Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

CMD 19-H2.1B

File / dossier : 6.01.07
Date: 2019-05-08
Edocs: 5898441

Supplementary Information

Presentation from Best Theratronics Limited

In the Matter of the

Best Theratronics Limited

Application for the renewal of the Class IB Nuclear Substance Processing Facility Operating Licence

Commission Public Hearing

May 16, 2019

Renseignements supplémentaires

Présentation de Best Theratronics Limited

À l'égard de

Best Theratronics Limited

Demande de renouvellement du permis d'exploitation d'une installation de traitement de substances nucléaires de catégorie IB

Audience publique de la Commission

Le 16 mai 2019

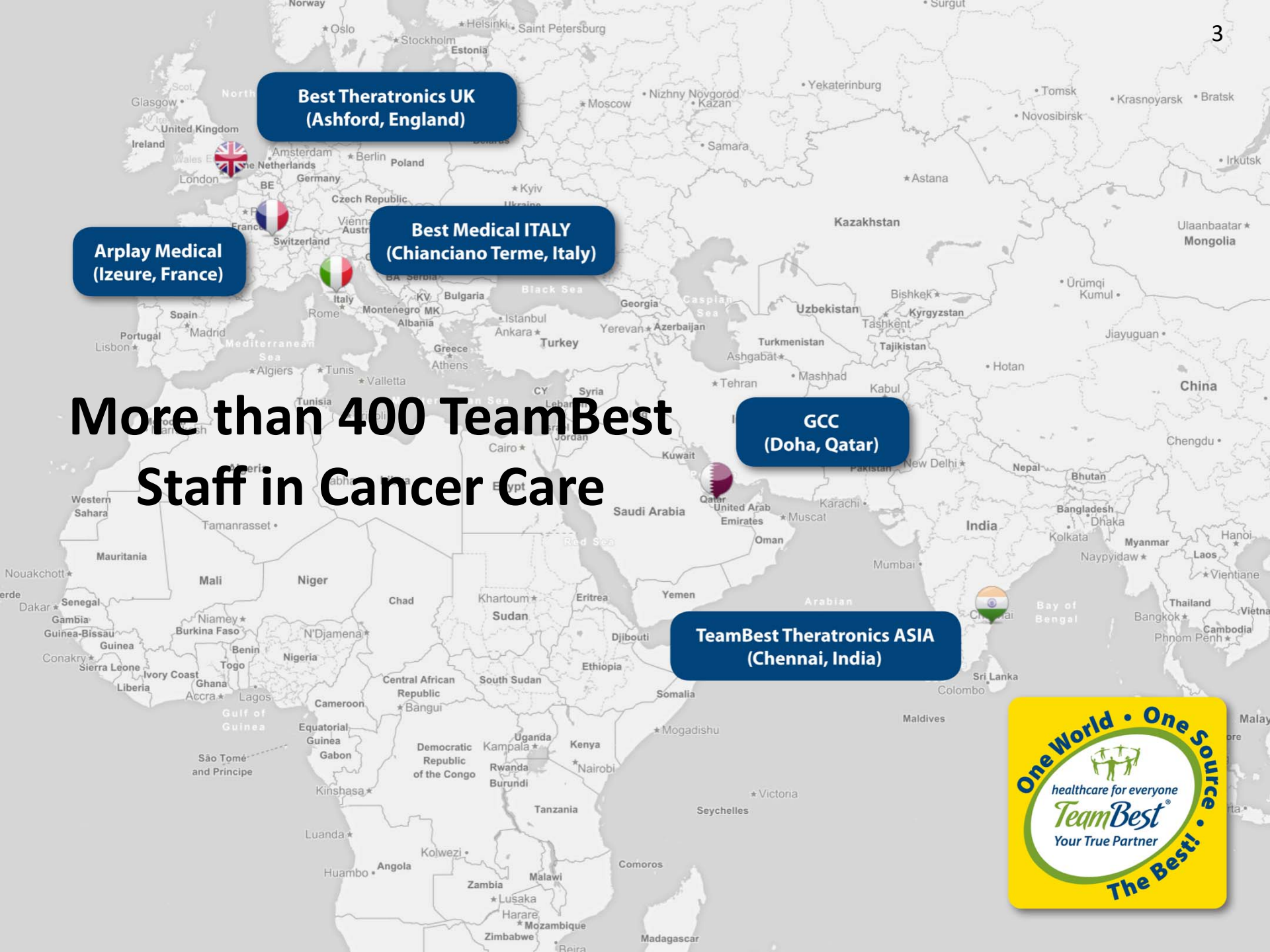
Canada

This page was intentionally left blank

Cette page a été intentionnellement laissée en blanc

Class 1B License Renewal
Class II Facility & NSRD License Applications
CMD 19-H2.1B

More than 400 TeamBest Staff in Cancer Care


Best Theratronics UK
(Ashford, England)
Arplay Medical
(Izeure, France)
Best Medical ITALY
(Chianciano Terme, Italy)
GCC
(Doha, Qatar)
TeamBest Theratronics ASIA
(Chennai, India)
More than 400 TeamBest Staff in Cancer Care
One World • One Source • The Best!
healthcare for everyone
TeamBest
Your True Partner

TeamBest Values & Mission

- Develop products that help in the prevention, early detection, and treatment of cancer.
- Our aim is to be the one partner that clinicians turn to for all their radiotherapy and oncology product and service needs.
- Key themes
  - Healthcare for all
  - Cost-effective solutions
  - Quality & Service
  - Single Source Oncology Solutions Provider

Operations Overview

BTL manufactures medical equipment:

- Radiation therapy systems using Co-60 for cancer treatment
- Irradiators for blood and research using X-rays or Cs-137
- Particle accelerators for medical isotope production

Worldwide approximately:

> 900 active Cobalt Teletherapy systems

> 1900 Gammacells

> 230 Raycells

Hiring highly skilled workforce of engineers, physicists & trades-people

BTL Radioactive Material

Legacy Depleted Uranium and Special Form Double-Encapsulated Sealed Sources

- Co60 therapy sources
- Cs137 irradiator sources

C-146 Capsule, Co-60

GammaCell

F147 Container [Type B(U)]

Type B(U) Transport Packages

F430

F431

F423

F147

F127

F168

R & D Class II Prescribed Equipment

- Loaded with a Cobalt-60 source with a total activity of 189 TBq
- Class II Facility operations were within licensed limits

Returned Sources & Waste

As defined by the International Atomic Energy Agency Waste is "material…for which no further use is foreseen."

- **A returned source is not categorized as waste by default**
- **Industry preferred strategies for returned sources are recycling and reutilization**

Safety Control Areas

- Satisfactory ratings in all safety control areas from the CNSC

Safety Highlights:

- Initiatives to decrease environmental impact
- Continuous learning opportunities
- Improvements to safety related program such as emergency preparedness and lead control
- Improvements to security measures

Management Systems

Quality system in place as an ISO 9001:2015 and ISO 13485:2016 certified company

Developed an extensive procedure framework that define roles and responsibilities for personnel

Notable Improvements:

- **CAPA system includes risk-based assessments**
- **Opportunity for improvement (OFI) system has been implemented**
- **Transitioning to paperless systems improving document control and record keeping**

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Best Theratronics Ltd
also trading as Best Medical Canada Ltd.
413 March Road
Ottawa
Ontario
K2K 0E4
Canada

DUNS Number: 24-360-6832

Holds certificate No: **MDSAP 689092**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan – MHLW Ministerial Ordinance 169, Article 4 to Article 68; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Design, manufacture, installation and servicing of Gamma and X-Ray systems and accessories, for the area of radiotherapy, blood irradiation and other related areas. Design and manufacture of patient dose verification systems.

For and on behalf of BSI:

Carlos Atanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-08-22 Effective Date: 2018-08-22 Expiry date: 2021-07-08

Page: 1 of 1

...making excellence a habit.

MDSAP

BSI Group America Inc. is an MDSAP authorized auditing organization

This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

One World • One Source • The Best!

healthcare for everyone

TeamBest®

Your True Partner

Best® Theratronics

Human Performance Management

- Success in recruiting and training qualified personnel
- Training program incorporates SAT principles
- Feedback and quality assessments on training have assisted with improving programs

Future Plans:

- Implement an electronic training management system
- Provide in-house licensing and regulatory training

Operating Performance

BTL operations continued with little change within the licensing period

Operating within licensed activity limits attributed to:

- Corrective Action and Preventative Action system in place
- Internal audits on operating performance
- Investigations related to all workplace incidences by both the H&S Committee and the RSS Committee
- Adequacy of procedures

Safety Analysis

The key implementation of the safety analysis framework is the use of safety analysis reports (SARs) for safety critical components:

- **Radiation Device and Class II Prescribed Equipment**
- **Radioactive Material Transport Containers**
- **The Facility**
  - **Safety Analysis Reports have been reviewed and concluded to be adequate**
  - **Safety concerns regularly discussed in both H&S and RSS Committee meetings**
  - **Updated fire hazard analysis of the facility was completed in 2016**

Physical Design

Facility improvements within the licensing period included:

- **Replacement of an old emergency exit door from a controlled access radiation area**
- **Roof replacement was initiated**
- **Upgrades to several of the facility air conditioning units**
- **Upgrades to exterior door systems**

Fitness for Service

The facility and the equipment are considered:

- **Preventative maintenance program proven to be effective**
- **Adequate program in place to complete immediate repairs on essential tools/ equipment, preventing potential health and safety issues**

Radiation Protection

- Radiation monitoring provided for all NEWs involved with licensed activity work
- ALARA program updated to decrease action level limits

Company Wide Whole Body Doses

	2014	*2015*	*2016*	*2017*	*2018*
Total workers monitored	74	76	73	77	77
Average dose (mSv)	0.03	0.05	0.08	0.11	0.20
Maximum dose received (mSv)	0.46	0.85	2.28	5.30	8.92
Regulatory maximum dose	50 mSv/year				

Company Wide Extremity Doses

	2014	*2015*	*2016*	*2017*	*2018*
Total workers monitored	30	32	31	25	27
Average dose , with zeros (mSv)	0.19	0.16	1.70	0.71	1.34
Maximum dose received (mSv)	3.70	2.10	29.90	11.20	14.94
Regulatory maximum dose	500 mSv/year				

Conventional Health & Safety

Health & Safety Committee meetings are conducted on a regular basis

- **Success with implementing near miss incident reporting**
- **Review of the lead control program took place**
- **Adequate number of first aiders on site and sufficient supplies on site**

Future plans:

- **Assess employee safety culture through survey**
- ***Importance to safety and awareness* refresher sessions annually**

Environmental Protection

- Decrease in the amount of solid effluent released from BTL
- Hazardous waste properly disposed of every 90 days
- Environmental impact of BTL's operations is evaluated annually
- Improvement to manufacturing procedures to help minimize chemical waste

Emergency Management & Fire Protection

The purpose :

- **Minimize adverse effects to humans and the environment from an emergency or disaster**
- **Ensure the earliest possible coordinated response**
- **Protect and preserve employees, public health and security**
- **Protect and preserve BTL and surrounding community property**
- **Restore normal operations with minimal interruption of service to BTL customers**

The procedures:

- **Radiation Emergency Response Plan**
- **Transportation Emergency Response Plan**
- **Fire Safety Plan – Best Theratronics Building**
- **Chemical Spill Response Plan**

Annual Fire Drill conducted throughout the licensing period

Full scale evacuation exercise conducted April 2019, involving Ottawa Fire, Police, and Paramedics

Facility familiarization tours are being offered to emergency responders regularly

Waste Management

Non-radioactive material

- Landfill diversion rate remained consistent
- Quantity of non-hazardous landfill waste decreased
- Initiative to reduce the amount of unused chemicals within the facility started

Radioactive Material

- Minimization of radioactive material located on-site
- Majority of returned sources were diverted to the recycling/ reutilization stream
- With a high price tag, all cobalt and most of cesium legacy sources, were removed from BTL license and transferred to other licensees for either long term storage or recycling.

Security

- Facility and monitoring system upgrades
- Incorporating Security involvement in Radiation Safety Committee meetings → Radiation Safety and Security Committee increasing nuclear security awareness
- Implementing procedures as BTL became a part of Transport Canada's Air Cargo Security Program

Safeguards & Non-Proliferation

Return of decommissioned legacy radiotherapy units contain depleted Uranium as part of shielding

- **PIT Evaluation conducted by the CNSC indicated BTL was adequately prepared for an inspection by the IAEA**

Packaging & Transport

- ERAP table top exercise conducted for transportation of depleted uranium from BTL to disposal facility on Canadian roadways
- Incidents occurred during licensing period were reported immediately to CNSC

Other Matters

– Import & export activities

BTL is a major importer and exporter of category 1 and 2 sealed sources, primarily Cs-137 and Co-60. BTL has implemented a robust import/export program. Due to the high activity of the sources, BTL obtains licenses from the CNSC for the exports. When required, BTL also obtains appropriate permits with DFAIT for exports that may be controlled under Canada's Export Control List or various sanctions.

Financial Guarantee

- An order was issued by the CNSC due to non-compliance with financial guarantee license condition
- Nuclear inventory was decreased and a revised preliminary decommissioning plan was submitted specifying an estimated cost of $1.8 million
- July 2017 the CNSC accepted BTL's financial guarantees

Public Information Program

BTL's Primary goal is to communicate operational activities to surrounding communities and allowing for community concerns to be heard.

- **Information distributed mainly through website**
- **Hosted community information session (May 12, 2018)**
- **Invitation was extended to Algonquins of Ontario for a face to face meeting and a facility tour**

Cyclotrons at Best Theratronics

Best Theratronics LTD (BTL) manufactures cyclotrons designed with the potential to produce energies between 15 to 70MeV. The potential can only be transformed into a capability after certain measures have been taken. These are our present models: B15P, B20U, B25P, B30U, B35P and B70P.

B15 PET	B25	B35 (28)	B70
15 MeV	20-25 MeV	15-35(28) MeV	35-70 MeV
200 µA +	400 µA +	1000(400) µA	1000 µA
Targets	Targets	Targets	Targets
Radiochemistry	Radiochemistry	Radiochemistry	Radiochemistry

Factory Testing

All Best Theratronics LTD (BTL) cyclotrons are *Factory Tested* at energies below 1MeV. Factory testing is performed through injection of the H- beam and acceleration in the center region of the cyclotron to energies below 1MeV.

The *Safety Measures* implemented in our design have been developed based on protocols from the Canadian Cyclotron laboratory TRIUMF, Vancouver that are internationally recognized and applied by all cyclotron manufacturers. The specific measures are scientifically and engineering documented and could be provided upon request.

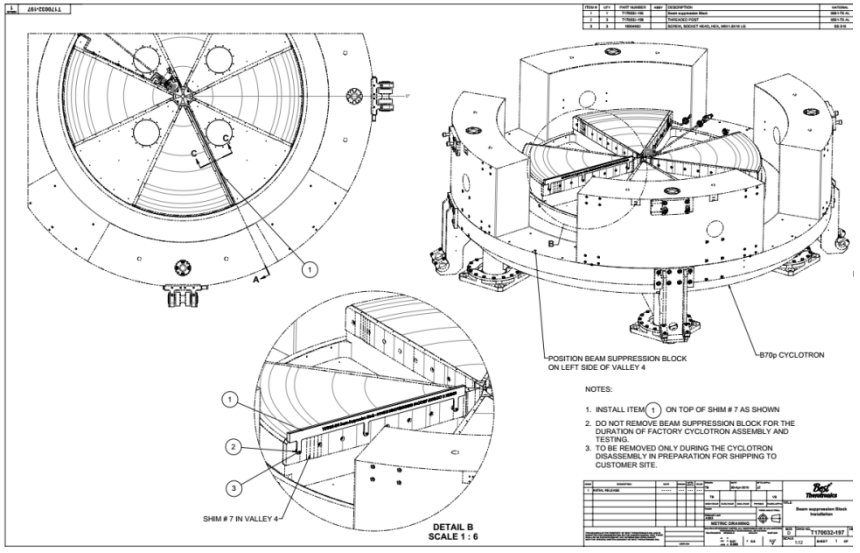
Their practical implementation is ensured by a complex of three (3) *Safety Measures* where each individual device is deemed to be sufficient to prevent the beam from being accelerated above the energy of 1MeV from where nuclear radiation can be produced. These are:

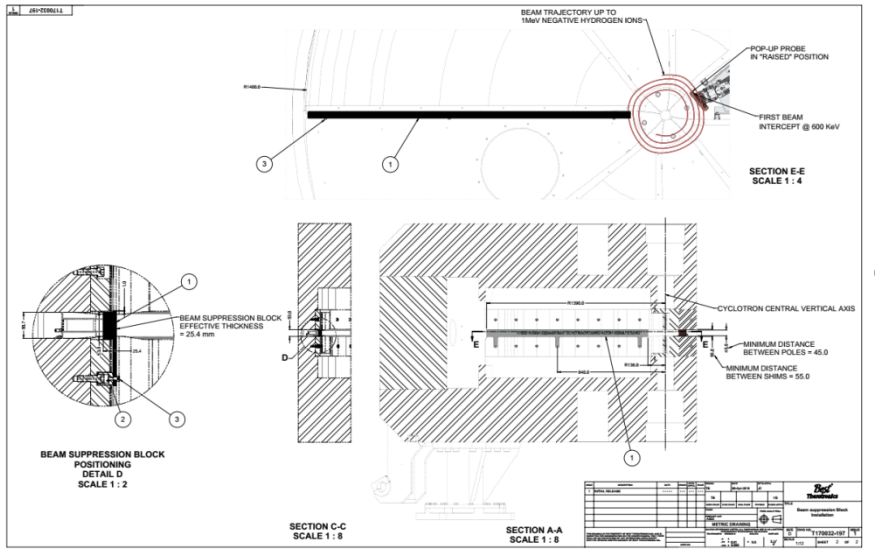
- **(1) Beam Intercept Probe (BIP) placed at the energy between 0.6 to 0.8MeV and blocked on "high" intercept position,**
- **(2) Beam Suppression Block which is a solid block of aluminum positioned between magnet poles completely obstructing the entire acceleration space up 70MeV.**
- **(3)Disable the hardware activation (PLC Control) actuating the BIP.**

B70P Cyclotron Example

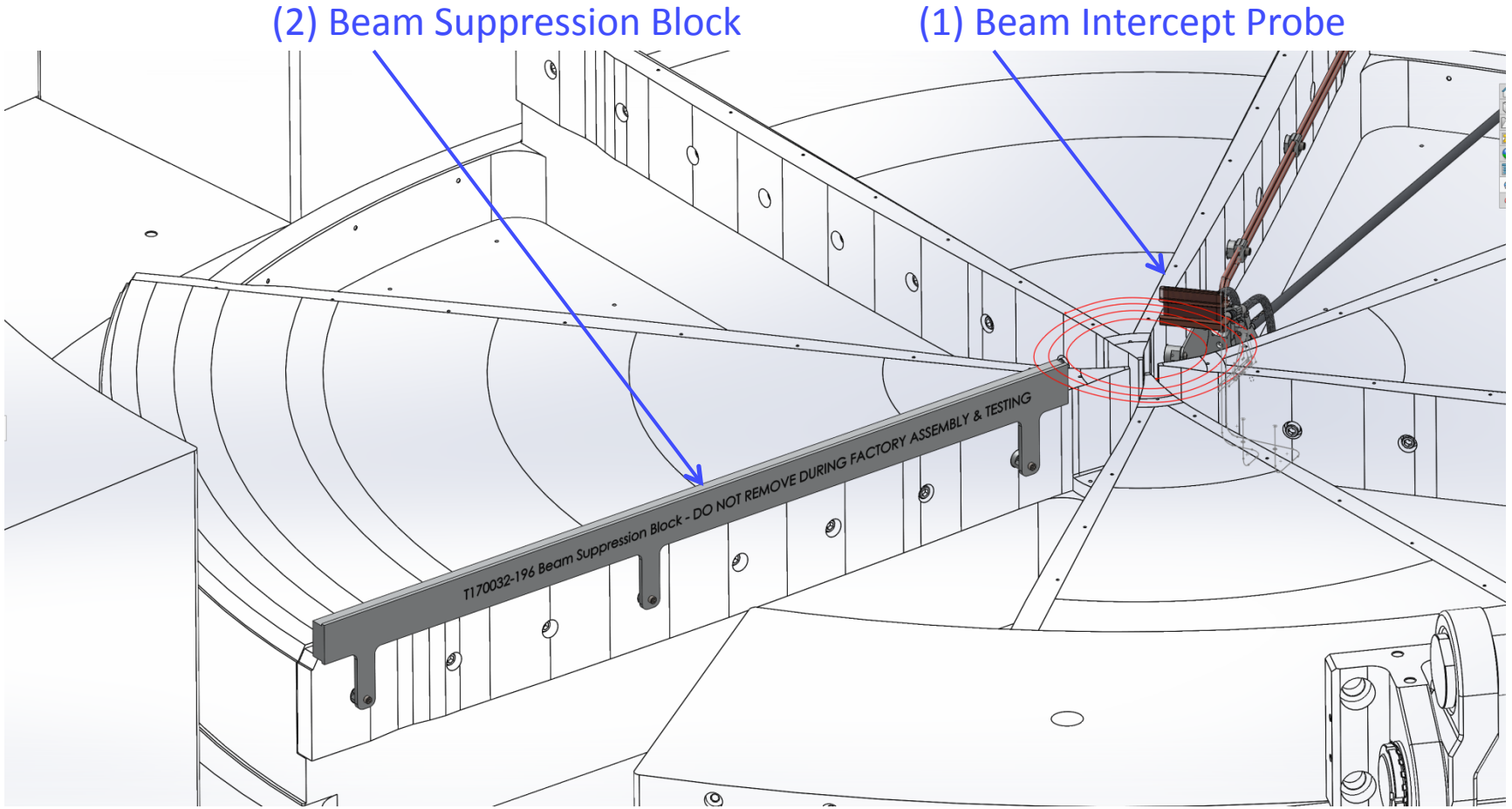
B70P Cyclotron Factory assembly (mechanical) is equipped with both mechanical safety devices as per factory drawing T170032-197 *Beam Suppression Block Installation* where specific NOTES indicated for the devices to "DO NOT REMOVE" during the factory testing.

Here below we include the drawing and detail renderings showing the devices and beam intercept mode.

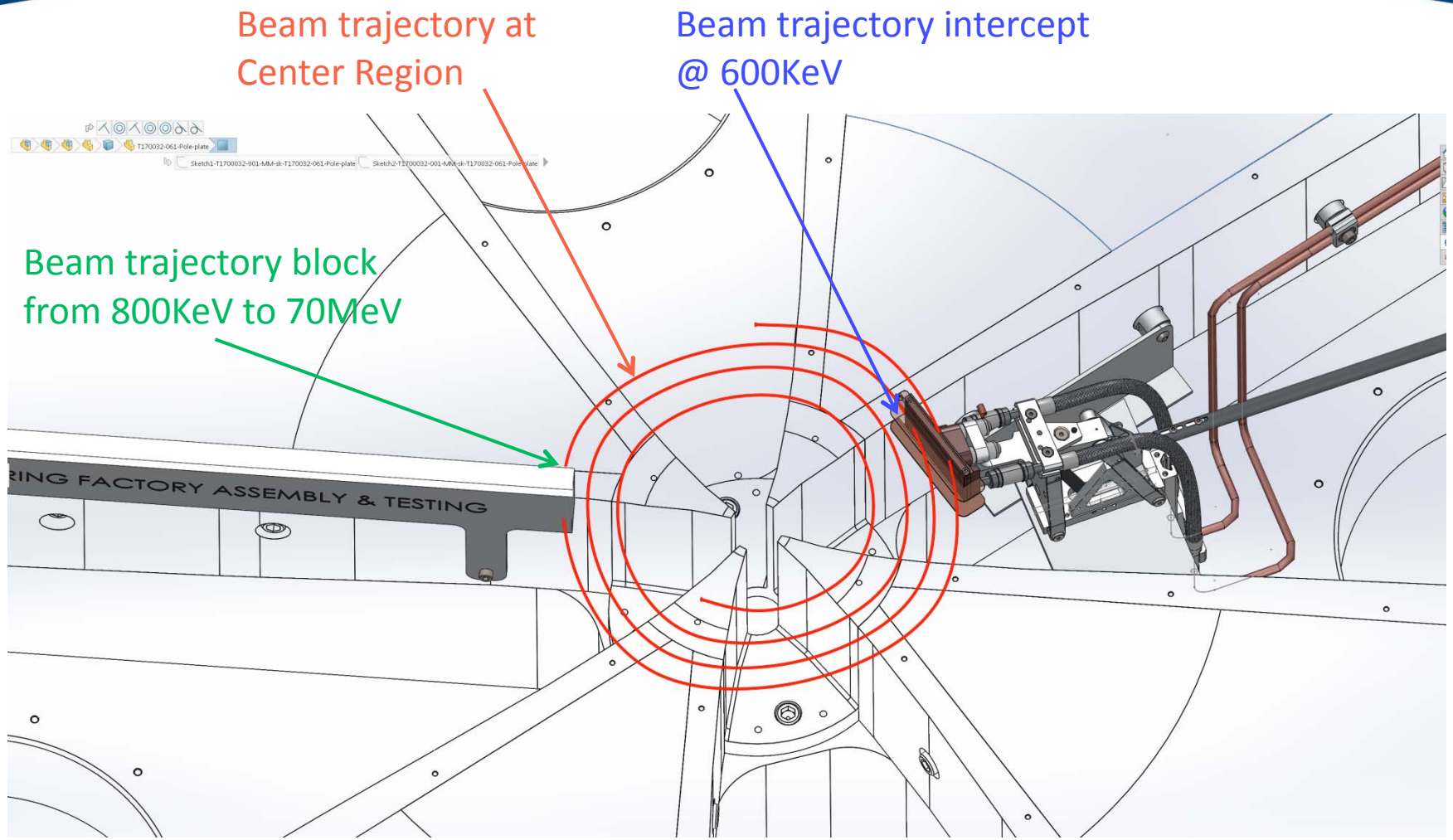




B70P Cyclotron Example

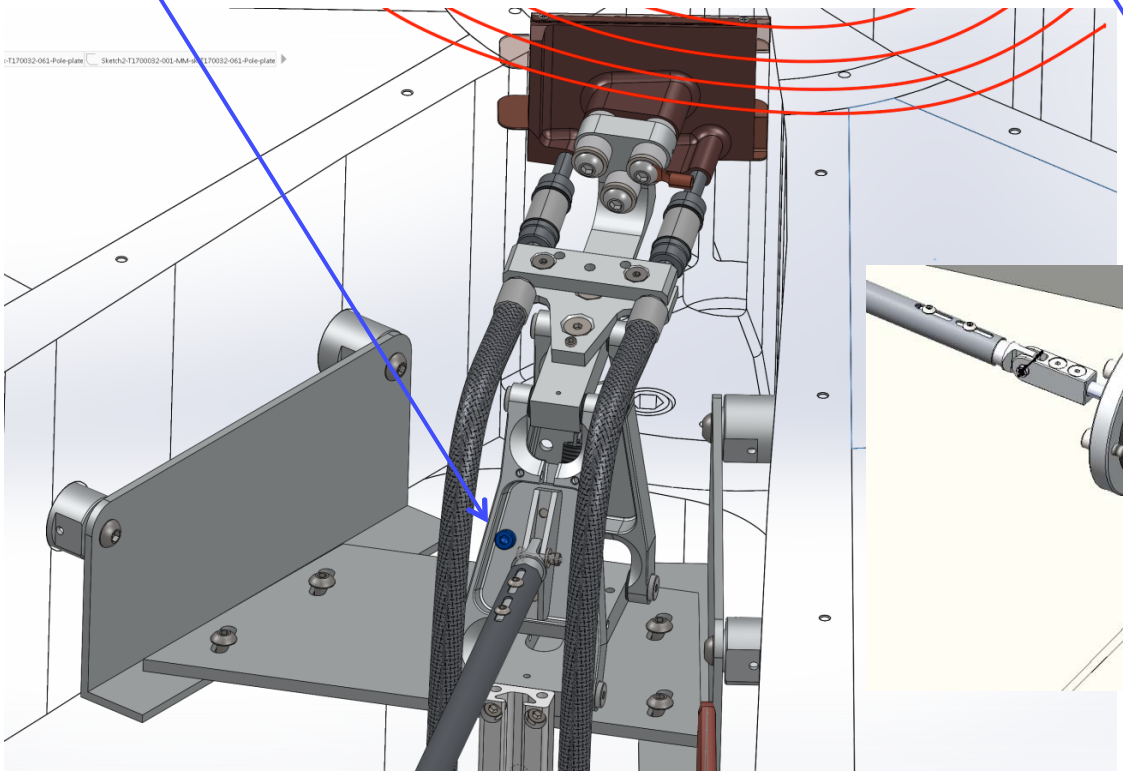


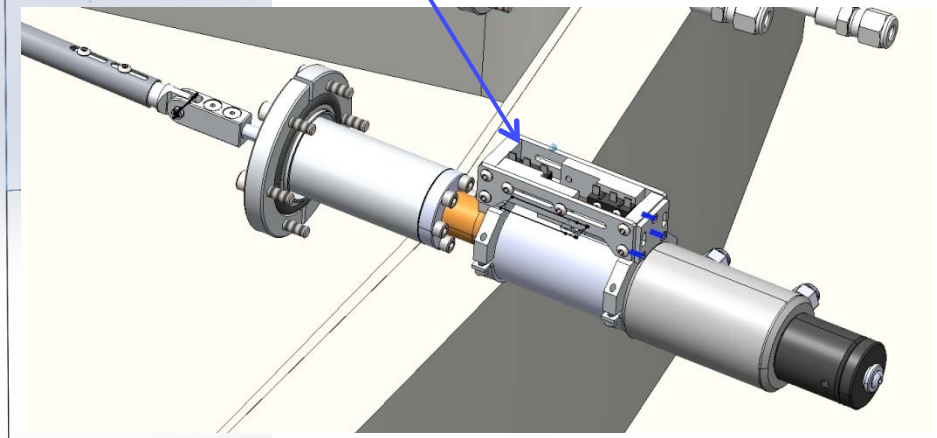
B70P Cyclotron Example



B70P Pop-Up Probe (Factory)

The Beam Intercept Probe (Pop-Up Probe)is locked in place in “beam intercept” position with a screw as shown below (blue) and the air actuator moving the probe is disabled (compressed air supply and PLC controlled air switch disconnected) during the entire factory testing.





Conclusion

Based on above considerations we presented sufficient detail information and documented that the B70P cyclotron model Factory Assembly is NOT:

"capable of producing nuclear energy or have a beam energy above 50MeV for beams of particle with a mass equal to or less than 4 atomic mass units" as defined in the CNSC relevant documentation (*Class IB Nuclear facility).*

We are also bringing to the committee attention that above definition refers to "capability" not "design". While our B70P cyclotron is *designed* for, it is not *capable* of producing nuclear energy as defined in regulatory act.

Matters for Consideration

There are essentially three questions of interpretation before the Commission:

- **Does the Applicant's facility include a particle accelerator "that is capable" (emphasis added) of producing nuclear energy of more than 50 MeV per atomic mass unit for certain beams of particle?**
- **Does the Applicant manage, store or dispose waste "containing radioactive nuclear substances at which the resident inventory of radioactive nuclear substances contained in the waste is 10^{15} Bq" or more?**
- **Does the Applicant "process or use" nuclear substances in a quantity in excess of 10^{15} Bq in a year?**

Conclusion

BTL has maintained programs and implemented improvements over the current licensing period to ensure adequate provisions are in place for the protection of the environment, employees, and the public.

- **No significant changes in operations has occurred nor planned for the future**
- **Operational oversight by Class II Facilities and NSRD Directorates is being requested**