From: "Dawn Edgerton" <edgerton@cbnc.org>
To: M. Silva -<mss@nrc.gov>
Date: NMSS 8/25/05 11:10AM
Subject: CBNC followup

Dear Mohammed,

Dr. Cerqueira responded to me faster than I thought. Before we send this in the mail to Tom Essig, Manuel asked if I could check with you to be certain this is what you need in the way of clarification. Could you have a little look and let me know? If you confirm that this is what you are needing, I will go ahead and put it all in the mail today.

Best regards and thank you again for your help.

Dawn Edgerton

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August 25, 2005

U.S. Nuclear Regulatory Commission
Attn: Mr. Thomas Essig, Chief, Materials Safety
and Inspection Branch (MS T8F3)
11545 Rockville Pike
Rockville MD 20852

Dear Mr. Essig:

Thank you for the opportunity to clarify an issue regarding the Certification Board of Nuclear Cardiology (CBNC)'s application for recognition of its certification process by the Nuclear Regulatory Commission (NRC) under the new **10 CFR § 35.290 - Training for Imaging and Localization Studies.**

In response to a question raised by your staff, let me confirm that CBNC's examination includes questions on dose calibrators and radiopharmacy quality control procedures as part of the exam's section on Radiation Safety. This was implied but not specifically stated. Based on our discussion, we have amended our examination content outline for the 2006 Candidate Bulletin so that this is clearer to candidates and other interested individuals (see attached).

This area was covered in the COCATS Guidelines (Revised 2000) as "b" under work experience "Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters" (see attached). It is anticipated that quality control of dose calibrators and radiopharmacy will be specifically listed under the COCATS currently under revision.

I would like to again emphasize the CBNC Board of Directors' and management's commitment to and responsibility for the completeness and accuracy of the information provided in this application.

If we can supply your office with any additional details, please do not hesitate to let us know. We look forward to hearing from you relative to our request for recognition by the NRC.

Sincerely,

Manuel D. Cerqueira, M.D.
President, Certification Board of Nuclear Cardiology

CC: Mohammed Saba

Encls.

COCATS GUIDELINES (Revised 2000)

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

Didactic, clinical case experience and hands-on training hours require documentation in a logbook* and having the trainee's name appear on the clinical report or other specific record. The hours need to be monitored and verified by the nuclear cardiology training preceptor

Specialized Training - Level 2
(Minimum of 4 Months)

Fellows who wish to clinically practice the specialty of nuclear cardiology are required to have at least 4 months of training. This includes a minimum of 700 hours of didactic, clinical study interpretation, and hands-on clinical case and radiation safety training in nuclear cardiology. In training programs with a high volume of procedures, clinical experience may be acquired in as short a period as 4 months. In programs with a lower volume of procedures, a total of 6 months of clinical experience will be necessary to achieve Level 2 competency. The additional training required of Level 2 trainees is to enhance clinical skills and to qualify to become an authorized user of radioactive materials in accordance with the regulations of the Nuclear Regulatory Commission (NRC) and/or the Agreement States. Requirements do vary among the Agreement States; therefore those seeking licensure are advised to check the Agreement State/NRC internet web site at: http://www.hsrd.ornl.gov/nrc/asfrnpc.htm.

Didactic

Lectures and self-study. The didactic training should include in-depth details of all 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 other fellowship assignments.

Radiation Safety. Classroom and laboratory training needs to include extensive review of radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, and radiation biology. There should be a thorough review of regulations dealing with radiation safety for the use of radiopharmaceuticals.

Interpretation of Clinical Cases

Fellows should participate in the interpretation of all nuclear cardiology imaging data for the 4-6 month training period. It is imperative that the fellows have experience in correlating catheterization/angiographic data with radionuclide-derived data in a minimum of 30 patients. A teaching conference in which the fellow presents the clinical material and nuclear cardiology results is an appropriate forum for such an experience. A total of 300 cases should be interpreted under preceptor supervision, either from direct patient studies or from a teaching file consisting of diverse types of procedures (see Table 1 below).

Hands-on Experience

Clinical Cases. Fellows acquiring Level 2 training should have hands-on supervised experience in a minimum of 35 patients: 25 patients with myocardial perfusion imaging and 10 patients with radionuclide angiography. Such experience should include pretest patient evaluation, radiopharmaceutical preparation (including experience with relevant radionuclide generators), performance of the study, administration of the dosage, calibration and setup of the gamma camera, setup of the imaging computer, processing the data for display, interpretation of the studies and generating clinical reports.

Work Experience. This experience must be under the supervision of an authorized user who meets the NRC requirements of Part 35.200 or equivalent Agreement State requirements, and must include:

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

b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

d) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

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

f) Administering dosages of radioactive drugs to patients or human research subjects; and

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

Additional experience

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

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 agents and thallium
      ii) Planar with technetium agents and thallium
      iii) EGC gating of perfusion images for assessment of global and regional ventricular function
      iv) Imaging protocols
      v) Stress protocols
         (1) Exercise stress
         (2) Pharmacologic stress
      vi) Viability assessment including reinjection and delayed imaging of thallium and metabolic imaging where available
   b) Equilibrium gated blood pool or "first pass" radionuclide angiography at rest and during exercise or pharmacologic stress
   c) Qualitative and quantitative methods of image display and analysis
2) Less commonly used nuclear cardiology procedures
   a) Metabolic imaging using single photon and/or positron emitting radionuclides
   b) Myocardial infarct imaging
   c) Cardiac shunt studies

* (Note: These logbooks are not to be submitted with the CBNC application.)

Examination Content Outline

The following is a detailed outline of the nine major content areas of the examination, with an indication (in parentheses) of the approximate percentage of the examination devoted to each area:

I. PHYSICS AND INSTRUMENTATION (10%)
   A. Basic physics as applied to clinical imaging (e.g., isotope decay, decay modes, generators, high energy imaging)
   B. Gamma cameras, collimation, and equipment - quality control procedures
   C. Photon attenuation and scatter

II. RADIOPHARMACEUTICALS (8%)
   A. Radiotracer kinetics and characteristics [Thallium-201 and Technetium-99m]
   B. PET agents
   C. Red blood cell tagging
   D. Newer agents

III. RADIATION SAFETY (10%)
   A. Radiopharmaceutical receiving, handling, monitoring, and containment
   B. Handling radiopharmaceutical spills and waste
   C. Dose calibrator and radiopharmacy quality control procedures
   D. Dosimetry and MIRD
   E. Radiation exposure and ALARA
   F. Radiation regulations

IV. NUCLEAR CARDIOLOGY DIAGNOSTIC TESTS AND PROCEDURES/PROTOCOLS (15%)
   A. Image acquisition (e.g., first pass and equilibrium RNA, gating, SPECT)
   B. Image processing (e.g., filtering, reorientation, reconstruction)
   C. Standards of image display
   D. Exercise and pharmacologic stress protocols
   E. Artifacts and causes of false-positive and false-negative results
   F. Quality control of image processing
   G. Quality assurance of interpretation
   H. Quantitative aids to interpretation
   I. Pharmacologic stress agents

V. GENERAL CARDIOLOGY AS IT RELATES TO IMAGE INTERPRETATION (10%)
   A. Principles of molecular biology as applied to nuclear cardiology
   B. Coronary anatomy, pathophysiology, and chronic/acute ischemia
   C. Endothelial dysfunction/myocarditis
   D. Unique characteristics of patient subgroups (e.g., patients with diabetes, elderly patients, male vs. female patients)
   E. Coronary angiography, interventions, and therapy
   F. Exercise physiology and testing; ECG and clinical parameters with rest and exercise
   G. Measurements of left ventricle systolic and diastolic function
   H. Valvular disease, cardiomyopathy, hypertension, CHF
   I. Coronary artery disease (stable and unstable, acute infarction)
   J. Medical therapy, percutaneous coronary intervention, and coronary bypass surgery
   K. Indications for the use of alternative diagnostic techniques (Echo, MRI, imaging of coronary calcification)
   L. Bayes' theorem, pre- and post-test likelihood, sensitivity, specificity, and referral bias
   M. Statistical analyses (e.g., kappa value, Bland-Altman, ROC curves, Kaplan-Meier)
   N. Cost-effectiveness of diagnostic tests and principles of outcome studies

VI. RISK STRATIFICATION (10%)
   A. Coronary artery disease
   B. Unstable angina
   C. Acute myocardial infarction
   D. Acute chest pain
   E. Candidates for noncardiac surgery
   F. Post revascularization: percutaneous coronary intervention and CABG
   G. Evaluation of medical therapy

VII. MYOCARDIAL PERFUSION IMAGING INTERPRETATION (22%)
   A. Interpretation of perfusion images with Technetium-99m-labeled tracers and Thallium-201
   B. Interpretation of images with PET agents
   C. Relationship of perfusion abnormalities to coronary anatomy
   D. Combined function-perfusion imaging

VIII. VENTRICULAR FUNCTION IMAGING (10%)
   A. Rest and stress first pass radionuclide ventriculography
   B. Rest and stress equilibrium radionuclide ventriculography (planar and SPECT), including volume measurements and systolic and diastolic function
   C. ECG-gated SPECT myocardial perfusion imaging
   D. Effect of arrhythmia on ECG gating
   E. Evaluation of shunts
   F. Effects of drugs, cardiotoxicity

IX. MYOCARDIAL VIABILITY (5%)
   A. Thallium-201 imaging
   B. Technetium-99m imaging
   C. Positron tracers
   D. Outcome data related to myocardial viability
   E. Myocyte imaging