

12-03-2010

DATE

This is to acknowledge the receipt of your letter/application dated 11-04-2010, and to inform you that the initial processing, which includes an administrative review, has been performed.

There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify other omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within days.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 573922.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murnahan

Licensing Assistant

RECEIVED
NOV 12 2010
DNMS

November 4, 2010

Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region IV
612 E. Lamar Blvd. Suite 400
Arlington, TX 76011-4125


Subject: Notification
NRC License No. 53-11966-02
Docket No. 030-34629

Dear License Reviewer:

We have added Stanley Skubic, Ph.D. as an authorized medical physicist for the Gamma Knife Perfexion. Dr. Skubic was previously listed as an authorized medical physicist for the Leskell Type B Gamma Knife on our license, and recently completed the Gamma Knife Perfexion upgrade course. We have enclosed a copy of the course outline and his certificate of attendance.

If you require any additional information please contact our Radiation Safety Officer, Ronald Frick at 808-373-7009.

Sincerely,



Maurice W. Nicholson, M.D.
Medical Director

Enclosures

Ft 573922

Gamma Knife® Perfexion™ Upgrade Course Outline

Washington Hospital Gamma Knife Center
2500 Mowry Ave.
Fremont, CA 94538

3-Day Course

Day 1

Location of first three lectures: Taylor McAdam Bell Neuroscience conference room

- 7:45 – 8:00** Welcome and Introduction
- 8:00 – 8:45 (0.75) Lecture 1:** Evolution and Development of Radiosurgery (Dr. Larson)
- 8:45 – 9:15 (0.5) Lecture 2:** WHHS experience with Perfexion™ (Dr. Kunwar)
- 9:15 – 10:00 (0.75) Lecture 3 (lecture hall):** Technical description of the Perfexion™, emphasizing the differences between the Perfexion™ and earlier Gamma Knife models, and how these differences lead to improved work flow. In particular, the new collimator system will be described including source configuration and sector design. (Dr. Petti)
- 10:00 – 10:15** *Coffee Break*
- 10:15 – 10:45 (0.5) Demonstration 1:** Tour of Perfexion™ suite and demonstration of operation of the Perfexion™ Gamma Knife® unit
- 10:45 – 11:15 (0.5) Demonstration 2 (Perfexion™ suite): Pre-planning workflow for Perfexion™** In advance, we will have attached the Leksell head frame to our 3D anthropomorphic skull phantom (CIRS Model 603) and we will have obtained both a CT and MRI scan of the phantom. We will demonstrate:
- “Frame cap” measurement, which is new with the Perfexion™
 - Skull radii measurements
 - How to attach MR and CT fiducial box to frame
- 11:15 – 11:45 (0.5) Demonstration 3 (Perfexion™ suite):** Demonstrate basic features of LGP8.0/8.02 on large screen (P. Petti or S. Lohman)
- 11:45 – 12:30 (0.75) Exercise 1: Workflow for treatment planning**
- Enter skull radii for CIRS phantom (determined in demonstration 2)

- b) Develop a treatment plan for the simulated lesion in the CIRS phantom
- c) Approve and export a plan developed by one of the attendees to the Perfexion™ Unit. The plan will demonstrate various basic features of the Perfexion™ system.
- d) Set up the phantom on the Perfexion™ unit, practice docking and undocking the phantom and deliver the planned treatment.

12:30 – 13:15 *Lunch (Taylor McAdam Bell Neuroscience conference room)*

Lectures 4 and 5 will be held in Taylor McAdam Bell Neuroscience conference room

13:15 – 13:45 (0.5) Lecture 4: Imaging Recommendations: Types of images required for specific sites and the use of image fusion and image co-registration in treatment planning. (Dr. Kunwar)

13:45 – 14:15 (0.5)Lecture 5: Treatment planning for the Perfexion™ : Isodose distributions for composite shots and for shots with sector blocking. Comparisons between Perfexion™ and Model C treatment plans (Dr. Petti)

14:15 – 14:30 Break

14:30 – 17:00 (2.5) Exercise 2: (lecture hall or GK planning area): Treatment planning using the 10 cases that Elekta used in their Technical Training Course in Stockholm and/or additional cases that we have planned here at Washington Hospital that are specific to the Perfexion™. These cases will demonstrate all facets of treatment planning, including planning for multiple metastases, co-registration of imaging studies, image fusion, composite shots, and dynamic sector blocking.

Total CME credit for Day 1 = 7.75 hrs

Day 2

Location for lectures 6 and 7: Taylor McAdam Bell Neuroscience Conference Room

8:00 – 8:45 (0.75) Lecture 6: Clinical lecture - Brain Metastases (Dr. Larson)

8:45 – 9:30 (0.75) Lecture 7: Clinical lecture - Benign Brain Tumors (Dr. Kunwar)

9:30 – 9:45 *Coffee Break (served in Taylor McAdam Bell Neuroscience Conference Room)*

- 9:45 – 10:15 (0.5) Demonstration 4:** TPS Administration (Gamma Knife Suite): Roles of “planner,” “physicist” and “administrator.” Storage and retrieval of patient data will also be demonstrated on large screen in GK suite (P. Petti or S. Lohman).
- 10:15 – 10:45 (0.5) Demonstration 5: Pre-planning, Re-treatment and follow-up** features of LGP 8.2 – demonstrate on large screen in GK suite (P. Petti or S. Lohman).
- 10:45 – 11:15 (0.5) Exercise 3: (Gamma Knife Suite): Clearance Check Procedure:** Practice clearance check using test run procedures provided with the Perfexion™ system
- 11:15 – 11:45 (0.5) Exercise 4: (Gamma Knife Suite): Clearance Check Example:** Attendees will be assigned a treatment plan that includes multiple gamma angles and clearance checks. This plan will be exported to the Gamma Knife, and the attendees will have the opportunity to practice changing gamma angles and perform clearance checks.
- 11: 45 – 12:00 (0.25) Exercise 5: (Gamma Knife Suite): QA procedure for clearance check tool:** Attendees will practice executing the procedure provided with the Perfexion™ for performing routine QA on the clearance check tool.
- 12:00 – 12:45** *Lunch served in Taylor McAdam Bell Neuroscience conference room*
- 12:45 – 13:15 (0.5) Lecture 8:** (Taylor McAdam Bell Neuroscience conference room) Radiation Safety Features of Perfexion™ including a discussion of reduced extracranial doses (Dr. Petti)
- 13:15 – 14:00 (0.75) Demonstration 6** (Gamma Knife Suite): Safety features of Perfexion™, including “treatment stop,” “treatment Pause,” manually moving the couch, how to manually place the sectors in the home position and manually close the shielding doors (Dr. Petti)
- 14:00 – 14:15 Break**
- 14:15 – 15:15 (1.0) Demonstration 7** (Gamma Knife Suite): New QA features including diode focus test tool. The discussion of QA procedures will be aimed primarily at physicists. Physicians may elect to continue treatment planning exercises (Drs. Petti, Larson and Kunwar)
- 15:15 – 17:00 (1.75) Exercise 6:** Continue treatment planning exercises

Total CME credit for day 2 = 7.75 hrs

Day 3

7:30 – 15:00 Attendees will observe the entire treatment process, from frame placement to treatment on the Perfexion™.

Coffee will be provided in the Gamma Knife Suite and Lunch will either be served in the Gamma Knife planning area or in the Taylor McAdam Bell conference room.

Following the patient treatment physicians and physicist will split up:

Physicians will be given the opportunity to observe the weekly Gamma Knife Case conference at WHHS. Questions and discussion will be encouraged.

Physicists will:

- a) Become acquainted with the “Test Run” procedures provided in the Perfexion™ system that have not already been discussed or demonstrated.
- b) Discuss/Compare QA procedures performed with new Physics Tool Kit including new film holder
- c) Review QA procedures in more detail (if needed).
- d) Continue treatment planning (if needed).

Total CME credits for Day 3 = 6.25 hrs

Washington Hospital Healthcare System

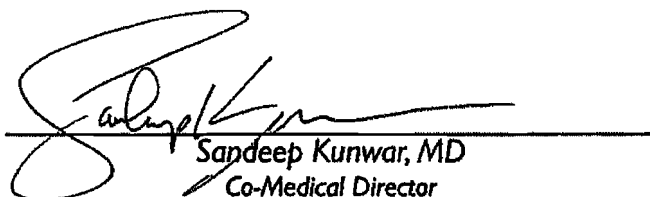
Taylor McAdam Bell Neuroscience Institute

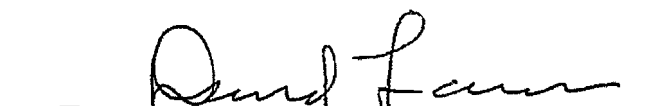
Stanley Skubic, Ph.D.


Attended

Gamma Knife® Radiosurgery Upgrade Course

From October 4-6, 2010


Sandeep Kunwar, MD
Co-Medical Director
Gamma Knife Program


David A. Larson, MD, PhD
Co-Medical Director
Gamma Knife Program


Paula Petti, PhD
Director of Gamma Knife Physics
Gamma Knife Program

 Washington Hospital
Healthcare System

TAYLOR MCADAM BELL 
NEUROSCIENCE INSTITUTE
WASHINGTON HOSPITAL HEALTHCARE SYSTEM

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM LTS

Program Code: 02240
Status Code: Pending Amendment
Fee Category: 7A 7C
Exp. Date:
Fee Comments:
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: GAMMA KNIFE CENTER OF THE PACIFIC
Received Date: 11/12/2010
Docket Number: 3034629
Mail Control Number: 573922
License Number: 53-11966-02
Action Type: Notifications

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Colleen Murnahan

Date: 11-17-2010

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____

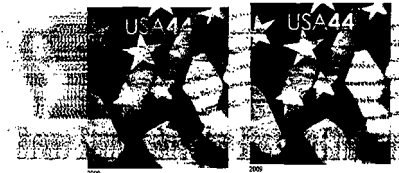


**GAMMA
KNIFE
CENTER**

OF THE PACIFIC

2226 Liliha Street, B1
Honolulu, Hawaii 96817

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