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MS 16  
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February 1, 2007

Licensee: Geisinger Health System  
License: #37-01421-01  
Subject: Response to NRC Request for Additional Information dated 1/22/07 (email and phone call)  
Amendment Request to add HDR to GWV Hospital  
Docket #: 03002984  
Control #: 139717

The information contained herein is the response to your email dated 1/22/07, requesting additional information relative to our request to add a second HDR to our broad scope license, to be used exclusively at Geisinger Wyoming Valley Medical Center, 1000 E. Mountain Drive, Wilkes-Barre, Pa. Please find attached the revised emergency procedures you requested. In addition, we would like to clarify the following points, which were expressed in our original amendment request, but may not have been completely clear to the NRC reviewer:

1. We will not conduct any HDR patient treatments unless both the AMP and AU are physically present, as per 10 CFR 35.615(f)(2)
2. We will be performing full calibration procedures quarterly, as per 10 CFR 35.633
3. Chamber and electrometer calibration will be performed at least every two years, or within the previous four years if intercompared, as per 10 CFR 35.630

We would appreciate your prompt review and expedited approval of this request.

Very Sincerely,

*Catherine M. Anderko*

Catherine M. Anderko, M.S., CHP, DABR  
Director, Radiation Safety Officer  
Geisinger Health System

*Robert W. Davies*

Robert W. Davies  
Vice President - System Services  
Geisinger Health System

**Attachment #5**

**HDR Remote Afterloader at Geisinger Wyoming Valley Medical Center (GWV)**

**Emergency Procedures for Varian Varisource HDR**

**Submitted on February 1, 2007**

**Emergency Equipment and Supplies:**

The following emergency equipment and supplies shall be readily available and accessible at all times, stored in the immediate vicinity of the HDR treatment room:

- Two pair of long-handled forceps (~ 30 cm)
- Shielded emergency storage container (pig)
- Heavy duty cable cutters and scissors
- Pliers
- Personnel dosimeters: whole body film badges and TLD rings
- Portable survey meter
- Stop watch or timer
- Emergency response flowchart provided by the manufacturer
- Emergency response flowchart for patient source retraction provided by the manufacturer
- Emergency response procedures and contact telephone numbers posted at the HDR console
- Sign "Do Not Enter By Order of Radiation Safety Officer"

**1. Source Retraction using the Emergency Return Switch:**

- In the case of an urgent situation which requires an immediate entry into the HDR treatment room, such as a patient care emergency, press the "INTERRUPT" button on the control console or the "EMERGENCY RETURN" switch located in the room. This is to be done by the AMP or AU. The "EMERGENCY RETURN" switch directly controls the source drive, bypassing the PC, and retracts the source with maximum speed.
- In the retracted mode, when properly executed, the "SOURCE SAFE LED" indicator on the control console illuminates and the "RADIATION" symbol light goes out. Verify that these two conditions are in place.
- The message "INTERRUPT MANUAL" or "EMERGENCY MANUAL" will be displayed in the Alarm window or in the status line of the Irradiation window. Confirm that the message is observed.
- Clear the cause of the alarm. Inform and calm the patient.

***To Continue Treatment Following an Interruption:***

- To continue a treatment after the "Interrupt" button has been used, press "START" on the control console. This is to be done by the AMP or an HDR Radiation Therapist. The treatment will continue and only the remaining dwell positions and times will be irradiated. The warning and status indicators

relevant for the treatment mode will re-illuminate. If the cause of the failure has not yet been corrected, the alarm report will be re-issued.

### ***To Continue Treatment Following an Emergency Return:***

- To continue a treatment after the “Emergency Return” button has been used, re-enter the total nominal time into the irradiation window and confirm it by clicking “START”. This is to be done by the AMP or the AU. Continue the treatment by pressing START on the control console. This is to be done by the AU or the HDR Radiation Therapist.

### **2. Source Retraction Using the Emergency Button:**

- In certain emergencies (a person is discovered in the treatment room after patient treatment is started, for example) an emergency source retraction can be made by pressing the “EMERGENCY” button on the chassis keyboard of the afterloader. The “EMERGENCY” button directly controls the source drive, bypassing the PC, and retracts the source with maximum speed.
- Press the “EMERGENCY” button on the afterloader chassis keyboard. Observe to ensure that the “RADIATION” warning light goes out and the hand held radiation monitor shows no radiation levels above background, to assure that the source has retracted into its shielded position. This is to be done by the AMP or AU.
- Clear the failure cause and continue the interrupted treatment. This is to be done by the AMP. (If an individual was present in the treatment room other than the patient, remove the person immediately).
- To continue, exit the treatment, and re-set the afterloader. Turn the POWER key on the control console to OFF and then ON again. Confirm the alarm window on the PC screen (a printout will be automatically generated). This is to be done by the AMP or AU.
- After passing the initial machine test, a window showing the treatment recovery protocol appears. Confirm the protocol by clicking “OK”. This is to be done by the AMP or AU.
- Re-enter the total nominal time in the irradiation window and confirm it by clicking “START” on the screen. This is to be done by the AMP or AU.
- Continue the treatment by pressing “START” on the control console. This is to be done by the AU or the HDR Radiation Therapist.

### **3. Manual Emergency Retraction with Handcrank:**

- In the unlikely case of the automatic emergency source retraction systems failure, and an acute radiation hazard exists because of an unshielded radiation source, immediate manual source retraction measures are necessary.
- Manual retraction may only be performed by trained and experienced AU’s or AMP’s (the individual must have received emergency response training from the manufacturer within the past 12 month period). Under no circumstances will pregnant workers or workers under the age of 18 be allowed to perform this task, due to the radiation level present in the room while the source is exposed.
- In this circumstance, the top priority is quickly and safely evacuating the patient from the HDR room. The 2<sup>nd</sup> priority is transferring the source to its shielded position so that radiation levels within the HDR room return to normal.

- The Radiation Safety Officer (RSO) or a Health Physicist designated by the RSO must be notified as soon as possible after it is recognized that a manual source retraction is necessary.
- An alarm signal will be audible and the ALARM indication lights on the control console will illuminate. Also illuminated will be the yellow indicators, "SOURCE OUT" and "RADIATION".
- Switch off the alarm signal by pressing the "BUZZER OFF" button on the control console. Check the last position of the source (channel and position) on the monitor.
- Attempt emergency retraction by pressing the "INTERRUPT" button on the control console, or the "EMERGENCY RETURN" switch located in the treatment room.
- If not successful with the automatic retraction mechanisms, enter the treatment room and go straight to the afterloader. **At the same time**, secure the treatment room against unauthorized entry by posting the door with a "DO NOT ENTER BY ORDER OF THE RADIATION SAFETY OFFICER." sign. The door shall be continuously monitored by personnel from Radiation Safety or the Department of Radiation Oncology to ensure that no one enters except for authorized Varian service personnel.
- Enter the treatment room with a portable radiation survey meter (ionization chamber). Calm the patient. Record the exposure rate(s) at relevant locations. Use a stopwatch to estimate stay times in the radiation area. Note distances of personnel within the room with respect to the patient and HDR unit. This is to be done by the AMP or AU.
- The AU or AMP shall work quickly and efficiently to manually return the source to the safe shielded position, using the procedure outlined by the manufacturer. Use the handcrank at the back of the afterloader. Pull the handle out of the hand-crank and turn the crank in the direction of the arrow until a distinct resistance is noticeable or the room radiation level is consistent with that measured while the source is properly seated in the shielded position.
- If the manual retraction of the source fails, even with the handcrank, the source must be recovered manually. Failure of the hand-crank may indicate a severed line, an obstruction in the source guide tube or the applicator, or a defective drive system. Regardless of cause, manual recovery may only be performed by Varian Service personnel.
- If the manual retraction of the source is indeed necessary, a severe defect of the system usually exists. Inform the Varian BrachyTherapy Service Department for the manual recovery of the source (see next section) and a safety check of the HDR unit.

#### 4. **Stuck or Detached Source- Manual Recovery:**

- Manual recovery is necessary when either the motor-driven automatic source retraction, or the manual emergency source retraction, fail. In such a case, manual recovery of the source is required immediately.
- The manual retrieval of the source may only be performed by Authorized Varian Service Personnel.
- Enter the treatment room with a portable radiation survey meter (ionization chamber). Calm the patient. Record the exposure rate(s) at relevant occupied locations (near patient and where others are standing). Use a stopwatch to estimate stay times in the radiation area. Note distances of personnel within the room with respect to the patient and HDR unit. This is to be done by the AMP or AU.
- Remove the applicator from the patient using pliers or another appropriate tool to facilitate the removal expeditiously. This is to be done by the AU and AMP. **Note: Only those HDR treatments where a plan for expeditious removal of a jammed or decoupled source has been identified may be performed.**

- Remove the patient from the treatment room. This is to be done by the AMP, AU, or the HDR Radiation Therapist. Survey the patient immediately with a portable radiation detector (GM meter) to ensure that no radiation source remains in or around the patient. The readings observed near the surface of the patient should be indistinguishable from normal background radiation.
- Place the applicator in the designated emergency container, making sure that the source guide tube is not damaged or kinked. Do not disconnect the applicator from the HDR unit under any circumstances. Record the exposure rate in the treatment room and other relevant locations. This is to be done by the AMP or AU.
- After removal of the patient, attempt to clear the cause of the problem and attempt emergency retraction by pressing the "Emergency" button on the chassis keyboard, or by turning the hand-crank on the back of the afterloader in the direction of the arrow until resistance is noticeable or the room radiation level is appropriate for a shielded source. If the automatic and manual retraction crank methods fail, lock the HDR treatment room in order to safeguard persons against unauthorized entry. Place a sign on the door that forbids entry by order of RSO. This is to be done by the AMP.
- Contact Authorized Varian Brachytherapy Service Personnel to immediately perform a manual recovery, and revalidate the unit for further operation.
- Before restarting the afterloader for normal operation, perform the usual safety checks.

#### **General Emergency Response Summary:**

- All staff involved with the HDR program including AMP's, Authorized Users, Radiation Therapists, Health Physicists, and the Radiation Safety Officer will be trained in the written HDR emergency response procedures at a minimum of annually, and provided a written copy. This training will be conducted by an Authorized Medical Physicist and the Radiation Safety Officer. The written emergency procedures will be readily available at the HDR Console.
- Only personnel who have attended annual Varian HDR emergency response training provided by the manufacturer are allowed to respond to an emergency involving the Varian HDR unit. A record of attendance and a description of the course content are required to be maintained in an auditable format.
- Remove the patient from the treatment room
- Survey the patient with a radiation detection survey meter to ensure that no sources remain in the patient
- Evacuate the patient out of the area
- Post a warning sign on the treatment room door clearly warning personnel not to enter the room
- Notify the RSO immediately
- The RSO shall make the appropriate notifications to the NRC and or State Radiation Protection Agency. Varian Medical Systems shall be notified as soon as possible by a member of the Radiation Oncology HDR team.
- Estimate stay times and personnel doses to all individuals involved with the response

**Emergency Contact Telephone Numbers (posted at the control):**

- 24 hour manufacturer emergency contact (Dispatch): (800) 864-1672  
Varian Technical Support: (800) 360-7909  
Stephen Crawford, Varian BrachyTherapy Service Manager  
(888) 666-7847 ext. 239 or (434) 977-8495 ext. 239  
(434) 244-7181 fax
- NRC Operations Center (301) 816-5100
- Radiation Safety Officer: Office: 570 271-5917 or 271-7015 Pager: [REDACTED] Cell phone: [REDACTED]
- Physician AU's: 570 820-6150
- Authorized Medical Physicist: 570 820-6162
- Director, Radiation Physics, Department of Radiation Oncology: 570 271-6304 Pager: [REDACTED]

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