Saint Luke's Hospital of Kansas City
SAINT LUKE'S HEALTH SYSTEM
saintlukeshealthsystem.org

Malcolm Baldrige National Quality Award
Saint Luke's Hospital 2003 Award Recipient

December 15, 2010

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrensville Road, Ste 210
Lisle, IL 60532-4352

Attn: Toye Simmons

Withhold from Public Disclosure in Accordance with 10 CFR 2.390

Re: Amendment to License 24-00889-01

Saint Luke's Hospital of Kansas City (SLH), License 24-00889-01 would like to amend our license. We wish to amend our license to change the model name of the VariSource HDR to the "VariSource iX." The iX version of the afterloader reflects a change to the control software of the HDR unit. There is no change to the afterloader mechanical systems, shielding or the source that is used. The iX version continues to use the VS2000 Ir-192 source with the same activity that is stated in our current license.

Enclosed please find a copy of the updated emergency procedures. Staff will be trained by the manufacturer on the new control software upon installation.

If you have any questions regarding this application, please contact Greg Sackett at (816) 932-6296. Thank you for your consideration.

Greg Sackett, CHP
Radiation Safety Officer

APR 19 2011

Chapter 5 Emergency Procedures

The VariSource 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 VariSource 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 VariSource 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 VariSource iX system detects the error and automatically retracts the source into the shielded position.
2. **Emergency retraction under machine power** — The operator of the VariSource iX system detects the error and presses the emergency **Stop** button to cause the source to retract into the shielded position.
3. **Emergency retraction using emergency handcrank** — The operator of the VariSource 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 emergency 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 VariSource 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)
- 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 radiation indicators and audible alarm signals of the VariSource iX system provide immediate feedback on system and treatment status.

Radiation Indicators

Indication of radiation from an unshielded source is detected and displayed by multiple independent methods on the VariSource iX system.

Built-in Radiation Detector

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

Note: The Geiger-Müller detector is also energized when the VariSource iX(t) is in transport mode with the Main umbilical loom (40 way Lemo) plugged in.

Radiation Warning Indicator on the Afterloader Status Panel

The **Radiation Warning Indicator** lights are flashing red lights that turn on when the VariSource iX detects radiation outside the storage safe. The lights indicate that the source is no longer in the shielded position and that there is the potential of radiation hazard. When radiation is present, a pulsed tone is sounded from the afterloader.

Note: *Other radioactive sources in range of the internal radiation detection unit influence the detection unit.* The radiation indicator on the Afterloader Status Panel turns on for each detected source of radiation.

Radiation Indicator on the Control Console

The yellow flashing **Radiation Indicator** light indicates the status of the source and serves as a safety function. It begins to flash when the VariSource iX detects radiation outside the storage safe. This shows that the source is no longer in the shielded position and that there is the potential of radiation hazard. When radiation is present, a pulsed tone is sounded from the Control Console.

WARNING 5-3: If the yellow **Radiation Indicator** does not light up during a treatment, there is a possibility of a system malfunction, and an error message is displayed on the control PC. The treatment must be interrupted immediately. Check for the cause of the error and correct the problem. Failure to do so may result in injury to the patient.

WARNING 5-4: Radiation detected upon completion of treatment causes the flashing yellow indicator light and pulsed tone to continue. The red **Error Indicator** turns on and the MANUAL RETRACT text message appears in the **Text Display**, indicating a possible failure to retract the active wire. In this case, emergency procedures are required.

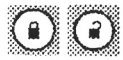
Independent Radiation Monitoring System

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

Audible Alarm Signals

When an error condition or emergency situation occurs, audible alarm signals may be heard on the Afterloader Status Panel, Control Console, Door Display Panel, and control PC. The alarm signals may be individually silenced.

The Afterloader Status Panel signal can be silenced by turning the key switch to the **Lock** (horizontal) position.



The Control Console signal can be silenced by turning the key switch to the **Lock** (leftmost) or **On** (vertical) position.

The Door Display Panel alarm is included to warn of a possible system failure requiring a manual retract. This alarm can be silenced by opening the treatment room door.

The control PC signal occurs when communications are lost between the PC and the afterloader during a treatment. The signal can be silenced by shutting off the control PC or reestablishing communications.

Note: You cannot proceed with a treatment until all error conditions have been cleared, the **Afterloader Status Panel** key and **Control Console** key are in the treat position, and the treatment room door is closed.

Automatic and Emergency Retraction of the Source

The automatic safety functions of the VariSource iX system are activated if a radiation hazard occurs as the result of a system malfunction or an error in the treatment sequence. Should a system malfunction affecting source travel occur, the retract mechanism automatically attempts to place the active source wire in the safe and parked position within 30 seconds. Under these circumstances, the emergency retract motor engages and the emergency handcrank automatically rotates as the source wire is retracting.

If retraction has not occurred after 50 seconds, the message MANUAL RETRACT is indicated in the Text Display of the Control Console and the control PC indicates that emergency procedures are required. This process is described in detail in Figure D-2 "Emergency Retract Flow Chart" in Appendix D, "Safety Information and Tests" along with other possible emergency failure modes and associated error messages.

In the case of an automatic retraction of the source, verify that the green **No Radiation Present Indicator** light on the Control Console is lit and the flashing yellow **Radiation Indicator** is off. Check the error message on the control PC for an indication of the possible cause of the alarm, and, if the error is user-resettable, resolve the problem. Press the **View Detail** button in the error message box in the control software to see additional information. Refer to the "Status and Error Messages" section in Chapter 3 "Delivery of Patient Treatment" for more information.

After you clear the cause of the alarm, press the **Clear Error** button in the error message box on the control PC. Use the Partial Treatment Strip to determine how to continue the treatment. Refer to the "Partial Treatment Strip" section in Chapter 3 "Delivery of Patient Treatment" for information on how to use the Partial Treatment Strip.

Note: The VariSource iX system logs all errors in a treatment sequence in the error log.

Emergency Response Procedures

As mentioned in the previous section, the VariSource iX automatically retracts the source into the shielded position if one of the automatic safety functions is activated due to a radiation hazard and logs this action in the error log. There are other 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.

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

- Press the **Stop** button on the Control Console.
- Press the **Stop** button on the Door Display Panel.
- Open the treatment room door.
- Press the **Stop** button on the Afterloader Status Panel.
- Use the handcrank to return the source to the shielded position.

If emergency retraction of the source is not possible, manual recovery of the source must be performed. Emergency retraction and manual recovery procedures are outlined in Figure 5-1 and described in detail in the sections below.

WARNING 5-5: 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.

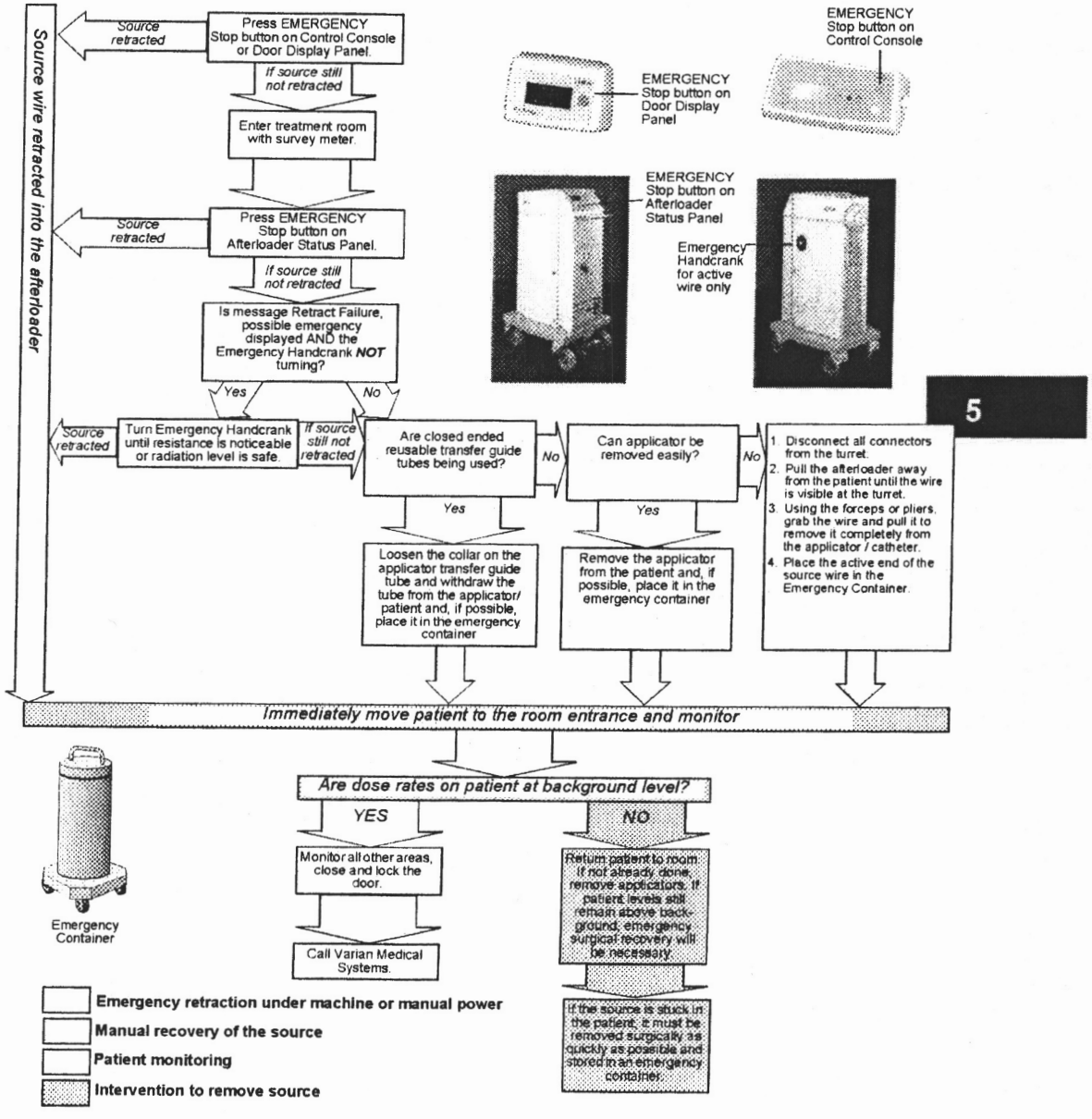
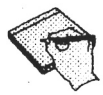


Figure 5-1 Emergency Response Procedures



Note: 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 Stop Button on Control Console or Door Display Panel

In emergency situations, you can retract the source immediately by pressing the emergency **Stop** button on the Control Console or the Door Display Panel located near the door outside the treatment room. This button stops treatment and retracts the source into the storage safe.

WARNING 5-6: The **Stop** button bypasses the control PC software and interfaces directly with circuit controlling the source motor drive to retract the source with maximum speed. As soon as the source is in its shielded position, the **Radiation Warning Indicator** lights are extinguished. **You must survey the room with a portable radiation meter to assure the source is back in its shielded position.** Failure to perform this survey may result in serious injury to you or the patient.

Press the Stop Button on the Afterloader Status Panel

During an emergency situation, if the source wire does not retract into the shielded position after pressing the **Stop** button on the Control Console or Door Display Panel, enter the treatment room with a portable survey meter and personal dosimeter and press the **Stop** button on the Afterloader Status Panel.

WARNING 5-7: ATTENTION: RADIATION HAZARD!

Emergency retraction of the source using the **Stop** button on the Afterloader Status Panel 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.

Note: It is important to note that the sole purpose of the emergency **Stop** button on the Control Console, Door Display Panel, and Afterloader Status Panel is to retract the source into the shielded position.

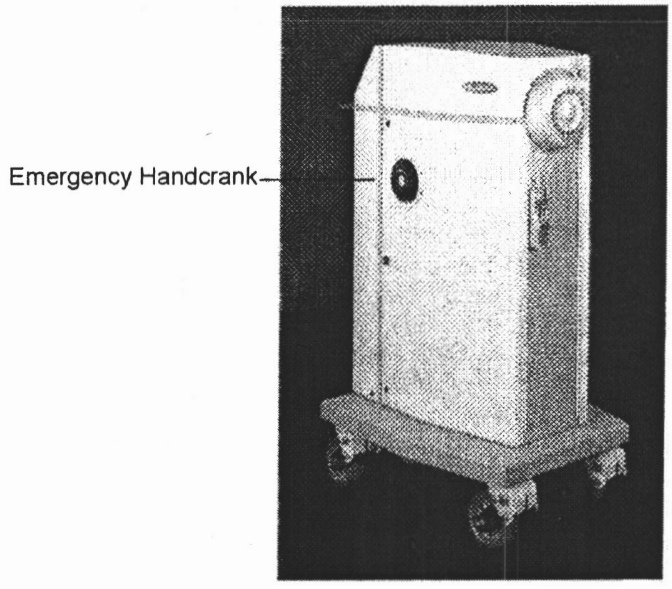
WARNING 5-8: When you press the **Stop** button, the source is retracted at maximum speed. Verify that the **Radiation Indicator** on the Control Console is off and the **No Radiation Present Indicator** is on. Confirm that radiation levels are at background level. If not, initiate the next step of the emergency response procedures as described in Figure 5-1.

Failure to follow these procedures my 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 Manual Retraction Using the Emergency Handcrank

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



It should be noted that operation of the emergency handcrank will only be effective in the following case:

- The afterloader has failed to park the active wire and the message

  Retract failure, possible emergency. Check source status.

  is displayed

  AND
- The handcrank is **NOT** automatically turning.

In this situation, the Control Console indicates that the source is extended and a radiation hazard exists. The radiation indicators on the Control Console and the Afterloader Status Panel flash and the audible alarm signal can be heard.

WARNING 5-9: ATTENTION: RADIATION HAZARD!

Manual recovery of the source using the emergency 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 5-10: 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 VariSource iX.

Follow these steps to manually retract the source using the emergency handcrank. This procedure should be followed if the emergency handcrank is **NOT** turning, radiation **IS** present, and a retract failure **IS** indicated:

1. Enter the treatment room with a portable survey meter and a personal dosimeter and go straight to the VariSource iX.
2. Turn the handcrank in the direction of the arrow through at least 8 revolutions, or until the independent radiation monitor no longer detects radiation. If after at least 8 revolutions of the handcrank radiation is still detected by the room monitor or portable survey meter, follow the procedures in the "Perform Manual Recovery of the Source" section below. These procedures are also outlined in Figure 5-1.

WARNING 5-11: Excessive turning of the emergency handcrank after the active wire is parked can cause the active wire to move outside of the internal shielding. If use of the handcrank is necessary, stop turning it as soon as the independent radiation monitor has stopped detecting radiation.

Failure to follow this warning may result in serious injury to the operator or patient.

WARNING 5-12: The dummy wire is not connected to the emergency handcrank. Do not use the handcrank in an attempt to return the dummy wire to the afterloader.

Failure to follow this warning may result in serious injury to the operator or patient.

At the Same Time

1. Secure the treatment room against unauthorized entry.
2. Inform the radiation safety officer of the situation.

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 emergency 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 5-13: 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 5-14: 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 VariSource iX.

Important: The procedures below should be followed under the following circumstances:

- The handcrank **IS** turning, radiation is present, and a retract failure **IS** indicated

  OR

- **NO** retract failure is indicated, radiation is present, and the handcrank is **NOT** automatically turning.

Remove the Transfer Guide Tube from the Applicator or Patient

If closed ended reusable transfer guide tubes are being used, 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. Loosen the collar on the transfer guide tube and withdraw the tube from the applicator or patient using the long handled forceps whenever possible. Maintain the maximum possible distance from the patient and the afterloader.
5. If possible, place the transfer guide tube in the Emergency Container, being careful not to damage or kink the 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.

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

1. Open the Emergency Container.
2. Disconnect all Quick Connects from the turret.

Note: The end of the Click-Fit Transfer Guide Tube that has the Click-Fit connector cannot be disconnected if a wire is inside the connector/tube. For this reason, you must disconnect the Quick Connects from the turret.

3. Pull the afterloader away from the patient until the wire is visible at the turret.
4. Using the forceps or pliers, grab the wire and pull it to remove it completely from the applicator and/or catheter.
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

Follow these steps to restart the system after pressing the **Stop** button on the Control Console, Door Display Panel, or Afterloader Status Panel:

1. Resolve the cause of the interruption or alarm.
2. Inform and calm the patient.
3. Press the **Clear Error** button in the WARNING message box.
4. Use the Partial Treatment Strip to determine where to resume the treatment. Refer to the "Partial Treatment Strip" section in Chapter 3 "Delivery of Patient Treatment" for information on how to use the Partial Treatment Strip.