

NRC LICENSE AMENDMENT REQUEST

NMSBL

FOR

**RIVERSIDE REGIONAL MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
500 J. CLYDE MORRIS BOULEVARD
NEWPORT NEWS, VIRGINIA 23601**

NRC license number 45-09001-01

03003330

By

**HAROLD PRUSSIA, BS, RTR, QM
RADIATION SAFETY OFFICER
(757) 594-2644**

May 3, 2006

138787

NRC/RONI MATERIALS-002

NRC License #45-09001-01 Amendment

May 3, 2006

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NRC License #45-09001-01 Amendment**May 3, 2006****Page 3 of 5****1. PURPOSE OF AMENDMENT**

- A. We request permission to clinically use our Gamma Stereotactic Radiosurgery sources (GSR).
- B. We request to delete Andrew D. Lauve, M.D from our list of authorized medical users.
- C. Expand the authorization of Medical Physicists John Freshcorn to include Gamma Stereotactic Radiosurgery Medical Physicists.

2. MAILING NAME, ADDRESS AND TELEPHONE NUMBER

The name of the Facility is: Riverside Regional Medical Center, Department of Radiology, located at 500 J. Clyde Morris Boulevard, Newport News, Virginia 23601, telephone (757) 594-2000

3. Address of use

No change in address of use is requested

4. CONTACT PERSON

No change. (Attn: Harold Prussia, Riverside Regional Medical Center, Department of Radiology, 500 J. Clyde Morris Boulevard, Newport News, Virginia 23601, telephone (757) 594-2644.)

The person to contact with regards to this notification is our Radiation Safety Officer, Harold Prussia, B.S. Mr. Prussia can be reached at the Riverside Regional Medical Center. He will be responsible for preparing all responses to any questions concerning use of byproduct material. Responses prepared by Mr. Prussia will be submitted for certification by Golden Bethune, Executive Vice President/ Administrator, Riverside Regional Medical Center, or Diana LoVecchio Vice President of Operations and Support Services , for review, approval and submission to the NRC.

Telephone number of Harold Prussia is 757-594-2757

ITEM 5: RADIOACTIVE MATERIAL, and ITEM 6: USE OF MATERIAL

We request permission to perform Gamma Stereotactic Radiosurgery (GSR). The unit is located at our 500 J. Clyde Morris Boulevard address.

We request no other change to our Radioactive Material and use Material. Qualifications of Authorized Users for Medical Use

NRC License #45-09001-01 Amendment**May 3, 2006****Page 4 of 5****ITEM 7: RESPONSIBLE INDIVIDUALS**

Please remove Andrew D. Lauve, M.D. from our list of authorized Medical users.

We request to expand the authorization of John Freshcorn to include - Authorized Medical Physicists for GSR.

	Authorized User	Authorized Uses
B	John Freshcorn Authorized Medical Physicist	Currently listed on our license as a HDR Authorized Medical Physicist. Please add- Gamma stereotactic radiosurgery Authorized Medical Physicists

No other changes to our Authorized user list are requested.

ITEM 8: TRAINING FOR INDIVIDUALS

GSR Training that John Freshcorn has received is attached as appendix 8. Additional training is scheduled and will be forwarded to the NRC upon completion.

Item 9: FACILITIES AND EQUIPMENT

No change

ITEM 10: RADIATION PROTECTION PROGRAM

The following updated policies are attached in the appendix

- 10.1. Gamma stereotactic radiosurgery unit updated procedures.
- RSO 36 01 Instructions for Gamma Knife Stereotactic radiosurgery unit
- RSO 36 02 Gamma Stereotactic Radiosurgery Operating Instructions
- RSO 36 03 Gamma Knife Emergency Procedures

ITEM 11: WASTE MANAGEMENT

No change

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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 CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER—NAME AND TITLE	SIGNATURE	DATE
Diana LoVecchio Vice President of Operations and Support Services		5/03/06

NRC License #45-09001-01 Amendment

May 3, 2006

EXHIBIT I

Authorized Physicist Training

John Freshcorn, M.S., Radiation Physicist, Certified, ABR received the following training to date:

- March 29th, 2006, Martin Knotts, Radiation Safety Officer and Installation/Planning Engineer for Elekta, provided training to include safety and emergency procedures for the Leksell Gamma Knife. Certificate included.
- March 29th - 31st, 2006, the Vendor provided a Leksell GammaPlan training course to include dose calculations, physics protocols, a demonstration of the GammaPlan 4C, individual GammaPlan work stations for attendee participation and hands-on for multiple matrices, conformity indices and plugging techniques. Training agenda included.

John Freshcorn, M.S., Radiation Physicist, Certified, ABR will receive the following training and a verification checklist will follow to the NRC upon completion.

- May 6th – 7th, 2006, James Mounts, Senior Installation Engineer for Elekta, will provide on site training to include:
 - Hands on device operation
 - Safety procedures
 - Clinical Use
 - Calibration and Films
- May 10th, 2006, John Freshcorn will receive on-site training at the University of Virginia's Gamma Knife Center.

On June 5th – 9th, Elekta will be providing clinical and technical application support on the Leksell Gamma Knife. The training will be held on-site at the Riverside and University of Virginia Radiosurgery Center on the campus of Riverside Hospital. This activity is the final step in the training process and is to provide confidence in daily clinical practice.

The start up team from Elekta will consists of one neurosurgeon and one physicist that have extensive experience in Gamma Knife Surgery. These consultants are trained and certified by Elekta. The System Start schedule is attached and consists of:

- Day 1
 - Selection of Patients
 - Ensure Leksell Gamma Knife and GammaPlan systems ready for use
 - Before the first patient is treated, ensure the procedures have been covered:
 - Technical training and performance of Emergency Procedures
 - Function test of Automatic Positioning System
 - QA test run
- Day 2

- Treatment of 1 to 2 patients
 - Practice of the different routines
 - Discussions on treatment, documentation, technical and quality assurance log book.
- Day 3
 - Treatment of 1 to 2 patients
 - Time to go through the routines, practice cases and the treatment planning procedure.
 - Day 4
 - Treatment of 1 to 2 patients.
 - Special training on treatment of less common indications and additional dose planning practice.
 - Day 5
 - Treatment of 1 to 2 patients.
 - Summary of the System Start.

Certificate of Completion

Mr. John Freshcorn

Fully attended

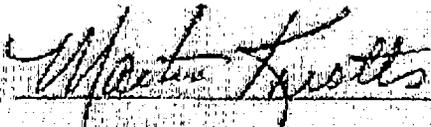
Leksell Gamma Knife®

Safety and security training for source
exchange and possession

March 29, 2006

Elekta Training Center, Norcross, GA

Issued by



Martin Knotts

Elekta Radiation Safety Officer, Leksell Gamma Knife®



ELEKTA

Certificate of Completion

Mr. John Freshcorn

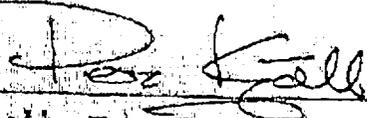
Fully attended

Leksell GammaPlan®
Advanced Training Course

March 29-31, 2006

Elekta Training Center, Norcross, GA

Issued by



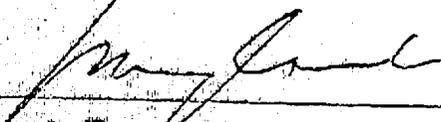
Per Kjäll, Ph.D.

Manager, Physics, Research & Development



Ian Paddick, M.Sc.

Medical Physicist, Cromwell Hospital



Vincent Denot, M.Sc.

Product Manager, Leksell GammaPlan®





ELEKTA
LEKSELL GAMMAPLAN®
Advanced Training Course
Elekta Training Center- Norcross, Georgia
March 29-31, 2006

WEDNESDAY, MARCH 29

12.45 pm	Shuttle pick up in the lobby of hotel (Homewood Suites & Marriott)	
1:00 - 1:10 pm	Welcome and Introduction	
1:10 - 2:10 pm M.Sc.	Image Distortion in Stereotactic Localization	Ian Paddick,
2:10 - 2:30pm	CT - The Gold Standard ?	Ian Paddick, M.Sc.
2:30 - 3:30 pm	Algorithms & Matrix Normalization	Per Kjäll, Ph.D.
3:30 - 4:00 pm	Coffee	
4:00 - 4:45 pm	Dose Calculation and Large Matrices	Ian Paddick, M.Sc.
4:45 - 5:30 pm	Dose Calculation QA	Per Kjäll, Ph.D.
5:30 pm <i>Free evening</i>	Shuttle pick up at ELEKTA to go to hotel	

THURSDAY, MARCH 30

8:10 am	Shuttle pick up in the lobby of hotel (Homewood Suites & Marriott)	
8:30 - 8:45 am	Continental Breakfast at Elekta office	
8:45 - 10:30 am Ph.D.	Physics Protocol	Per Kjäll,
10:30 - 10:50 am	Coffee	
10:50 - 11:30 am	Radiobiology, a primer from a Stereotactic Radiosurgery point of view	Per Kjäll, Ph.D.
11:30 - 12:00 pm M.Sc.	Imaging, A clinical perspective	Ian Paddick,
12.00 - 1.00 pm Denot, M.Sc.	Leksell Gamma Knife® Demonstration of GammaPlan 4C	Vincent
1.00 - 1:30 pm	Lunch at Elekta office	



1:30 - 2:15 pm M.Sc.	Multiple Targets and Multiple Matrices	Ian Paddick,
2:15 - 3:00 pm	Multiple Targets Hands-on for Multiple Matrices M.Sc. and Multiple targets in one matrix	Ian Paddick, Per Kjäll, Ph.D. Vincent Denot,
	M.Sc.	

LEKSELL GAMMAPLAN® Advanced Training Course - PAGE 2
March 29-31, 2006

3:00 - 3:15 pm	Coffee	
3:15 - 4:15 pm Ph.D. M.Sc.	Hands-on for Dose calculation	Per Kjäll, Vincent Denot,
4:15 - 5:15 pm M.Sc.	Dose Optimization Tools: Conformity Indices & hands-on	Ian Paddick,
5.30 pm	Shuttle back to hotel (Homewood Suites & Marriott)	
7:00 pm	Shuttle pick up in lobby of hotel (Homewood Suites & Marriott)	
7.15 pm	Dinner at Dominick's: Italian Cuisine (attire is business casual, jeans are OK)	
Friday, March 31		
8:10 am	Shuttle pick up in the lobby of hotel (Homewood Suites & Marriott)	
8:15 - 8:30 am	Continental Breakfast at Elekta office	
8:30 - 9:30 am Denot, M.Sc.	Future of Leksell GammaPlan®	Vincent
9:30 - 11:00 am M.Sc.	Advanced plugging techniques, including hands-on	Ian Paddick,
11:00 - 12:00 pm	Tips & Tricks	Ian Paddick, M.Sc.
12:00 - 12:30	Questions and answers and Workshop evaluation	
12:30 - 1:00 pm	Lunch	



1:00 - 2:30 pm Hands-on planning for those who would like to stay or have further questions

2:30 pm Course adjourned

Elekta staff:

Ashley Braswell	Marketing Manager, Education & Training
Vincent Denot, M.Sc.	Product Manager, Leksell GammaPlan
Per Kjäll	Manager, Physics, Research & Development
Susan Lohman	Manager, Clinical Applications, Neurosurgery
Susan Totilas	Clinical Applications Specialist, Neurosurgery
Raven Turberville	Marketing Coordinator

Honored guest faculty from Cromwell Hospital, London, UK:

Ian Paddick, M.Sc. Medical Physicist

NRC License #45-09001-01 Amendment

May 3, 2006

EXHIBIT II


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: RRMC
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

**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: RRMC****Category: Radiation Safety**

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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.
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 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

**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

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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 either 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



RIVERSIDE
HEALTH SYSTEM

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

Policy / Procedure

RIVERSIDE FACILITY: RRMC

Category: Radiation Safety

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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: 03/06

Last Revision Date: 05/2006

Authorized By: Radiation Safety Committee

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

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.

**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: RRMC****Category: Radiation Safety**

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

Policy / Procedure**RIVERSIDE FACILITY: RRMC****Category: Radiation Safety**

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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**

**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 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. 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: RRMC**

Category: Radiation Safety

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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. 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. Timer termination;
 - e. Radiation monitors used to indicate room exposures; and
 - f. Emergency off buttons.
- 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.
- 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.

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: RRMC****Category: Radiation Safety**

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Subject: Gamma Knife® Stereotactic Radiosurgery Quality Assurance Plan**Policy #: RSO - 36-04****Distribution Group: Radiosurgery Department**

- 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

9 Emergency Procedures

9.1 What to do in an Emergency

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

- Treatment Pause (see page 192);
- Couch Out (see page 192);
- Emergency Stop (see page 193);
- Manually Releasing the Couch (see page 194).
- Couch stuck in Treatment Position (see page 195).

Each option is outlined in the flowcharts below.

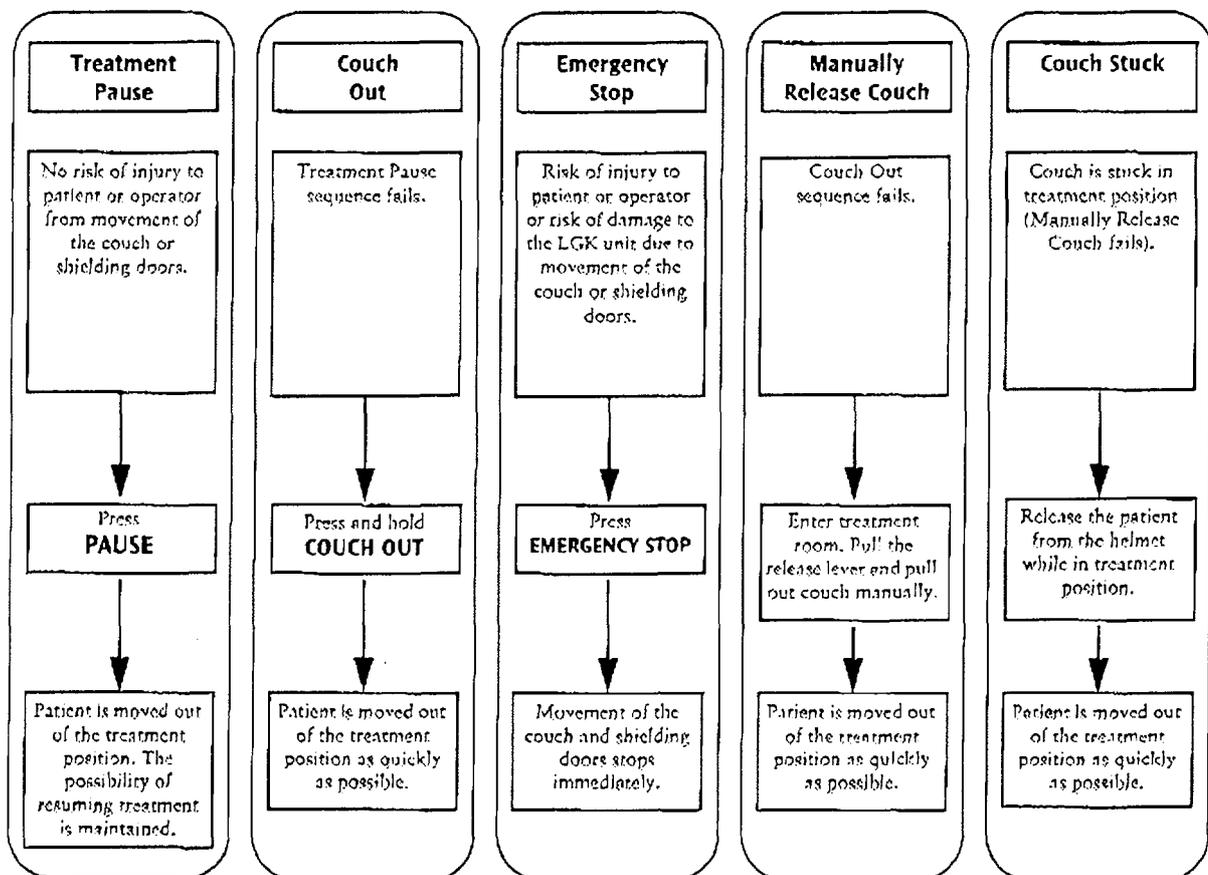
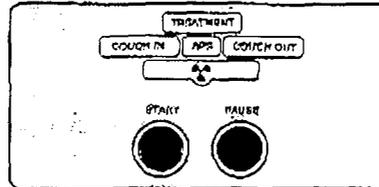


Figure 9.1 What to do in an Emergency: Options

9.1.1 Treatment Pause

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.

- 1 Activate a treatment pause by pressing the **Pause** button on the control panel.



Note: If the remaining time of the current step is less than 4 seconds the initiation of pause is delayed the time needed to complete the step.

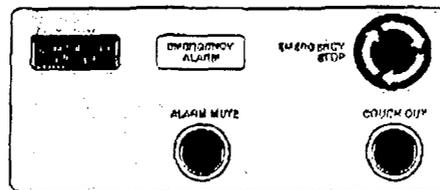
- 2 If the treatment pause sequence fails, press the **Couch Out** button on the control panel.

9.1.2 Couch Out

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** button can be used even if the control unit is non-operational but it will not operate if the emergency stop is activated.

- 1 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.

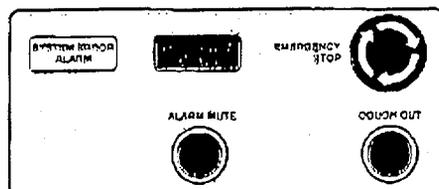
- 2 Release the patient from the collimator helmet.
- 3 Escort the patient from the treatment room.
- 4 If the shielding doors do not close automatically you must close them manually. See *Closing the Shielding Doors* on page 198.

9.1.3 Emergency Stop

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.

- 1 Press the **Emergency Stop** button.



- 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.
 - The couch and radiation shielding doors hold their positions until the emergency stop is released.
- 2 If necessary, pull out the sliding couch manually, see *Manually Releasing the Couch* on page 194.

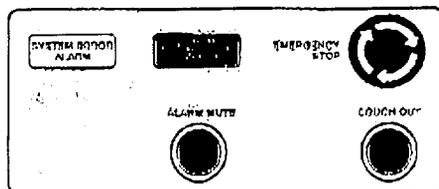
Note: The **Couch Out** button will not operate while the emergency stop is activated.

9.1.4 Restarting After an Emergency Stop

Note: If the emergency stop was initiated in response to a system malfunction, contact your Elekta® service representative. Do not use the system again until it has been inspected by your service representative.

To restart 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. If the doors cannot be closed in this way, refer to *Closing the Shielding Doors* on page 198.

9.2 Manually Releasing the Couch

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

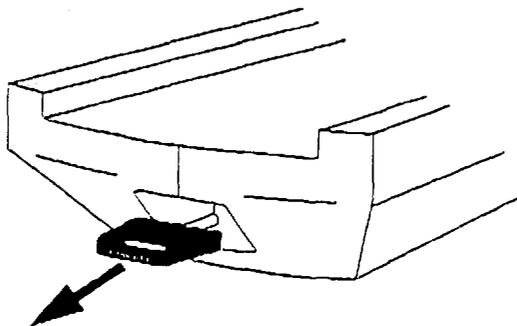
- 1 Enter the treatment room.



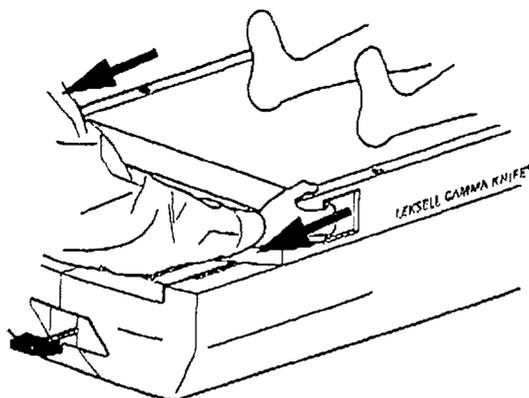
Personnel entering the treatment room while the shielding doors are open must keep their exposure time to a minimum. Overexposure to gamma radiation can endanger health.

WARNING 63

- 2 Pull the couch release handle.



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



Note:

If the sliding couch cannot be pulled out manually, the patient must be released from the collimator helmet without withdrawing the couch. Please refer to Section 9.3.1 or Section 9.3.2.

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

9.3 Couch Stuck in Treatment Position

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.

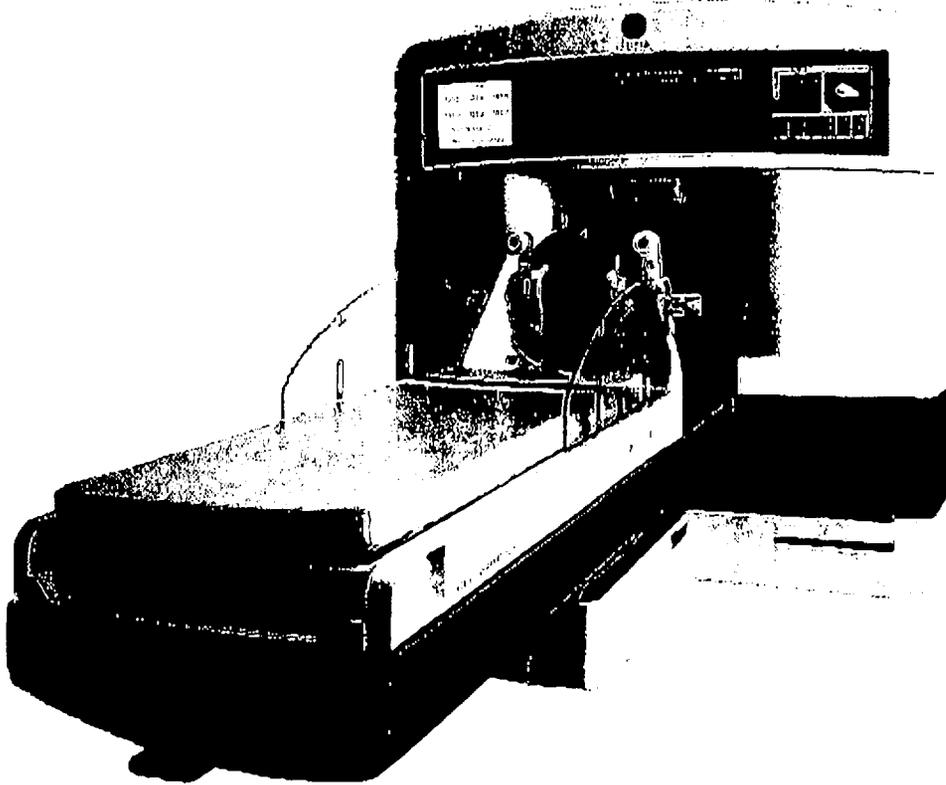
NRC License #45-09001-01 Amendment

May 3, 2006

EXHIBIT III

GAMMA KNIFE® SURGERY

Leksell Gamma Knife® 4C



Instructions for Use

017337 Rev 00 Rev. 00 (2004.11)

US/English version



ELEKTA



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