



Missouri Baptist
MEDICAL CENTER

3015 N. Ballas Road
St. Louis, Missouri 63131

314-996-5000
www.missouribaptist.org

April 20, 2011

Nuclear Regulatory Commission (NRC)
Region III
2443 Warrenville Road,
Suite 210
Lisle, IL 60532-4352

Dear Sir/Madam,

Re: NRC Material License No. 24-11128-02, Docket No. 030-08325.

We would like to amend our NRC material license # 24-11128-02 and include the following changes:

- 1- Add Mark Wiesmeyer, PhD as an authorized medical physicist for the material and use of Iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device: for calibration, spot checks and training. Dr. Mark Wiesmeyer is an Authorized Medical Physicist on the NRC material license No. 24-02490-03 (Docket No. 030-02308) for the material and use of Iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device: for the calibration, spot checks and training.

Dr. Wiesmeyer has completed the required emergency training for our Varian GammaMed HDR unit on 1/13/2011. A copy of the training document course that lists Mark Wiesmeyer as one of the trainees is attached.

If you need further information, or if you have any question, please let me know.

Sincerely,

Thomas J. Moenster, RSO
Missouri Baptist Medical Center
3015 N. Ballas Road,
St. Louis, MO 63131
Phone: 314-996-5397
Fax: 314 -996-5470
e-mail: tjm0476@bjc.org

| | | | |
|--|--|-------------------|--|
| Varian Medical Systems | TITLE: <i>Gammamed</i> Customer Emergency Training Course | | |
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|---|
| Document Family : Quality System Format |
| Document Type : N/A |
| Affected Business Units : Brachytherapy VMS Haan |
| This Document is available in : English |

Document Approval

| Name | Title | Date | Signature |
|---------------------|--------------------------|-------------|------------------|
| Achim Flessenkämper | Product Support Engineer | 25-AUG-2008 | A. Flessenkämper |
| David Kuligowski | Service Supervisor US | 8/26/2008 | David Kuligowski |
| Richard Dillon | Service Manager | | |

Implementation & Training

1. Quality System Documents

This document is released for use on the effective date recorded on this page. When required, training is to be completed within 15 business days of release or prior to use, which ever comes first.

| REV | DOCUMENT CHANGE RECORD | Effective Date |
|-----|---|-----------------------------|
| 01 | This document will supersede FO 19.51e Transferred into LiveLink format – no training necessary for this change notice to employees in charge only | 15 th Sep., 2008 |

| | | | |
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| Richard Dillon | Service Manager | 4-Sep-2008 | [Signature] |

Implementation & Training

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GammaMed Customer Emergency Training Course

The following information is to be presented to the site Radiation Safety Officer (RSO), authorized user and the medical physicist and provides an overview of the GammaMed safety features and emergency responses. This training does not represent clinical or applications training.

During all patient treatments, the authorized user and either a medical physicist or the site Radiation Safety Officer must be physically present (see U.S. NRC Bulletin 93-01, April 20, 1993).

The site Radiation Safety Officer shall be responsible for the formal radiation safety training as required by site policy and local regulatory requirements. For the GammaMed transportable models, this course shall be conducted with relevant personnel at all operational sites.

It is the responsibility of the site to ensure regulatory compliance through the provision of maintenance and adequate testing of safety equipment and facilities.

| Feature | Available |
|---|---|
| Independent Treatment Room Radiation Monitor | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Slave Radiation Monitor in Console Area | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Beam on lamps | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Calibrated Survey Meter | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Patient Video Monitoring | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Patient Audio Monitoring | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Emergency Lighting in Treatment Room | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Emergency Lighting in Console Area | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| GAMMAMED Emergency Procedures on Display | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| VARIAN 24hr. Emergency Dispatch or Regional Office phone number displayed | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |

| | | | |
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3. GammaMed Safety Features

Confirm that the location of the following features and the correct operation where required.

| | |
|--|---|
| System Passwords | Confirmed <input checked="" type="checkbox"/> |
| Power Key Switch on Console (On/Off) | Confirmed <input checked="" type="checkbox"/> |
| Mode Key Switch on Console | Confirmed <input checked="" type="checkbox"/> |
| Mains & Battery Indicator on Console | Confirmed <input checked="" type="checkbox"/> |
| Normal & Special Mode Indicators on Console | Confirmed <input checked="" type="checkbox"/> |
| Safe Indicator on Console | Confirmed <input checked="" type="checkbox"/> |
| Locked Indicator on Console | Confirmed <input checked="" type="checkbox"/> |
| Start and Interrupt Switches on Console | Confirmed <input checked="" type="checkbox"/> |
| Emergency Return Switches | Confirmed <input checked="" type="checkbox"/> |
| (Console area and treatment room) | Confirmed <input checked="" type="checkbox"/> |
| Treatment Room Door Interlock Switch | Confirmed <input checked="" type="checkbox"/> |
| Last Man Out Switch / optional | Confirmed <input checked="" type="checkbox"/> |
| UPS for Console | Confirmed <input checked="" type="checkbox"/> |
| Afterloader self-contained Emergency Retract Batteries | Confirmed <input checked="" type="checkbox"/> |
| Afterloader Emergency Return Button | Confirmed <input checked="" type="checkbox"/> |
| Key on Afterloader Released/Locked | Confirmed <input checked="" type="checkbox"/> |
| Afterloader Radiation Detector | Confirmed <input checked="" type="checkbox"/> |
| Afterloader Wire Lock (transportable units only) | Confirmed <input checked="" type="checkbox"/> |
| Closed-end catheters and applicators | Confirmed <input checked="" type="checkbox"/> |
| Importance of containment issues discussed | Confirmed <input checked="" type="checkbox"/> |

4. Retract Operations / Conditions

There are five separate levels of Active Wire retract condition on the GammaMed Afterloader.

4.1 Normal Retract

A normal motor retract occurs due to treatment completion or treatment interruption.

Confirmed ☒

4.2 Emergency Retract by Error Conditions

Automatic Emergency Return is initiated (e.g. Failure of Data Connection). The motor retracts until source is in shielded position and Safe Indicator is lit.

Confirmed ☒

4.3 Emergency Retract by Pressing Emergency Return Switch

Automatic Emergency Return is initiated. The motor retracts until source is in shielded position and Safe Indicator is lit.

Confirmed ☒

4.4 Emergency Retract by Pressing Emergency Button Trolley

Automatic Emergency Return is initiated. The motor retracts until source is in shielded position and Safe Indicator is lit.

Confirmed ☒**4.5 Active Source Wire Manual Retract Hand Wheel**

The manually operated Active Source Wire Emergency Retract hand wheel is provided in the event that the Afterloader fails to retract the active wire to its park position:

Active Source Wire only (Not for Dummy Wire Manual Retract) Confirmed ☒

5. Emergency Procedures

It is essential that the user familiarize themselves with and regularly rehearse the procedures outlined below.

Refer to the GammaMed User Manual and relevant User Manual Amendment sheets for relevant Emergency Procedures.

Confirmed ☒

With an Inactive wire installed, discuss failure mode scenarios and simulate activating Emergency Return Switches and using Manual Retract hand wheel to return source to a Safe Position.

Confirmed ☒**6. Emergency Procedures**

Varian Brachytherapy must be immediately notified by phone and provide a written account of the occurrence as soon as possible when any activity related emergency is encountered during the use GammaMed equipment.

U.S. Contact:

24 Hours GammaMed Dispatch (800) 864-1672
VBT North America Customer Support Manager
Charlottesville, VA
Ph: 434-977-8495, Extension 239
VBT Radiation Safety Officer
Varian Brachytherapy
Charlottesville, VA
Ph: 434-977-8495, Extension 275

Confirmed ☒**International Sites Contact:**

The Regional Service Office as applicable.

Confirmed ☐

7. Acknowledgment of course demonstration

To be copied to each member of site personnel attending training course.

| | |
|---|---------------------------------------|
| Institution Name: | Missouri Baptist Med Center |
| Address: | 3015 N. BALLAS ST. LOUIS, MO 63131 |
| GammaMed Afterloader Serial Number: | 640 568 |
| Date on which training completed: | 1/13/11 |
| GammaMed Representative: (Print name) | Danny Bernard |
| Signature: | <i>Danny Bernard</i> |
| Customer Representative(s): (list names) | Mano Fagundes |
| | Amy Sommer |
| | Mark W. Wiesmeyer |
| | <i>[Signature]</i> |
| | Louis Fadel |

MISSOURI BAPTIST MEDICAL CENTER

3015 N. Ballas Road
St. Louis, Missouri 63131-2374

Tom Moenster

BJC HEALTH SYSTEM

PLACE STICKER AT TOP OF ENVELOPE
OF THE RETURN ADDRESS.

CERTIFIED



7010 1870 0002 2433 8433

Hasler

04/20/2011

US POSTAGE

\$05.79



ZIP 63110
011D12601696

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