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Exposé oral

Mémoire de Anna Tilman

In the Matter of the

BWXT Medical Ltd.

Application for a Class IB nuclear substance processing facility operating licence

Commission Public Hearing

June 9, 2021

À l'égard de

BWXT Medical Ltd.

Demande pour un permis d'exploitation d'une installation de traitement de substances nucléaires de catégorie IB

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Submission to the Canadian Nuclear Safety Commission (CNSC)

with respect to

BWXT Medical Ltd's
Application for a Class 1B nuclear substance processing Facility Operating Licence for a 10-year period

April 26, 2021

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Table of Contents

BWXT - LICENCE APPLICATION REQUEST - NORDION FACILITY

Background

Nordion (Canada) Inc. (Nordion) owns and operates a Class IB nuclear substance processing facility located at 447 March Rd, Ottawa, Ontario, in an industrial zone within the Kanata Research Park. The site has been used for industrial purposes since the 1960s.[1]

The facility as a whole is comprised of two portions, namely, Medical Isotopes and Gamma Technologies.

> The Medical Isotopes portion involves the processing of a variety of radioisotopes used in nuclear medicine. It includes radiopharmaceutical facilities in the Nuclear Medicine Production Facility (NMPF) and the radiopharmaceutical facilities in the Kanata Radiopharmaceutical Manufacturing Facility (KRMF).
>
> The Gamma Technologies portion involves high activity sealed sources used in cancer therapy and irradiation technologies.

Licensed activities are currently conducted under a single Class IB licence issued to Nordion as the site is owned and the facility is operated by Nordion. The function of the facility, referred to as the Kanata Operations Building (KOB), is to acquire, process, store and ship radioactive isotopes worldwide. The KOB contains a Nuclear Medicine Production Facility (NMPF) and a Cobalt Operations Facility (COF).

The NMPF has been operating for over 30 years. The Cobalt-60 Source Production Facilities were built in 1972. In 1982, the Nuclear Medicine Production Facility (NMPF) was constructed and in 2000, the Kanata Radiopharmaceutical Manufacturing Facility (KRMF) was completed.[2]

Nordion's current 10-year licence, NSPFOL-11A.01/2025, which expires in October 2025, authorizes it to process unsealed radioisotopes for health and life sciences applications and to manufacture sealed radiation sources for industrial applications.

BWXT Acquisition

In April 2018, BWX Technologies Ltd. (BWXT) acquired the NMPF portion of Nordion's medical isotope business. This acquisition was completed in August 2018, under a subsidiary of BWXT, referred to as BWXT Medical Ltd. (formerly BWXT ITG Canada, Inc.). No licence amendment or Commission approval was required for the acquisition as Nordion remained and would remain the licensee for the entire facility and all of the licensed activities until the time that BWXT Medical would obtain a licence.

Approximately 118 employees (roughly half of the Nordion personnel at the Ottawa site at the time of the acquisition) were hired by BWXT Medical. As of February 2021, BWXT Medical currently has 187 employees in Ottawa, of which 55% are former Nordion employees.[3]

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[1] CNSC CMD 21-H5.1 document notes
[2] BWXT CMD 21-H5.1 p.3
[3] Ibid p.3 Note: Some employees retired since the acquisition

OVERVIEW OF BWXT'S OPERATIONS AND LICENCE APPLICATION

In December 2018, BWXT Medical applied to the CNSC for the issuance of a Class IB nuclear substance processing facility licence to operate the NMPF located within the Nordion KOB. An operating licence is required in order that BWXT Medical can continue to produce and supply critical medical radioisotopes for diagnoses and treatment of serious diseases such as cancer and heart disease.[4]

The activities requested by the BWXT Medical licence application are those currently authorized to be carried out at the facility by Nordion. BWXT Medical considers that the activities it has proposed are independent of and are not a duplication of those activities related to Nordion's Gamma Technologies business.

Nordion has leased the medical isotopes portion of the KOB and associated areas to BWXT Medical for a 20 year period, with agreement that the lease can be renewed by five-year intervals up to four times. Nordion retains control and management of the KOB.

Under a Class IB licence, BWXT Medical would have ultimate responsibility and accountability for security, fire protection and facility maintenance requirements. Nordion would be sub-contracted to provide those services for BWXT Medical. BWXT Medical must seek Nordion's approval for building modifications and introduction of processes that were not carried out previously at Nordion. Coordinated joint emergency response plans have been developed between Nordion and BWXT Medical.

In its licence application to the CNSC, BWXT Medical proposes to manufacture nuclear substances in excess of 1×10^{15} Bq/year. Isotopes with > 1 year half-life would not be manufactured, although some impurities (well below 1×10^{15} Bq/year) would be present that have longer half-lives. According to the company, the total radioactive material processed would remain below the historical production levels for the facility.

However, no reference is provided with respect to the specific nuclear substances to be manufactured or the activity of these substances. Hence the ramifications of the amount of radiation resulting from the manufacturing process are not known. This is a major omission in BWXT's application.

Furthermore, and importantly, as stated in its licence application, BWXT Medical has developed a technology for producing molybdenum-99 (Mo-99) using a natural (stable) molybdenum-98 target that has been irradiated in a reactor. This is a major change in production, as the NMPF has historically been used to process Mo-99 produced by the fission of highly enriched uranium targets in the National Research Universal (NRU) reactor at Chalk River Laboratories.

While I do not support the "traditional" or customary means of producing molybdenum-99 via fission, especially using Highly Enriched uranium (HEU), as is the case in a number of countries, BWXT's proposed methodology will require the approval of Health Canada and the U.S. Food and Drug Administration. BWXT Medical has indicated that such approvals could result in a commercial launch in late 2022. However, this could well be an unlikely scenario, especially

[4] https://www.nuclearsafety.gc.ca/eng/the-commission/hearings/cmd/pdf/CMD21/CMD21-H5-1.pdf; https://www.bwxt.com/what-we-do/medical-isotopes/cnsc-licence-application

given many competing and unknown issues that could well affect its methodology, which is yet to be proven.

As BWXT Medical is a new licence applicant, no trending data are available with respect to its performance history. Consequently, CNSC's CMD includes information concerning Nordion's past performance at the facility, as it anticipates that it would appropriately reflects CNSC staff's regulatory expectations for the operation of the facility. This anticipation may be questionable and even not appropriate, especially in the absence of trending data. This is especially important in light of the world-wide significance of medical isotopes, and in particular, the safe production and availability of the supply of Technetium-99 not only in Canada, but worldwide.

Should the Commission issue a 10-year licence to BWXT Medical as requested, Nordion's activities would be reduced in a commensurate manner. The proposed BWXT Medical licence would authorize BWXT Medical to operate the NMPF, and the operation of this facility would be removed from Nordion's licence conditions handbook (LCH). Nordion would continue to operate the COF only, in accordance with its licence, and no amendment to its licence would be required.

Nordion's LCH would need to be revised prior to the BWXT Medical's licence taking effect, in order to ensure that the activities conducted at the Nordion facilities are accurately reflected in its LCH. In addition, Nordion is required to submit a revised preliminary decommissioning plan, decommissioning cost estimate and financial guarantee for Commission approval once BWXT Medical has its financial guarantee in place.

As an additional matter that has not received discussion by BWXT or the CNSC at this time is the Cobalt Operating Facility (COF) operated by Nordion. Its licence expires in 2025, which in terms of licencing, is only a few years from now. This raises the question as to the future of this facility, which in itself, has been a source of issues, especially related to disposal of unused sources, as well as heightened radiation exposure to Cobalt-60 to workers.

Considering BWXT's expanding interest in operating nuclear facilities in Canada (e.g., the cyclotron in BC, the fuel pellet and assembly of tubes formerly under GE-Hitachi), it would be worth knowing whether BWXT has an interest in operating and taking over that facility.

CNSC STAFF RECOMMENDATIONS AND CONCLUSIONS

As noted in its CMD, CNSC staff conclude that BWXT Medical:

a. is qualified to carry on the activities authorized by the licence and

b. will, in carrying on those activities, 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.

CNSC staff have also concluded that the financial guarantee of $10.54 million proposed by BWXT is based on a credible cost estimate, with acceptable financial guarantee instruments.

Thus, CNSC staff have recommended that:

The Commission issue a Class IB Nuclear Substance Processing Facility Licence to BWXT Medical for a 10-year period; accept the proposed financial guarantee of $10.54 million and direct BWXT Medical to provide the original instruments to the CNSC within 90 days of the issuance of a decision on this matter.

CNSC staff have also indicated that they are satisfied that BWXT Medical's organizational structure, roles and responsibilities are appropriately documented in BWXT Medical's proposed management system.

COMMENTS ON BWXT'S LICENCE APPLICATION

There are a number of issues and some concerns regarding the BWXT's licence application and its "takeover" of Nordion's NWMF. Some of these issues pertain to the health and safety of the workforce (both Nuclear Energy Workers (NEWs) and contract workers); the disposal and waste issues; and the potential increase in the production of radioisotopes.

There is also concern regarding the issuing of a 10-year licence with no indication of an interim review of operations of the facility and any unforeseen issues that could arise that pertain to safety, including the continuance of safe production of essential medical isotopes domestically and internationally, and the level of research that would be or should be carried out in a vast field which is in a state of flux of new discoveries and applications of medical isotopes.

In addition, BWXT Medical's licence application proposes to manufacture nuclear substances in excess of 1×10^{15} Bq/year. According to the company, the total radioactive material processed would remain below the historical production levels for the facility.

The lack of specificity as to these substances, other than indicating that isotopes with > 1 year half-life would not be manufactured, yet indicating the potential presence of some impurities with longer half-lives, is unacceptable. Hence the ramifications of the amount of radiation and waste resulting from the manufacturing process are not known.

The CNSC must insist on full disclosure of this matter. Otherwise it is not fulfilling its mandate "to protect the health and safety of Canadians, as well as our environment".

While BWXT does operate nuclear facilities in Canada, such as the cyclotron in Vancouver, the world's largest cyclotron, and the manufacturing of fuel pellets and bundles in Ontario, its further expansion into the arena of nuclear medicine raises concerns over its vast and increasing role and control of this sector.

Such matters may not seem to be the purview of the CNSC, but they are of concern to the public, especially given the nature of this industry as a whole, and in this case, its role in manufacturing specific radioisotopes for medical applications to ensure the availability of critical isotopes in Canada and worldwide.

In light of major issues that have occurred in the past that led to worldwide shortages of Technitium-99, of which Canada was once a major producer, one can never take for granted that things cannot go wrong, that accidents cannot happen.

Is a 10-year licence appropriate? Does it allow for the oversight needed for such a facility and the medical products being produced for tracing and medication of numerous diseases?

Will BWXT Medical carry out research into novel radioisotopes?

Is the patent approach to new methodologies (as cited by BWXT for the production of Mo-99) positive or could restrictive?

While some of these issues cannot be dealt with in the context of this intervention, this may be the one and only avenue for public intervention to raise these matters.

Certainly, COVID-19 has shown us the need for precaution, prevention, protection, and the impact of shortages in medication (vaccination), etc., worldwide. The safety and supply of essential medication is paramount and take precedence over company profits.

At the same time, the operations involved must be carried out safely, protect and avoid worker exposure, as well as minimize and properly account for the radioactive and non-radioactive emissions to the environment and releases sewers, and in particular, the waste resulting from all the operations at the site.

There have been a number of changes at the Nordion site, especially the expanding role of BWXT Medical, potentially new technologies to manufacture medical isotopes, and the continuing production of Cobalt-60.

This industry, especially medical isotope production is in a very fluid state, with various technologies being brought on line for producing medical isotopes, some of which is novel, such as the use of cyclotrons, and other methods which rely on reactors, and in some cases are controversial. None of this work is without risks.

In its review of BWXT's licence application, the CNSC staff have indicated its approval. Despite this, it is urgent that the Commission take a broad and thorough view of BWXT's licence application and several issues that remain shrouded and unclear in its licence application and the complexity of issues that are not clarified and remain unresolved.

BWXT OPERATIONS - OVERVIEW

As mentioned, medical isotopes have been produced at the Nordion 447 March Road, Ottawa site (Kanata) for over 30 years. The purpose of BWXT Medical's this application was to request issuance of a Class IB licence in order to operate the existing medical isotope facility currently being operated by Nordion.

The activities proposed by BWXT Medical as indicated in its CMD are considered by the company to be independent of and not duplicate those activities related to Nordion's Gamma Technologies business. An operating licence is required for BWXT Medical to continue to produce and supply critical medical radioisotopes for diagnoses and treatment of serious diseases such as cancer and heart disease.[5]

[5] https://www.nuclearsafety.gc.ca/eng/the-commission/hearings/cmd/pdf/CMD21/CMD21-H5-1.pdf; https://www.bwxt.com/what-we-do/medical-isotopes/cnsc-licence-application

CURRENT OPERATIONS – OTTAWA SITE

Currently, BWXT Medical's Ottawa operation is comprised of two product lines: Yttrium-90 (Y-90) and Indium-111 Oxine (In-111).[6]

> Y-90 is a sterile, active implantable Class III medical device used to treat liver cancer and is manufactured under the Nordion operating licence for BWXT Medical. BWXT Medical is under contract by a third party to supply this product. It is produced by the nuclear decay of strontium-90 (half-life of nearly 29 years) and is a fission product of uranium used in nuclear reactors.
>
> In-111 is a diagnostic radiopharmaceutical used for the assessment of inflammation and infection within the body, for example, diabetic foot infection. The Indium-111 product line was approved in 2018 by the US Food and Drug Administration and commercially launched in late 2019. The product is produced in the Nuclear Medicine Production Facility (NMPF) using In-111 obtained from BWXT Medical's Vancouver operation.

As indicated in its's licence application, BWXT Medical is seeking to furnish a stable North American-based supply of Technetium-99m (Tc-99m) generators. Tc-99m is a decay isotope of Molybdenum-99 (Mo-99). At this stage, there is no indication by BWXT as to what other medical isotopes or radiopharmaceuticals it plans to manufacture.

Technetium-99 and 99m – A Brief background

Tc-99 is a radioactive metal and decays via the emission of beta particles, the most common isotopes being technetium-99 (Tc-99) and metastable technetium-99 (Tc-99m), with half-lives respectively of 210,000 years and 6 hours.

Tc-99 was first obtained from the decay of Molybdenum (Mo-99), but is mainly produced from the nuclear fission of Uranium-235 (^{235}U), a component in Highly Enriched Uranium (HEU). Tc-99m is also a component of gaseous and liquid effluent from nuclear reactors and industrial and institutional wastes from hospitals and research facilities.

Tc-99m is the most widely used isotope in Nuclear Medicine worldwide. Both its short half-life of six hours and energy emitted (140 keV) make it an ideal imaging agent, as further discussed in this submission.

As a further and incidental note on Tc-99, it has been found in the groundwater beneath uranium processing facilities. Contamination from Tc-99 is of concern if individuals are exposed to it by drinking contaminated water and ingesting contaminated plants. (Technetium-99m is not a concern at these sites because of its short half-life.)[7]

This submission reviews the plans proposed by BWXT Medical for the production of Tc-99m and the issues and concerns from a public and health perspective; potential limitations arising from private ownership and control of the manufacturing of Tc-99m; amongst other matters pertaining to BWXT's submission. It also recalls the world-wide shortage of this critical isotope,

[6] BWXT Business Plan - CMD 21-H5.1 p.8

[7] https://semspub.epa.gov/work/HQ/175253.pdf

as a reminder that operations can go astray, if caution and safety is not the underlying basis for producing this or other medical isotopes.

BWXT- Production of Tc-99m

In 2018, BWXT Technologies, Inc. announced its *patent-pending* innovative technology to produce Mo-99, the parent isotope of technetium-99m (Tc-99m) for the Tc-99m generator product. This process of production differs from the fission Mo-99 process in that it does not require the use of uranium (either Highly Enriched Uranium (HEU) or Low-Enriched uranium (LEU)), and does not generate long-lived radioactive waste associated with the use of uranium.

Accordingly, BWXT is seeking to provide a stable North American-based supply of Tc-99m generators by the development of this technology. At this stage, the company is aiming for a commercial launch in late 2022, pending approval by Health Canada and the US Food and Drug Administration.

BWXT AND NORDION – A BRIEF HISTORY

In July 2018, BWXT acquired Sotera Health's Nordion medical isotope business to provide a stable North American-based supply of Mo-99 and Tc-99m and support its new technology. On December 17, 2018, BWXT ITG Canada Inc. submitted an application to the Canadian Nuclear Safety Commission (CNSC) to request issuance of its own Class 1B nuclear substance processing facility operating licence (instead of continuing operations being managed under the Nordion licence). On January 22, 2021, BWXT ITG Canada Inc. changed its legal name to BWXT Medical Ltd. (referred to as BWXT Medical).

The use and need for medical isotopes in modern diagnostic imaging and treatment is broad and ever increasing worldwide. Thus, having an adequate and reliable supply of these isotopes to carry out diagnoses of heart disease and various cancers, and perform other medical applications, both in Canada and worldwide, is of great significance and compelling. BWXT Medical has indicated that it is committed to meeting this demand by continuing to manufacture existing critical medical isotopes.

As stated in its application, "BWXT Medical systems to protect employees, the environment and members of the public against environment, health and safety hazards are well established and BWXT Medical is committed to continuously improving them. BWXT Medical will work to implement programs and objectives to conserve natural resources, prevent pollution and minimize waste. Maintaining a safe and healthy work environment for employees is a top business priority."[8]

Upon issuance of its own Class IB licence, BWXT Medical indicates that it will adopt the existing Nordion Management System for Safety. Nordion has leased the medical isotopes portion of the building and associated areas to BWXT Medical for a 20-year period, with agreement that the lease can be renewed by five-year intervals up to four times.

[8] CNSC CMD 21-H5.1 p.1

BWXT Medical would have ultimate responsibility and accountability for security, fire protection and facility maintenance requirements under its Class IB licence. Nordion is to be subcontracted to provide those services for BWXT Medical. Furthermore, BWXT Medical must seek Nordion's approval for building modifications and introduction of processes that were not carried out previously at Nordion. Coordinated joint emergency response plans have been developed between Nordion and BWXT Medical.

Comments

A shortage in supply of medical isotopes can be devastating, both in Canada and abroad, as witnessed just over 10 years ago. Thus, it is critical that the production and supply of medical isotopes, in particular, although not limited to Tc-99, be carried out in a safe manner and without interruption.

It is also critical that BWXT Medical lives up to its commitment that employees would be provided with a safe and healthy work environment and that BWXT addresses efforts to prevent pollution and minimize waste so as not to endanger the surrounding environment or added to the volumes of radioactive waste that are sent elsewhere (off-site) or are "cleared" and end up in landfills or recycled products in the marketplace.

Furthermore, it is essential that emergency response plans jointly adopted by both Nordion and BWXT Medical facilities are reviewed and upgraded routinely.

These matters call to question a number of issues, for example:

- How and at what frequency will CNSC and Health Canada monitor all the operations at the Nordion site to ensure safety in production **and** safety for the employees and the surrounding communities?
- How BWXT Medical will adapt to a growing and changing market as to the manufacturing of radioisotopes using in scanning and treatment of diseases;
- How BWXT and the CNSC will handle potential implications (e.g., due to shortage of supply, accidents on site, etc.,) domestically, especially given that in the past, the industry facilities in Canada were government-owned.
- What plans are in place by federal agencies in the case of a lack of supply and/or technical issues affecting the production and supply of Molybdenum-99 (Mo-99) and/or Tc-99m and any other medical isotopes that may be produced at the site?

It also raises questions as to the transferability, trading and selling of assets of a private company, namely BWXT, and the implications that such activities would have domestically and internationally.

While the five facilities worldwide that were the major producers of Tc-99m experienced shutdowns resulting in shortages in world-wide supply, these facilities were government-owned and funded. This is no longer the case in Canada. BWXT Medical has taken over many operations at Nordion's medical isotope business, except for the Cobalt-60 operations which further solidifies the private control of the production of medical isotopes.

WORLD-WIDE SHORTAGE OF TC-99M (2009-2010) - HISTORY

As of November 2010, each of the five major isotope producing reactors in the world (Canada, the Netherlands, Belgium, South Africa, France) were more than 40 years old and had exceeded their planned operating lives by 10 or more years, requiring increasing maintenance that were considered time-consuming and costly. This was clearly not a wise consideration.

At that time, both Canadian and Dutch reactors, which together produce over two-thirds of the global supply of ^{99}Mo, were out of service. While other reactors attempted to maximize their output to alleviate the isotope supply deficit, they were unable to compensate for the entire global isotope demand.[9] In fact, unanticipated closures of each of these reactors had already occurred approximately twice a year 5 years prior to 2010.

Furthermore, more than 90% of the world supply of Mo-99 was produced via irradiation of highly-enriched uranium (HEU) targets, which in itself had led to concerns politically as well as environmental, although those concerns were trumped by the "benefits" seen in producing medical isotopes.

The Tc-99m shortages experienced in May and July of 2010 were the worst experienced in medical isotope history. The question is – what have we learned from that experience? Certainly, using age-old equipment was not a good idea, especially given the problems that had been noted, but ignored in some of the reactors.

The use of HEU as targets was recognized by many parties as an unsound practice, both from the waste produced, but also for security reasons, in that the wastes resulting from the use of HEU can be used nefariously, and potentially to produce nuclear weapons.

Some practices in producing Tc-99m have been changed, in particular, phasing out HEU and using low enriched uranium (LEU), as was the case for Canada's 52-year old National Research Universal Reactor NRU) by the Ottawa facility, which had been producing at least 30-40% of the world's supply of Mo-99.[10] But that is not the case worldwide.

Even though these issues and shortages occurred over 10 years ago, the continuous supply of Mo-99 could still become a problem worldwide. It is important to recall that Mo-99 is no longer being produced in Canada (as of 2016).

Outstanding Concerns

While BWXT Medical is aiming for a commercial launch in its production of Mo-99 in late 2022, subject to approvals by Health Canada and the US Food and Drug Administration, these approvals may be delayed or not necessarily come as early as presumed, for a number of reasons, especially at a time of a world-wide pandemic of COVID.

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[9] https://www.cadth.ca/global-impact-technetium-99m-shortages; (Also refer to "The Isotope Crisis and the Chalk River Reactor", The Watershed Sentinel, 07/10/2009)

[10] The Global Impact of Technetium-99M - Environmental Scan https://www.cadth.ca/sites/default/files/pdf/ES-11-504_Global_Issues_e.pdf . https://www.advancingnuclearmedicine.com/en/reference-cases/from-heu-to-leu-medical-isotopes

To reiterate, once again, the loss of federal control or involvement in the production of a critical isotope does not serve public interest in Canada.

> Does CNSC, Health Canada, etc., have plans as to securing a reliable and sufficient supply of Mo-99 and Tc-99 presently and in the future, domestically as well as abroad?
>
> How or what from facility or facilities is Canada currently obtaining supplies of Tc-99? Are any of the facilities using HEU? If so, that speaks of a political and societal problem.

So here we are, as a country, once more, in a quandary, as to how to ensure that Canadians will have adequate and sufficient access to critical medical isotopes that are not produced using HEU.

WORKERS' HEALTH - POTENTIAL EXPOSURE

For a comparison of risk and associated doses to Nuclear Energy Workers (NEWs), historical data from Nordion can be used as a conservative approximation as the licenced activity is similar with the exception of the work in Nordion's Cobalt Operations Facility. Workers involved in Cobalt operations account for the highest doses received at the Nordion facility.

Between 2015 and 2019, the maximum effective dose received by a worker was 5.49 millisieverts (mSv), approximately 11 percent of the regulatory dose limit of 50 mSv in a one-year dosimetry period. (P. 28 CNSC)

Releases associated with the Nuclear Medicine Production Facility (NMPF) include beta emitters, radioiodines, radioxenons, Molybdenum-99, and Cobalt-60 (as a waste impurity). The releases associated with the Cobalt Operations Facility (COF) include Cobalt-60, Niobium-95, Zirconium-95, and Cesium-137.

The CNSC compares air emissions monitoring results and liquid effluent monitoring results for releases of these substances with Derived Release Limits (DRLs) set by the CNSC for the years 2015-2019. (Note: The production of Mo-99, I-125, I-131 and Xe-133 ceased in November of 2016.)[11]

The maximum equivalent skin and extremity doses received by a worker from 2015 to 2019 were 2.54 mSv and 16.40 mSv, respectively which represent approximately 0.5 and 2.6 percent, respectively, of the regulatory dose limits of 500 mSv/one-year dosimetry period.

BWXT Medical's licence application includes proposed procedures to conduct routine thyroid screening of NEWs working with iodine-125 and iodine-131.

Urine analysis and whole body counting is available to quantify doses to workers in the event of elevated screening results or if elevated air and/contamination monitoring indicates a potential intake.

[11] CNSC CMD 21-H5 pp. 28, 102

Radiation Protection [12]

The Medical Isotopes area comprises an administrative area known as the "Non-Active Area" and a controlled access production area known as the "Active Area." The Active Area encompasses the Kanata Radiopharmaceutical Manufacturing Facility (KRMF) and the radiochemical and radiopharmaceutical facilities in the Nuclear Medicine Production Facility (NMPF)[13]. The products produced are used for diagnosis and treatment of disease worldwide.

The handling of radioisotopes takes place in processing containment units such as hot cells, glove boxes and fume hoods. The hot cell wall shielding (lead wall, lead bricks, steel, and concrete) is selected to minimize dose rates to the operator. The hot cells are typically grouped in banks which have a step down pressure differential to facilitate clean processing.

High radioactivity materials are handled in hot cells while lower activity amounts are handled in glove boxes where the level of radiation and the amount of required shielding is reduced. Glove boxes are typically constructed of Lucite and stainless steel. They are typically equipped with general and localized lead shielding of sufficient thickness to minimize occupational radiation exposure. Neoprene gloves are sealed in place over the flanges at the glove ports. Lucite will eventually be phased-out for construction of future glove boxes due to amendments to regulations on glove box materials.

Fume hoods are generally designed to handle low levels of radioactivity (i.e., Quality Control samples, decontamination of equipment, etc.) and allow easier unrestricted manipulation of parts and chemicals used by the operator. Fume hoods are constructed of stainless steel, inside and out, with service controls located on the exterior face. Localized shielding is used where required to minimize occupational radiation exposure.

Radiation Monitoring Program [14]

As indicated in BWXT's submission, a monitoring program to control radiation exposure is in place at BWXT Medical. Routine radiation surveys are carried out in all Active Areas to ensure that the external exposure of NEWs to ionizing radiation from all routine work is kept to a minimum and within safe limits. Workplace air sampling and monitoring programs identify any release of contamination into the air or onto surfaces and process controls are present throughout the facility to help prevent employee exposures to radioactive materials.

All employees who regularly work in the Active Area are classified as NEWs and are assigned dosimeters licensed by the CNSC. Optically Stimulated Luminescent Dosimeters (OSLD's are referred to as TLDs) are used as body and ring dosimeters.

Production technicians are trained to work in various production processes and move from one production area to another during the year. As a result, personnel may receive exposure from working with more than one radionuclide in the NMPF. Personnel who routinely work in the Active Area are assigned monthly TLDs. Other employees who normally work outside the Active

[12] BWXT CMD 21-H5.1 p.4

[13] Unless otherwise indicated, reference to NMPF throughout this document includes the KRMF.

[14] BWXT CMD 21-H5 p. 31,32 .71

Area and visit the Active Area on a regular basis are also classified as NEWs, but are assigned quarterly TLDs.

Contractors who are given access to the Active Area are called "Contractor NEWs." While they are trained as NEWs, tested and have security clearance, they are subject to the regulatory dose limit and internal administrative levels of non-NEWs and are not permitted to handle radioactive material.

Comments

- As indicated in BWXT's submission, "personnel may receive exposure from working with more than one radionuclide." What are these specific radionuclides? At what point (or level of exposure) will a worker not be allowed in the Active Area?
- Why are "Contractor NEWs" subject to the radiation limits set for non-NEWs? Even though they may not be permitted to handle radioactive material, nonetheless they can be exposed to radionuclides in accessing the Active Area.
- What portion of the total workforce, both NEWs and non-NEWs, has access to the "Active Area"?
- Employees who normally work outside the Active Area but visit it on a regular basis are classified as NEWs, but they are assigned quarterly TLDs instead of monthly TLDs. Does "normally work" imply that they do on occasions work in the Active Area? Without knowing the regularity or length of such visits, this speaks of an inequity in protection of the workforce.
- Does BWXT ITG expect to do more hiring during its licence request period? What portion of the workforce will be "Contract NEWs"?

DERIVED RELEASE LIMITS (DRLS)

Comparison of DRLs to Reported Emissions

Derived Release Limits (DRLs) are the legal upper regulatory bounds set by the CNSC for releases of specific radioactive substances to the environment. The DRL represents the quantity of a radionuclide that, if released from the specified facility in a year, would result in a dose to the most exposed member of the public of 1 mSv/yr, i.e., the International Commission on Radiological Protection (ICRP) public dose limit. Exceedances of the DRL trigger reporting to the CNSC, followed by a formal investigation and regulatory oversight.[15]

DRLs are calculated for specific radionuclides expected to be found in the airborne and liquid operational effluents.[16] However, there is a significant difference between the emissions reported for a specific radionuclide and the associated DRL.

[15] CMD 15-H.2 e-Doc: 4579312 Environmental Assessment Information Report p. 16

[16] CSA Standard N288.1 The methodology for establishing DRL models is based on the Canadian Standards Association (CSA) standard CSA N288.1-08: *Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities.*

As noted in the CNSC document CMD 21-H5 p. 102, the DRLs for releases to air for specific radionuclides associated with the NMFP (and the COF) for the years 2015-2017 were modified in the following years 2018-2019. Regardless, there are striking differences between the DRLs and the monitored air emissions by magnitudes.

For example, the DRL for air emissions of I-131 was 3,790 GBq/year for the years 2015-6, but the monitored air emissions were 0.15, 0.35 GBq for those years. With respect to the beta emitters and releases to sewers, the DRL was 23,300 GBq/yr, while releases were 0.006 GBq/yr. The DRL was later changed to 389 GBq/yr.

Two fundamental issues need to be addressed in examining the DRLs compared to the emissions, namely:

i) The methodology used to determine DRLs; and/or

ii) The accuracy of the releases that are reported and whether they account for what is actually being emitted (both monitored and fugitive emissions).

If the basis for such differences lies with the reported emissions, then one would presume that there are problems with monitoring and/or the models. Even if the reported releases are off by a factor of two or three, that would not, by any means, make the DRLs more plausible or credible because of the sheer differences in magnitude.

DRLs are independent of how a radioactive emission is produced, but depend on the degree of exposure to the emissions. Exposed individuals are classified as groups. The group predicted to receive the highest dose is referred to as the representative or critical group.

The determination of DRLs involves many factors, including the modeling method employed, and the characterization of representative persons, exposure pathways, meteorology, and dose conversion factors which provide the estimated radiation dose imparted to a cell, tissue or organism by the radioactive decay of one atom of that radionuclide.

An underestimation of this dose factor can result in misrepresenting the impact of a particular radionuclide. As well, there are complications with the specific locations selected, and the critical (or representative) groups identified.

Clearly, DRLs do not or cannot account for the combined, cumulative exposure from all the sources of emissions of a particular radionuclide or the combination of radionuclides, annually let alone for decades.

The vast differences between the DRLs and the actual emissions can lead one to draw unwarranted and unsupportable conclusions - either the emissions are trivial, or the DRLs are fundamentally flawed. Neither conclusion is a healthy scenario.

MOLYBDENUM-99 (MO-99)/ TECHNETIUM-99M

History and Production

Given the importance of this topic, this section reviews specific element regarding the production of Technetium-99 m (Tc-99m). Tc-99m (a daughter of Molybdenum-99 (Mo-99)), has been mainly produced in nuclear reactors from the nuclear fission of Uranium-235 (^{235}U),

referred to as targets, resulting from the irradiation thermal neutrons. (When HEU targets are irradiated, some of the U-235 nuclei absorb these neutrons, causing them to fission.)

The use of HEU is of great concern as it is considered to pose a potential nuclear proliferation risk, and consequently has resulted in some reactors converting to use Low-Enriched Uranium (LEU) fuel instead.

The importance of the supply of Tc-99m cannot be overstated. It has been used and continues to be used for several decades worldwide.

Tc-99m is used globally in more than 40 million diagnostic medical procedures each year. It is considered to be the "workhorse" of medical isotopes, covering about 80% of the all the nuclear diagnostics procedures. It is the most widely used and sought after radioisotope as a tracer for medical diagnosis of serious illnesses, such as heart disease and cancer and in medical therapy in brain, bone, liver, spleen, kidney, thyroid scanning and blood flow studies.

While many countries have been producing Mo-99, the largest suppliers have come from four reactors in Belgium, the Netherlands, Russia and South Africa. The U.S. has not produced Mo-99 for well over thirty years, relying on imports for its requirements.

The National Research Universal (NRU) reactor at Chalk River had produced "Fission" Mo-99 at the Nordion facility since the mid-1980's and previously at Atomic Energy of Canada Limited (AECL) Tunney's Pasture. This process resulted in producing long–lived radioactive waste, including Highly Enriched Uranium (HEU), as well as noble gases and radioiodines.

The production of Fission Mo-99 ceased in late 2016 with the shutdown of the NRU reactor. Consequently, Canada is also relying on imports to meet its requirements of Mo-99 and thus Tc-99m.

Given the world-wide use of Tc-99m and its very short half-life (6 hours), the stability of its steady and continuous production and supply is both critical and essential.

Furthermore, Mo-99 has a half-life of only 66 hours and thus cannot be stockpiled. The instability and security of the supply has become an important issue on an international scale. Recent years have illustrated how unexpected shutdowns at any of those reactors can quickly lead to shortages.

The aging of major Mo-99 production reactors has resulted in frequent shutdowns on production and has triggered movements to establish new research reactors for Mo-99 production, as well as the development of various production technologies.

As indicated in its licence application, BWXT Medical has developed a technology for producing Mo-99 using neutron activation of natural Mo-98 targets in a reactor. The company is proposing to restart the Mo-99 process using modified equipment to accommodate natural Molybdenum targets. Accordingly, these targets are to be neutron-activated at a reactor facility elsewhere, not at the NMPF. There is no indication as to the location of that reactor facility.

The activated targets would then be transported to the NMPF for further processing. This would entail extracting Technetium-99m from the Mo-99 using a technetium generator which would be loaded at the NMPF.

BWXT Medical estimates that releases to air and water from the proposed Mo-99 process will pose a negligible risk to persons or the environment and that estimates of waste volumes and activities of the proposed Mo-99 process would be within the amounts generated from the previous process, with the exception of an increased volume of low-level liquid waste. The total activity of the waste is estimated to remain below that of the previous process, and the waste would be managed in accordance with the established waste management program.

Any changes to the Mo-99 process must be made in accordance with regulatory and program requirements.[17]

Comments

No information is provided as to the nature of wastes that would result from this process, or estimates of the increased volume of low-level liquid waste and its contents, nor the use of technetium generators.

Furthermore, it would seem that the operations and processes involved may require a specialized workforce, but that matter has not been mentioned.

This makes it very difficult to comment on the benefits or detriments of a novel technology. Whether or not proprietary rights may be involved, it must certainly be under CNSC's purview to have full disclosure of these novel techniques and any potential adverse effects on workers' health, the ensuing waste produced, and the local environment.

This is troublesome, especially in light of the checkered history in producing such vital isotopes as Tc-99m. To quote, "absence of information is not evidence of absence".

Yet, there are some developments of interest worth noting, one being the use of a reactor at the Darlington Nuclear Generating Station, and the use of cyclotrons.

If such techniques could work, there would be benefits derived from being able to provide a domestic supply of Tc-99 (as well as imports). If that is the case, then it would be in the interest of Canada to ensure that there would be a dedicated supply for the country. But such matters have not received any discussion.

DARLINGTON NUCLEAR GENERATING STATION

Potential Source of Molybdenum-99

Ontario Power Generation's (OPG) Darlington nuclear power plant is intending to produce Mo-99 for use in new technetium-99m (Tc-99m) generators designed by BWX Technologies Inc. The Candu plant would be the first large-scale commercial nuclear power plant in the world to produce Mo-99.[18]

This follows BWXT's announcement In May 2018 that it had developed an innovative process to produce Mo-99 for use in newly designed Tc-99m generators that are currently in commercial

[17] CNSC CMD Sections 3.5.2.3, 4.5
[18] https://www.world-nuclear-news.org/RS-Darlington-to-supply-molybdenum-99-2106187.html

development. A key element of this process is the irradiation of molybdenum targets, for which BWXT requires a long-term, reliable and continuous supply.

Medical isotope targets can be inserted and removed from the Darlington reactors while they remain in operation, thus allowing for a continuous supply of the material. The use of Candu reactors, which use natural uranium fuel, also removes the proliferation risk associated with the production of Mo-99 by the irradiation of enriched uranium targets.

As noted in this submission, North America has been without a large-scale domestic supply of the radioisotope since 2016, when production of Mo-99 in Canada's NRU research reactor ceased. Darlington Nuclear would be the only source of Mo-99 in North America, which may ensure a stable domestic supply of this critical isotope.

Subject to regulatory approvals, production of Mo-99 was expected to begin at Darlington by the end of 2019. To date, that has clearly not happened. So we need to ask what is happening with respect to this proposed project.

NORDION'S GAMMA TECHNOLOGIES OPERATIONS (COF) - COBALT-60

While not a component of BWXT's submission, the fact that the facilities under the NMPF include Cobalt-60 production, there may be issues that arise that could affect operations.

Nordion is the world's largest provider of Cobalt-60 (Co-60), a widely used isotope used in the gamma sterilization process and the treatment of various diseases and cancers.[19]

Approximately 40% of the world's single-use medical devices, such as syringes, gloves, implants and surgical instruments, are irradiated and sterilized with Co-60. The isotope emits gamma radiation, which makes it ideal to enhance the safety of medical products and perishable foods such as fruits, meats and spices.

The activities proposed by BWXT Medical are independent of and are not intended to duplicate those activities related to Nordion's Cobalt Operations Facility (COF). While not a component of its licence application request, nevertheless, it is worth noting the operations at the COF, as there may well be overlap with personnel at both facilities and both operations are, of course, producing radioactive and chemical wastes.

Cobalt-60 – Production and Waste (disposal of used sources)

Ontario's CANDU reactors produce 50% of the world's supply of the isotope. Co-60 is produced in nuclear reactors by inserting naturally occurring Co-59, which is converted to Co-60 during the operation of the reactor.[20]After conversion, Co-60 is removed from the reactor and shipped to Nordion's facility, where it is used to manufacture sealed sources for shipment to customers in more than 40 countries.

[19] https://www.nordion.com/products/medical-grade-cobalt-60/; https://www.opg.com/innovating-for-tomorrow/medical-isotopes/

[20] Currently, Co-60 is extracted from reactors at Pickering and Bruce Power. Plans are underway to expand Co-60 production to Darlington Nuclear to ensure a steady supply in that operations at Pickering are set to close in 2024.

Because of Cobalt-60's relatively short half-life, longer sterilization times are required for materials put in the irradiators, until they finally are no longer usable, and become what is referred to as "disused" sources, which are shipped back to Kanata, and eventually to Chalk River, Canada's only commercial rad waste storage facility.

As Canada is the major manufacturer of category 1 cobalt-60 sources, Canadian firms re-import large quantities of disused sources that are held in storage, but awaiting disposal. Citizens' organizations in the area of Nordion's facilities are concerned about a proposal to landfill imported disused sources at a federally-owned facility and, among other things, about risks of worker exposure in a landfill that would also receive a wide variety of other radioactive wastes.

E-beam technologies (electrons accelerated to speeds just under the speed of light) are an alternative to Co-60 for food irradiation (and possibly other applications) that would not produce difficult-to-manage radioactive waste.

It would be worth noting if Canada would support the use of e-beam technology as a potential replacement of Co-60.

Radioactive releases associated with the NMPF include Beta emitters, Radioiodines, Radioxenons, Molybdenum-99, and Cobalt-60 (as waste impurities).[21] The releases associated with the COF include Cobalt-60, Niobium-95, Zirconium-95, and Cesium-137.[22]

Nuclear Energy Workers (NEWs) at COF account for the highest doses of Co-60 received at the Nordion facility. For example, between 2015 and 2019, the maximum effective dose received was 5.49 millisieverts (mSv), which is approximately 11 percent of the regulatory dose limit of 50 mSv in a one-year dosimetry period.[23] Nevertheless, one can argue that the regulatory dose limits are not necessarily as protective as CNSC may indicate. Furthermore, these workers are being continually subjected to this exposure.

CYCLOTRONS

"Made-in-Canada method of producing life-saving radioisotopes receives Health Canada approval - December 18, 2020" [24]

A Canadian consortium, which includes UBC, BC Cancer, and TRIUMF, is the first in the world to obtain regulatory approval for this approach, allowing for the production of technetium-99m (Tc-99m) for clinical use in Canada using small particle accelerators known as cyclotrons.

With Tc-99m now able to be produced for clinical use at regional cyclotron facilities in Canada, starting in B.C., dependence on nuclear reactor technology will be reduced, helping secure a stable, diversified, and environmentally friendly supply chain. The approval also clears Canada to bring the new technology to the global marketplace, facilitating regional production of Tc-

[21] The production of Molydenum-99, Iodine-125, Iodine-131 and Xenon-133 at the NMPF ceased November 2016.
[22] CNSC CMD 5 p.102
[23] CNSC CMD P. 28
[24] https://www.med.ubc.ca/news/made-in-canada-method-of-producing-life-saving-radioisotopes-receives-health-canada-approval/

99m either by upgrading existing cyclotrons around the world or installing new, dedicated high capacity regional production facilities.

The process was approved by Health Canada on November 26, 2020 and is expected to be deployed first in B.C. at the Institute for Advanced Medical Isotopes (IAMI), which is currently under construction and expected to be operational in 2022.

As with any technology, there are some drawbacks, such as concerns about the quality and cost of producing Tc-99m via accelerators (cyclotrons). However, that must be weighed with the advantages and availability, and with the disadvantages of relying on nuclear reactors, given potential breakdowns, the radioactive waste produced, and so far, the lack of a domestic producer of technetium.

WASTE "MANAGEMENT"

This is a "grey" area in both the CNSC and BWXT CMDs.[25]

According to CMD CNSC p. 43:

> "in general, waste from BWXT Medical operations will be considered low-level radioactive waste as per CSA N292.0-14, *General principles for the management of radioactive waste and irradiated fuel*."
>
> BWXT Medical has also established a diversion program designed to divert waste with activity concentrations below the unconditional clearance levels in the *Nuclear Substances and Radiation Devices Regulations*.

As stated in BWXT's document, p. 45:

> Waste from the Active Area is categorized into four types: routine waste, liquid waste, non-routine waste, and divertible waste. Routine waste is waste generated from production processes that is routinely shipped to approved external radioactive waste management facilities. Low-level liquid waste is collected separately and routinely shipped to an approved radioactive liquid waste receptor.
>
> Radioactive waste not so is evaluated for conventional waste disposal or packaged for shipment to a licensed radioactive waste management facility. Waste generated within the Active Area that meets CNSC's unconditional clearance levels is separated from solid active waste and is disposed of by conventional waste disposal methods, such as a landfill. Solid active waste generated in the Active Area is sent to licensed radioactive waste facilities.

As a general comment, I hardly think that "waste management" has taken on a meaning of not being important and is being sluffed off. Is the management of waste being handled responsibly or is it being too readily dismissed? We (the public) do not know – nor do we have the means to actually find out. Any information given by these parts is far too general and frankly of no use.

[25] CMD CNSC p. 43, and CMD BWXT p. 43,45

CONCLUDING REMARKS AND RECOMMENDATIONS

Based on numerous concerns and issues that have been raised in this submission, I urge the CNSC to use utmost caution in approving BWXT's licence request as it stands. There are far too many uncertainties that would need to be cleared up and clarified, including the approval of BWXT's "patent technology" by Health Canada and the US FDA for the production of Molybdenum-99 (Mo-99) and hence, Technetium-99m (Tc-99m), its important decay element in Canada.

The development of novel technologies and approvals tend to take far more time than presumed, and for a number of reasons, including testing the technology, and assuring that it is, in fact a safe or safer method than has been used, (namely fission in reactors).

It is also important to recall the worldwide crisis in supply of Tc-99m just over 10 years ago and what had primarily led to this crisis – aging reactors. Given the importance and use of this isotope, the causes for this shortage must be recalled and avoided.

Regarding the current means of production worldwide, it is high time to evaluate the use of reactors, in particular, those using Highly Enriched Uranium (HEU), to produce "fission Mo-99" extracted from the waste. This is not only because many of the reactors are at a critical age, (and using this technique has been a potential nuclear proliferation matter) but also because there are other ways, for example, cyclotrons. One would logically surmise that moving to methodologies that do not carry the baggage associated with reactor production would be the goal of the methodology to produce medical isotopes.

With respect to the workforce, there is a lack of clarity (and discrepancies) as to the number of workers (classified as NEWs) transferred from Nordion to BWXT in its takeover of Nordion operations of the Nuclear Medicine Production facility (NMPF). Furthermore, there is no discussion as to the future of the workforce, both NEWs and non-NEWs. Thus it is difficult to know how BWXT's new technology will affect the workforce, not only in numbers but how they are classified. Given the differences in levels of protection for these two groups of workers, this is concerning, as it could lead to potentially higher exposure levels being permitted to non-NEWs, which is unfortunately presently the case.

Another matter deals with waste produced by the facilities at Nordion.

At present, BWXT is manufacturing two medical isotopes, Yttrium-90 and Indium -111. However, there is no mention in the CMDs of the CNSC or BWXT of any other medical isotopes that BWXT plans to manufacture in its 10-year licence request. One would expect the company to venture further into this area and perhaps it has, but there is no discussion on this, which for a request of a 10-year licence, is particularly odd.

As well, it is worth noting that the Cobalt-60 (Co-60) operations carried at by Nordion at the Cobalt Operations Facility (COF) are not addressed. Presumably, Nordion would continue with these operations, especially given the world-wide market for the use of Co-60. At the same time, I question BWXT's interest in this operation, especially in light of its expansion and take-over of nuclear operations in Canada.

With respect to Canada's current source of supply of Tc-99, as it is no longer producing it domestically, (and neither is the United States – a situation of over 30 years), it begs the question as to from what facilities is Canada getting its supply of this medical isotope, and perhaps others. The field of producers is large, and the processes are variable.

Is there any domestic requirement that Mo-99 not be produced using HEU (in other words, fission Mo-99)? After all, this has been and remains an important international issue, yet worldwide, many facilities still are using HEU, while some are using LEU, which might be a better scenario, but far from ideal.

There is a bittersweet irony in all of this – producing medical isotopes that rely on processes (i.e. fission) in aging reactors. At some point, many of these reactors will have to shut down. The failure to have a domestic source and supply of Tc-99m that is not controlled by profit-making companies speaks volumes as to how dependent Canada is on imports, when the country would be and should be quite capable of producing its own medicines using techniques that are safer, far less dangerous, and does not generate hazardous waste.

It would be of interest knowing the role of Health Canada in the supply chain of medical isotopes. Certainly they should be front and centre, but it seems as though there is a veil of silence on this whole matter. Yet Health Canada bears the responsibility of approving BWXT's proposed novel approach to manufacture Mo-99 (and hence Tc-99m).

Much more effort needs to be placed on clarifying these matters and others that have not been addressed by CNSC or BWXT. As Canadians, we deserve the right-to-know.

Therefore, in all conscience, the wisest path for CNSC to follow is to reject BWXT's 10-year licence request. Given several uncertainties as to when or if this novel technique of producing Mo-99 will be approved and if so, when it will come into fruition, It is recommended that the licence period be no more than 5 years.

Furthermore, BWXT must prepare a detailed decommissioning plan within 5 years and this plan must be subject to public review. The matter of "waste management" including disposal and clearance of waste must receive attention and be addressed.

Most importantly, workers (NEWs and non-NEWs) must be afforded appropriate protection from exposure to radiation and other chemicals involved in all processes and facilities at Nordion.