

Rami M. Akel, MD, FACC
Phillip G. Apprill, MD, FACC
Manoj K. Eapen, MD, FACC
Darlene L. Eyster, MD, FACC
Mark A. Friedman, MD
M. Carolyn Gamache, MD, FACC
M. Kiran Kancherla, MD, FACC
David J. Kardesch, MD, FACC

METRO
HEART & GROUP
OF ST. LOUIS, INC.

John W. Kilgore, MD, FACC
Roberto Pacheco-Coronado, MD
Jeffrey T. Reese, MD, FACC
Bassam A. Roukoz, MD, FACC
Robert Snitzer, MD, FACC
Mark D. Taber, MD, FACC
Richard B. Whiting, MD, FACC

U. S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352


License Number 24-32184-01

Dear Materials Licensing Section:

We are requesting an amendment to our radioactive material license to add Rami Akel, M.D., to our license as an Authorized User permitted to use radioactive material in 35.200 for cardiovascular imaging and localization studies. Attached is a completed NRC FORM 313A (AUD) and other documents to support Dr. Akel's training and experience with radioactive materials.

If you have any additional questions, please contact me or John Derhake (Director of Nuclear Cardiology) at (314) 880-6100.

Sincerely,


N. Reck Erekson, MBA, CMPE
Executive Director

8-31-11
Date



RECEIVED SEP 08 2011



**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

Rami Akel, MD

State or Territory Where Licensed

Missouri

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	Health and Radiological Seminars, Inc in Conjunction with The University of Texas Health Science Center at Houston, TX	100	May, 2005 to May, 2006
Radiation protection	Health and Radiological Seminars, Inc in Conjunction with The University of Texas Health Science Center at Houston, TX	30	May, 2005 to May, 2006
Mathematics pertaining to the use and measurement of radioactivity	Health and Radiological Seminars, Inc in Conjunction with The University of Texas Health Science Center at Houston, TX	20	May, 2005 to May, 2006
Chemistry of byproduct material for medical use (not required for 35.590)	Health and Radiological Seminars, Inc in Conjunction with The University of Texas Health Science Center at Houston, TX	30	May, 2005 to May, 2006
Radiation biology	Health and Radiological Seminars, Inc in Conjunction with The University of Texas Health Science Center at Houston, TX	20	May, 2005 to May, 2006

Total Hours of Training: 200

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	University of Texas Medical Branch Houston, TX Tx RAM Lic#L01299	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	May 2005 to May, 2006
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Texas Medical Branch Houston, TX Tx RAM Lic#L01299	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	May 2005 to May, 2006

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	University of Texas Medical Branch Houston, TX Tx RAM Lic#L01299	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	May 2005 to May, 2006
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Texas Medical Branch Houston, TX Tx RAM Lic#L01299	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	May 2005 to May, 2006
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Texas Medical Branch Houston, TX Tx RAM Lic#L01299	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	May 2005 to May, 2006
Administering dosages of radioactive drugs to patients or human research subjects	University of Texas Medical Branch Houston, TX Tx RAM Lic#L01299	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	May 2005 to May, 2006
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	University of Texas Medical Branch Houston, TX Tx RAM Lic#L01299	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	May 2005 to May, 2006

Supervising Individual: Vani Vijayakumar, MD
License/Permit Number listing supervising individual as an authorized user: TX Lic# L01299

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 _____ 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 Rami Akel, MD has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

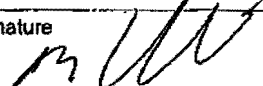
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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
M. E. KANCHERLA, MD		314-645-6450	5-10-11

License/Permit Number/Facility Name
NRC Lic.# 24-32184-01 Metro Heart Group of St. Louis, Inc.

July 27, 2011

To whom it may concern:

This letter is to affirm that Rami Akel, M.D. has obtained supervised nuclear medicine, nuclear cardiology, clinical and work experience in our institution. This experience and preceptorship occurred during April, December 2005 and January, April and May 2006.

The clinical experience included active participation in the following procedures:

- 50 PYP/RBC multi-gated acquisition procedures
- 500 Tc99m Myoview myocardial perfusion studies, gated SPECT with wall motion and ejection fraction calculation stress and rest. Of these, 60 had angiographic correlation
- 9 Thallium myocardial perfusion studies, SPECT, stress and rest or rest and redistribution. Of these, 4 had angiographic correlation

In addition, the clinical experience included review of the following teaching file cases:

- 400 PYP/RBC multi-gated acquisition procedures
- 110 Tc99m myocardial perfusion studies, gated SPECT with wall motion and ejection fraction calculation stress and rest.
- 10 Thallium myocardial perfusion studies, SPECT, stress and rest or rest and redistribution.

During this clinical experience the physician examined patients and reviewed histories to determine the suitability for these procedures; selected the suitable radiopharmaceutical and dose; administered radiopharmaceuticals using a syringe shield; collaborated with the authorized user in the interpretation of the procedures and used the interpretation in the management of patients.

Concurrent with the clinical experience was supervised work experience which included observing and participating in procedures for ordering, receiving, and unpacking radioactive materials; use of the dose calibrator and other instruments as well as check for proper operation;

calculating and preparing patient dosages; using administrative controls to prevent misadministration; and using procedures to contain spills and decontamination procedures.

Also included were reading assignments in nuclear cardiology, presentation of a nuclear cardiology topic to the cardiology department, and video seminars in nuclear cardiology.

The American Society of Nuclear Cardiology self-assessment program (NCSAP-II) was also available for review.

The total hours of concurrent supervised clinical and work experience during this period was 800 hours.

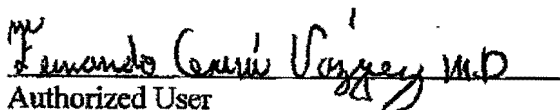
Rami Akel, M.D. has completed a fellowship training program in nuclear cardiology that meets the requirements as outlined in the ACC/ASNC COCATS Guidelines (revised 2002).

Level II training according to COCATS 2002 guidelines have been met.

This letter also confirms that upon completion of 200 hours of didactic training in Radiation Safety including:

1. Principles of radiation physics
2. Medical radiation instrumentation
3. Radio-pharmaceuticals
4. Medical radiation protection

Rami Akel, M.D. will achieve a level of competence sufficient to function independently as an authorized user for the medical uses authorized under NRC part 35.100 and 35.200


Authorized User

Fernando Cesani-Vazquez, M.D.
University of Texas Medical Branch
Department of Radiology

Jun 9 2009 08:25am P0027005

METRO HEART GROUP MDS Fax 6369373609

Health & Radiological Seminars, Inc.

In conjunction with the University of Texas Health Science Center at Houston

Hereby certifies that

RAMI AKEL, M.D.

has successfully completed the 200 Hour Physician Training Program in Basic Radioisotope Handling conducted in accordance with the requirements of the U.S. Nuclear Regulatory Commission (10 CFR 35).

COURSE OUTLINE

- Radiation Physics and Instrumentation - 100 hours
- Mathematics pertaining to the use and measurement of radioactivity - 20 hours
- Radiopharmaceutical Chemistry - 30 hours
- Radiation Biology - 20 hours
- Radiation Protection - 30 hours

May 21, 2006

Derek H. Noland

Derek H. Noland
Program Director

Stephen M. Dyer

Stephen M. Dyer, MMS
Scientific Advisor



Metro Heart Group of St. Louis, Inc.
 12855 N. Forty Dr, Suite 300
 St. Louis, MO 63141

PIRESORTED
 FIRST CLASS



Hasler

016H26524263
\$01.057
 09/01/2011
 Mailed From 63000
 US POSTAGE



U. S. Nuclear Regulatory Commission
 Region III
 Materials Licensing Section
 2443 Warrenville Road, Suite 210
 Lisle, IL 60532-4352

148

60532
 H012NM1

