

Rakesh Passi, MD
3000 Hadley Road
South Plainfield, NJ 07080
908-222-7212

United States
Nuclear Regulatory Commission
Medical Licensing Branch
475 Allendale Road
King of Prussia, PA 19406-1415

Br. 2

2008 JUL 25 PM 1:00

RECEIVED
REGION 1

July 18, 2008

Subject: Amend License 29-30917-01 03036579

This is a request to amend this license and add Gerald Weisfogel, MD, as an authorized user. Enclosed please find all the necessary documents to support his training and experience.

The current RSO and Authorized User will remain the same.

Please direct all questions regarding this request to Desiree Clisura who can be reached at 908-222- 7212 ex. 413.

Regards,

R Passi, MD
Rakesh Passi, MD
Authorized User
RSO

142659
NMSS/RGNI WATER,ALS-002

NRC FORM 313A (AUD) <small>(10-2005)</small>	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
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]		

Name of Proposed Authorized User <i>Gerald Weisfogel, MD</i>	State or Territory Where Licensed <i>New Jersey</i>
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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	Dates of Experience*
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			

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
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Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*.

35.290 35.390 + generator experience in 32.290(c)(1)(ii)(G)

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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 35.590)			
Radiation biology			
Total Hours of Training: 100 hrs.			

Please see attached certificate from Nuclear Medicine Ed. (INME)

b. Supervised Work Experience (completion of this table is not required for 35.590).
 (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	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	3000 Hadley Rd. NRC lic.# South Plainfield, NJ. 29-30917-01 07080		June 2006 to present
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	3000 Hadley Rd. NRC lic.# So. Plainfield, NJ. 29-30917-01 07080		June 2006 to present
Calculating, measuring, and safely preparing patient or human research subject dosages	3000 Hadley Rd. NRC lic.# So. Plainfield, NJ. 29-30917-01 07080		June 2006 to present

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	3000 Hadley Rd. NRC Lic # So. Plainfield, NJ. 29-30917-01 07080		June 2006 to present
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	3000 Hadley Rd. NRC Lic # So. Plainfield, NJ. 29-30917-01 07080		June 2006 to present
Administering dosages of radioactive drugs to patients or human research subjects	3000 Hadley Rd. NRC Lic # So. Plainfield, NJ. 29-30917-01 07080		June 2006 to present
* 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	"see attached" RWJ University Hosp. New Brunswick NJ.		6/26/08

Total Hours of Experience: 700+ hrs.

Supervising Individual: Rakesh Passi, MD
License/Permit Number listing supervising individual as an authorized user: # 29-30917-01

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).

- 35.190 35.290 35.390 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 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.

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. (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 _____ 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 _____ 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 Gerald Wersfogel, MD 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 35.290 35.390 35.390 + generator experience

Name of Preceptor <u>Rakesh Passi, MD</u>	Signature <u>R Passi, MD</u>	Telephone Number <u>732-238-6440</u>	Date <u>7/18/08</u>
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License/Permit Number/Facility Name
NRC # 29-30917-01

Attachment

Enclosure 6
RIS 2006-27
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(10-2005) U.S. NUCLEAR REGULATORY COMMISSION
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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			
Administering dosages of radioactive drugs to patients or human research subjects			
* 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	Robert Wood Johnson Univ. Hospital		6/26/08

Total Hours of Experience:

Supervising Individual: *M. Dama* RAO DASIKA RSO
License/Permit Number listing supervising individual as an authorized user: NRC 29-10173-02

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

c. For 35.590 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.

CME CREDIT CERTIFICATE

This is to certify that
Gerald Weisfogel, M.D.

Has completed up to
100 Hours

Of Category 1 CME credit through participation in the course(s)/activities conducted by the Institute for Nuclear Education (INME), March 8th - 16th, 2008, in Secaucus, NJ.

This CME activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) thru the Joint Sponsorship of the Institute for Medical Studies (IMS) and INME.

IMS is accredited by the ACCME to provide continuing medical education for physicians.

IMS designates this educational activity for a maximum of 100 credit hours AMA PRA Category 1 Credits™.

Participants should claim only those hours of credit that he/she actually spent in the activity as established by registration and attendance.

Please retain this Certificate for your records.

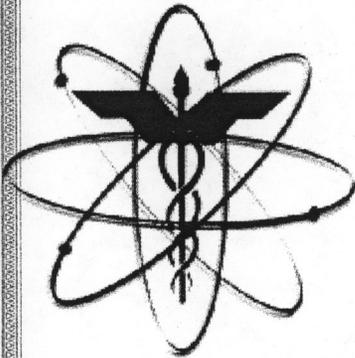
The Institute for Medical Studies
14 Monarch Bay Plaza, Suite 202
Monarch Bay, CA 92629

FUNDAMENTALS
Radioisotope Handling
Attestation and Certification
Completion and Competency

This document is an affidavit that

Gerald Weisfogel, M.D.

*has successfully completed the prescribed didactic program of
education and has achieved the objectives of this program
as evidenced by written examination*



This Program provides the following levels of documented accomplishment

- 100 Continuing Education Units (CEU)
 - 100 Didactic Instructional Hours (DIH)
- In compliance with 10CFR35/AEA 73-689
- 100 Board Accepted Hours NUSPEX, NMTCB
ABMRSO, ABR, ABNM, CBNC

Certifying Official

16 March 2008

Date Completed

204081

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

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

7/18/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-30917-01) 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** 142659.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.