

CARDIOSPECIALISTS GROUP, LTD.
801 MacArthur Boulevard, Suite 203
Munster, IN 46321

November 15, 2010

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

Re: Amendment to License No. 13-32400-01:

To Whom It May Concern:

Please add the names of Dinesh K. Kalra, M.D., as an authorized user for 10CFR35.200 procedures, limited to cardiovascular clinical procedures.

To support this request, we have attached a copy of Dr. Kalra's Certification Board of Nuclear Cardiology certificate, documentation of his safe use of radioactive materials training, a completed NRC Form 313A form, including signed preceptor attestation, and copy of his State of Indiana physician's license.

Please remove the name of A. Arif Khalil, M.D. from our license. Dr. Khalil is no longer associated with this licensee

If you need additional information to process this request, please contact Margie Biltgen, CNMT at 219-836-9390.

Sincerely,



Robert L. Litchfield, D.O.
Radiation Safety Officer

Copy: Margie Biltgen, CNMT
M.M. Corrales, M.D.

RECEIVED NOV 19 2010

NRC FORM 313A (AUD)
(3-2009)

**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

DINESH K. KALRA, M.D.

State or Territory Where Licensed

INDIANA

Requested Authorization(s) (check all that apply)

- ☐ 35.100 Uptake, dilution, and excretion studies
- ☒ 35.200 Imaging and localization studies (LIMITED TO NUCLEAR CARDIOLOGY)
- ☐ 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. (SEE ATTACHED CBNC)
- 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 | | | |
| 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.)

| 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 | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |

NRC FORM 515A (ADD)
(3-2009)

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 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 type="checkbox"/> Yes <input type="checkbox"/> No | |
| Using administrative controls to prevent a medical event involving the use of unsealed byproduct material | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Using procedures to contain spilled byproduct material safely and using proper decontamination procedures | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Administering dosages of radioactive drugs to patients or human research subjects | | <input type="checkbox"/> Yes <input type="checkbox"/> 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 | | <input type="checkbox"/> Yes <input type="checkbox"/> 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☒ 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 DINESH K. KALRA, M.D. 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 * |
| Robert L. Litchfield | <i>Robert Litchfield</i> | 219-836-9390 | 11-15-10 |
| * License/Permit Number/Facility Name | | | |
| License # 13-32400-01 Cardio Specialists Group, LTD. | | | |

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Dinesh K. Kalra, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING
IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED

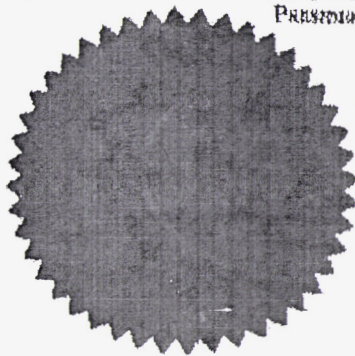
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 2003 THROUGH 2013

David D. Reiguen
PRESIDENT

[Signature]
SECRETARY



CERTIFICATE # 2660



OCTOBER 26, 2003



TEXAS HEART INSTITUTE

Affiliated with St. Luke's Episcopal Hospital and Texas Children's Hospital

Certifies that

Dinesh K. Kalra, MD

has successfully completed the course

"Safe Use of Radioactive Materials in Medical Imaging"

conducted over five 40-hour sessions between July 7, 2000 and September 11, 2000.

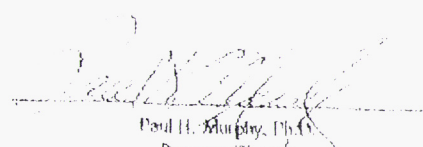
The lectures and laboratory training were presented by members of the faculties of the

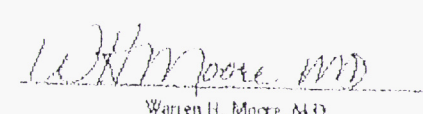
Nuclear Medicine and Cardiology Sections of Baylor College of Medicine and

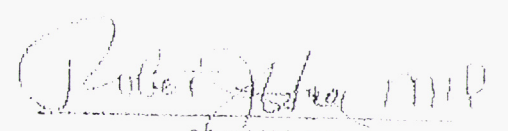
The University of Texas-Houston Health Science Center

in the classrooms and Nuclear Medicine Laboratories of St. Luke's Episcopal Hospital and the Texas Heart Institute.

The course was designed to meet the licensing requirements of the Nuclear Regulatory Commission and agreement states for medical use of diagnostic radiopharmaceuticals.


Paul H. Murphy, PhD
Program Director


Warren H. Moore, MD
Director, Nuclear Medicine Residency Program


Robert J. Hall, MD
Director, Cardiology Education



Indiana Professional Licensing Agency
Medical Licensing Board
402 W. Washington St., Room W072, Indianapolis IN 46204
(317) 234-2060

Physician License

Dinesh Kumar Kalra

| License Number | Expiration Information |
|----------------|-----------------------------------------|
| 01047767A | Expires June 30 th Odd Years |

Current License Status can be verified online
www.pla.in.gov License Express Option

State of Illinois
 Department of Financial and Professional Regulation
 Division of Professional Regulation

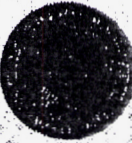
LICENSE NO.
036.120360

The person, firm or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below.

EXPIRES:
07/31/2011

**LICENSED
 PHYSICIAN AND SURGEON**

**DINESH KUMAR KALRA MD
 1001 W MADISON ST APT 607
 CHICAGO, IL 60607**

 *Dean Martinez* DEAN MARTINEZ
 SECRETARY

Daniel E. Bluthardt DANIEL E. BLUTHARDT
 DIRECTOR

The official status of this license can be verified at www.idfpr.com

3230814

Cut on Dotted Line

State of Illinois
 Department of Financial and Professional Regulation
 Division of Professional Regulation

LICENSE NO.
036.120360

**LICENSED
 PHYSICIAN AND SURGEON**

DINESH KUMAR KALRA MD

EXPIRES:
07/31/2011

SIGN: *[Signature]*

Dean Martinez DEAN MARTINEZ
 SECRETARY

Daniel E. Bluthardt DANIEL E. BLUTHARDT
 DIRECTOR

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