

**MidMichigan
Medical Center**
Midland



RADIATION ONCOLOGY
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Midland, MI 48670

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FAX TRANSMITTAL

Date: ~~9/11/08~~ 9-12-08

To: COLLEEN C. CASEY, USNRC REGION III, CHICAGO

Fax No.: 630-515-1078

From: LARRY LANGRILL, RSO MMC MIDLAND

No. of Pages: 7

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MidMichigan
Medical Center
Midland

September 12, 2008

Colleen C. Casey, Health Physicist
Materials Licensing
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: Control No. 317361
Additional Information

Dear Ms. Casey,

This letter supplies additional information and request to the pending amendment number 64, for NRC license number 21-01549-02, MidMichigan Medical Center, Midland, Michigan.

Please add Paul G. Kocheril, MD as an authorized user for 35.600 Gamma Stereotactic Radiosurgery and 35.1000 Leksell Perfexion gamma stereotactic radiosurgery (GSR). NRC FORM 313A (AUS) is attached and has been modified to indicate the 35.1000 Leksell Perfexion GSR as an authorization option.

For further information or questions, please contact me directly at 517-839-3450 or at fax number 989-839-1347.

Sincerely,



Larry Langrill, RSO
Perfexion AMP
MidMichigan Medical Center
4005 Orchard Dr.
Midland, MI 48670

NRC FORM 313A (AUS)
(10-2007)

U.S. NUCLEAR REGULATORY COMMISSION

**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]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User

Paul G. Kocheril, MD

State or Territory Where Licensed

Michigan

Requested

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)

Authorization(s)

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

(check all that apply)

35.600 Remote afterloader unit(s) 35.1000 Leksell Perfexion GSR

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.

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.

2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above and 35.1000 Use 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.

3. Training and Experience for Proposed Authorized User

- a. Classroom and Laboratory Training 35.490 35.491 35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Total Hours of Training:			

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 type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User

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		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	N/A	N/A	Univ. of Pittsburgh, Center for Image Guided Neurosurgery Leksell Gamma Knife 4C and Leksell Perfexion GSR July 7-8, 2008
Safety procedures for the device use	N/A	N/A	Univ. of Pittsburgh, Center for Image Guided Neurosurgery Leksell Gamma Knife 4C and Leksell Perfexion GSR July 9, 2008
Clinical use of the device	N/A	N/A	Univ. of Pittsburgh, Center for Image-Guided Neurosurgery Leksell Gamma Knife 4C and Leksell Perfexion GSR July 7 - 11, 2008
Supervising Individual. <i>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.)</i> Radiation Oncology, Medical Physics and Neuroscience Faculty at UPMC		License/Permit Number listing supervising individual as an Authorized User	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input checked="" type="checkbox"/> 35.1000 Perfexion GSR <input checked="" type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

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."

N/A

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

N/A

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 _____ 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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

I attest that **Paul G. Kocheril, MD** 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)
- 35.1000 Perfexion GSR**

AND

Fourth Section

I attest that **Paul G. Kocheril, MD** 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)
- 35.1000 Perfexion GSR**

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)
- 35.1000 Leksell Perfexion GSR**

Name of Preceptor <i>RAJNIKANT H. MEHTA M.D.</i>	Signature <i>R. Mehta</i>	Telephone Number <i>989-839-3451</i>	Date <i>9-5-08</i>
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License/Permit Number/Facility Name
NRC License # 21-01549-02, MidMichigan Medical Center, Midland, Michigan



UPMC | University of Pittsburgh
Medical Center

*University of Pittsburgh Physicians
Department of Neurological Surgery*

**Center for Image
Guided Neurosurgery**
UPMC Presbyterian
Suite B-400
200 Lothrop Street
Pittsburgh, PA 15213-2582
412 647-7744
Fax: 412-647-8447

www.neurosurgery.pitt.edu

July 22, 2008

Re: Paul Kocheril, M.D.

L. Dade Lunsford, MD, FACS
Director

**Douglas Kondziolka, MD,
MSc, FRCS(C), FACS**
Co-Director

Ajay Niranjani, MCh
Spinal Radiosurgery
Peter Gerszten, MD, MPH

Radiation Oncology
John C. Flickinger, MD
Melvin Deutsch, MD
Susan Rakfal, MD
Yoshio Arai, MD

Neuroimaging
Emanuel Kanal, MD

Neuro-Oncology
Frank Lieberman, MD
Hideho Okada, MD, PhD

Physics and Informatics
Jagdish Bhatnager, ScD
Josef Novotny, PhD
Mubina Quader, PhD
M. Saiful Haq, PhD
Grace Yum, MSc

Nursing
Janet Vaccaro, RN, BSN
Donna Bronlove, HN
Cheryl Rogers, RN
Frank Tacimma, STS
Debra J. Jonneth, HN

Administration
David Bissonette, PA-C, MBA
Paul J. Sullivan, PA-C
Charlene Baker
Kelly Powell
Laurie Finnigan

To Whom It May Concern:

This letter is to inform you that Dr. Paul Kocheril participated in the training course entitled Principles and Practice of Gamma Knife Radiosurgery presented July 7-11, 2008 at the University of Pittsburgh Medical Center. This course was conducted at a licensed Gamma Knife Facility (NCF License 3370024509) under the supervision of authorized users, L. Dade Lunsford, M.D., Douglas Kondziolka, M.D., John C. Flickinger, M.D., Jagdish Bhatnager, Sc.D., and Josef Novotny, Ph.D.

During this time the above named participant obtained the knowledge and experience in observation of twelve procedures, dose planning, installation and acceptance testing.

Sincerely,

Douglas Kondziolka, M.D.,FRCS
Professor of Neurological Surgery
And Radiation Oncology

/cb