Winchester Cardiology
Cardiovascular Imaging Center
190 Campus Blvd., Suite 201
Winchester, VA
Phone Number: (540) 542-1844
Fax Number: (540) 542-1843

August 11, 2008

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License Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety & Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Amendment Application
Winchester Cardiology & Internal Medicine
License Number: ~~45-2541-01~~ 45-25541-01 RLS

Dear License Reviewer:

Please amend our byproduct material license to add Manish Lakhani, M.D. as an authorized user for all materials and procedures approved on our current license. Training and experience documentation has been enclosed is Attachment A. Please refer to this section for details.

If you have additional questions regarding this correspondence, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 693-2277.

We thank you in advance for your assistance.

Sincerely,

James Dixon Brown MD

James Dixon Brown, M.D.
Administrative Representative/Radiation Safety Officer

142723
NMSS/RGN1 MATERIALS-002

Attachment A

SUNY
DOWNSTATE
Medical Center
University Hospital of Brooklyn

Jason M. Lazar, MD
Director, Non-Invasive Cardiology
Director, Cardiology Fellowship Training Program
Clinical Assistant Dean, College of Medicine
Associate Professor of Medicine

July 27, 2007

Certification Board of Nuclear Cardiology
19562 Club House Road
Montgomery Village, MD 20886-3002

Re: Manish Lakhani, MD

Dear Sirs:

Dr. Manish Lakhani has completed a nuclear cardiology training program that meets the requirements for level 2 as outlined in the ACCF/ASNC COCATS Guidelines for Nuclear Cardiology, revised 2006, within an accredited fellowship program.

Dr. Lakhani completed level 2 Nuclear Cardiology training between the dates of July 1, 2005 and July 27, 2007.

I attest that Dr. Lakhani is competent to independently function as an authorized user under NRC 10 CFR 35.200 uses.

Dr. Lakhani completed a minimum of 80 hours of Radiosotope Handling Classroom and Laboratory training which meets the requirements of the Nuclear Regulatory Commission as an integral part of his fellowship program.

Sincerely,

Jason M. Lazar, MD
NRC License#: 75-2934-01-202

/dv

STATE UNIVERSITY OF NEW YORK
DOWNSTATE MEDICAL CENTER

THE DEPARTMENT OF RADIOLOGY AND RADIATION PHYSICS HEREBY CERTIFIES THAT

MANISH LAKHANI M.D.

successfully completed a Radiation Physics course designed specifically for the education in the use of radioactive materials in humans for diagnostic imaging. This certificate is awarded only after the physician has attended the classroom and laboratory instruction and passed a rigorous three hour written exam

The course consisted of 50 hours of classroom and laboratory instruction specifically covering:

RADIATION PHYSICS
INSTRUMENTATION
RADIATION PROTECTION
RADIATION BIOLOGY
RADIATION IMAGING EQUIPMENT
RADIATION MEASUREMENTS

ARTHUR OLSON, RADIATION SAFETY OFFICER
DIRECTOR RADIATION PHYSICS
CERTIFIED BY THE AMERICAN BOARD OF RADIOLOGY

Sept 2006
SEPT 2006

STATE UNIVERSITY OF NEW YORK
DOWNSTATE MEDICAL CENTER

THE DEPARTMENT OF RADIOLOGY AND RADIATION PHYSICS HEREBY CERTIFIES THAT

MANISH LAKHANI M.D.

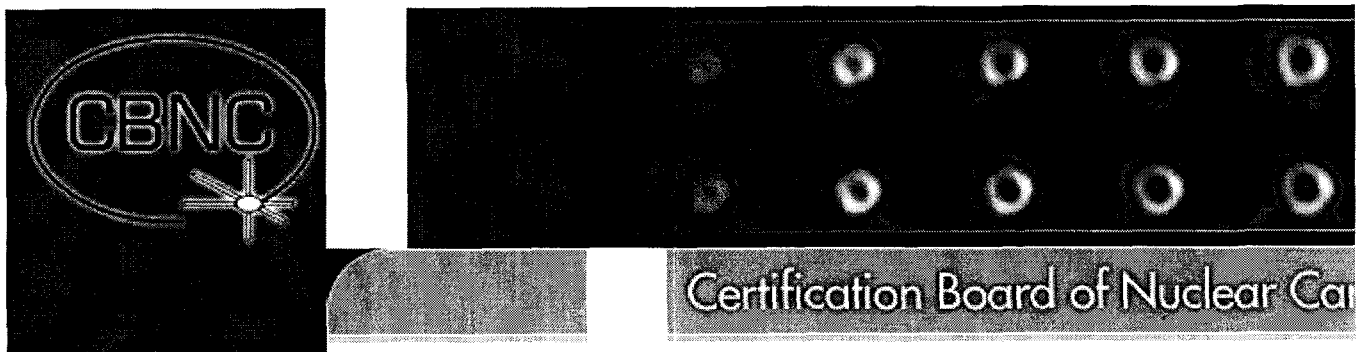
successfully completed a Radiation Physics course designed specifically for the education in the use of radioactive materials in humans for diagnostic imaging. This certificate is awarded only after the physician has attended the classroom and laboratory instruction and passed a rigorous three hour written exam

The course consisted of 30 hours of classroom and laboratory instruction specifically covering:

RADIATION PHYSICS
INSTRUMENTATION
RADIATION PROTECTION
RADIATION BIOLOGY
RADIATION IMAGING EQUIPMENT
RADIATION MEASUREMENTS

ARTHUR OLSON, RADIATION SAFETY OFFICER
DIRECTOR RADIATION PHYSICS
CERTIFIED BY THE AMERICAN BOARD OF RADIOLOGY

July 2007
JULY 2007



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SEARCH

The Examination

COCATS Guidelines for Level 2 Training in Nuclear Cardiology

The COC Guidelines revised in Preceptor Att referencin document are for certificati applicar

**COCATS GUIDELINES (Revised 2006)
AMERICAN COLLEGE OF CARDIOLOGY/
AMERICAN SOCIETY OF NUCLEAR
CARDIOLOGY COCATS GUIDELINES FOR
TRAINING IN NUCLEAR CARDIOLOGY**

Overview of Nuclear Cardiology Training

Training in nuclear cardiology at all levels should provide an understanding indications for specific nuclear cardiology tests, the safe use of radionuclides instrumentation and image processing, methods of quality control, image interpretation, integration of risk factors, clinical symptoms and stress testing appropriate application of the resultant diagnostic information for clinical management. Training in nuclear cardiology is best acquired in Accreditation for Graduate Medical Education (ACGME) approved training programs in ca nuclear medicine or radiology. An exception to this ACGME requirement is didactic and laboratory training in radiation safety and radioisotope handling be provided by qualified physicians/scientists in a non-ACGME program wh program is not available as part of the clinical ACGME training program.

Didactic, clinical case experience and hands-on training hours require docum in a logbook[1] and having the trainee's name appear on the clinical report or o specific record. The hours need to be monitored and verified by the nuclear c training preceptor.

Specialized Training - Level 2 (Minimum of 4 Months)

Fellows who wish to practice the specialty of nuclear cardiology are required least 4 months of training. This includes a minimum of 700 hours of didactic study interpretation, and hands-on clinical case and radiation safety training i cardiology. In training programs with a high volume of procedures, clinical e may be acquired in as short a period as 4 months. In programs with a lower v procedures, a total of 6 months of clinical experience will be necessary to acl Level 2 competency. The additional training required of Level 2 trainees is t

clinical skills and to qualify them to become authorized users of radioactive r in accordance with the regulations of the Nuclear Regulatory Commission (N and/or the Agreement States.

Didactic Program
Lectures and self-study. The didactic training should include in-depth details aspects of the procedures listed in Table 1 (see below). This program may be scheduled over a 12- to 24-month period concurrent and integrated with othe fellowship assignments.

Radiation Safety. Classroom and laboratory training need to include extensiv of radiation physics and instrumentation, radiation protection, mathematics p to the use and measurement of radioactivity, chemistry of byproduct material medical use, radiation biology, the effects of ionizing radiation and radiopharmaceuticals. There should be a thorough review of regulations deal radiation safety for the use of radiopharmaceuticals and ionizing radiation. T experience should total a minimum of 80 hours and be clearly documented.

Interpretation of Clinical Cases
Fellows should participate in the interpretation of all nuclear cardiology imag for the 4-6 month training period. It is imperative that the fellows have exper correlating catheterization or CT angiographic data with radionuclide-derive minimum of 30 patients. A teaching conference in which the fellow presents clinical material and nuclear cardiology results is an appropriate forum for su experience. A total of 300 cases should be interpreted under preceptor superv

Hands-on Experience
Clinical cases. Fellows acquiring Level 2 training should have hands-on supe experience in a minimum of 35 patients: 25 patients with myocardial perfusi imaging and 10 patients with radionuclide angiography. Such experience sho include pretest patient evaluation, radiopharmaceutical preparation (includin experience with relevant radionuclide generators and CT systems), performa study, administration of the dosage, calibration and setup of the gamma came system, setup of the imaging computer, processing the data for display, inter of the studies and generating clinical reports.

Radiation safety work experience. This experience should be acquired contin during training in the clinical environment where radioactive materials are be and under the supervision of an authorized user who meets the NRC requiren Part 35.290 or Part 35.290(c)(ii)(G) and 35.390 or the equivalent Agreement requirements, and must include:

a) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys;

b) Performing quality control procedures on instruments used to deter activity of dosages and performing checks for proper operation of surv

c) Calculating, measuring and safely preparing patient or human resear dosages;

d) Using administrative controls to prevent a medical event involving t unsealed byproduct material;

e) Using procedures to safely contain spilled radioactive material and u proper decontamination procedures;

f) Administering dosages of radioactive material to patients or human r subjects; and

g) Eluting generator systems appropriate for preparation of radioactive imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prep labeled radioactive drugs.

Additional experience
In addition, the training program for Level 2 training must provide experienc computer methods for analysis. This should include perfusion and functional derived from thallium or technetium agents and ejection fraction and regiona motion measurements from radionuclide angiographic studies.

[1] Note: These logbooks are not to be submitted with the CBNC application.

Table 1 Classification of Nuclear Cardiology Procedures

1) Standard nuclear cardiology procedures

a) Myocardial perfusion imaging
- i) Single photon emission computed tomography (SPECT) with technetium-99m agents and thallium-201
- ii) Positron emission tomography (PET) with rubidium-82 and n ammonia
- iii) Planar with technetium-99m agents and thallium-201
- iv) Electrocardiographic (ECG) gating of perfusion images for a of global and regional ventricular function
- v) Imaging protocols
- vi) Stress protocols
  - 1) Exercise stress
  - 2) Pharmacologic stress
- vi) Viability assessment including reinjection and delayed imagi thallium-201 and metabolic imaging where available

b) Equilibrium gated blood pool or "first pass" radionuclide angiograp and during exercise or pharmacologic stress
c) Qualitative and quantitative methods of image display and analysis

2) Less commonly used nuclear cardiology procedures

a) Combined myocardial perfusion imaging with cardiac CT
b) Metabolic imaging using single photon and/or positron emitting rad
c) Myocardial infarct imaging
d) Cardiac shunt studies

To receive a copy of the complete COCATS Guidelines for Training in N Cardiology, visit the American Society of Nuclear Cardiology Website: www.asnc.org.

CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY
101 Lakeforest Boulevard, Suite 401, Gaithersburg MD 20877 - (T): 240.631.8151 - (F): 24(