



Molecular Imaging Services, Inc.

"Excellence in Patient Care through State of the Art Imaging"

NMSB 2

February 17, 2006

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RECEIVED
REGION 1
2006 FEB 21 PM 1:15

RE: Radioactive Materials Amendment Request
Molecular Imaging Services, Inc.
License Number - 07-30790-01
Docket Number - 03036176

License Reviewers:

I am writing on the behalf of Molecular Imaging Services, Inc. We request that Georges Dahr, M.D. be added as an authorized user to our radioactive material license. Dr. Dahr's credentials are enclosed.

If there are any questions or additional information is needed, please contact myself at (302)832-2002, or our Radiation Safety Officer, Frank DiGregorio at (302) 832-7689.

Sincerely,

William Moore, CNMT
VP, Business Development

Enclosures:
Dr. Dahr's credentials

138462

NMCS/RGN MATERIALS-002

**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**

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)

GEORGES DAHR, MD

2. For Physicians, Podiatrists, Dentists, Pharmacists – State or Territory Where Licensed

DELAWARE

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	UNIVERSITY OF LOUISVILLE LOUISVILLE, Ky	100 hrs	7/11/1999 ↓ 6/30/2002
Radiation Protection	UNIVERSITY OF LOUISVILLE LOUISVILLE, Ky	20 hrs	7/11/1999 ↓ 6/30/2002
Mathematics Pertaining to the Use and Measurement of Radioactivity	UNIVERSITY OF LOUISVILLE LOUISVILLE, Ky	20 hrs	7/11/99 ↓ 6/30/2002
Radiation Biology	UNIVERSITY OF LOUISVILLE LOUISVILLE, Ky	20 hrs	7/11/99 ↓ 6/30/2002
Chemistry of Byproduct Material for Medical Use	UNIVERSITY OF LOUISVILLE LOUISVILLE, Ky	30 hrs	7/11/99 ↓ 6/30/2002
OTHER			

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
- PROCEDURES FOR ORDERING & impacting Radioactive Material	STEPHEN WAGNER, MD	UNIV. OF LOUISVILLE Hospital	40 hrs July 99 →
	STEPHEN WAGNER, MD		June 2002
Calibrating the dose calibrator	STEPHEN WAGNER, MD	UNIV. OF LOUISVILLE Hosp	100 hrs July 99 → June 2002
	STEPHEN WAGNER, MD		
Preparation of doses and administration	STEPHEN WAGNER, MD	UNIV. OF LOUISVILLE	125 hrs 7/99 → 6/2002
Supervising of Stress Test	STEPHEN WAGNER, MD	UNIV. OF LOUISVILLE	> 200 hrs 7/99 → 6/2002
ROUTINE CHECK UPS ON GAMMA CAMERA & HOT LAB.	STEPHEN WAGNER, MD	UNIV. OF LOUISVILLE	7-99 → 6-2002
			<u>60 HRS</u>

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
TC-99m	CARDIAC IMAGING	400	STEPHEN WAGNER, MD	UNIV. OF LOUISVILLE	200 hrs 7/99-6/2002
Tl-201	CARDIAC IMAGING	105	STEPHEN WAGNER, MD	UNIV. OF LOUISVILLE	150 hrs 7/99-6/2002

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)
MD/Cardiology Training and board/ Nuclear Cardiology board/	UNIV. OF LOUISVILLE	7/99 → 6/2002	ACGME

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 requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

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

STEPHEN WAGNER, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.190-35.290

for medical uses in Part 35, Section(s) 35.100 35.200

D. Address DEPT. OF MEDICINE
ACB, THIRD FLOOR
550 SOUTH JACKSON ST.
UNIVERSITY OF LOUISVILLE

E. Materials License Number

202-029-22

LOUISVILLE, KY 40292

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: GEORGES NAHR, MD

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.290 35.190 as documented in section(s) 5/6/27 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 IMAGING for Cardiac imaging 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 35.290 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): 35.200

A. Address UNIVERSITY OF LOUISVILLE
CARDIOVASCULAR DIVISION
AMBULATORY CARE BUILDING
550 SOUTH JACKSON ST.
LOUISVILLE, KY 40292

B. Materials License Number

C. NAME OF PRECEPTOR (print clearly)

STEPHEN WAGNER, MD

D. SIGNATURE - PRECEPTOR

Stephen Wagner

E. DATE

2/1/06



Department of Medicine
Division of Cardiology
Division of Radionuclide Studies

This is to certify that Georges Dahr, M.D. has satisfactorily completed the training and experience criteria for diagnostic studies limited to Nuclear Cardiology, above the minimum as set by the Nuclear Regulatory Commission standards. This training, from **July 1, 1999 – June 30, 2002**, involved at least 250 hours in basic radioisotope handling techniques, 500 hours of experience with the use of byproduct material, and 500 hours of supervised clinical training in the Nuclear Cardiology Program.

Ibrahim B. Syed, Sc.D., Ph.D.
Clinical Professor of Medicine
(Medical Physics and Nuclear Sciences)
Director, Nuclear Medicine Sciences

Stephen Wagner, M.D.
Program Director and
Assistant Professor of Medicine
Acting Director, Nuclear Cardiology

Roberto Bolli, M.D.
Professor and Chief
Cardiovascular Division

Richard Redinger, M.D.
Professor and Chairman
Department of Medicine

APPLICATION FOR AUTHORIZATION TO USE RADIOACTIVE MATERIALS
UNDER BROAD MEDICAL LICENSE

NON-HUMAN USE

HUMAN-USE

INDIVIDUAL USER(S) (Name and title of individual(s) who will use and/or directly supervise use of radioactive material)

NAME(S) STEPHEN G. WAGNER, M.D. DEPT. Medicine (Cardiology) TEL. NO. 895-3401 x 384

LOCATION (Areas where radioactive material will be used)

Veterans Administration Medical Center - 2nd Floor - Room C225.

RADIOISOTOPE USE

RADIOISOTOPE (Chemical and/or physical form)	MAXIMUM QUANTITY (mCi)		SPECIFIC USE (attach additional sheets if necessary)
	TOTAL INVENTORY	SINGLE EXPERIMENTAL USE	
Technetium-99m RBC	20 mCi		Radionuclide ventriculogram (MUGA scan)
Thallium 201	2 mCi		Exercise Thallium studies

IONIZATION PROTECTION DEVICES

(List devices available for measuring of ionizing radiations for personnel monitoring, decontamination, protection surveying, radioisotope calibration, and for safe handling of radioactive materials.)

Film badges, dose calibration, syringe shield, GM counter.

INDIVIDUAL USER(S) TRAINING AND EXPERIENCE WITH RADIOACTIVE MATERIALS

NAME (title, degree and date conferred)	DESCRIPTION OF TRAINING AND EXPERIENCE (attach additional sheets if needed)
Stephen G. Wagner, M.D. Asst. Professor of Medicine, University of Louisville School of Medicine Acting Chief, Cardiology, VAMC Diplomate Am. Board of Internal Medicine 1972; Cardiology 1975	12 years

SIGNED Stephen Wagner DATE 5/22/91

ACCEPTED BY: (1) Veronica J. Rain (2) John A. ... (3) John A. ... (4) John A. ... (5) John A. ... (6) John A. ...

(1) Veronica J. Rain RAD. SAFETY OFFICER (2) John A. ... COMMITTEE MEMBER (3) John A. ... COMMITTEE MEMBER

DATE 7/22/91 APPROVED [Signature] CHAIRMAN, RADIOISOTOPE COMMITTEE

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

2/17/2006, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 07-30790-01
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 138462.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.