

January 31, 2012

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Attention: Sandy Gabriel

As per your request, I have provided vendor specific training for Dr. Allen Kratzer to become an Authorized User on license number: 06-08349-04, I am detailing the results of the training.

As per 10 CFR 35.690(c), Dr. Kratzer has been instructed in the proper operation of the device, safety procedures and site specific clinical uses of the device. The clinical focus of the training was on endometrial cancer being treated with vaginal cylinders and breast cancer cases being treated with a multi-lumen balloon catheter. A discussion of the importance of proper written directives and appropriate dosing schemes were also discussed. In addition, proper operation of the device was also reviewed. A complete description of the site specific applicators, transfer tubes and associated equipment was reviewed. To ensure that adequate training was delivered to Dr. Kratzer, I utilized the emergency training guide provided by Varian for Gamma-Med users when discussing emergency procedures. I have attached the document which details the specific items covered during our training session.

In addition to the training described above, I have also highlighted the differences between the Nucletron system (for which Dr. Kratzer is currently an AU) and the Varian Gamma-Med system. The primary differences noted were the fact that the Varian treatment planning system utilizes a nominal 10 Curie source while the Nucletron TPS decays the source at the time of planning, the Varian system uses a universal and fixed length 130 cm catheter/applicator combination while the Nucletron system has the ability to use variable length combinations and how the Varian after-loader has 5 active channels of which only three may be used at any given time with channels 1 through 3 performing and end test while channels 23 and 24 do not perform the end test.

If you have any technical question regarding this amendment request, please do not hesitate to contact me at (860) 331-9379 or by e-mail at gp219@columbia.edu

Prepared by:

A handwritten signature in black ink, appearing to read 'G. Pavlonnis', with a long horizontal line extending to the right.

George Pavlonnis, III M.S. DABR
American Board of Radiology Certified Medical Physicist
NRC Authorized Medical Physicist

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|--|--|-------------------|--------------------|
| Varian Medical Systems | TITLE: <i>GammaMed</i> Customer Emergency Training Course | | |
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Varian Brachytherapy

GammaMed Customer Emergency Training Course

1. Introduction

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.

US ONLY:

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.

2. Regulatory Compliance / Site Specific Issues

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 (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 type="checkbox"/> N/A |
| 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 type="checkbox"/> N/A |
| 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

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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 10/12