



801 Ostrum Street  
Bethlehem, PA 18015  
610-954-4000

May 17, 2007

Tara Weidner  
Medical Licensing Branch  
U.S.N.R.C. Region I  
475 Allendale Rd.  
King of Prussia, PA 19406-1415

Dear Ms. Weidner,

Q-8

03003100

Please amend our N.R.C. byproduct material license, 37-07939-01 to include the following change of Radiation Safety Officer (RSO). Due to an unexpected and extended medical condition our Radiation Safety Officer Walter L. Robinson has determined that he can no longer fulfill his responsibilities as RSO. Mark Liddington of Walter L. Robinson and Associates assumed the roll of temporary RSO under the 60-day provision of 10 CFR 35.24 (3)(c) as of April 1, 2007. As Mr. Robinson and his team of physicians recently determined that he will be unable to return in the foreseeable future, we wish to amend our license to delegate the responsibilities of RSO to Mr. Liddington. Effective May 29, 2007, Mr. Liddington will assume the duties associated with this appointment. Mr. Liddington is currently R.S.O. at Easton Hospital, Easton, PA (NRC license #37-09938-01) (3 days/month) and Advanced Breast Care Imaging, LLC, Allentown, PA (NRC license #37-31178-01) (1 day/month). Mr. Liddington has confirmed that he has adequate time to facilitate the necessary contracted services of R.S.O. at our facilities and will be available 24/7 by pager, email or cellular phone. Mr. Liddington's credentials are on file under the two facilities mentioned above, and additional training related to high dose rate brachytherapy is enclosed. Due to the time sensitive nature of this amendment, we request that you expedite your review of this proposal.

Like Mr. Robinson, Mr. Liddington is an outside consultant/contractor employed by Mr. Robinson and has over 15 years of experience in the field of medical physics. An overview of his ability to adequately manage the radiation safety program follows.

- **Regarding the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.**

140530

NMSS/RGN1 MATERIALS-002

BEST PLACES  
to work in **PA**

We have delegated Mr. Liddington the duties and responsibilities of the Radiation Safety Officer as stated in 10 CFR 35.24 and as outlined in NUREG 1556 rev. 1 (final version).

Mr. Liddington will have authority to meet these responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety.

Mr. Liddington will be required to notify management if staff do not cooperate and do not address radiation safety issues as advised or recommended.

Mr. Liddington will have the authority to raise issues with the Nuclear Regulatory Commission at any time.

- **Explanation of the relationship that will exist between the consultant-RSO and institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.**

Mr. Liddington will communicate with institutional management on a monthly basis outlining any needs that are required to facilitate the objectives of the radiation safety program and related regulatory requirements. Also Mr. Liddington will participate in the quarterly Radiation Safety Committee meetings.

- **Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).**

Mr. Liddington's consultant contract states that he will be on site a 4 days per month (one day per week). Additional times will be authorized if required to perform his duties.

Mr. Liddington is currently listed as the RSO at Easton Hospital in Easton, PA (NRC license #37-09938-01) and Advanced Breast Care Imaging, LLC in Allentown, PA (NRC license #37-31178-01).

- **Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.**

Helene Oplinger will continue to be the point of contact during Mr. Liddington's absence.

- **Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires this presence.**

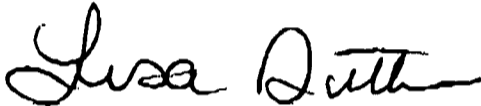
Mr. Liddington will be available 24 hours a day, seven days a week via a pager, email and/or cellular phone to respond to any questions or to address any operational issues. The consulting firm that employs Mr. Liddington has three other consultants that are also available - one of these associates, Mr. Jack Olley, is the RSO at multiple facilities.

The maximum amount of time it could take Mr. Liddington to arrive at the facility in the event of an emergency that requires his presence is 2.0 hours.

Mr. Liddington's residence is less than 30 minutes from all of the hospital network's facilities.

If you have any questions please contact Mr. Liddington at 1-800-446-7622 ext. 2.

Sincerely,



Lisa Dutterer  
Associate Vice President, Administration  
St. Luke's Hospital and Health Network



801 Ostrum Street  
 Bethlehem, PA 18015  
 610-954-4000

**Memo To: Radiation Safety Officer**  
**From: Lisa Dutterer, Associate Vice President**  
**Subject: Delegation of Authority**

You, Mark D. Liddington, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at anytime.

Signature of Management Representative,

A handwritten signature in cursive script that reads "Lisa Dutterer". The signature is written in black ink and is positioned above a horizontal line.

Lisa Dutterer, Associate Vice President, Administration

I accept the above responsibilities,

Signature of Radiation Safety Officer

A handwritten signature in cursive script that reads "Mark D. Liddington". The signature is written in black ink and is positioned above a horizontal line.

# The Reading Hospital and Medical Center



**DEPARTMENT OF RADIOLOGY**  
Section of Radiation Oncology  
Albert Yuen, MD, Chief  
Michael L. Haas, MD  
Telephone: 610-988-8067  
Facsimile: 610-988-9500

May 18, 2007

To whom it may concern:

I, Rene Smith, Ph.D., am an authorized medical physicist on NRC license # 37-00485-04 (Reading Hospital & Medical Center). On this license, condition 11. C. states that I am authorized for training in High Dose Rate Remote Afterloader units.


On May 18, 2007, I held a training session covering regulatory compliance, safety issues, retract operations and emergency procedures associated with high dose rate remote afterloader brachytherapy. The specific unit referenced during the training session was a Varian, Varisource 200. A copy of the training course is attached.

This letter certifies that Mark D. Liddington attended and completed the training referenced above and in the attached training course outline.

Sincerely,

Rene Smith, Ph.D.  
Authorized Medical Physicist  
Reading Hospital & Medical Center

Berks Radiation Oncology Associates  
Mailing Address: PO Box 16052 • Reading, PA 19612-6052  
Located at: Sixth Avenue and Spruce Street • West Reading, Pennsylvania

	<b>Varian Brachytherapy</b>
AL25244000 - <b>VarSource 200 Series Customer Emergency Training Course</b>	

### 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 VarSource 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 VarSource 200t model, 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 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"/>
VarSource Emergency Procedures on Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
VarSource 24hr. Emergency Dispatch or Regional Service Office Phone Number Displayed	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

	<b>Varian Brachytherapy</b> AL25244000 - <i>VarSource</i> 200 Series Customer Emergency Training Course
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### 3 VariSource Safety Features

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

- |   |           |                                     |
|---|-----------|-------------------------------------|
| Three position key switch on Console (Lock, On, Treat)        | Confirmed | <input checked="" type="checkbox"/> |
| Two position key switch on Afterloader (Lock, Treat)          | Confirmed | <input checked="" type="checkbox"/> |
| STOP switch on Afterloader, Wall Box and Console Box          | Confirmed | <input checked="" type="checkbox"/> |
| Emergency Stop Switch   | Confirmed | <input checked="" type="checkbox"/> |
| Treatment Room Door Interlock Switch                          | Confirmed | <input checked="" type="checkbox"/> |
| Last Man Out Switch   | Confirmed | <input checked="" type="checkbox"/> |
| UPS for Afterloader and Console                               | Confirmed | <input checked="" type="checkbox"/> |
| Afterloader self-contained Emergency Retract Batteries        | Confirmed | <input checked="" type="checkbox"/> |
| User mode Passwords (System access and Physics mode)          | Confirmed | <input checked="" type="checkbox"/> |
| Unique 5 digit Password to deliver patient treatment          | Confirmed | <input checked="" type="checkbox"/> |
| Afterloader Radiation Detector (with battery back-up)         | Confirmed | <input checked="" type="checkbox"/> |
| Afterloader Active Wire Lock and status indicator (200t only) | Confirmed | <input type="checkbox"/> NA         |
| 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 three separate levels of Active Wire retract condition on the *VarSource* 200 Series Afterloader.

#### 4.1 Main (Normal) Retract

A Stepper Motor retract occurs due to treatment completion, treatment interruption, or as a result of a non-emergency error.

Confirmed

#### 4.2 D.C. Motor Emergency Retract

Engagement of the Emergency Retract Motor is initiated by a self-detected emergency condition or as a result of Main (Normal) Retract failure, such as falling to park the Active Source wire.

Confirmed



The Emergency Retract Motor will operate until the Active wire reaches the parked position or until the Afterloader Retract Battery is drained. Site

<b>VARIAN</b> <small>medical systems</small>	<b>Varian Brachytherapy</b>
<b>AL25244000 - VarSource 200 Series Customer Emergency Training Course</b>	

personnel are advised that the source may continue moving back into the Afterloader anytime that the hand wheel is turning.

**4.3 Active Source Wire Manual Retract Handwheel**

The manually operated Active Source Wire Emergency Retract Handwheel is provided in the event that the Afterloader fails to retract the Active wire to the parked position:

- Active Source Wire Only (Not for Dummy Wire Manual Retract) Confirmed
- Maximum of 12 Turns or until Radiation Detector is silenced Confirmed

**5 Emergency Procedures**



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

Refer to the VarSource 200 Series User Manual and relevant User Manual Amendment sheets for relevant Emergency Procedures.

Confirmed

With an Inactive wire installed, VarSource personnel will disconnect the Emergency Retract Batteries extend the Inactive wire to 150.0cm under Diagnostic Mode, and remove A/C power, leaving the Inactive wire extended.

Each site-designated person will perform a manual retract of the wire by turning the Emergency Handwheel until the wire is in the safe and parked position.

Confirmed

**6 Emergency Procedures**

Varian Oncology Systems 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 VarSource equipment.

**U.S. Contact:**

24 Hours VarSource 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



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AL25244000 - <i>VariSource</i> 200 Series Customer Emergency Training Course	

**International Sites Contact:**

The Regional Service Office as applicable.

Confirmed



801 Ostrum Street  
Bethlehem, PA 18015  
610-954-4000

May 15, 2007

To whom it may concern:

On May 15, 2007, I met with Mr. Mark Liddington of Walter L. Robinson and Associates to educate him about our Nucletron, Microselection High Dose Rate remote afterloader system. I spoke with him about our quality control procedures, protocols and emergency procedures.

I am an authorized user on NRC license # 37-08939-01 (St. Luke's Hospital).

Sincerely,

A handwritten signature in black ink, appearing to read "Tianyou Xue".

Tianyou Xue, Ph.D.  
Medical Physicist  
St. Luke's Hospital & Health Network