

JAMES CLIFFORD, M.D.
CARDIOLOGY & INTERNAL MEDICINE
255 WEST SPRING VALLEY AVE
MAYWOOD, NJ 07607
(732) 996-0055

September 28, 2007

Q-9

Stephen Hammann
U.S. Nuclear Regulatory Commission
Region 1
License Assistance Team
475 Allendale Rd
King of Prussia, PA 19406-1415

RE: NRC License # 29 - 31003 -01
James Clifford, M.D.

Docket # 03036843

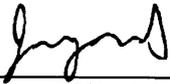
Control # 140787 *new*
141161

Dear Mr. Hammann:

This letter is in reference to the additional information you requested:

- 1 Please add **Kamran Hamirani, M.D.** as an Authorized User. NRC Form 313A (AUD) is attached.
- 2 Please keep **Karan Nejad, M.D.** as the Radiation Safety Officer and as an Authorized User on this license.

If you need any additional information please contact me.



James Clifford, M.D.

141161

NMSS/RGN1 MATERIALS-002

REF. 140787

NRC FORM 313A (AUC) (3-2007) **U.S. NUCLEAR REGULATORY COMMISSION**

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3180-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User: **KAMRAN HAMIRANI** State or Territory Where Licensed: **NJ**

Requested Authorization(s) (check all that apply):
 35.100 Uptake, dilution, and excretion studies
 35.200 Imaging and localization studies
 35.500 Sealed sources for diagnosis (specify device _____)

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. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization

a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience. (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Date of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience:			
Supervising Individual	License/Permit Number listing supervising individual as an authorized user		

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).
 35.290 35.390 + generator experience in 22.290(c)(1)(ii)(G)

NRC FORM 312A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
 (2-2007) AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

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			
Chemistry of byproduct material for medical use (not required for 35.59U)			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.59U).
 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

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*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

NRC FORM 313A (AUD) **U.S. NUCLEAR REGULATORY COMMISSION**
 (2-2007) **AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

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

b. Supervised Work Experience (continued)

Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Date of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual _____ License/Permit Number listing supervising individual as an authorized user _____

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).
 35.190 35.280 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.390 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

INCE 3

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. (Not required to meet training requirements in 35.590)

First Section

Check one of the following for each use requested:

~~For 35.190~~

Board Certification

I attest that KAMRAN HAMIRANI has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that KAMRAN HAMIRA has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190 35.200 35.300 35.300 + generator experience

Name of Preceptor JEROME G. JACOBSTEIN	Signature <i>[Signature]</i>	Telephone Number 215-587-9420	Date 9/25/07
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License/Permit Number/Facility Name
(Previously) NRC License # 57-28359-01



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 13, 2007

Docket No. 03036843
Control No. 140787

License No. 29-31003-01

James Clifford, M.D.
Owner
James Clifford, M.D.
255 West Spring Valley Avenue
Maywood, NJ 07607

SUBJECT: JAMES CLIFFORD, M.D., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 140787

Dear Dr. Clifford:

This is in reference to your letter dated July 2, 2007 requesting to amend Nuclear Regulatory Commission License No. 29-31003-01. Your letter requests that Kamran Hamirani, M.D. be named on your license as Radiation Safety Officer (RSO) and as an authorized user. In order to continue our review, complete and submit NRC Form 313A (RSO) and NRC Form 313A (AUD). The forms may be found on the NRC website at:
<http://www.nrc.gov/reading-rm/doc-collections/forms/>.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 140787. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5399.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Stephen Hammann

Stephen Hammann
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

J. Clifford
James Clifford, M.D.

DOCUMENT NAME: C:\FileNet\ML072250548.wpd

SUNSI Review Complete: SHammann

After declaring this document "An Official Agency Record" it will be released to the Public.

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI			
NAME	SHammann/STH						
DATE	8/13/2007						

OFFICIAL RECORD COPY

JAMES CLIFFORD, M.D.
CARDIOLOGY & INTERNAL MEDICINE
255 WEST SPRING VALLEY AVE
MAYWOOD, NJ 07607
(732) 996-0055

N7562

July 2, 2007

U.S. Nuclear Regulatory Commission
Region 1
License Assistance Team
475 Allendale Rd
King of Prussia, PA 19406-1415

03036843

RE: NRC License # 29 - 31003 -01
James Clifford, M.D.

To Whom It May Concern:

We would like to amend our license:

- 1 Please add **Kamran Hamirani, M.D.** as an Authorized User and as the Radiation Safety Officer. His credentials are attached. (ATT 1)
- 2 Please remove **Karan Nejad, M.D.** as the Radiation Safety Officer and Authorized User on this license.

If you need any additional information please contact me.



James Clifford, M.D.

2007 JUL -9 PM 1:15
RECEIVED
REGION 1

140787

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Health & Radiological Seminars, Inc.

Hereby certifies that

Kamran Hamirani, 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
- Radio pharmaceutical Chemistry - 30 hours
- Radiation Biology - 20 hours
- Radiation Protection - 30 hours

Margorie Goodenough
 Margorie Goodenough
 Course Coordinator

May 7, 2001

David J. Goodenough
 David J. Goodenough, Ph.D.
 Scientific Advisor

Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies That

Kamran Ismail Hamirani, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS TRAINED IN THE UNITED STATES
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED

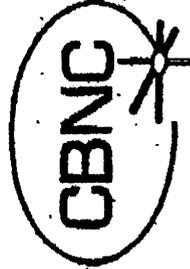
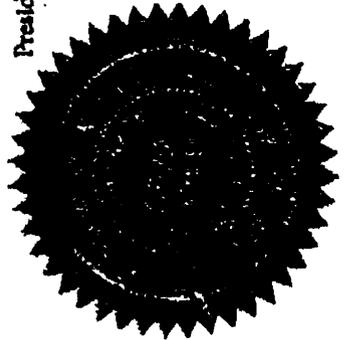
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 2006 - 2016



President



Secretary

CERTIFICATE NUMBER: 4969

Graduate Hospital

One Graduate Plaza
1800 Lombard Street
Philadelphia, Pennsylvania 19146
tel: 215.893.2000

June 30, 2001

U.S. Nuclear Regulatory Commission:

Dear Sir:

This is to certify that Dr. Kamran Hamirani has been under my supervision during his training in the performance of imaging and localizing techniques as related to the field of nuclear cardiology.

Dr Hamirani served in the Graduate Hospital Nuclear laboratory as a trainee for four months. During this period Dr Hamirani accrued more than the required number of hours of training in the clinical practice of nuclear cardiology and has had the appropriate hands on experience in terms of properly handling radioactive isotopes, selection of patients, appropriate dose calculation, administration of radionuclides, and scanning patients using Single Photon Emission Computerized Tomography (SPECT) and planar imaging equipment. His training also included radiation safety, radiopharmacy (including elution of molybdenum/technetium generators, and the preparation of various radiopharmaceuticals from kits), and radiopharmaceutical quality control.

Dr Hamirani has had training in first pass and gated pool studies as well as in myocardial uptake and localization studies and their proper evaluation and interpretation.

Dr Hamirani has completely fulfilled the following NRC requirements:

- A- 200 hours of classroom and laboratory training, given by Health and Radiological Seminars Incorporated (HRSI) in Gaithersburg, MD, that includes:
 - 1- Radiation physics and instrumentation;
 - 2- Radiation protection and biology;
 - 3- Mathematics pertaining to the use and measurement of radioactivity; and
 - 4- Radiopharmaceutical chemistry
- B- 500 hours of supervised work experience under the supervision of an authorized user that includes:
 - 1- Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
 - 2- Calibrating dose calibrators and diagnostic instruments, and performing checks for proper operation of survey meters;
 - 3- Calculating and safely preparing patient doses;
 - 4- Using administrative controls to prevent the misadministration of byproduct material;
 - 5- Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
 - 6- Eluting technetium-99m from generator systems, measuring and testing the eluate for Molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

tenet

CONFIDENTIAL TITLE
Kamran Hamrani MD

PRESENTATIONS:

- " BARI TRIAL "
- " Aortic Thrombo-emboli "
- " Renal Artery Stenosis "
- " Acute and chronic mitral regurgitation "
- " Stroke Prevention in Atrial Fibrillation " TRIAL
- " Outcomes in patients with acute non q wave myocardial infarction randomly assigned to an invasive as compared with a conservative management strategy "
- Coronary artery stenting compared with balloon angioplasty for Restenosis after initial balloon angioplasty "
- " vasovagal pacemaker study "
- " Tolerability and efficacy of carvedilol in patients with NYHA Class IV Heart Failure "

PROCEDURES:

- Cardiac catheterizations -> approx 5000
- Coronary interventions -> 2000. > 500 in last 18 months.
- TEE -> approx 150
- Nuclear Medicine -> All the requirement for nuclear license met

COMMITTEE MEMBERSHIPS:

(Current)

- Utilization review committee
- Cardiac services committee
- Invasive and other procedures committee
- Cardiac cath lab quality assurance committee
- Fellow of the American College of Cardiology.
- Member of the Council in Clinical Cardiology activities at the AHA

(Previous)

- Member of residency review committee
- Member of the Graduate education committee
- Member of the subcommittee of GME for policy and procedures development

LICENSE:

- Georgia, NY, NJ, and Pennsylvania.
- Texas (applied)

VISA STATUS:



(3)

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

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

9/28/2007 ^(RECEIVED) 10/2/2007 and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 29-3103-01 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** 141161.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.