

2011-11-22 14:28

groc admin

>> 515 1078

P 2/9

BARBARA ANN
KARMANOS
CANCER CENTER
At the Detroit Medical Center

November 21, 2011

U.S. Nuclear Regulatory Commission, Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Request for Authorized User Status for License #21-04127-06

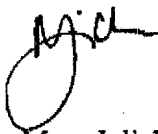
Dear Sir or Madame,

This letter is a request to grant Authorized User Status to Abhirami Hallock, M.D. for Co-60 in a Leksell Gamma Knife System radiation therapy unit. We have attached the NRC Form 313A(AUS) and supporting documents.

If you require further assistance please feel free to contact our RSO Joe Rakowski at (313)745-1435.

Thank you.

Sincerely,



Mara Jelich
Director of Radiation Oncology
Karmanos Cancer Center

NRC FORM 313A (AUS) (3-2009)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012																									
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]																													
Name of Proposed Authorized User <i>Abhirami Hallock, M.D.</i>			State or Territory Where Licensed <i>MI</i>																										
Requested <input type="checkbox"/> 35.400 Manual brachytherapy sources <input type="checkbox"/> 35.600 Teletherapy unit(s) Authorization(s) <input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 <input checked="" type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s) (check all that apply) <input type="checkbox"/> 35.600 Remote afterloader unit(s)																													
PART I - TRAINING AND EXPERIENCE (Select one of the three methods below)																													
* Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.																													
<input type="checkbox"/> 1. Board Certification a. Provide a copy of the board certification. b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought. c. Skip to and complete Part II Preceptor Attestation.																													
<input type="checkbox"/> 2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above a. Go to the table in section 3.e. to document training for new device. b. Skip to and complete Part II Preceptor Attestation.																													
<input checked="" type="checkbox"/> 3. Training and Experience for Proposed Authorized User a. Classroom and Laboratory Training <input type="checkbox"/> 35.490 <input type="checkbox"/> 35.491 <input checked="" type="checkbox"/> 35.690																													
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Description of Training</th> <th style="width: 30%;">Location of Training</th> <th style="width: 15%;">Clock Hours</th> <th style="width: 25%;">Dates of Training*</th> </tr> </thead> <tbody> <tr> <td>Radiation physics and instrumentation</td> <td>London Regional Cancer Program University of Western Ontario London Canada</td> <td>3 hrs 12 hrs 40 hrs</td> <td>June - Aug 08 Sept 08 - May 09 Sept 07 - Dec 07</td> </tr> <tr> <td>Radiation protection</td> <td>"</td> <td>7 hrs 12 hrs</td> <td>July 7/2007 May /07</td> </tr> <tr> <td>Mathematics pertaining to the use and measurement of radioactivity</td> <td>"</td> <td>60 hrs</td> <td>Sept 09 - May 10</td> </tr> <tr> <td>Radiation biology</td> <td>University of Western Ontario London, Canada</td> <td>40 hrs</td> <td>Jan 08 - May 08</td> </tr> <tr> <td colspan="2" style="text-align: right; padding-top: 10px;">Total Hours of Training:</td> <td colspan="2" style="text-align: center; padding-top: 10px;">310</td> </tr> </tbody> </table>						Description of Training	Location of Training	Clock Hours	Dates of Training*	Radiation physics and instrumentation	London Regional Cancer Program University of Western Ontario London Canada	3 hrs 12 hrs 40 hrs	June - Aug 08 Sept 08 - May 09 Sept 07 - Dec 07	Radiation protection	"	7 hrs 12 hrs	July 7/2007 May /07	Mathematics pertaining to the use and measurement of radioactivity	"	60 hrs	Sept 09 - May 10	Radiation biology	University of Western Ontario London, Canada	40 hrs	Jan 08 - May 08	Total Hours of Training:		310	
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(10-2007)

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for 10 CFR 35.890

☐ Remote afterloader unit(s)
 ☐ Teletherapy unit(s)
 ☒ Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks	Karmanos Cancer Center NRC 21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Oct 1 - Nov 18 2011
Preparing treatment plans and calculating treatment doses and times	Karmanos Cancer Center NRC 21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Oct 1 - Nov 18 2011
Using administrative controls to prevent a medical event involving the use of byproduct material	Karmanos Cancer Center NRC 21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Oct 1 - Nov 18 2011
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Karmanos Cancer Center NRC 21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Oct 1 - Nov 18 2011
Checking and using survey meters	Karmanos Cancer Center NRC 21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Oct 1 - Nov 18 2011
Selecting the proper dose and how it is to be administered	Karmanos Cancer Center NRC 21-04127-06	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Oct 1 - Nov 18 2011

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(10-2007)

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input checked="" type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association	London Regional Cancer Program University of Western Ontario London, Canada	July 2007 to May 2010
Supervising Individual DR. T. SEXTON (Program Director)		License/Permit Number listing supervising individual as an Authorized User CNSC 13559-9-25.12

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates UPMC		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			4C8 Perflexion
Safety procedures for the device use			4C8 Perflexion
Clinical use of the device			4C8 Perflexion
Supervising Individual. If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.) John Flickinger MD		License/Permit Number listing supervising individual as an Authorized User PA 190A University of Pittsburgh	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input checked="" type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

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U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**PART II – PRECEPTOR ATTESTATION**

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.490:**Board Certification**

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR**Training and Experience**

☐ I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

☐ I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section**For 35.690:****Board Certification**

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR**Training and Experience**

☒ I attest that Abhirami Hallock, M.D. has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

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(3-2009)

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

☒ I attest that Abhirami Hallock has received training required in 35.690(c) for device
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☒ Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

☒ I attest that Abhirami Hallock has achieved a level of competency sufficient to
Name of Proposed Authorized User

achieve a level of competency sufficient to function independently as an authorized user for:

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☒ Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

☒ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.400 Manual brachytherapy sources ☐ 35.600 Teletherapy unit(s)

☐ 35.400 Ophthalmic use of strontium-90 ☒ 35.600 Gamma stereotactic radiosurgery unit(s)

☐ 35.600 Remote afterloader unit(s)

Name of Preceptor

John C Flickinger MD

Signature

[Signature]

Telephone Number

412 623 6720

Date

11/22/11

License/Permit Number/Facility Name

PA-190AUniversity of Pittsburgh

This application is for Karmanos Cancer Center,
NRC License # 21-04127-06.

UPMC / University of Pittsburgh Medical Center
Center for Continuing Education in the Health Sciences

Abhirami Hallock, M.D., FRCPC

Attended the Continuing Medical Education Activity

*Principles and Practices of Gamma Knife
Radiosurgery*

October 24-28, 2011

**University of Pittsburgh Medical Center Health System
Pittsburgh, Pennsylvania**

The University of Pittsburgh School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Pittsburgh School designates this live activity for a maximum of 49.50 AMA PRA Category 1 Credit(s). Physician's Recognition Award. Physicians should claim only those credit commensurate with the extent of their participation in the educational activity.

*Other healthcare professionals are awarded 4.95 continuing education units (CEU's), which are equivalent to 49.5 hours of instruction.

For your credit transcript, please access our website six (6) weeks post-course at:
<http://ccehs.upmc.edu> and follow the link to the Credit Transcript screen

University of Pittsburgh

Center for Image-Guided Neurosurgery

This is to Certify That

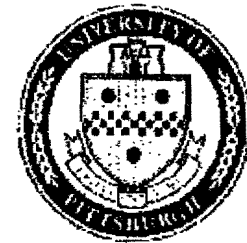
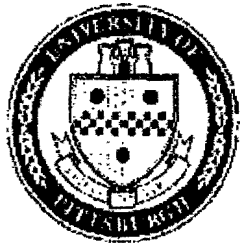
Abhirami Hallock, M.D., FRCPC

Attended

**Principles and Practice of Gamma
Knife® Radiosurgery**

Special Emphasis on Perfexion Training

From October 24-28, 2011



L. Dade Lunsford, M.D., FACS



Douglas Kondziolka M.D., M.Sc., FRCS(C)

Jagdish Bhatnagar, MD

John C. Flickinger, M.D.

2011-11-22 14:27

groc admin

>> 515 1078

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FAX

TO: NRC Region III

FAX NUMBER: 630-515-1078

FROM: Joe Rakowski Karmanos Cancer Ctr.

FAX NUMBER:

DATE: 11/22/2011

REGARDING: License Amendment

TOTAL NUMBER OF PAGES INCLUDING COVER: 9

PHONE NUMBER FOR FOLLOW-UP: 313-745-1435

COMMENTS:

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DETROIT, MI 48201
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FAX: 313-745 2314