Best Theratronics

Q-9

413 March Road
Ottawa, Ontario
Canada K2K 0E4
Tel: 613-591-2100

Jul 27, 2017

Ms. Orysia Masnyk Bailey
USNRC, DNMS, Decommissioning
2100 Renaissance Blvd. Suite 100
King of Prussia, Pennsylvania 19406
Fax : 610-680-3497

03037620

Subject: Addition of an Approved Radiation Device to our Licence 45-31299-01

Dear Ms. Masnyk Bailey:

While we could not locate a copy of the initial application, we have been advised by former RSO Samantha Mason (and it is our best information and belief that her assertion is correct) that she sent a request for amendment to add the Gammabeam 500 to our NRC License 45-31299-01. This is supported by her follow up letter in June of 2017 (attached) in which she notes this is a 2nd request for amendment to add this device to our Material License. It is our understanding you did not receive either the original application or the June follow up 2nd request letter. Please note, this device was already in our Sealed Source and Device Registration Certificate as of October 2015. (see attached).

In addition, we have created a Corrective And Preventive Action, CAPA # 170713 to avoid this issue of a device being on our Device License but not our Material License going forward.

If you require any further information, please do not hesitate to contact me.

Best Regards,

Mojgan Soleimani, M.Sc.
Medical Physicist, Radiation Safety Officer
Best Theratronics Ltd.
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600053

NMSS/RGN1 MATERIALS-002

Best Theratronics

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June 8, 2017

Blake Welling
US Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Commercial, Industrial, R&D and Academic Branch

Subject: Addition of an Approved Radiation Device to our Licence 45-31299-01

This is a second request to include the GammaBeam 500 Teletherapy device to our license for the purpose of distribution and service as per condition 10(C) of our license.

The activity limit is 15,000 Ci (555 TBq) as per out Registration of Radioactive Sealed Source and Devices Safety Evaluation of Device No: NR-1307-110-S (see attached).

Please not we are the sole manufacturer and distributor of this device, and it follows all of our standard procedures for service technician handling and installation.

In addition, our service trainer Daniel Arvisais has retired and we would like to replace him with Victor Moga to designate individuals per the training requirements for working with licensed material.

Samantha Mason
Radiation Safety Officer

REGISTRATION OF RADIOACTIVE SELAED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-1307-D-110-S DATE: October 5, 2015 PAGE 1 OF 8

DEVICE TYPE: Teletherapy Unit

MODEL: GammaBeam 500

DISTRIBUTOR: Best Theratronics Ltd.
7643 Fullerton Road
Springfield, VA 22153

MANUFACTURER: Best Theratronics Ltd.
413 March Road
Ottawa ON
Canada K2K 0E4

SEALED SOURCE MODEL DESIGNATION: Best Theratronics Ltd Model C-146

ISOTOPE:	MAXIMIM ACTIVITY:
Coblt-60	15,000 Ci (555 TBq)

LEAK TEST FREQUENCY: 6 Months

PINCIPAL USE: (AD) Photon-emitting Teletherapy Unit

CUSTOM DEVICE: _____ YES __X__ NO

REGISTRATION OF RADIOACTIVE SELAED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Teletherapy Unit

DESCRIPTION:

The GammaBeam 500 is a Total Body Irradiator designed to be used to deliver radiation to the whole body of a patient for the treatment of cancer. The device is intended to be used in hospital or clinical facility to deliver a prescribed dose of radiation at specified position and to deliver radiation in accordance with the treatment setup. The unit should be used by personnel having adequate training.

The GammaBeam 500 consists of the main unit, the optional patient support couch, and the optional portal imaging panel. The GammaBeam 500 is designed as a stand-alone unit to deliver Total Body Irradiation (TBI). The device consists of a base, column, and a carriage with a teletherapy head mounted at a maximum height of 2.5 m from the source to the floor. The height can be adjusted by adjusting the Source-to-Skin Distance as required. An optional manual mechanism allows the head to rotate trough any angle up to 180 degrees in either direction from the head lock position. The design of the GammaBeam 500 is similar to previously registered Model Theratron Equinox 80, which has the same head assembly, source drawer motion mechanism, source, and similar control system. The unit is equipped with an emergency shutter mechanism. The shutter is comprised of two leads bars that can be driven toward each other by the shutter motor/gearbox assembly. The shutter is designed to automatically close if the source is unexpectedly exposed. The vertical motion of the head is motorized and can be controlled by any of the two control panels located at each side of the column. The TBI has an accessory couch with an optional imaging panel to aid in the positioning of lung attenuators during treatment. The assembled TBI weight is 4000 Kg (16,500 lbs). The overall dimensions are 291 cm height and 127 cm width.

The GammaBeam 500 uses one cobalt-60 source model number C-146 containing a maximum activity of 15,000 Ci (555 TBq). The source capsule assembly is mounted in the source drawer in a cavity approximately 2.8 cm (1.1 in,) in diameter by 12 cm (4.7 in.) long, held in place with an end plug and security

DEVICE TYPE: Teletherapy Unit

DESCRIPTION (Cont.):

clip. The source is held in the source cavity by a source sleeve, made of tungsten plus 8% molybdenum alloy plug and a retaining ring.

The GammaBeam 500 has a pneumatic system that is designed to automatically retract to the "OFF" position in the event of power loss of more than 10 seconds, or pressure loss. A lead-steel auxiliary shield is located in the front of the source drawer to prevent radiation streaming. The design of the GammaBeam 500 does not allow the source to remain in the open position when loss of air supply occurs under normal conditions or during maintenance. Air is stored in the reservoir to retract the source to the shielded position in the event of a power outage. In the unlikely event that the source remains in the open position there are visual, audible, and mechanical indicators that alerts the operator to the position of the source. The shutter mechanism is located between the bottom plate holding the lead beam definer and the bottom disk. The shutter mechanism reduces radiation to less than 4% of the open beam.

The source head assembly consist of a lead filled, cast steel shell 1.13 m (44.25 in.) long by 53.3 cm (21 in.) high by 61 cm (24.25 in,) wide and it is secured to the arm by means of a rectangular steel casing. An unalloyed tungsten billet is located within the source head as part of the shielding for the "OFF" position. A 6.4cm (2.5 in.) diameter by 54.6 (21.5 in.), brass encased, lead filled source drawer moves horizontally through a distance of 33 cm (13 in.) in 2 seconds by the pneumatic system.

The device visual ON-OFF indicators alert the individuals of the position of the source. The head panel contains a beam lamp and a beam rod indicator. The beam ON (red lamp) lamp is illuminated when the source is in any position other that the fully shielded. The beam OFF (green lamp) is illuminated when the source is in the fully shielded position. The beam ON indicator rod (red lamp) protrudes from the front of the head

DEVICE TYPE: Teletherapy Unit

DESCRIPTION (Cont.):

cover when the source is in, or near, the BEAM ON position. It is retracted into the head when the source returns to the fully shielded position. If this rod is not visible but the Beam ON indicator on the head is illuminated, radiation levels will be substantially less than the levels when the source is fully exposed. The control console also has a beam ON/OFF indicator. The control console beam ON (amber/yellow lamp) is illuminated when the source is in the fully shielded position. The "In Transit" flashing amber lamp indicates that the source is between the fully shielded position and fully exposed position. The beam OFF indicator (green) is illuminated when the source is in the fully shielded position. A series of messages displayed on the exposure timer, most of them accompanied by an audible signal, show the interlock conditions that will stop or prevent the radiation.

The unit has emergency STOP buttons located on both sides of the column of the TBI and control panel. When the emergency button is pressed the source will return to, or remain in, the fully shielded position. If the source drawer mechanism fails to operate, a T-bar can be used to manually return the source to the fully shielded position with a force of at least 25 lb.

If personnel were to enter the radiation room when the source is exposed, the door interlock system will ensure that the source returns to the shielded position. In the event the operator turns the beam enable key switch to "ON" and the door is open, the circuit does not provide power to the solenoid in the pneumatic system, therefore, the source will not move from the shielded position.

CONDITIONS OF NORMAL USE:

The GammaBeam 500 is designed to meet ANSI 43.10, 2001 [1]. The device is typically operated in hospital or clinical facilities with the following environmental conditions:

DEVICE TYPE: Teletherapy Unit

CONDITIONS OF NORMAL USE (Cont.):

- Ambient operating temperature range 10°C - 40°C
- Humid operating range < 90% RH, non-condensing
- Atmospheric pressure between 54 kPa to 106 kPa

The device is designed for transport and storage in the following atmospheric conditions:

- Ambient operating temperature range -15°C - 50°C
- Humid operating range < 90% RH, non-condensing
- Atmospheric pressure between 50 kPa to 106 kPa

The working life of GammaBeam 500 is 20 years from the date of installation and being maintainable for at least 100,000 irradiation cycles.

PROTOTYPE TESTING:

The GammaBeam 500 is similar to previously registered teletherapy unit Model Theratron Equinox. The Theratron Equinox 80 use the same design platform and have been designed to meet the same intended use as the Theratron Elite 80 and Elite 100. The Theratron Elite head design has been installed and used worldwide for over 40 years with no reported failures due to metal integrity of the lead contained in the head assembly. The expected working life is 20 years (25,000 clinical hours). However, the recommended working life may be extended by Best Theratronics based on inspection and technical assessment for an additional 40,000 hours. The device is not expected to be subjected to vibrations, pressure or impact under normal operating conditions or maintenance.

The sealed source, Model C-146, used in the device has achieved an ISO classification 97E64534.

DEVICE TYPE: Teletherapy Unit

LABELING:

The label affixed to the device contain the radiation symbol, isotope, activity, model number, serial number, name of manufacturer and the words "DANGER RADIOACTIVE MATERIAL". The labels are made of aluminum and are permanently attached to the device by the use of an adhesive, screws or bolts. The labels will be located on the lower side of the GammaBeam 500 device.

RADIATION PROFILES:

The licensee indicated that the head assembly of the GammaBeam 500 is identical to that of the previously approved THERATRON UNIT, cast steel shell with lead and tungsten shielding with a lead source drawer. The GammaBeam 500 unit does not contains Depleted Uranium. The average dose rate readings taken from points around the device, with the source in the OFF position, do not exceed 0.02 mSv/hr (2 mrem/hr) at 1 m from the source and no point exceeds 0.1 mSv/hr (10 mrem/hr). The licensee expects that the maximum radiation levels while the device is operating will be equal or less than: 62.3 R/hr at the external surface of the device, 45.8 R/hr at 5cm, 15.6 R/hr at 30 cm, and 3.32 R/hr at 100cm.

QUALITY ASSURANCE AND CONTROL:

Best Theratronics maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. Best Theratronics Quality System is ISO 9001:2008 certified. A copy of the program is on file with NRC.

All manufacturing of the Model GammaBeam 500 devices and related operations are to be carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR Part 820, under the supervision if the Quality Assurance group at Best Theratronics.

REGISTRATION OF RADIOACTIVE SELAED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Teletherapy Unit

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- GammaBeam 500 teletherapy units shall be distributed only to persons specially licensed under 10 CFR 35.600 by the Nuclear Regulatory Commission or under equivalent Agreement State Regulation.

- The device shall be installed by Best Theratronics service representative or by specifically licensed Best Theratronics authorized agent.

- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.

- The device shall be leak tested at intervals not to exceed six (6) months using techniques capable of detection 0.005 microcuries (185 Bq) of removable contamination.

- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

FDA APPROVAL SUMMARY:

This device was approved by the U.S. Food and Drug Administration, Approval No. K150191, Form 510 (k), dated April 17, 2015.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below and the past history of similar designs, we conclude that the teletherapy unit device GammaBeam 500 is acceptable for licensing purposes.

Furthermore, we conclude that these devices would be expected to maintain their integrity for normal and accidental conditions of use which might occur during the uses specified in this registrations sheet.

REGISTRATION OF RADIOACTIVE SELAED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Teletherapy Unit

REFERENCES:

The following supporting documents for the GammaBeam 500 as described in this device registration are hereby incorporated by reference and are made a part of this registry document:

- Best Theratronics Ltd. application dated April 13, 2015, with enclosures thereto(ML1511A311).
- Best Theratronics Ltd. letter dated August 4, 2015, with enclosures thereto(ML1517A004).
- Best Theratronics Ltd. e-mail dated September 2, 2015, with enclosures thereto(ML15253A008).
- Best Theratronics Ltd. e-mail dated September 15, 2015, with enclosures thereto(ML15260A544).

ISSUING AGENCY:

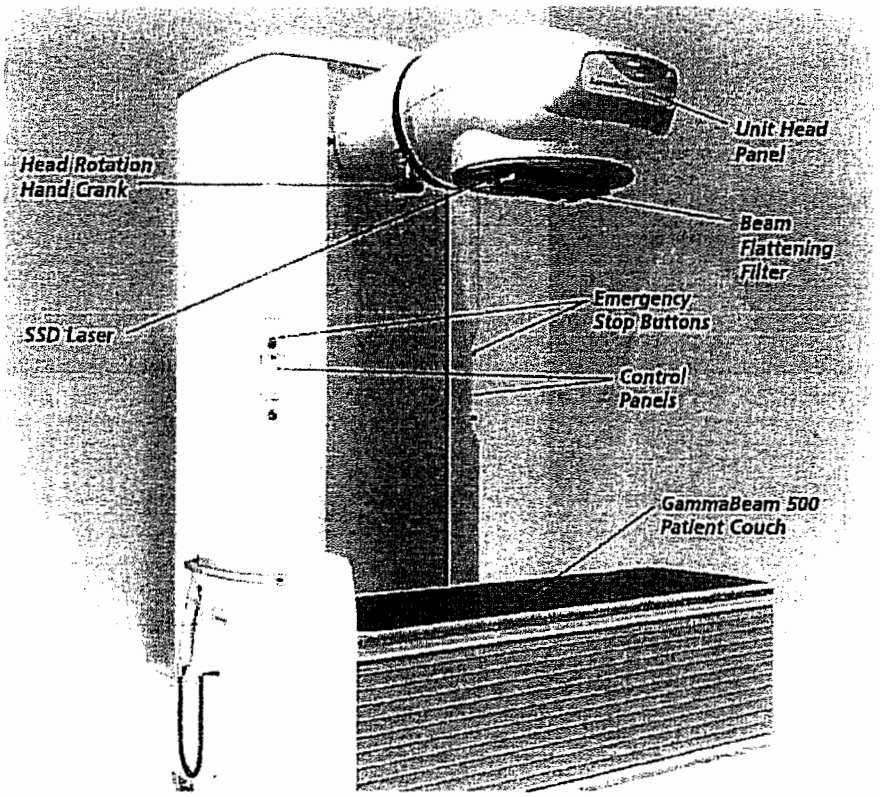
U.S. Nuclear Regulatory Commission

Date: October 5, 2015 Reviewer: Lymari Sepulveda

Date: October 5, 2015 Concurrence: Maria Arribas-Colon

REGISTRATION OF RADIOACTIVE SELAED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICE

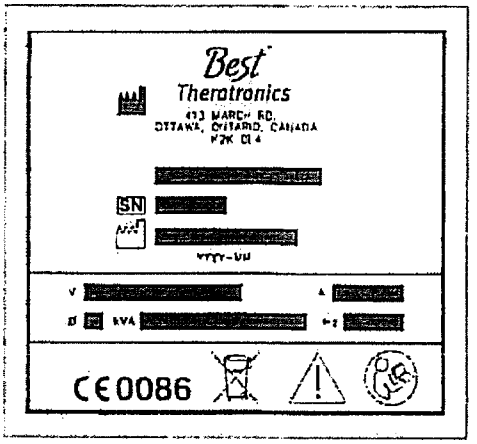
NO.: NR-1307-D-110-S DATE: October 5, 2015 ATTACHMENT 1 OF 2



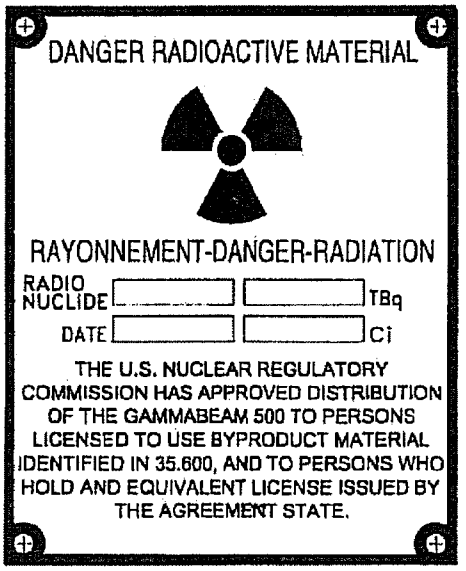
GammaBeam 500 Teletherapy Unit with Patient Couch

REGISTRATION OF RADIOACTIVE SELAED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-1307-D-110-S DATE: October 5, 2015 ATTACHMENT 2 OF 2



Manufacturer/Distributor Label



Radioactive Caution Plate