

C O V E R

FAX

S H E E T

To: BILL REICHHOLD
Fax #: 630-515-1028
Subject: DR JANI INFU
Date: 8/28/07
Pages: 6, including this cover sheet.

COMMENTS:

Bill,

Dr Shah in Luckhans is going to
FAX the revised signature page to my office.
Today (Wednesday) My secretary will fax it to
you. Enclosed is a copy of the generator training
letter and the revised prescriber form pending
Dr Shah's signature.

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August 23, 2007

To Whom It May Concern:

Please be informed that on August 23, 2007, Dr. Hareesh Jani, M.D. spent several hours at Capital Pharmacy learning the basic operation of Mo-99/Tc-99m Generators and the preparation of Tc-99m reagent kits. Matthew Kazmierski, R.Ph., Authorized Nuclear Pharmacist and RSO demonstrated the following:

- Elution of Mo-99/Tc99m Generators, including the Moly Assay procedure and calculations of the Mo99 to Tc99m concentration and aluminum assay.
- Preparation of Tc99m reagent kits Tc99m tetrofosmin, MDP and Sestimibi including explanation of kit concentrations and unit dose assay.
- Quality Control procedures for Tc99m Reagent kits .

CPI Pharmacy Services Holding, LLC's , d/b/a, Capital Pharmacy NRC license is 21-26597-01MD. If you have any questions please contact myself or Matt Kazmierski. .

Regards,



Randy A. Asmus, R.Ph.
General Manager

Nuclear Pharmacy Services and Consultation

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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: 10/31/2008

Name of Proposed Authorized User

Haresh Jani, M.D.

State or Territory Where Licensed

Michigan

Requested Authorization(s) (check all that apply)

35.100 Uptake, dilution, and excretion studies

X 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	INSTITUTE FOR MEDICAL EDUCATION, BOULDER, CO	50	1994
	RADIOLOGICAL PHYSICS SVC. PLYMOUTH, MI	2	7/21/07
Radiation protection	"	50	1994
		2	7/21/07
Mathematics pertaining to the use and measurement of radioactivity	"	25	1994
		1	7/21/07
Chemistry of byproduct material for medical use (not required for 35.590)	"	25	1994
		1	7/21/07
Radiation biology	"	50	1994
		2	7/21/07
Total Hours of Training:		208	

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: 1000	
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	CARDIOVASCULAR CLINICS, PC MERRILLVILLE	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2005 - 2007
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	2005 - 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	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	CARDIOVASCULAR CLINICS PC	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2005 - 2007
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2005 - 2007
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2005 - 2007
Administering dosages of radioactive drugs to patients or human research subjects	"	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2005 - 2007
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	CAPITAL PHARMACY LANSING, MI 21-26597-01MD	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	8/23/07

Supervising Individual VIJAY P. SHAH, M.D. RANDY ASMUS, R.Ph.	License/Permit Number listing supervising individual as an authorized user 13-32122-01 21-26597-01MD
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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 **Haresh Jani, 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

Signature

Telephone Number

Date

License/Permit Number/Facility Name

13-32122-01

Cardiovascular Clinics, PC