Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

CMD 21-H5.1B

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Supplementary Information

Renseignements supplémentaires

Presentation from BWXT Medical Ltd. (formerly BWXT ITG Canada, Inc.)

Présentation de BWXT Medical Ltd. (anciennement BWXT ITG Canada, Inc.)

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

Class IB Licence Application

Application for a Class IB Nuclear Substance Processing Facility Licence

Presenter: Martyn Coombs, President, BWXT Medical Ltd.

June 9, 2021

A Testimonial from a Patient

“I had TheraSphere treatment in December 2016 for HCC. I was expecting an extension of life of 13.8 months; we are now sitting at 53 months and still feeling strong.”

Jan Louw (May 2021)

BWXT Medical in Kanata

- BWXT acquired business from Nordion in 2018, operating under its licence and oversight.
- Application for BWXT Medical licence covers same products, processes and controls as existing licence.
- 200+ employees with 30 years experience producing medical isotopes and radiopharmaceuticals.
- Historically, the Kanata facility had provided over 60% of the global supply of Mo-99.

SAME FACILITY. SAME PRODUCTS. SAME COMMITMENT TO PATIENT HEALTH.

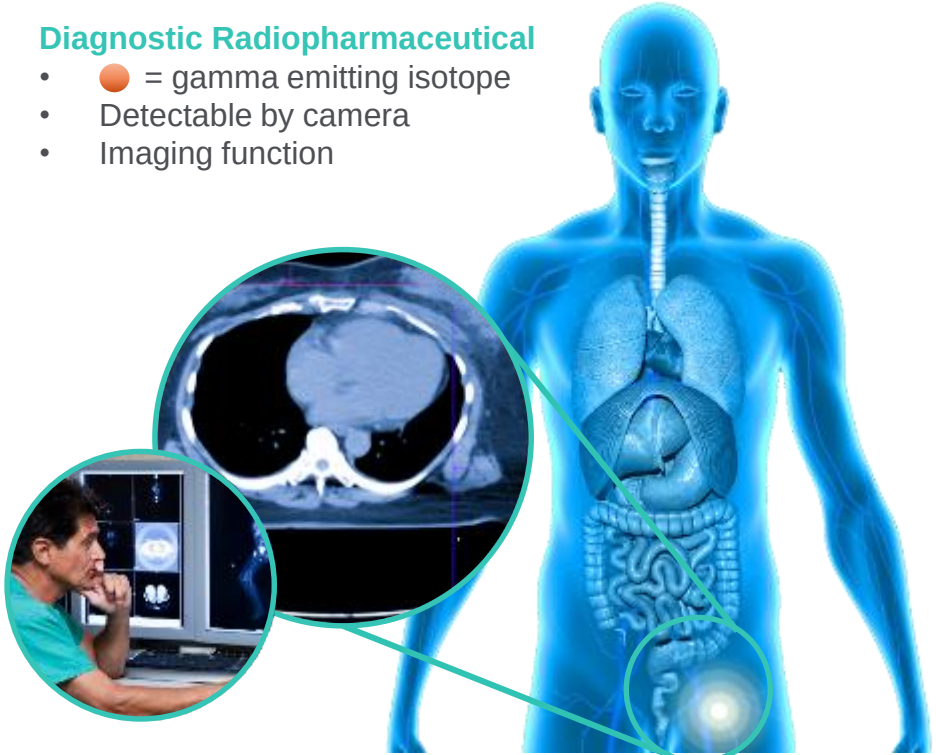
What is Nuclear Medicine?

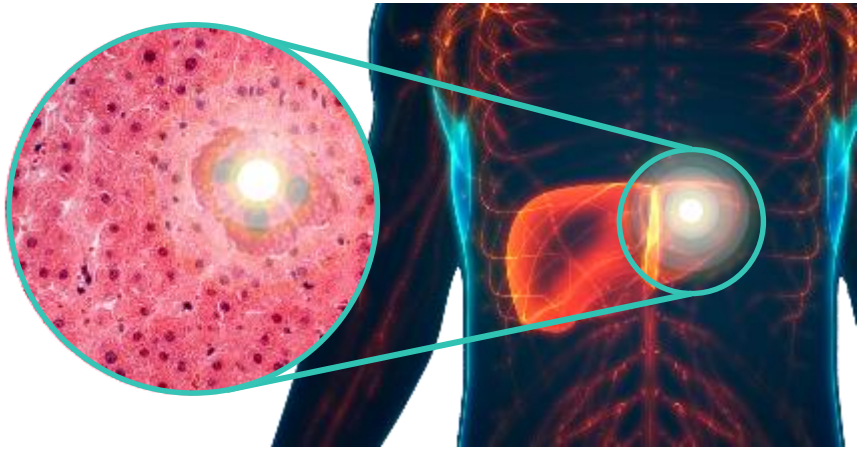
Nuclear Medicine is a medical specialty that uses radiopharmaceuticals to specifically image and to selectively treat disease.

Radiopharmaceutical a specialized drug containing a radioactive isotope. 

Diagnostic Radiopharmaceutical
- = gamma emitting isotope
- Detectable by camera
- Imaging function

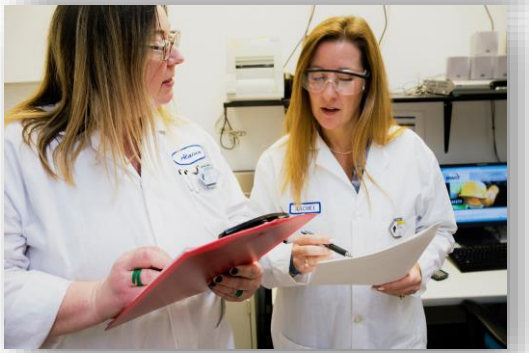
Therapeutic Radiopharmaceutical
- = beta or alpha emitting isotope
- High energy deposition – kills cells
- Treatment of cancer





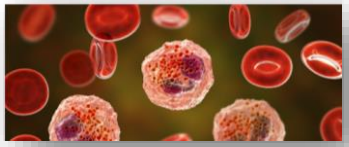
Committed to Improving the Lives of Patients

- Experienced manufacturer and supplier of critical medical isotopes and radiopharmaceuticals for research, diagnostic and therapeutic uses.
- Over 40 million diagnostic imaging procedures are performed every year to diagnose life threatening conditions like heart disease and cancer.
- Our passion to deliver quality nuclear medicine is driven by our commitment to improving the lives of patients around the world by enabling them to recover from illnesses.



Our vision is to ensure Canada is self-sufficient in the supply of nuclear medicine.

Nuclear Medicine at BWXT Medical in Kanata

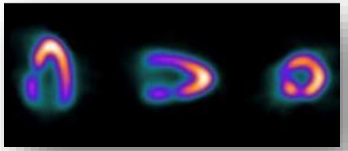


Indium In 111 Oxyquinoline

- Diagnostic radiopharmaceutical used in assessment of inflammation & infection.
- For example, diabetic foot.

TheraSphere™

- Sterile, active implantable Class III medical device used to treat liver cancer.
- Under contract by Boston Scientific Corporation to supply this product.



Technetium-99m (Tc-99m) [in development]

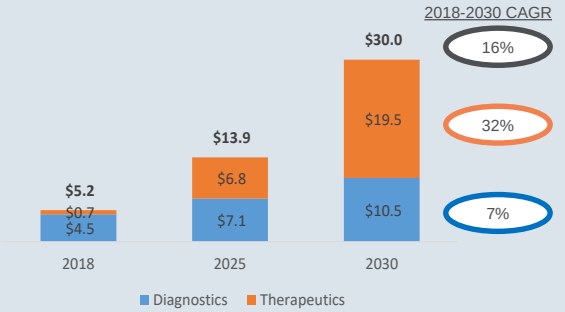
- Innovative technology to produce Molybdenum-99 (parent isotope of Tc-99m).
- Used in over 40 million diagnostic imaging procedures worldwide each year.
- Diagnose cancer, coronary artery disease & other adverse medical conditions.
- Pending approval from FDA and Health Canada.
- Expect to provide stable, reliable, long-term supply.

Medical isotopes have been produced at the Kanata site for over 30 years.

Market Dynamics: Rapid Growth in Global Nuclear Medicine Market

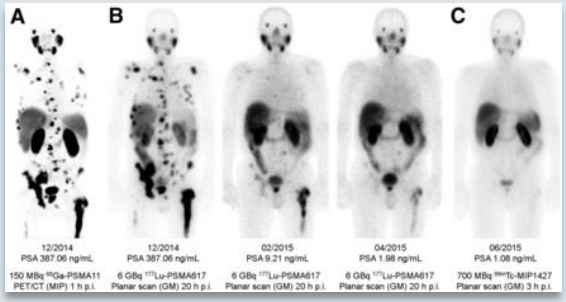
Nuclear Medicine market is growing rapidly…

2020 Nuclear Medicine Market: $7B(1)



…mostly through new therapeutics

Prostate Cancer Treatment(2)



Novartis announces positive result of phase III study in patients with advanced prostate cancer

> "Novartis today reported the first interpretable results of the Phase III VISION study evaluating the efficacy and safety of ^{177}Lu-PSMA-617, a targeted radioligand therapy in patients with progressive PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) compared to best standard of care alone." (3/31/21)

(1) MEDraysintell Report 2019; BWXT Medical estimates
(2) Kratochwil, et al. (2016). Journal of Nuclear Medicine

What Activities Are Carried Out At The Kanata Site?

Four Step Process

Product	1. Receive Medical Isotopes (produced off site)	2. Process / Purify	3. Manufacture Final Product	4. Distribute to Customers

In Kanata, we are performing precision manufacturing, using radioactivity created elsewhere to create sophisticated products that benefit patients.

What Activities Are Carried Out At The Kanata Site?

Four Step Process

This part is done in Kanata

Product	1. Receive Medical Isotopes (produced off site)	2. Process / Purify	3. Manufacture Final Product	4. Distribute to Customers
TheraSphere™	Receive Y-90 (Eg. from MURR)	Clean glass ampoules	Dispense into patient-specific doses & autoclave	Daily delivery to Canada, US & RoW
Indium Oxine	Receive In-111 (from Vancouver)	Synthesize In-111 oxine	Dispense into unit doses & autoclave	Weekly delivery to Canada & US
Tc-99m Generators (in development)	Receive Mo-99 (from MURR or OPG) Note, do not use Uranium in process	Immobilize Mo-99 in Titanium oxide powder	Dispense Titanium-Molybdate powder into columns & E-Beam sterilize	Thrice-weekly shipments to Canada & US

In Kanata, we are performing precision manufacturing, using radioactivity created elsewhere to create sophisticated products that benefit patients.

BWXT Medical Audit History

- 2020 Inspection:
  - CNSC: work conducted by BWXT under Nordion's licence was in full compliance with all criteria.

- 2019 Inspections:
  - FDA: compliant
  - Health Canada: compliant
  - ISO Certification: compliant

We work in two of the most highly regulated industries in the world: Nuclear and Medicine. We are in full compliance with all regulations.

Our Licence Application

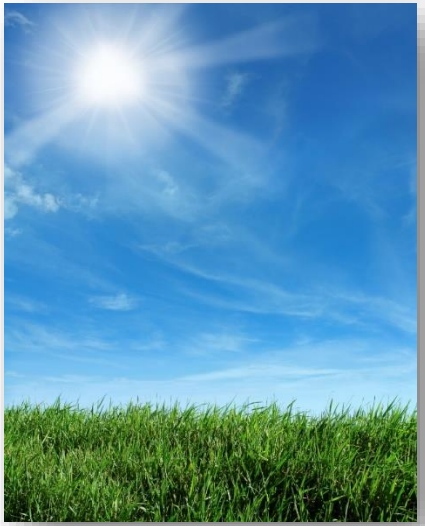
- Processing same types of radioactive products in the existing medical isotope facility.
- Quantities to be processed will remain below historical production levels.
- Licenced activities will be independent of, and will not duplicate those activities related to Nordion’s Gamma Sterilization business.

Any new products developed fall within the scope of the current and new licence we have applied for.

Management System

- Adoption of Nordion's established safety and security programs.

- Comprehensive and robust procedures and policies:
  - Ensure the safety of employees, contractors, the public, and the environment.



- Programs subject to CNSC review, approval and inspection for decades:
  - Consistently assessed as satisfactory or fully satisfactory.
  - Successfully adapted to changes in regulatory requirements.
  - Meets requirements of CSA N286-12 Management system requirements for nuclear facilities.

Safety and Control Area Highlights

Radiation Protection: Radiation doses as low as reasonability achievable **(ALARA).**

- Worker doses last 5 years [regulatory limit 50 mSv (per year) or 100 mSv (over 5 years)].
  - » Annual average effective dose: 0.23 mSv.
  - » Maximum effective dose: 2.58 mSv.
- Estimated public dose for 2020: [regulatory limit 1 mSv (per year)].
  - » 0.00122 mSv (conservative overestimate; includes contributions from Nordion).

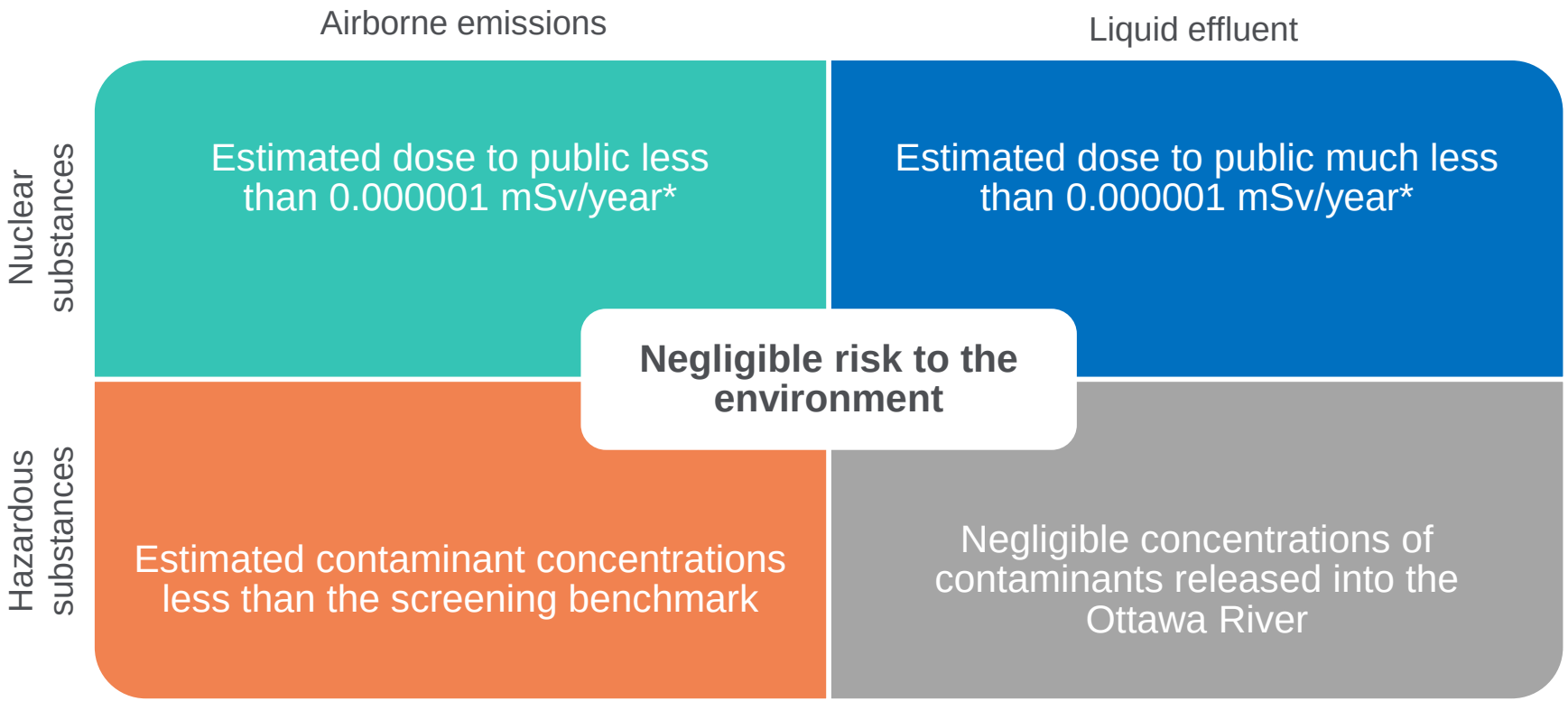
Conventional Health and Safety: Strong safety culture and focused on continuous improvement.

- 2019 Incident Rate: 0.68 [Average Schedule 1 Ontario Employer Incident Rate 2.32].
- 2020 Incident Rate: 1.11 [Average Schedule 1 Ontario Employer Incident Rate not yet published].

Environmental Protection: Application of ALARA and Pollution Prevention principles.

- No expected environmental or health impacts.

Environmental Risk Assessment (ERA)



* Estimated real dose from modelling the ERA
Note: regulatory public dose limit: 1 mSv/year

Other Matters of Regulatory Interest – Waste Handling

- All radioactive waste is collected and sent to an approved radioactive waste management facility.
- Waste water which might potentially contain small amounts of radioactive contamination is:
  - Collected in holding tanks.
  - Sampled and analyzed against release limits prior to being released to the municipal sanitary sewer.
- Waste below CNSC accepted clearance levels:
  - Segregated at source.
  - Screened using sensitive monitoring equipment.
  - Released through conventional waste methods.

Other Matters of Regulatory Interest - Planning for Decommissioning

- Preliminary Decommissioning Plan (PDP)
  - Meets the criteria of CNSC Regulatory Guides G-219, Decommissioning Planning for Licensed Activities, and G-206, Financial Guarantees for the Decommissioning of Licensed Activities.
  - Updated at a minimum every five years, unless required earlier for significant changes to the facility.
  - Updated in 2018 for the licence application.
  - Next update will be initiated in late 2021.

- Cost estimate:
  - $10.54 million CAD.
  - Financial guarantee will be put in place as required by the CNSC.

Other Matters of Regulatory Interest – Public Information Program

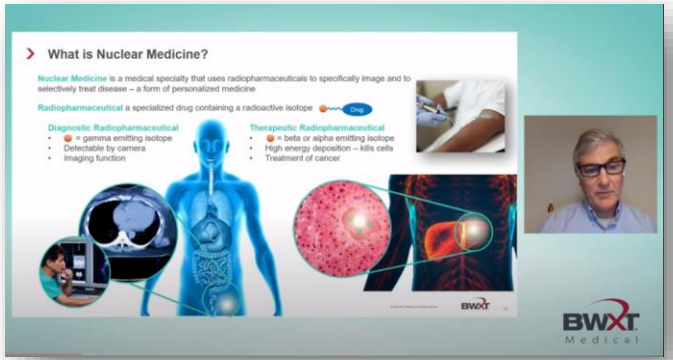
- Committed to timely, transparent engagement with our communities.

- Proactive and responsive engagement with Indigenous communities.
  - Member of Canadian Council for Aboriginal Business / Progressive Aboriginal Relations Program.
  - Active communications team ensures outreach is timely, consistent and responsive.
  - Committed to long-term future engagement with Indigenous Communities.
  - BWXT's Indigenous Relations Commitment and Policy is published on its website.

- Communication methods:
  - Dedicated website updated regularly.
  - Toll-free phone number and email address.
  - Communications, meetings, events and dialogue.
  - Letters and electronic updates.
  - Social media updates and advertisements.

- March 31st Webinar.

- Community Investment.



Clarifications Around Intervenor Statements

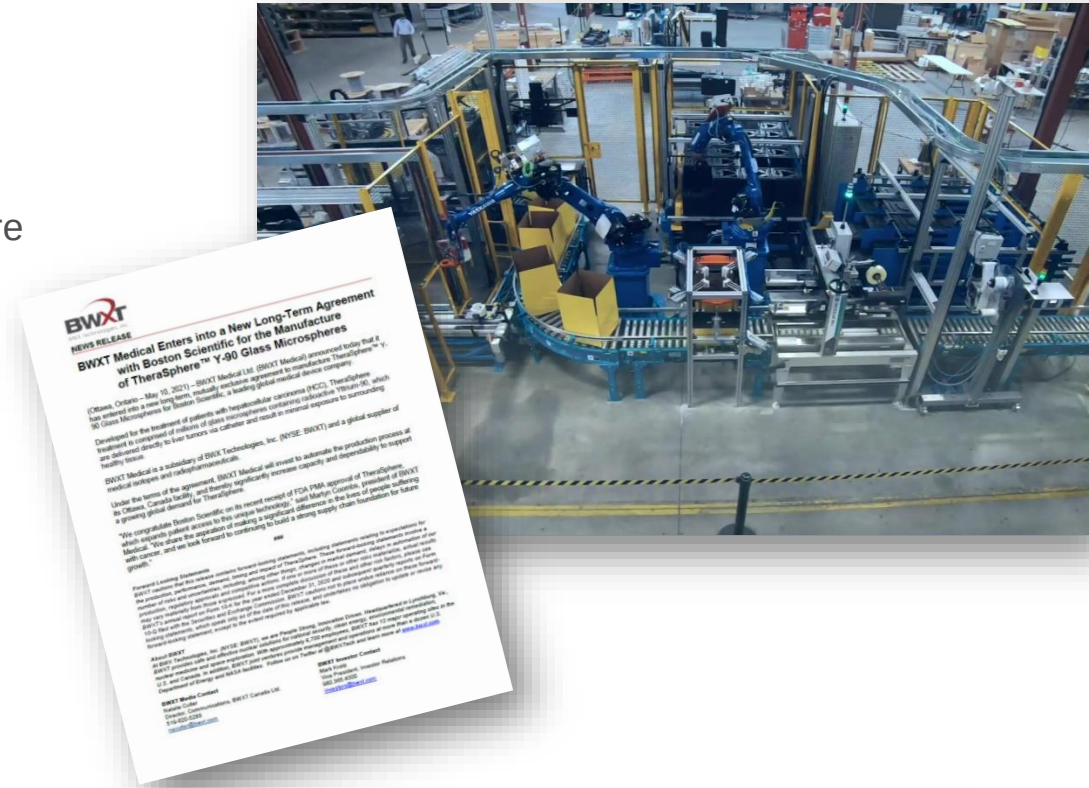
- We appreciate the opportunity to clarify statements provided by some interventions:
  - Kanata facility does not house a nuclear reactor or cyclotron and does not irradiate product.
  - Mo-99 associated with Tc-99m generator development will be produced off-site; processing and manufacturing will take place within Kanata's existing facility and is bound by the same licence conditions as the existing and newly sought operating licence.
  - Uranium is not used as part of our core business processes.
  - Kanata facility has produced Tc-99m generators in the past.
  - BWXT Medical acquired existing and experienced medical isotope personnel from the 2018 acquisition, as this division was already well-established.

Continued Collaboration with Nordion

- Long-term lease agreement.
- Nordion:
  - Approves building and building system modifications.
  - Performs facility maintenance.
  - Provides physical security/security personnel.
- Framework to jointly manage site-wide programs, including:
  - Security
  - Environmental monitoring
  - Emergency response
  - Joint Nordion/BWXT Medical EHS Committee

Recent Announcements Signal Commitment to Future Growth

- Making investments in infrastructure and automation to produce life-saving products.
  - March 8th announcement: Joint Venture with Global Medical Solutions.
  - May 10th announcement: Long-term agreement with Boston Scientific to produce TheraSphere™.
  - Continued infrastructure / automation investments in support of Tc-99m generator manufacturing.



BWXT Medical is Creating Many Good Jobs in the Kanata Community

- Since 2018, BWXT Medical has significantly expanded its workforce from approximately 120 to over 200 skilled professionals.
- The company plans to continue to add more local skilled jobs.
- BWXT Medical is proud of our diverse, talented and educated staff:
  - 71 with Bachelor Degrees
  - 4 with PhDs
  - 36 with Masters Degrees
  - 99 with College Diplomas

Working for BWXT Medical means being part of a team focused on safety, technology, innovation, operational excellence and serving patients and customers.

careers.bwxt.com

Conclusion

- Our licence application has demonstrated that BWXT Medical:
  - Is qualified to undertake the licensed activities.
  - Will make adequate provisions for the protection of the environment, employees and the public, and the maintenance of national security and the implementation of measures required to uphold international obligations to which Canada has agreed.
- Our application supports issuance of 10 year licence for operations of the existing medical isotopes facility.
- BWXT Medical requests an effective licence date of November 1, 2021.