



Regulatory Oversight of Rapidly Changing Technology

Case Studies in Regulating Accelerators

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Regulation*

Canadian Nuclear Safety Commission

13th International Topical Meeting on Nuclear
Applications of Accelerators
Quebec, Canada
2017-08-02





The CNSC and its Regulatory Approach



Canadian Nuclear Safety Commission

- ▶ Regulates the use of nuclear energy and materials to protect **health, safety, security** and the **environment**
- ▶ Implements Canada's **international commitments** on the peaceful use of nuclear energy
- ▶ **Disseminates objective scientific, technical and regulatory information** to the public



We will never compromise safety



The CNSC regulates all nuclear facilities and activities in Canada

- ▶ Uranium mines and mills
- ▶ Uranium fuel fabrication and processing
- ▶ Nuclear power plants
- ▶ Nuclear substance processing
- ▶ Industrial and medical applications
- ▶ Nuclear research and educational activities
- ▶ Transportation of nuclear substances
- ▶ Nuclear security and safeguards
- ▶ Import and export controls
- ▶ Waste management facilities

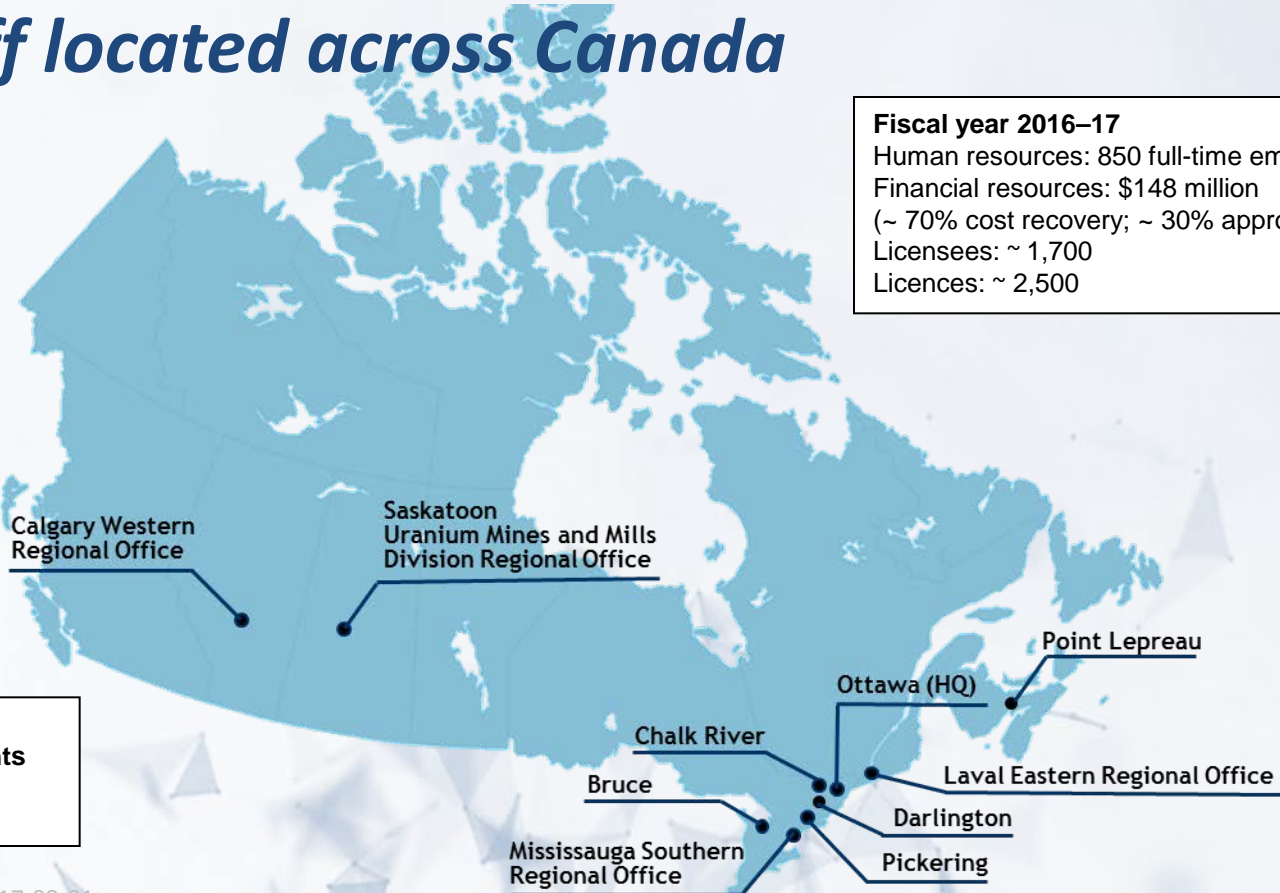


...from cradle to grave

CNSC staff located across Canada

Fiscal year 2016–17

Human resources: 850 full-time employees
Financial resources: \$148 million
(~ 70% cost recovery; ~ 30% appropriation)
Licensees: ~ 1,700
Licences: ~ 2,500

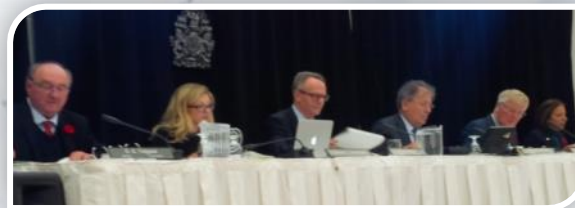


HQ in Ottawa
4 site offices at power plants
1 site office at Chalk River
4 regional offices



Independent Commission

- ▶ Quasi-judicial administrative tribunal
- ▶ Agent of the Government of Canada (the Crown)
- ▶ Reports to Parliament through Minister of Natural Resources
- ▶ Commission members are independent and part-time
- ▶ Commission hearings are public and webcast
- ▶ Staff presentations in public
- ▶ Decisions are reviewable only by Federal Court



Transparent, science-based decision making



Safety – The Cornerstone of the CNSC Mandate

Section 24(4) of the Nuclear Safety and Control Act (NSCA)

No licence shall be issued, renewed, amended or replaced... unless, in the opinion of the Commission, the applicant...

- (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
- (b) will, in carrying on that activity, 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

Regulatory philosophy

Licensees responsible for the protection of health, safety, security and the environment, and respecting Canada's international commitments

CNSC responsible for regulating licensees, and assessing whether licensees are compliant with the NSCA, regulations, and international obligations

The Licensees are held accountable by their licence



Regulatory Framework

Adaptable to an
evolving industry
and advancements
in policy, science
and engineering



Risk-informed and independent of technology

Regulatory Approach

- ▶ **The CNSC establishes safety requirements**
 - applicant proposes how to meet the requirements
 - CNSC regulations were designed to allow for flexibility
- ▶ **Graded approach**
 - safety commensurate with risk
- ▶ **Uses a mix of management, performance-based and prescriptive approaches used**
 - a largely performance-based approach is used for accelerators
 - a more prescriptive approach is used for nuclear substances and radiation devices



Many requirements allow for alternative approaches to meet their safety objectives



CNSC Oversight of Accelerators

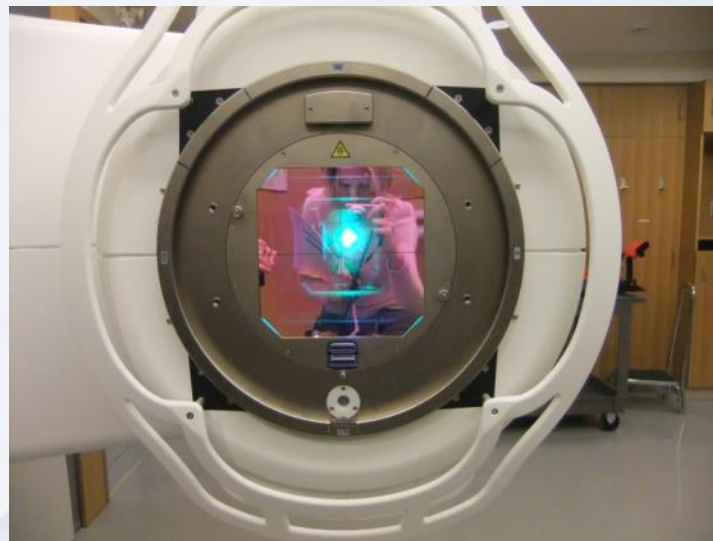
Who and what we regulate



Medical Applications



Source: CNSC



Source: CNSC

225 accelerators used primarily for cancer treatment



Industrial Applications



Source: CNSC



Source: CNSC

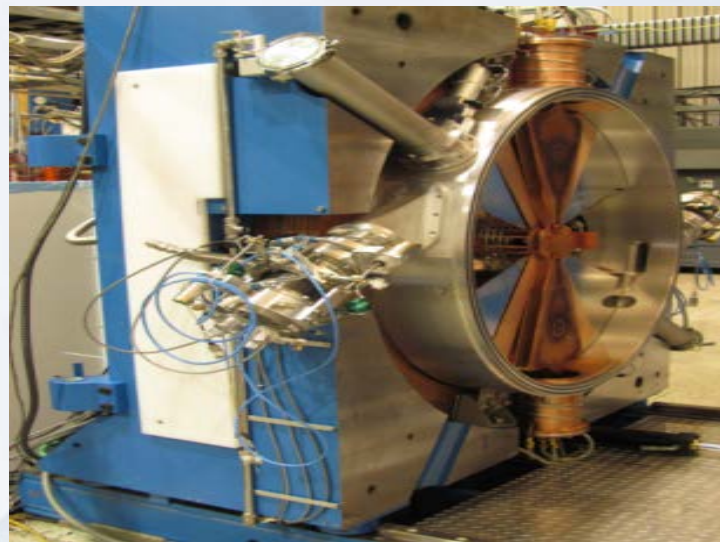
9 accelerators used for cargo screening, sterilization, radiography



Commercial Applications



Source: CNSC



Source: advancedcyclotron.com

24 accelerators including isotope producers and third-party servicing companies



Research Applications



Source: triumf.ca



Prototype MR-Linac (source: mp.med.ualberta.ca)

10 accelerators used for physics research, imaging, prototype development



Responsive Regulation

Case Studies in Regulating Accelerators

Responding to Evolving Technology – Medical Sector

Proton therapy

- > 50 MeV: Class 1

Design oversight appropriate to risk

- Assess adequacy of
regulatory framework
- Develop guidance for
applicants



Dedicated proton therapy facility (source: Mevion.com)



Responding to Evolving Technology – Medical Sector

Constantly developing new applications

- Prescriptive regulations aren't nimble enough

Leverage third parties

- Support development of consensus guidelines



Robotic arm accelerator (source: cyberknife.com)



Responding to Evolving Technology – Medical Sector

Portable and mobile accelerators

- Transition from source based to accelerator based technology

Use a hybrid regulatory approach

- Mirror existing regulations
- Require licensee processes
- Performance-based inspections



Field inspection (source: CNSC)



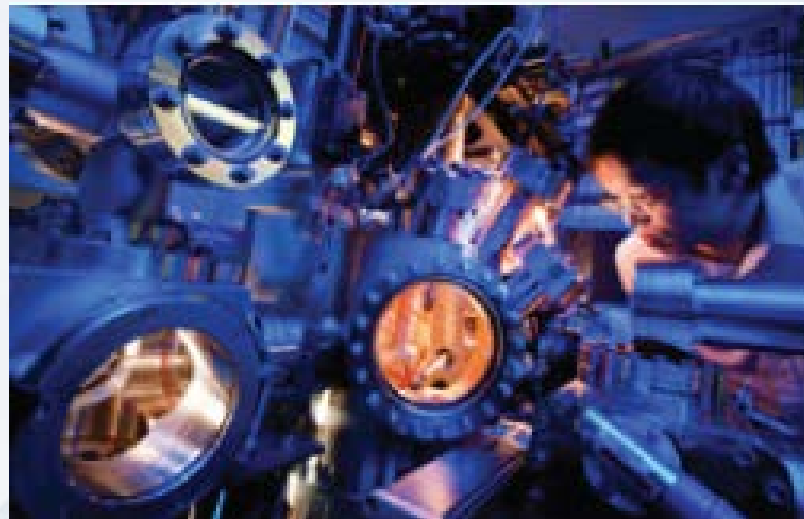
Responding to Evolving Technology – Research Sector

New processes regularly developed for experiments

- Regular changes in materials, methods and personnel

Adopt management-based approach

- Oversight of change management processes



Experimental station (source: Canadian Light Source)

Responding to Evolving Technology – Research Sector

Development of novel technologies

- Prototypes of subcomponents
- New equipment designs

Adapt licensing scheme

- Development and testing
licence



Plasma injector (source: generalfusion.com)

Responding to Evolving Expectations – Commercial Sector

Increasing use of isotope production accelerators

- Increasing public awareness
- Potential public concern

Requires responsive programs

- Consult and develop public information and disclosure program in response



Cyclotron exhaust stack
(source: CNSC)

Responding to Evolving Performance Trends – Commercial Sector

Change in licensee mandate

- Switch from research to production focus

Broaden regulatory perspective

- Recognize impact of production focus on workers
- Increased focus on safety culture



Isotope processing facilities (source: CNSC)



Considerations for Regulators

Make regulated parties responsible

- Review processes and hold licensees accountable

Stay flexible to technological developments

- Allow testing and development with appropriate safety margins
- Leverage industry best practices and consensus standards
- Make appropriate use of prescriptive requirements

Be responsive to evolving expectations and trends

- Continuous effort to maintain and modernize regulatory framework



The CNSC will never
compromise safety...

...it's in our DNA!



nuclearsafety.gc.ca



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