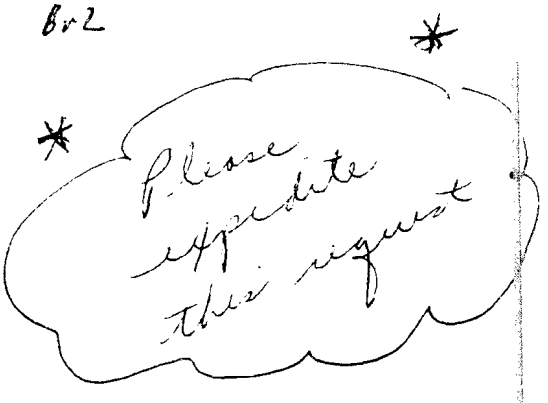
Physicians Imaging Center
New Jersey

Br2

March 2,2009



Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

Ph: 610.337.5000

Re: License No. 29-28041-01 03030030

Dear Sir or Madam,

This is a request for an amendment to our NRC license to add Dr. James A. Miner as an Authorized User for cardiac procedures.

Copies of documents verifying the training and experience of Dr. James A. Miner are enclosed.

Please feel free to contact us if you need any additional information.

Sincerely

Charles H. Rose, MA, MDSPH, D(ABSNM)
Administrator
Physicians Imaging Center
180 Avenue at the Common
Shrewsbury, NJ 07702

Cc: file

Enclosures

143543

NRC FORM 313A (AUD) (10-2007) 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 35.5901

APPROVED BY OMB: NO. 3150-012(
EXPIRES: 1013112008

Name of Proposed Authorized User	State or Territory Where Licensed
James A. Miner	State of Florida

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	INME Training, Secaucus, NJ	50	Feb 7-15, 2007
Radiation protection	Same as above	15	" "
Mathematics pertaining to the use and measurement of radioactivity	Same as above	10	" "
Chemistry of byproduct material for medical use (not required for *35.590)*	Same as above	15	" "
Radiation biology	Same as above	10	" "
	Total Hours of Training:	100 hrs	

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:**	
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	No specific training; 18 years of experience	☒ Yes ☐ No	1990 to present
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Same as above	☒ Yes ☐ No	" "

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	No specific Training - 18 years of experience	[X] Yes [ ] No	1990 to present
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Same as above	[X] Yes [ ] No	" "
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Same as above	[X] Yes [ ] No	" "
Administering dosages of radioactive drugs to patients or human research subjects	Same as above	[X] Yes [ ] No	" "
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	Same as above	[X] Yes [ ] No	" "

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 [X] 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.

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 Pmposed 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

Trainina 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 Pmposed 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

Trainina and Experience

☒ I attest that James A. Miner, 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	Signature	Telephone Number	Date
Salvador Lanza	Salvador Lanza	407.894.4474	2/16/09

License/Permit Number/Facility Name
1816-1 and 1816-3 Florida Heart Group

FUNDAMENTALS

Radioisotope Handling

Attestation and Certification
Completion and Competency

This document is an affidavit that,
as evidenced by written examination,

James Miner, M.D.

has successfully completed this program of education and has achieved the objectives of this program.

This Program provides the following levels of documented accomplishment

100	Continuing Education Units (CEU)
100	Didactic Instructional Hours (DIH)
	In compliance with 10CFR35/AEA 73-689
100	Board Accepted Hours NUSPEX, NMTCB ABMRSO, ABR, ABNM, CBNC

Certifying Official	Date Completed	Certification
	February 15th, 2009	204087

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the American Council on Education (ACE), recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

CME CREDIT CERTIFICATE

This is to certify that

James Miner, M.D.

Has completed up to

100 Hours

Of Category 1 **CME** credit through participation in the course(s)/activities conducted by the Institute for Nuclear Education (INME), February 2009, in Secaucus, NJ.

This CME activity has been planned and implemented in accordance with the Essential Areas and 'Policies of the Accreditation Council for Continuing Medical Education (ACCME) thru the Joint Sponsorship of the Institute for Medical Studies (IMS) and INME.

IMS is accredited by the ACCME to provide continuing medical education for physicians.

IMS designates this educational activity for a maximum of 100 credit hours AMA PRA Category 1 Credits™.

Participants should claim only those hours of credit that he/she actually spent in the activity as established by registration and attendance.

Please retain this Certificate for your records.

The Institute for Medical Studies
14 Monarch Bay Plaza, Suite 202
Monarch Bay, CA 92629

CURRICULUM VITAE

NAME: James Allen Miner, M.D.

BUSINESS ADDRESS:
Florida Heart Group
1613 North Mills Avenue
Orlando, Florida 32803
(407) 894-4474

LICENSURE:
Florida #0022154 (Active)
Georgia #16396 (Inactive)

CERTIFICATION:
Diplomate, American Board of Internal Medicine
June 16,1976

Diplomate, American Board of Cardiovasuclar Disease
November 11,1981

EDUCATION:

Undergraduate
Indiana University, 1965 - 1969
Bloomington, Indiana
Degree: Bachelor of Arts
Major: Zoology

Graduate
Indiana University,
Bloomington, Indiana
Doctor of Medicine
1969 - 1973

Internship
University of Florida
University Hospital of Jacksonville
Jacksonville, Florida
1973 - 1974

EDUCATION, CONTINUED:

Residency
University of Florida
University Hospital of Jacksonville
Jacksonville, Florida
1975 - 1976 Chief Resident of Medicine
1974 - 1975 Assistant Resident of Medicine

Fellowship
University of Florida
University of Florida Affiliated Hospitals
Gainesville, Florida
1976 - 1978

ACADEMIC APPOINTMENTS:

Director of Clinical Cardiology and Coronary Care Unit
University Hospital of Jacksonville
Jacksonville, Florida
7/78 - 6/79

Assistant Professor
University of Florida College of Medicine
Department of Medicine
Jacksonville, Florida
1978 - 1988

Clinical Professor
Jacksonville Health Education Program
University of Florida College of Medicine
Jacksonville, Florida
1978 - 1988

Chief of Cardiology
Memorial Medical Center
Jacksonville, Florida
1981 - 1984

RESEARCH AND PROFESSIONAL EXPERIENCE:

Chairman
Pharmacy & Therapeutics Committee
Memorial Hospital of Jacksonville
Jacksonville, Florida
1981 - 1985

Founder and President
Nielsen Transplant Foundation
1981 - 1988

Expert Defense Witness (Medical)
St. Paul Fire & Marine Insurance Company
Tucker, Georgia
1988 - 1990

Medical Consultant
MediRisk, Incorporated
Atlanta, Georgia
1988 - 1990

Florida Heart Group
1613 North Mills Avenue
Orlando, Florida 32803
August 1990 - present

HOSPITAL AFFILIATIONS:

Florida Hospital Medical Center
Orlando, Altamonte & Apopka, Florida
May 1991 - present
Active Staff

Florida Hospital Medical Center,
Florida East Orlando
May 1991 - present
Courtesy Staff

HOSPITAL AFFILIATIONS, CONTINUED:

Health Central
Orlando, Florida
July 1991 - present
Courtesy Staff

SOCIETY MEMBERSHIPS:

1. American College of Cardiology	
2. Duval County Medical Society	1978 - 1988
3. Florida Medical Association	1.979- 1988
4. American Medical Association	1979 - 1988
5. American College of Physicians	1982 - 1988
6. Orange County Medical Society	1990 - Present

PUBLICATIONS:

Miner, JA, Conti, CR: The Use of Nitroglycerin Paste in Coronary Artery Disease. Journal of the American Medical Association. May 1978.

INVESTIGATIONAL TRIALS - PHARMACEUTICALS

Co-Investigator: *Atorvastatin* (Access). A *54 week open label assessment of the safety* and efficacy profile of Atorvastin as compared to Fluvastatin, Lovastatin, Simvastatin, and Pravastatin when used to optimally control primary hypercholesterolemia (typeIIA) and mixed dyslipidemia (typeIIB).

Co-Investigator: Atorvastatin (TNT). The effect of LDL- cholesterol lowering beyond currently recommended minimum targets on coronary heart disease (CHC) recurrence in patients with pre-existing CHD.

Co-investigator: Attach. (2000) A Phase II, multicenter, randomized, double-blind, placebo-controlledpilot trial evaluating the effects of Infliximab (Remicade®).

Co-Investigator: Avid. Antiarrhythmics versus implantable defibrillators.

INVESTIGATIONAL TRIALS - PHARMACEUTICALS (CONT)

Co-Investigator: *Azimilide (1995116). (1998-2000) A multi-center, double blind* placebo controlled parallel design clinical trial to assess the safety and efficacy of 35 mg and 75 mg of Azimilide Dihydrochloride for the Prophylactic treatment of symptomatic atrial fibrillation/flutter and /or symptomatic paroxysmal supraventricular tachycardia.

Co-Investigator: Azimilide (1998118) . A multi-center open label clinical trial to assess the long term safety of daily oral dose of 125 mg of Azimilide Dihydrochloride in patients with atrial fibrillation/ flutter and/or paroxysmal supraventricular tachycardia.

Co-Investigator: Belles. (2000) Beyond Endorsed Lipid Lowering with **EBCT** *Scanning*.

Co-Investigator: Bravo. (1999-2001) Blockade of the GP IIB/IIA Receptor to Avoid Vascular Occlusion.

Co-Investigator: Charm. **(1999) Candesartan** Cilexetil in Heart Failure: Assessment of Reduction in Mortality.

Co-Investigator: Copernicus. (1998) A multi-center, randomized, double-blind, placebo- controlled study to determine the effect of Carvedilol on mortality m patients with severe chronic heart failure.

Co-Investigator: Coppa 11. (1998-2000) Clinical Outcome from Prevention of Post-Operative Arrhythmia II.

Co-Investigator: DMP. A phase II, randomized, doubleblind, multicenter, acetylsalicylic acid controlled, multi-dose study of DMP 754 alone or in combination with ASA in patients with coronary artery disease.

Co-Investigator: ET *005*. (2000) Double-blind, randomized placebo-controlled, parallel group study evaluating the effects of different doses of LU 135252 on left ventricular dimensions, function, and left and right ventricular mass, neurohormone levels, and symptoms in patients with advanced congestive heart failure.

Co-Investigator: *Guardian.* A double-blind, placebo-controlled, multinational trial to investigate the effect of the Na+/H+ exchange inhibitor (cariporide) on all-cause mortality and MI in patients at risk of myocardial necrosis due to acute coronary syndrome related to the disease process or to an interventional cardiac procedure.

INVESTIGATIONAL TRIALS - PHARMACEUTICALS (CONT)

Co-Investigator: Madit II. A randomized study (ICD versus non-ICD) in moderately high-risk coronary patients to evaluate whether there is a significant reduction in death in patients who receive an ICD as compared to patients not treated with ICD.

Co-Investigator: Merit. A double-blind, placebo-controlled, survival study with *Metroprolol CR in patients with decreased ejection fraction* and *symptoms sf heart failure.*

Co-Investigator: Natrecor. A randomized open label active controlled, multicenter Phase III safety study of two doses of Natrecor® hBNP administered as a continuous infusion in the treatment of decompensated CHF.

Co-Investigator: Niaspan. An open label, community based clinical practice study of Niaspan in patients with hyperlipidemia.

Co-Investigator: Overture. (1999) Omapatrilat Versus Enalapril Randomized Trial of Utility in Reducing Events.

Co-Investigator: Praise *2.* (1997) Prospective Randomized Amlodipine Survival Evaluation-2. A randomized, double-blind, dose-titration, parallel group, placebo-controlled study to evaluate the effect of amlodipine on survival in patients with congestive heart failure.

Co-Investigator: *Pravastatin.* A *study to compare the* LDL-C lowering efficacy of Pravastatin 40 mg administered once daily versus a divided dosing regimen.

Co-Investigator: Prove It. (2000) Pravastatin or Atorvastatin Evaluation and Infection Therapy.

Co-Investigator: Raft. A double blind, placebo- controlled, randomized, clinical trial of *slow release Propafenon in the prevention of symptomatic recurrences of atrial fibrillation.*

Co-Investigator: Valsartan. (1997-2000) Multicountry randomized, double-blind, parallel, placebo- controlled trial to assess the effect of Valsartan on morbidity and mortality, signs and symptoms, and quality of life in patients with stable, chronic congestive heart failure (NYHA Class II-IV).

UPDATED 2/03/05

Salvador N. Lanza, MD
Harvard Vanguard Medical Associates
Department of Cardiology
133 Brookline Ave.
Boston, Ma 02215

March 5, 2009

Dear Sir or Ms,

I have known and worked with Dr lames Miner since 1990 and Dr Miner is an excellent clinician. Since 1993 I have overseen his work in nuclear cardiology and can attest to his appropriateness of testing, his ability to interpret and communicate findings to patients and referring physicians in a fashion that benefits the care of his patients. He has shown in his practice an unbiased approach in his assessment of his patients with the selective use of different diagnostic modalities, and the avoidance of duplicative or unnecessary testing. I have also found him to be an excellent resource as a colleague, helping in management of difficult patients , as well as routine cases,

If I can be of further help in this process please contact me.

Sincerely,

Salvador N. Lanza, MD

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

3/2/2009, and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 29-28041-01
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

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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** 143543.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM **532** (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader