

From: "Dawn Edgerton" <edgerton@cbnc.org>
To: "Mohammad Saba" <MSS@nrc.gov>, <cerquem@ccf.org>
Date: 8/30/05 12:52PM
Subject: RE: The CBNC's Application Followup

Dear Mohammad,

Thank you again for your guidance on this matter. Please also thank your colleague for her help as well.

We have mailed the revised letter and exam content outline to Mr. Essig. I have attached copies here for your information as well.

Dr. Cerqueira and I would be happy to address any other questions you or Mr. Essig may have.

Best regards,
Dawn Edgerton

-----Original Message-----

From: Mohammad Saba [mailto:MSS@nrc.gov]
Sent: Tuesday, August 30, 2005 12:05 PM
To: cerquem@ccf.org
Cc: Dawn Edgerton
Subject: The CBNC's Application Followup

Dr. Cerqueira,

This email is a follow-up on my telephone conversation with you last week and our telephone conversation with Ms. Edgerton this morning regarding the CBNC's application for NRC recognition of CBNC's certification process under the requirements of 10 CFR 35.290. Per our discussions, NRC staff requested clarification on the topic of quality control procedures listed in the 'Examination Content Outline.'

NRC staff recognize that the 'Radiation Safety' section of the COCATS Guidelines lists quality control procedures for dose calibrators and survey meters as a topic for training and experience. However, the examination content must also describe the same type of quality control procedures (i.e., dose calibrators and survey instruments).

Review of CBNC's application for recognition will continue upon receipt of your reply to the issue needing attention and the revised response that is listed and explained above.

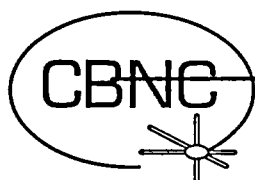
Communications from the CBNC associated with applying for recognition of its certification processes should continue to be addressed to:

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

For further information or for questions, please contact me by phone or via e-mail at MSS@nrc.gov. Thank you.

A-9

Mohammad Saba
Phone: 301-415-7608



Certification Board of Nuclear Cardiology

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August 30, 2005

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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 survey instruments 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).

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.

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 survey instruments 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
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