

## Mullauer, James

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**From:** Paul Jursinic [pjursinic@wmcc.org]  
**Sent:** Friday, October 01, 2010 11:45 AM  
**To:** Mullauer, James  
**Subject:** HDR operation and safety procedures  
**Attachments:** WMCC Op and Safety Emergency.doc

James,

This is a copy of the HDR "operation and safety procedures" guide that all staff members must read, understand, and sign prior to working with our Varian GammaMed Plus HDR unit.

Please call if you have other questions.

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# West Michigan Cancer Center High Dose Rate, HDR, Brachytherapy

## Operation and Safety Procedures

### INTRODUCTION

These procedures are applicable to HDR brachytherapy carried out at West Michigan Cancer Center, WMCC.

These procedures are written to promote high confidence that brachytherapy radiation treatments using the GammaMed HDR unit will be administered as directed by the authorized user, and in doing so, insure that the patient, staff, and general public are not exposed to unnecessary radiation.

The Nuclear Regulatory Commission (NRC) defines and enforces the regulations for the use of radiation in Michigan. A copy of the regulations, 10 CFR Part 35, is kept in the Physicists office. In addition, these regulations can be accessed on the NRC's website (<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/>)

The regulations require that each facility that uses radioactive materials for the treatment of humans, have a radioactive material license that is granted by the NRC. The Radioactive Material License for this facility (and all supporting materials and procedures) is kept in the Physicist's office. Compliance with the Conditions of the Radioactive Material License is mandatory.

Compliance with these Operating and Safety Procedures is also mandatory.

### CREDENTIALS

1. All physicians, physicists, and therapists carrying out HDR procedures will have read these procedures and signed the log kept by the WMCC Radiation Safety Officer before initial use of the unit and annually thereafter.
2. Authorized Physician Users shall be approved by the NRC and be listed by name on the Radioactive Material License in order to perform HDR brachytherapy.
3. The Medical Physicist shall maintain a certification in Therapeutic Physics. In addition, the Medical Physicist shall be approved by the NRC and be listed by name on the Radioactive Material License in order to participate in HDR procedures and perform (or directly supervise) calibrations and quality assurance testing.
4. Any Therapist assisting in HDR procedures shall maintain a current AART registration

## PERSONNEL RADIATION EXPOSURE MONITORING

1. All personnel shall wear LUXEL radiation dosimeters supplied by Landauer, Inc (or other NVLAP accredited provider).
2. The LUXEL badges will be processed at least quarterly.
3. Radiation exposure reports will be reviewed by the physicist and the RSO. The reports will be maintained in the physicist's office.

## FACILITIES

1. The HDR unit will be located and operated only in the dedicated HDR suite.
2. The HDR suite is equipped with an intercom and CCTV system so that the patient can be continuously monitored during treatment. These systems must be operational for a treatment to be given.
3. A Survey Meter (Victoreen 451P or comparable instrument that is capable of measuring radiation exposures from 0.1 mR/hr to 5 R/hr) will be located at the control console during all treatments.
4. The treatment room door shall be posted with a "CAUTION, RADIOACTIVE MATERIAL" sign and a "DANGER, HIGH RADIATION AREA" sign.
5. The HDR unit shall be labeled with a "CAUTION, RADIOACTIVE MATERIAL" sign that includes the source activity, date, and initials of the person who made the measurement.
6. A copy of these Operation and Safety Procedures and the training log shall be located at the control console.
7. The Varian Emergency Procedures, which are shown in Fig. 1, shall be posted at the control console.
8. When the device is not in use, the afterloader unit will be secured in a locked closet in the HDR room. The GammaMed unit and console shall both be disabled by removing their lock keys. All keys will be maintained in a secure location.

## MAINTENANCE

1. Maintenance shall only be performed by Varian Medical Systems. This includes installation, repair, preventative maintenance inspections and source exchanges.
2. The HDR unit will be fully inspected and maintained during each source exchange.
3. The Certified Medical Physicist or RSO shall be physically present during all maintenance on the HDR unit.
4. Records of all maintenance and repair work shall be maintained for the duration of the license.

# QA PROCEDURES

## 1. **Before first clinical use after: initial installation, source replacements, and software upgrades**

- The Certified Medical Physicist will review the treatment planning system documentation to understand the algorithms used in the system and their inherent limitations and assumptions.
- The Certified Medical Physicist shall perform acceptance testing on the Treatment planning software to determine the accuracy of the calculations. This includes verifying the accurate transfer of data from CT to the Planning system and to the HDR console.
- The Certified Medical Physicist will verify that both the treatment planning computer and the HDR console units have the correct factors for treatment planning and treatment delivery.
- All new applicators will be characterized before clinical use.
- The Certified Medical Physicist will perform the quarterly (source change) QA procedures.

## 2. **Prior to first treatment each treatment day**

- The day-of-use checks must be carried out successfully by a physicist before a treatment is given.

## 3. **Prior to each patient treatment.** The Certified Medical Physicist will perform the following checks before each patient is treated:

- Verify that the Physician's written prescription is in the chart and that the plan agrees with the prescription.
- Verify source activity and calibration date on treatment planning printouts
- Verify patient identity and correct patient file name
- Plan dwell times verified by physician and physicist
- If multiple channels are used, verify that the correct catheter is connected to the correct machine channel
- Verify correctness of patient information on printouts
- Insure that all catheter connections from the afterloader to patient are as straight as possible
- Insure that all catheters are fully seated into the machine connectors
- Verify that the Daily QA has been performed and verified by a physicist.

**4. At Source change (or quarterly).**

- The source-exchange checks must be carried out successfully by a physicist before a treatment is given with a new source.

**5. Annual checks**

- Survey Meter Calibrations - Each survey meter will be calibrated annually by an authorized vendor.
- Annual review of training will be performed by the RSO or Certified Medical Physicist.
- Electrometer/Well chamber calibration – each electrometer/well chamber will be calibrated every two years by an authorized vendor (ADCL).

## **GENERAL SAFETY PROCEDURES**

1. HDR Brachytherapy treatments shall be only given according to the signed, written prescription of an Authorized Physician User. The prescription shall include at least the patient's name, radionuclide, treatment site, dose/fraction, location of the dose prescription, number of fractions, and the total dose.
2. HDR brachytherapy shall not be administered unless there is a signed, witnessed consent of the patient or legally responsible party.
3. The radiation oncologist and medical physicist shall be physically present, within a distance of a normal speaking voice, during the treatment.
4. The radiation oncologist will perform a visual and mechanical test of the applicator before insertion into the patient. Applicators that are suspect will not be used.
5. The radiation oncologist shall approve the treatment plan before treatment.
6. The physicist shall approve the technical aspects of the treatment plan before treatment.
7. The patient will be visually monitored via a closed circuit TV system and monitored aurally with an intercom system. The patient shall not be treated if these monitoring systems are not functional.
8. Only the patient shall be in the treatment room when the source is exposed during the treatment. (No personnel or visitors)
9. After the treatment is complete, the Certified Medical Physicist (or Authorized User, or Dosimetrist or Therapist) shall survey the patient and the room to verify that the source has retracted into the HDR unit. This shall be documented in the treatment chart.
10. If the source has not retracted into the HDR unit, the posted Emergency Procedures, Fig. 1, shall be followed.

11. The Certified Medical Physicist (or Authorized User, or Dosimetrist or Therapist) will complete the treatment sheet in the chart after the treatment fraction has been completed.
12. The Certified Medical Physicist will check the treatment plan, calculation and delivery prior to every fraction. If a discrepancy is found, it will be reviewed with the Radiation Oncologist prior to the next fraction.
13. The Certified Medical Physicist will perform a final chart check at the completion of the treatment course.

# EMERGENCY PROCEDURES

1. **Required Equipment:** The following emergency equipment shall be readily available at all times:
  - a. A pair of long handled forceps (~ 30 cm).
  - b. Shielded container large enough to hold source and applicator.
  - c. Portable survey meter.
  - d. Flashlight.
  - e. Gloves.

## 2. Emergency Procedures for the GammaMed*plus* HDR Afterloader

### Emergency Response

In case of an operational failure of the system, alarm reports are displayed on the control console and the PC video display.

**Note:** Normally, the automatic safety functions of the afterloader system are activated, which retract the source immediately into its shielded position and the SOURCE SAFE LED indicator is illuminated. Nevertheless, an immediate control and clearing of the alarm cause is necessary.

**WARNING:** If the source has not retracted, follow the instructions in Fig. 1:

Figure 1.

 **GAMMAMED HDR AFTERLOADER  
EMERGENCY PROCEDURES**

Hierarchy of Interrupt Actions in case Emergency Retract is necessary. Each step assumes the failure of the previous step(s).

1. Press the **Interrupt** button on the Control Console Panel.
2. Press the **Emergency button** on the wall.
3. Open the **Treatment Room door** to allow Control Console Panel to indicate "Door Open".
4. Enter the Treatment Room and press the red **Emergency button** on the HDR Unit.
5. Turn the Emergency **Hand Crank** in the direction of the arrow.
6. If radiation survey shows the source is still in the patient, immediately summon attending physician to begin surgical or other removal procedure. Remove the Applicator from the patient and insert the Applicator containing the stuck or broken source into the Emergency Container. **DO NOT** cut the cable or guide tube, or disconnect guide tube from applicator or HDR unit.
7. Remove the patient from treatment room, and re-survey the patient. Seal the Treatment Room door with radioactivity warning labels and notify the RSO, physician, state regulatory agency, and Varian BrachyTherapy.

<p><b>VARIAN</b> medical systems</p> <p><b>24 HOUR DISPATCH &amp; EMERGENCY</b> <b><u>1-800-864-1672</u></b></p> <p><u>RADIATION SAFETY OFFICER - RICK PICCOLO</u> Office = 1-888-666-7847 x275, Cell = (434) 242-3314</p> <p><u>VARIAN BRACHYTHERAPY OFFICE</u> 1-888-666-7847 FAX = (434) 244-7181</p> <p>FORM: Plus 2/17/04 Excel</p>	
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## Automatic Emergency Retraction of the Source

In case of malfunction of the system (e.g. failures of the data connection to the afterloader or interruption of main AC power), the automatic safety function is activated. The radioactive source is immediately retracted automatically into its shielded position.

- The respective failure report appears in an alarm window of the PC video display. Acknowledge by pressing OK.
- A report of the interrupted treatment is printed automatically by GammaWin.
- Switch off the acoustic alarm signal by pressing BUZZER OFF on the control console.

**Note:** the ALARM indication keeps flashing until the cause is cleared and the ALARM is reset or START is pressed again.

**WARNING: RADIATION HAZARD!** Act quickly but carefully. Keep the maximal distance possible from the source. All operational personnel must be trained in radiation safety and emergency procedures as well as the functions of the afterloader. Perform the steps outlined in Figure 2 until successful.

Figure 2. GammaMedplus Emergency Response Flowchart



BRACHYTHERAPY

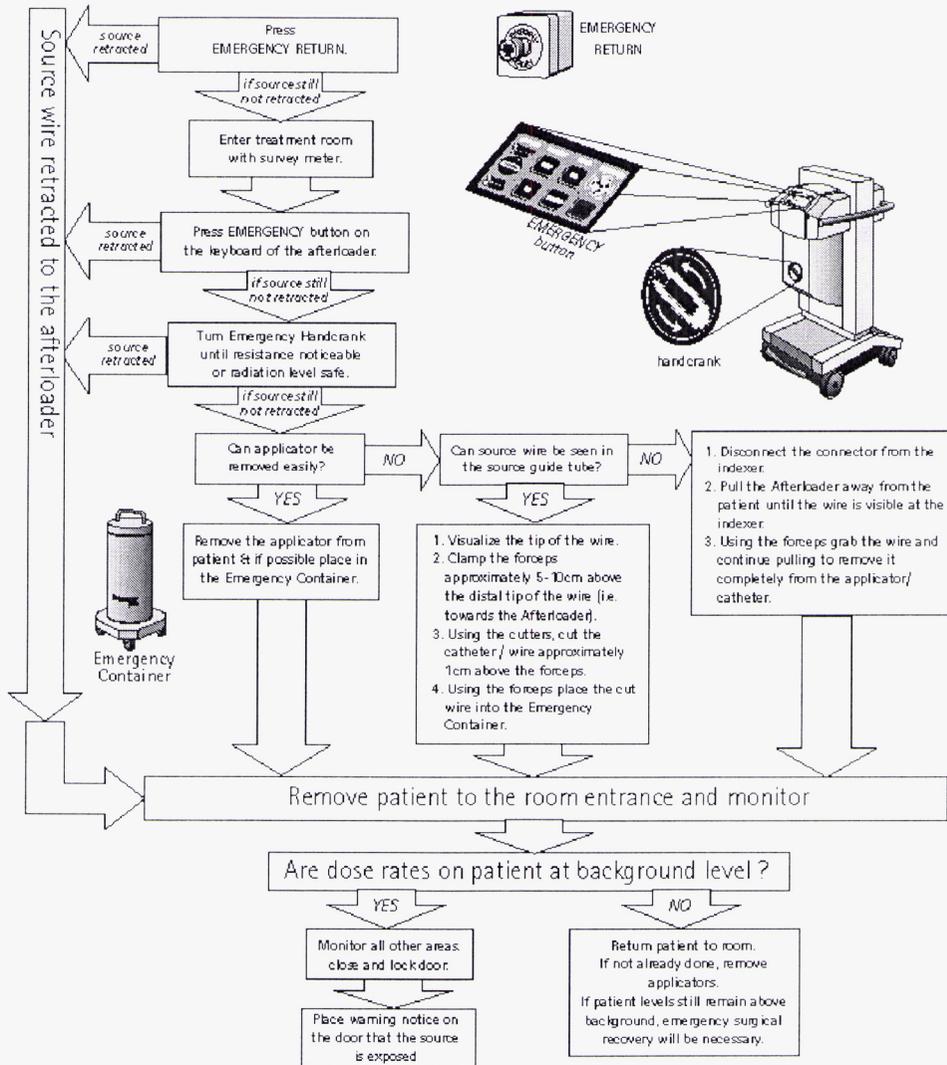
# EMERGENCY RESPONSE

In cases when automatic retraction of the source doesn't work.

**Attention: Radiation Hazard!**

Act quickly but carefully and keep maximal possible distance from the source!

All operational personnel must be trained in radiation safety and emergency procedures as well as the functions of the afterloader.



• Because of possible damage of safety relevant parts a safety check of the entire afterloading system has to be performed. We recommend to check the device by an authorized service technician before releasing for treatments.

Emergency-Information: call local service or  
 Varian Medical Systems Haan GmbH (Germany) : +49 21 29 551-0  
 Service Hotline USA: # 800 864-1672

Date : June, 06 2003

## Continuing an Interrupted Treatment

- Clear the alarm cause.
- Calm the patient and give her/him information about the incident and reassure her/him about the safe continuation of the treatment.
- Select a further detailed printout with the OK button.

**CAUTION:** CANCEL deletes all treatment data!

**Note:** The treatment continues and only the remaining dwell positions and times will be irradiated. The warning and status indicators relevant for the treatment mode illuminate, again. If the cause of failure has not yet been corrected, the alarm report is issued again. Re-enter the **total nominal time** into the **Irradiation** window and confirm it by clicking READY.

- Continue the treatment by pressing START on the control console.

## Emergency Retraction of the Source with Emergency Return Switch

- In case of an urgent emergency situation which requires an immediate entry into the treatment Room (e.g. an emergency situation with the patient), press the INTERRUPT button on the control console or the EMERGENCY RETURN switch located in the room.
- In the retracted mode, the SOURCE SAFE LED indicator on the control console lights and the RADIATION symbol is out.
- The message INTERRUPT MANUAL or EMERGENCY MANUAL is displayed in the Alarm window or in the status line of the **Irradiation** window.

**Note:** The EMERGENCY RETURN switch controls the source drive directly, bypassing the PC, and retracts the source with maximum speed. Clear the cause of alarm. Inform and calm the patient.

## Continuing an Interrupted Treatment

### **After Pressing INTERRUPT**

- Continue the treatment by pressing START on the control console.

**Note:** The treatment continues and only the remaining dwell positions and times will be irradiated. The warning and status indicators relevant for the treatment mode illuminate, again.

If the cause of failure has not yet been corrected, the alarm report is issued again.

### **After Pressing EMERGENCY RETURN**

- Re-enter the total nominal time into the irradiation window and confirm it by clicking START.
- Continue the treatment by pressing START on the control console.

## Emergency Retraction of the Source with Emergency Button

- In emergency cases (e.g. person in the treatment room and treatment is started) an emergency retraction can be made by pressing the EMERGENCY button on the chassis keyboard of the afterloader.

**Note:** The EMERGENCY button controls the source drive directly, bypassing the PC, and retracts the source with maximum speed.

- Press the EMERGENCY button on the afterloader chassis keyboard. Observe the RADIATION warning light and hand held radiation monitor to assure the source has retracted into its shielded position.
- Clear the failure cause and continue the interrupted treatment.
- To continue, quit the treatment room and switch the afterloader by turning the POWER key on the control console to OFF and ON again. Confirm the alarm window on the PC screen (a printout will be automatically generated).
- After passing the initial machine test, a window with the treatment recovery protocol appears. Confirm the protocol by clicking OK!
- Reenter the total nominal time in the irradiation window and confirm it by clicking START on the screen.
- Continue the treatment by pressing START on the control console.

## Manual Emergency Retraction with Handcrank

In the unlikely but possible case in which the automatic emergency retraction of the source does not work and an acute radiation hazard exists because of the unshielded radiation source, immediate manual measures are necessary.

**WARNING:** Entering the treatment room when there is an unshielded source exposes the person to an intensified radiation exposure. Persons under the age of 18 years and pregnant women are not allowed to perform this measure.

**Note:** The person in charge of radiation protection is obligated to take action and full responsibility.

- On the control console the ALARM indication lights and an alarm signal can be heard. The yellow indicators, SOURCE OUT and RADIATION, are illuminated.
- 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.
- Try emergency retraction by pressing the INTERRUPT button on the control console or the EMERGENCY RETURN switch located in the treatment room.
- If not successful, enter the treatment room and go straight to the afterloader.

### Simultaneously:

- Secure treatment room against unauthorized entry.
- Inform radiation safety officer.

**WARNING:** RADIATION HAZARD! Act quickly but carefully. Keep the maximum distance possible from the source. Use the handcrank at the back of the afterloader. Pull the handle out of the handcrank and turn the crank in direction of the arrow until a distinct resistance is noticeable or the room radiation level is safe.

- If the manual retraction of the source is impossible even with the handcrank, the source must be recovered manually.

**Note:** 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 and a safety check of the GammaMed*plus*.

## Manual Recovery of Source

A very unlikely but possible emergency situation might occur, if neither a motor-driven nor a manual emergency retraction of the source is possible. In such a case, a manual recovery of the source is required immediately.

**WARNING:** The manual salvage of the source is only allowed to be performed by Varian BrachyTherapy service.

## Stuck or Detached Source

If the source cannot be retracted even with the handcrank, it might be severed from the extension cable. Other possibilities are that it might be stuck in the source guide tube or the applicator, or the drive system is defective.

**WARNING:** RADIATION HAZARD! Act quickly but carefully. Keep the maximum distance possible from the source.

- Enter the treatment room with a hand held radiation survey meter. Calm the patient.
- Remove the applicator carefully with help of the pliers and under supervision of a doctor from the patient. Remove the patient from the radiation area.
- While placing the applicator in the emergency container, make sure that the source guide tube will not be damaged or kinked.
- After removal of the patient, if possible clear the cause of the problem and perform emergency retraction by operating the Emergency button on the chassis keyboard or by turning handcrank on the back of the afterloader in direction of the arrow until resistance is noticeable or the room radiation level is safe. If this is not possible lock the treatment room in order to safeguard persons against unauthorized entry.

**WARNING:** Inform the Service Department of Varian BrachyTherapy immediately. The afterloader has to be opened exclusively by Service Engineers of Varian BrachyTherapy.

- Before restarting the afterloader, perform a safety check.

### Emergency Contacts:

Authorized User: Linda Grossheim, M.D. 269-373-0104

Authorized Medical Physicist: Renu Sharma 269-373-7408  
Jim Reuter 269-373-0102

Radiation Safety Officer: Paul Jursinic, Ph.D. 269-373-7407

Nuclear Regulatory Commission Region III: 1-800-522-3025

Varian Medical Systems: 1-800-864-1672



