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J-6

Dennis R. Lawyer
Health Physicist
US NRC Region I
475 Allendale Road
King of Prussia, PA 19406

May 31, 2007

Dear Mr. Lawyer,

03033684

I, Dr. Stanley Pamilis, the Radiation Safety Officer for Parkersburg Cardiology Associates, INC, in Parkersburg, West Virginia am writing this letter as a follow up to the submission to amend and add Dr. David A. Gnegy as an Authorized User to license number 47-25319-01. Please disregard the submission for Dr. M. David Avington as we will not, at the present time, be adding him as an Authorized User.

Dr. Gnegy is a board certified in Internal Medicine and Cardiology through the American Board of Internal Medicine in 1992 and 1995, respectively. He has practiced in our facility since 1995 and during that time he has completed and interpreted over 4500 Nuclear Stress Test. Throughout his time in our practice, he has maintained his certifications by completing yearly Radiation Safety Inservices given by Shana Collins BS, CNMT, RT(N) and Lisa Broadwater RT(R), (N). These inservices are reviewed by Mark Perna, Health Physicist and myself. Also, over the course of his practice with us, quarterly reviews and training of quality control procedures of instruments, dose calibration usage, administration of radioactive materials during stress tests, proper spill management techniques and prevention of medical events involving radiative materials. Dr. Gnegy has maintained his proficiency in all these areas by completing the nuclear stress lab policy of 20 hours of training per quarter required by all physicians. All training is completed in our lab by our Nuclear Medicine Supervisor and again reviewed by myself.

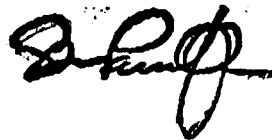
Dr. Gnegy has also met all CME requirements to maintain his board certifications.

140235

Docket No: 03033684
Control No: 140235

Please feel free to contact our with any questions you may have.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Pamfilis', written in a cursive style.

Stanley Pamfilis, MD, FACC

NRC FORM 313A (AUD)
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

**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

State or Territory Where Licensed

DAVID A. Eneagy M.D.

West Virginia

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)

NRC FORM 313A (AUD)
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

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.)**

| 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 | 47-2531A-01 Parkersburg CARDIOLOGY ASSOCIATES 600 18th St. Suite 512 WV 26101 | 135 hours | 1995, 96, 97, 98, 99, 2000, 2002, 2003, 2004 |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | 47-2531A-01 Parkersburg CARDIOLOGY | 150 hours | 1995-96, 97, 98, 99, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007 |
| Calculating, measuring, and safely preparing patient or human research subject dosages | 47-2531A-01 Parkersburg Cardiology | 150 hours | 1995, 96, 97, 98, 99, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007 |

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(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

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 | 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 | 47-25319-01 PARKERSBURG CARDIOLOGY | 100 hrs | 95, 96, 97, 98 99, 2000, 2001, 2002 2003, 2004, 2005, 2006, 2007 |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | 47-25319-01 PARKERSBURG CARDIOLOGY | 125hr | 95, 96, 97, 98 99, 2000, 2001, 2002 2003, 2004, 2005, 2006, 2007 |
| Administering dosages of radioactive drugs to patients or human research subjects | 47-25319-01 PARKERSBURG CARDIOLOGY | 100hrs | 95, 96, 97, 98 99, 2000, 2001, 2002 2003, 2004, 2005, 2006, 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 | | | |

Total Hours of Experience:

| | |
|--|--|
| Supervising Individual Stanley M. Pamfilis, M.D. | License/Permit Number listing supervising individual as an authorized user 47-25319-01 |
|--|--|

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.

NRC FORM 313A (AUD)
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

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 DAVID A. Aneary 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 _____ 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

Stanley M. Pamalis

304-424-4574

5/30/2007

License/Permit Number/Facility Name

47-25319-01

Parkersburg Cardiology Associates


EXHIBIT 2
SUPPLEMENT A

| SUPPLEMENT | | U.S. NUCLEAR REGULATORY COMMISSION | | |
|--|--|--|---|----------------------------|
| TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER | | | | |
| 1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER David Gnegy, M.D. | | 2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED Pennsylvania/West Virginia | | |
| 3. CERTIFICATION | | | | |
| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C | | |
| Internal Medicine Cardiovascular Diseases Board Eligible November 1995 | | 9/1992 | | |
| 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES | | | | |
| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING | | |
| | | CLOCK HOURS IN LECTURE OR LABORATORY | CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE | |
| a. RADIATION PHYSICS AND INSTRUMENTATION | University of Pittsburgh Presbyterian University Hospital | | | |
| b. RADIATION PROTECTION | | | 20 | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | | | | |
| d. RADIATION BIOLOGY | | | | |
| e. RADIOPHARMACEUTICAL CHEMISTRY | | 10 | | |
| 5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience) | | | | |
| ISOTOPE | mCi USED AT ONE TIME | LOCATION | CLOCK HOURS | TYPE OF USE |
| TL201 | 2.5 - 3.5 | Nuclear Cardiology Presbyterian University | | Exercise or Rest Studies |
| Tc 99m | 30 -50 | Nuclear Cardiology Presbyterian University Hospital | | MUGA Studies (Rest/Stress) |

EXHIBIT 3
SUPPLEMENT B

| SUPPLEMENT | | U. S. NUCLEAR REGULATORY COMMISSION | |
|---|--------------------------------------|--|--|
| PRECEPTOR STATEMENT | | | |
| <p><i>Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.</i></p> | | | |
| 1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS | | KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF: | |
| FULL NAME David Gnegy, M.D. | | 1-Supervised examination of patients to determine the suitability for radiotope diagnosis and/or treatment and recommendation for prescribed dosage. | |
| STREET ADDRESS 5301 13th Avenue | | 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data. | |
| CITY STATE ZIP CODE Vienna, West Virginia 26105 | | 3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment. | |
| 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN | | | |
| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS (Additional information or comment may be submitted in duplicate on separate sheets.) D |
| | Thyroid scan | | |
| | Thyroid uptake | | |
| | Lung perfusion scan | | |
| | Xenon ventilation study | | |
| | Aerosol ventilation scan | | |
| | Renal flow scan | | |
| | Brain scan | | |
| | Liver/spleen scan | | |
| | Bone scan | | |
| | Gastroesophageal study | | |
| | LeVeen shunt study | | |
| | Cystogram | | |
| | Dacryocystogram | | |
| | Cardiac perfusion scan. | | 450 |
| Cardiac stress ventriculogram | | 7 | |
| Cardiac rest ventriculogram | | 325 | |
| Gallium scan | | | |
| | | | |
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EXHIBIT 3 (Continued)

| PROPOSED PHYSICIAN USER DAVID GNEGY, M.D. | | | | | | | | | |
|--|---|--|---|----------|-------|---------------------------|--|--|-----|
| PRECEPTOR STATEMENT (Continued) | | | | | | | | | |
| 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued) | | | | | | | | | |
| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D | | | | | | |
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | | | | | | | |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | | | | | | | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | | | | | | | |
| | TREATMENT OF HYPERTHYROIDISM | | | | | | | | |
| Au-198 | INTRACAVITARY TREATMENT | | | | | | | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | | | | | | | |
| | INTRACAVITARY TREATMENT | | | | | | | | |
| I-125 or Ir-192 Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | | | | | | | |
| | TELE THERAPY TREATMENT | | | | | | | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | | | | | | | |
| | RADIOPHARMACEUTICAL PREPARATION | | | | | | | | |
| Mo-99/ Tc-99m | GENERATOR | 5 | | | | | | | |
| Sr-113/ In-113m | GENERATOR | | | | | | | | |
| Tc-99m | REAGENT KITS | | | | | | | | |
| Other | | | | | | | | | |
| 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING <table style="width: 100%; border: none;"> <tr> <td style="text-align: center; border: none;">LOCATION</td> <td style="text-align: center; border: none;">DATES</td> <td style="text-align: center; border: none;">CLOCK HOURS OF EXPERIENCE</td> </tr> <tr> <td style="border: none;">PRESBYTERIAN UNIVERSITY HOSPITAL PITTSBURGH, PA</td> <td style="border: none;"></td> <td style="border: none; text-align: right;">500</td> </tr> </table> | | | | LOCATION | DATES | CLOCK HOURS OF EXPERIENCE | PRESBYTERIAN UNIVERSITY HOSPITAL PITTSBURGH, PA | | 500 |
| LOCATION | DATES | CLOCK HOURS OF EXPERIENCE | | | | | | | |
| PRESBYTERIAN UNIVERSITY HOSPITAL PITTSBURGH, PA | | 500 | | | | | | | |
| 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF: a. NAME OF SUPERVISOR WILLIAM P. FOLLANSBEE, M.D. b. NAME OF INSTITUTION UNIVERSITY OF PITTSBURGH c. MAILING ADDRESS PRESBYTERIAN UNIVERSITY HOSPITAL ROOM A 382 SCARFF HALL TERRACE STREET d. CITY PITTSBURGH, PA 15213 e. MATERIALS LICENSE NUMBER(S) 37-00245-02 | | 5. PRECEPTOR'S SIGNATURE  7. PRECEPTOR'S NAME (Please type or print) William P. Follansbee, M.D. 8. DATE JUNE 20, 1995 | | | | | | | |

JUL-07-95 FRI 14:29

RADIOLOGY DEPT/NUC MED

FAX NO. 412 647-0399

P.03

July 5, 1994

David Guegy, M.D.
Nuclear Cardiology
3rd Floor
Presbyterian University Hospital

Dear David:

Congratulations on having passed the Nuclear Medicine Physics course. Your grade for assignments was 90.3% and 59.5% for the final exam, for a combined weighted average (.30F + .70A) of 81%.

If you should have any questions or comments regarding the course or grading scheme, please feel free to contact me.

Regards,

Nicole Ranger, M.Sc.
Physicist

N: D

N: D