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November 11, 2005

Nuclear Materials Safety Branch I  
 U.S. Nuclear Regulatory Commission, Region I  
 475 Allendale Road  
 King of Prussia, Pennsylvania 19406

RE: License #37-11866-04

*02035003*

Dear Sir or Madam:

Lancaster General Hospital requests amendment of its Gamma Knife materials license with respect to the following:

- 1) In mid-December, we will be upgrading from the Elekta model 23004 type B to a 23004 Type C/B. Our license should reflect this new model designation. Under "9.A. Authorized Use", the wording on our license should be changed to be, "For medical use permitted by 10 CFR 35.600, in a Leksell Gamma System Model 23004 Type C/B or Type C/B-2 (a.k.a. Gamma Knife or Cerebral Stereotactic Radiosurgical Unit) radiation therapy unit." The exact date of this change-over is not guaranteed by the manufacturer; therefore, we wish this to be worded so that we may continue to operate with our current system in the case where the upgrade is delayed for some period of time.
- 2) Our QA procedures for the Gamma Knife will remain as submitted previously, with the following exceptions/additions:
  - a) An "APS Test" will be performed weekly and after APS/Trunion exchange. The procedure used for this test will be that described in the Leksell Gamma Knife 4C "Instructions for Use" manual to verify x, y, and z coordinates to within  $\pm 0.5$  mm.
  - b) The helmet microswitch test will now include checks for the helmet identity and the helmet cap microswitch, as described in the Leksell Gamma Knife 4C "Instructions for Use" manual.

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**NMSB/RONI MATERIALS-002**

**Kathleen L. Harrison, Vice President - Operations**

Lancaster General Hospital • 555 North Duke Street • P.O. Box 3555 • Lancaster, PA, 17604-3555

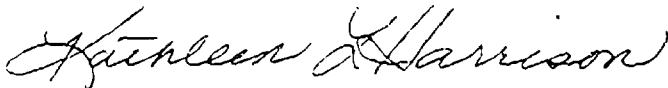
(717) 544-5862 • Fax (717) 291-9657 • [KLHarris@LancasterGeneral.org](mailto:KLHarris@LancasterGeneral.org) • [www.LancasterGeneral.org](http://www.LancasterGeneral.org)

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- 3) Our Gamma Knife emergency procedures will be amended to reflect differences between the old and now models. The amended procedure is attached as Attachment A.
- 4) We would like to alter the restrictions on the neurosurgeon's presence during Gamma Knife treatments. In our original application process (letter dated 5/13/1999), we stated that we would require the authorized user, authorized medical physicist, and the neurosurgeon to be physically presented during all patient treatments. We would like to remove this restriction in the case of the neurosurgeon, which is in line with current rule 10 CFR 335.615(f)(3).

Thank you for your attention to this matter. If you have any questions, please contact our Radiation Safety Officer, Anthony Montagnese, at 717-544-4384.

Sincerely,



Kathleen L. Harrison  
Vice President/Chairperson of Radiation Safety Committee

Attachment A  
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Lancaster General Health Campus  
Radiation Oncology Department

EMERGENCY PROCEDURES FOR GAMMA KNIFE UNIT

1) Treatment Pause

- a) Activate a treatment pause by pressing the Pause button on the control panel.
- b) If the treatment pause sequence fails, press the Couch Out button on the control panel.

2) Couch Out

- a) Press and hold the Couch Out button until the shielding doors are closed.
- b) Release the patient from the collimator helmet
- c) Escort the patient from the treatment room.
- d) If the shielding doors do not close automatically you must close them manually.

3) Emergency Stop

- a) Press the Emergency Stop button.
- b) If necessary, pull out the sliding couch manually.

4) Restarting after an emergency stop

- a) Turn the Emergency Stop button clockwise to release it as indicated by the arrows on the button.
- b) If the shielding doors do not close automatically, try to close them by use of the Couch Out button.

5) Manually releasing the couch

- a) Enter the treatment room
- b) Pull the couch release handle.
- 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.

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f) If the shielding doors did close, push back the release handle into locking position and verify that the couch is locked.

6) Manually releasing patient from the APS

- a) Ask the patient to keep his/her head up and be ready to take the weight of the coordinate frame.
- b) Loosen one or both of the X axes slides of the APS units using the APS Special Release Tool.
- c) If necessary, insert the Spade Tool between the APS Y slide and the coordinate frame and gently lever out the frame.
- d) Release the patient and leave the treatment room together with the patient
- e) Lock the door to the treatment room and inform the Radiation Safety Officer.

7) Manually Releasing the Patient from the Trunnions

- a) Ask the patient to keep his/her head up and be ready to take the weight of the coordinate frame.
- b) Loosen one or both of the helmet trunnions using the long Allen key.
- c) If necessary, insert the Spade Tool between the coordinate frame and the trunnion and gently lever out the frame.
- d) Release the patient and leave the treatment room together with the patient.
- e) Lock the door to the treatment room and inform the Radiation Safety Officer.

8) Closing the Shielding Doors

- a) Exit the system until the log-in dialog opens. Turn the power keyswitch to the off position. Bring the key with you.
- b) Open the cover on the left side of the radiation unit.
- c) Lift the ratchet handle from the hook and attach it to the shaft pivot of the electrical motor unit with the label CLOSE upwards.
- d) Pull and hold the brake release handle of the motor.

ATTACHMENT A  
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- e) While holding the brake release handle, turn the ratchet handle from side to side to close the shielding doors.
- f) If the shielding doors cannot be closed manually, inform the Radiation Safety Officer or the physicist in charge and ensure that no-one reenters the room.
- g) Contact your Elekta Service Representative.