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CARDIOLOGY

5845 CENTRE AVENUE
PITTSBURGH, PA 15206
(412) 363-7474 FAX (412) 363-9971

SOUTH HILLS MEDICAL BUILDING
SUITE 210 • 575 COAL VALLEY ROAD
CLAIRTON, PA 15025
(412) 469-7788 FAX (412) 469-1905

April 17, 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

NMSS

37-30082-01

03033320

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RECEIVED
REGION 1

1404-22

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, MD	State or Territory Where Licensed Pennsylvania
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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)

X 3. Training and Experience for Proposed Authorized User

Jack E. Smith, MD

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 Associates in Medical 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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Jack E. Smith, MD

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			
Administering dosages of radioactive drugs to patients or human research subjects			
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 Transportation Blvd Cleveland, OH 44125 Phone: 216-663-7000 via General Electric Radiopharmacy 8300 Sweet Valley, Suite 304 Valley View, OH 44125	2	March 15, 2007

Total Hours of Experience: 2

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 Jack E. Smith, MD

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 has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

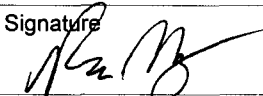
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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>Ricci A. Minella, MD</u>	Signature 	Telephone Number <u>412 363 7474</u>	Date <u>4/17/07</u>
License/Permit Number/Facility Name <u>37-30082-01</u>			

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Abe W. Friedman, M.D., P.C.</p> <p>2. 5845 Centre Avenue Pittsburgh, Pennsylvania 15206</p>	<p>In accordance with the letter dated October 17, 2006,</p> <p>3. License number 37-30082-01 is amended in its entirety to read as follows:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.200</p>	<p>4. Expiration date April 30, 2014</p> <p>5. Docket No. 030-33320 Reference No.</p> <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p>
<p>9. Authorized use:</p> <p>A. Any imaging and localization study permitted by 10 CFR 35.200.</p>	

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 5845 Centre Avenue, Pittsburgh, Pennsylvania and the South Hills Medical Building, 575 Coal Valley Road, Suite 210, Clairton, Pennsylvania.
11. The Radiation Safety Officer for this license is Ricci A. Minella, M.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated:

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
37-30082-01

Docket or Reference Number
030-33320

Amendment No. 7

Authorized Users

Material and Use

Ricci A. Minella, M.D.

35.200

- 13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing financial assurance for decommissioning.
- 14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated February 17, 2004 [ML040720553]

For the U.S. Nuclear Regulatory Commission

Date December 6, 2006

By *Dennis R. Lawyer*
 Dennis R. Lawyer
 Commercial and R&D Branch
 Division of Nuclear Materials Safety
 Region I
 King of Prussia, Pennsylvania 19406

Wednesday, December 06, 2006 8:15:10 AM

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

4/17/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 37-30082-CV
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 140422.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.