8 July 2024

Ms. Candace Salmon
Commission Registrar
Canadian Nuclear Safety Commission
280 Slater Street, P.O. Box 1046
Station B Ottowa, ON, K1P 5S9

Dear Candice,

I am writing on behalf of WestCan Proton Therapy, Inc. ("WestCan") to formally request an exemption from the requirement to obtain a CNSC Licence to Prepare a Site; pursuant to the construction of the first proton therapy facility in Canada on the University of Alberta South Campus at 11321 65 Ave NW, Edmonton AB T6H 5V7 Canada.

WestCan is an entity organized under the laws of the Province of Alberta and will perform services as The Ben Stelter Center for Proton Therapy and the Neurosciences. WestCan has formed a strategic alliance with The Ben Stelter Foundation that will include funding for ongoing research and development and for the treatment of pediatric cancers with proton therapy. WestCan Proton Therapy. Inc. will be owned by local investors, community foundations, philanthropic investors and indigenous investment with debt funding support expected to be provided by the Royal Bank of Canada.

WestCan is partnering with the following leading entities specializing in advanced medical facilities such as proton therapy centers:

University of Alberta/Cross Cancer Institute/Alberta Health Services

WestCan's academic alliance with the University of Alberta will create a collaboration for research and development in cancer treatment and the neurosciences.

- Cross Cancer Institute is a comprehensive cancer center located northern Alberta. The institute is located in Edmonton near the southwest corner of the University of Alberta and is one of two tertiary cancer centers in the province. The Cross Cancer Institute is a leading cancer center for province-wide prevention, research, and treatment programs. The center provides inpatient and outpatient services for cancer patients, advanced medical and supportive cancer care, as well as patient and professional education. The Cross Cancer Institute conducts research in coordination with the Alberta Cancer Research Institute.
- The Department of Oncology, a branch of the University of Alberta's Faculty of Medicine and Dentistry, is located at the Cross Cancer Institute. The department offers training in medical oncology, radiation oncology, palliative care medicine, as well as medical physics.
- WestCan will contract with Alberta Health Services for the provision of clinical staffing to include Radiation Oncologists, Physicist, Dosimetry and therapists.

Ben Stelter Foundation

- Westcan has formed a strategic alliance with The Ben Stelter Foundation that will include funding for ongoing research and development and for the treatment of cancer with proton therapy.
- The Ben Stelter Foundation invests in unique, creative, innovative, entrepreneurial projects and entities that are anticipated to have an impact on cancer treatments and potential cures.

HHS Healthcare LLC

- HHS has worked on the development of the proton therapy center in Edmonton for the last several years, evaluating the need and financial feasibility of the project.
- HHS is a U.S. based healthcare strategy and development company that provides vertically integrated solutions to the global healthcare community. HHS' management team has more than 40 years of experience in the turn-key planning, development, financing and commercialization of healthcare strategies across a variety of service lines and has developed several proton therapy centers globally.
- HHS aligns the objectives of all the stakeholders in each project to ensure that the greatest value is achieved. This is accomplished by understanding and mitigating risk, creating a strategy to accelerate the speed to market, and procuring vendor support.
- HHS' service portfolio includes financial modeling, advisory and consultative services, project funding, project development and management, and equipment selection.

Stantec

- WestCan has executed an agreement with Stantec for the engineering and design of its Edmonton based facility. Stantec is a world leader in the design and construction of proton therapy facilities across the globe.
- Based in Edmonton, Stantec recently completed Calgary Cancer Center, a large-scale comprehensive cancer center.
- Stantec is currently collaborating with IBA and UPenn in the development of additional cancer centers in the US.
- Stantec has designed and delivered over 30 proton therapy centers around the world.

IBA

- WestCan has reached an agreement with IBA to provide the proton therapy system and ongoing technical training and support. IBA is the world leader in proton therapy equipment, with 75 centers sold and 43 centers in operation across 23 countries.
- Over 120,000 patients have been treated with IBA proton therapy systems.
- IBA is a solid public company with a proven track record of innovation, installation, operation, and service support.
- Over 1500 employees worldwide and support centers located in every major region around the globe.
- IBA is committed to the advancement of proton therapy with continuing research in FLASH Therapy and Combination Therapies.

PCL

- WestCan is currently in negotiations with PCL, a group of independent construction companies that carries out work across Canada, the United States, the Caribbean and in Australia. These diverse operations in the civil infrastructure, heavy industrial, and building markets are supported by a strategic presence in more than 30 major centers.
- Together, these companies have an annual construction volume of more than $8 billion, making PCL the largest contracting organization in Canada and one of the largest in North America.
- Recently, PCL Construction, in collaboration with Stantec and other partners, delivered the $1.4 billion Calgary Cancer Center, which included over 100 chemotherapy chairs and patient exam rooms, 160 inpatient unit beds, and 12 radiation vaults, among other programs and spaces.

Our combined team has a proven track record of successful projects in this domain, and we are well-equipped to manage all phases of this project. We anticipate PCL holding the license to Prepare and Construct the Edmonton-based site. WestCan will then hold the license to commission and operate the facility, thereby ensuring compliance with regulatory requirements throughout both the development and operational phases.

Outlined below is a high-level timeline for the project:

Program Validation – 1 month
Schematic Design – 2months
Design Development – 2.5 months
Construction Documents – 3.5 months
Permitting/Bidding and Negotiation- 2 months (may overlap other phases)
Construction Administration

- Notice to Proceed to Ready for Equipment – 12 months
- Ready for Equipment to Substantial Completion – 4 months
- Substantial Completion to Equipment Turnover – 8 months
- Clinical Commissioning – 3 months

IBA recognizes the importance of Health Canada approval and will diligently adhere to their guidelines. We plan to submit applications for medical equipment approval in alignment with our project timeline.

IBA is committed to patient health and ecological responsibility. WestCan's proton therapy center is being designed with precision to minimize environmental impact while providing cutting-edge cancer treatment. Generating high-energy protons requires significant energy and a highly controlled level of radiation. However, the process is contained within the facility, ensuring no adverse effects on the surrounding air quality. Water is safeguarded through a closed loop circulating cooling system, preventing groundwater contamination. As per local regulations, every new facility undergoes a rigorous radiation shielding design and a radiation safety assessment. This ensures that the operation of proton therapy centers remains within safe environmental thresholds, contributing to the well-being of patients and the community at large. Air and water contamination levels have been measured at similar proton therapy facilities in other countries, and values are well below safety standards.

To date, the University of Alberta Property Trust (UAPT) has initiated Phase 1 environmental assessments to identify, address and mitigate potential impacts. WestCan and UAPT will engage with the public and indigenous communities to ensure transparency and inclusivity in the project's development. We are committed to ongoing communication and collaboration with all stakeholders.

A detailed justification for requesting an exemption from the requirement to obtain a license to prepare a site is attached. Also attached are four IBA documents describing the standardized design of the proposed proton therapy facility and specifications relating to the cyclotron and beam delivery system.

Sincerely,

Mr. Gordon Baltzer
Chairman and CEO
WestCan Proton Therapy. Inc.
Mobile: 954-684-5173
Email: gbaltzer@westcanprotontherapy.ca

Request for Exemption from Licence to Prepare a Site

Regulatory Background

All accelerator facilities in Canada are classified as “Nuclear Facilities” via the following definition in Section 2 of the ***Nuclear Safety and Control Act***.

> ***nuclear facility means*** any of the following facilities, namely,
>
> > …
> >
> > **(b)** a particle accelerator,

Class II accelerator facilities are distinguished from Class I via the definitions in section 1 of the ***Class II Nuclear Facilities and Prescribed Equipment Regulations***:

> ***Class II nuclear facility*** means a facility that includes Class II prescribed equipment.
>
> ***Class II prescribed equipment*** means
>
> > …
> >
> > **(d)** a particle accelerator that is capable of producing nuclear energy and has a beam energy of less than 50 MeV for beams of particles with a mass equal to or less than 4 atomic mass units;
> >
> > **(e)** a particle accelerator that is capable of producing nuclear energy and has a beam energy of no more than 15 MeV per atomic mass unit for beams of particles with a mass greater than 4 atomic mass units; or

An accelerator is deemed “capable of producing nuclear energy” if the radiation(s) it produces are capable of causing nuclear transformations in a target material. As protons have a mass of 1 AMU, they fall within the purview of (d) above. However, since the proton therapy facility will have a beam energy of 250 MeV, they do not meet the definition of Class II Prescribed Equipment. By default, this implies that proton therapy facilities are designated as Class I (B) nuclear facilities.

For any Nuclear Facility, the following Regulatory requirements apply:

> ***Nuclear Safety and Control Act***
>
> > **Prohibitions**
> >
> > **26** Subject to the regulations, no person shall, except in accordance with a licence,…
> >
> > - **(e)** prepare a site for, … a nuclear facility;

Commission may exclude certain substances

7 The Commission may, in accordance with the regulations, exempt any activity, person, class of person or quantity of a nuclear substance, temporarily or permanently, from the application of this Act or the regulations or any provision thereof.

General Nuclear Safety and Control Regulations

Exemption by the Commission

11 For the purpose of section 7 of the Act, the Commission may grant an exemption if doing so will not

- **(a)** pose an unreasonable risk to the environment or the health and safety of persons;
- **(b)** pose an unreasonable risk to national security; or
- **(c)** result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.

A pre-established exemption from the need for a licence to prepare a site for all Class II Nuclear Facilities has long been established in the Regulations.

Class II Nuclear Facilities and Prescribed Equipment Regulations

Exemptions from Licence Requirement

Activities in Relation to Class II Nuclear Facilities
8 A person may carry on any of the following activities without a licence:
(a) prepare a site for a Class II nuclear facility;

Rationale for Exemption of Proton Therapy from Requiring a Site Preparation Licence

It is important to note that this designation of proton therapy accelerator facilities as Class I (B) is really just an artifact of an outdated regulatory definition that was suitable for the technology that existed 25 years ago. At that time, proton therapy was in its infancy worldwide. It is now an established international cancer treatment modality with over 150 operational facilities worldwide. It is in no way representative of the radiological risks associated with a proton therapy facility, which are similar in both nature and magnitude to those of the hundreds of Class II medical linear accelerators and cyclotrons in Canada.

During the public meeting of December 13, 2018 (Minutes of the Commission Meeting held on December 12-13, 2018 (cnsc-ccsn.gc.ca)), the Commission acknowledged that:

> "*Based on the information presented, the Commission agrees with CNSC staff's findings that the regulation of hadron therapy facilities may be better suited under the Class II Regulations. The Commission directs CNSC staff to continue the work that has been initiated by CNSC staff for the amendment of the Class II Regulations and to bring forth recommendations in this regard*."

Such a change was proposed in 2022 in Discussion Paper DIS-22-01, Proposal to Amend the Class II Nuclear Facilities and Prescribed Equipment Regulations | Let's Talk Nuclear Safety (letstalknuclearsafety.ca)

> ***"4.1.1.1 Proposed change****: Revise the definition of Class II prescribed equipment to include all particle accelerators capable of producing nuclear energy, with no explicit upper or lower limit on beam energy.*
>
> *Reasoning: Under the current definitions in the C2NFPER, any particle accelerator designed to operate with a beam energy of less than 50 million electron volts (MeV) is regulated as Class II prescribed equipment.2 Conversely, any accelerator designed to operate at energies higher than this limit automatically falls under the Class I regulatory regime.*
>
> *While the beam energies of accelerators that would be captured by this proposal may be one or two orders of magnitude higher than those currently regulated under the C2NFPER, this increase in beam energy does not translate to a proportional increase in radiological risk. Many such accelerators operate with a very low beam current, so while the accelerated particles may have a higher energy when compared to accelerators currently licensed under the C2NFPER, there are usually not as many particles accelerated in a given time. Because of this, the overall radiological risk due to prompt radiation from these accelerators is similar to that presented by accelerators currently licensed under the Class II regime.*
>
> *As mentioned earlier, any accelerator currently producing a beam with an energy greater than 50 MeV is licensed as a Class I facility in Canada. Other examples of Class I facilities include nuclear fission power reactors and processing facilities for nuclear fuel products, such as uranium. Some of these facilities require stringent containment facilities and processes in order to prevent unauthorized or unintended releases to the environment. Accelerators, however, regardless of operating energy, do not have these same containment risks since no*

radiation is produced unless the accelerator is actively powered by electricity. Material that may be activated by the accelerator beam will only remain in such a state for a time period on the order of months or at most a few years before it returns to background radiation levels. By comparison, waste products from the aforementioned examples of other Class I facilities may have a considerably longer lifetime.

The complexity of other Class I facilities is related to the potential risk and can include multiple redundant systems to provide safety and security under almost any condition. In addition, there tends to be an understandably high level of interest from the public in such facilities due to the risks that may be posed in the to the public and the environment. The level of complexity of the systems for any accelerator are less complex and there is little risk of releases to the public or the environment.

Given that accelerators operating at any energy do not present these complexities, it is reasonable that the licensing regime for accelerators also be reduced in complexity, and all accelerators, regardless of beam power, be regulated under the Class II regime. This would lead to a simplified licensing model for existing Class IB-licensed accelerators, such as TRIUMF and CLS, as well as for facilities that are expected to come to Canada in the future, such as proton radiotherapy accelerators. Note that while the licensing process may be simplified, it will still be commensurate with the risks involved in constructing, operating and decommissioning these types of facilities."

External comments received on this proposal were consistently positive, but it has not as yet been implemented. (https://letstalknuclearsafety.ca/sites/default/files/2023-04/comment_table_for_dis-22-01.docx)

In the context of site preparation, the most important similarity proton therapy and most Class II facilities, and the primary difference from other existing Class IB facilities, is that ***a proton therapy facility does not directly incorporate or utilize nuclear substances in any way.*** This has very significant implications for radiological safety, including:

- No nuclear fuel, no possibility of criticality
- Is not designed for the intentional production of significant quantities of nuclear substances
- Like medical electron accelerators, the only nuclear substances associated with proton therapy are byproducts of activation in metallic beam line components, cooling water and air.
    - Measured levels of the longest-lived activation products within the cooling water in the closed loop cooling system are assessed in attached IBA *Metadoc ID 115244 Version 0*. Also included are Monte Carlo estimates of the potential activation of ground water beneath the facility. The results clearly demonstrate that the activity concentrations are several orders of magnitude below the corresponding IAEA levels for exemption of bulk amounts of material without further consideration, as given in ***IAEA General Safety Guide No. GSG-17 Application of the Concept of Exemption***

Table 3*. These are equivalent to the unconditional Clearance Levels defined in Schedule II of the ***Nuclear Substance and Radiation Device Regulations.***

*NOTE – the use of UCL's derived for bulk solid waste when addressing liquid waste is discussed in ***IAEA General Safety Guide No. GSG-18 section 5.12***.

- The production of gaseous isotopes is described in detail in the attached IBA *Metadoc ID 63598*. That document does not explicitly address environmental releases of these activation products. However, the potential doses from environmental releases can be derived using the saturation activity concentrations, room volumes and air exchange rates specified. That is:

Room	**Volume m^3**	**Air Exchange Rate h^{-1}**	**Operating h y^{-1}**	**Volume exhausted annually $m^3\ y^{-1}$**
CGTR	650	6	4800	1.87×10^7
S2C2	180	6	4800	5.18×10^6

Nuclide	**T ½**	**CGTR Saturation activity**	**CGTR activity exhausted annually**	**S2C2 Saturation activity**	**S2C2 activity exhausted annually**	**TOTAL activity exhausted annually**	**Dose Coefficient for Inhalation (N13 & O15 from LUDEP, others ICRP72)**	**Dose to a single person exposed 24 h per day at saturation**	
		Bq m^{-3}	**MBq**	**Bq m^{-3}**	**MBq**	**MBq**	**mSv MBq^{-1}**	**mSv**	**µSv**
H-3	12.32 y	2.59E-05	6.34E-04	8.27E-03	4.29E-02	4.35E-02	2.60E-01	3.83E-06	3.83E-03
Be-7	53.22 d	1.64E-04	4.01E-03	7.04E-02	3.65E-01	3.69E-01	5.50E-02	6.88E-06	6.88E-03
C-11	20.39 min	8.69E-01	2.13E+01	3.80E+02	1.97E+03	1.99E+03	1.80E-02	1.21E-02	1.21E+01
N-13	9.965 min	6.09E+00	1.49E+02	2.16E+03	1.12E+04	1.13E+04	1.34E-02	5.15E-02	5.15E+01
O-15	122.24 sec	3.98E+00	9.74E+01	1.60E+03	8.29E+03	8.39E+03	4.85E-04	1.38E-03	1.38E+00
			H*(10) at centre of room µSv h^{-1}		**H*(10) at centre of room µSv h^{-1}**				
Ar-41 **	109.61 min	5.35E-01	6.6E-07	8.91E+02	6.6E-07			< 3E-6	< 0.003
							TOTAL DOSE	***6.51E-02***	***6.51E+01***

*** Note – Ar-41 is an inert gas. Consequently, unlike the other 5 isotopes generated in air, the primary radiological hazard is not from inhalation but rather external gamma exposure from immersion in air containing Ar-41. The following dose estimate is representative of the worst-case dose rates within the CGTR and S2C2 rooms. As can be seen, the potential dose from continuous exposure for the entire operating time (4800 hours y^{-1}) is trivially small (2 nSv y^{-1}). This value represents the absolute upper bound of the doses which could potentially be incurred from environmental releases of the Ar-41.*

- *Ambient dose rate at the centre of hemisphere of radioactive gas having radius R and saturation concentration C is* $H^*(10) = 2\pi C\ \Gamma_{H^*(10)}\ R$
- *Ambient dose rate constant* $\Gamma_{H^*(10)}$ *for Ar-41 is 0.181 µSv·m²/h/MBq*

- *Volume V of a hemisphere is $2\pi R^3/3$, so room volumes are equivalent to hemispherical radii of:*

  $R = (3V/2\pi)^{1/3}$
  At $V = 650\ m^3$, 6.8 m
  At $V = 180\ m^3$, 4.4 m

  $H^*(10)_{CGTR}$ = (5.35E-01 $Bq\ m^{-3}$) x (1E-6 $MBq\ Bq^{-1}$) x (6.8 m) x (0.181 $\mu Sv{\cdot}m^2\ h^{-1}\ MBq^{-1}$)
  $H^*(10)_{CGTR}$ = (5.35E-07 $MBq\ m^{-3}$) x (1.23 $\mu Sv{\cdot}m^3\ h^{-1}\ MBq^{-1}$)
  $H^*(10)_{CGTR}$ = 6.6E-07 $\mu Sv\ h^{-1}$

  $H^*(10)_{S2C2}$ = 4.3E-07 $\mu Sv\ h^{-1}$

Assuming a mean adult inhalation rate of 22.2 $m^3\ day^{-1}$ and 365 days per year of exposure at the saturation activity, a single individual could at most inhale 22.2 $m^3\ day^{-1}$ = 8100 $m^3\ y^{-1}$ of the air exhausted from these rooms. This is equal to 8100 m3 y^{-1} / (650 m^3 + 180 m^3) x 6 h^{-1} x 4800 h y^{-1} = 0.0034% of the total exhausted volume.

- Assuming no further dilution and no decay (which is extremely conservative, especially for the short-lived C-11, N-13 and O-15, which are the dominant contributors to the inhalation dose); inhalation of this volume would result in a maximum annual dose from all nuclides combined of 65 μSv.

- If an average transit time of 1 hour from exhaust to inhalation is applied, this reduces to less than 2 μSv per year due to decay of the short-lived isotopes in transit. This is well below the normal UCL dose criterion of 10 μSv.

- There is no possibility of significant environmental contamination with radionuclides under any circumstances, regardless of any internal (operational malfunctions) or external (geo-seismic, environmental, or deliberate sabotage) factors.

  - Any such event would cause the production of these activation byproducts to immediately cease.

  - Any release of cooling water would, as evaluated in *Metadoc ID 115244 Version 0*, would involve activity concentrations which are well below the corresponding unconditional clearance levels.

  - Gaseous nuclides would either continue to vent normally, or would simply decay very rapidly within the rooms in which they are produced. The total volume of air inhaled by a person in 1 hour is approximately 1 m^3. In the absence of further production of air activation products, after one hour any additional inhalation dose would essentially drop to zero due to the decay of C-11, N-13 and O-15. Thus, under worst case accident conditions, the inhalation dose would be less than 10 nSv as illustrated below.

Nuclide	T ½	CGTR Saturation activity	CGTR room activity	S2C2 Saturation activity	S2C2 activity exhausted annually	TOTAL activity exhausted annually	Dose from Inhalation (N13 & O15 from LUDEP, others ICRP72)	Dose from one hour of inhalation at the saturation activity	
		Bq m^{-3}	MBq	Bq m^{-3}	MBq	MBq	mSv MBq^{-1}	mSv	µSv
H-3	12.32 y	2.59E-05	1.68E-08	8.27E-03	1.49E-06	1.51E-06	2.60E-01	4.72E-10	4.72E-07
Be-7	53.22 d	1.64E-04	1.07E-07	7.04E-02	1.27E-05	1.28E-05	5.50E-02	8.47E-10	8.47E-07
C-11	20.39 min	8.69E-01	5.65E-04	3.80E+02	6.84E-02	6.90E-02	1.80E-02	1.50E-06	1.50E-03
N-13	9.965 min	6.09E+00	3.96E-03	2.16E+03	3.89E-01	3.93E-01	1.34E-02	6.34E-06	6.34E-03
O-15	122.24 sec	3.98E+00	2.59E-03	1.60E+03	2.88E-01	2.91E-01	4.85E-04	1.70E-07	1.70E-04
Ar-41	109.61 min	5.35E-01	3.48E-04	8.91E+02	1.60E-01	1.61E-01	N/A	***TBD***	***TBD***
							TOTAL DOSE	***8.01E-06***	***8.01E-03***

- Similarly, there are no other hazardous substances produced by operation of a proton therapy facility which might potentially be released to the environment.
  - As with any hospital, there will be some conventional medical biological and chemical wastes, which will be subject to the appropriate waste disposal methods for such materials.
  - Non-radiological environmental impacts for site preparation will be addressed via the applicable provincial regulations for environmental protection under the Alberta Environmental Protection and Enhancement Act. These regulations include:
    - Activities Designation Regulation
    - Administrative Penalty Regulation
    - Approvals and Registration Procedures Regulation
    - Conservation and Reclamation Regulation
    - Disclosure of Information Regulation
    - Environmental Assessment Regulation
    - Environmental Assessment (Mandatory and Exempted Activities) Regulation
    - Environmental Protection and Enhancement (Miscellaneous) Regulation
    - Methane Emission Reduction Regulation
    - Ozone Depleting Substances and Halocarbons Regulation
    - Remediation Regulation
    - Release Reporting Regulation
    - Substance Release Regulation
    - Waste Control Regulation
    - Wastewater and Storm Drainage Regulation
    - Wastewater and Storm Drainage (Ministerial) Regulation

  Please note that The University of Alberta Property Trust (UAPT) has initiated Phase 1 environmental assessments to identify, address and mitigate potential impacts. The results of the environmental assessment will be submitted as part of the application to construct the facility.

- No nuclear substance specific security requirements are needed.

- No special nuclear substance related fire safety requirements are needed. Conventional fire safety will be addressed via compliance with municipal and provincial regulations and building codes.

- No need for conventional or cyber security measures above and beyond those already employed in existing radiotherapy facilities across Canada.

- There are no international obligations or commitments relating to proton therapy facilities whatsoever.

For these reasons, we believe that proton therapy facilities are suitable for an exemption from the requirement for a license to prepare a site similar to that already in place for Class II accelerator facilities, which effectively present identical hazards.

In summary, site preparation for a proton therapy facility:

- **Does NOT** pose *any* radiological risk to the environment or the health and safety of persons. Projected lifecycle radiological releases to the environment are below the corresponding unconditional clearance levels for isotopes produced in air and water via activation.
- **Does NOT** pose *any* risk to national security; and
- **Does NOT** result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed (*which currently do not exist in the context of proton therapy*).

Attachments:

Proteus®One Single Room Building Requirements Summary
IBA Metadoc ID 115244 Version 0, ***Water Activation in ProteusONE Facility***
IBA Metadoc ID 63598, ***Air Activation in Proteus®ONE System***
Proteus®ONE Environmental Impact Report (2024)