

THE HEART GROUP
LANCASTER MEDICAL CENTER, SUITE 200
217 HARRISBURG AVENUE
LANCASTER, PA 17603-2962
(717) 390-4651
FAX (717) 481-7397
www.theheartgroup.com

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JOSELUIS IBARRA, M.D., F.A.C.C.
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MELISSA L. McKERNAN, M.D.
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JILL REPOLEY, C.R.N.P.
KIMBERLY SHEA, C.R.N.P.
KELLY TRYNOSKY, C.R.N.P.
JENNIFER WARDLE, C.R.N.P.
ALEXANDRA WYANT, C.R.N.P.
BRENDA YOUNG, C.R.N.P.

June 19, 2006

HM562

2006 JUN 22 AM 11:59

RECEIVED
REGION 1

United States Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

03034622

RE: Material License No. 37-30426-01

The Heart Group is requesting to add Melissa L. McKernan, M.D. to the group's Materials License. Enclosed is Dr. McKernan's letter certifying her training in an approved Cardiology Fellowship Program at the University of Pennsylvania Health System, Department of Radiology, and the Training and Experience and Preceptor Attestation.

Should you have any questions, please call me directly at 717-481-7391. Thank you for your time and consideration of this request.

Sincerely,

Shelvy J Frank

Shelvy J. Frank
VP & Chief Operating Officer

Enclosures

Cc: Department of Environmental Protection

139040

KLCC/RCN MATERIALS-032



Luis I. Araujo, MD
Director, Nuclear Cardiology
Associate Professor of
Radiology and Medicine

Department of Radiology

December 14, 2005

Ms. Beth Widdowson
Administrative Assistant
The Heart Group, Ltd.
217 Harrisburg Avenue
Lancaster, PA 17603
Telephone: 717 390-4651

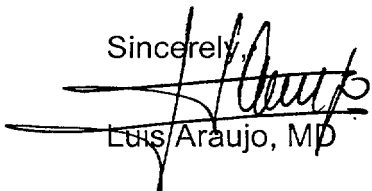
Re: Melissa McKernan, M.D.

To Whom It May Concern:

This letter is to certify that Dr. McKernan participated as a trainee in the activities of the Nuclear Cardiology Laboratory at the Hospital of the University of Pennsylvania between 2001 and 2005. During the training in the Laboratory, Dr. McKernan participated in the patient evaluation, stress test supervision, nuclear image acquisition and interpretation of 760 myocardial perfusion imaging and 100 radionuclide ventriculographies under my supervision.

Please do not hesitate to contact me if you need further information.

Sincerely,



Luis Araujo, MD

LA:akd



UNIVERSITY OF
PENNSYLVANIA
HEALTH SYSTEM

Luis I. Araujo, MD
Director, Nuclear Cardiology
Associate Professor of
Radiology and Medicine

Department of Radiology

May 17, 2006

Certification Board in Nuclear Cardiology
19562 Club House Road
Montgomery Village, Maryland 20886

Re: Melissa McKernan, M.D.

To Whom It May Concern:

This letter is to certify that Dr. McKernan has completed a training program in nuclear cardiology that meets the requirements for Level 2 training as outlined in the ACC/ASNC COCATS Guidelines [revised 2006].

Dr. McKernan is competent to independently function as an authorized user under NRC 10 CFR 35.290 uses and has compiled with the requirements for training on imaging and localization studies under 10 CFR §35.290, Section C1.

Please do not hesitate to contact me if you need further information.

Sincerely,

Luis Araujo, MD
Director, Nuclear Cardiology
Preceptor, Nuclear Cardiology
Authorized User at the Hospital of the University of Pennsylvania
NRC Broad Scope Medical License #37-00118-07 and PA License #0131

LA:akd

NRC FORM 313A (10-2005)	U.S. NUCLEAR REGULATORY COMMISSION MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008	
PART I -- TRAINING AND EXPERIENCE			
Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)			
1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50) <div style="text-align: center; font-family: cursive;">Melissa McKernan, M.D.</div>			
2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed <div style="text-align: center; font-family: cursive;">Pennsylvania</div>			
3. CERTIFICATION			
a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.) b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c). c. Provide completed Part II Preceptor Attestation, Items 11a through 11d. Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.			
4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS			
a. Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c) b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c). c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).			
5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)			
Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Heathland Radiologic Seminars, Inc. Frederick MD	100	7/10/05 - 5/7/06
Radiation Protection	"	30	7/10/05 - 5/7/06
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	20	"
Radiation Biology	"	20	"
Chemistry of Byproduct Material for Medical Use	"	30	"
OTHER			

NRC FORM 313A
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Cardiology Fellow - trainee in Nuclear Cardiology Laboratory at the Hospital of the University of Pennsylvania	Dr. Luis Araujo	Hospital of the Univ. of Pennsylvania	7/01 - 7/05
- Patient evaluation - stress test supervision - nuclear image acquisition - nuclear image interpretation			7/01 - 7/05 7/01 - 7/05 7/01 - 7/05 7/01 - 7/05
Electrophysiology Fellow - Hospital of the University of Pennsylvania	Dr. Francis Marchlinski	Hospital of the University of Pennsylvania	7/03 - 7/05
- use of fluoroscopy in implanting pacemakers + internal cardiac defibrillators - use of fluoroscopy in performing radiofrequency ablations			

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
^{99m} Tc & ²⁰¹ Thallium	Myocardial imaging	800	Luis Araujo, MD	Hospital of the University of Pennsylvania	7/01 - 8/05

NRC FORM 313A **U.S. NUCLEAR REGULATORY COMMISSION**
 (10-2005) **MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic or vendor training.

7. FORMAL TRAINING **Physicians (for uses under 35.400 and 35.600) and Medical Physicists**

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
Cardiology Fellowship Electrophysiology Fellowship Trainee Nuclear Cardiology Laboratory	Hospital of the University of Pennsylvania " "	7/1/2001 - 7/1/2005 7/1/2005 - 8/30/2005	GME } 10 CFR 35.490 GME }

8. RADIATION SAFETY OFFICER (RSO) – ONE-YEAR FULL-TIME EXPERIENCE

☐ YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
☒ N/A of _____ the RSO for License No. _____

9. MEDICAL PHYSICIST – ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____
☒ N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____
☐ N/A under the supervision of _____ who is a medical physicist (35.961) or meets

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL - IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (If more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each):

A. Name of Supervisor

Luís Arango, MD

B. Supervisor is:



Authorized User



Authorized Medical Physicist



Radiation Safety Officer



Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.910; 35.920; 35.930for medical uses in Part 35, Section(s) 35.910; 35.920; 35.930

D. Address

Director Nuclear Cardiology
Associate Professor of Radiology and Medicine
110 Donner Bldg.
3400 Spruce Street, Philadelphia, PA 19104-4283

E. Materials License Number

37-00118-07

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.



has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.930B
as documented in section(s) 5, 6a, 6b of this form.

11b. Select one



meets the requirements in ☐ 35.50(e) ☐ 35.51(c) ☐ 35.390(b)(1)(ii)(G) ☐ 35.690(c) for _____
types of use, as documented in section(s) _____ of this form.



N/A

11c.



has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); OR



has achieved a level of competency sufficient to function independently as an authorized
_____ user for 35.100; 35.200; 35.300 uses (or units); OR



has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety
Officer for a medical use licensee; OR



N/A

11d.



I am an Authorized Nuclear Pharmacist; OR ☐ I am a Radiation Safety Officer; OR



I meet the requirements of 35.910; 35.920; 35.930 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor ☒ AU or ☐ AMP

for the following byproduct material uses (or units): 10 CFR 35.100; 35.200; 35.300 uses

A. Address

Hospital of the University of Pennsylvania B. Materials License Number
Dept. of Radiology, Nuclear Medicine Division
110 Donner Building, 3400 Spruce St.
Phila., PA 19104-4283

37-00118-07

C. NAME OF PRECEPTOR (print clearly)

Abass Alavi, MD

D. SIGNATURE - PRECEPTOR



E. DATE

5/23/06

Health & Radiological Seminars, Inc.

Hereby certifies that

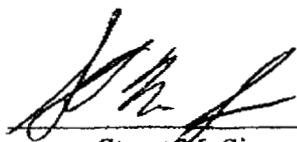
MELISSA McKERNAN, M.D.

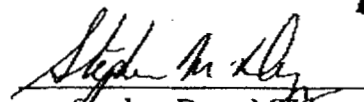
has successfully completed the 200 Hour Physician Training
Program in Basic Radioisotope Handling conducted
in accordance with the requirements of the
U.S. Nuclear Regulatory Commission (10 CFR 35).

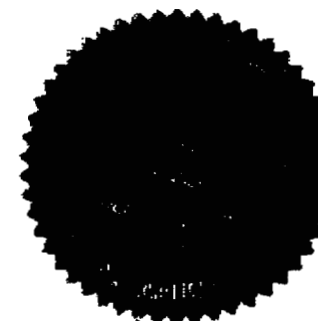
COURSE OUTLINE

Radiation Physics and Instrumentation - 100 hours
Mathematics pertaining to the use and measurement of radioactivity - 20 hours
Radiopharmaceutical Chemistry - 30 hours
Radiation Biology - 20 hours
Radiation Protection - 30 hours

May 7, 2006


Stuart M. Simon
Program Director


Stephen Dyer, MHS
Scientific Advisor



This is to acknowledge the receipt of your letter/application dated

6/19/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 37-30426-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

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

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** 139040.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.