Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

CMD 21-H107.10

File/dossier : 6.01.07
Date : 2021-08-23
e-Docs pdf : 6626341

Written submission from Anna Tilman

Mémoire de Anna Tilman

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

Submission to the Canadian Nuclear Safety Commission (CNSC)

with respect to

Ontario Power Generation's Licence Amendment Request
To authorize the Production and Possession of Molybdenum-99 at
Unit 2 of the Darlington Nuclear Generating Station

August 23, 2021

Prepared by

Anna Tilman

Submission to the CNSC re:

OPG's Licence Amendment Request re: Production of Molybdenum-99 (Mo-99)

Overview and Comments

In May 2018, Ontario Power Generation (OPG) notified CNSC staff of its intention to apply for a licence amendment to allow it to produce the radioisotope molybdenum-99 (Mo-99) from neutron irradiation of natural molybdenum (Mo-98) in reactor units at the Darlington Nuclear Generating Station (NGS). OPG, in partnership with BWX Technologies Inc. (BWXT), has selected Unit 2 for the installation and operation of the first Mo-99 Isotope Irradiation System (IIS).

Subsequently, OPG submitted a request to amend its Power Operating Reactor Licence (PROL) to allow it to possess, transfer, produce, package, manage and store Mo-99 and its associated decay products at the Darlington NGS and ship the retrieved Mo-99 by an external third party to a processing facility which would produce metastable technetium-99m (Tc-99m) generators for diagnostic nuclear medicine.

Generator Supply Chain - Mo-98 – Mo-99 – Tc-99m

In the proposed supply chain for Mo-99, OPG would be responsible for the irradiation of natural molybdenum and packaging of the irradiated molybdenum into specialized transport containers. Upstream, the company BWXT, located in Kanata, would be responsible for procuring a stable supply of natural molybdenum of "suitable purity", target manufacturing, and nuclear inventory management. All other aspects of the supply chain would be handled by third parties (vendors and processing facilities) and are external to OPG and fall out of scope in OPG's license amendment request.[1]

All other aspects of the supply chain downstream of OPG's production of Mo-99 (transport, radioisotope processing, generator manufacturing, shipping, use, and disposal) will be handled by qualified parties with the necessary CNSC nuclear facility and nuclear substances & radiation devices (NSRD) licences. In particular, BWXT-Medical and the hospital end users will be responsible for all wastes associated with the processing and use of Mo-99 and Tc-99m.

OPG plans to manage the operation and maintenance of the Mo-99 IIS under its existing nuclear operations program and utilize its existing training programs to carry out the proposed licensed activity for the production of Mo-99. However, OPG does not plan to create any certified positions for its proposed activity. CNSC staff is to review these plans to confirm that the Mo-99 IIS will be safely and adequately maintained.

CNSC staff have concluded that the installation and operation of the Mo-99 IIS will have negligible impacts on the existing safety case and 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, CNSC staff has found the existing security and safeguards programs at Darlington NGS sufficient to accommodate the additional activities associated with the production of Mo-99.[2]

[1] CNSC CMD 21-H107 p.6 Section 1.1.3
[2] Ibid: summary Sec. 3.6, p.21 Sec.4.5

In light of the evolving and sequential nature of the proposed Mo-99 IIS project, a number of project outputs can only be finalized during or after future stages of the project, such as installation and commissioning. Accordingly, CNSC staff are proposing to use **Regulatory Hold Points (RHPs)** to ensure key aspects of the ECC process are performed in accordance with regulatory requirements. The RHPs are intended to ensure the operational readiness of the Mo-99 IIS has been confirmed as OPG progresses through the installation and commissioning phases. (CNSC staff noted that RHPs have been used effectively at Darlington NGS for much larger projects, such as the Unit 2 Refurbishment project under Licence Condition 15.4 of the existing PROL.) However, given the lack of specificity as it what specifically these RHPs would consist of, the effectiveness of such a tool is questionable.

OPG has established two internal Quality Release Hold Points (QRHPs), each with their own set of criteria that must be met to allow the installation and commissioning of a Mo-99 IIS on Unit 2 to proceed. Similar to the QRHPs, CNSC's proposed two regulatory hold points (RHPs) allow for that CNSC staff can complete regulatory oversight activities associated with the installation and commissioning phases of a Mo-99 IIS on **any** unit.

This is confusing, to say the least. Who authorizes and sanctions these hold points? Why are both sets of "hold points" needed?

CNSC staff have concluded that the installation and operation of the Mo-99 IIS will have negligible impacts on the existing safety case and will not result in significant doses to workers or members of the public, or result in significant releases to the environment. It has further deemed the existing security and safeguards programs in place at Darlington NGS sufficient to accommodate the additional activities associated with the production of Mo-99.[3]

In light of the lack of specific information, it is difficult to understand why or how CNSC staff could arrive at that conclusion.

Additional issues and concerns are described in the following sections.

Production of Mo-99

As noted in both CNSC and OPG CMDs, the continuous online production and retrieval of Mo-99 in a CANDU reactor from natural molybdenum is a *first-of-a-kind (*FOAK) initiative in the development of a Canadian supply chain and would provide a constant and reliable supply of Mo-99 for diagnostic nuclear medicine. However, several issues have not been adequately addressed or at all, in either OPG's or CNSC's CMDs that deserve attention, and in particular, the production of Mo-99. As well, there is the matter of determining what is considered to be "suitable purity" of natural molybdenum.

The safety of the IIS is the critical piece of the whole operation. It could take time beyond what may have been expected to ensure that there are no problems or issues with the IIS and that it is safe and reliable. It is not clear how the process would be tested prior to being utilized. Nor is it clear what responsibility OPG would have as to the production and safety of the IIS or the timing as to when it would be functional.

[3] CNSC CMD 21-H107 Summary Sec.3.6 p. 21, 4.5

While expectations are to have the production of Mo-99 in place by 2022, pending regulatory approvals, this may not be doable in that timeframe for a number of reasons, such as whether the equipment to be manufactured (IIS) and/or the process itself in the reactor may or may not be ready or trouble-free. There could be potential delays in supply, availability of an adequate and trained workforce, and other unforeseen issues.

While CNSC staff has indicated that OPG has adequate provision to ensure safe production of Mo-99 and that the installation of the equipment to be manufactured (i.e., the IIS) would not result in significant doses to the public or the workers or in releases to the environment. However, such indication is not based on any supporting evidence or even on precautionary concerns. That is troublesome.

Given the complexity of OPG's and CNSC's submission and lack of clarity in many factors, the following sections address specific concerns related to OPG's licence request and the position taken by CNSC on some of these issues.

Fitness for Duty - Work Organization and Training [4]

OPG's fitness for duty program, which meets the requirement of REGDOC-2.2.4, *Fitness for Duty;* specifically sets out CNSC's requirements and guidance with respect to managing and monitoring worker fatigue or other factors that could adversely impact worker performance.

OPG is required to ensure the presence of a sufficient number of qualified workers to safely carry out all licensed activities. Furthermore, OPG must maintain a minimum shift complement (MSC) at all times in accordance with their PROL (Power Reactor Operating Licence).

A mock-up of the Mo-99 IIS is to be assembled at BWXT's facility in Peterborough Ontario, to facilitate training and finalize operating procedures. A Mo-99 IIS simulator will be used to provide further training. The scope of all maintenance is to be defined as per the Fitness for Service documentation targeted to be submitted to CNSC staff in Q4 2021.

The Workforce

OPG plans to manage the operation of the Mo-99 IIS under its existing nuclear operations program (e.g., maintenance and aging management programs). No certified positions are to be created as a result of the proposed licensed activity, as OPG plans to utilize its existing training programs to ensure that its workers will be qualified to carry out the proposed licensed activity for the production of Mo-99 safely (i.e., installation, commissioning and operation of the Mo-99 IIS).

CNSC staff has concluded that OPG has demonstrated use of their training system to conduct preliminary analyses of training impacts for Mo-99 production. However, specific training details and the scope of maintenance activities remain outstanding. CNSC staff is planning to review such activities under regulatory oversight to ensure that workers are trained and qualified prior to carrying out activities associated with various milestones for the production of Mo-99.

[4] Ibid p. 49

The specific nature of these maintenance activities is not evident. Nor is the means by which workers are selected to do specific tasks, what qualifications are required, and what would constitute training for such activities. Certainly, it would seem logical and obvious that CNSC would review training and maintenance activities, prior to any such work is to be done and licencing is considered, but that does not seem to be the case. This is a gross deficiency in OPG's proposed planning.

Identification of Hazards [5]

OPG completed a qualitative assessment to determine the impact of installing and operating the Mo-99 IIS on existing hazard assessments and to identify any new internal hazards that need to be considered in the Darlington's *Probabilistic Safety Assessment* (PSA). Based on this assessment, OPG generated a list of applicable hazards (Table 2 in Appendix B.4), and assessed them as part of the Darlington Hazards Screening Analysis [11, 25].

CNSC staff's review of OPG's hazard analysis indicated that the assessments were comprehensive and aligned with the requirements of REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*. CNSC staff further concluded that new hazards have been accounted for and that their impact on the Darlington PSA will be negligible.

In its license application, OPG states that the Mo-99 IIS will have no impact on the management of safety issues and OPG's Research and Development programs and that the installation and operation of the Mo-99 IIS has negligible impact on the management of the CANDU Safety Issues (CSIs).

CNSC staff have concluded that these assessments are acceptable and systematic, and that OPG has adequate provisions in place to ensure the safe production of Mo-99. CNSC staff further concur that the Mo-99 IIS will have a negligible impact on reactor operations and the existing safety case for Darlington NGS.

OPG's **qualitative** assessment of the impacts the installation and operation of the Mo-99 IIS indicated that the Mo-99 IIS would have a negligible impact on the severe accidents source terms, and no effect on severe accident management and recovery.

It is important to note that this is a **qualitative assessment**, without the necessary rigour to assess whether installation and operation of this system would indeed have negative impacts. Nevertheless, CNSC staff has echoed OPG's findings on this matter, accepting OPG's assessment of the impacts of the Mo-99 IIS on severe accidents. With respect to accident scenarios, OPG also concluded that the Mo-99 IIS would not result in releases outside of containment.

Thus, OPG determined that the Mo-99 IIS would have a **negligible** impact on <u>all</u> elements of the Darlington PSA, and the impact of the Mo-99 IIS on the quantification of Severe Core Damage Frequency (SCDF) and Large Release Frequency (LRF) in the various PSA elements was negligible.

[5] Ibid p. 20

Have all possible hazards and all elements of the Darlington PSA, and the Mo-IIS been considered? What is the rationale for considering these new hazards "negligible"? How is that even possible?

OPG has committed to preparing preventive maintenance plans. CNSC staff is to review these plans to confirm that the Mo-99 IIS will be safely and adequately maintained. What elements will constitute maintenance plans? Certainly, such plans should be presented in detail in a licence request.

The Mo-99 IIS system - how it works

In reviewing CNSC and OPG's submissions, it is important to understand the elements involved in developing this system and potential issues that may occur. The following is a brief description of the system:

The Mo-99 IIS is a custom system designed to irradiate high purity molybdenum metal (Mo-98) in the Unit 2 CANDU reactor at Darlington NGS. The Mo-98 is enclosed in special cylindrical zirconium capsules designed to be transported through the shielded flight tubes of the Mo-99 IIS. These zirconium capsules containing Mo-98 are referred to as *targets*.[6]

To deliver the natural molybdenum into the reactor core for irradiation and recover it after irradiation, OPG's Mo-99 IIS would utilize a mechanical elevator and multi-fluid target transport system to propel molybdenum to and from the reactor. After irradiation of the molybdenum, a worker would use the Mo-99 IIS to transfer the targets into a Type-B transport flask, which would then be shipped offsite to BWXT for processing. The system uses an instrumented winch mechanism to insert and retrieve molybdenum targets inside the reactor core.

CNSC staff have not identified any barriers to the installation, commissioning, and operation of the Mo-99 IIS in Darlington NGS Unit 2. However, as noted in its submission, several aspects of OPG's process have not been reviewed by CNSC staff as they can only be produced closer to their associated installation or commissioning stages.

A review of the CMDs by CNSC and OPG clearly indicates that the underlying assumptions by these parties that there will essentially be no adverse effects, or for that matter, "negligible" impacts on the environment from the operation of the Mo-99 IIS. That, in itself, is impossible. It is also important to note that "workers" bear the major responsibility in carrying out this work.

Another issue that needs to be discussed is the "purity" of natural molybdenum, especially given that there are several naturally-occurring isotopes of naturally-occurring molybdenum.

CNSC and OPG must be clear in indicating whether isotopes other than the desired isotope, Mo-98, may be present in the target, as this could result in potential contamination of Tc-99m, the desired product.

Furthermore, potential issues may develop in inserting and removing targets. For example, targets may be stuck in the reactor core. How that issue could or would be handled should be a top concern, not only for the impact on operations of the reactor, but also, the impact on workers involved in the necessary repair work. However, bbased on OPG and CNSC staff

[6] P.8 OPG submission

submissions, it would seem that there would be no testing of the capsule irradiation. That is a failure of procedure.

As workers are front-line in potential risks of exposure to radionuclides, in the event that targets may get stuck in the reactor, or other issues may unexpectedly occur, it is critical to know what plans OPG has developed to retrieve a stuck capsule or rectify other unexpected issues and how workers involved in such issues would be adequately trained and protected.

Emissions from Mo-99 IIS Process

Through operations of the Mo-99 IIS, no increases in non-radiological releases or emissions from Darlington NGS are expected as no chemicals would be used. While OPG indicates that emissions resulting from the Mo-99 IIS process will include tritium and particulate emissions, the constituents of the particulate emissions are not specified.

OPG has estimated that tritium emissions from operation of the Mo-99 IIS would result in a potential additional dose to a member of the public of no more than 0.006 µSv/year[7]. The design of the Mo-99 IIS includes an on-line tritium monitoring system with an alarm and manual isolation valves capable of isolating potential leaks.

While the estimated emissions from the Mo-99 IIS Process may be relatively minor, it is incumbent on the CNSC that OPG be required to detail precisely all nuclear and non-nuclear substances expected to be released as a result of the operation of the Mo-99 IIS.

As indicated in OPG's submission[8]:

> The Mo-99 IIS will not result in increased non-radiological releases or emissions from Darlington NGS. Chemicals will not be used to support Mo-99 IIS operation and the molybdenum target capsules, consisting of the molybdenum metal encased in a zirconium outer sheath, will not dissolve in the heavy water nor interact with the reactor components.
>
> **Source Term**
>
> In addition to the irradiated Molybdenum within the target capsules, the capsule sheath represents a radiation source to workers requiring innovative design considerations. To lower the radiation source term, low magnesium content (Zirconium-4) was selected for the target capsule sheath material to reduce radiation fields from the sheath.
>
> During target-harvesting, the targets will be held in the dwell position to allow decay of high-energy short-lived activation products. Accordingly, the reactivity mechanism deck (RMD) will provide the required shielding. The design allows for the dwell time to be changed if required to ensure radiation fields during harvesting are within the limits of the Mo-99 IIS shielding.[9]

While such protections are important, they do not detract from the possibilities that must be considered in the event of failure and what emergency measures would be taken.

---

[7] Refer to Section 2.9 OPG CMD. The tritium emissions represent an additional 1% dose above the current dose estimate based on current Darlington emissions, or 0.0006% of the regulatory dose limit of 1 mSv/year.
[8] OPG CMD Section 2.9.6
[9] OPG CMD Section 2.7.5.1

Waste

The waste produced from routine operation of the Mo-99 IIS is expected to be “minimal” and managed by OPG’s existing waste management program. The waste associated with Mo-99 and its processing will be owned by BWXT and will be managed under its Class IB nuclear substance processing facility operating licence.

BWXT-Medical is responsible for the package design, certification, maintenance and transportation between the Darlington NGS to BWXT-Medical’s medical isotope processing facility in Kanata, Ontario. OPG’s responsibility with respect to transportation is limited to loading the transport packages with irradiated Mo-99 targets produced in the Mo-99 IIS and managing the on-site transportation requirements.

CNSC Staff Conclusions

Based on the information submitted, CNSC staff have determined that OPG has applied the appropriate codes and standards and met regulatory requirements. CNSC staff concur with OPG’s assessment that the Mo-99 IIS design will have negligible impact on existing station operations, reactor safety, and on the existing SSCs and safety related systems; including containment, electrical systems, and instrumentation and control systems.

The CNSC staff “expect” that the Mo-99 IIS would have a negligible impact on the current safety case of Darlington NGS Unit 2 and OPG has adequate provisions in place to ensure that Mo-99 will be safely produced without additional risks to the environment and the health of persons.

CNSC staff have not identified any barriers to the installation, commissioning, and operation of the Mo-99 IIS in Darlington NGS Unit 2. Due to the evolving and sequential nature of the design process, a number of design documents and reports were not finalized at the time of the application and thus have not been reviewed by CNSC staff. CNSC staff will perform regulatory oversight activities concerning any outstanding matters.

OPG is targeting to start Mo-99 non-reactor system equipment installation in the second half of 2021 and expects to be ready to install the Mo-99 IIS on Unit 2 reactor in the first quarter of 2022. Assessments submitted to CNSC staff conclude that the proposed activities to support production of Mo-99 will not compromise continued safe reactor operation, environmental protection and public safety.

In reviewing these determinations by OPG and CNSC staff, one should be rightfully concerned that in the absence of in-depth analysis and information, identifying impacts as “negligible”, a lack of analysis and attention is being paid to OPG’s licence request. One may presume that this may have more to do with the production of Tc-99m and its broad applications.

Design Basis Accidents (DBA) – OPG submission

2.10.2.1: Station Minimum Shift Complement

The Minimum Shift Complement (MSC) is the minimum number of qualified staff required to be present to ensure the safe continued operation of the Darlington NGS, to respond to all credible postulated Design basis Accidents (DBA) and to ensure adequate emergency response capability is available for the most resource intensive conditions.

Safety assessments of the impact of the Mo-99 IIS on postulated Design Basis Accidents (DBAs) (OPG submission, 2.10.2) conclude that the operation of the Mo-99 IIS will have no material impacts on most of the existing safety analyses with the presence of the system being bounded by existing analyses. This conclusion is due, in large part, to minimal interactions between the Mo-99 IIS with other processes and safety systems.[10]

Recommendations to the Commission

The degree to which the Mo-99 IIS is to be tested prior to operation and after installation must be fully described and be a requirement of licensing.

In light of the key role played by BWX Technologies (BWXT) in the design of the IIS system, the division of maintenance responsibilities and preventative maintenance plans, testing and periodic inspections to be carried out by OPG and BWXT must be specified. There must be 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.

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.

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

Detailed information on the types and amounts of nuclear substances expected to be emitted as a result of the operation of the Mo-99 IIS, including any cumulative impacts, must be a requirement of re-licensing.

Before proceeding with licensing, OPG must demonstrate that the releases will not have direct, indirect or cumulative impacts on the environment over time 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.

OPG must be required to submit a more fulsome licence application, in line with regulatory requirements, thus reducing the need to rely on Regulatory Hold Points (RHP's).

Consequently, it would be premature for the CNSC to proceed with OPG's licence request. There are far too many unknowns, many companies involved, some of which may not be subject to CNSC oversight.

Methods to Producing Medical isotopes

While Research Reactors (RRs) continue to be a major source of Radioisotopes (RIs), not only for medical uses but also for industry and research, reactor-produced RIs, including 99Mo/99mTc, have been substantially supplemented by the cyclotron-produced RIs.[11]

[10] OPG submission, 2.10.2.1 and 2.10.2

[11] TRENDS IN RADIOPHARMACEUTICALS (ISTR-2019)- International Atomic Energy Agency (IAEA) https://www.iaea.org/publications/14736/trends-in-radiopharmaceuticals-istr-2019

Cyclotrons are a quicker, more flexible, more reliable and safer way to directly generate Tc-99m as there is no need for Mo-99.

However, there are a number of issues which puts a positive spin on nuclear reactors, while ignoring major outstanding issues ranging from health effects to waste from their operations. OPG's proposal is to shine a positive light on the use of its reactors by promoting the use of nuclear power reactors to produce medical isotopes. A similar case in point, for example, is Bruce Power's licence request to produce the medical isotope Lutetium-177. OPG's proposal is of a similar ilk.

The history of producing medical isotopes (in particular, Tc-99m) in Canada goes back several decades, and along with that history, were the problems that emerged, not only because of the use of Highly Enriched Uranium (HEU), but also the shortages of thee isotope due to shutdowns of reactors, in particular the Research Reactor at Chalk River and the world-wide shortage of this isotope due to numerous issues, ancient reactors shutting down, etc.

But that scene has changed, and while Canada has not been a producer of Tc-99 for several years, there is an ample world-wide availability of Tc-99, mainly due to new practices in production and the number of countries involved in medical isotope production.

OPG's proposal does not really indicate that its production of Mo-99 is directed to a Canadian market, nor would it be presumed so. This is an extremely difficult and complicated matter.

Should OPG's project be undertaken now or delayed until or if it addresses numerous shortcomings in its proposed licence request? After all, at some time, the reactors will have to be retired. As mentioned in this submission, there are other means of producing such isotopes that do not depend on nuclear reactors.

In summary, while I am not opposed to work being done on developing radiopharmaceuticals for the treatment of diseases that affect so many directly and indirectly in the world, there must also be caution in the means of production in producing these drugs and potential longterm adverse aftereffects. This topic as a whole is far more complicated than simply employing a technical device (IIS) to produce this one isotope.

An additional matter of concern is the impact (short and long-term) that the potential radiological and non-radiological health and safety hazards specific to OPG's licence amendment application. This is not an easy issue to parse out, mainly because OPG's production of the isotope Tc-99m requires reactors, and that alone, will result in emissions of the typical substances from the operation of a reactor and safety hazards for a very long time.

Any additional procedure beyond the production of power will add a complexity in that additional levels of substances will be emitted and this cannot be ignored. Perhaps the most important issue is the effect on front-line workers. This topic rarely gets the attention needed.

While exposure on an annual basis may lie within CNSC's limits, it is the cumulative exposure that could take a toll on health and the environment that must be considered.