Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

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Supplementary Information

Renseignements supplémentaires

Presentation from Anna Tilman

Présentation de Anna Tilman

In the Matter of the

À l'égard de

BWXT Medical Ltd.

BWXT Medical Ltd.

Application for a Class IB nuclear substance processing facility operating licence

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

Commission Public Hearing

Audience publique de la Commission

June 9, 2021

9 juin 2021

Canada

Presentation to the Canadian Nuclear Safety Commission (CNSC)

- **BWXT Medical Ltd.'s**
- **Application for a 1B Class nuclear Facility Operating Licence for a 10-year Period**
- **June 9, 2021**
- **Anna Tilman**

Current License / Operations: Nordion

1. **Medical isotope portion:**
   includes radiopharmaceutical facilities in the Nuclear Medicine Production Facility (NMPF) and the Kanata Radiopharmaceutical Manufacturing Facility (KRMF). The NMPF was constructed in 1982; the (KRMF) was completed in 2000.
2. **The Gamma Technologies portion:**
   involves high activity sealed sources used in cancer therapy and irradiation technologies, including Cobalt-60 production. The Cobalt-60 Source Production Facilities (COB) were built in 1972.

Both portions are housed under the facility referred to as the Kanata Operations Building (KOB).

BWXT Acquisition

The acquisition of the NMPF medical isotope portion of Nordion was completed in August 2018 under BWXT Medical Ltd, a subsidiary of BWXT.

Conditions and activities re acquisition:

- 20 year lease with Nordion with renewals in five-year intervals- Nordion retains control and management of the KOB.
- Activities are those currently authorized and independent of those activities related to Nordion's Gamma Technologies business.
  - A licence amendment or Commission approval was not required.
  - Approximately 118 employees, ~ half of the Nordion personnel, were hired by BWXT Medical. Currently BWXT Medical has ~ 187 employees.

BWXT Medical's Proposed Operations

- Manufacture nuclear substances in excess of 1 x 10^{15} Bq/year. Isotopes > 1 year half-life would not be manufactured (although some impurities with longer half-lives would be present).

  "The total radioactive material processed would be below historical production levels."

- No reference is given as to the specific nuclear substances to be manufactured or the activity and half-lives of these substances.

Molybdenum-99 (Mo-99) Production

Historically, Mo-99 was produced at NMPF by the fission of highly enriched uranium (HEU) targets in the National Research Universal (NRU) reactor at Chalk River Labs. That ceased in 2016.

- BWXT Medical has developed a technology to produce Mo-99 using a natural (stable) Mo-98 target irradiated in a reactor.
- BWXT Medical anticipates a commercial launch of this methodology in late 2022.

This methodology will require the approval of Health Canada and the U.S. Food and Drug Administration.

Given so many unknown factors, delays in such a launch should and could be expected, especially in these times.

CNSC: Conclusions & Recommendations

BWXT Medical:

- is qualified to carry on the activities authorized by the licence and will make adequate provision for the protection of the environment, the health and safety of persons, will maintain the national security measures required to implement Canada's international obligations.
- Its proposed financial guarantee of $10.54 million is based on a credible cost estimate, with acceptable financial guarantee instruments.

Thus, CNSC staff recommend that:

The Commission issue a Class IB Nuclear Substance Processing Facility Licence to BWXT Medical for a 10-year period and accept the proposed financial guarantee.

Issues – a 10 year licence

- Does it allow for the oversight needed to ensure **safe and continuous** production of Mo-99 or other isotopes to be produced?
- Does the CNSC plan to conduct interim reviews of operations of the facility? If so, at what frequency?
- What emergency measures are in place in the event of an interruption potentially causing delays in the production of Mo-99?

Manufacturing Other Isotopes??

Currently, BWXT is manufacturing two medical isotopes, Yttrium-90 &Indium - 111 at the Nordion facility.

However, there is no indication in the CMDs of the CNSC or BWXT as to whether these operations would continue in its 10-year licence request.

Manufacturing Other Isotopes? (cont'd)

As stated in its CMD:

BWXT Medical's intention is to manufacture nuclear substances in excess of 1 x 10^{15} Bq/year.

- No indication is given as to identifying these nuclear substances, or their potential application in medical treatments
- While BWXT notes that isotopes with > 1 year half-life would not be manufactured, it also comments on the potential presence of some impurities with longer half-lives.

The CNSC must require BWXT to identify what nuclear substances it intends to produce in this category, what function they would serve in medical treatments, and the specific impurities. Only then would it be CNSC's purview to permit such production...or not.

Production and Distribution Mo-99 to Technetium (Tc-99)

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 without interruption.

- **Will or can BWXT (and the CNSC) be able to guarantee sufficient and adequate supply of essential isotopes for domestic and international use?**
- **Is the patent approach (as cited by BWXT for the production of Mo-99) limited or restrictive in any way that would affect production and distribution?**

Worker's Health and Exposure Limits – Active Areas (KRMF and NMPF)

Nuclear Energy Workers (NEWs) and non-NEWs:

- What portion of the total workforce have access to the "Active Area"?
  - Inequity in protection: Employees working outside the Active Area but visit it regularly are classified as NEWs, and assigned quarterly dosimeters (TLDs) instead of monthly TLDs.
  - At what point (or level of exposure) will a worker not be allowed in the Active Area?
- Why are "Contractor NEWs" subject to radiation limits set for non-NEWs?
- What portion of new hires will be "Contractor NEWs"?

Worker's Health & Environment

- **Workers' health** - emergency response plans by both Nordion and BWXT Medical facilities must be reviewed and upgraded routinely.
- **Radioactive wastes** - transferring these wastes off-site only to end up in landfills and/or be "cleared" and/or recycled products in the marketplace is not minimizing waste.

BWXT Medical has committed to provide employees a safe and healthy work environment and address efforts to prevent pollution and minimize waste.

It remains to be seen whether or how these commitments will be upheld over time.

Overriding Issues – Safety and Production

- How and at what frequency will CNSC and Health Canada monitor operations to ensure safety in production and for the employees and the surrounding communities?
- How will BWXT Medical adapt to a growing and changing market in the manufacturing of specific and novel medical radioisotopes?

Overriding Issues – Federal Roles

- 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 Mo-99 and/or Tc-99m and any other medical isotopes that may be produced at the site?
- How will the Government of Canada deal with issues such as the transferability, trading and selling of assets of a private company, namely BWXT, and the implications that such activities would have domestically and internationally?

Concluding Comments & Recommendations

- The CNSC reject BWXT's 10-year licence request and restrict the licence period to 5 years.
- BWXT must be required to prepare a detailed decommissioning plan in that period subject to public review.
- NEWs and non-NEWs must be provided full and equitable protection from exposure to radiation and other hazardous substances.
- Other means of producing many of these isotopes than nuclear reactors, for example, cyclotrons, need to be utilized.