

Lutheran Hospital of Indiana

To: Toye SimmonsFax No. 630-829-9782

From: RADIOLOGY

Date/Time: 9/19/07 0900Subject: DR Sanghvi, DR. Lacunza.Pages: 9., including this one

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Toye,

Here is the 313's on 2 of 3 radiologists.
When I get the 3^d I will resubmit

Thanks

Jim Ruschmeyer
260-435-7297

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7950 W Jefferson Blvd
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NRC FORM 313A (AUD) (3-2007)		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 Amit Narendra Sanghvi, MD			State or Territory Where Licensed		
Requested Authorization(s) (check all that apply)					
<input checked="" type="checkbox"/> 35.100 Uptake, dilution, and excretion studies					
<input checked="" type="checkbox"/> 35.200 Imaging and localization studies					
<input type="checkbox"/> 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.					
<input checked="" type="checkbox"/> 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.					
<input type="checkbox"/> 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).					
<input type="checkbox"/> 35.290 <input type="checkbox"/> 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:			

- 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 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 checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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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		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input checked="" 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 checked="" 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 ☐ 35.290 ☒ 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.

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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 Amit Sanghvi, MD 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 Amit Sanghvi, 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 Amit Sanghvi, MD 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 Amit Sanghvi, 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

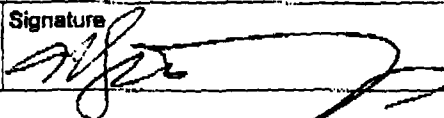
Complete the following for preceptor attestation and signature:

☒ 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
H. Scott Beasley, MD

Signature



Telephone Number
412-578-1890

Date
8/31/07

License/Permit Number/Facility Name

NRC # 37-01236-01; The Western Pennsylvania Hospital, Pittsburgh, PA 15224

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**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)**

John Lacunza, Authorized user

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

Indiana

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	UCI medical Center	35	7/2002 - 3/2003
Radiation Protection	↓	4	
Mathematics Pertaining to the Use and Measurement of Radioactivity	UCI medical Center	included in physics training	
Radiation Biology		3	
Chemistry of Byproduct Material for Medical Use		2	
OTHER		36	

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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
Diagnostic Radiology Residency Training	Dr. Paul Lizotte	U.C. Irvine Medical Ctr Orange, CA	7/02 - 8/06
Diagnostic Radiology Residency Training	Dr. W. Brown	V.A. Medical Ctr. Long Beach, CA	9/03 - 6/06

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-99	Lympho-scan-2 Bone-103 HIDA-4 Cardiac-87 Liver-14 V/a-3 Renal-14 Gastric-3	230	Dr. Brown	VA Med Ctr Long Beach	
I-123 / I-131		16 / 5	↓	VA Med Ctr Long Beach	
In-111		5	↓	VA Med Ctr Long Beach	
Ga-67		10	↓	VA Med Ctr Long Beach	
Tc-99		182	Dr. Lizotte	UC Irvine Med Ctr	
I-123 / I-131		15 / 13	↓	UC Irvine Med Ctr	
In-111		21	↓	UC Irvine Med Ctr	
Ga-67		3	↓	UC Irvine Med Ctr	

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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)
Diagnostic Radiology Residency Program	UC Irvine Medical Center, Orange, CA	July 2002 - June 2006	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 8a) 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) _____

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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

Dr. Paul Lizotte

B. Supervisor is:



Authorized User



Authorized Medical Physicist



Radiation Safety Officer



Authorized Nuclear Pharmacist

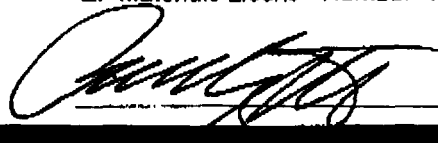
C. Supervisor meets requirements of Part 35, Section(s)

for medical uses in Part 35, Section(s)

0278-30

D. Address

E. Materials License Number



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) _____, as documented in section(s) 1-7 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 _____

N/A types of use, as documented in section(s) _____ of this form.

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 _____ for _____ 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 _____ 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): _____

A. Address

UCIMC
101 The City Dr.
Orange, CA 92868

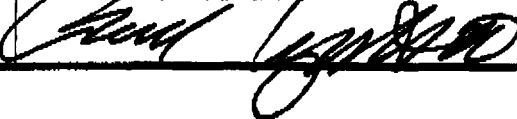
B. Materials License Number

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C. NAME OF PRECEPTOR (print clearly)

PAUL Lizotte

D. SIGNATURE - PRECEPTOR



E. DATE

8/20/07

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