BWXT Medical Ltd.

Application for a Class IB Nuclear Substance Processing Facility Licence for a Medical Isotope Facility in Ottawa, Ontario

CNSC Staff Presentation

Commission Hearing
June 9, 2021
CMD 21-H5.A

E-Docs: #6502265.pptx
E-Docs: #6571816.pdf

Presentation Outline

- Application for a Class IB Licence
- Facility Overview
- Summary of CNSC Staff's Assessment of BWXT Medical Application
- Public and Indigenous Engagement and Participant Funding
- Licence and Licence Conditions Handbook
- CNSC Staff Conclusions and Recommendations

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

APPLICATION FOR A CLASS IB LICENCE

Application for a Class IB Licence

BWXT Medical requests:

- That the Commission issue a Class IB Nuclear Substance Processing Facility licence for a 10-year period
- The acceptance of a financial guarantee through two instruments, a surety bond and a letter of credit

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

Background

BWXT Medical's Acquisition of Nordion's Medical Isotope Business

1988
Nordion operates NMPF under its Class IB licence. All workers are Nordion employees

April 2018
BWXT announces agreement to acquire the medical isotope business from Nordion

August 2018
Acquisition completed.
Workers at the medical isotope facility are BWXT-Medical employees, working as subcontractors to Nordion. Nordion remains accountable for the operations

December 2018
BWXT- Medical applies to CNSC to obtain a licence to operate the facility under a separate licence

June 2021
Hearing

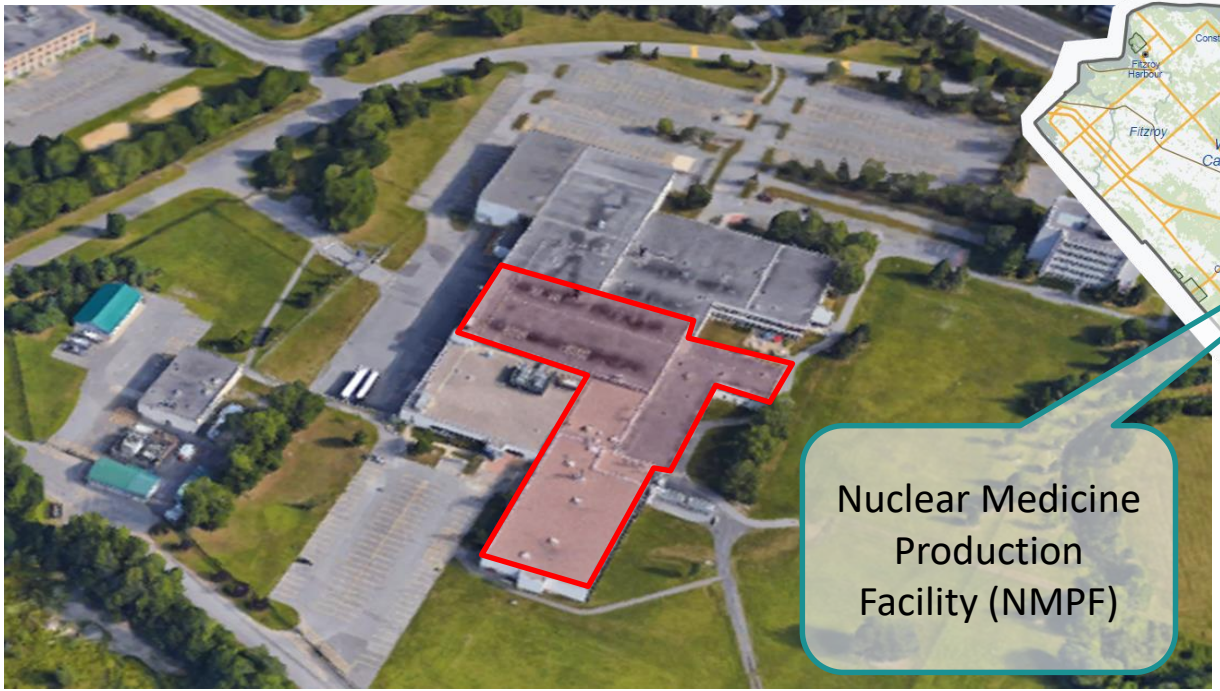
If granted a licence, BWXT will be accountable and responsible for the NMPF

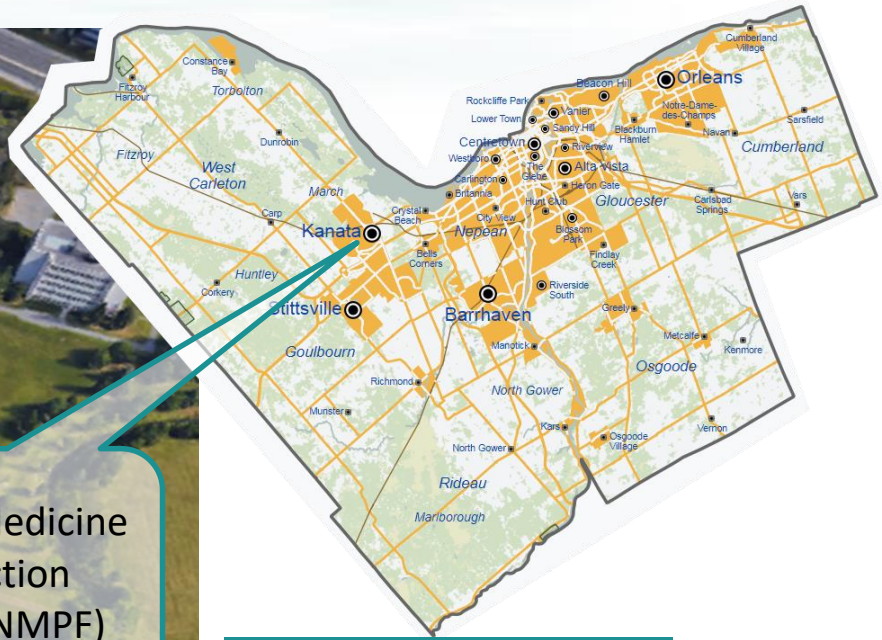
BWXT Medical Ltd. Licence Application: CMD 21-H5.A

FACILITY OVERVIEW

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

Facility Location and Overview





Ottawa Region

Medical Isotope Production

- Target is irradiated in a reactor to produce desired isotope
- Irradiated target shipped to Nordion Facility in Kanata
- Target is brought to the Nuclear Medicine Production Facility for processing
- Final product is labelled, packaged and sent to end-user facilities

Photo credit: IAEA

Current Isotope Production

The Nuclear Medicine Production facility is currently producing two medical isotopes:

- Yttrium-90: used to treat liver cancer
- Indium-111: a diagnostic radiopharmaceutical

BWXT Medical proposes to continue producing these two isotopes

Photo credit: BWXT Medical

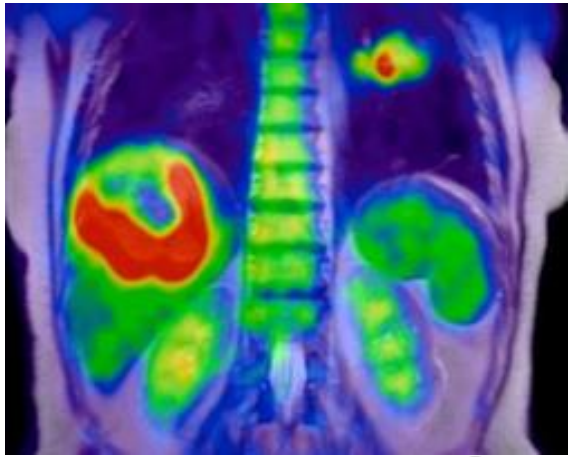


Photo credit: BWXT Medical

Proposed Future Activities

Historical Production of Molybdenum-99 (Mo-99):

- The Nuclear Medicine Processing Facility was used to process Mo-99 obtained through the fission of highly enriched uranium in the National Research Universal reactor at Chalk River Laboratories
- The process ceased in 2016 as a result of the shutdown activities of the National Research Universal reactor

BWXT Medical's proposed future activities:

- Production of Mo-99 using a natural molybdenum-98 target
- Technetium-99m (Tc-99m) will be extracted from the Mo-99 using a technetium generator
- Installation of two electron beam accelerators that will be used to sterilize the Tc-99m product line

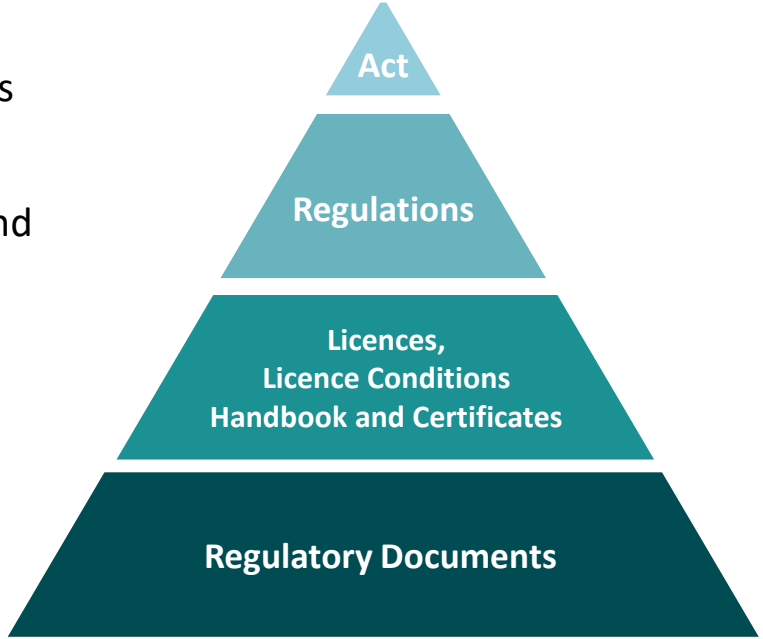
BWXT Medical plans to continue developing new products

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

CNSC STAFF ASSESSMENT OF THE APPLICATION

CNSC Staff Assessment of The Application

- *Nuclear Safety and Control Act* and its regulations provide requirements
- CNSC Licence and Licence Conditions establish and set licensee-specific requirements
- Licence Conditions Handbook provides clear and comprehensive criteria for compliance according to the licence
- Regulatory documents, CSA standards and international guidance provide clarity on expectations



Assessment of Safety and Control Areas (SCA)

- CNSC staff reviewed all 14 Safety and Control Areas for BWXT Medical's licence application
- Information submitted in support of the application satisfies CNSC requirements under the NSCA and its regulations
- Assessment criteria and results are summarized in CMD 21-H5

BWXT's Medical's programs meet regulatory requirements

Safety and Control Areas
Management System
Human Performance Management
Operating Performance
Safety Analysis
Physical Design
Fitness for Service
Radiation Protection
Conventional Health and Safety
Environmental Protection
Emergency Management and Fire Protection
Waste Management
Security
Safeguards and Non-Proliferation
Packaging and Transport

SCA – Management System

Program Highlights

- Measures to understand and promote safety within the organization
- Safety culture surveys every three years
- Measures to collect and share information with other licensees, and follow operating experience and best industry practices
- Management review of performance and internal audits
- Change management and records management process

Management system is compliant with CSA N286-12: *Management Systems for Nuclear Facilities*

SCA – Management System

Leveraging operating experience

- Since 2018, BWXT Medical management and staff have worked under the programs developed under Nordion's management system
- Employees have been trained to work in the facility and have continued to safely implement the programs and procedures that are in place at the facility
- CNSC staff have assessed and inspected the programs and found them acceptable
- BWXT Medical has committed to completing the rebranding of the documents to reflect the new corporate entity within a 12-month period following the issuance of a licence

BWXT's Management System governs all licensed activities and meets requirements

SCA – Safety Analysis

Program Highlights

- Safety analysis report (SAR) includes a description of the methods used to ensure that:
  - Nuclear substances are processed inside a hot cell, glove box or fume hood
  - Nuclear substances are transferred and stored in containers with appropriate shielding
  - Activity limits are established and maintained for hot cells, glove boxes and fume hoods
- Submitted assessments to ensure safety of its operations were sufficient under normal conditions and under abnormal conditions (earthquake, fire, aircraft impact)
- SARs are reviewed a minimum of once every five years, or whenever a facility undergoes significant changes

BWXT Medical's SAR meets CNSC requirements

SCA – Physical Design

Program Highlights

CNSC staff assessed and concluded that BWXT Medical's:

- Design of the Nuclear Medicine Production Facility including structures and equipment, complies with all applicable national codes and standards
- Fire protection program meets regulatory requirements
- The management system governs all modifications and effectively mitigates hazards

BWXT Medical's Physical Design program meets CNSC requirements

SCA – Radiation Protection

CNSC staff assessed and concluded that:

- BWXT Medical's Radiation Protection (RP) program meets regulatory requirements
  - No regulatory dose limit exceedances (historical)
- Doses are kept As Low As Reasonably Achievable (ALARA)

BWXT Medical's radiation protection program is protective of workers

SCA – Radiation Protection

Occupational Exposures to NMPF Nuclear Energy Workers (NEWs)

Dose data	2015	2016	2017	**2018**	**2019**	**2020**	**Regulatory limit**
Average effective dose (mSv)	0.26	0.35	0.25	**0.28**	**0.13**	**0.15**	N/A
Max individual effective dose (mSv)	1.72	1.92	2.58	**2.16**	**1.84**	**2.23**	50 mSv/year
Average skin dose (mSv)	0.27	0.44	0.25	**0.27**	**0.13**	**0.15**	N/A
Maximum skin dose (mSv)	1.73	2.44	2.54	**2.18**	**1.90**	**2.28**	500 mSv/year
Average extremity dose (mSv)	0.40	0.67	0.48	**0.88**	**0.64**	**0.68**	N/A
Maximum extremity dose (mSv)	9.30	8.30	16.40	**9.08**	**12.92**	**16.48**	500 mSv/year

SCA – Radiation Protection

Dose to the Public

Maximum Annual Effective Dose to a Member of the Public (mSv)						
Year	2015	2016	2017	2018	2019	2020
Dose (mSv)	0.0057	0.0021	0.000052	0.000067	0.00087	0.00122

- Radiation doses to the public are well below the regulatory limit of 1 mSv/yr
- There is no impact to public health and safety from BWXT Medical's operations in the Nuclear Medicine Production Facility.

The public is protected

SCA – Environmental Protection

Environmental Risk Assessment

- As part of its application in 2018, BWXT Medical submitted the Nordion Environmental Risk Assessment (ERA) (2017) which CNSC staff deemed acceptable and is reflected in CMD 21-H5
- BWXT Medical submitted a standalone ERA for the Nuclear Medicine Production Facility and posted it on their website. The principle conclusions remained the same. CNSC staff accepted the ERA in April 2021
- BWXT Medical submitted the ERA to the Secretariat as supplementary information on May 17, 2021

CNSC staff accept the ERA conclusion that there is negligible risk from the NMPF

SCA – Environmental Protection

Program highlights

- BWXT Medical's Environmental Risk Assessment meets the requirements of CSA N288.6
- BWXT's Medical's proposed measures to control and monitor airborne and liquid releases comply with requirements of CSA N288.5
- Environmental Action levels are not required as releases are very low (near detection limits) and in alignment with CSA N288.8

BWXT Medical's environmental protection program meets regulatory expectations

SCA – Environmental Protection
Derived Release Limits

- Derived Release Limits (DRLs) established for the Nuclear Medicine Production facility meet requirements set out in CSA N288.1
- Radionuclides considered in the DRL assessment include:
  - Radionuclides currently measured in the environmental protection program
  - Known or anticipated radionuclides that will be released
  - Radionuclides that may be introduced in future operations

Whole-site DRL

- Established to account for releases from the BWXT Medical and Nordion facilities
- Managed under the joint BWXT Medical-Nordion Environmental Health and Safety Committee
- **Will not result in an exceedance of the regulatory dose limit of 1mSv/year to any member of the public**

SCA – Environmental Protection

Historical Performance

- Nordion has an acceptable Environmental Risk Assessment in place
- CNSC staff have assessed and inspected the environmental monitoring program and found that it meets expectations.
- Historically, airborne emissions and liquid effluent releases have remained well below regulatory limits
- CNSC's Independent Environmental Monitoring Program has confirmed protection of the public and environment

Existing environmental monitoring program indicates public and the environment are protected

SCA – Emergency Management and Fire Protection

CNSC staff assessed and concluded that BWXT Medical:

- Meets the requirements of CNSC REGDOC 2.10.1 version 2: Nuclear Emergency Preparedness and Response
- Meets the requirements of CSA N393-13: Fire protection for facilities that process, handle, or store nuclear substances and will conduct annual fire response drills

Emergency Management and Fire Protection program meets regulatory requirements

Preliminary Decommissioning Plan

CNSC staff assessed and concluded that BWXT Medical's:

- Preliminary Decommissioning Plan (PDP) meets the requirements of CSA N294-09 and CNSC regulatory guide G-219
- PDP captures strategies, activities and cost estimates for decommissioning the Nuclear Medicine Production facility

Financial Guarantee

As part of the licence application, BWXT Medical proposed a financial guarantee of $10.54 million through two proposed instruments:

- A letter of credit in the amount of $2.6 million
- A surety bond in the amount of $7.94 million

CNSC staff assessed the proposed financial guarantee amounts and instruments, and determined that they meet the criteria of CNSC regulatory Guide G-206.

Proposed amounts are credible and the financial instruments are acceptable

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

PUBLIC INFORMATION AND PARTICIPANT FUNDING

Public Information and Disclosure Program

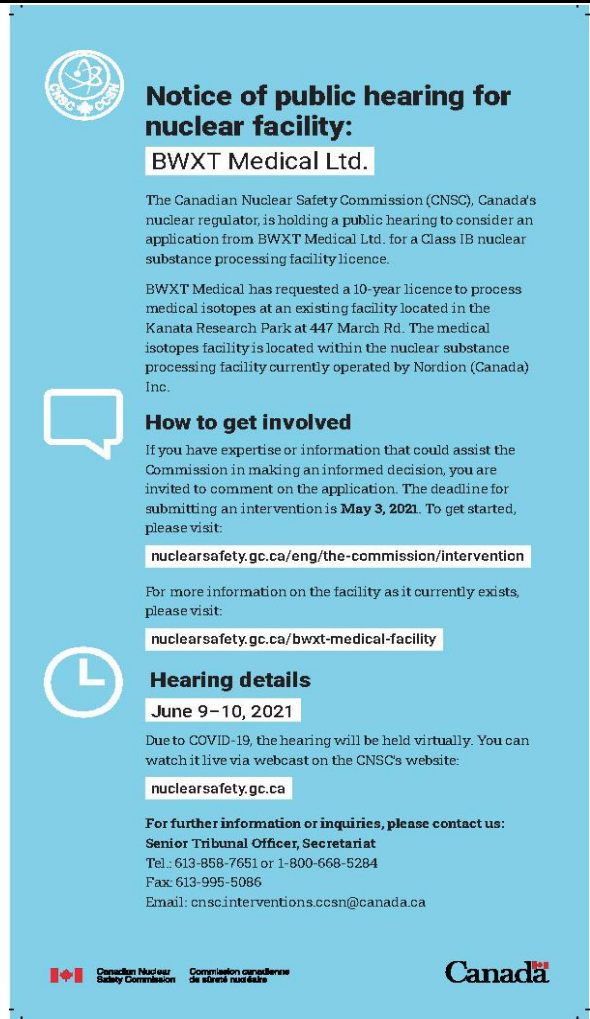
CNSC staff have reviewed BWXT Medical's Public Information Disclosure Program and determined that it:

- Identifies clear goals and objectives in terms of dissemination of information
- Identifies that a public disclosure protocol will be available to the public and posted on their website
- Provides contact information for members of the public who want to obtain additional information
- Identifies multiple target audiences in close proximity to the licensed facility

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

CNSC Staff Outreach

Event	Date
Announcement for Notice of Hearing	November 18, 2020
Participation in BWXT Medical Public Outreach Session	March 31, 2021
CNSC Webinar	April 8, 2021



Notice of public hearing for nuclear facility:

BWXT Medical Ltd.

The Canadian Nuclear Safety Commission (CNSC), Canada's nuclear regulator, is holding a public hearing to consider an application from BWXT Medical Ltd. for a Class IB nuclear substance processing facility licence.

BWXT Medical has requested a 10-year licence to process medical isotopes at an existing facility located in the Kanata Research Park at 447 March Rd. The medical isotopes facility is located within the nuclear substance processing facility currently operated by Nordion (Canada) Inc.

How to get involved

If you have expertise or information that could assist the Commission in making an informed decision, you are invited to comment on the application. The deadline for submitting an intervention is **May 3, 2021**. To get started, please visit:

nuclearsafety.gc.ca/eng/the-commission/intervention

For more information on the facility as it currently exists, please visit:

nuclearsafety.gc.ca/bwxt-medical-facility

Hearing details

June 9–10, 2021

Due to COVID-19, the hearing will be held virtually. You can watch it live via webcast on the CNSC's website:

nuclearsafety.gc.ca

For further information or inquiries, please contact us:
Senior Tribunal Officer, Secretariat
Tel.: 613-858-7651 or 1-800-668-5284
Fax: 613-995-5086
Email: cnscinterventions.ccsn@canada.ca

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire
Canada

Engagement with Indigenous Groups

The Nordion/BWXT Medical site is situated in proximity of traditional and treaty territories of many Indigenous groups.

CNSC staff are satisfied that BWXT Medical engaged with the appropriate Indigenous groups regarding their planned licensed activities.

CNSC engagement activities included:

- July 2019 - Letters of notification sent to identified Indigenous groups with follow-up phone calls
- November 2020 - Follow-up letters sent to each Indigenous group with follow-up phone calls
- March-April 2021 - Identified groups provided with CMDs, and follow-up communications
- April 2021 - CNSC webinar

The CNSC continues to engage with Indigenous groups to build trust and foster positive relationships

Participant Funding Program

Funding was provided to assist members of the public and Indigenous groups in providing valuable information directly to the Commission.

CNSC awarded $68,200.00 to the following 5 recipients:

Algonquins of Ontario
Algonquins of Pikwakanagan First Nation
Anna Tilman
Kebaowek First Nation
Women in Nuclear

Main Themes in Interventions

Engagement and communication with Indigenous groups, including participation in monitoring activities	Consideration of Indigenous knowledge
Proposed Mo-99 process	Waste handling
Specific nuclear substances for processing activities not listed	Licence term
Health and Safety of workforce (NEW's and contractors)	Potential increase in the production of radioisotopes

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

LICENCE AND LICENCE CONDITIONS HANDBOOK

Proposed Licence and Draft Licence Conditions Handbook

Proposed BWXT Medical Operating Licence

- 10 year licence term
- Standard licence conditions

Draft Licence Conditions Handbook (LCH)

- Preamble
- Compliance Verification Criteria
- Guidance

Proposed Licence Term

- Since the acquisition by BWXT Medical in 2018, the Nuclear Medicine Production Facility continues to operate safely
- A large portion of the BWXT Medical workforce is highly qualified and has considerable experience in being a qualified Class IB licensee
- The processes and procedures for the safe operation of the facility are effective and will be retained
- Requested 10-year term is consistent with CNSC licences issued to other nuclear facilities

CNSC Regulatory Focus if Issued a Licence

CNSC staff will:

- Monitor compliance by
  - Conducting inspections according to CNSC's compliance verification plan to ensure safe operation of the facility
  - Assessing annual compliance reports, other periodic reports, event reports
  - Assessing any changes to the licensees program against the approved licensing basis and safety case
- Report on BWXT's performance to the Commission, in its Regulatory Oversight Report

Nordion/BWXT Medical Relationship

If Issued a Licence

Due to co-location of BWXT Medical and Nordion in the same building, BWXT Medical plans to:

- Subcontract certain aspects to Nordion such as:
  - Security of the property, physical security systems and security personnel
  - Fire safety plan, physical fire protection systems
  - Facility maintenance
- In the implementation of its programs and activities that might overlap with that of Nordion as a Class IB licensee, establish joint mechanisms with Nordion such as:
  - Joint emergency response plan
  - Jointly manage site releases within a single DRL
  - Joint EHS Committee to oversee joint program elements

BWXT Medical will have ultimate responsibility and accountability for all activities if issued a licence

BWXT Medical Ltd. Licence Application: CMD 21-H5.A

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Based on the technical assessment of BWXT Medical's application and supporting information, CNSC staff conclude that:

- BWXT Medical is qualified to carry on the activities requested in its licence application
- The requested activities are within the facility's current licensing basis
- BWXT Medical's operations would remain protective of public health and the environment

Conclusions (cont'd)

BWXT Medical's proposed financial guarantee is acceptable.

- Cost estimate is credible
- Financial guarantee instruments are acceptable
  - Letter of credit
  - Surety Bond

Recommendations

CNSC staff recommend that the Commission:

- Issue a nuclear substance processing facility licence to BWXT Medical for a 10-year period, with the proposed licence conditions
- Authorize the delegation of authority set out in the CMD
- Accept the proposed financial guarantee and direct BWXT to provide the original instruments within 90 days of the issuance of a decision on this matter

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Canada

Connect With Us

Join the conversation

nuclearsafety.gc.ca