

SAINT BARNABAS
 HEALTH CARE SYSTEM
Kimball Medical Center

ALBERT R. GAMPER, JR.
Chairman
Saint Barnabas Health Care System

RONALD J. DEL MAURO
President and Chief Executive Officer
Saint Barnabas Health Care System

JOE HICKS
Executive Director
Kimball Medical Center

April 23, 2009

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

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RECEIVED
REGION 1

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RE: Kimball Medical Center, License No. 29-14017-01

To Whom It May Concern:


Kimball Medical Center wishes to amend its materials license referenced above.

We would like to add Alex Langman, MD as an authorized user for uses defined under 10CFR35.100 and 10CFR35.200. The Authorized User Training and Experience and Preceptor Attestation (NRC Form 313A) for Dr. Langman is enclosed.

Please note that the supervised work experience for the elution of generator systems described in Section 3b took place at a nuclear pharmacy and a separate Preceptor Attestation is enclosed for that specific training.

If you have any questions or require additional information, please do not hesitate to contact me or our consultant medical physicist, Karen Wheeler, MS, DABR at (908) 788-9440 ext. 45 or via email at kwheeler@biomedphysics.com.

Sincerely,


Joe Hicks
Executive Director
Kimball Medical Center

Enclosure (NRC Form 313A AUD)

143699
NMSS/RGN1 MATERIALS-002



**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. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

Alex Langman, MD

State or Territory Where Licensed

New Jersey

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

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)

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	Montefiore Medical Center 111 East 210 Street Bronx, NY 10467	200	7/98 - 6/02
Radiation protection	Montefiore Medical Center 111 East 210 Street Bronx, NY 10467	150	7/98 - 6/02
Mathematics pertaining to the use and measurement of radioactivity	Montefiore Medical Center 111 East 210 Street Bronx, NY 10467	150	7/98 - 6/02
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	Montefiore Medical Center 111 East 210 Street Bronx, NY 10467	100	7/98 - 6/02
Radiation biology	Montefiore Medical Center 111 East 210 Street Bronx, NY 10467	50	7/98 - 6/02
Total Hours of Training: 650			

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.)

Supervised Work Experience		Total Hours of 1000 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	Montefiore Medical Center 111 East 210 Street Bronx, NY 10467 NY City# 75-2885-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/98 - 6/02
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Montefiore Medical Center 111 East 210 Street Bronx, NY 10467 NY City# 75-2885-01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/98 - 6/02

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	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	Montefiore Medical Center NY City# 75-2885-01 111 East 210 Street Bronx, NY 10467	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/98 - 6/02
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Montefiore Medical Center NY City# 75-2885-01 111 East 210 Street Bronx, NY 10467	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/98 - 6/02
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Montefiore Medical Center NY City# 75-2885-01 111 East 210 Street Bronx, NY 10467	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/98 - 6/02
Administering dosages of radioactive drugs to patients or human research subjects	Montefiore Medical Center NY City# 75-2885-01 111 East 210 Street Bronx, NY 10467	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/98 - 6/02
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	Nuclear Diagnostic Products 2 Keystone Avenue Suite 200 Cherry Hill, NJ 08003 NRC Lic. # 29-30500-01MD	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3/31/2009

Supervising Individual
Leonard M. Freeman, MD

License/Permit Number listing supervising individual as an authorized user
NY City #75-2885-01

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
	N/A	

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 35.500)

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."

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 Alex Langman MD 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 Alex Langman, 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 Leonard M. Freeman, MD	Signature <i>Leonard M. Freeman</i>	Telephone Number 718-920-6060	Date 4/20/09
License/Permit Number/Facility Name NYCLic # 75-2885-01			

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

1. Name of Individual, Proposed Authorization
ALEX LANGMAN, MD

2. For Physicians, State or Territory Where Licensed
NJ

3. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING

Description of Training	Location	Clock Hours	Dates of Training
Eluting generators, measuring and testing the eluate and processing the eluate with reagent kits to prepare labeled radionuclides	Nuclear Diagnostic Products 29-30500-01MD	4	03/31/2009

4. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License	Dates and/or Clock Hours of Experience
Eluting generators, measuring and testing the eluate and processing the eluate with reagent kits to prepare labeled radionuclides	GAVIN M. KAHN, RPh	Nuclear Diagnostic Products 29-30500-01MD	3/31/09 4 hours

5. SUPERVISION INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

A. Name of Supervisor: GAVIN M. KAHN, RPh

B. Supervisor is an Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.290 for medical uses in Part 35 Section 35.20

D. Address: NUCLEAR DIAGNOSTIC PRODUCTS
2 Keystone Ave / Unit 200
Cherry Hill, NJ 08003

E. Materials License Number
29-30500-01MD


PART II -- PRECEPTOR ATTESTATION

I attest the individual named in item 1 has satisfactorily completed the requirements in Part 35, Sections and Paragraph 35.290ciiG as documented in sections 3 & 4 of this form

I am an Authorized Nuclear Pharmacist at Nuclear Diagnostic Products in Cherry Hill, NJ

Address: NUCLEAR DIAGNOSTIC PRODUCTS
2 KEYSTONE AVE / UNIT 200
CHERRY HILL, NJ 08003

Material License Number
29-30500-01MD

NAME OF PRECEPTOR (print clearly)	SIGNATURE OF PRECEPTOR	DATE
<u>GAVIN M. KAHN, RPh</u>		<u>03/31/2009</u>

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

4/23/2009, and to inform you that the initial processing which includes an administrative review has been performed.

Amend. 29-54017-01
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** 143689.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader