to carry out the activities that the licence amendment would permit.

Secondly, for these same reasons, it cannot at this point in time be determined with sufficient degree of certainty whether OPG has or will make adequate provision for the protection of the environment, health and safety of persons.

In general, it is CELA's view that the Commission can and should require far greater clarity in licence applications such as this one. Allowing an application that is lacking in specific information and which leaves numerous issues still to be determined, is a poor basis for rendering a decision and is not conducive to ensuring future applications meet a reasonable standard.

Public participation rights are furthermore constrained due to the 2018 Licence Application and supporting CMD being too deficient in detail as well as the number of issues still left to be determined or resolved – all of which the public will not be given the opportunity to comment on if they are left for CNSC staff alone to consider. Indeed, when authority is delegated from the Commission to CNSC staff, the opportunity for public involvement in the decision-making process is reduced in equal measure.

Additionally, according to section 9(b) of the NSCA, one of the Commission's two stated goals is "*to disseminate objective scientific, technical and regulatory information to the public concerning the activities of the Commission and the effects, on the environment and on the health and safety of persons, of the development, production, possession and use referred to in paragraph (a).*" At the same time, section 40(5)(a) of the NSCA requires that the Commission hold public hearings on, among other things, licence amendments. Like any public hearing, the purpose of this hearing is to involve the public in the Commission's decision making process by providing them an opportunity to comment on the proposed decommissioning project.

To further the objective of the Commission described in Section 9(b) and in line with the requirement to hold public hearings under Section 40(5) as well as the conditions for licencing set out in Section 24(4) , CELA recommends that the Commission require OPG to revise its licence application and the supporting OPG CMD to ensure that they contain sufficiently detailed information that lives up to the licencing requirements and provides a better basis for meaningful public hearings that allow the public to participate effectively.

For these reasons and given the deficiencies discussed below, the Commission should set an appropriate standard for such applications by refusing to consider OPG's licence application in its current form.

RECOMMENDATION NO. 14: The Commission should not proceed with licensing given the deficiencies in OPG's licence application, in particular the lack of key details and the number of issues still to be determined or resolved. Instead, the Commission should wait until the recommendations above have been addressed.

VI. ORDER REQUESTED

For the foregoing reasons provided in this intervention, CELA seeks:

(1) An order denying OPG's request to amend the operating licence for the Darlington Nuclear Generating Station; and

(2) An order to the proponent remitting the licence application with direction that all deficiencies noted in this submission and the accompanying expert report be remedied and the information demonstrating fulfillment of all statutory and regulatory requirements be clearly set out prior to proceeding with a licence amendment request.

Sincerely,

CANADIAN ENVIRONMENTAL LAW ASSOCIATION

Morten Siersbaek
Counsel

APPENDIX A
EXPERT REPORT

Prepared by:
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Prepared for:
Intervention by the Canadian Environmental Law Association regarding OPG's Application for an amended Licence for the manufacture of molybdenum-99 used in the creation of the radiopharmaceutical technetium-99m

August 15, 2021

Executive Summary
This submission:

a. discusses the proposed licence in tandem with the recent licence granted to BWXT in Kanata
b. reviews the health and safety risks arising from the licence amendment requested by OPG for the manufacture of Mo-99 and
c. analyzes the cyclotron alternative for the safer means of providing Tc-99m by hospitals.

It concludes that the proposed reactor method using Mo-99 to obtain Tc-99m supplies has disadvantages when compared with the available cyclotron method which is quicker, safer, more reliable, more resilient and less complex. The Canadian Nuclear Safety Commission is recommended to examine this alternative in detail before proceeding with licensing in the above noted matter.

1. Explanatory Background for CNSC

The OPG is applying for Licence amendments at its Darlington nuclear power station. It is proposing to manufacture the highly radioactive isotope molybdenum-99 (Mo-99) by irradiating target pellets of stable molybdenum inside OPG's nuclear reactors nos 2 and 4 at Darlington.

It is then proposed that the radioactive Mo-99 will be transported to Kanata near Ottawa – a distance of approximately 450 km - where BWXT Nuclear Energy Canada Inc. will insert it into its generators from which radioactive Tc-99m will be eluted for use in diagnosis and treatment in hospital procedures.

2. OPG's Request for Licence Amendment

OPG is requesting a Licence amendment[1] to activate stable[2] molybdenum targets inside two of its nuclear reactors at Darlington, ON in order to create radioactive molybdenum-99 (Mo-99). It is proposed the targets will then be withdrawn approximately at weekly intervals and sent to BWXT facilities at Kanata near Ottawa via trucks using highways 401 and 416 (a distance of approximately 450 km). Here, the Mo-99 will be removed from the targets, separated from the other radioactive products inside the targets and inserted into its technetium-99m generators which (it is assumed) will then be delivered to major hospitals in Canada and elsewhere. These large hospitals will then use the generators to elute the radioactive decay product technetium-99m for use in nuclear medicine procedures. Smaller hospitals are expected to be directly supplied with Tc-99m from larger hospitals.

Relevant to this matter is the hearing which occurred in June 2021, when CNSC heard BWXT's request for a licence to handle and manufacture Tc-99m generators at Kanata using Mo-99 from Darlington. This licence by BWXT is being sought before any approval has been given to OPG to actually manufacture the Mo-99. As these matters are related, they should be heard and considered together.

RECOMMENDATION 1: Given the close relationship between the licence amendment sought by OPG and the new licence sought by BWXT, the two matters should be heard together so that the public and Commission can best adjudicate this matter in the public interest.

2. Is there a need for additional sources of Mo-99?

[1] The OPG's licence application is at Application-Molybdenum-99.pdf (nuclearsafety.gc.ca)
[2] As will be explained later, naturally -occurring molybdenum has several isotopes most of which are in fact stable. Only Mo-99 is unstable ie radioactive.

There seems to have been little examination in the hearing documents as to whether Canada needs an additional source of Mo-99. Since the shutdown of the NRU in 2016, Mo-99 is mainly extracted for medical purposes from fission products created in research reactors in the Netherlands, Belgium, France and South Africa using uranium targets. It is understood that another research reactor for Mo-99 supplies is under construction in Missouri, US.

As far as can be ascertained, in the past 5 years there has been no perceived shortage of supplies of these radioactive materials. The main perceived advantage for the Darlington plan is that avoids the need to import Mo-99 from the US and abroad.

Most major hospitals in Canada currently obtain their Tc-99m supplies from their Mo-99 generators (often referenced as "mo-cows") from which Tc-99m is routinely eluted. With these generators, it is necessary to top up Mo-99 at approximately weekly basis, currently from overseas sources. This topping up is necessary because Mo-99 cannot be stored due to its short 2¾ day half-life. Every day, about 11% of its original amount decays away.

However a newer, more direct, method now exists which obviates the need for Mo-99. This is discussed later below.

Recommendation 2: CNRC should ask OPG whether there is a supply issue with the importation of Mo-99 supplies.

3. Information on Mo-99

Mo-99 is a highly radioactive nuclide with a half-life of 66 hours or 2¾ days. This means it has quite a high specific activity (ie Bq per g of the isotope). It is both a powerful beta emitter (with 82% of its decays emitting a 1.2 MeV beta particle) and a strong gamma emitter (with 90% of its decays emitting 170 keV photons). This means that the above proposed transports and procedures will inevitably incur added radiation exposures to workers and to members of the public.

This is because when electrons (beta particles) pass through matter, several radiation processes occur:

1. **Ionisation and excitation** of the atoms in matter;
2. **Bremsstrahlung**, ie the creation of X-rays from electron decelerations;
3. **Elastic scattering** from nuclear and electron interactions.

All result in radiation exposures to workers and other people nearby.

This means, inter alia, that wherever Mo-99 is used, comprehensive shielding needs to be put in place to protect workers and the public against not only its relatively powerful beta emissions but also the 360 degree scatter from its gamma emissions when it is used indoors.

4. Information on Tc-99m

When Mo-99 decays, its main daughter is technetium-99m (Tc-99m) which has a half-life of 6 hours and is therefore also highly radioactive. The letter “m” is short for “metastable” which indicates that its nucleus is in an excited state. When it decays via what is called isomeric[3] transition (where excited protons or neutrons descend to their normal energy levels) it gives off gamma radiation.

Tc-99m decays by gamma emissions 88% of the time. Almost all result in 140.5 keV gamma rays: these are picked up by gamma cameras when Tc-99m is used for medical imaging. The remaining 12% of Tc-99m decays are by means of internal conversion, resulting in the ejection of high speed electrons at sharp peaks. These conversion electrons will ionize surrounding matter contributing with the gammas to the total deposited dose.

With Tc 99m, its single decay product is weakly radioactive Tc-99 (NB - without the “m”) which has a very long half-life of 210,000 years and which itself decays via the emission of a beta particle[4] to stable ruthenium-99.

Tc-99m is widely used for disease diagnosis and treatment in many medical conditions, particularly in cardiology and cancer. Almost one-third of Canadian hospital admissions involve nuclear medicine in the patient’s diagnosis or treatment. The isotope Tc-99m alone accounts for over 80% of medical diagnoses and treatments which use radiation.

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[3] A nuclear isomer is a metastable state of the nucleus, in which one or more protons or neutrons have higher energies than the ground state of the nucleus.

[4] This intervention does not discuss the health effects of exposures to Tc-99m administrations in patients. Health Canada has issued licences for the medical uses of Tc 99m. However it can be estimated from the data cited in Mettler et al (2009) that the collective dose from Tc-99m administrations in the US in 2004 was ~200,000 person Sv per year. This figure will have increased substantially since 2004. In other words, patient doses from Tc-99m are not negligible, and clinicians must balance the advantages and disadvantages of using Tc-99m, especially in pregnant women and in boys and girls.

All this means that adequate protections must be provided for workers and clinical and technical staffs who handle Tc-99m. Patients will also be exposed but it is presumed that the clinical advantages outweigh the disadvantages of these radiation exposures - see footnote 4.

5. A Newer, Safer Method to Obtain Tc-99m

It may be argued that we need to carefully examine the best way to satisfy our needs for Tc-99m. However there has been little, if any, discussion of alternative methods in the Commission Member Documents (CMDs) by OPG or CNSC Staff.

A second method currently exists to obtain Tc-99m without using Mo-99. This would use hospital cyclotrons - (using the Mo-100 (p,2n) Tc-99m reaction) on stable Mo-100 enriched target material. This directly produces Tc-99m, without the need for Mo-99: the IAEA (2017) has noted that this direct method "*may be a long term solution*" and is "*quite sufficient to manufacture Tc-99m on-site for supplying regional radiopharmacies and may supplement* ***or in some instances even replace*** *Mo-99 generators*" (emphasis added). A technical note is contained at Figure 1 below.

A cyclotron is a particle accelerator, a machine that uses electro-magnetic fields to propel charged particles (protons or electrons) to high speeds and energies. These can be used to produce various radioisotopes, including Tc-99m. Hospital cyclotrons used to produce Tc-99m can use relatively low energy electrons and protons (ie not high energy neutrons in reactors) and are therefore less dangerous to workers and members of the public. They also produce less radioactive waste caused by the neutron activation of adjacent structures.

Figure 1. Tc-99m without using Mo-99

This technical discussion is reproduced from IAEA (2017).

"*Usable quantities of Tc-99m can be produced by stable Mo-100 (p,2n) Tc-99m reaction, which has a peak in the cross-section at 15–16 MeV, well within the reach of many commercial cyclotrons. A higher current cyclotron has been used to produce 350 GBq of 99mTc, which could supply a large metropolitan area (18 MeV protons, 250μA, 6 h irradiation). Higher yields can* *be reached with higher energy cyclotrons and/or with a more intense beam current (>1.184 TBq) at 24 MeV and 450 µA)."*

"However, there are several considerations that may affect the practicality of this production method. The 6 hour half-life of Tc-99m is a factor that constrains the time (and therefore the distance) from production to use. The distribution model and the ability to make use of existing distribution networks will influence practicality. A local distribution model would include a small accelerator and lower power target and would produce only enough for the local vicinity, whereas a regional or national distribution model would include a larger accelerator and higher power targets to enable a wider distribution of the Tc-99m. These models have other implications, such as delivery schedules and the influence of irradiation parameters on isotopically enriched molybdenum supply and recovery."

"Another aspect of practicality is the cost per MBq of accelerator-produced Tc-99m when compared with the price of generator-produced Tc-99m, assuming the Organisation for Economic Co-operation and Development (OECD) goal of full cost recovery. Although an exact estimate is probably not possible at this time, rough estimates put the cost per MBq at about the same level for both production methods, although this will again depend on the distribution model chosen and whether existing cyclotron facilities can use the time when the cyclotron is not occupied with other radionuclide production for the production of Tc-99m. Mo-100 is a natural-occurring isotope of molybdenum and is sold by commercial isotope suppliers with greater than 99% enrichment."

Indeed, the above new technology is already in use in Canada, see Triumf (2012).

See also

Triumf (2012) Canadian team develops method for hospitals to make critical medical isotope without reactor. Press release. https://www.triumf.ca/sites/default/files/NR-Isotopes-20-Feb-2012-vFINAL.pdf#:~:text=technology-one%20that%20makes%20use%20of%20existing%20cyclotron%20machines,The%20team%20developed%20these%20tools%20along%20with%20chemistry

Guérin, B.; Tremblay, S.; Rodrigue, S.; Rousseau, J. A.; Dumulon-Perreault, V.; Lecomte, R.; van Lier, J. E.; Zyuzin, A.; van Lier, E. J. (April 2010). "Cyclotron production of 99mTc: an approach to the medical isotope crisis" (PDF). Journal of Nuclear Medicine. **51** (4): 13N–6N. PMID 20351346.

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Martini P et al (2018) "In-house cyclotron production of high-purity Tc-99m and Tc-99m radiopharmaceuticals". Applied Radiation and Isotopes. **139**: 325–331. 2018-09-01. doi:10.1016/j.apradiso.2018.05.033. ISSN 0969-8043.

The two methods are shown schematically in the diagrams below

Diagram 1.Indirect Method producing radioactive Mo-99 in reactor

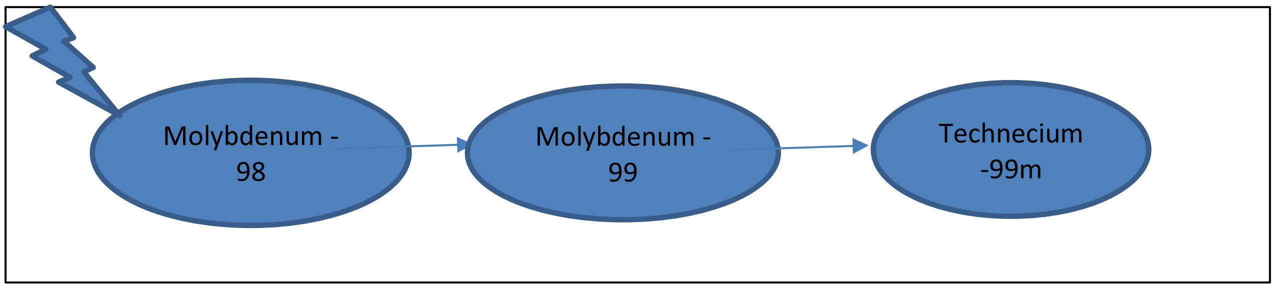
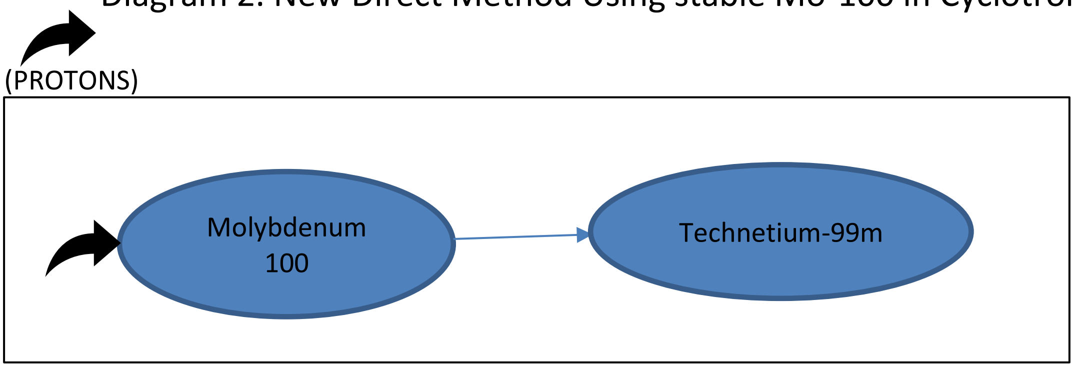


Diagram 2. New Direct Method Using stable Mo-100 in Cyclotrons



About 25 Canadian hospitals and research establishments listed in table 1 below have cyclotrons[5], most of which have the ability to manufacture Tc-99m.

Table 1

City	Name/Location	Manufacturer	Type	MeV
Edmonton, AB	Cross Cancer Institute / Alberta Health Services	ACSI	TR-19/9	19
Edmonton, AB	University of Alberta	ACSI	TR-24	24
Halifax, NS	Victoria General Hospital	GE	PET trace	16

[5] IAEA Interactive Report (No date) "Cyclotrons used for Radionuclide Production" https://nucleus.iaea.org/sites/accelerators/Pages/Cyclotron.aspx

Hamilton, ON	McMaster University	GE	PET trace	16
Hamilton, ON	Not given	Siemens	RDS112	11
London, ON	Lawson Health Research Institute	GE	PET trace	16
Mississauga ON	Not given	Siemens	ECLIPSE	11
Montreal, QC	Pharmalogic 5	GE	PET trace	16
Montreal, QC	Montreal Neurological Institute and Hospital	IBA	CYCLONE	18
St John's, NF	Mount Pearl Hospital	IBA	CYCLONE	18
Ottawa, ON	Not given	Siemens	ECLIPSE	11
Saskatoon, SK	University of Saskatchewan	ACSI	TR-24	24
Sherbrooke, QC	Centre Hospitalier Universitaire de Sherbrooke	ACSI	TR-24	24
Sherbrooke, QC	Centre Hospitalier Universitaire de Sherbrooke	ACSI	TR-19	19
Thunder Bay, ON	Thunder Bay Regional Health Sciences Centre	ACSI	TR-24	24
Toronto, ON	Toronto General Hospital UHN	GE	PET trace	16
Toronto, ON	Not given	IBA	CYCLONE 18	18
Vancouver BC	TRIUMF	ACSI	TR-13	13
Vancouver BC	BC Cancer Agency	ACSI	TR-19	19
Vancouver BC	TRIUMF	ACSI	TR-24	24
Vancouver BC	Nordion (TRIUMF)	ACSI	TR-30	30
Vancouver BC	Nordion (TRIUMF)	ACSI	TR-30	30
Vancouver BC	Nordion Inc.	TCC	CP-42	42
Vancouver BC	Nordion (TRIUMF)	Not given	TR-700	700

Recommendation 3: The CNSC should establish an expert committee to examine the efficacy of Canadian hospital cyclotrons to directly manufacture Tc-99m.

7. Government Policy

The preferred way to make Tc-99m is a governmental policy matter and for this reason in 2009, the Federal government set up an expert scientific Committee to examine the matter in some detail. Its 129 page report[6] recommended that, in general terms, the cyclotron method rather than the reactor method was the preferable route for the many reasons set out in its report. There has been no examination of the matter since 2009. Medical cyclotrons[7] are already used in many large hospitals in Canada to make various

[6] Report of the Expert Review Panel on Medical Isotope Production (2009) Presented to the Minister of Natural Resources, Canada, 30 November 2009. http://nrcan.gc.ca/eneene/sources/uranuc/pdf/panrep-rapexp-eng.pdf

[7] IAEA Newsletter (2021) "Cyclotrons – What are They and Where Can you Find Them" https://www.iaea.org/newscenter/news/cyclotrons-what-are-they-and-where-can-you-find-them#:~:text=Some%20hospitals%20house%20their%20own%20cyclotrons%20and%20produce,then%20become%20radiopharmaceuticals%20for%20direct%20use%20by%20patients

radiopharmaceuticals: see above list. Commercial supplies already exist of high purity Mo-100.

Cyclotrons are a quicker, more flexible, more reliable and safer way to directly generate Tc-99m as there is no need for Mo-99. The direct production method utilizes the Mo-100 (p,2n) Tc-99m reaction on stable Mo-100-enriched target material. The use of cyclotrons instead of reactors to generate Tc-99m is well-recognised internationally. For example, the IAEA has convened several international conferences (IAEA, 2020) and published several reports (IAEA,2017) on the matter.

8. Comparison to the United States

In the US, the main US supplier of Mo-99 and its daughter Tc-99m, North Star Medical Radioisotopes LLC (northstarnm.com) recently announced that it was expanding its supply capacity not via reactors but by using two IBA Rhodotron 300-HE (High Energy) electron beam accelerators at its facility in Beloit, Wisconsin.

According to Northstar, the use of accelerators "*enable flexible production and accurate scheduling thus minimizing customer supply risks*". NorthStar Medical Radioisotopes Receives Electron Beam Accelerators for First-of-its-Kind Advanced Medical Radioisotope Production | NorthStar Medical Radioisotopes, LLC (northstarnm.com)

It is understood that Northstar was encouraged to choose its cyclotron technology partly because of its technical advantages and because of its close links with, and recommendations from, USDOE and FDA.

9. Which Target is to be used?

OPG states that it is proposing to activate "molybdenum" targets. But in some documents it states "Mo-98" targets: the difference in terminology is important. The reason is that, when mined, naturally-occurring molybdenum has 7 stable isotopes as indicated in table 2 below.

Table 2. Stable Molybdenum Isotopes

Stable Molybdenum Isotope	% Abundance On Earth
Mo-92	14.84%
Mo-94	9.25%
Mo-95	15.92%

Mo-96	16.68%
Mo-97	9.55%
Mo-98	24.13%
Mo-100	9.63%
total	**100%**

Source: IAEA (2017)

If expensive, high purity Mo-98 were chosen by OPG to irradiate, then it can reasonably be expected that the main product will be mostly Mo-99. However if the less expensive option of naturally-occurring molybdenum (ie not Mo-98) were chosen by OPG, then an array of different molybdenum isotopes (and possibly other isotopes) will result in the irradiated targets, **not just Mo-99**. The other isotopes would be impurities and would need to be removed by BWXT before the Mo-99 was inserted into the Tc Generators.

In their Licence Application (CMD 21-H107.1) - see section 1.3, page 5, (PDF page 29), OPG states : "*the BWXT method uses naturally occurring Molybdenum metal as the target material for irradiation in the CANDU reactors owned and operated by OPG at the Darlington NGS*."

Recommendation 4: CNSC should therefore confirm with OPG that it is proposing to irradiate all the molybdenum isotopes which exist in natural molybdenum.

Recommendation 5. CNSC should then request OPG to inform it about exactly which Mo isotopes (and in what percentages) would be created in their molybdenum targets.

Recommendation 6. CNSC should request OPG to provide information regarding which *other* isotopes (i.e. apart from Mo isotopes) will result from the irradiation of the targets.

Recommendation 7. CNSC should then inform itself of the possible disadvantages to patients of using Tc-99m supplies contaminated with other Tc isotopes originating from using natural molybdenum.

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Appendix B

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Centre for Environmental Technology
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- PhD (health impacts of radioactive waste technologies)

1996
Princeton University
Centre for Energy and Environmental Studies
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- Visiting Fellow (health impacts of radioactive waste technologies)

1990-1992
Medical College of St Bartholomew's Hospital
Department of Radiation Biology
Charterhouse Square
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- MSc Radiation Biology

1962-1965
University of Western Ontario
London, Ontario, Canada
- BSc Chemistry

1957-1962
Sarnia Northern Collegiate Institute and Vocational School
Sarnia, Ontario, Canada
- Honours Graduation Certificate (Grade 13)

Consultancy Work

2005 – to the present

Ontario Clean Air Alliance, Toronto, Ontario, Canada
Canadian Environmental Law Association, Toronto, Ontario, Canada
City Government of Vienna, Austria
International Agency on Research on Cancer, Lyon, France
SAGE Peterborough, Ontario, Canada
Greenpeace Canada
Greenpeace Europe
European Parliament
UK Nuclear Free Local Authorities
International Physicians for the Prevention of Nuclear Warfare, Germany
International Society of Doctors for the Environment, Italy and
Physicians for Global Survival, Canada

EMPLOYMENT

2000-2005
UK Government Committee Examining the Radiation Risks of Internal Emitters(CERRIE) www.cerrie.org
Department for the Environment, Food and Rural Affairs
Nobel House, 17 Smith Square
LONDON SW1P 3JR, UK

- Head of Secretariat of Ministerial Committee on internal radiation risks

1996-2000
UK Food Standards Agency
Radiological Safety Unit
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- Higher Scientific Officer in the Radiological Safety Unit on regulation of nuclide discharges and nuclear waste management programmes in UK

1992-1996
Imperial College of Science, Technology and Medicine
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- PhD researcher and lecturer on radiation exposures from radioactive waste technologies

1975 -1989
Trades Union Congress

Great Russell Street
LONDON WC1B 3LS, UK

- Research Officer in occupational health and safety

Scientific Publications

2016
TORCH-2016: An independent scientific evaluation of the health-related effects of the Chernobyl nuclear disaster.
https://www.global2000.at/sites/global/files/GLOBAL_TORCH%202016_rz_WEB_KORR.pdf

2014
Fairlie I and Koerblein A. Comment on 'Updated investigations of cancer excesses in individuals born or resident in the vicinity of Sellafield and Dounreay': premature all-clear for nuclear power. British Journal of Cancer (2014) , 1 | doi: 10.1038/bjc.2014.581

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2011
Smith KR, Frumkin H, Balakrishnan K, Butler CD, Chafe Z, Fairlie I, Kinney P, Kjellstrom T, Mauzerall DL, McKone TE, McMichael AJ, Schneider M. Annual Review of Public Health 34: 1-25, (web published, Jan 16, 2013, 10.1146/annurev-publhealth-031912-114404)

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