CBNC

Certification Board of Nuclear Cardiology

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August 4, 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:

The Certification Board of Nuclear Cardiology (CBNC) is pleased to submit evidence that it meets the requirements for recognition of its certification process by the Nuclear Regulatory Commission (NRC) under the new 10 CFR Part 35 Medical Use of Byproduct Material - Recognition of Specialty Boards; Final Rule, published March 30, 2005 in the *Federal Register*. CBNC is applying for recognition of its certification process under **10 CFR § 35.290 - Training for Imaging and Localization Studies.**

The CBNC was founded in 1996. The CBNC is a not-for-profit corporation established to develop and administer practice-related examinations in the field of Nuclear Cardiology and to award certification to those physicians who successfully complete the CBNC examination process. CBNC currently offers one examination annually, in October of each year. Certification is valid for a period of 10 years, after which time re-certification is required to maintain certification and diplomate status.

CBNC's certification process was recognized by the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR § 35.290 in May 2002. We have carefully reviewed the new requirements for Training and Experience required in Section 35.290 and believe that our program continues to meet the NRC's requirements.

CBNC's certification process involves two major elements: 1) determination of eligibility based on training and/or experience, and 2) successful performance on CBNC's examination in nuclear cardiology. To be eligible to sit for the exam given by our Board, a candidate must have completed the training/experience required in Section 35.290 prior to application. CBNC's Board of Directors has opted to require a minimum of 80 hours of classroom and laboratory training in radiation safety as part of our training /experience eligibility. We have also elected to retain our requirement for a preceptor statement as part of the applicant's eligibility documentation.

By way of additional background relative to our exam, a national survey of experts in the field of nuclear cardiology periodically defines the knowledge areas appropriate for this exam. This forms the basis for the exam content area, which is published in the Candidate Bulletin and on CBNC's website (www.cbnc.org). CBNC's website also lists training documents, eligibility requirements and other information pertinent to the program.

The CBNC certification examination in nuclear cardiology is comprised of approximately 175 multiple choice questions, devised to assess candidates' knowledge in all aspects of nuclear cardiology. The area of radiation safety

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constitutes 10% of the exam. In addition physics and instrumentation (10%) and radiopharmaceuticals (8%) test basic concepts important for safe use of radioactive materials. We believe that this measurement is ample to determine whether a candidate has the competency in radiation safety to become licensed by the NRC or an Agreement State.

The examination questions are developed by the CBNC Examination Committee, an expert panel of the CBNC who works under the guidance of Knapp & Associates International, Princeton, NJ. The examination question pool is updated on a regular basis to reflect current knowledge. Individual questions are modified or deleted based on statistical analysis of the exam.

Knapp & Associates International is a research and development firm that serves certification bodies by planning, developing and administering assessment procedures and programs designed to measure professional competence.

In support of our application, please find attached the following documents:

- A copy of Requirement 3 of the "Eligibility Requirements for US Candidates" who wish to sit for our certification examination. This pertains solely to Training and/or Experience;
- A copy of the current American College of Cardiology/American Society of Nuclear Cardiology COCA TS Guidelines (Revised 2000) for Level 2 training, referenced in Requirement 3. The COCATS are currently under revision by the authoring societies. We are informed that they will be released prior to publication of CBNC's 2006 Candidate Bulletin so that the document can be incorporated into our material;
- A catalog of the eligibility requirements that differ from the current COCATS Guidelines, which CBNC will require beginning for 2006 applicants, and which we expect will be incorporated into the 2005 COCATS revision; and
- A copy of CBNC's examination content outline.

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

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

Sincerely,

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

2005 ELIGIBILITY REQUIREMENTS FOR CANDIDATES RESIDING IN THE UNITED STATES

Requirement 1: Licensure

Applicants must hold a current, unconditional, unrestricted license to practice medicine in the US at the time of application and must provide a copy of the current license.

Requirement 2: Board Certification

Applicants must be physicians who, at the time of application, are Board Certified by a board which holds membership in either the American Board of Medical Specialties, or the Bureau of Osteopathic Specialists of the American Osteopathic Association.

Requirement 3: Training/Experience in the provision of Nuclear Cardiology Services

A. If you have completed/will complete an accredited fellowship in cardiovascular disease after July 1, 1998, you must submit the following: A verification letter written on organizational letterhead addressed to CBNC and signed by your principal preceptor. That individual must be an authorized user* who meets the NRC requirements in Part 35.200 uses or equivalent Agreement State requirements. The letter must state precisely that ***"Dr. _____ has completed a training program in nuclear cardiology that meets the requirements as outlined in the ACC/ASNC COCATS Guidelines (revised 2000)."*** The Guidelines are shown on page 16 of the 2005 Bulletin. The verification letter must also state precisely that ***"Dr. _____ is competent to independently function as an authorized user under 10 CFR 35.290 uses."***

B. If you completed an accredited fellowship in cardiovascular disease prior to July 1, 1998, you must submit the following:

A verification letter addressed to CBNC and signed by your principal preceptor. That individual must be an authorized user* who meets the NRC requirements in Part 35.200 uses or equivalent Agreement State requirements. The letter must be written on organizational letterhead within the last 6 months and must state precisely that ***"Dr. _____ 's training and/or experience in nuclear cardiology meets the requirements as outlined in the ACC/ASNC COCATS Guidelines (revised 2000)."*** The Guidelines are shown on page 16 of the 2005 Bulletin. The verification letter must also state precisely that ***"Dr. _____ is competent to independently function as an authorized user under 10 CFR 35.290 uses."***

C. If you have completed an accredited residency in nuclear medicine or radiology, you must submit:

A verification letter written on organizational letterhead addressed to CBNC and signed by your principal preceptor. That individual must be an authorized user* who meets the NRC requirements in Part 35.200 uses or equivalent Agreement State requirements. The letter must state precisely that ***"Dr. _____ 's training was equivalent to Level 2 training in nuclear cardiology as outlined in the ACC/ASNC COCATS Guidelines (revised 2000)."*** The Guidelines are shown on page 16 of the 2005 Bulletin. The verification letter must also state precisely that ***"Dr. _____ is competent to independently function as an authorized user under 10 CFR 35.290 uses."***

D. If you have completed an accredited residency/fellowship in a specialty other than cardiology, nuclear medicine or radiology, you must submit the following:

A verification letter written on organizational letterhead addressed to CBNC and signed by your principal preceptor. That individual must be an authorized user* who meets the NRC requirements in Part 35.200 uses or equivalent Agreement State requirements. The letter must state precisely that ***"Dr. _____ has satisfactorily completed at least 700 hours of didactic training or work experience which includes radiation safety, interpretation of clinical cases and hands-on experience as outlined in the ACC/ASNC COCATS Guidelines (revised 2000)."*** The Guidelines are shown on page 16 of the 2005 Bulletin. The verification letter must also state precisely that ***"Dr. _____ is competent to independently function as an authorized user under 10 CFR 35.290 uses."***

*NOTE: The preceptor verifying training/experience must include in the preceptor letter his or her NRC or Agreement State Authorized User Number.

NOTE: Your application will be placed "on hold" and your Preceptor letter returned to you if you do not include this verification letter which includes the precise wording shown above. (See sample Preceptor letters on page 5.)

NOTE: All applicants who completed training after July 1, 1998 must have had formal training in nuclear cardiology, nuclear medicine or radiology. The nuclear cardiology training must be taken as a part of an accredited fellowship or residency in cardiology, nuclear medicine or radiology.

Training and experience requirements for licensure by the Nuclear Regulatory Commission [NRC] or Agreement States vary from state to state; therefore, candidates seeking licensure should check with their regional NRC office or the office responsible for licensure in the Agreement State in which they practice. Information is also available on the NRC Internet website at: http://www.hsrd.ornl.gov/nrc/asdirectr.htm.

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/asframe.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.)

CBNC Training and/or Experience Eligibility Requirements 2006 - Differences from current COCATS GUIDELINES (revised 2000) noted in red

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[1] 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 authorized users 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.orml.gov/nrc/.~~

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Lectures and self-study. The didactic training should include in-depth details of all aspects of the procedures listed in Table 1. 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, radiation biology, the effects of ionizing radiation and radiopharmaceuticals. 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 four to six-month training period. It is imperative that the fellows have experience in correlating catheterization and CT 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, right).

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~~*Work Experience*~~ *Radiation Safety.* This experience should total 80 hours and be under the supervision of an authorized user who meets the NRC requirements of Part 35.200 or equivalent Agreement State requirements, and should 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~~—Performing quality control procedures on 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;

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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) Positron emission tomography (PET) with rubidium-82 and nitrogen-13 ammonia
      iii) Planar with technetium agents and thallium
      iv) Electrocardiographic (EGC) gating of perfusion images for assessment of global and regional ventricular function
      v) Imaging protocols
      vi) Stress protocols
         (1) Exercise stress
         (2) Pharmacologic stress
      vii) Viability assessment including reinjection and delayed imaging of thallium-201 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

[1] **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. Storage and calibration of radiopharmaceuticals
- 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