



April 16, 2013

Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
US Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Chief, Radioactive Materials Safety Branch, Mail Stop T-8E24

The AOBR is writing today for the purpose of requesting recognition by the Nuclear Regulatory Commission (NRC) of its certification processes leading to certification in Diagnostic Radiology under the board recognition requirements in **10 CFR § 35.394-Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).**

The American Osteopathic Board of Radiology (AOBR), founded in 1939 as the first osteopathic certifying board, is one of eighteen approved specialty boards of the American Osteopathic Association. The American Osteopathic Association, through its certifying body, the Bureau of Osteopathic Specialists, is the primary source of certification for osteopathic physicians. The AOBR offers primary certification in two fields, Diagnostic Radiology and Radiation Oncology, as well as Certification of Added Qualifications in the subspecialties of Neuroradiology, Pediatric Radiology and Vascular and Interventional Radiology.

On June 28, 2006, the American Osteopathic Board of Radiology (AOBR) received notice from Thomas H. Essig, Chief, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards at the Nuclear Regulatory Commission that AOBR's certification process for the Diagnostic Radiology specialty met the applicable requirements in 10 CFR § 35.290 and § 35.392 for NRC recognition with the effective recognition date of July 1, 2000. Today we are seeking recognition in the applicable requirements in 10 CFR § 35.394 for certification in Diagnostic Radiology. The following documentation outlines the training and examination process that applies to candidates qualifying for recognition in 10 CFR § 35.394.

CANDIDATE TRAINING REQUIREMENTS

The Basic Standards for Residency Training in Diagnostic Radiology –American Osteopathic Association and American Osteopathic College of Radiology, which was revised and approved in July 2011 and became effective July 2012, includes the following requirements for additional training to meet the requirements as stated in 10 CFR § 35.394:

ARTICLE V. PROGRAM REQUIREMENTS AND CONTENT

C. Clinical Components

5.3 Clinical Training must:

- d. Provide a minimum of 700 hours (approximately four months) of documented training and experience in clinical nuclear medicine, which may include the required 80 hours of classroom and laboratory instruction *(see V.B.5.4c)
 1. Each resident must participate with preceptors in at least three documented therapies involving oral administration of I-131 in quantities less than or equal to 33 millicuries (mCi) and at least three therapies in quantities greater than 33 mCi. Documentation of the resident's participation must include the date, diagnosis, and dose of each I-131 therapy.

***V.B.5.4c**

- c. There must be documented at least 80 hours of didactic (classroom and laboratory training) training under the direction of an authorized user (AU). This training must include the following subjects as they relate to nuclear medicine:
 1. Diagnostic radiologic physics, instrumentation, and radiation biology;
 2. Patient and medical personnel safety (i.e., radiation protection);
 3. The chemistry of by-product material for medical use;
 4. Biologic and pharmacologic actions of materials administered in diagnostic and therapeutic procedures; and
 5. Topics in safe handling, administration, and quality control of radionuclide doses used in clinical medicine.
 6. The didactic instruction (or work experience) must include ordering, receiving, and unpacking radioactive material safely, and performing the related radiation surveys; the safe elution and quality control (QC) of radionuclide generator systems; calculating, measuring, and safely preparing patient dosages; calibration and QC of survey meters and dose calibrators; safe handling and administration of therapeutic doses of unsealed radionuclide sources (i.e., I-131); written directives; response to radiation spills and accidents (containment and decontamination procedures); radiation signage and related materials; using administrative controls to prevent medical events involving the use of unsealed byproduct material. Residents must demonstrate hands-on work experience when they perform the supervised work experience requirements. Observation alone is not sufficient.

Each resident completing an osteopathic residency training program must comply with the AOCR Basic Standards. Inspections are performed periodically by the American Osteopathic Association to ensure adherence to the standards. Upon NRC approval, the first examination will be offered in May of 2014.

ELIGIBILITY OF APPLICANTS

Admissibility to the written and oral examinations is determined by the Board. In addition to the current examination admission requirements, the applicant's program director will be required to present documentation attesting to the following by the time of the oral examination:

1. Successful completion of the hours of training and experience as outlined in 10 CFR § 35.290, § 35.392, and § 35.394
2. The applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy $\leq 33\text{mCi}$
3. The applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy $>33\text{mCi}$
4. Submission of the applicant's log of these therapy experiences (date, dose and preceptor attestation)
5. The work experience cited above for § 35.290 was obtained under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.290 or equivalent Agreement State requirements
6. The work experience cited above for § 35.392 was obtained under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.390, § 35.392 or § 35.394 or equivalent Agreement State requirements
7. The work experience cited above for § 35.394 was obtained under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.390 or § 35.394 or equivalent Agreement State requirements

In addition, the applicant must submit the I-131 Therapy Experience Log documenting the date of the administration, dose administered, and the name of the preceptor (AU) followed by the signature of the Preceptor for ≥ 3 cases of oral administration of I-131 therapy $\leq 33\text{mCi}$ and ≥ 3 cases of oral administration of I-131 therapy $>33\text{mCi}$ to the AOB prior to admittance to the oral examination.

EXAMINATION CONTENT

The AOCR Basic Standards for Residency Training in Diagnostic Radiology effective July 1, 2012 requires residents to complete documented training to meet current Nuclear Regulatory Commission (NRC) licensure requirements as stated in NRC § 10 CFR, Part § 35.

The examination will test the candidate's knowledge and competence in radiation safety, radionuclide handling, quality control, and clinical use of unsealed byproduct material for which a written directive is required. In order for an applicant to receive the additional designation "AU-eligible," he/she must pass all three sections of the Diagnostic Radiology certification examination, i.e. written Physics, written Diagnostic Imaging and oral Diagnostic Radiology in which appropriate questions will be embedded.

REQUIREMENTS FOR CERTIFICATION

Candidates accepted for examination may be in training during the examination process; however, all candidates must submit the I-131 Therapy Experience Log for approval prior to admission to the oral examination. No candidate is recommended for certification until the AOBR receives verification that the American Osteopathic College of Radiology has approved each year of training including "Program Complete" approval status. Upon verification of successful completion of residency training from the AOCR and successful completion of the AOBR examinations, a candidate is recommended for certification by the AOA Bureau of Osteopathic Specialists.

Examination candidates who fulfill all the requirements and who pass each section of the AOBR Diagnostic Radiology certification examination will receive an AOBR certificate that contains the additional designation "AU-eligible." This allows the diplomate to be eligible to be approved by the NRC or Agreement State as an AU of medical radionuclides for imaging and localization studies and for oral administration of sodium iodide I-131. NRC approval is obtained upon written application to the NRC/Agreement State and also requires submission of an NRC preceptor form which has been completed and signed by the preceptor who must be an AU. Candidates will be referred to the NRC web site for the required forms.

VALIDITY

All examinations conducted by the AOBR meet or exceed the standards established for criterion-referenced examinations. They are constructed of items representative of the set of knowledge, skills, and abilities considered important to the profession. Candidate scores represent a level of mastery relative to this set of knowledge, skills, and abilities. Standard setting exercises are routinely conducted to establish mastery level requirements on all AOBR examinations. Candidates are expected to demonstrate mastery by answering questions correctly at a difficulty level corresponding to a competence considered excellent. Each AOBR examination undergoes extensive psychometric analysis by AOBR's psychometrician who is a member of the American Educational Research Association. Each AOBR examination is in compliance with the APA/AERA/NCME Standards for Educational and Psychological Testing.

CERTIFICATION

The American Osteopathic Board of Radiology is authorized by the American Osteopathic Association (AOA) to examine candidates for certification and make recommendations to the Bureau of Osteopathic Specialists. The Bureau of Osteopathic Specialists (BOS) functions under the auspices of the American Osteopathic Association Board of Trustees from which it receives its purposes and authority. The AOA is the official certifying body of the osteopathic profession.

OSTEOPATHIC CONTINUOUS CERTIFICATION

Osteopathic Continuous Certification (OCC) was implemented in 2012 as a continuous, lifelong learning process. It serves as a way in which board certified DOs can maintain currency and demonstrate competency in their specialty area. Time-limited certificates were first issued in 2002 and all recipients must participate in OCC to maintain board certification. Non time-limited certificate holders may voluntarily participate. The five components of OCC are:

- Component 1 – Unrestricted Licensure
- Component 2 – Life Long Learning/Continuing Medical Education
- Component 3 – Cognitive Assessment
- Component 4 – Practice Performance Assessment and Improvement
- Component 5 – Continuous AOA Membership

The Cognitive Assessment for candidates who successfully completed the certification examination as of the date of NRC approval and who received the designation “AU-eligible” will include examination in medical radionuclides for imaging and localization studies and for oral administration of sodium iodide I-131.

Further information on OCC may be viewed on our website.

WEBSITE

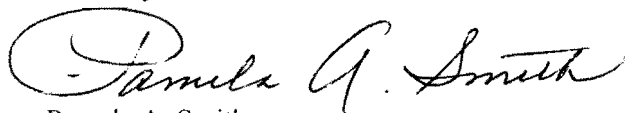
The American Osteopathic Board of Radiology provides examination and certification information to applicants through the website of the American Osteopathic College of Radiology. Information may be viewed at www.aocr.org and click on the AOBR tab.

COMMITMENT

This letter of application has been prepared by Pamela A. Smith, Executive Director. The Chair of the AOBR, Jeffrey M. Wilseck, DO, and the Nuclear Medicine Section Chair, Paul J. Chase, DO, have reviewed this letter, and together with the Executive Director, accepts responsibility for the completeness and accuracy of the information provided. The Executive Director has been authorized by the Board to prepare and submit the application on behalf of the American Osteopathic Board of Radiology.

Thank you for the opportunity to apply for recognition by the Nuclear Regulatory Commission (NRC) of AOBR's certification processes for certification in Diagnostic Radiology under the board recognition requirements in **10 CFR § 35.394-Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)**. Please do not hesitate to contact me if further information is required.

Sincerely



Pamela A. Smith
Executive Director

cc Jeffrey M. Wilseck, DO, FAOCR, Chair
Roy S. Teng, DO, Vice Chair
Michael Wilczynski, DO, FAOCR, Secretary-Treasurer
Paul J. Chase, DO, FAOCR, Nuclear Medicine Section Chair

**AMERICAN OSTEOPATHIC BOARD OF RADIOLOGY
ORAL I-131 UNSEALED SOURCE EXPERIENCE LOG**

Examinee Name

Date of Training Completion

The following information must be submitted to the AOBR office no less than 30 days prior to admission to the AOBR Oral Examination.

≤ 33mCi (minimum of 3 required)

	<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor Name/Signature (AU)</u>
1.	_____	_____	_____ Print Name _____ Signature
2.	_____	_____	_____ Print Name _____ Signature
3.	_____	_____	_____ Print Name _____ Signature

> 33mCi (minimum of 3 required)

	<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor Name/Signature (AU)</u>
1.	_____	_____	_____ Print Name _____ Signature
2.	_____	_____	_____ Print Name _____ Signature
3.	_____	_____	_____ Print Name _____ Signature

Date

Signature of Residency Program Director

Telephone Number of Program Director

Name of Residency Training Institution