



December 9, 2009

U.S. Nuclear Regulatory Commission  
Region III  
2443 Warranville Road, Ste 210  
Lisle, IL 60532-4352

Re: NRC License 13-188879-01

Dear Sir/Madam:

We would like to amend our NRC License No. 13-18879-01 to include Brion Shin, M.D. as authorized user for Iridium-192 remote afterloading brachytherapy device. Dr. Shin is currently authorized user of 10 CFR 35.400 under our license.

In support of this request we have included Dr. Shin's records of his training on the operation and safety features of the remote afterloading device and his clinical training under the preceptorship of Dr. Cohen and Dr. Tran. Dr. Cohen and Dr. Tran are currently authorized users of the remote afterloading device under our license. Dr. Cohen and Dr. Tran have also signed the enclosed statements attesting the records of Dr. Shin.

If you have any question please contact me at (574) 523-7857.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Steven Leung', is written over a light blue horizontal line.

S. Steven Leung, Ph.D.  
Radiation Safety Officer

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**Preceptor Attestation (continued)**

**Third Section**

**For 35.690: (continued)**

I attest that Brian Shin, M.D. has received training required in 35.690(c) for device  
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Remote afterloader unit(s)     Teletherapy unit(s)     Gamma stereotactic radiosurgery unit(s)

**AND**

**Fourth Section**

I attest that Brian Shin, M.D. has achieved a level of competency sufficient to  
Name of Proposed Authorized User

achieve a level of competency sufficient to function independently as an authorized user for:

Remote afterloader unit(s)     Teletherapy unit(s)     Gamma stereotactic radiosurgery unit(s)

**Fifth Section**

**Complete the following for preceptor attestation and signature:**

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

35.400 Manual brachytherapy sources     35.600 Teletherapy unit(s)

35.400 Ophthalmic use of strontium-90     35.600 Gamma stereotactic radiosurgery unit(s)

35.600 Remote afterloader unit(s)

Name of Preceptor

Signature

Telephone Number

Date

Toel N. Cohen, M.D.

574-523-7857

12/9/09

License/Permit Number/Facility Name

13-18879-01 Elkhart General Hospital

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**Preceptor Attestation (continued)**

**Third Section**

**For 35.690: (continued)**

I attest that Brian Shin, M.D. has received training required in 35.690(c) for device  
Name of Proposed Authorized User  
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Remote afterloader unit(s)      Teletherapy unit(s)      Gamma stereotactic radiosurgery unit(s)

**AND**

**Fourth Section**

I attest that Brian Shin, M.D. has achieved a level of competency sufficient to  
Name of Proposed Authorized User  
achieve a level of competency sufficient to function independently as an authorized user for:

Remote afterloader unit(s)      Teletherapy unit(s)      Gamma stereotactic radiosurgery unit(s)

**Fifth Section**

**Complete the following for preceptor attestation and signature:**

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

35.400 Manual brachytherapy sources      35.600 Teletherapy unit(s)

35.400 Ophthalmic use of strontium-90      35.600 Gamma stereotactic radiosurgery unit(s)

35.600 Remote afterloader unit(s)

Name of Preceptor

Nguyen Binh Tran, M.D.

Signature

Telephone Number

572-523-7857

Date

12.19.09

License/Permit Number/Facility Name

13-18879-01 Elkhart General Hospital

Clinical Training Record of Ir-192 Remote Afterloading Device (HDR) Treatments of Brion Shin, M.D.

Date	Patient's Name	Type of Treatment	Preceptor	Remark
8/11/2009	DF	virginal cuff	Joel Cohen, MD	
8/12/2009	RP	virginal cuff	Binh Tran, MD	
8/19/2009	RP	virginal cuff	Binh Tran, MD	
8/26/2009	RP	virginal cuff	Binh Tran, MD	
8/19/2009	BT	virginal cuff	Binh Tran, MD	
8/26/2009	BT	virginal cuff	Binh Tran, MD	
9/2/2009	BT	virginal cuff	Binh Tran, MD	
9/3/2009	BM	virginal cuff	Joel Cohen, MD	
9/28/2009	MM	Mammosite	Joel Cohen, MD	2 treatments, AM & PM
10/5/2009	CT	virginal cuff	Joel Cohen, MD	
10/5/2009	BW	Mammosite	Binh Tran, MD	
10/9/2009	BW	Mammosite	Binh Tran, MD	
10/20/2009	BC	Mammosite	Joel Cohen, MD	
10/28/2009	ML	Mammosite	Joel Cohen, MD	
10/29/2009	ML	Mammosite	Joel Cohen, MD	
10/28/2009	DJ	virginal cuff	Binh Tran, MD	
11/30/2009	BR	virginal cuff	Joel Cohen, MD	

<b>Varian Medical Systems</b>	<b>TITLE: <i>GammaMed</i> Customer Emergency Training Course</b>		
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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
- Slave Radiation Monitor in Console Area
- Beam on lamps
- Calibrated Survey Meter
- Patient Video Monitoring
- Patient Audio Monitoring
- Emergency Lighting in Treatment Room
- Emergency Lighting in Console Area
- GAMMAMED Emergency Procedures on Display
- VARIAN 24hr. Emergency Dispatch or Regional Office phone number displayed

- Yes  No
- Yes  No
- Yes  No
- Yes  No
- Yes  No
- Yes  No
- Yes  No
- Yes  No
- Yes  No
- Yes  No

*Flashlight*

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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 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

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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



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### 7. Acknowledgment of course demonstration

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

Institution Name:	Elkhart General Hospital
Address:	Radiation Oncology 600 East Blvd Elkhart, IN 46510
GammaMed Afterloader Serial Number:	64A050
Date on which training completed:	Nov 19, 2009
GammaMed Representative: (Print name)	Mike Wells
Signature:	<i>Mike Wells</i>
Customer Representative(s): (list names)	<i>X Dwight MD, Guy Kedziora, MD,</i> <i>Brian Shin, M.D.</i> <i>Lang Wauzy, MS, PARR</i>



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### 7. Acknowledgment of course demonstration

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

Institution Name:	<i>Elkhart General Hospital</i>
Address:	<i>Radiation Oncology 600 East Blvd Elkhart, IN 46514</i>
GammaMed Afterloader Serial Number:	<i>64A050</i>
Date on which training completed:	<i>Nov 19, 2009</i>
GammaMed Representative: <i>(Print name)</i>	<i>Mike Wells</i>
Signature:	<i>Mike Wells</i>
Customer Representative(s): <i>(list names)</i>	<i>X <del>Shing</del> MD. Guy Kedziora, MD, Briou Shin, M.D. Shing Wang, MS, DABR</i>

S. Leung  
Elkhart General Hospital  
Elkhart, IN 46514

PRESORTED  
FIRST CLASS



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12/10/2009

Mailed From 46528

US POSTAGE

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Region III

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Lisle, IL 60532-4352

TEMP RETURN SERVICE REQ.

\*\*12-11-09 SB IN 466

EMDJNMT 60532

