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Authorize the establishment of new classes of licence for the regulation of hadron therapy facilities.

Autoriser la création de nouvelles catégories de permis pour la réglementation des installations de thérapie par hadron.

Establishing new classes of licence for the regulation of hadron therapy facilities

Établissement de nouvelles catégories de permis pour la réglementation des installations de thérapie par hadron

Public Meeting

Réunion publique

Scheduled for:
12 December 2018

Prévue pour :
12 décembre 2018

Submitted by:
CNSC Staff

Soumise par :
Le personnel de la CCSN

Summary

This CMD pertains to a request for a decision regarding:

- Establishing new classes of licence as authorized under section 24 of the *Nuclear Safety and Control Act* specific to hadron therapy facilities
- Authorizing DNSR designated officers to exercise the licensing authority under section 37(2)(c) and (d) of the *Nuclear Safety and Control Act* respecting licenses of the newly established classes of licence for the 3 phases of licensing of hadron therapy facilities

The following actions are requested of the Commission:

- To approve the proposed classes of licence for the regulation of Class IB hadron therapy facilities.
- To authorize designated officers to have section 37(2)(c) and (d) authority over licences of the established Class IB hadron therapy facility classes of licence, as outlined in Annex D.

The following items are attached:

- Annex A: International Benchmarking
- Annex B: Preliminary Qualitative Risk Analysis
- Annex C: Proposed classes of licence for hadron therapy facilities
- Annex D: Proposed Designated Officer Positions and Duties Table

Résumé

Le présent CMD concerne une demande de décision au sujet de :

- Établir de nouvelles catégories de permis, en vertu de l'article 24 de la *Loi sur la sûreté et la réglementation nucléaires*, relatives aux installations de thérapie par hadron
- Autoriser les agents désignés d'exercer leur pouvoir de délivrance des permis en vertu de l'article 37(2)(c) et (d) de la *Loi sur la sûreté et la réglementation nucléaires* au sujet des nouvelles catégories de permis pour les trois phases de permis des installations de thérapie par hadron

La Commission pourrait considérer prendre les mesures suivantes :

- Approuver les catégories de permis proposées par le personnel pour la réglementation des installations de thérapie par hadron.
- Autoriser les agents désignés à exercer l'autorité prévue aux alinéas 37(2)(c) et (d) sur les permis des catégories établies pour les installations de thérapie par hadron de classe IB, comme indiqué à l'annexe D

Les pièces suivantes sont jointes :

- Annexe A : Analyse comparative internationale
- Annexe B : Analyse qualitative préliminaire des risques
- Annexe C : Catégories de licences proposées pour les installations de thérapie par hadron
- Annexe D : Tableau des postes et des fonctions proposés pour les officiers désignés

Signed/signé le

28 November 2018

A handwritten signature in black ink, appearing to read 'Colin Moses', written over a horizontal line.

Colin Moses

Director General

Directorate of Nuclear Substance Regulation

Directeur général

Direction de la réglementation des substances nucléaires

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1 EXECUTIVE SUMMARY

Hadron therapy is industry standard terminology for cancer treatment that uses charged particles other than electrons, with protons being the most commonly used particle. Unlike conventional x-ray treatment, hadron therapy allows a more targeted treatment, better protecting sensitive and/or critical tissues. For example, hadron therapy can target a tumour immediately adjacent to the spinal cord, or treat pediatric patients, whose tissues are more susceptible to radiation than adults.

Hadron therapy accelerators operate with a beam current above the upper threshold for Class II nuclear facilities (50 MeV) and therefore are categorized as a Class IB nuclear facility. Staff have conducted an analysis and determined that the level of risk to the public, workers and the environment is lower than existing Class IB facilities and is comparable to existing Class II medical facilities and lower than existing Class II cyclotrons. Based on this analysis, staff are proposing a regulatory oversight approach that is commensurate with the risk.

Until the *Class II Nuclear Facilities and Prescribed Equipment Regulations* are amended to address the existing threshold value of 50 MeV so that it is commensurate with the risk of current technology, staff propose an interim solution. Staff propose creating new classes of licence specific to Class IB hadron therapy facilities – which address the three phases of site preparation & construction, operating, and decommissioning – and to authorize CNSC designated officers to issue licences of these classes. With these proposed changes, designated officers would be authorized to make licensing decisions regarding hadron therapy facilities. This would ensure that safety is not compromised, and allow for expeditious decision making for the benefit of Canadian patients.

In Canada, one proponent has come forward with an application, and is targeting construction to start in spring 2019 and clinical operations by 2020.

2 OVERVIEW

2.1 Background

The Canadian Nuclear Safety Commission (CNSC) regulates nuclear facilities in Canada through its regulatory framework in accordance with The *Nuclear Safety and Control Act* and the regulations. The licensing process is based on the class of the nuclear facilities. There are three classes of nuclear facility:

- Class IA Nuclear Facility - defined in the *Class I Nuclear Facilities Regulations*, which includes power reactors.
- Class IB Nuclear Facility - defined in the *Class I Nuclear Facilities Regulations*, includes particle accelerators that are not Class II.
- Class II Nuclear Facility - defined in the *Class II Nuclear Facilities and Prescribed Equipment Regulations* as a facility that contains Class II Prescribed Equipment. Class II Prescribed Equipment includes particle accelerators with a beam energy < 50 MeV.

Pursuant to Subsection 24(1) of the *Nuclear Safety and Control Act* (NSCA), the Commission may establish classes of licence. This was done at the May 31, 2000 meeting of the Commission as recommended by CMD 00-M16 and subsequently revised January 23, 2001 under CMD 01-M17. These documents list classes of licence for the above nuclear facilities. The classes of licence for nuclear facilities include the phases of site preparation, construction, operation, decommissioning and abandonment.

Pursuant to Paragraph 37(2)(c), the Commission may authorize designated officers to issue licences of a class established by the Commission. The duties for which designated officers are authorized are outlined in CMD 14-M24.B. Currently, the Commission has authorized designated officers to issue all Class II Nuclear Facility classes of licence as a result of their low relative risk. However, all Class IA and IB licence decisions have been retained by the Commission.

In response to new technologies being considered in Canada, this CMD seeks a decision by the Commission to establish new classes of licence for a subset of low risk Class IB facilities, hadron therapy facilities, and to authorize designated officers to issue these classes of licence.

2.2 Hadron Therapy

Hadron therapy is a form of radiotherapy that uses charged particles, other than electrons, with protons being the most commonly used particle.

Hadron therapy provides radiation oncologists with a treatment option in situations where high doses are required to meet the treatment objective but sensitivity of surrounding critical tissues prevents the use of conventional radiation therapy options. Unlike conventional x-ray treatment where dose

gradually declines with depth, with hadron therapy, dose declines rapidly due to the Bragg peak. In short, the Bragg peak explains how the charged particle radiation, protons in this example, can be directed more precisely thereby sparing healthy tissue compared to conventional x-ray therapy. This provides a clinical advantage when a critical organ such as the spinal cord reside immediately adjacent to the tumour. This is especially true in pediatric patients where some healthy tissues are more susceptible to radiation damage than in adults.

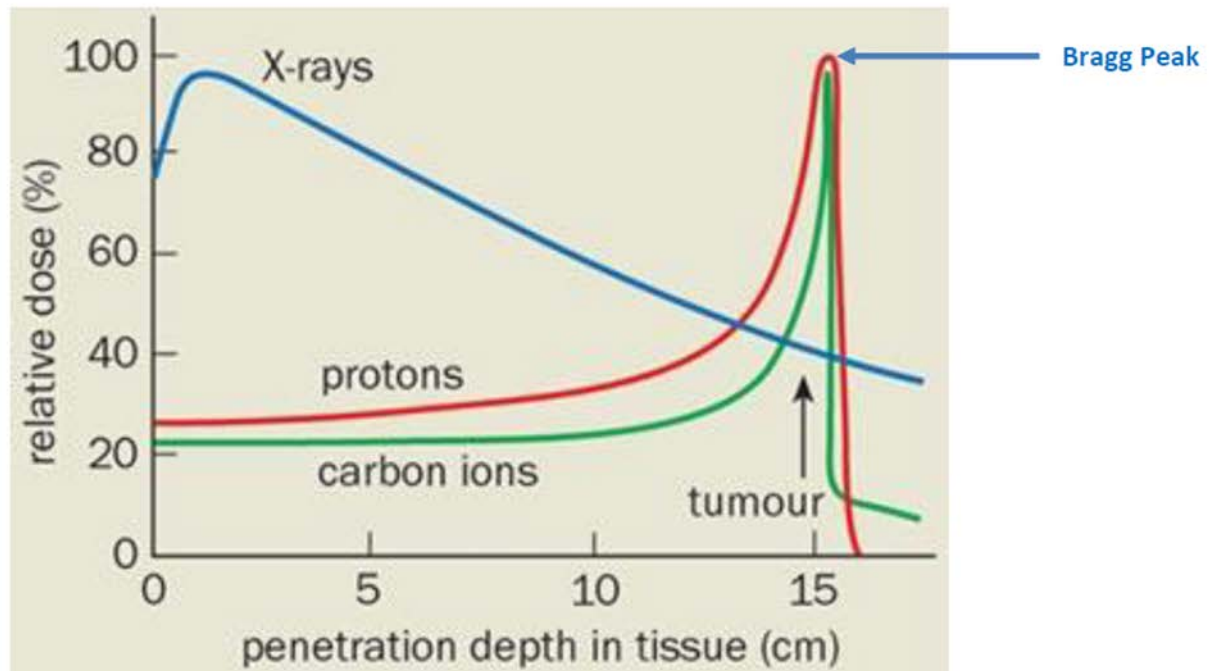


Figure 1 X-rays lose energy rapidly as they travel through the body. Protons and other ions deposit most of their energy at a specific depth, depending on their energy (the Bragg Peak). Therefore, they can deliver a high radiation dose at a tumour site, sparing surrounding healthy tissue.

Ref. Matthew, C. (2003). "How particle physics can be therapeutic". *Physics World*, 16(8), 32.

In Canada, only TRIUMF (Class 1B accelerator) offers limited hadron therapy treatments for treatments of eye tumours. For other applications, provincial health authorities send patients to the United States for hadron therapy treatment where the clinical evidence warrants such expenditure. Typically this is justified if and only if another currently available technology cannot yield a similar clinical result, such as the treatment of pediatric cancers using conventional medical accelerators.

The justification for use of hadron therapy is increasing due to favorable results from clinical trials coupled with the reduction of the capital cost to construct such a facility. As a result, a business case can now be made by the proponents that demonstrate the construction and operation of a hadron therapy facility in Canada is more economical than sending patients to the United States.

The definition for Class II prescribed equipment includes an upper beam energy threshold of 50 MeV. This threshold was established with the creation of the current regulations in 2000 as a means of delineating between Class IB and Class II accelerators. Any device with a beam energy greater than 50 MeV would be

categorized as a Class IB device and would therefore be regulated in accordance with the Class I regulatory framework. Any equipment with a beam energy less than the 50 MeV threshold would fall under the Class II regulatory framework.

This threshold was an appropriate delineation at the time to ensure that existing large complex particle accelerator facilities, conducting novel research activities, would need to apply for licensing with the formalities and rigor of a Class IB facility. For example, TRIUMF and CLS are regulated as Class IB Facilities; conversely, medical accelerators being used to conduct routine treatments in the highly controlled medical setting are licensed under the more appropriate Class II regulatory framework. There are currently over 200 medical linear accelerators in use in Canada licensed as Class II nuclear facilities.

Delineation between existing Class I and Class II accelerator facilities needs to be retained, but staff are suggesting that this threshold is not the most appropriate parameter for characterizing risk. A more appropriate parameter for this threshold would be beam power, as opposed to beam energy. Hadron therapy accelerators operate with a high beam energy, but also with a low beam current. Beam power is the product of the beam energy and current and is more representative of the overall risk. Risk is proportional to dose rate and the radiation therapy prescription that can be delivered to any person correlates with beam power rather than simply with beam energy. Therefore, hadron therapy poses no more risk than conventional medical Class II accelerators.

Consequently, staff recommends that hadron therapy facilities be regulated in a manner similar to Class II Nuclear Facilities. Based on international benchmarking, regulating hadron facilities as a Class I facility is inconsistent with international practice. Refer to Annex A for the international benchmarking of hadron therapy. A relative risk comparison between existing class II facilities and hadron therapy facilities is included in Annex B.

The mid-term solution is to revisit this threshold in the next amendment of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*. The analysis phase for the amendments to these regulations began in November 2018. In the interim, until these regulations are amended, staff are proposing that new classes of licence be created for hadron therapy facilities. These classes of licence include three phases of licensing: site preparation/construction, operating and decommissioning, as listed in Annex C. These three new classes of licence would be an addendum to the current classes of licences issued by the CNSC in CMD 01-M17. It is feasible and appropriate to regulate hadron therapy facilities as Class IB nuclear facilities subject to the Class I nuclear facilities regulations, but in a risk informed manner.

Staff are also requesting the authorization of the Executive Vice-President and Chief Regulatory Operations Officer (EVP and CROO) and DNSR designated officers to issue, renew, suspend, revoke, replace or amend a licence within the above classes of licence for hadron therapy facilities on behalf of the Commission. The proposed table in Annex D would be a replacement to the current table in Annex D of CMD 14-M24.B.

2.3 Risk Analysis

The risk profile comparison included in Annex B demonstrates that a hadron therapy facility is similar in risk to Class II conventional medical accelerators and lower risk than other Class II facilities, such as isotope production accelerators (“cyclotrons”) where a higher beam power is required to create isotopes in a target. Compared with cyclotrons, the hadron therapy facilities have a lower risk ranking in the safety and control areas of *Safety Analysis, Radiation Protection and Environmental Protection*.

International benchmarking has indicated that other countries currently licence hadron therapy facilities in a manner consistent with CNSC Class II Facilities.

The regulatory requirements of a Class IB facility still apply to hadron therapy facilities, but creating the new classes of licence allows designated officers to apply these requirements in a risk-informed manner and according to their knowledge and experience regulating Class II facilities. This change does not affect how licensing is conducted with facilities that currently hold CNSC Class IB or Class II licenses. The proposed changes are exclusively for hadron therapy facilities in a medical setting with a view to designated officers applying the Class IB nuclear facilities regulatory requirements in a risk-informed manner, until the necessary regulatory amendments can be made.

2.4 Overall Conclusions

Notwithstanding the definition of a Class II Facility in the regulation, a risk informed analysis indicates that hadron therapy facilities pose a similar, or lower, risk level to existing Class II facilities. Based on the following considerations, staff conclude that the creation of the proposed classes of licence for hadron therapy facilities would be appropriate.

1. Based on international benchmarking, regulating hadron facilities as a high risk facility is inconsistent with international practice.
2. The requirements of the *Class I Nuclear Facilities Regulations* will be applied in a risk informed manner.
3. The radiological risk to workers and the environment is comparable to risks for current Class II prescribed equipment, such as medical accelerators and cyclotrons.
4. The current Class IB licencing process would unnecessarily delay the availability of this technology for patients in Canada.
5. The facility design, routine operations and type of hazards closely align with conventional Class II radiation therapy facilities where the licensing process is both mature and appropriate.
6. Authorizing designated officers to make licensing decisions for hadron therapy facilities would be consistent with other low risk licensing decisions currently being made by designated officers.

2.5 Overall Recommendations

CNSC staff recommend the following:

- 1) Create new classes of licence under the title *Class IB Hadron Therapy Facilities* for the three phases of licensing listed in Annex C.
- 2) Authorize the EVP and CROO and DNSR designated officers to issue, transfer, renew, suspend, revoke, replace or amend licences in the above classes for Class IB Hadron Therapy Facilities. The proposed table in Annex D would be a replacement to the current table in Annex D of CMD 14-M24.B.

These changes would remain in effect until such time that the *Class II Nuclear Facilities and Prescribed Equipment Regulations* subsection 1(d) is amended to revise the threshold of the definition for Class II Prescribed Equipment. Concurrent with the regulatory amendment process, designated officers can adequately regulate these facilities under the *Class I Nuclear Facility Regulations*, informed by experience with more similar Class II Nuclear Facilities.

REFERENCES

1. CMD 01-M17 Classes of Licences Issued by the CNSC (current) (e-Doc 3007344)
2. Supplemental CMD 14-M24.B Designated Officer Positions and Duties (current) (e-Doc 4426417)

GLOSSARY

Hadron Therapy Facility	A nuclear facility that includes a proton or heavy ion accelerator used for therapeutic purposes.
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A. BASIS FOR THE RECOMMENDATIONS

A.1 Regulatory Basis

The regulatory basis for the recommendations presented in this CMD is as follows:

Subsection 24(1) of the *Nuclear Safety and Control Act* (NSCA) allows the Canadian Nuclear Safety Commission (CNSC) to establish classes of licences. This was done at the 2000 May 31 meeting of the Commission as recommended by CMD 00-M16 and subsequently revised 2001 January 23 under CMD 01-M17. Staff are now recommending that additional classes of licence be established for the regulation of *Class IB Hadron Therapy Facilities*.

Subsection 37(1) of the NSCA states the Commission has the authority to designate, by title of office or by name, any person it considers qualified as a designated officer (DO) to carry out duties on behalf of the Commission.

Subsections 37(2)(c) and (d) of the NSCA state the Commission may authorize a designated officer to issue, renew, suspend, amend revoke or replace a licence, of a class established by the Commission, on receipt of an application. Staff recommends that the table in Supplemental CMD 14-M24.B be replaced with Annex D to include the new classes of licence (above) under the duties of the appropriate DNSR designated officers.

Annex A: International Benchmarking

	Proton 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

The above countries, with the exception of Canada, regulate proton therapy accelerators either through their state run programs or under a Class II equivalent program.

Annex B: Preliminary Qualitative Risk Analysis

Hadron therapy vs existing accelerator facilities

The following risk comparison has been prepared to rationalize a modified, risk informed approach to licensing these facilities.

Table 1: Risk profile comparison of hadron therapy vs existing accelerator facilities

	Hadron Therapy Accelerators	Medical Electron Accelerators	Isotope Production Accelerators	Class IB Research Accelerators (TRIUMF, CLSI)
Beam Energy	50 - 500 MeV	4-25 MeV	< 50 MeV (Class II)	> 50 MeV (Class IB)
Beam Power (Typical)	2W	7W	2,000-60,000W	<1W (P+ treatment @ TRIUMF) 125,000W (Research @ TRIUMF)
SCA or Area of Interest				
Management System	<ul style="list-style-type: none"> Similar to medical electron accelerators in all respects 	<ul style="list-style-type: none"> Medical treatment Highly controlled and subject to multiple external regulators and accreditations. 	<ul style="list-style-type: none"> Medical and/or commercial environment Limited scope for most operations (5 to 15 staff). For commercial operations, minimization of overhead/ maximization of profits may impact safety 	<ul style="list-style-type: none"> Primarily research environments May or may not include isotope production Large and complex sites may involve multiple different accelerators, hazards Minimal external control and regulation beyond CNSC Strong MS is critical for safety for the most complex and varied facilities.
Human Performance. Management	<ul style="list-style-type: none"> Similar to medical electron accelerators in all respects 	<ul style="list-style-type: none"> Engineering design highly standardized. Moderate number of staff involved in licenced activity (50-250) Most staff require specific, nationally accredited degrees (Medical Physics, Radiation Therapy) with detailed training to ensure the safe conduct of the licensed activity. 	<ul style="list-style-type: none"> Engineering design of facilities is highly standardized. Typically very few staff (5-15). Staff require specific, specialized training to ensure the safe conduct of the licensed activity. Some potential for moderate impact incidents due to human error - involving contamination of persons, vehicles and facilities with relatively low activity/risk quantities of nuclear substances. 	<ul style="list-style-type: none"> Highly variable depending on nature of the operations. For complex facilities engineering, staff training, and internal non-conformity reporting-investigation-correction processes are critical for ensuring site safety.
Operating Performance	<ul style="list-style-type: none"> Similar to medical electron accelerators in all respects 	<ul style="list-style-type: none"> Basic operational safety procedures are the same/similar for almost any site/equipment model Beam QA for patient treatment subject to highly prescriptive industry wide controls 	<ul style="list-style-type: none"> Basic operational safety procedures are similar for almost any site/equipment model Radiopharmaceutical products subject to strict cGMP requirements 	<ul style="list-style-type: none"> Operational safety procedures may be significantly different for different facilities on a single site
Safety Analysis	<ul style="list-style-type: none"> Similar to medical electron accelerators but somewhat less standardized and more complex 	<ul style="list-style-type: none"> Limited scope of hazards (external beam only, no activation, no unsealed NS, no environmental impact) One time shielding and safety system design, no need for ongoing safety analysis program Highly standardized methodology used internationally for safety analysis 	<ul style="list-style-type: none"> Cyclotron SA similar to medical accelerator Must also take into account medical isotope processing, packaging and transport Activities relatively low, risk in the event of uncontrolled release is minimal Safety analysis includes supporting infrastructure such as hot cells and ventilation 	<ul style="list-style-type: none"> Very non-standardized, may involve entirely new technologies Both external exposure and contamination hazards exist Scope is somewhat similar to isotope production accelerators but less standardized, more complex. Each new safety analysis may be different, depending on nature of change – strong management system to verify and validate is required
Physical Design	<ul style="list-style-type: none"> CSA standard for proton therapy facility design has recently been released. (CSA 60601-2-64) 	<ul style="list-style-type: none"> Accelerator design is subject to international standards and certification – highly standardized/similar even for different 	<ul style="list-style-type: none"> Accelerator design is subject to international standards and certification – highly standardized/similar even for different manufacturers 	<ul style="list-style-type: none"> Accelerator design is not standardized and may involve development of entirely new technologies Facility is usually static once built

	<ul style="list-style-type: none"> IEC standard includes 25 safety interlock systems and 5 specs for dose rates outside of primary beam – these should be verified as part of licensing. Facility design similar to but more complex than typical medical electron accelerators 	<p>manufacturers</p> <ul style="list-style-type: none"> Facility is static once built Adequacy of facility shielding design and safety interlock systems is highly dependent upon initial safety analysis Facility does not degrade over time and accelerator equipment can readily be removed and replaced without hazard to persons or the environment 	<ul style="list-style-type: none"> Facility is static once built Adequacy of facility shielding design, safety interlock systems and processing labs is highly dependent upon initial safety analysis Facility does not degrade over time and equipment can readily be removed and replaced without hazard to persons or the environment 	<ul style="list-style-type: none"> Adequacy of facility shielding design, safety interlock systems and other physical design elements highly dependent upon initial safety analysis Facilities may operate using the same accelerator for decades Facilities can often be repurposed for use with new accelerators or other technologies Individual components (control systems, beam steering, targets, etc.) can readily be replaced without risk to workers, the public or the environment
Fitness for Service	<ul style="list-style-type: none"> Similar to medical electron accelerators 	<ul style="list-style-type: none"> Degradation of equipment does not increase hazards – non-operational equipment presents no hazard (no sources, no criticality) Standardized servicing procedures and training by manufacturer. CII Service license required (ensure servicing activities conducted safely) Beam QA for patient treatment subject to highly prescriptive industry wide controls, ensures equipment is safe to used post-servicing 	<ul style="list-style-type: none"> Degradation of cyclotron equipment does not increase hazards (no sources, no criticality). Degradation of hot cells or processing equipment can increase risk of contamination Standardized servicing procedures and training by manufacturer. CII Service license required to ensure servicing activities conducted safely 	<ul style="list-style-type: none"> In general, degradation of equipment does not increase hazards – (no sources, no criticality) For many facilities, the staff who designed and built the equipment are also the ones servicing it/training others to service.
Radiation Protection	<ul style="list-style-type: none"> Similar to class II facilities. 	<ul style="list-style-type: none"> Primary radiation hazard is potential for exposure to lethal photon dose rates within the treatment beam. Hazard zone is completely enclosed within a heavily shielded facility Prescriptive requirements for engineered access controls. Minimal activation of accelerator components Minimal air activation – no hazard No other nuclear substances PPE generally not required RP procedures highly standardized and of limited complexity Doses incurred by staff are generally low. 	<ul style="list-style-type: none"> Most probable radiation hazard is contamination of personnel during handling of unsealed nuclear substances during QC testing, processing and packaging. Resulting doses (E) would typically be very low although extremity doses (H) may approach dose limits External exposure hazard from high neutron and prompt gamma fields during cyclotron operation, but this is mitigated in the same manner as for medical electron accelerators. Only basic PPE (gloves, lab coats) typically required RP procedures highly standardized and of limited to moderate complexity Actual staff doses typically <2 mSv E and <50 mSv H, primarily from isotope handling and target rebuilds 	<ul style="list-style-type: none"> Highly variable depending on the number, type and use of accelerators at the site Typically minimal in experimental areas accessible to researchers May involve working in or near very high dose rate areas during servicing and maintenance activities May involve significant contamination hazards Extensive RP controls, including full PPE (respirators, independent oxygen supply, contamination suits) may be required for some tasks RP procedures must be very comprehensive and adaptable to complex operational requirements. Includes dose budgeting and monitoring for specific tasks and task specific hazard analyses.
Environmental Protection	<ul style="list-style-type: none"> Similar to medical electron accelerators. 	<ul style="list-style-type: none"> Effectively no interactions with the environment, air activation is minimal and presents no hazard No other nuclear substances 	<ul style="list-style-type: none"> Potential for airborne releases during production and processing of gaseous compounds Typically presents a negligible hazard to persons or the environment (< 10 uSv) even for worst case releases. Environmental monitoring and control measures in place to mitigate the potential for and impact of such releases. 	<ul style="list-style-type: none"> Highly variable depending on the number, type and use of accelerators at the site Minimal for some types of facilities (e.g., synchrotrons) which do NOT use or produce NS Potential releases from on-site isotope production accelerator facilities, may involve longer lived (non-PET) isotopes May also involve significant “routine” airborne releases (e.g., due to air activation from high neutron fields). However, these generally involve very short lived B+ species which present minimal radiological hazards to persons or the environment. All potential release points must be monitored and control measures must be implemented to mitigate the potential for and

				<p>impact of such releases.</p> <ul style="list-style-type: none"> • A local environmental monitoring program may be required
Waste Management	<ul style="list-style-type: none"> • Possibility for greater volume / number of activated components along beam line due to beam impinging on beam steering / shaping devices. • Otherwise, similar to medical electron accelerators in all respects. 	<ul style="list-style-type: none"> • Minimal radiological waste – a few low activity activated beam line components may require disposal every few years • Conventional hazardous wastes are those associated with any normal hospital and are handled via established hospital waste management streams 	<ul style="list-style-type: none"> • Moderate radiological waste includes activated target windows and contaminated processing modules and PPE • Contamination is generally short live PET isotopes (half live of minutes to hours) and can be disposed of via non-radioactive waste streams following a brief period of delay and decay • Conventional hazardous wastes are similar to conventional medical accelerator facilities and are handled in a similar way. 	<ul style="list-style-type: none"> • Highly variable depending on the number, type and use of accelerators at the site • May involve handling and storage of fairly high active items such as spent targets (typically 10 TBq) • May also involve large quantities of bulk waste (mostly PPE) from large scale isotope processing facilities. • Typically requires long term storage of activated beam line components on site. • Conventional hazardous wastes encompass a broad spectrum of materials (explosives, flammables, corrosives, biohazard, poisons, etc.) depending upon the nature of the research or other operational activities conducted at the site.
Conventional. Health & Safety	<ul style="list-style-type: none"> • Similar to medical electron accelerators in all respects 	<ul style="list-style-type: none"> • No different from any other hospital environment and addressed via normal Provincial occupational health and safety legislation. 	<ul style="list-style-type: none"> • No different from any other hospital environment and addressed via normal Provincial occupational health and safety legislation. 	<ul style="list-style-type: none"> • Highly variable depending on the number, type and use of accelerators at the site, and any other activities that me be in progress (e.g., construction of new buildings etc.) • May involve extensive conventional hazard mitigation requirements (e.g., fall arrest, PPE for handling a broad range of chemicals, oxygen deficiency hazards from cryogenics, laser safety, flammables, etc.)
Emergency management and fire protection	<ul style="list-style-type: none"> • Similar in all respects to any other medical accelerator facility used for radiation therapy 	<ul style="list-style-type: none"> • Any foreseeable damage to equipment from natural disasters of any sort will simply result in shutdown of the accelerator/removal of primary radiological hazard • No fissile material, no criticality issues/concerns • No NS so no special measures required • All normal Provincial Fire Safety and Emergency Management requirements for a hospital apply • Emergencies Procedures for fire, equipment malfunction etc. must be in place 	<ul style="list-style-type: none"> • Any foreseeable damage to equipment from natural disasters of any sort will simply result in shutdown of the accelerator/removal of primary radiological hazard • No fissile material, no criticality issues/concerns • Limited quantities of short lived NS only, basic precautions such as signage indicating the presence of NS, awareness training for first responders are sufficient to mitigate hazards. • All normal Provincial Fire Safety and Emergency Management requirements apply • Emergencies Procedures for fire, equipment malfunction etc. must be in place 	<ul style="list-style-type: none"> • Any foreseeable damage to equipment from natural disasters of any sort will simply result in shutdown of the accelerator/removal of primary radiological hazard • No fissile material, no criticality issues/concerns • Hazards from NS dependent upon the isotopes, chemical and physical forms, and activities of NS produced (if any) on site. • For facilities which do not produce NS (other than limited activation of beamline components) no special precautions are necessary • Provisions of Standard for Fire Protection for Facilities Handling Radioactive Materials (NFPA801) are necessary for facilities producing/storing significant activities of NS • Emergency Management provisions must be implemented commensurate with the nature of the risks at any given facility.
Security	<ul style="list-style-type: none"> • Similar to medical electron accelerators in all respects 	<ul style="list-style-type: none"> • NO cat 1-5 sealed sources • Routine public access • No NS • Minimal security required falls within the normal scope of hospital security to protect assets 	<ul style="list-style-type: none"> • NO cat 1-5 sealed sources • NO routine public access to the cyclotron or processing facilities (within a locked controlled access area) • Open NS • Minimal security required - falls within the normal scope of hospital security to protect assets 	<ul style="list-style-type: none"> • Typically NO Cat 1-3 sealed sources on site • No routine unescorted public access • May have some high activity components (e.g., spent targets – 10 TBq) in storage for decay • Security provisions assessed on a case by case basis
Safeguards	<ul style="list-style-type: none"> • Very unlikely to be any safeguarded material 	<ul style="list-style-type: none"> • Safeguarded material limited to depleted uranium used as shielding. 	<ul style="list-style-type: none"> • No safeguarded materials 	<ul style="list-style-type: none"> • May or may not have safeguarded materials (e.g., DU, Unat, Th) for research purposes. • No fissile materials used, but may involve technologies which can produce small activities (kBq) of fissile isotopes. • May require safeguards program, depending upon type of accelerators and nature of research.

Packaging and Transport	<ul style="list-style-type: none"> Similar to medical electron accelerators. 	<ul style="list-style-type: none"> Rarely required, only for transport of activated components for disposal. Typically Exempt packages or Type A 	<ul style="list-style-type: none"> Routine shipment of PET isotopes for clinical use in hospitals Typically very short lived (e.g., F-18, T_{1/2} = 2 hours) Moderate activities (< 1TBq) Usually type A packaging (NO type B) 	<ul style="list-style-type: none"> Highly variable depending on the number, type and use of accelerators at the site May involve shipping of items such as DECAYED spent targets (typically 100 GBq) May also involve shipping of medical or research isotopes produced on site (may include Type B packaging) Because of variability in isotopes and quantities shipped, considerable expertise in PTNS may be required on site.
Public Information.	<ul style="list-style-type: none"> Expect high public interest Likely positive: high tech, new way to more effectively treat cancer. 	<ul style="list-style-type: none"> Generally little public interest No special considerations beyond what is typically required for any new hospital facility Public interest is generally POSITIVE – new clinic to treat cancer Any concerns tend to be non-radiological e.g., parking, noise etc. 	<ul style="list-style-type: none"> Basic PIDP program required due to potential releases, but Scope of public consultation required depends Public interest is generally POSITIVE – non-reactor technology for producing medical diagnostic isotopes Any concerns tend to be non-radiological e.g., parking, noise etc. 	<ul style="list-style-type: none"> Public / community interest may be significant, depending on nature of activities Balance of positive and negative interest <ul style="list-style-type: none"> Research good Not “nuclear” in the sense of fission Potential releases may be of concern May requires a strong, active process of public information and consultation, especially for changes to facilities and/or if community expands into previously unoccupied adjacent areas
Aboriginal Consultation	<ul style="list-style-type: none"> May need to consult, dependent upon proposed site for facility 	<ul style="list-style-type: none"> Need to consult dependent upon proposed site for facility Generally in core area of a major centre, unlikely to be of significant concern to aboriginal community No site contamination concerns 	<ul style="list-style-type: none"> Need to consult dependent upon proposed site for facility Generally in core area of a major centre, unlikely to be of significant concern to aboriginal community No site contamination concerns 	<ul style="list-style-type: none"> Need to consult dependent upon proposed site for facility
Preliminary Decommissioning, Plan and Financial Guarantee	<ul style="list-style-type: none"> Likely existing and established sites. Facility does not degrade over time. Equipment can operate indefinitely with routine maintenance and periodic upgrade / replacement of components Accelerator equipment can readily be removed and replaced without hazard to persons or the environment PDP should be relatively simple Decommissioning costs likely similar to IPA Publicly funded 	<ul style="list-style-type: none"> Facility does not “degrade” over time and accelerator equipment can readily be removed and replaced without hazard to persons or the environment No PDP required Publicly funded 	<ul style="list-style-type: none"> Facility does not “degrade” over time and accelerator equipment can readily be removed and replaced without hazard to persons or the environment Simple PDP required May be private or publicly funded 	<ul style="list-style-type: none"> Detailed PDP required Dedicated FG fund required Typically indirectly publicly funded (university based, federal research grants via NRC or other sources) Different FG mechanisms in place for different facilities Accelerators may operate indefinitely with routine maintenance and periodic upgrades to components and systems. Likely that full “decommissioning” will never actually occur Estimated full decommissioning costs may be \$10 M to \$100 M

Annex C: Proposed classes of licence for hadron therapy facilities

The following classes of licence are to be added as an addendum to **Classes of Licences Issued by the CNSC** in CMD 01-M17

Class IB Hadron Therapy Facilities

Class of CNSC Licence	Purpose of Licence
Hadron Therapy Facility Site Preparation and Construction	Prepare a site and construct a hadron therapy facility, including the activities normally associated with site preparation and construction.
Hadron Therapy Facility Operating Licence	Operate a hadron therapy facility, including the activities normally associated with operation. (e.g. uses of prescribed equipment, possession of nuclear substances, etc.)
Hadron Therapy Decommissioning Licence	Decommission a hadron therapy facility, including the activities normally associated with decommissioning. (e.g. dismantling of equipment, waste management, etc.)

Annex D: Proposed Designated Officer Positions and Duties Table

[This table will replace Annex D of CMD 14-M24.B]

	Title of Office ↓	Duties →	References to Sections of the Nuclear Safety and Control Act	Certify and decertify prescribed equipment for the purposes of the Act	Certify and decertify persons referred to in paragraph 44(1)(k) as qualified to carry out their duties under this Act or the duties of their employment, as the case may be.	Issue, on receipt of an application referred to in subsection 24(2), a licence of class identified in part I, II or V of the "Classes of Licences" [CMD 01-M17] or Annex C of [CMD 18-M64]	Renew, suspend in whole or in part, amend, revoke or replace, or authorize the transfer of, upon receipt of an application referred to in subsection 24(2), a licence of class identified in part I, II or V of the "Classes of Licences" [CMD 01-M17] or Annex C of [CMD 18-M64]	Designate any person whom the Designated Officer considers qualified as an Inspector under subsection 29(1).	Make any order that an Inspector may make under subsection 35(1) or (2).	Confirm, amend, revoke or replace any order made by an Inspector.	Authorize the return to work of persons whose dose of radiation has or may have exceeded the prescribed radiation dose limits.	Issue notices of violations (related to Administrative Monetary Penalties)
				37(2)(a)	37(2)(b)	37(2)(c)	37(2)(d)	37(2)(e)	37(2)(f)	37(2)(g)	37(2)(h)	65.01(b)
REGULATORY OPERATIONS BRANCH	Executive VP and Chief Regulatory Operations Officer Regulatory Operations Branch			✓	✓	✓	✓	✓	✓	✓	✓	✓
	Director General Directorate of Nuclear Substance Regulation (DNSR)			✓	◆	◆	◆	◆	◆	◆		◆
	Director Accelerators and Class II Facilities Division			✓	◆◆	◆◆	◆◆		◆	◆		
	Senior Project Officer (maximum 1 position) Accelerators and Class II Facilities Division					◆◆	◆◆					
	Program Officer (maximum 1 position) Accelerators and Class II Facilities Division					◆◆	◆◆					
	Director Nuclear Substances and Radiation Devices Licensing Division					◆◆	◆◆		◆	◆		
	Licensing Project Officer (maximum 4 positions) Nuclear Substances and Radiation Devices Licensing Division					◆◆	◆◆					
	Director Transport Licensing and Strategic Support Division			✓		◆◆	◆◆		◆	◆		
	Transport Specialist (maximum 1 position) Transport Licensing and Strategic Support Division			◆◆		◆◆	◆◆					
	Program Officer (maximum 1 position) Transport Licensing and Strategic Support Division			◆◆		◆◆	◆◆					
	Director Operations Inspection Division								◆	◆		
	Director General Directorate of Nuclear Cycle and Facilities Regulation (DNCFR)						◆	◆	◆	◆	◆	◆
	Director Nuclear Laboratories and Research Reactors Division								◆◆			
	Director General Directorate of Power Reactor Regulation (DPRR)								◆	◆	◆	◆
	Director Bruce Regulatory Program Division									◆◆		
Director Pickering Regulatory Program Division									◆◆			

Director Darlington Regulatory Program Division							◆◆			
Director Gentilly-2/Point Lepreau Regulatory Program Division							◆◆			
Director General, Directorate of Regulatory Improvement and Major Projects Management (DRIMPM)						◆	◆	◆		◆
Legend	✓ fully authorized	◆ authority restricted to the directorate's licensing and certification mandate	◆◆ authority restricted to the division's licensing and certification mandate	* Decertification of Nuclear Power Plant operator(s) will only be exercised by the VPs						