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June 19, 2006

U.S. Nuclear Regulatory Commission
Attn: Mr. Thomas Essig, Chief
Materials Safety and Inspection Branch MST8F3
11545 Rockville Pike
Rockville, MD 20852

Dear Mr. Essig:

The American Board of Radiology (ABR) is writing regarding recognition of the ABR certificate in Diagnostic Radiology as meeting the newly revised training and education requirements of 10CFR part 35. The purpose of this letter is to provide the clarifications that were requested by the NRC regarding Diagnostic Radiology.

Issue #1

ABR-provided responses are okay, but do not comport with information posted on the ABR website.

Response: The ABR has posted a new document on its website that pertains to the nuclear medicine portions of diagnostic radiology training. We shared drafts of this website information with NRC and have made the changes that were recommended. This information, which the ABR now believes is in compliance with NRC training and experience requirements, is available for viewing on the website. In addition, the website document is attached to this letter.

Issue #2

The ABR website indicates that the residency must include a 16-week rotation in clinical nuclear medicine and that didactic instruction will be required to cover the nuclear medicine topic cited in sections 35.290 and 35.392. First, a 16-week rotation in clinical nuclear medicine may not provide 700 hours of training and experience. Second, *it appears*

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by the way the website is stated that a significant part of the 700 hours is spent in clinical areas not directly related to basic radionuclide handling technique and radiation safety (e.g., interpretation of the films and images). Considering the fact that residents may spend a significant portion of this rotation on subjects not related to basic nuclide handling techniques and radiation safety applicable to the topics listed in the 10CFR 35.290(c)(1)(i) and (c)(1)(ii) and 10CFR 35.392(c)(1) and (c)(2), please clarify how the ABR can ensure that all ABR candidates meet the 700 hours of training and work experience in radiation safety in nuclear medicine.

Response: Residents are to obtain the training and experience specified in §§35.290 and 35.392. Program Directors must provide this training and attest to this fact (the attestation is attached in the website materials). The ABR does not restrict the nuclear medicine training and experience to 16 weeks. The ABR estimates that a typical resident work schedule in Nuclear Medicine would exceed 50 hours per week. Dictation constitutes only a very limited amount of resident time. The ABR also allows up to 48 weeks of elective time during the four-year residency, some of which could be spent on Nuclear Medicine. Accordingly, some candidates or programs may choose to add elective weeks of nuclear medicine to achieve their objectives. Candidates who have a signed attestation to the fact that they have received their training, have provided the required I-131 therapy log book to document these experiences, and also pass all examinations, will carry the designation "AU-eligible" on their ABR certificates.

The clinical laboratory experience will include the items required in §§ 35.290 and 35.392. It will be the responsibility of the Program Directors and the AUs under whom the training will be provided to be sure that the proper training is received and to attest to that fact through the Program Director and preceptor forms.

Issue #3

The ABR-provided responses are okay but do not comport with the information posted on the ABR website.

Response: As indicated in the response to issue #1, the ABR has posted a revised description of the program requirements on its website.

Issue #4

The ABR website indicates that the ABR accepts candidates from Canadian residency programs. Please provide the method that ABR uses to distinguish candidates that meet the requirements in 10CFR 35.290 and 10CFR 35.392 (i.e., work experience obtained under the supervision of an authorized user) from those candidates who do not.

Response: The ABR has altered its certificate to indicate to NRC which diplomates have fulfilled all requirements, including the fact that their training was provided under the supervision of an AU. Program Directors must sign an attestation form that assures the ABR that the NRC-relevant curriculum was completed under the guidance of an AU. Because there are no AUs in Canada or other foreign countries, no such candidate for the ABR certificate would qualify to have the term "AU- eligible" on the certificate. The term "AU-eligible" will be added only to the certificates of diplomates who have been trained under the supervision of an AU, who have in their files all the appropriate attestations and logs, and who have passed all components of the ABR examination. The ABR submitted a request to the ABMS to be allowed to add the "AU-eligible" designation to the certificates of qualified diplomates, and this was approved. A copy of the new certificate that will be awarded to diplomates who fulfill all the requirements is attached, along with a copy of the standard certificate that will be awarded to foreign trainees or U.S.A. trainees who do not qualify as indicated above.

Issue #5

This is okay but does not comport with the information posted on the ABR website. If the provided answer is correct, the website information needs to be revised.

Response: As indicated in response #1, the ABR has added new information to its website. This information was reviewed by NRC prior to its posting. Information is attached and is available on the ABR website.

The ABR believes that its certification process for nuclear medicine training in diagnostic radiology complies with the requirements of the NRC in the various sections of 10CFR 35.290 and 10CFR 35.392. All the actions and requirements referred to in this communication are current components of the ABR process and will be required for all candidates who attempt to become diplomates of the ABR in Diagnostic Radiology in June, 2006 and in future years.

The ABR hopes that the new website materials and the clarifications provided in this letter assure the NRC that ABR training in nuclear medicine within the Diagnostic Radiology group is a compliant program. We thank you for your help and look forward to your response.

Sincerely,

Philip O. Alderson, MD
President, ABR

Robert R. Hattery, MD
Executive Director

Enclosure

THE AMERICAN BOARD OF RADIOLOGY

NRC Update

To: Radiology Residency Program Directors
Radiology Chief Residents
Chairs/Directors of Service

From: Philip O. Alderson, MD, Robert R. Hattery, MD
American Board of Radiology (ABR)

Date: March 2, 2006
Re: Nuclear Regulatory Compliance

ABR Training in Nuclear Medicine – Compliance with NRC Regulations

Effective with the publication of the final revised version of the new 10 CFR part 35 in March, 2005, the Nuclear Regulatory Commission (NRC) established new guidelines for physicians who wish to achieve the status of Authorized User (AU). The ABR is committed to compliance by:

1. providing information about the required components of training and experience;
2. requiring from program directors written attestation and case log documentation (for I-131 therapy) that the proper training has been given, and;
3. testing knowledge of the required subjects in both its written and oral examinations.

Testing applies to the Nuclear Medicine portion of the primary certificate in Diagnostic Radiology and to the certificate of added competence in Nuclear Radiology. The detailed cross-references to 10 CFR 35.290 and 35.392 follow.

Candidates seeking certification for diagnostic radiology must meet the specific training and experience requirements described in 10 CFR 35.290(c) (1) (i) and (c) (1) (ii) and 10 CFR 35.392(c) (1) and (c) (2). Radiation safety, radionuclide handling and quality control and related topics specified in 10 CFR 35.290 and 10 CFR 35.392 must be covered.

Specifically, each candidate for AU status through the ABR pathway must have completed a minimum of 700 hours of training and experience in imaging and localization studies, including classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. In addition, each candidate must also meet the training and experience requirements specified in § 35.392 for medical uses of radioiodine I-131 (≤ 33mCi) that require a written directive. The training and experience must include, at a minimum, the following:

1. Classroom and laboratory training in the areas of

a) Radiation physics and instrumentation;
b) Radiation protection;
c) Mathematics pertaining to the use and measurement of radioactivity;
d) Chemistry of by-product material for medical use; and
e) Radiation biology.

2. Work experience for imaging and localization studies under the supervision of an AU, who meets the requirements in § 35.290, or 35.290(c)(1)(ii)(G) and 35.390 or equivalent Agreement State requirements, involving the following:

a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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b) 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 materials;
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 radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

3. Work experience for the oral administration of sodium iodide I-131 requiring a written directive. This experience must be obtained under the supervision of an AU who meets the requirements in § 35.390, 35.392, 35.394 or equivalent Agreement State requirements. A supervising AU who meets the requirements in § 35.390 (b) must also have experience in the oral administration of sodium iodide I-131 for which a written directive is required. This work experience must involve the following:

a) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b) 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 materials;
e) using procedures to safely contain spilled radioactive material and using proper decontamination procedures; and
f) administering doses to patients or human research subjects that include at least three cases involving the oral administration of ≤33mCi of sodium iodide I-131.

<u>Case experience, including that specified above, must be documented as follows:</u>

Regarding § 35.392, candidates must have completed a minimum of three cases that involved administration of ≤33mCi of I-131 for therapy under an AU who meets the requirements in § 35.390, 35.392, 35.394 or equivalent Agreement State requirements. A supervising AU who meets the requirements in § 35.390 (b) must also have experience in the oral administration of sodium iodide I-131 for which a written directive is required. A logbook of these therapies must be kept by the resident and submitted in the following format:

FORM B

I-131 Therapy Experience

_____ _____

Resident Name Program & Number

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

4. _____ _____ Sign Name

_____ Print Name

_____ Sign Name

Because of HIPAA regulations, identifying patient data are to be excluded from the log book. This log is to be submitted by the program director along with the other materials that attest to the resident's oral exam eligibility. To assure the ABR that each candidate has completed the required training, the Program Director must submit an attestation form as follows:

FORM A

American Board of Radiology – Program Director Attestation

COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS

More information can be found at the following link:
http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html

Resident Name	Program	Program #

	Yes	No
By the time of the ABR oral examination, this applicant will have successfully completed the hours of training and experience as outlined in 10 CFR 35.290 and 35.392.....	☐	☐
This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy (≤ 33mCi).....	☐	☐
The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached.....	☐	☐
The work and 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	☐	☐
The work and experience cited above for § 35.392 was obtained under the supervision of an Authorized User (AU) who meets the requirements under § 35.390, 35.392 or 35.394 or equivalent Agreement State requirements	☐	☐

Residency Program Director (Print Name)	Program Director (Signature)	Date

The preceding ABR forms do not have to be completed for a resident to take the ABR exam including the Nuclear Medicine section of the exam. Completing the form documents the training and allows the candidate to receive authorized user (AU)-eligible designation on his/her certificate.

Candidates who fulfill all the requirements listed above on Form A and Form B and who pass all their ABR exams will receive an ABR certificate that contains the additional designation "AU-eligible". This means that the person is eligible through the ABR pathway to be approved by the NRC as an AU of medical radionuclides for imaging and localization studies and for oral administration of sodium iodide I-131 requiring a written directive (≤33mCi). 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. The forms are available on the NRC website.

Also presented on the ABR website are copies of informational memos about the NRC (ABR put hot link to NRC Regs section). These memos are not as specific as the information above regarding the content required in the Nuclear Medicine portion of Diagnostic Radiology training programs. Such memos are simply guidance from the ABR. The sections above delineate the detailed content as required by NRC and also are the most complete compilation of the types of material subject to ABR testing relevant to NRC principles related to Nuclear Medicine. This testing will focus on radiation safety, radionuclide handling, quality control, quality assurance and clinical uses of unsealed by-product materials for which a written directive is required. Such testing will be part of the exam in physics, the part-2 written examination and the oral exam taken by all candidates seeking ABR certification in Diagnostic Radiology.