

Certification Board of Nuclear Cardiology

19562 Club House Road • Montgomery Village, Maryland 20886

Tel: +240.631.8151 • Fax: +240.631.8152

administration@cbnc.org • www.cbnc.org

BOARD OF DIRECTORS

Representing the American Society of Nuclear Cardiology

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Dawn M. Edgerton
Executive Director

October 14, 2005

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

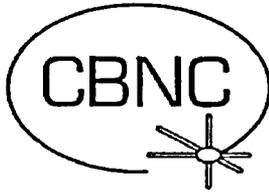
Dear Mr. Essig:

Thank you for the opportunity to respond to several issues raised by your staff 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. Four issues were identified and further clarified in an email.

First, with regard to staff's question about the breakdown of the 700 hours of required training and work experience in radiation safety and radionuclide handling techniques, the 80 hours referenced is applicable to didactic classroom and laboratory training and was incorrectly listed in the hands-on experience. This has been corrected in the attached version guidelines. The remaining 620 hours consists of hands-on work experience and ongoing training supervised by an authorized user in a nuclear cardiology/nuclear medicine environment where the application of radiation safety and radionuclide handling techniques, as specifically listed in the COCATS Guidelines, is part of daily practice.

Secondly, CBNC does accept candidates whose training was provided outside the US and therefore by preceptors who are not Authorized Users, though the training and experience criteria required by CBNC for eligibility for these individuals are no less stringent. CBNC differentiates between these candidates and the rest of our candidates who have preceptor letters signed by Authorized Users (whose numbers are included on their statements), by issuing certificates with alternate wording indicating their non-US status. CBNC has used the two certificates since our 2000 exam. Copies of the 2 certificates are attached and were developed in consultation with the NRC as clarification for our previously submitted and accepted application for recognition. Lastly, with regard to the instrumentation issue, the strikethrough referenced in our earlier letter was an error in the revision of the COCATS and has since been corrected. We appreciate your bringing it to our attention. The instrumentation requirement has been a part of the COCATS Training Guidelines since the first publication in 1995 and will remain in the 2005 revision.

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After significant analysis of CBNC's certification program, we believe that it meets the requirements for recognition of its certification process by the NRC under the new section 10 CFR § 35.290 - Training for Imaging and Localization Studies published March 30, 2005. We have made a language revision to meet NRC's clarification of Work Experience Item B¹, which was approved by CBNC's Board of Directors in July 2005 and takes effect beginning with CBNC's 2006 examination, but this principle has always been a part of the nuclear cardiology training program requirements. As such, we believe that our program was in compliance with the March 30, 2005 revision since the first examination which was administered in September 1996.

I wish to 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.

I apologize for the length of this letter, but hopefully it answers whatever questions you and your staff may have had with regard to CBNC's certification process. 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: Mohammad Saba

¹ Changed from:

- o Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters

to:

- o Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS RESIDING OUTSIDE THE UNITED STATES
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

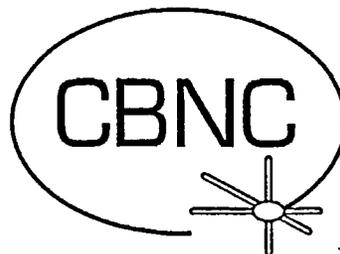
NUCLEAR CARDIOLOGY

FOR THE PERIOD 2003 THROUGH 2013

PRESIDENT

SECRETARY

CERTIFICATE #



OCTOBER 26, 2003

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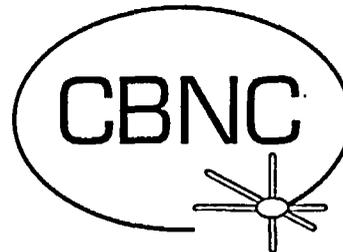
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CBNC Training and/or Experience Eligibility Requirements 2006 - Differences from current COCATS GUIDELINES (revised 2000) noted in red

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 radiolabeling 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 logbook¹ 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 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 their clinical skills and qualify them 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.hsrp.ornl.gov/nrc/>.~~

Didactic

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 need 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 and ionizing radiation. This 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 imaging data for the four to six-month training period. It is imperative that the fellows have experience in correlating catheterization or CT angiographic data with radionuclide-derived data for 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).

Hands-on Experience

Clinical Cases. Fellows acquiring Level 2 training should have hands-on supervised experience with 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 and CT systems), performance of the

study, administration of the dosage, calibration and setup of the gamma camera and CT system, setup of the imaging computer, processing the data for display, interpretation of the studies and generating clinical reports.

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

- a) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys;
- b) ~~Calibrating instruments~~ 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;
- e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
- f) Administering dosages of radioactive ~~drugs~~ material 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

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.

Dear Ms. Edgerton:

This e-mail is in response to your e-mail to me dated October 12, 2005, regarding the CBNC application for NRC recognition of CBNC's certification process under the requirements of 10 CFR 35.290.

The NRC staff reviewed the draft CBNC application and confirmed the changes you made to the application. However, you need to incorporate in your application the following minor changes.

1. Page one, paragraph three of your letter you need to indicate that how long the CBNC has been issuing different certificate for foreign trained individuals.
2. You need to change "Part 35.390 " to "Part 35.290(c)(ii)(G) and Part 35.390" in Column 2, paragraph 2, of your 2006 COCATS guidelines, you list authorized users that meet the training and experience requirements in 35.290o35.390. In the 2005 amendment of Part 35.390 NRC removed generator elution requirements from the work experience requirements in 10CFR 35.390. Therefore, the supervision authorized user for 35.290 has to meet the requirements in 35.290 or " Part 35.290(c)(ii)(G) and Part 35.390." Please confirm and correct this information to reflect that the supervising authorized user will meet the requirements in the revised 35.290.

Review of the CBNC's application for recognition will continue upon receipt of CBNC's official reply to the issues needing attention that are listed and explained above.

Official communications from the CBNC associated with applying for recognition of its certification processes should continue to be addressed to:

U.S. Nuclear Regulatory Commission
ATTN: Mr. Thomas H. Essig, Chief
Materials Safety and Inspection Branch (MS T8F3)
1545 Rockville Pike
Rockville, MD 20852

If I have not accurately captured the issues discussed or you have any questions, please feel free to contact me at (301) 415-7608, mss@nrc.gov.

Mohammad Saba