West Michigan Cancer Center
Together, we win.

22 August 2013

Sara Forster
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Rd.
Lisle, IL 60532-4352

Re: *Amendment requests for license number 21-32501-01*

Dear Ms. Forster:

We will be upgrading our HDR delivery system in November of this year. Before this equipment installation occurs we wish to amend our license to change the model name of the Varian HDR GammaMedplus HDR unit to "GammaMedplus iX". The iX version of the afterloader reflects a change only 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.

Updated emergency procedures are attached.

All personnel who use the GammaMedplus iX equipment will receive one day of on-site training on use of the new control software and the new emergency procedures. This training is conducted by a Varian trainer and will occur at the time of equipment installation.

All other HDR administrative and operational program elements remain unchanged.

If there are any questions, please do not hesitate to contact me at (269) 373-7407.

Thank you.

Sincerely,

Paul Jursinic

Paul Jursinic, Ph.D.
Radiation Safety Officer

Enclosed: Attachment 1

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ATTACHMENT 1

Chapter 5 Emergency Procedures

The GammaMed*plus* iX system is equipped with multiple independent safety and alarm functions that reduce the risk of uncontrolled radiation exposure in the event of an operational error or system malfunction. If an emergency situation should occur, the primary objective is to get the source out of the patient and into shielded storage. This chapter describes the recommended procedures that support this objective. These procedures are summarized in flowchart format in Figure 5-1 Emergency Response Procedures and in text format following the figure. Refer to the "Emergency Response Procedures (for posting)" section in Appendix D, "Safety Information and Tests" for procedural information that you can post at your facility.

It is imperative that essential personnel familiarize themselves with and regularly rehearse all of the emergency response procedures required at your site. Many regulatory agencies require that operators, physicists, and physicians participate in drills of emergency procedures initially and at least annually thereafter.

All users are advised to carefully read the safety information included in the "Important Safety Information" section of Chapter 1. For additional safety information, including safety tests and checks, refer to Appendix D "Safety Information and Tests".

WARNING 5-1: After an emergency, the physical condition of the source wire cannot be known unless it is inspected by a Varian Medical Systems service engineer. If there is any possibility that a GammaMed*plus* iX source wire has been damaged, you must contact Varian Medical Systems before treatment may resume. A damaged wire may fail to properly track through the GammaMed*plus* iX unit.

In This Chapter

Emergency Contact Information

In the United States, please call:
VariSource Dispatch 1-800-864-1672 (24 hour service)

In the event of an emergency, contact the following:

David Kuligowski/ BrachyTherapy Service Supervisor
Varian Medical Systems
700 Harris Street, Suite 109
Charlottesville, Virginia 22903
Office: 847-543-1293
Fax: 847-543-1293
Cell: 847-910-3717

Stephen Crawford/ BrachyTherapy Service Manager
Varian Medical Systems
700 Harris Street, Suite 109
Charlottesville, Virginia 22903
Phone: 1-888-666-7847 ext. 239
Fax: 434-244-7181
Cell: 408-887-9892

For all sites outside of the United States and Canada, please contact your regional service office, as applicable.

Definition of Emergency

In the context of this document, an emergency is defined as a radiation hazard to the operator or patient that occurs as the result of a system malfunction or an error in a treatment sequence. In such an emergency, you must follow the sequence below without skipping a step:

1. **Automatic retraction of the source** — The GammaMed*plus* iX system detects the error and automatically retracts the source into the shielded position.
2. **Emergency retraction under machine power** — The operator of the GammaMed*plus* iX system detects the error and presses one of the emergency buttons (**INTERRUPT** button, **EMERGENCY RETURN** switch, or **EMERGENCY** button) to cause the source to retract into the shielded position.
3. **Emergency retraction using emergency handcrank** — The operator of the GammaMed*plus* iX system detects the error and performs a manual retraction of the source into the shielded position using the handcrank.
4. **Manual recovery of the source** — If the source cannot be retracted using the handcrank, the wire may be kinked, there might be a mechanical malfunction of the source drive mechanism, or the source might be severed from the wire. In this case, the source must be recovered manually.

As mentioned above, during an emergency, it is imperative that you remove the source from the patient and secure it in shielded storage.

Precautions, Limitations, and Pre-requisites

The source strength of the Iridium-192 HDR source is typically 370–407 GBq (10–11 Ci) when it is installed, both initially and during routine source exchanges. Dose rates are on the order of 490 Gy/hr (49,000 Rad/hr) at 1 cm and 3 cGy/hr (3 Rad/hr) at 1 meter. Always practice radiation safety when working with the HDR source, always use a calibrated portable meter, and always wear your dose monitoring badge.

Precautions

WARNING 5-2: Fundamental rules in case of radiation hazard:

- Carry a radiation monitoring instrument.
- Spend as little time as possible in the field of radiation.
- Keep the maximum possible distance from the source of radiation.
- If necessary, move the source as quickly as possible into the shielded position or Emergency Container.

Failure to follow emergency response procedures may result in serious injury to the patient or operator of the system.

- All persons engaged in the use of the GammaMed*plus* iX system must be trained in the safe operation of the device. They must be familiar with the safety features and emergency response procedures.
- All members of the treatment team should conduct practice drills in emergency response.
- The EMERGENCY RESPONSE procedures must be posted near the door outside the treatment room. The Emergency Container (including forceps and pliers) must be accessible in the treatment room.

Limitations

The procedures recommended in this chapter may or may not encompass every emergency you may encounter. For example, you may experience an emergency situation resulting from a fire or earthquake, neither of which is addressed in this chapter. This information is provided as guidance only. Formal emergency procedures must be adopted by your facility in compliance with your license and local regulations.

Pre-requisites

All of the safety features in the "Important Safety Information" section of Chapter 1, "Introduction" must be satisfied in addition to the emergency equipment and radiation safety officer pre-requisites stated below. Only properly trained and authorized persons should operate the HDR unit. All personnel working with or around the HDR unit must be trained in radiation safety.

Emergency Equipment

The emergency equipment at your facility must be operational according to the manufacturer's specifications. The following emergency equipment must be readily available at all times:

- A pair of long handled forceps (~ 30 cm)
- A pair of pliers
- Shielded emergency container
- Heavy duty wire cutters
- Personal dosimeter
- Portable survey meter
- Stop watch or timer

Radiation Safety Officer (RSO)

The radiation safety officer is responsible for ensuring that all radiation safety procedures and policies are appropriate. The RSO should have proper training in the operation of the HDR unit and should actively participate in the initial and annual practice of HDR emergency procedures.

During an actual emergency, it may not be practicable to contact the RSO immediately at the beginning of the emergency. Despite this, the RSO should be contacted as soon as possible after an emergency is detected.

Note: In case of emergency (e.g. if the source is not retracted automatically), the persons responsible for radiation protection are obliged to remove other persons, e.g. patients, out of radiation areas.

Emergency Features and Functions

The alarm and radiation indicators of the GammaMed*plus* iX system provide immediate feedback on system and treatment status.

Alarm Indicators

When an error condition occurs, the red **ALARM** indicator in the **ALARM** section of the Control Console flashes, and an audible warning signal can be heard.

On the control PC, a red message box at the bottom of the screen indicates an error condition and the possible cause of the alarm.

If there is a communication failure between the control PC and the GammaMed*plus* iX, an audible alarm will be heard on the control PC. The alarm continues until communications are restored.

Turn Off the Audible Alarm Signal

The audible **ALARM** signal draws attention to the emergency situation. You can turn off the audible signal by pressing the **BUZZER OFF** button in the **ALARM** section of the Control Console. In this case, the **BUZZER OFF** indicator light turns on and the red **ALARM** indicator continues to flash. If the error condition remains uncleared, the audible signal will sound again in 5 minutes.

Resolve the Cause of the Alarm

Verify that the **SAFE** indicator light in the **SOURCE** section of the Control Console is lit and the **RADIATION** indicator is off.

Check the error message on the control PC for an indication of the possible cause of the alarm, and resolve the problem. Press the **View Detail** button in the error message box to see additional information. Refer to the "Status and Error Messages" section in Chapter 3 "Delivery of Patient Treatment" for more information.

WARNING 5-3: If the **SAFE** indicator light is not lit, and the **RADIATION** indicator is on, follow the emergency procedures at your site. Refer to the "Automatic and Emergency Retraction of the Source" section below for more information.

Reset the Alarm

In order to accept the alarm condition and recover the treatment process, you must press the **ALARM RESET** button on the Control Console. The red flashing **ALARM** indicator is reset and the buzzer is automatically turned off.

Note: If you do not correct the cause of the alarm, the alarm signal is repeated when you press the **START** button.

Radiation Indicators

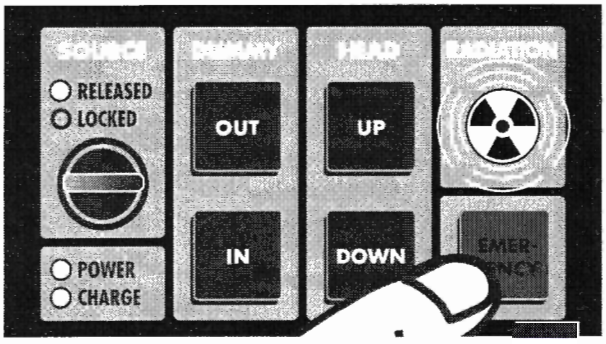
Indication of radiation from an unshielded source is detected and displayed by multiple methods on the GammaMed*plus* iX system.

Built-in Radiation Detector

The built-in Geiger-Müller detector of the GammaMed*plus* iX is energized as long at theGammaMed*plus* iX is turned on and in treatment mode. In this configuration, it detects any radiation while the source is outside the shielded tungsten safe.

Radiation Indicator on the Afterloader Keypad

On the afterloader keypad, the **RADIATION** indicator light illuminates when the GammaMed*plus* iX detects radiation outside the shielded safe. This shows that the source is no longer in the shielded position and that there is the potential of radiation hazard.



Note: Other sources of radiation in range of the built-in Geiger-Müller detector may be detected by it and may cause the radiation indicator on the afterloader keypad to illuminate.

Radiation Indicator on the Control Console

On the Control Console, the yellow **SOURCE OUT** indicator and the yellow **RADIATION** symbol illuminate when the source is outside the shielded safe.

Independent Radiation Monitoring System

An independent radiation monitoring system with visual and audible output is required in the treatment room. This monitor indicates radiation when the source is outside the shielded position.

Automatic and Emergency Retraction of the Source

The automatic safety functions of the GammaMed*plus* iX are activated if a radiation hazard occurs as the result of a system malfunction or an error in the treatment sequence. Alarm signals appear on the Control Console and control PC, and the source is automatically retracted into the shielded position.

There are situations in which you might need to manually interrupt a treatment, such as an emergency that requires immediate entry into the treatment room, or in the unlikely event that automatic source retraction does not occur when necessary.

Note: The GammaMed*plus* iX system logs all errors in the treatment sequence in the error log.

You can initiate an emergency retraction of the source wire using the following methods:

- Press the **INTERRUPT** button on the Control Console.
- Press the **EMERGENCY RETURN** switch in the control room.
- Press the **EMERGENCY** button on the afterloader keypad.
- Use the **handcrank** to return the source to the shielded position.

If emergency retraction of the source is not possible using the actions stated above, manual recovery of the source must be performed. Manual recovery means removing the source from the patient without the use of the **INTERRUPT** button, **EMERGENCY RETURN** switch, **EMERGENCY** button, or **handcrank**. Emergency retraction and manual recovery procedures are outlined in Figure 5-1 and described in detail in the sections below.

WARNING 5-4: The radiation safety officer must be informed immediately in an emergency situation. Emergency response procedures must be performed quickly and accurately in order to assure the safety of the patient and medical staff. Avoid panic and calm the patient. Practice emergency response procedures with the staff on a regular basis in order to assure patient and operator safety.

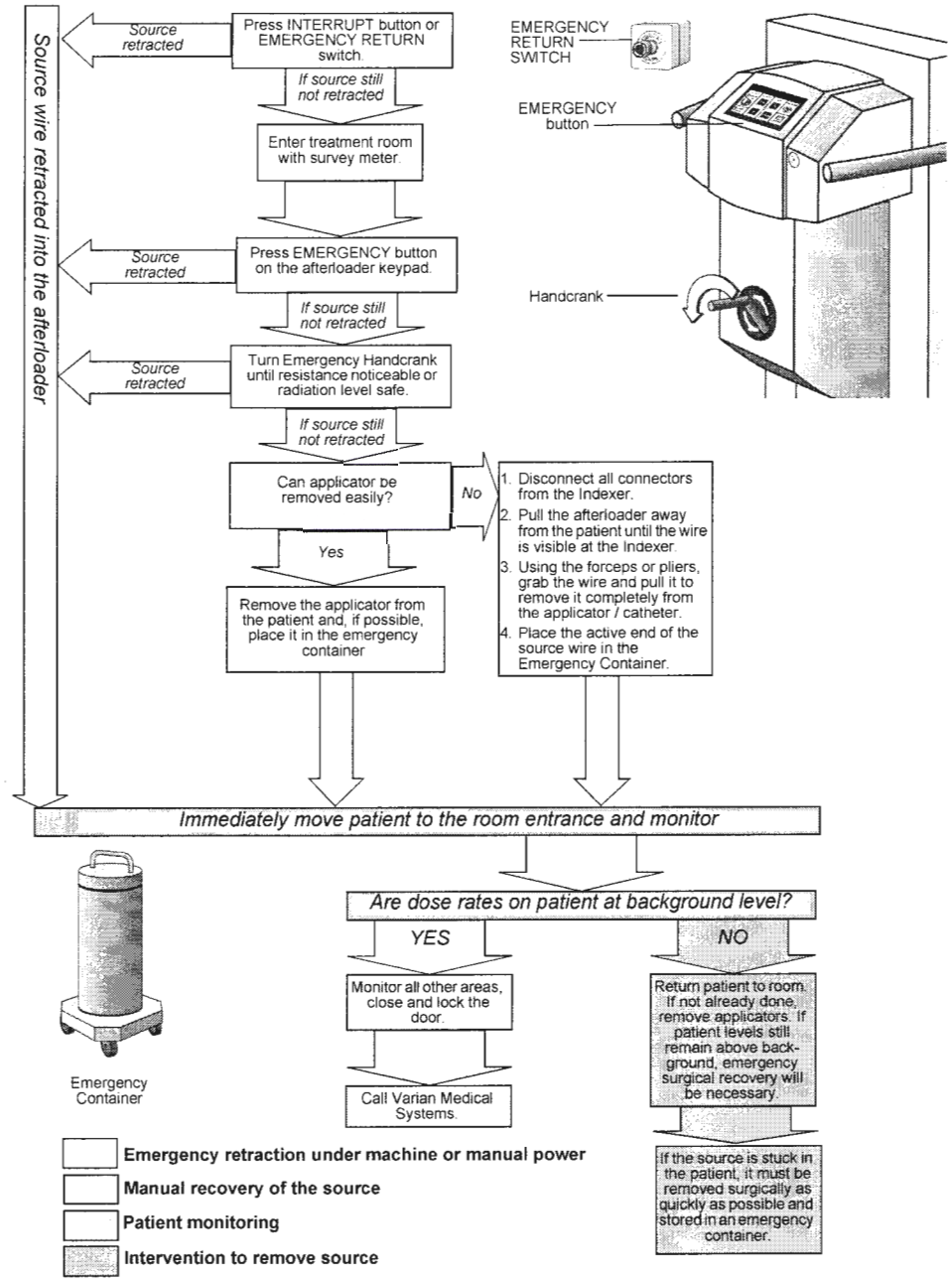


Figure 5-1 Emergency Response Procedures

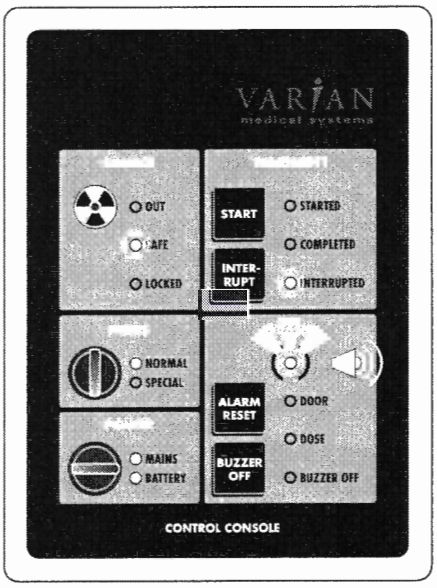
Emergency Response Procedures

The following sections describe Figure 5-1 "Emergency Response Procedures" in detail, beginning with the first emergency procedure listed in the flowchart. Refer to the "Emergency Response Procedures (for posting)" section in Appendix D, "Safety Information and Tests" for a version of the procedures that you may post.

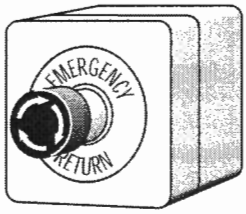
Press the Interrupt Button or Emergency Return Switch

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.



INTERRUPT Button



EMERGENCY RETURN Switch

WARNING 5-5: Verify that the **SAFE** indicator light in the **SOURCE** section of the Control Console is on, and the **RADIATION** symbol is off. If not, implement the next step of the emergency response procedures as described in Figure 5-1 above.

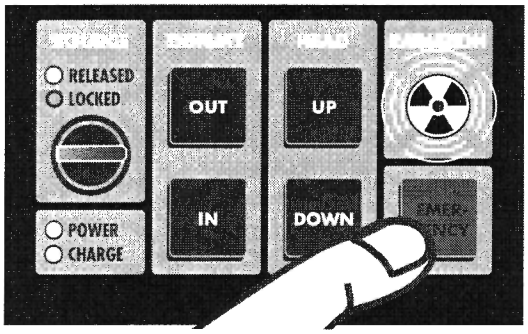
Important: If you press the **EMERGENCY RETURN** switch during treatment delivery when the active wire is extended, the radiation symbol in the System Status Strip of the control PC continues to flash even if the active wire has been retracted into the shielded position. The symbol continues to flash because communication between the control software and afterloader has been interrupted.

The control software displays the following message: "WARNING: EMERGENCY MANUAL. Waiting for afterloader to restart." Audible signals can be heard from both the afterloader and control PC.

Be sure to follow emergency response procedures concerning detection of radiation as outlined in the warning above. The red flashing error message and the flashing radiation symbol display until you pull the **EMERGENCY RETURN** switch out and press the **ALARM RESET** button.

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 lamps, indicators, and the Geiger-Müller detector
- Initiates emergency battery power that is exclusively directed to the source drive to retract the source wire into the safe, shielded position

Note: It is important to understand that the sole purpose of the **EMERGENCY** button is to retract the source into the shielded position.

WARNING 5-6: ATTENTION: RADIATION HAZARD!

Emergency retraction of the source using the EMERGENCY button on the afterloader keypad may expose the operator to high levels of radiation. Persons under the age of 18 years and pregnant women are not allowed to perform this task.

WARNING 5-7: 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 on-board 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 5-1.

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.

Important: If you press the **EMERGENCY** button during treatment delivery when the active wire is extended, the radiation symbol in the System Status Strip of the control PC continues to flash even if the active wire has been retracted into the shielded position. The symbol continues to flash because communication between the control software and afterloader has been interrupted.

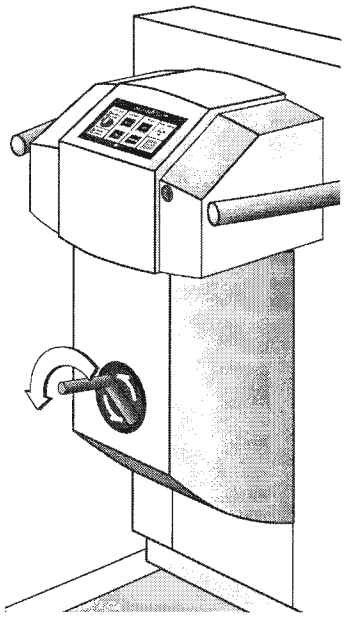
The control software displays the following message: "WARNING: EMERGENCY MANUAL FROM TROLLY. Waiting for afterloader to restart." Audible signals can be heard from both the afterloader and control PC.

Be sure to follow emergency response procedures concerning detection of radiation as outlined in the warning above. The red flashing error message and the flashing radiation symbol display until you turn the **POWER** key switch on the Control Console to the **OFF** and then the **ON** position.

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.



WARNING 5-8: ATTENTION: RADIATION HAZARD!

Manual recovery of the source using the handcrank may expose the operator to high levels of radiation. Persons under the age of 18 years and pregnant women are not allowed to perform this task.

WARNING 5-9: ATTENTION: RADIATION HAZARD!

Act quickly but carefully. Keep the maximum possible distance from the source. All operational personnel must be trained in radiation safety and emergency procedures as well as all functions of the GammaMed*plus* iX.

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 5-1.

CAUTION: If emergency retraction of the source by handcrank is necessary, the primary goal is to ensure patient safety. Do not restart the treatment. Call your Varian BrachyTherapy service representative immediately to arrange an afterloader inspection.

Perform Manual Recovery of the Source

In the unlikely event that you are unable to perform motor-driven or manual emergency retraction of the source, 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.

WARNING 5-10:ATTENTION: RADIATION HAZARD!

Manual recovery of the source may expose the operator to high levels of radiation. Persons under the age of 18 years and pregnant women are not allowed to perform this task.

WARNING 5-11: ATTENTION: RADIATION HAZARD!

Act quickly but carefully. Keep the maximum possible distance from the source. All operational personnel must be trained in radiation safety and emergency procedures as well as all functions of the GammaMed*plus* iX.

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.

Note: In all cases above, remove the patient from the immediate area, survey the patient, and, if safe to do so, evacuate the patient from the room. Post a warning and notify all emergency contacts immediately. Since, in most jurisdictions, you will be expected to report on estimated exposure to staff and patient as a result of the incidents, you would be advised to estimate times and dose rates involved to produce a reasonable estimate of exposure to all concerned.

How to Continue an Interrupted Treatment

The following sections describe how to continue an interrupted treatment.

Restart After Pressing the INTERRUPT Button

Follow these steps to restart the system after interrupting the treatment:

1. Resolve the cause of the interruption or alarm.
2. Inform and calm the patient.
3. Press the **START** button on the Control Console.

The GammaMed*plus* iX resumes the treatment from the last dwell position, and only the remaining dwell positions in the current fraction will be delivered.

Important: In the case where you have pressed the **INTERRUPT Button** and need to stop and resume the treatment at a later time, you can press the **EMERGENCY RETURN** switch, the **EMERGENCY** button, or turn the **POWER** key switch on the Control Console off and then back on (after waiting sufficient time for the system to shut down). Each of these methods causes the control software to display the Partial Treatment Options where you can choose to abort the treatment.

Restart After Pressing the EMERGENCY RETURN Switch

Follow these steps to restart the system after pressing the **EMERGENCY RETURN** switch:

1. Resolve the cause of the interruption or alarm.
2. Inform and calm the patient.
3. Pull the **EMERGENCY RETURN** switch to the "OUT" position.
4. Press the **ALARM RESET** button on the Control Console.
5. Use the Partial Treatment Strip in the control software to determine how to continue the treatment.

The control software displays a Treatment Delivery Report containing data on the interruption in treatment. When you close this report, the Patient Selection Page is displayed.

Restart After Pressing the EMERGENCY Button

Follow these steps to restart the system after pressing the **EMERGENCY** button:

1. Inform and calm the patient.
2. Resolve the cause of the interruption or alarm.
3. Turn the **POWER** key switch on the Control Console to the **OFF** and then the **ON** position.
4. Use the Partial Treatment Strip in the control software to determine how to continue the treatment.

The control software displays a Treatment Delivery Report containing data on the interruption in treatment. When you close this report, the Patient Selection Page is displayed.

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