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CARDIOLOGY

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May 8, 2007

United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Training and Experience of Dr. Jack E. Smith

To Whom It May Concern:

This letter is to affirm that Jack E. Smith, M.D. has satisfactorily completed the requirements of 10 CFR 35.290(c) (1) and a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.200 (limited to cardiovascular clinical procedures.)

The total hours of concurrent training and experience was not less than 700 hours.

Sincerely,



Ricci A. Minella, M.D.
Preceptor

P-7

37-30082-01

03033320

140422

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: 10/31/2008

Name of Proposed Authorized User

Jack E. Smith, M.D

State or Territory Where Licensed

Pennsylvania

2007 JUN 15 AM 11:05

RECEIVED
REGION 1

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)

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	80 Hour Nuclear Licensing Course for Physicians held by Assoc. in Medial Physics, LLC 5288 Transportation Blvd. Cleveland, OH 44125 Phone: 216-663-7000	36	March 9-16, 2007
Radiation protection	"	28	March 9-16, 2007
Mathematics pertaining to the use and measurement of radioactivity	"	8	March 9-16, 2007
Chemistry of byproduct material for medical use (not required for 35.590)	"	3	March 9-16, 2007
Radiation biology	"	5	March 9-16, 2007
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 Jack E. Smith, M.D.		Total Hours of Experience: 712	
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	Abe W. Friedman, M.D., PC 5845 Centre Avenue Pittsburgh, PA 15206 575 Coal Valley Road, Suite 210 Clairton, PA 15025	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 180 hrs	1/2/06-3/31/07
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 180 hrs	"

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 180 hrs.	.
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 10 hrs.	.
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 10 hrs.	.
Administering dosages of radioactive drugs to patients or human research subjects	.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 150 hrs.	.
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	Associates in Medical Physics LLC 5288 Transporation Blvd. Cleveland, OH 44125 Phone: 216-663-7000 via General Electric Radiopharmacy 8300 Sweet Valley, Suite 304 Valley View, OH 44125	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 2 hrs.	March 15, 2007

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.

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 Jack E. Smith, M.D. has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

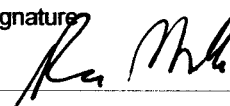
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 Ricci A. Minella, M.D.	Signature 	Telephone Number 412-363-7474	Date 6/8/07
License/Permit Number/Facility Name 37-30082-01			