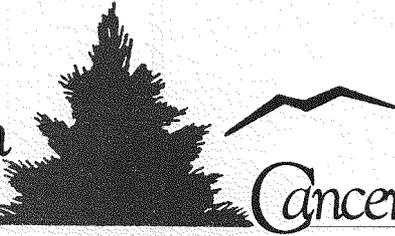


Raleigh
Regional



Cancer Center

Carl S. Larson, M.D.
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Sharon Bailey, FNP-BC

Crystal McGraw Davis, FNP-BC

August 18, 2009

Br. 1

Licensing Assistance Team
Attn: Tara Weidner
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License #47-31304-02 Amendment

03037863

2009 AUG 19 AM 10:50

RECEIVED
REGION I

Dear Ms. Widener:

We wish to amend our license to change the **model name** of the Varian GammaMedplus 3/24 to "GammaMedplus iX". The iX version of the afterloader reflects an increase in the number of treatment channels from 3 to 24 and a change to the console and control software of the HDR unit. There is no change to the afterloader shielding or the source that is used. The iX version continues to use the GammaMed 232 Ir-192 source with the same activity that is stated in our current license.

Enclosed you will find the updated emergency procedures.

The physicist, the physician and all the brachytherapy team will receive one day of on-site training on use of the new control software. This training will be conducted by a Varian trainer.

All other HDR administrative and operational program elements remain unchanged.

Please feel free to contact me should you have further questions.

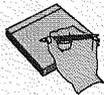
Sincerely,

David S. Shimm, MD

ENCLOSURES

Emergency Response Procedures (for posting)

The following sections describe Figure D-1 Emergency Response Procedures in text format, beginning with the first emergency procedure listed in the flowchart.



Note: The graphics, cautions, and warnings have been deliberately removed from the text in Chapter 5, “Emergency Procedures” to make the text more concise for posting. It is intended that you use the text in this section as a companion piece to the information in Chapter 5.

Press the Interrupt Button or Emergency Return Switch

In case of an emergency situation, such as one that requires immediate entry into the treatment room, do one of the following:

- Press the **INTERRUPT** button on the Control Console to retract the source at normal speed or
- Press the **EMERGENCY RETURN** switch in the control room to retract the source at maximum speed.

Press the Emergency Button

If the source wire does not retract into the shielded position after pressing the **INTERRUPT** button or the **EMERGENCY RETURN** switch, enter the treatment room with a portable survey meter and press the **EMERGENCY** button on the keypad of the GammaMed*plus* iX.

When you press the **EMERGENCY** button on the afterloader keypad, the GammaMed*plus* iX does the following:

- Terminates external power
- Shuts down all console indicators and indicator lights
- Initiates emergency battery power that is exclusively directed to the source drive to retract the source wire into the safe, shielded position

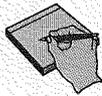


WARNING D-4: When you press the **EMERGENCY** button on the afterloader keypad, the external power supply of the GammaMed*plus* iX is switched off, and the source is retracted at maximum speed. After that, all remote monitors, including the Control Console and onboard radiation monitoring, are also turned off. The only indication whether the source is in the shielded position is the independent radiation monitoring system installed in the treatment room and your portable survey meter. Confirm that radiation levels are at background level. If not, initiate the next step of the emergency response procedures as described in Figure D-1.

Failure to follow these procedures may result in the following:

- Source may still be in the patient and you will not be aware of this.
- Source may be outside the shielded position and will expose the operator and patient to high levels of external radiation.

Perform Emergency Retraction with Emergency Handcrank



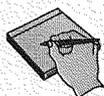
Note: Remember that when you press the **EMERGENCY** button on the afterloader keypad, all indicators and indicator lights are disabled. Radiation detection is provided only by the independent radiation monitoring equipment.

In the unlikely event that emergency retraction of the source does not occur after pressing the **INTERRUPT** button, the **EMERGENCY RETURN** switch, or the **EMERGENCY** button, the source can be retracted manually into the shielded position using the handcrank.

D

Follow these steps to manually retract the source using the handcrank:

1. Enter the treatment room with a portable survey meter and go straight to the GammaMed*plus* iX.
2. Pull the handle out of the handcrank and turn the crank in the direction of the arrow until a distinct resistance is noticeable and the room radiation level is safe.



Note: If the source wire has been retracted and the radiation level is still high or if manual retraction of the source is not possible using the handcrank, follow the procedures in the “Perform Manual Recovery of the Source” section below. These procedures are also outlined in Figure D-1.

Perform Manual Recovery of the Source

In the unlikely event that you are unable to perform motor-driven emergency retraction of the source or emergency retraction using the emergency handcrank, manual recovery of the source is required immediately. If the source cannot be retracted with the handcrank, the wire may be kinked or there might be a mechanical malfunction of the source drive mechanism. If the wire was retracted but the radiation level is still high, the source might be severed from the wire.

Remove the Applicator from the Patient

If you can easily remove the applicator from the patient, follow the steps below. Otherwise, continue to the next section.

1. Enter the treatment room with a portable survey meter and personal dosimeter.
2. Calm the patient.
3. Open the Emergency Container.
4. Remove the applicator carefully from the patient using the long handled forceps whenever possible. Maintain the maximum possible distance from the patient and the afterloader.

5. If possible, place the applicator in the Emergency Container, being careful not to damage or kink the source guide tube.
6. Move the patient to the room entrance and monitor the patient's radiation levels.
7. If there is no indication that the source is still in the patient, remove him/her from the treatment room. Monitor the patient's radiation levels.
8. If the radiation levels are at background level, close and lock the door to the treatment room and place a warning sign on the door indicating that the source is exposed.

Pull the Source Wire from the Applicator

If you cannot easily remove the applicator from the patient, follow the steps below:

1. Open the Emergency Container.
2. Disconnect all connectors from the indexer head.
3. Pull the afterloader away from the patient until the wire is visible at the indexer.
4. Using the forceps or pliers, grab the wire and pull it to remove it completely from the applicator and/or source guide tube.
5. Immediately place the active tip of the source wire in the Emergency Container.
6. Move the patient to the room entrance and monitor the patient's radiation levels.
7. If the patient survey confirms the source is no longer in the patient, secure the door to the treatment room and contact the radiation safety officer immediately.
8. If the patient survey indicates the source is still in the patient, return the patient to the treatment room and remove any applicators (if still present).
9. After removal of the applicator, monitor the patient's dose levels to ensure the source is no longer in the patient.
10. If the levels indicate the source is still in the patient, emergency surgical recovery of the source will be necessary.

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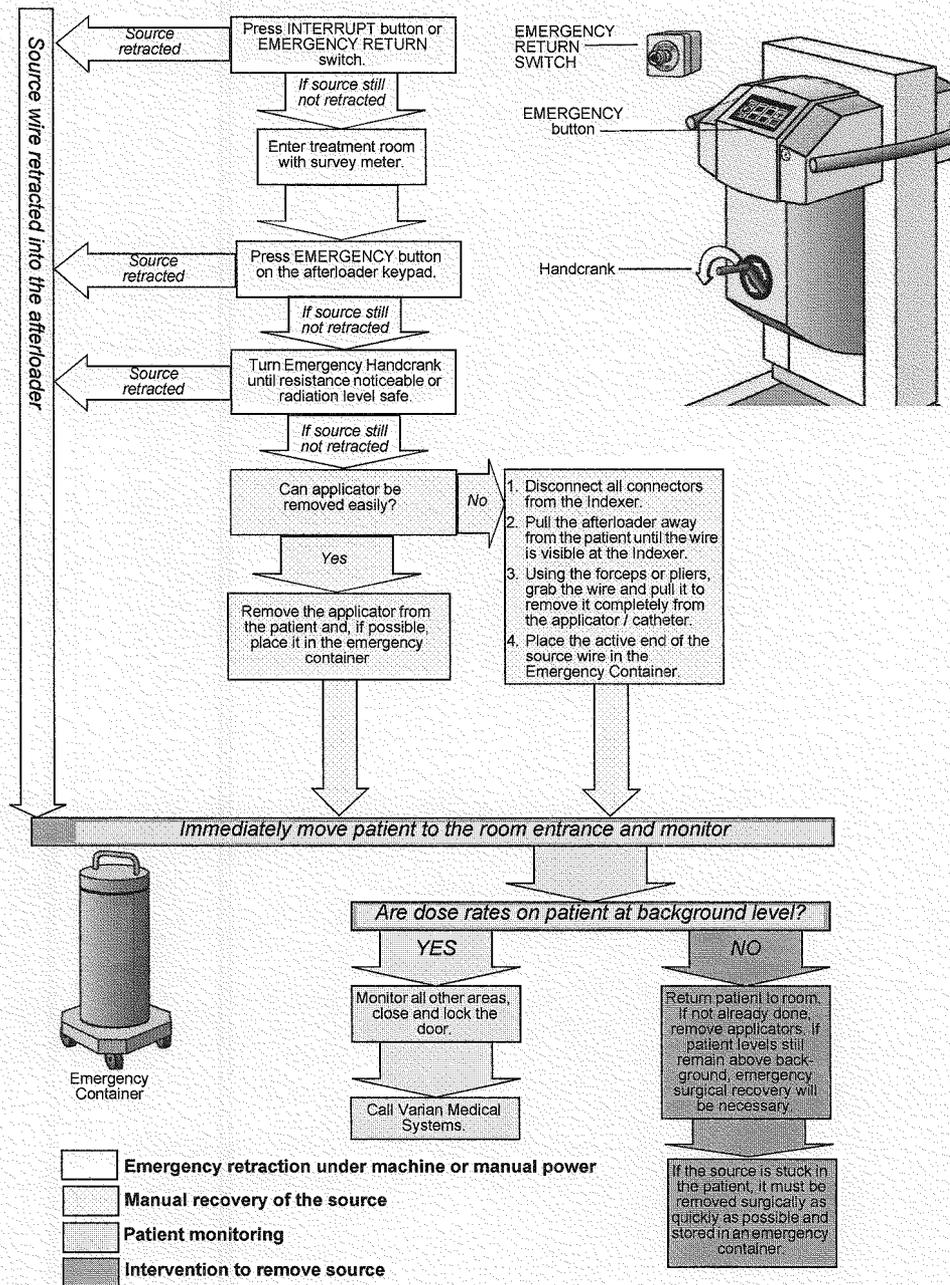


Figure D-1 Emergency Response Procedures

This is to acknowledge the receipt of your (letter) application dated

8/18/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (47-31304-02) There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 144075.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader