

June 23, 2011

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

G-8

RECEIVED
REGION 1
2011 JUN 28 PM 12: 10

03001276

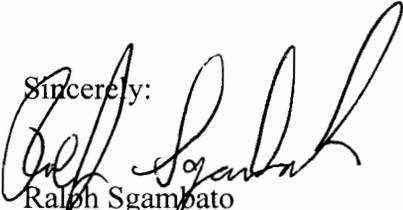
RE: License No. 06-09522-01, Mail Control No. 575058

Dear Sir or Madam:

I have enclosed a completed NRC Form 313 A (AUD) for Kapil R. Desai, M.D. I request the addition of Dr. Desai to our license for use of Materials in 35.100 and 35.200.

If you have any additional questions regarding this correspondence, please contact me at 203-863-3036 or ralph.sgambato@greenwichhospital.org.

Sincerely:


Ralph Sgambato
Program Director Radiology

575058

NMSS/RGN1 MATERIALS-002

5 Perryridge Road
Greenwich, CT 06830-4697
(203) 863-3000

**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
Kapil Rajendra Desai, MD

State or Territory Where Licensed
NY, CT

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 | Tisch Hospital | 16 | 7/04 - 6/05 |
| Radiation protection | Tisch Hospital | 16 | 7/04 - 6/05 |
| Mathematics pertaining to the use and measurement of radioactivity | Tisch Hospital | 16 | 7/04 - 6/05 |
| Chemistry of byproduct material for medical use (not required for 35.590) | Tisch Hospital | 16 | 7/04 - 6/05 |
| Radiation biology | Tisch Hospital | 16 | 7/04 - 6/05 |
| Total Hours of Training: | | 80 | |

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: | |
|--|---|--|----------------------|
| | | | 700 |
| 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 | Tisch Hospital | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 7/04 - 6/08 |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | Tisch Hospital | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 7/04 - 6/08 |

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 | Tisch Hospital | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 7/04 -6/08 |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | Tisch Hospital | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 7/04 -6/08 |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | Tisch Hospital | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 7/04 -6/08 |
| Administering dosages of radioactive drugs to patients or human research subjects | Tisch Hospital | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 7/04 -6/08 |
| 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 | Tisch Hospital | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | 7/04 -6/08 |

Supervising Individual

[Signature] MD

License/Permit Number listing supervising individual as an authorized user

75 - 2955 - 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)

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 Kapil Rajendra Desai 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

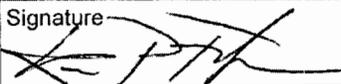
Training and Experience

I attest that Kapil Rajendra Desai 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>Kent Friedman MD</u> | Signature  | Telephone Number <u>212 263 7410</u> | Date <u>5/2/11</u> |
| License/Permit Number/Facility Name <u>City of New York RAM #75-2955-01 NYU Hospitals Center</u> | | | |