Establishing New Classes Of Licence For The Regulation Of Hadron Therapy Facilities

CMD 18-M64.A

December 12, 2018

Staff Presentation

e-Docs #5687594 (PPTX)
e-Docs #5728094 (PDF)

Purpose

Seek a Commission decision to establish new classes of licence for Class IB hadron therapy facilities, and authorize CNSC Designated Officers duties to license these low risk facilities

Outline

- Background
- Current regulatory approach
- Proposed regulatory approach

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BACKGROUND

Hadron Therapy Accelerator

WHAT IT IS.

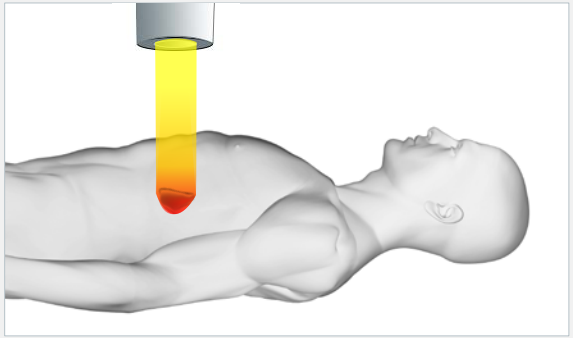
A special type of medical accelerator used for cancer treatment with a beam energy greater than the current threshold for Class II facilities

WHAT IT IS NOT.

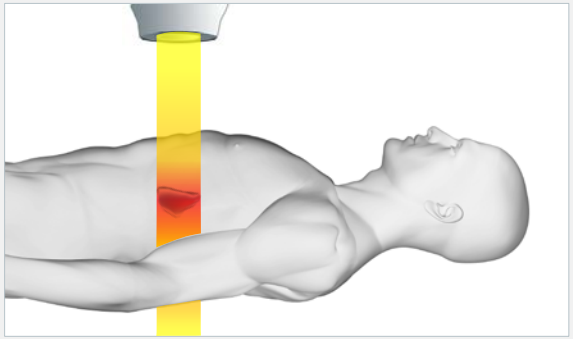
- A power reactor
- A research reactor
- Part of the fuel cycle
- A large, complex, high-power research facility

Hadron Therapy

- Hadron therapy is a form of radiotherapy.
- The treatment utilizes charged particles rather than the more conventional electrons or photons.
- The charged particles can be protons or heavy ions; with protons being the most common.
- Its typical application is for killing cancerous tumours in the body.



HADRON THERAPY (Proton)
Deposits most energy on target



CONVENTIONAL RADIATION THERAPY
Deposits most energy before target

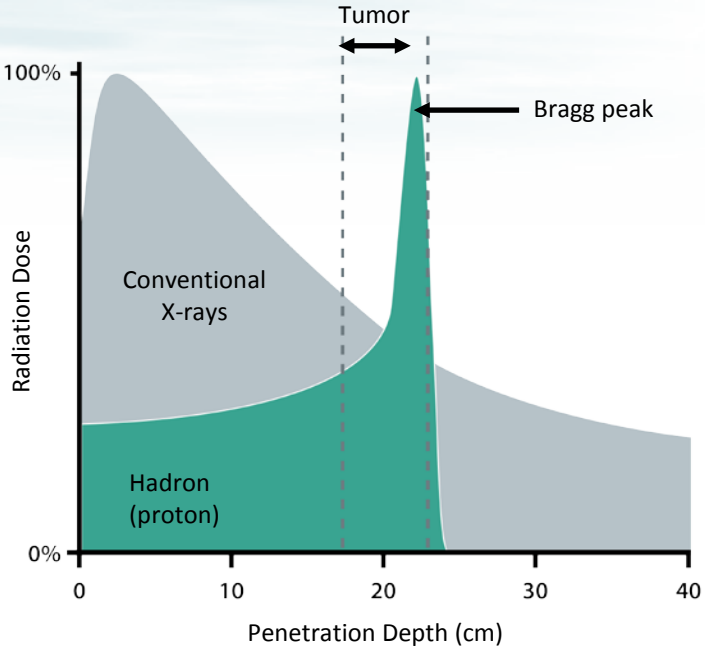
Source: CNSC

Why interest in hadron therapy?

- Hadron therapy is used primarily for treatment of malignant and benign tumours adjacent to critical organs
  - Paediatric
  - Chordomas
  - Ocular melanoma
  - Head and Neck cancer (e.g. sinus)
- Takes advantage of the “Bragg peak”

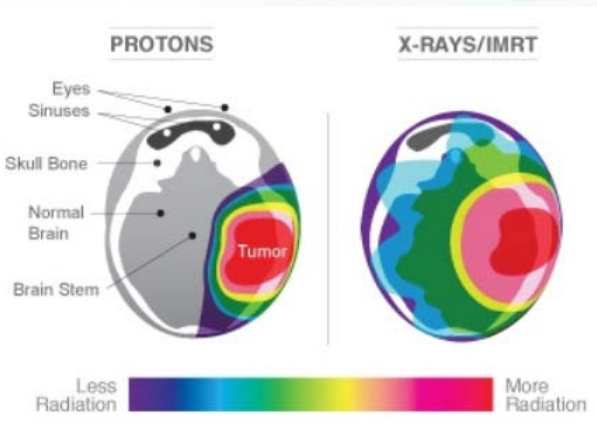
Why interest in hadron therapy?

- The Bragg peak is the sharp rise in Dose along the Dose/Depth curve
- In comparison to conventional x-ray treatments where there is a gradual decline in dose with the increase in tissue depth.



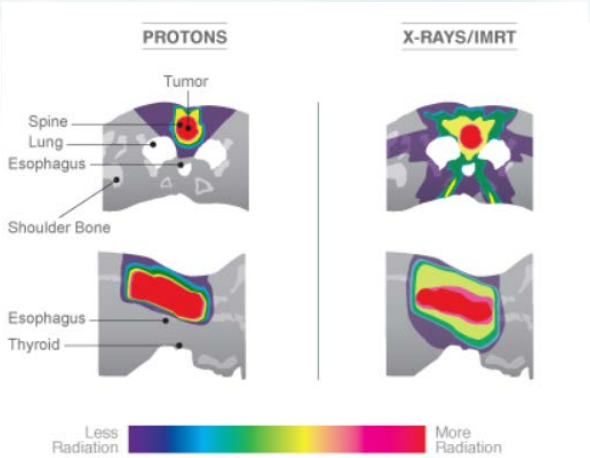
Source: CNSC

Why interest in hadron therapy?



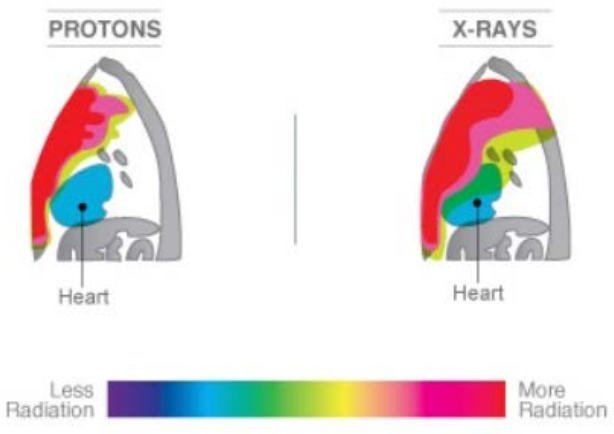
Hadron (proton) vs x-ray treatment: brain

Source: Procure.com



Hadron (proton) vs x-ray treatment: chordoma

Source: Procure.com



Hadron (proton) vs x-ray treatment: breast

Source: Procure.com

North American Landscape

HADRON THERAPY FACILITIES

- TRIUMF
- In Operation
- Under construction or in development
- Expanding

Source: adapted from proton-therapy.org

International Landscape

Particle Type	In Operation	Under Construction	Planned	Total
Proton Beam	USA - 24	USA - 11	USA - 3	38
	Europe - 10	Europe - 12	Europe - 7	29
	Asia - 14	Asia - 10	Asia - 4	28
	Other - 8	Other - 6	Other - 4	18
Carbon Ion	Asia - 5	Asia - 1		6
Proton/Carbon Ion			USA - 1	1
	Europe - 3			3
	Asia - 2	Asia - 1		3
	Other - 1			1
Total	**66**	**42**	**19**	**127**

As of Jan 2017

Source – Adapted from State of Queensland Department of Health, Australia [Particle Therapy Co-operative Group 2016)

Background – Canadian context

- Increasing clinical evidence supporting the benefits of hadron therapy
  - ~500 published papers/yr re: hadron therapy
- Decreased capital costs to build a dedicated facility
  - From US$150M to US$50M
- Increased demand in Canada
  - Provinces send patients to US for hadron therapy treatment ($$$)
  - Now exceeding break even point
- Funding has become available

CNSC stands ready to meet the demand

Status in Canada

- CNSC has received an application from CDL Proton Therapy Center. Staff are awaiting payment of cost recovery fees to initiate review for completeness
- There is supporting evidence on the benefits of hadron therapy for children and adult cancer patients. The health of Canadians would therefore benefit with the implementation of this technology.

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CURRENT REGULATORY APPROACH

Current Canadian regulatory approach

- Demarcation between Class I & Class II Accelerators
  - Established in the Regulations in 2000,
  - Based on energy (50 MeV threshold)
  - At the time, separated out the two very large complex research facilities (TRIUMF, CLSI) as the only Class I accelerators
  - Designated all existing medical accelerators as Class II facilities
- Hadron therapy
  - Is a medical accelerator, but energy >200MeV
  - Surpasses 50 MeV threshold which makes it Class I in accordance with current regulations
  - New technology doesn't fit 18 year old framework
- **The Issue**
  - **Current approach to regulating Class I facilities is not commensurate with the risks associated with this type of facility**

Current Designated Officer duties

- The Commission may authorize CNSC Designated Officers to issue licences of a class established by the Commission
  - CMD 01-M17 establishes the classes of licence
  - CMD 14-M24.B provides the authorized duties of Designated Officers
- Currently Designated Officers are authorized to issue licences for Class II Nuclear Facilities and other low-risk activities

International regulatory approach

Country	Hadron therapy	Medical accelerator	Isotope production accelerators
Australia	State	State	State
Belgium	Federal/Class II	Federal/Class II	Federal/Class II
Canada	Federal/Class I	Federal/Class II	Federal/Class II
United states	State	State	State/NRC

Regulatory processes should not unduly impede the implementation of technologies critical to the health of Canadians

1. New classes of licence - Risk analysis

- Relative risk comparison of hadron therapy demonstrates comparable levels to existing Class II accelerator facilities
  - Detailed analysis by SCA contained in CMD

1. New classes of licence - Risk analysis

- Primary radiological risk associated with accelerators is prompt radiation exposure (when beam is on)
- Radiological risks are mitigated by facility design:
  - Shielding to minimize radiation levels outside facility
    - Conventional (existing) medical accelerator facilities:
      - Radiotherapy staff doses typically << 50 µSv/yr
    - Hadron therapy facilities:
      - Publications indicate worker doses < 0.001 µSv per treatment – expect public and worker doses to be well below 50 µSv/yr
  - Standardized “defense in depth” safety systems for accelerator facilities prevent exposure in high dose rate areas when machine is in operation
    - Interlocked doors, area search “last person out” switches, emergency shut-offs, etc.

1. New classes of licence – SCA Comparison Sample

Safety and Control Area	Conventional Medical Electron Accelerators	Hadron Therapy Accelerators
Radiation Protection	• Primary radiation hazard is potential prompt radiation. • Hazard zone is completely enclosed within a heavily shielded facility. • Engineered access controls. • No other nuclear substances. • RP procedures highly standardized and of limited complexity • Doses incurred by staff are very low	The RP program for hadron therapy facility will be similar to conventional medical accelerators. There will be processes and programs expected to ensure doses are ALARA.
Safety Analysis & Physical Design	• Limited scope of hazards (external beam only, no environmental impact) • One time shielding and safety system analysis • Highly standardized methodology used	The safety analysis for hadron therapy facility will be similar to medical electron accelerators. There are well established processes and programs within the medical setting to ensure no deterioration of machine or safety system performance.

Refer to Annex B of CMD 18-M64 annex for comparison of all 14 SCAs

1. New classes of licence - Risk analysis

CNSC staff conclude:

- Risks are equivalent to existing Class II medical facilities
- Mitigation measures are standardized, similar to existing Class II facilities
- Hazards and complexity significantly less than existing Class 1B accelerators (e.g. TRIUMF, CLS)
- Authorizing CNSC Designated Officers to issue licenses, who already have authority for Class II medical accelerator facilities, would be appropriate

2. Revising the CIINFPE Regulations

- An accelerator beam is somewhat analogous to water in a pipeline
  - Pressure = Beam energy (MeV)
  - Pipe diameter/volume = Current (Amps)
  - The total water flow Pressure x Volume (Litres/second)

    = to the beam **Power** (Watts)

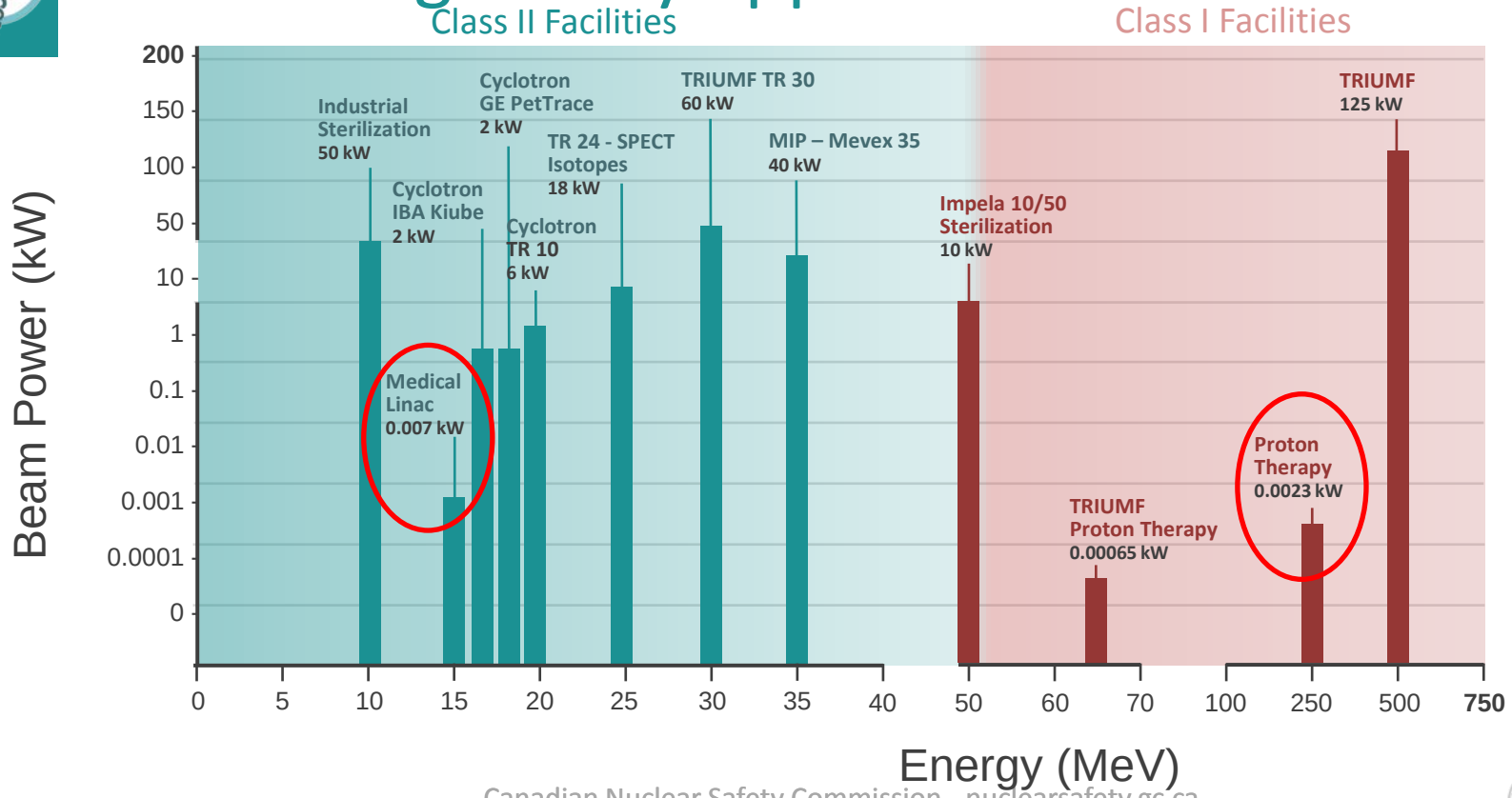
2. Revising the CIINFPE Regulations

TRIUMF Cyclotron
500 MeV
300 μA
150,000 Watts

Medical Electron Accelerator
15 MeV
20 μA
300 Watts (internal)
10 Watts (external)

Hadron (proton) Therapy
230 MeV
0.01 μA
1.25 Watts

Current regulatory approach



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CONCLUSIONS AND RECOMMENDATIONS

Conclusions

- Hadron therapy facilities pose similar risk and therefore require similar regulatory oversight as existing Class II medical facilities
- Authorizing the CNSC Designated Officers to issue licences for hadron therapy facilities would be consistent with other low risk licensing decisions currently being made by Designated Officers.
- As part of the ongoing regulatory review/amendment process, the demarcation between Class I and Class II particle accelerators as defined in the Class II Nuclear Facility and Prescribed Equipment Regulations should be revised.

Ensuring appropriate regulatory oversight

CNSC Staff Propose

1. **Interim measure**
   - Create new classes of licence for site preparation and construction, operation and decommissioning of Class IB Hadron Therapy Facilities
   - Authorize CNSC Designated Officers to issue, transfer, renew, suspend, revoke, replace or amend licences of the above classes
2. **Longer term**
   - Revise the 50 MeV threshold during the next amendment of the Class II Nuclear Facilities and Prescribed Equipment Regulations.
     - Process to revise regulations has been initiated
     - A more appropriate measurement parameter of risk would be beam power, as opposed to beam energy.

Questions

Thank You!

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