



# Regulatory Oversight of Rapidly Changing Technology

## *Case Studies in Regulating Accelerators*

*Colin Moses, Director General Nuclear Substance  
Regulation*

Canadian Nuclear Safety Commission

13<sup>th</sup> 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

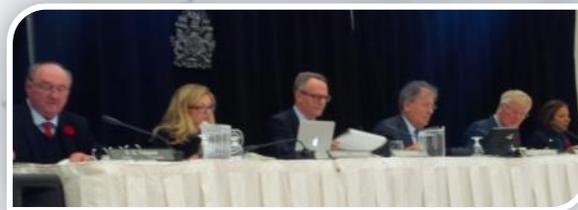


HQ in Ottawa  
4 site offices at power plants  
1 site office at Chalk River  
4 regional offices



## *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

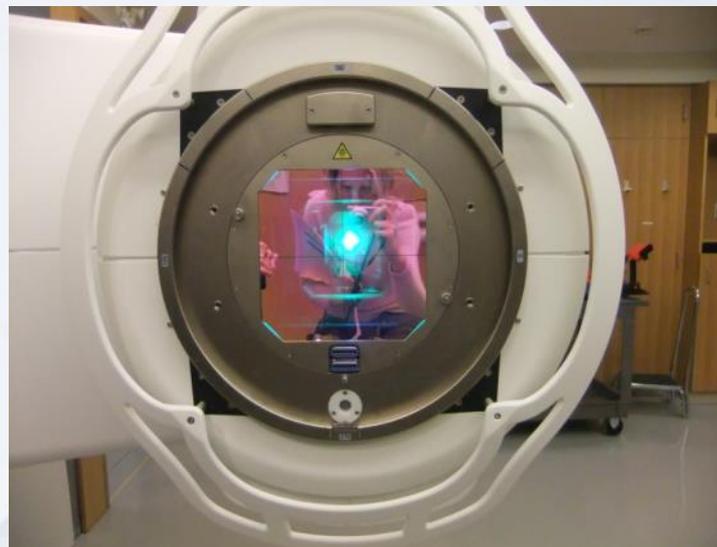
Who and what we regulate



## *Medical Applications*



Source: CNSC



Source: CNSC

***225 accelerators used primarily for cancer treatment***



## *Industrial Applications*



Source: CNSC



Source: CNSC

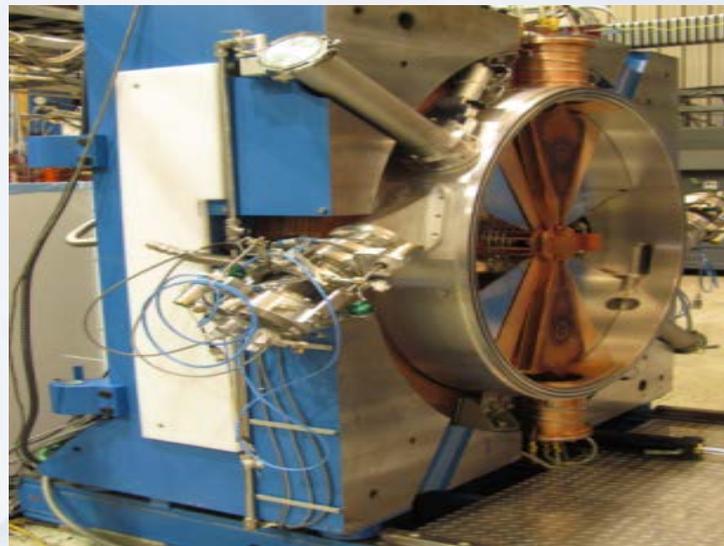
***9 accelerators used for cargo screening, sterilization, radiography***



## Commercial Applications



Source: CNSC



Source: advancedcyclotron.com

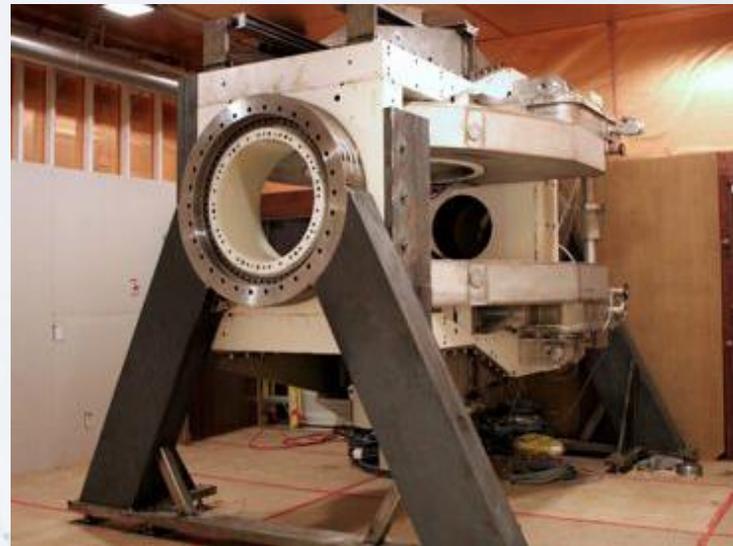
***24 accelerators including isotope producers and third-party servicing companies***



## *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)

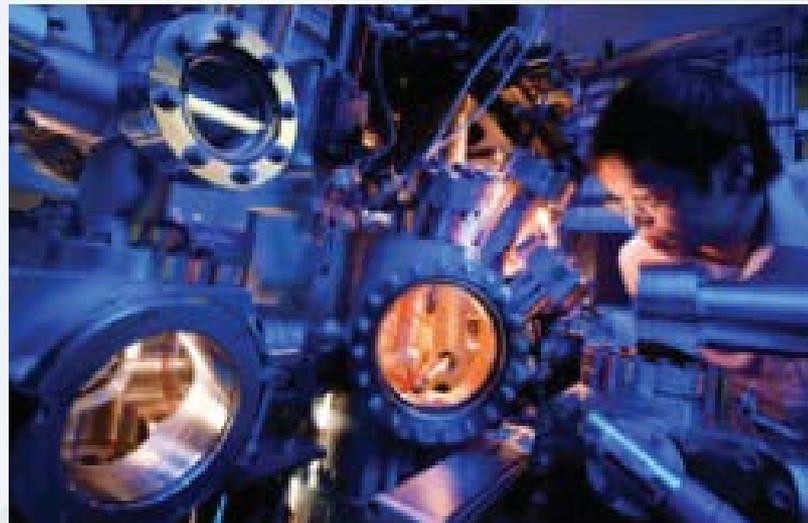
## ***Responding to Evolving Technology – Research Sector***

### **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](http://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](http://nuclearsafety.gc.ca)





# Find Out More About Us

# Participate and contribute

**[nuclearsafety.gc.ca](http://nuclearsafety.gc.ca)**



Visit us online



Like us on Facebook



Follow us on Twitter



View us on YouTube



Subscribe to updates



Contact us