

Expedited Amendment Request Letter

Licensee: Riverside Regional Medical Center
License No.: 45-09001-01
Docket No.: 03003330
Control No.: ~~138787~~ 13 8887

K-8

WMP

We request an expedited amendment request change to our license to include authorization of clinical use for our new Gamma Knife unit.

Included with this letter are the following documents:

- 1) Policy RSO - 36-01: Gamma Knife Stereotactic Radiosurgery Instructions
- 2) Policy RSO - 36-02: Gamma Knife Operating Instructions
- 3) Policy RSO - 36-03: Gamma Knife Emergency Procedures
- 4) Policy RSO - 36-04: Gamma Knife Quality Assurance Plan
- 5) Policy RSO - 36-05: Gamma Knife Spot-Check Procedure
- 6) Gamma Knife Center Daily Start-up Checks
- 7) Gamma Knife Center Monthly Checks
- 8) Gamma Knife Annual Calibration Checks

CERTIFICATION

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND

CERTIFYING OFFICER—NAME AND TITLE	SIGNATURE	DATE
Sandra M. Snapp Administrator Gamma Knife Center	<i>Sandra M. Snapp</i>	5/23/2006

13 8887

NMCC/RONI MATERIALS-002

**RIVERSIDE****H E A L T H S Y S T E M**

701 Town Center Drive, Suite 1000, Newport News, Virginia 23606

Policy / Procedure

RIVERSIDE FACILITY: RPMC**Category: Radiation Safety**

Page 1 of 5

Subject: Gamma Knife® Stereotactic Radiosurgery Instructions**Policy #: RSO - 36-01****Distribution Group: Radiology****Authorized Devices**

Intracranial stereotactic radiosurgery may be conducted by using the Gamma Knife® stereotactic radiosurgery device. Afterloading (Gamma Knife®) device contains a cobalt source. The only device authorized for purchase is:

Distributor: Elekta**Manufacturer: Elekta****Leksell Gamma Knife® System Model 24001 Type C****Device Registry: AB ELEKTA Models 43047 and 43685****Authorized Users**

Only individuals listed as authorized users by the Radiation Safety Committee and the Nuclear Regulatory Commission (NRC) are permitted to use, and supervise the use of, the Gamma Knife® device. Proposed new users must complete the required training before having their names forwarded for review and addition to the licenses.

Only personnel listed as trained and authorized operators and who have practiced the emergency procedures may use the Gamma Knife® device under the supervision of an Authorized User. Proposed new operators must be a radiation therapist or a registered nurse and must have completed the required training for the Gamma Knife® device.

Gamma Knife® Treatment Room**Room Location**

The Gamma Knife® Device can only be used in the Gamma Knife® vault located in the Radiosurgery Center.

Date of Origin: 03/06**Last Revision Date: 05/2006****Authorized By: Radiation Safety Committee****Source: U.S. Nuclear Regulatory Commission, VA Radiological Health**



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Policy / Procedure

RIVERSIDE FACILITY RRM

Category: Radiation Safety

Page 2 of 5

Subject: Gamma Knife® Stereotactic Radiosurgery Instructions

Policy #: RSO - 36-01

Distribution Group: Radiology

Room Safety Features

01. Access to the room housing the Gamma Knife® device shall be controlled by a door at the entrance which is normally closed when the source is in the exposed position. The door shall be posted with signs indicating "Caution-High Radiation Area" and "Personnel Monitoring Required" or the equivalent and an additional sign containing "Caution-Radioactive Materials".
02. The door shall be equipped with an interlock system that causes the source to return to the shielded position immediately upon opening the door. The Gamma Knife® interlock system shall be independent of any other unit's door interlock system. The interlock shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is set at the control panel and the operator start button is pressed to initiate treatment. Door interlocks shall be tested for proper operation on each day of use. Records of test results shall be maintained for inspection by the NRC. In the event of a malfunction of the door interlock, the Gamma Knife® device shall be locked in the shielded position and not used, except as may be necessary for repair or replacement of the magnetic interlock system, until the interlock system is shown to be functioning properly.
03. In addition to an interlock system, the door shall also contain a badge reader access device limiting entry into the Gamma Knife® treatment room for only trained personnel, authorized operators and authorized users of the device.
04. A Source-Position-Indicator (SPI) light shall be located above the door or at the control console. This light shall be electrically connected to either the machine or a radiation monitor in the room such that the SPI light indicates when the source is moved from its storage position.
05. Two (2) CCTV systems shall be installed that will permit the patient to remain under observation during treatment.

Date of Origin: 03/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health

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Policy / Procedure

RIVERSIDE FACILITY: REMC**Category: Radiation Safety****Page 3 of 5****Subject: Gamma Knife® Stereotactic Radiosurgery Instructions****Policy #: RSO - 36-01****Distribution Group: Radiology**

06. A built in intercom system shall be installed that will permit the operator to have two-way communication with the patient.
07. A radiation-detection alarm monitor with remote display shall be installed that will indicate when the cobalt source has been moved into the "expose" position.
08. No other radiation-producing device may be energized when the Cobalt source is in the expose position.
09. A set of written emergency instructions shall be posted at the operator's console informing the operator of the procedures to be followed if the source fails to return to the shielded position.

Installation and Replacement of Sources

Installation and replacement of sources contained in the Gamma Knife® Device shall be performed only by persons specifically authorized and trained by the device manufacturer and/or distributor.

Maintenance and Repair of Device

Any maintenance or repair of the Gamma Knife® device involving work on the source head, the source driving unit, or cobalt shielding door that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels shall be performed only by persons specifically authorized by the manufacturer.

Date of Origin: 03/06**Last Revision Date: 05/2006****Authorized By: Radiation Safety Committee****Source: U.S. Nuclear Regulatory Commission, VA Radiological Health**



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Policy / Procedure

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Category: Radiation Safety

Page 4 of 5

Subject: Gamma Knife® Stereotactic Radiosurgery Instructions

Policy #: RSO - 36-01

Distribution Group: Radiology

Dosimetry Equipment Calibration and Checks

01. The dosimetry systems used for full calibration and spot-check measurements shall be calibrated at least once every two years as required by 10 CFR 35.630(a)(1).
02. Records of the calibration of dosimetry equipment shall be kept in accordance with 10 CFR 35.2630.
03. An authorized medical physicist will make the full calibration measurements in accordance with 10 CFR 35.635 and documented on a data form. The data form contains the measurements required to be done during full calibration.
04. The full calibration measurements shall be performed on the unit:
 - a) Before the first medical use of the unit,
 - b) Following any repair that includes removal of the sources or reinstallation of the unit in a new location,
 - c) Following a major repair associated with source assembly; and
 - d) Annually.

Leak Tests

01. Leak tests of the Cobalt-60 sources shall be made by the authorized medical physicist or radiation safety officer at intervals not to exceed six months.
02. The appropriate surfaces to be wiped for this test are the convex surface of the collimator helmet and the external interface line between the upper hemispherical shield and the base section of the radiation unit.

Date of Origin: 03/05

Last Revision Date: 03/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health

RIVERSIDE FACILITY: Riverside Regional Medical Center-
Policy #: RSO-35-02 Distribution Group: Radiology

Page 5 of 5

Survey Reports

01. A Radiation Protection survey shall be performed after the installation of the unit or with a source change. Surveys shall be performed by an Authorized Medical Physicist and/or RSO.

Record Keeping

01. All records required for compliance with NRC's regulations, the conditions of our license and commitments made in our license application and correspondence with NRC shall be maintained.



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Policy / Procedure

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Category: Radiation Safety

Page 1 of 2

Subject: Gamma Knife® Stereotactic Radiosurgery Operating Instructions

Policy #: RSO - 36-02

Distribution Group: Radiology

- 1) Operating procedures will be maintained current as modified by manufacturer, the NRC, or the Facility's Radiation Safety Committee. One copy along with the Emergency Procedures shall be maintained at the control console. In addition, one copy will be given to each operator and/or each user, the Radiosurgery Center Manager, the physicist and attending physicians.
- 2) The operating computer will be secured when the unit is either unattended or not in use. The computer system will be secured by removal of the operating key. The key(s) will be secured. The procedure for securing the key(s) will be maintained within the department.
- 3) The treatment room door will remain closed and locked when the unit is unattended.
- 4) The entrance to the treatment room is equipped with an electrical interlock system that will: (1) prevent the start of the treatment (i.e., opening of the unit shield door) unless the treatment room door is closed, (2) terminate treatment (i.e., withdraw the patient couch and closed shield door) if the door is opened; and (3) prevent resumption of treatment after an interlock interruption until the door is closed and reset is activated at the console.
- 5) During treatments, only the patient may remain in the room. All attending personnel must remain outside the treatment room during the actual treatment. During emergencies the treatment door is equipped with a door switch and an external emergency stop switch is available outside the treatment room. The attending personnel may re-enter the treatment room after the emergency stop switch has been activated and the couch has withdrawn from the shielding doors. Emergency procedures are posted at the operators console and shall be initiated if the couch does not return properly, the couch is stuck in the treatment position and/or the shielding doors do not shut.
- 6) A closed circuit television system permits continuous observation of the patient from the control console during treatment. The camera zoom lens and focus can be adjusted from the control console. Treatments will be suspended if both TV systems malfunction. An intercom system is installed for communication between the operator and the patient.

Date of Origin: 01/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health



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Policy / Procedure

RIVERSIDE FACILITY RRM

Category: Radiation Safety

Page 2 of 2

Subject: Gamma Knife® Stereotactic Radiosurgery Operating Instructions

Policy #: RSO - 36-02

Distribution Group: Radiology

- 7) Prior to treating the first patient on each day of use, checks will be performed and logged of all interlocks, source-position-indicator lights, safety systems, and alarm monitor.

Date of Origin: 01/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health

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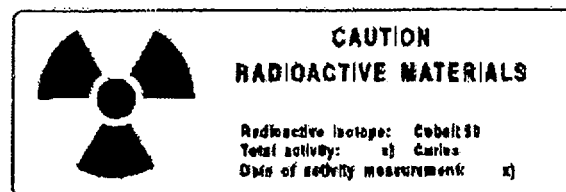
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RIVERSIDE FACILITY: RPMC**Category:** Radiation Safety

Page 1 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures**Policy #:** RSO - 36-03**Distribution Group:** Radiosurgery and Radiation Therapy**Related Policies:** RSO-36:01 and RSO-36:02.**References:** Leksell Gamma Knife® 4C Users Manual**POLICY:** Gamma Knife® Emergency Procedures**PURPOSE:** The Leksell Gamma Knife® is a radiosurgery system for the treatment of various conditions diagnosed within the brain. The precautions below should be observed at all times.**PROCEDURE:****I. Labels:** The following are examples of some of the warning labels that may be found on the LGK.**A. General warning**

1. Instructs users to refer to the manual Leksell Gamma Knife® *Instructions for Use*. This warning label is present a several places.

**B. Radiation warning labels on the radiation unit****Individual Authorized By:****Committees Authorized By:** Radiation Safety Committee**Authoring Department:** Riverside and University of Virginia Radiosurgery Center**Date Approved:****Effective Date:****Last Date Reviewed:****Last Revision Date:** 03/2006**Replace Policy Date:****Retired:**

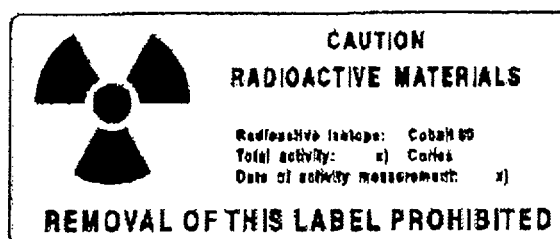
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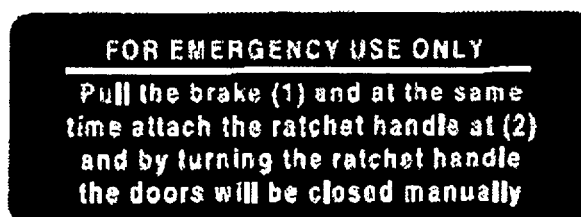
Policy / Procedure

RIVERSIDE FACILITY: RRMC**Category: Radiation Safety**

Page 2 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures**Policy #: RSO - 36-03****Distribution Group: Radiosurgery and Radiation Therapy**

C. Labels on the radiation unit



D. Labels on the ratchet handle



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Last Date Reviewed:

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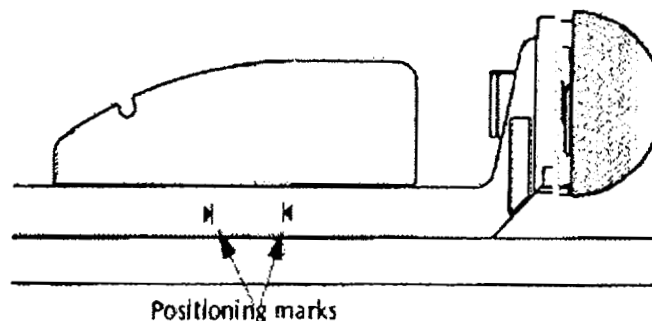
Page 3 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures

Policy #: RSO - 36-03

Distribution Group: Radiosurgery and Radiation Therapy

E. Positioning marks on the treatment couch



F. Label on the treatment couch

COUCH RELEASE

G. Label on models with handwheel

FOR EMERGENCY USE ONLY
Handwheel for manually
closing the shielding doors

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Policy / Procedure

RIVERSIDE FACILITY: RRMC

Category: Radiation Safety

Page 4 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures

Policy #: RSO - 36-03

Distribution Group: Radiosurgery and Radiation Therapy

II. Radiation

- A. Only qualified and authorized personnel are permitted to operate this system. A list of names and telephone numbers of the authorized users, the authorized medical physicist and the Radiation Safety Officer is posted at the Treatment Console for use and reference during an emergency. Full use must be made of all radiation protection features, devices, systems, procedures and accessories.

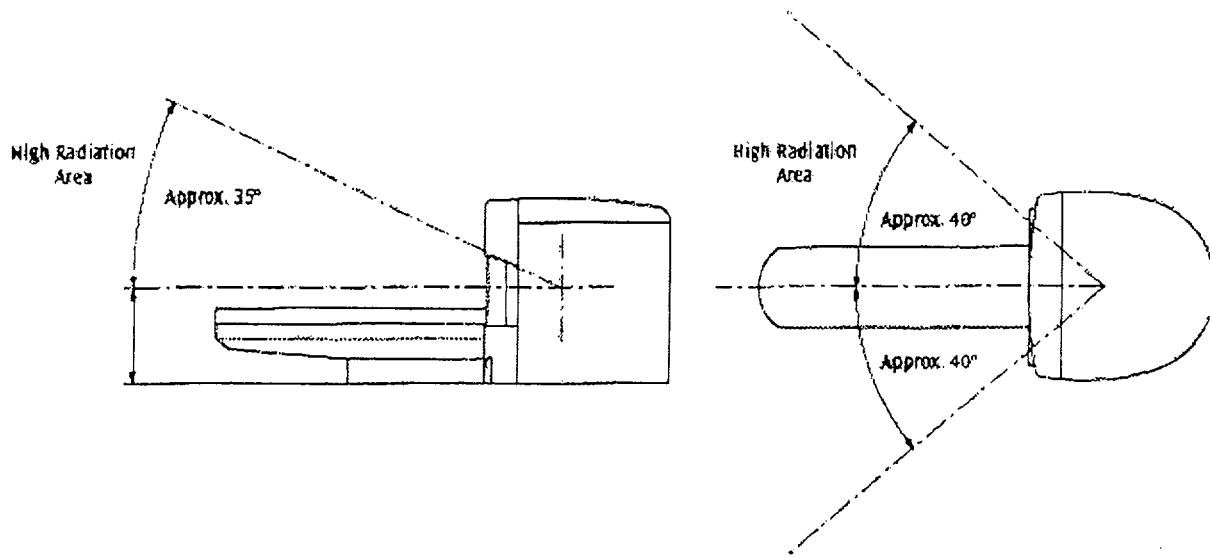


Figure T.1 High Radiation Area

III. Special Tools

A. APS Release Tools

1. The APS release tool and the spade tool allows you to release the patient from the helmet if the couch is stuck in the treatment position when the APS is used. The emergency equipment is located upon entrance of the treatment room immediately on the left wall.

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Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

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Policy / Procedure

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Category: Radiation Safety

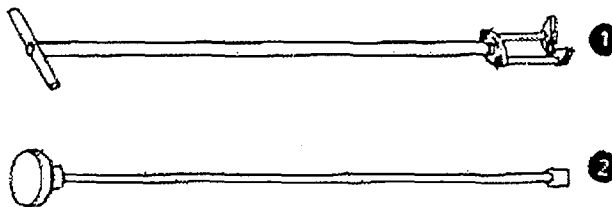
Page 5 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures

Policy #: RSO - 36-03

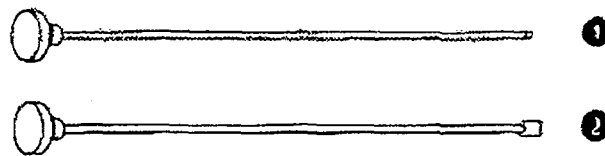
Distribution Group: Radiosurgery and Radiation Therapy

2. Normally, the couch is moved out of the treatment position when the emergency **Couch Out** button is pressed, or can be pulled out manually. If both of these methods fail, the patient can be released by use of the APS Special Release Tool (1) and the Spade Tool (2).



B. Trunnion Release Tools

1. The long allen key and spade tool allow you to release the patient from the helmet if the couch is stuck in the treatment position when trunnions are used. The emergency equipment is located upon entrance of the treatment room immediately on the left wall
2. Normally, the couch is moved out of the treatment position when the emergency **Couch Out** button is pressed, or can be pulled out manually. If both of these methods fail, the patient can be released by use of the Long Allen Key (1) and the Spade Tool (2).



C. Collimator Pliers

1. The collimator pliers are used to insert or remove collimators/plugs from the helmet. Depending on the collimator/plug socket, two types are available:
 - a) Pliers for spring socket (1).

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Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

Replace Policy Date:

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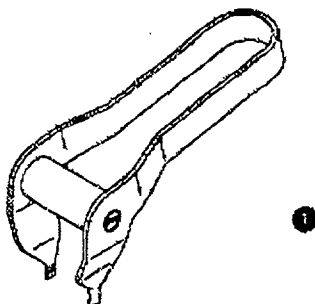
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Category: Radiation Safety

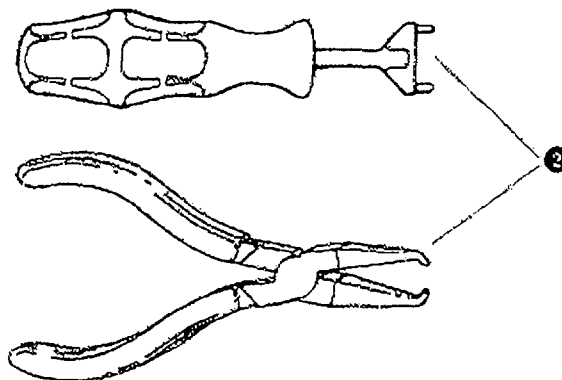
Page 6 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures

Policy #: RSO - 36-03

Distribution Group: Radiosurgery and Radiation Therapy


b) Pliers and screwdriver for bayonet socket (2).



D. APS Test Tool

1. The APS test tool should be used to perform a test of the APS weekly and after installation of the APS units.
2. The APS test tool comprises a frame (1) which docks into the APS units. Unlike the coordinate frame, the test tool docks with all four gamma angle setting pins. A handle (2) is provided to carry the tool.
3. Two bars (3) and (4) with spring loaded tips project from the frame towards the collimator helmet. The springs are compressed as the bars press against the face of the

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Last Revision Date: 03/2006

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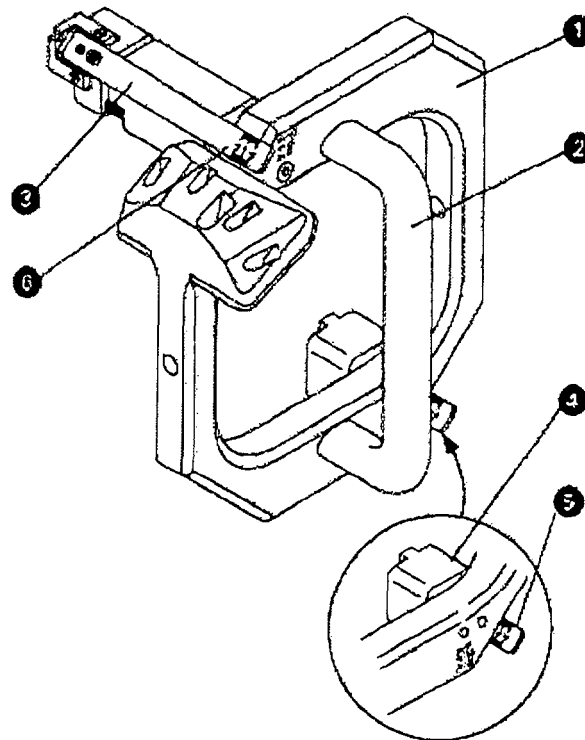
Policy / Procedure

RIVERSIDE FACILITY: RRM
Category: Radiation Safety

Page 7 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures
Policy #: RSO - 36-03
Distribution Group: Radiosurgery and Radiation Therapy

collimator helmet, causing the attached indicator scale (5) and (6) to move. If the APS is functioning correctly the scale should read 0 + or - 0.5 mm when the APS is at the test position.



E. Patient Docking Indicator

1. The patient docking indicator (PDI) is used to verify a correct docking position of the coordinate frame to the APS. It comprises of a slightly curved magnetic base plate (1) with a handle (2).
2. The lower face of the plate houses a microswitch and five optical sensors (3).
3. The microswitch closes when the PDI is placed correctly on top of the left APS y-slide above the coordinate frame, causing the status lamp (4) on the top of the plate to illuminate.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

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Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

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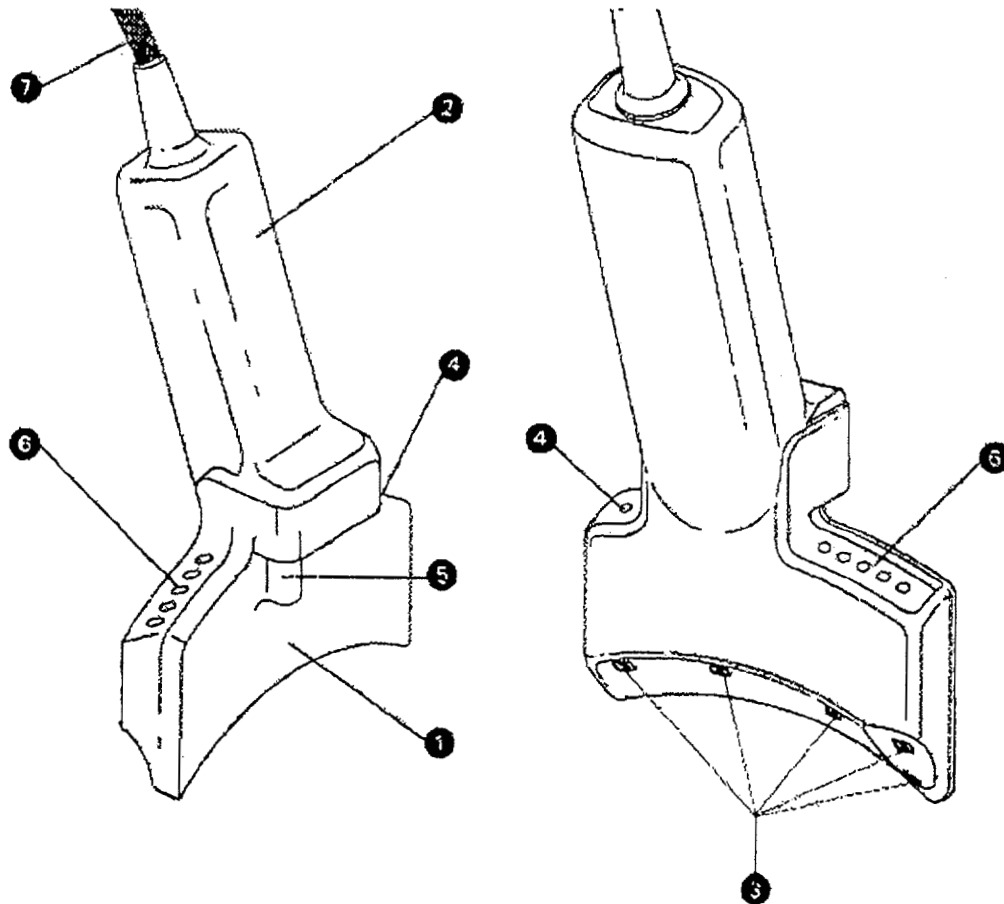
Policy / Procedure

RIVERSIDE FACILITY: RRM
Category: Radiation Safety

Page 8 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures
Policy #: RSO - 36-03
Distribution Group: Radiosurgery and Radiation Therapy

4. The guiding pin (5) fits into the notch on top of the y-slide.
5. The five optical sensors are positioned so that each one corresponds to one of the five possible docking positions: 72°; 90°; 110°; 125° or **HIGH**. When checking the docking position the corresponding lamp (6) illuminates to indicate the reading angle.
6. The PDI is stored in the cabinet at the front of the radiation unit and is permanently connected by an electrical cable (7).



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Replace Policy Date:

Retired:


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Policy / Procedure

RIVERSIDE FACILITY: RRM

Category: Radiation Safety

Page 9 of 21

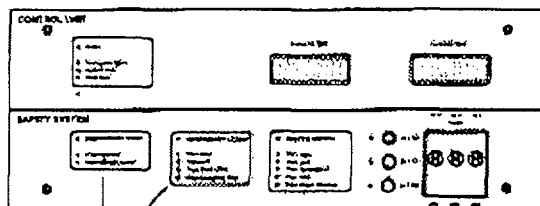
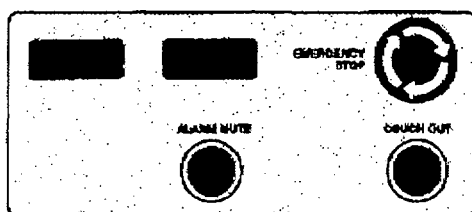
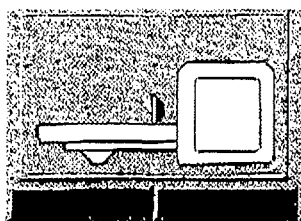
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Policy #: RSO - 36-03

Distribution Group: Radiosurgery and Radiation Therapy

IV. Emergency Alarm

A. An **emergency alarm** indicates a situation which has the potential to expose the patient or personnel to excessive radiation or some other hazard and requires immediate operator action.



Emergency Stop and Alarm Indicators

1. The **Emergency Alarm** indicators on the control panel and computer monitor lights up and the alarm buzzer is activated.
2. Information about the cause or nature of the alarm is shown in the System Information field at the bottom of the Treatment View dialog.
3. The Safety System also indicates the source of the emergency stop as either;

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Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

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Last Revision Date: 03/2006 Replace Policy Date: Retired:

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Policy / Procedure**RIVERSIDE FACILITY: RRMC****Category: Radiation Safety****Page 10 of 21****Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures****Policy #: RSO - 36-03****Distribution Group: Radiosurgery and Radiation Therapy****a) From Operator**(1) Emergency caused by the operator by pressing the **Emergency Stop** button on the Control Panel.**b) External Pushbutton**

(1) Emergency caused by pressing an external emergency button (other emergency button than on the Control Panel).

B. Resetting an Emergency Alarm1. Once the cause of the alarm has been cleared the interlocking can be reset by clicking the appropriate button in the **Configuration dialog**.**V. Emergency Procedures****A. What to do in an Emergency**

1. If any patient emergency occurs during the automatic treatment sequences you must assess the situation and decide on the most appropriate course of action:

- a) Treatment Pause
- b) Couch Out
- c) Emergency Stop
- d) Manually Releasing the Couch
- e) Couch stuck in Treatment Position

Each option is outlined in the flowcharts on the next page:**Individual Authorized By:****Committees Authorized By: Radiation Safety Committee****Authoring Department: Riverside and University of Virginia Radiosurgery Center****Date Approved:****Effective Date:****Last Date Reviewed:****Last Revision Date: 03/2006****Replace Policy Date:****Retired:**


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Policy / Procedure

RIVERSIDE FACILITY: RRM

Category: Radiation Safety

Page 11 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures

Policy #: RSO - 36-03

Distribution Group: Radiosurgery and Radiation Therapy

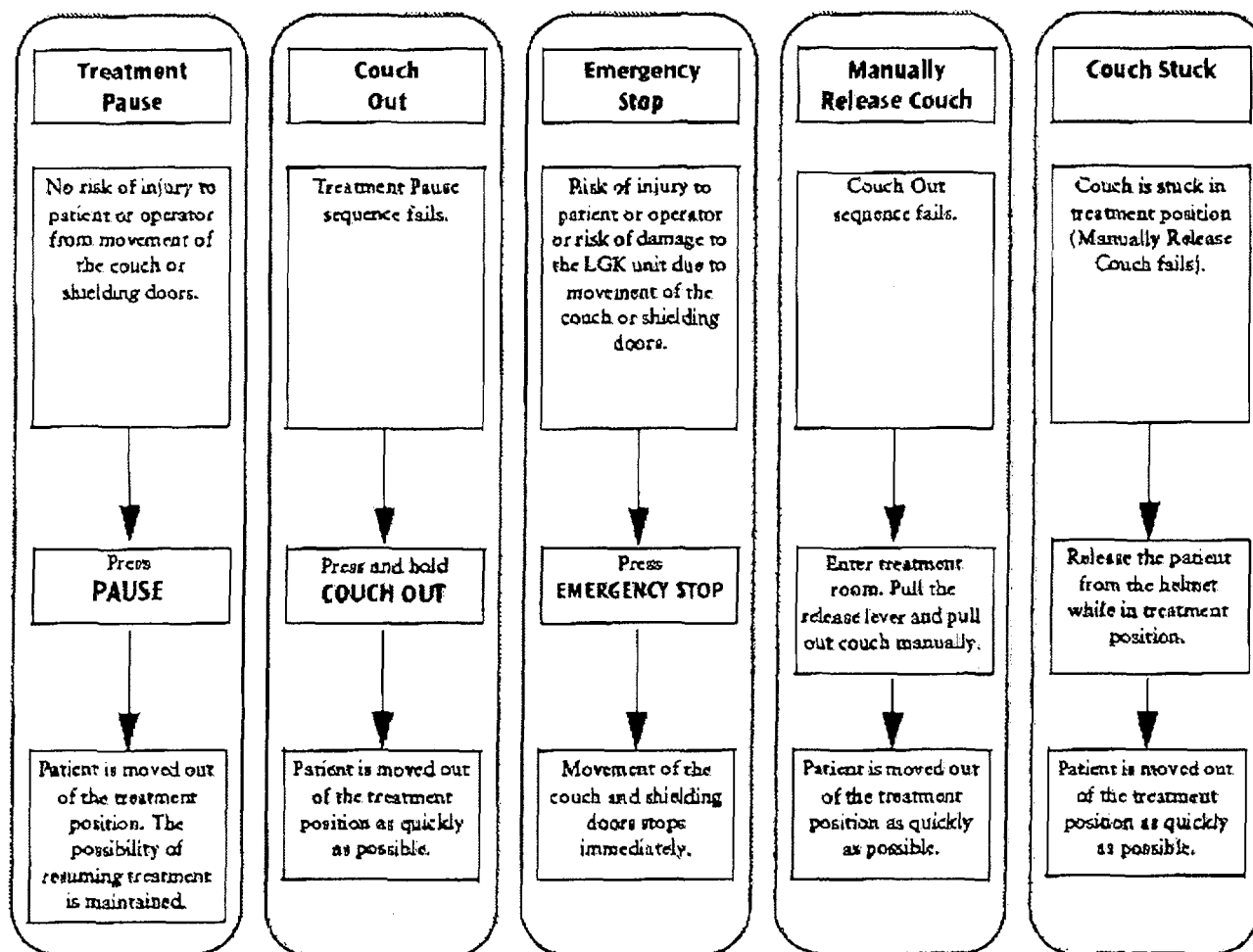


Figure 9.1 What to do in an Emergency: Options

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Policy / Procedure

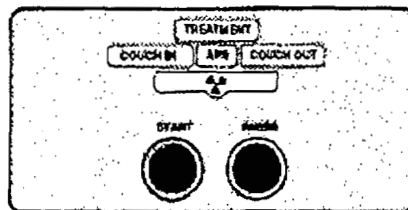
RIVERSIDE FACILITY: RRMC
Category: Radiation Safety

Page 12 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures
Policy #: RSO - 36-03
Distribution Group: Radiosurgery and Radiation Therapy

B. Treatment Pause

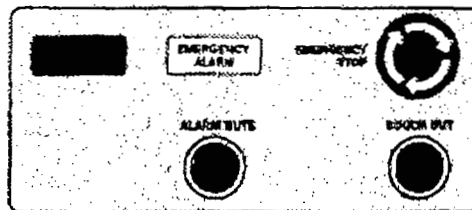
1. A treatment pause can be initiated if there is no risk of injury to the patient or operator from movement of the couch or shielding doors.
2. Activate a treatment pause by pressing the **Pause** key on the keyboard.



3. If the treatment pause sequence fails, press the **Couch Out** button at the operator panel.

C. Couch Out

1. If a treatment pause is activated but fails, the Couch Out button is used to move the patient out of the treatment position as quickly as possible. *Note: the Couch Out can be used even if the control unit is non-operational but it will not operate if the emergency stop is activated.*
2. Press and hold the **Couch Out** button until the shielding doors are closed.



The couch moves at high speed all the way to its outer position.

3. Release the patient from the collimator helmet.
4. Escort the patient from the treatment room.
5. If the shielding doors do not close automatically you must close them manually.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved: Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006 Replace Policy Date:

Retired:


RIVERSIDE
HEALTH SYSTEM

701 Town Center Drive, Suite 1000, Newport News, Virginia 23606

Policy / Procedure

RIVERSIDE FACILITY: RRM

Category: Radiation Safety

Page 13 of 21

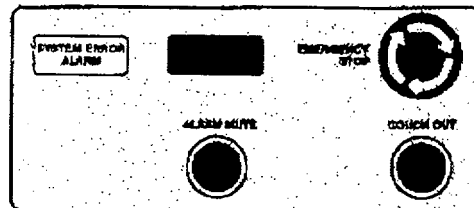
Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures

Policy #: RSO - 36-03

Distribution Group: Radiosurgery and Radiation Therapy

D. Emergency Stop

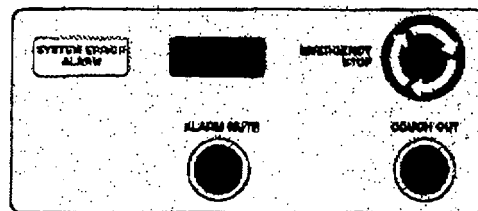
1. Use the emergency stop button when there is a risk of injury to patient or operator or risk of damage to the LGK unit due to movement of the couch or shielding doors. Movement of the couch and shielding doors stops immediately when the button is pressed.
2. Press the Emergency Stop button.



- a) The emergency alarm buzzer sounds, the emergency alarm indicators on the control panel and the treatment view monitor flash and the message Emergency Stop activated is displayed in the system information field.
- b) The couch and radiation shielding doors hold their positions until the emergency stop is released.
3. If necessary, pull out the sliding couch manually. *Note: The Couch Out button will not operate while the emergency stop is activated.*

E. Restarting After an Emergency Stop

1. Turn the Emergency Stop button clockwise to release it as indicated by the arrows on the button. The couch moves out and the shielding doors close automatically.



2. If the shielding doors do not close automatically, try to close them by use of the **Couch Out** button.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

Replace Policy Date:

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701 Town Center Drive, Suite 1000, Newport News, Virginia 23606

Policy / Procedure**RIVERSIDE FACILITY: RRMC****Category: Radiation Safety****Page 14 of 21****Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures****Policy #: RSO - 36-03****Distribution Group: Radiosurgery and Radiation Therapy****F. Manually Release Couch**

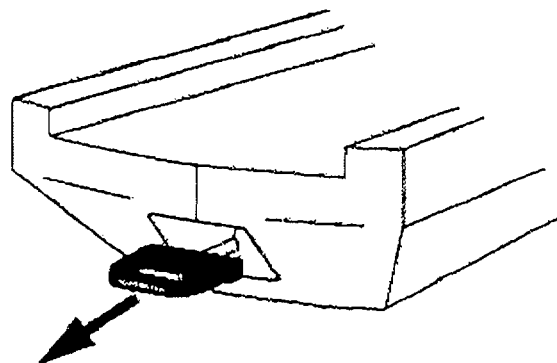
1. If the couch out sequence fails and the couch is stuck in the treatment position you have to manually release the couch as follows:

- a) Enter the treatment room.

**WARNING 63**

Personnel entering the treatment room while the shielding doors are open must keep their exposure time to a minimum. Overexposure to gamma radiation can endanger health.

- b) Pull the couch release handle.



Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

Replace Policy Date:

Retired:


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HEALTH SYSTEM

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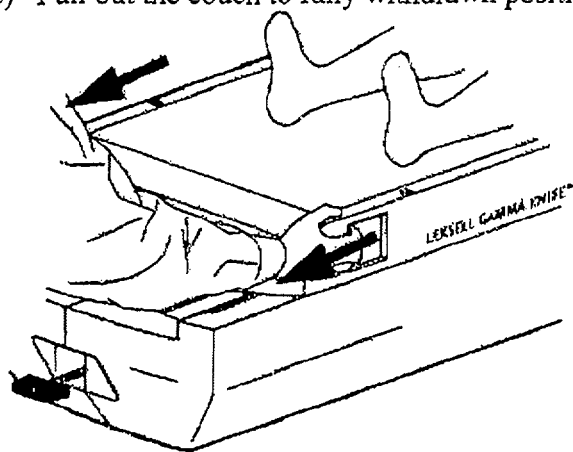
Policy / Procedure

RIVERSIDE FACILITY: RRMC
Category: Radiation Safety

Page 15 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures
Policy #: RSO - 36-03
Distribution Group: Radiosurgery and Radiation Therapy

- c) Pull out the couch to fully withdrawn position by hand.



- d) Release the patient and leave the treatment room together with the patient.
 e) If the shielding doors **did not** close, lock the door to the treatment room and inform the Radiation Safety Officer.
 f) If the shielding doors did close, push back the release handle into locking position and verify that the couch is locked.

G. Couch Stuck in Treatment Position

1. If the couch becomes stuck in the treatment position and cannot be withdrawn manually, the patient must be released from the helmet using the special release tool(s).


WARNING 64

Personnel entering the treatment room while the shielding doors are open must keep their exposure time to a minimum. Overexposure to gamma radiation can endanger health.


WARNING 65

The patient's head must be supported at all times when the coordinate frame is being docked to or removed from the APS or trunnions to avoid injury to the patient.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved: Effective Date: Last Date Reviewed:

Last Revision Date: 03/2006 Replace Policy Date: Retired:

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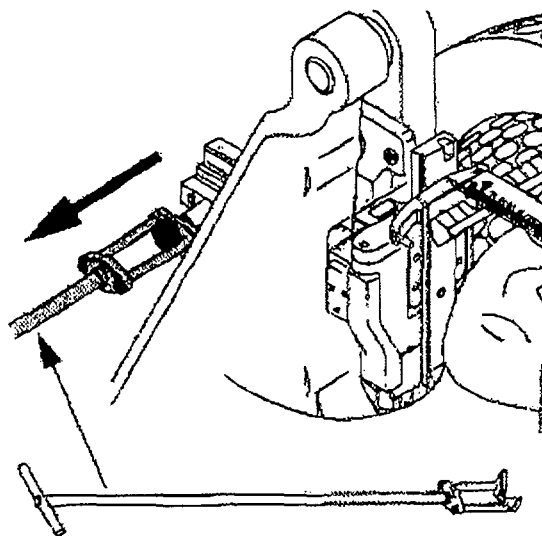
Policy / Procedure

RIVERSIDE FACILITY: RRMC**Category: Radiation Safety**

Page 16 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures**Policy #: RSO - 36-03****Distribution Group: Radiosurgery and Radiation Therapy****H. Manually Releasing the Patient from the APS**

1. Ask the patient to keep his/her head up and be ready to take the weight of the coordinate frame.
2. Loosen one or both of the X axes slides of the APS units using the APS Special Release Tool.



3. If necessary, insert the Spade Tool between the APS Y slide and the coordinate frame and gently lever out the frame.
4. Release the patient and leave the treatment room together with the patient.
5. Lock the door(s) to the treatment room and inform the Radiation Safety Officer.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

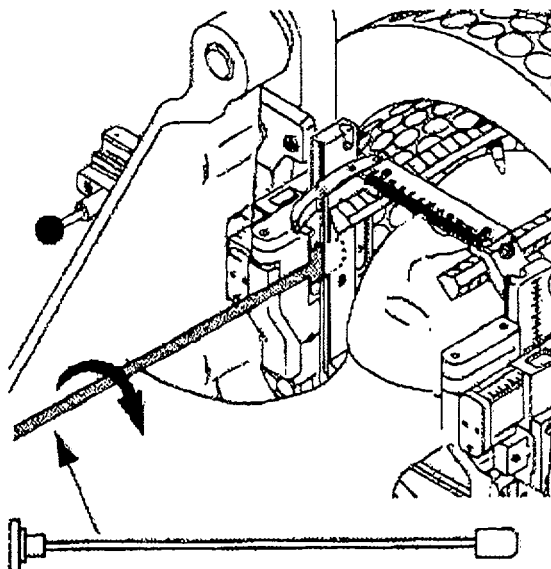
Last Revision Date: 03/2006

Replace Policy Date:

Retired:

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Policy / Procedure**RIVERSIDE FACILITY: RRMC****Category: Radiation Safety****Page 17 of 21****Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures****Policy #: RSO - 36-03****Distribution Group: Radiosurgery and Radiation Therapy****I. Manually Releasing the Patient from Trunnions****WARNING 66**

Personnel entering the treatment room while the shielding doors are open must keep their exposure time to a minimum. Overexposure to gamma radiation can endanger health.

**WARNING 67**

The patient's head must be supported at all times when the coordinate frame is being docked to or removed from the APS or trunnions to avoid injury to the patient.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved: Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006 Replace Policy Date:

Retired:

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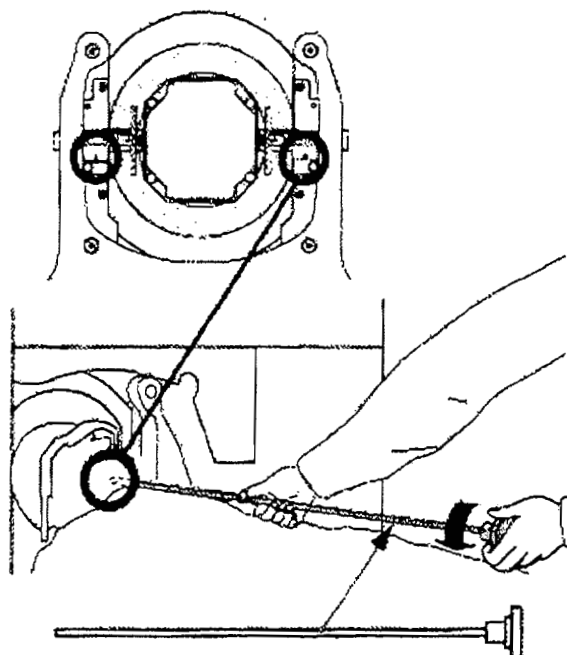
Policy / Procedure

RIVERSIDE FACILITY: RRMC**Category: Radiation Safety**

Page 18 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures**Policy #: RSO - 36-03****Distribution Group: Radiosurgery and Radiation Therapy**

1. Ask the patient to keep his/her head up and be ready to take the weight of the coordinate frame.



2. Loosen one or both of the helmet trunnions using the long Allen key.
3. If necessary, insert the Spade Tool between the coordinate frame and the trunnion and gently lever out the frame.
4. Release the patient and leave the treatment room together with the patient.
5. Lock the door(s) to the treatment room and inform the Radiation Safety Officer.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

Replace Policy Date:

Retired:

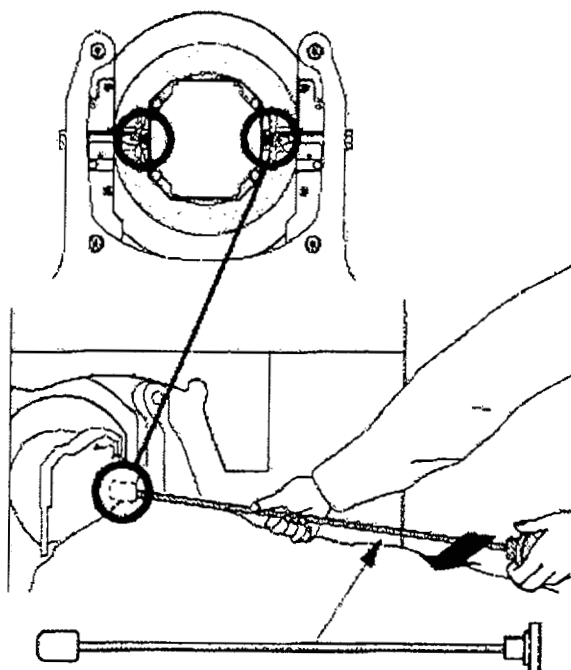
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Policy / Procedure

RIVERSIDE FACILITY: RRM**Category:** Radiation Safety

Page 19 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures**Policy #:** RSO - 36-03**Distribution Group:** Radiosurgery and Radiation Therapy

J. Closing the Shielding Doors, New & Upgrades C/B-2

**WARNING 68**

Personnel entering the treatment room while the shielding doors are open must keep their exposure time to a minimum. Overexposure to gamma radiation can endanger health.

Individual Authorized By:**Committees Authorized By:** Radiation Safety Committee**Authoring Department:** Riverside and University of Virginia Radiosurgery Center**Date Approved:****Effective Date:****Last Date Reviewed:****Last Revision Date:** 03/2006**Replace Policy Date:****Retired:**


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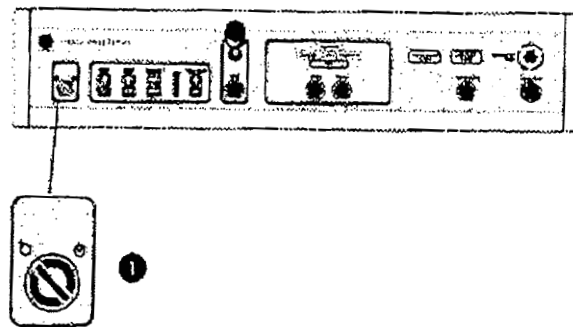
Policy / Procedure

RIVERSIDE FACILITY: RRM
Category: Radiation Safety

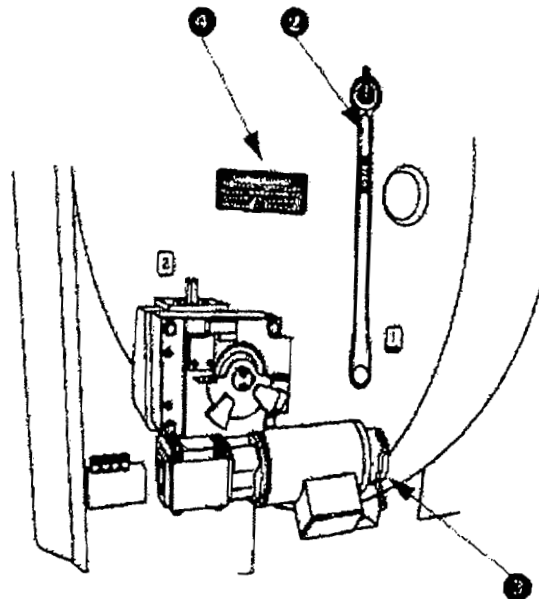
Page 20 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures
Policy #: RSO - 36-03
Distribution Group: Radiosurgery and Radiation Therapy

1. Exit the system until the log-in dialog opens. Turn the **Power** keyswitch (1) to the off position. Bring the key with you.



2. Open the cover on the left side of the radiation unit.



- ② Ratchet handle
- ③ Brake release handle
- ④ Instruction label:

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

Replace Policy Date:

Retired:


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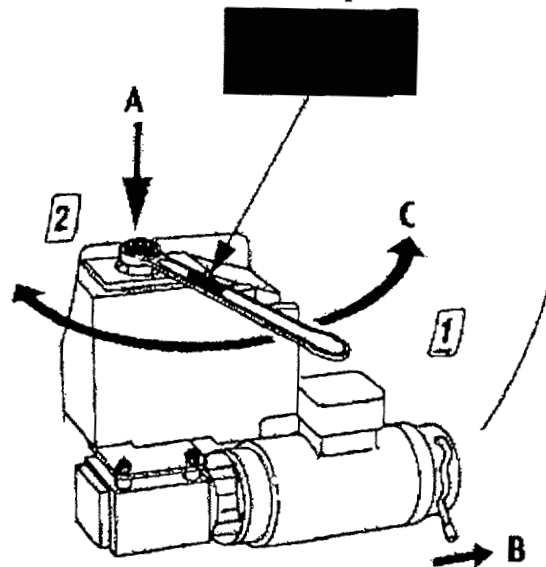
RIVERSIDE FACILITY: RPMC
Category: Radiation Safety

Page 21 of 21

Subject: Gamma Knife® Stereotactic Radiosurgery Device Emergency Procedures
Policy #: RSO - 36-03
Distribution Group: Radiosurgery and Radiation Therapy
FOR EMERGENCY USE ONLY

Pull the brake (1) and at the same time attach the ratchet handle at (2) and by turning the ratchet handle the doors will be closed manually

3. Lift the ratchet handle from the hook and attach it to the shaft pivot of the electrical motor unit with the label **CLOSE** upwards. A



4. Pull and hold the brake release handle of the motor. B
5. While holding the brake release handle, turn the ratchet handle from side to side to close the shielding doors. C
6. If the shielding doors cannot be closed manually, inform the radiation safety officer or the physicist in charge and ensure that no-one enters the treatment room.
7. Contact your Elekta® service representative.

Individual Authorized By:

Committees Authorized By: Radiation Safety Committee

Authoring Department: Riverside and University of Virginia Radiosurgery Center

Date Approved:

Effective Date:

Last Date Reviewed:

Last Revision Date: 03/2006

Replace Policy Date:

Retired:



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Policy / Procedure

RIVERSIDE FACILITY: REMC

Category: Radiation Safety

Page 1 of 3

Subject: Gamma Knife® Stereotactic Radiosurgery Quality Assurance Plan

Policy #: RSO - 36-04

Distribution Group: Radiosurgery Department

- 1) Periodic spot-checks shall be performed for the gamma knife stereotactic radiosurgery unit.
- 2) Periodic spot-check measurements shall be performed:
 - a. Monthly;
 - b. Before the first use of the unit on a given day; and
 - c. After each source installation.
- 3) Measurements shall be performed in accordance with this written policy which has been established by the authorized medical physicist (Policy RSO 36-05). The authorized medical physicist need not actually perform the spot check measurements.
- 4) The authorized medical physicist will review the spot-check measurements within 15 days and will notify the stereotactic radiosurgery facility as soon as possible in writing the results of each spot-check.
- 5) The monthly spot-checks shall assure proper operation of:
 - a. Timer accuracy
 - b. Timer linearity
 - c. On-Off error
 - d. Machine output in phantom with 18mm Helmet
 - e. Difference between the measured output and the expected (decayed output expressed as a percentage of the expected output)
 - f. Alignment (using Trunnion test tool)
 - g. Microswitch test (using Helmet test box)
 - h. Treatment table retraction mechanism
 - i. Interlock systems
 - j. Source exposure indicator lights
 - k. Viewing and intercom systems

Date of Origin: 05/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health

**RIVERSIDE****H E A L T H S Y S T E M**

701 Town Center Drive, Suite 1000, Newport News, Virginia 23606

Policy / Procedure

RIVERSIDE FACILITY: RRMU**Category: Radiation Safety**

Page 2 of 3

Subject: Gamma Knife® Stereotactic Radiosurgery Quality Assurance Plan

Policy #: RSO - 36-04

Distribution Group: Radiosurgery Department

- l. Radiation monitors used to indicate room exposures
 - m. Emergency off buttons
 - n. Emergency timing circuits
 - o. Stereotactic frames and localizing devices
- 6) The monthly spot-check measurements of the Leksell Gamma Knife Unit will contain all of the items listed on the Monthly Quality Checklist. A record of each spot-check measurement will be maintained for a period of at least 3 years. If the difference between the measured and the decayed output is 5% or more, the authorized medical physicist will immediately notify the RSO and the facility administrator.
- 7) Before the first use of the unit on a given day, spot-checks must assure proper operation of:
- a. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 - b. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 - c. Viewing and intercom systems;
 - d. Emergency response tools;
 - e. Timer termination;
 - f. Radiation monitors used to indicate room exposures; and
 - g. Emergency off buttons; and
 - h. APS/Trunnion exchange check.
- 8) A daily check of the Leksell Gamma Knife Unit shall be made before the first treatment of a patient. The daily check will contain all of the items listed on the Daily Quality Assurance Checklist. The record of each daily check will be maintained for a period of at least 3 years.
- 9) The gamma knife stereotactic radiosurgery facility shall arrange for the repair of any system not operating properly.

Date of Origin: 05/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health

**RIVERSIDE****HEALTH SYSTEM**

701 Town Center Drive, Suite 1000, Newport News, Virginia 23606

Policy / Procedure

RIVERSIDE FACILITY: RRMC**Category: Radiation Safety**

Page 3 of 3

Subject: Gamma Knife® Stereotactic Radiosurgery Quality Assurance Plan

Policy #: RSO - 36-04

Distribution Group: Radiosurgery Department

- 10) If the results of the spot-checks indicate the malfunction of any system the facility shall lock the control console in the off position and will not use the gamma knife unit except to repair, replace, or check the malfunctioning system.

- 11) The gamma knife stereotactic radiosurgery department shall retain a record of the periodic spot-checks. All records required for compliance with the NRC's regulations, the conditions of our license and commitments made in our license application and correspondence with NRC shall be maintained.

Date of Origin: 05/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health


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HEALTH SYSTEM

701 Town Center Drive, Suite 1000, Newport News, Virginia 23606

Policy / Procedure

RIVERSIDE FACILITY RRM
Category: Radiation Safety

Page 1 of 3

Subject: Gamma Knife® Stereotactic Radiosurgery Spot-Check Procedure
Policy #: RSO - 36-05
Distribution Group: Radiosurgery Department

- 1) Periodic spot-check measurements shall be performed:
 - a. Monthly;
 - b. Before the first use of the unit on a given day; and
 - c. After each source installation.
- 2) Measurements shall be performed in accordance with this procedure which has been established by the authorized medical physicist. The authorized medical physicist need not actually perform the spot check measurements.
- 3) The authorized medical physicist will review the spot-check measurements within 15 days and will notify the stereotactic radiosurgery facility as soon as possible in writing the results of each spot-check.
- 4) The spot-check procedure is as follows:
 - a. **Absorbed Dose Rate:**
 - i. Measured leakage during 5 minutes: $L = \text{nC}$
 - ii. Temperature = C° , Pressure = mbar
 - iii. Took 10 different readings for 1 min each:
 - iv. Average $M = (\text{nC/min})$
 - v. $C_{tp} =$
 - vi. $M_u = M - L/5 [\text{nC/min}]$
 - vii. Dose Rate in water $D_w(t) = C_{tp} \cdot N_{D,w} \cdot M_u \cdot k_c [\text{Gy/min}]$
 - viii. $N_{D,w} = [\text{Gy/nC}]$
 - ix. So the Dose Rate = Gy/min at Date

Date of Origin: 05/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

Source: U.S. Nuclear Regulatory Commission, VA Radiological Health

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Policy / Procedure

RIVERSIDE FACILITY: RRMC**Category: Radiation Safety**

Page 2 of 3

Subject: Gamma Knife® Stereotactic Radiosurgery Spot-Check Procedure**Policy #:** RSO - 36-05**Distribution Group:** Radiosurgery Department**b. Ring Test:**

- i. Micro switches test performed for all four helmets by putting 0.1 mm shim under each helmet and tested and set the switches.
- ii. Adjust ring attached, "green signal"
- iii. adjust ring & shims 0.1 mm attached, "red signal"
- iv. check the Helmet ID = 1 and that helmet cap sensor is ok"

c. Helmet Position Test:

- i. Mount and check Trunnions pair with helmet test tool, center coordinate left and right and 100 ok
- ii. Select timer run first select wrong collimator helmet then correct result ok
- iii. Start treatment, the door opening time is 7 ± 2 seconds
- iv. Treatment with shims 0.1 mm attached, couch return after 6 seconds during incorrect position.

d. Safety Switches Test:

- i. Check that it is not possible to start the treatment when
- ii. The cap is removed ok
- iii. Left patient protection panel is removed ok
- iv. Right patient protection panel is removed ok
- v. The helmet changer is elsewhere than in stored position ok
- vi. The treatment room door is open ok
- vii. If emergency release handle on couch door is pulled
- viii. Checked the helmet screw sensor at helmet consol work properly ok
- ix. Check the helmet changer "in" sensor works properly i.e. press "couch in". Pull helmet changer Couch stop ok
- x. Checked that the helmet trolley sensor works properly i.e. helmet can only be lowered to the helmet trolley if this sensor is activated ok

Date of Origin: 05/06**Last Revision Date:** 05/2006**Authorized By:** Radiation Safety Committee**Source:** U.S. Nuclear Regulatory Commission, VA Radiological Health

**RIVERSIDE****HEALTH SYSTEM**

701 Town Center Drive, Suite 1000, Newport News, Virginia 23606

Policy / Procedure

RIVERSIDE FACILITY: RRMC**Category: Radiation Safety**

Page 3 of 3

Subject: Gamma Knife® Stereotactic Radiosurgery Spot-Check Procedure**Policy #:** RSO - 36-05**Distribution Group:** Radiosurgery Department

- xi. Checked that the helmet changer "down" sensor works properly i.e. helmet cannot be released from changer if this is not in down position even when helmet table is in position.ok
- xii. Checked the mattress slide lock/unlock works and that the squeeze protection works at front, middle and back on both right and left side. Ok

e. Emergency Safety Test:

- i. Switch on mains start treatment shut off mains. Treatment interrupted after 1 minute. Ok

f. Treatment Stop Test:

- i. Pushed "Treatment Pause" when couch is in treatment position:
- ii. checked that couch return ok
- iii. checked that elapsed time have stopped ok
- iv. pushed "Treatment Start" and checked that the treatment is continuing from existing elapsed time when the couch is in position ok
- v. pushed emergency stop. All movements stopped in the treatment room while shielding doors are opening .ok

g. Timer Safety Test:

- i. Checked synchronization during 30 minutes treatment
- ii. Verified timer correctness by
- iii. 60.00 min. = ? min. (accepted 60.00 min+- 10 sec)
- iv. 1.00 min = ? min. (accepted 1.00 min +- 1 sec)
- v. On the treatment planning side we tested the treatment plan exported correctly to the treatment computer
- vi. Exported the CT and MRI images from image server to the LGP. Timer accuracy

Date of Origin: 05/06**Last Revision Date:** 05/2006**Authorized By:** Radiation Safety Committee**Source:** U.S. Nuclear Regulatory Commission, VA Radiological Health

Gamma Knife Center
Riverside and University of Virginia Radiosurgery Center
Neuroscience Department

Daily Startup Procedure:

Week of ____ / ____ / ____	Mon	Tues	Wed	Thurs	Fri
Initials Physicist					
Emergency Release Tools Available					
Emergency Procedures Posted					
2 Video Monitors Operational					
Audio Communication Operational					
Which Helmet? (4, 8, 14 or 18 mm):					
Perform Alarm Test					
Test Run: Interlocks:					
1) Door Interlock					
2) Helmet Cover Interlock					
3) Lt. Patient Protection Interlock					
4) Rt. Patient Protection Interlock					
Test Run: Emergency Stops: Verify that the couch returns and treatment is paused under the following conditions:					
1) Open Door During Test Run					
2) Press "Couch Out" during Rx					
a) Press "Stop" while couch is moving out – verify that couch motion stops					
b) Pull out "Stop" and push "Reset" – verify that couch returns and doors close					
3) Press "Pause" during Rx					
Test Run: Verify proper completion					
Both radiation monitors flashing during "Beam On" conditions:					
Both radiation monitors cease flashing when shield doors close:					
Radiation Survey: Meter reading less than 2.0 mR/hr?					
If indicated, run APS QA Test. Record Helmet Size (4, 8, 14, or 18 mm)					

Comments: _____

Riverside and University of Virginia

Gamma Knife Center

Gamma Knife Monthly Checks

Date: _____

Performed by: _____

Mechanical Checks	tolerance	P	F	Comments
Posted Safety Instructions	—			
Posted Emergency Instructions	—			
Audio/ Visual system	—			
Survey Meter/ Check Source	+20 %			
Door Lock Operation	—			
Room Radiation Monitor	—			
Remote Indication for Room Radiation Monitor	—			
Emergency Tools (Allen Key, Trunnion Release)	—			
Trunnion Tests (2sets) 18mm	0.3mm			
Trunnion Tests (2sets) 14mm	0.3mm			
Trunnion Tests (2sets) 8mm	0.3mm			
Trunnion Tests (2sets) 4mm	0.3mm			
Microswitch Test 18mm	0.1mm			
Microswitch Test 14mm	0.1mm			
Microswitch Test 8mm	0.1mm			
Microswitch Test 4mm	0.1mm			
Stereotactic Frames and accessories				
Door Interlock Operation	—			
Radiation (beam) Status Indicators	—			
Treatment Stop Buttons (in room)	—			
Emergency Interrupt Button (console)	---			
Emergency Strobe Light Activation	<80s			
Timer Accuracy	±2%			
Timer Reproducibility	±2%			
Timer Linearity	±2%			
End Effect Value (from linearity curves)	—			
Timer Termination of Exposure	—			

Comments: _____

Reviewed by Physicist: _____

Riverside and University of Virginia

Gamma Knife Center

Gamma Knife Annual Calibration

Date: _____

Performed by: _____

Function Inspected	P	F	Comments
Timer Constancy; tolerance +/- 0.1 min			
Timer Linearity; correlation coeff ≥ 0.99			
On-Off Error; tolerance +/- 0.01 min			
Trunnions; tolerance +/- 0.3 mm			
Door Interlock			
Helmet Shim Test			
Beam Condition Light:			
at console			
at door (radiation in use light)			
Viewing Systems:			
TV console			
Communication System			
Emergency Off Buttons:			
on console			
on side wall			
on back wall			
Room Monitor:			
on A/C line			
emergency line			
monitor light on console			
Emergency Instructions Posted			
Timer Reproducibility			
NRC Postings			
Emergency Release Rod Present			
Operational Survey Meter Present			

Comments: _____

Reviewed by Physicist: _____