

Phillip G. Apprill, MD, FACC  
Sara Baig, MD  
Sudip Datta, MD, FRCPC, FACC  
Manoj K. Eapen., MD, FACC  
Mark A. Friedman, MD, FACC  
M. Kiran Kancherla, MD, FACC



David J. Kardesch, MD, FACC  
Jeffrey T. Reese, MD, FACC  
Bassam A. Roukoz, MD, FACC  
Robert Snitzer, MD, FACC  
Mark D. Taber, MD, FACC  
Richard B. Whiting, MD, FACC

May 30, 2013

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 Sudip Datta, 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 CBNC Certificate to support Dr. Datta'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. Rock Ereksan, MBA, CMPE  
Executive Director

RECEIVED JUN 11 2013

**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: (05/31/2015)

Name of Proposed Authorized User

Sudip Datta, M.D.

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
<b>Total Hours of Training:</b>			

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	

**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.**

# Certification Board of Nuclear Cardiology

Incorporated 1996

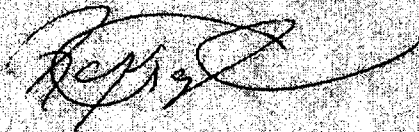
Certifies that

## Sudip Datta, MD

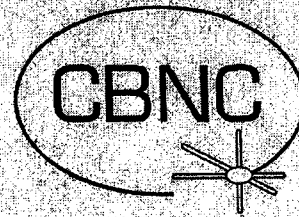
HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD  
FOR PHYSICIANS TRAINED IN THE UNITED STATES  
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,  
IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF  
**NUCLEAR CARDIOLOGY**

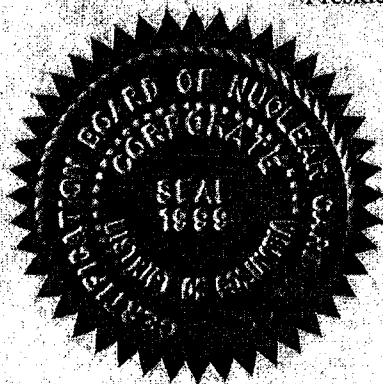
**FOR THE PERIOD 2008 - 2018**



President



Secretary

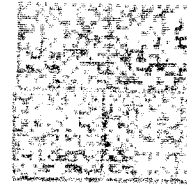


CERTIFICATE NUMBER: 6072

**METRO**  
HEART  GROUP  
OF ST. LOUIS, INC.

12855 N. Forty Drive  
Suite 300  
St. Louis, MO 63141

PRESORTED  
FIRST CLASS



PostNet

016H26524167

\$00.994  
06/06/2013

Mailed From: 63185  
US POSTAGE



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