# **Nuclear Regulatory Compliance**

### ABR training in nuclear medicine - compliance with NRC regulations

The U.S. Nuclear Regulatory Commission (NRC) has established guidelines for physicians who wish to achieve the status of Authorized User (AU) of radioisotopes. The ABR is committed to compliance by:

- 1. Providing information about the required components of training and experience
- Requiring from program directors a written attestation that the proper training has been given, and a case log of I-131 therapy work experience supervised and attested to by appropriate AUpreceptor(s) and
- 3. Testing knowledge of the required subjects

The ABR requires a resident training program to fulfill the NRC requirements for training and experience of radiology residents as does the Diagnostic Radiology Residency Review Committee (see reference to these requirements below). The ABR endeavors to meet those requirements within the context of an overall balanced radiological curriculum and with a set of didactic, laboratory and clinical experiences in nuclear medicine that ensure safe and effective use of radionuclides by board-certified radiologists. The ABR believes that these items are important components of a responsible education for radiologists and contribute to the safety of medical practice in ways that are broadly supported by organized medicine, regulators and the public.

### NRC training and experience requirements

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); 10 CFR 35.392 (c)(1) and (c)(2); and 10 CFR 35.394 (c)(1), (c)(2), and (c)(3). Radiation safety, radionuclide handling and quality control, and related topics specified in 10 CFR 35.290, 10 CFR 35.392, and 10 CFR 35.394 must be covered.

Detailed information regarding 10 CFR 35.290, 35.392, and 35.394 may be found via the NRC Electronic Reading Room, which provides access to the NRC Regulations, Frequently Asked Questions and other pertinent references.

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, which must include 80 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to both the medical use of unsealed byproduct material for imaging and localization studies as well as the medical use of sodium iodide I-131 for procedures requiring a written directive. In addition, each candidate must also meet the training and experience requirements specified in §35.392 and §35.294 for medical uses of radioiodine I-131 (≤33 mCi and >33 mCi, respectively) requiring a written directive. The training and experience must include, at a minimum, the following:

- 1. Classroom and laboratory training (minimum of 80 hours) 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
  - e. radiation biology

- Work experience for imaging and localization studies (§35.290) under the supervision of an preceptor AU who meets the requirements in §35.57, §35.290, or §35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, involving 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
  - f. administering dosages of radioactive drugs to patients or human research subjects
  - 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 (§35.392 and §35.394) requiring a written directive.
  - A. Experience under §35.392 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
- f. administering doses to patients or human research subjects that include at least three cases involving the oral administration of  $\leq$  33mCi of sodium iodide I-131

#### I-131 case experience documentation

- Regarding §35.392, the ABR requires that candidates must have completed a minimum of three (3) cases that involve administration of ≤33mCi of I-131 for therapy under an preceptor 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 to the ABR in the format given below.
- 2. Regarding §35.394, the ABR requires that candidates must have completed a minimum of three (3) cases that involve the administration of >33 mCi of I-131 for therapy under a preceptor AU who meets the requirements in §§35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising AU, who meets the requirements in §35.390(b), must also have experience in administering dosages as specified in §35.390(b)(1)(ii)(G)(2). A logbook of these therapies must be kept by the resident and submitted to the ABR in the format given below.

### Forms to be submitted to the ABR

Two (2) forms have been designed by the ABR to document compliance with and completion of the required NRC training and experience. Both completed forms must be submitted on behalf of each candidate in order for the candidate to be eligible for an ABR Diagnostic Radiology Certificate with the *AU-Eligible* designation.

- 1. ABR Form A (Program Director Attestation)
- 2. ABR Form B (Candidate I-131 Case Log)

### ABR Form A - Program Director Attestation

This form is intended to assure the ABR (and, thus, the NRC) that each individual candidate has completed the required training. The program director must submit an attestation form. There should not be blanket approval of a resident class, because the training and experience in NRC-related aspects of nuclear medicine may vary within the group. The decision to provide attestations should be individualized and linked to completion of the NRC curriculum by individual residents.

Under no circumstances should program directors designate as NRC-compliant a candidate who has not completed the full course of study mandated in the NRC curriculum for authorized users. Further, false attestation of completion of training for NRC noncompliant residents would jeopardize the reputation and integrity of the residency program, the ABR, and the Residency Review Committee (RRC), and threaten the relationship between these organizations and the NRC.

The ABR reserves the right to further survey or explore with those residents the manner in which they completed the curricular requirements. Whether or not a resident completes the full NRC-mandated curriculum, the resident must have completed 16 or more clinical weeks of nuclear medicine during the four years of training as required by the Diagnostic Radiology RRC and will be responsible to answer NRC-related questions on all ABR examinations. Time away (e.g., vacations, AFIP, etc.) cannot be counted toward the 16-week requirement in nuclear medicine.

### Form B - Candidate I-131 Case Log

Because of HIPAA concerns, no data that might identify a patient are to be included on Form B.

Please note that participation in three (3) I-131 administrations in each of the two categories is required. Because patients requiring I-131 therapy in amounts  $\leq$ 33 mCi and >33 mCi present in very different clinical settings, and to assure clinical experience with both levels of I-131 administration, each set of three cases must be discrete and obtained in the proper category. Thus, administered amounts of I-131 in each category,  $\leq$ 33 mCi and >33 mCi, must actually be within the appropriate category in the case log. Administered activity >33 mCi of I-131 cannot be used in the category designated for  $\leq$ 33 mCi of I-131 or vice versa. This log is to be submitted by the program director along with the other materials that attest to the resident's oral exam eligibility.

Both Form A and Form B are to be submitted by the program director along with the other materials that attest to the resident's oral exam eligibility.

### ABR examinations and the NRC curriculum

The NRC accepts ABR certification as evidence that a practitioner is properly trained to safely and effectively use radioactive materials in nuclear medicine. Content addressing safety and the handling of radioisotopes as specified by the NRC-required curriculum is embedded in the ABR examinations leading to initial certification in diagnostic radiology, including the physics examination, the written examination, and the oral examination taken by all candidates. The same content will also be included in the Core and Certifying examinations beginning in 2013.

Candidates who take the ABR oral examination are tested on NRC items during the examination in nuclear medicine. The NRC content counts towards the pass/fail score in the nuclear medicine category of the oral examination. Some of the oral examination items depict situations/scenarios that allow the examiner and candidate to discuss pertinent NRC principles. Other questions come from clinical scans and relate to issues of radiopharmaceutical biodistribution (e.g., critical organ doses), to I-131 therapy or to other relevant issues.

The ABR recommends that all residency programs assure that their training in nuclear medicine is compliant with all the elements listed by NRC and on the ABR website. In this way, all residents will be well prepared and qualified to take the nuclear medicine portion of the ABR oral exam, and also will be well prepared to provide nuclear medicine services safely and effectively.

### ■ The ABR *AU-eligible* certificate in diagnostic radiology

The preceding ABR forms do not have to be completed for a resident to take the ABR exams, including the nuclear medicine section of the oral exam. Timely submission of the ABR forms, however, documents completion of the required NRC training and allows candidates who fulfill all the requirements listed above on Form A and Form B and who pass all their ABR exams, including the required NRC-related content, to receive an ABR certificate that contains the additional designation *AU-eligible*. This designation will appear near the left lower corner of the certificate.

If Forms A and B are not completed and submitted to ABR for a candidate, *AU-eligible* certificate designation will not be possible, even though the NRC-required training and experience may have been completed and the examinations passed by the candidate.

An *AU-eligible* certificate indicates that the diplomate has fulfilled all the training and experience requirements of the NRC and passed all the ABR examinations. It means that the person is eligible through the ABR board certification pathway to be approved by the NRC as an Authorized User (AU) of medical radionuclides for imaging and localization studies and for oral administration of sodium iodide I-131 in amounts  $\leq$  33 mCi and > 33 mCi requiring a written directive. Such a person can apply to the NRC for authorized user status, which allows the diplomate to be listed on the institutional or practice site license and oversee the safe and effective medical uses of radionuclides.

Authorized User status is obtained upon written application to the NRC/Agreement State and also requires submission of an NRC preceptor form that has been completed and signed by the preceptor, who must be an AU. The forms are available on the NRC website.

ABR diplomates who do not have the designation *AU-eligible* on their certificates also may apply to the NRC for status as an AU via the alternate pathway, but they will be required to provide detailed information to the NRC about their relevant training and experience.

#### **Reference:**

### NRC-relevant diagnostic radiology RRC program requirements

There must be at least 80 hours of didactic (classroom and laboratory) training under the direction of an authorized user (AU). This training must include the following subjects as they relate to nuclear medicine:

- a. diagnostic medical physics, instrumentation, and radiation biology;
- b. patient and medical personnel safety (i.e., radiation protection);
- c. the chemistry of byproduct material for medical use;
- d. biologic and pharmacologic actions of materials administered in diagnostic and therapeutic procedures; and
- e. topics in safe handling, administration, and quality control of radionuclide doses used in clinical medicine.

The didactic instruction and 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; and 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.