



American Osteopathic Board of Nuclear Medicine

142 E. Ontario, 6th Floor ♦ Chicago, IL 60611 ♦ 1-800-621-1773, ext 8266

July 5, 2005

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

Dear Mr. Essig:

The American Osteopathic Board of Nuclear Medicine (AOBNM) is writing you for the purpose of ensuring its recognition by the NRC of its certification processes under the board recognition requirements in 10 CFR Part 35 B and D through H. Our request relates specifically to:

- § 35.900 Radiation Safety Officer
- § 35.910 Training for uptake, dilution, and excretion studies
- § 35.920 Training for imaging and localization studies

The AOBNM has been offering certification of osteopathic physicians under the auspices of the American Osteopathic Association (AOA) continuously since 1974; it is the sole board with the capacity to offer certification in nuclear medicine to osteopathic physicians.

At present the AOBNM is negotiating to offer both certification and recertification examinations through the auspices of the American Board of Nuclear Medicine (ABNM) using their certification and recertification examinations, and their examination administration services. The decision to use ABNM as a vendor of examination services was made when the last osteopathic residency program closed. At this time the AOBNM is prepared to create and administer its own psychometrically valid examinations should changes in the area of nuclear medicine cause these programs to become available to osteopathically trained residents in the future.

As you review this letter, please be aware of the following:

7/7/05

- The AOBNM is the only avenue for osteopathically trained physicians to achieve certification and recertification in nuclear medicine, and
- While all physicians are alike in the requirement that they understand the principles of medicine and science, osteopathically trained physicians bring a unique environmental experience and medical perspective to medicine and it is important that this perspective not be lost.

The requirements for certification of D.O.s by the ABNM are:

Requirements for certification

Section 1.

To be eligible to receive certification from the American Osteopathic Board of Nuclear Medicine, the applicant must meet the following minimum requirements. The applicant must:

- 1) Be a graduate of an AOA-accredited college of osteopathic medicine.
- 2) Be licensed to practice in the state or territory where his/her practice is conducted.
- 3) Be able to show evidence of conformity to the standards set in the Code of Ethics of the AOA.
- 4) Be a member in good standing of the AOA, or the Canadian Osteopathic Association for the two years immediately prior to the date of certification, and is encouraged to maintain membership in the divisional society of the AOA of the state or province in which he/she practices.
- 5) Have satisfactorily completed an AOA-approved internship.
- 6) Have completed one of the following combinations of training and experience:

For full certification in nuclear medicine

- a) Certification by the AOA in internal medicine, pathology, or radiology and one year AOA-approved residency training in nuclear medicine.
- b) Two years of AOA-approved residency training in nuclear medicine following an AOA-approved internship.
- c) Other combinations of training and experience may be approved on an individual basis after review by the Board, and with the approval of the AOA.

For certification of added qualifications

- a) To receive certification of added qualifications in nuclear cardiology, a period of not less than 500 hours of clinical training and 200 hours of didactic training are required. In addition, the individual must have AOA certification in at least one of the following: internal medicine, pathology, radiology, or a subspecialty certification in cardiology.
- b) To receive certification of added qualifications in nuclear imaging and therapy, a period of not less than 1,000 hours of clinical training and 200 hours of didactic

training are required. AOA certification in internal medicine, pathology or radiology are required.

- c) To receive certification of added qualifications in in vivo and in vitro nuclear medicine, a period of not less than 500 hours of clinical training and 200 hours of didactic training are required. The individual must be AOA-certified in internal medicine, pathology or radiology. Training shall include basic radiation biology, radiation physics, instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiopharmaceutical chemistry and principles of radiation safety.

Each candidate for board certification in nuclear medicine must comply with the requirements of the Nuclear Regulatory Commission regulations, Title 10-CFR Part 35, Medical Use of By-Product Material, effective date, April 1, 1987 and any future revisions as they relate to the subsections 35.920, Training for Imaging and Localization Studies, section 35.21, Radiation Safety Officer and section 35.22, Radiation Safety Committee. In addition, the candidate should have had experience with or knowledge of quality assurance programs as they pertain to the human uses of by-product material.

Section 2.

Following satisfactory compliance with the prescribed requirements stated in Section 1 above, the applicant shall be required to pass appropriate examinations planned to evaluate an understanding of the scientific basis of the problems involved in the specialty, familiarity with the current advances in the specialty, the possession of sound judgment and a high degree of skill in the diagnostic and therapeutic procedures involved in the practice of the specialty.

- 1) Oral, written, and clinical examinations shall be conducted and required in the case of each applicant. The members of this Board shall personally review, if not perform, the grading of each written examination.
- 2) Applicants desiring examination for certification shall be required to file an application which shall set forth the applicant's qualifications as stated in Section 1. The procedure for filing applications shall be set forth in the Regulations and Requirements.

Section 3.

Subject to the recommendation of the Bureau of Osteopathic Specialists and the approval of the AOA Board of Trustees, the Board may require such further training in each of the fields coming under the jurisdiction as in its judgment such field may require, provided that the additional requirements for each field are clearly set forth in the Regulations and Requirements of this Board. Additions to requirements shall go into effect one year subsequent to the announcement of such change.

Recertification

Certificants of the AOBNM holding time limited certificates must take and pass the appropriate recertification exam to retain certified status.

Certificate Longevity

Certification by the AOA through the American Osteopathic Board of Nuclear Medicine is valid for ten (10) years, beginning with certificates issued after January 1, 1995.

The following assurances are in place to ensure that certificants have complied with certification requirements:

- An outside vendor known to the NRC, specifically the ABNM, administers a psychometrically validated examination.
- Examination processes are validated by the AOA Board of Specialists (BOS), which meets twice a year for the purpose of overseeing the certification processes used by AOA certification boards and ensuring that they are both appropriate and defensible.
- Certificants are evaluated by the AOBNM to ascertain whether they have met the criteria for certification, and then the AOA BOS reviews the provided documentation and evidences submitted before actually conferring certification or recertification on any applicant.

An overview of the section of the certification examination on radiation safety follows:

Basic Science and Regulatory

- A. Physical science 24 ABNM Content Manual (includes PET) (Revised 7/26/2004)
2003 ABNM
 - 1. The structure of matter
 - 2. Radioactive decay
 - 3. Interaction of radiation with matter
 - 4. Basic principles of non-nuclear medicine imaging procedures

- B. Instrumentation
 - 1. Principles of radiation detection
 - a. Scatter
 - b. Attenuation

2. Imaging devices
 - a. Gamma scintillation camera
 - b. Single photon emission computed tomography (SPECT)
 - c. Positron emission tomography (PET)
 - d. Dual x-ray absorptiometry (DEXA)
3. Collimation for the various types of radiation detectors and their response to point, line, and plane sources
 - a. Parallel-hole
 - b. Diverging and converging
 - c. Slant-hole
 - d. Pinhole
 - e. Fan-beam
 - f. Cone-beam
4. Electronics
 - a. Pulse amplifiers
 - b. Pulse-height analyzers
 - c. Scalers
 - d. Count rate meters
5. Image production and display technology
 - a. Photographic principles
 - b. Sensitivity
 - c. Resolution
 - d. Contrast
 - e. Latitude
6. Non-imaging radiation detectors: design and operation
 - a. Whole-body counter
 - b. Gamma well counter
 - c. Scintillation probe
 - d. Liquid scintillation counter
 - e. Radiation monitoring devices
 - f. Dose calibrator
 - g. Gamma/Beta surgical probes

C. Mathematics and statistics

1. Fundamental concepts of mathematics
2. Fundamental concepts of statistics 24 ABNM Content Manual (includes PET) (Revised 7/26/2004) 2003 ABNM
3. Medical decision making including Bayes' theorem, comparative accuracy of diagnostic tests and effectiveness of therapeutic procedures and principles of clinical study design and analysis
5. Counting statistics

D. Computer science

1. Basic aspects of computer structure, function, and programming
2. Image processing: filters, etc...
3. Principles of data transport and storage, picture archiving, and communication systems

E. Radiation biology and protection

1. Biological effects of radiation exposure
 - a. Deterministic
 - b. Stochastic
2. Calculation of radiation dose from internally administered radionuclides; dosimetry; biodistribution
3. Diagnosis, evaluation, clinical management, and treatment of patients experiencing radiation overexposure in any form: radiation accidents
4. Radiation protection
5. Risk estimation
6. Radiation units

F. Radiopharmaceutical production, biochemistry, and quality control

1. Production of radionuclides
 - a. Reactors
 - b. Cyclotrons
 - c. Other particle accelerators
 - d. Radionuclide generators
2. Formulation of radiopharmaceuticals considering chemical properties and quality control including sterility and pyrogenicity testing
3. Biochemistry

G. Clinical physiology

1. Mathematical models of physiologic systems
2. Physiology and pharmacokinetics of radiopharmaceuticals

H. Quality Control

1. Camera
2. Radiopharmaceutical
3. Artifacts

I. Regulatory

1. License requirements
2. Patient release criteria
3. NRC vs. agreement states, etc...
4. Regulations regarding limits of radiation exposure, handling of radioactive patients, and disposal of radioactive wastes
 - a. ALARA concept
5. Regulations applicable to the use of radiopharmaceuticals in nuclear medicine practice and research

While the AOBNM does not have a continuing competency CME assessment program in place at that time, it has a commitment to pursue putting such a program in place in addition to recertification testing which is required for holders of time limited certificates, and encouraged for those who hold lifetime certificates.

Fraternally,

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C/O AOBNM

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American Osteopathic Association

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