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September 26, 2016

Daniel Collins

Director

Division of Material Safety, State, Tribal, and Rulemaking Programs

c/o Pamela Henderson

Deputy Director

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

Sent by USPS and by email to: Pamela.Henderson@nrc.gov

CC: Email to Donna-Beth.Howe@NRC.gov

RE:

- (1) **ABR CERTIFICATE IN NUCLEAR RADIOLOGY with the words "AU-eligible" appearing above the ABR seal: Request for NRC Specialty Board Certificate Recognition in 10 CFR 35.190, 35.290, & 35.300**
- (2) **ABR CERTIFICATE IN INTERVENTIONAL RADIOLOGY AND DIAGNOSTIC RADIOLOGY (IR/DR) with the words "AU-eligible" appearing above the ABR seal: Request for NRC Specialty Board Certificate Recognition in 10 CFR 35.290, 35.392 & 35.394**
- (3) **ABR CERTIFICATE IN DIAGNOSTIC RADIOLOGY with the words "AU-eligible" appearing above the ABR seal: Request for removal of 4-year limitation of NRC Specialty Board Certificate Recognition**

Dear Mr Collins:

I am writing on behalf of the American Board of Radiology (ABR) to request initial NRC specialty board recognition of two ABR certification processes not currently recognized: 1. ABR Certification in Nuclear Radiology and 2. ABR Certification in Interventional Radiology and Diagnostic Radiology (IR/DR)) as well as modification of the current recognition of ABR Certification in Diagnostic Radiology.

I. ABR CERTIFICATE IN NUCLEAR RADIOLOGY with the words "AU-eligible" appearing above the ABR seal: Request for NRC Specialty Board Certificate Recognition in 10 CFR 35.190, 35.290, & 35.300

The ABR respectfully requests NRC recognition through its Specialty Board Recognition Program for 10 CFR 35.190, 35.290, & 35.300 of ABR's Nuclear Radiology Certificate with the

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words “AU-eligible” appearing above the seal. (A copy of the ABR Nuclear Radiology certificate is attached/enclosed.) This certificate is awarded to those candidates completing and documenting the training requirements in (a) or (b) below and who subsequently pass the ABR’s Nuclear Radiology Certifying Examination, which addresses the required NRC curriculum. The NRC-required training and experience in these training pathways must be completed and documented before taking the certifying examination in Nuclear Radiology. It is noted that graduates of the nuclear radiology training pathways below are also currently recognized by the ABNM as eligible for its certification process leading to an ABNM Nuclear Medicine Certificate which is recognized by the NRC for 10 CFR 35.190, 35.290 and 35.300. (<https://www.abnm.org/index.php/exam/training-requirements/>). Thus, ABR is only asking that NRC recognize its certification process for these Nuclear Radiology trainees in the same 10 CFR 35 sections.

ABR’s Nuclear Radiology Certificate has been issued since the early 1980s, but NRC recognition has not been sought until the recent changes in the ACGME Nuclear Radiology Program Requirements which comply with the sections of the rule requested. That is, as of July 1, 2013, all eligible candidates for Nuclear Radiology subspecialty certification must meet ACGME program training and experience requirements which meet or exceed the NRC requirements of sections 35.190, 35.290 and 35.300. (Please see Table 1 below outlining the ACGME-required case experience.) Further, the recent *decline* in the numbers of physicians being qualified in 35.300 of the NRC regulations coupled with the recent *increase* in FDA approval and availability of radiopharmaceuticals for diagnostic and especially therapeutic use under 35.300 compel ABR to request NRC recognition of the ABR Nuclear Radiology Certification process in order to increase patient access to appropriately trained and qualified physicians to administer these diagnostic procedures and therapies.

Nuclear Radiology Certificate Training Requirements

Candidates for ABR certification in Nuclear Radiology must successfully complete one of the following:

- a. Twelve (12) months of additional training in a nuclear radiology fellowship accredited by the ACGME or twelve (12) months of nuclear medicine residency accredited by the ACGME either before or after completion of a ACGME-accredited Diagnostic Radiology Residency (which itself requires at least four (4) additional months of nuclear medicine/nuclear radiology training). In order to be awarded the ABR Certificate in Nuclear Radiology with an “AU-Eligible” designation above the seal, such a trainee must take and pass an examination covering the NRC-prescribed training and experience described in 10 CFR 35.190, 35.290 & 35.300 after completion and documentation of the related training and experience.

https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/425_nuclear_radiology_2016_1-YR.pdf,

OR

- b. 16-months of training in nuclear medicine/nuclear radiology in an ACGME-accredited 48-month diagnostic radiology program fulfilling the training requirements of both the diagnostic radiology residency and an ACGME-accredited nuclear radiology fellowship. (See internet link above.) Such a trainee must take and pass an examination covering the NRC-prescribed training and experience described in 10 CFR 35.190, 35.290 & 35.300 after completion and documentation of the related training and experience.

Documentation of NRC-required Training and Experience

ABR's validation process will be an extension of that already used for Diagnostic Radiology certificate candidates and recognized by the NRC. The appropriate NRC-related training and experience must be documented by letter from the program director and by submission of required Authorized User (AU)-attestations for NRC-required experience.

(1) Candidates in (a) above who are already ABR-certified in Diagnostic Radiology with AU-eligible certificates will have attestations for 10 CFR 35.290 and case experience in 35.392 and 35.394 on file with ABR and thus need only have documentation of additional training and AU-attestations for case experience for 35.190 and 35.300 (35.396).

(2) Candidates in (a) above certified in Diagnostic Radiology without the AU-eligible certificates must submit documentation of training and experience for parts 35.190, 35.290 and 35.300.

(3) Candidates in (a) above who have obtained prior certification by the ABNM in Nuclear Medicine need only submit documentation of such certification as such certificates are recognized by NRC in 10 CFR parts 35.190, 35.290 and 35.300. Candidates in (b) above must document training and experience completion by submission of required AU-attestations for NRC-required experience in 10 CFR 35.190, 35.290 and 35.300.

Any candidate completing the 12 months of additional training in Nuclear Radiology who does not have the required NRC training and experience documentation in the possession of the ABR and who passes the Nuclear Radiology Certifying Examination is eligible to receive a certificate, but *without* "AU-eligible" appearing above the seal. This certificate distinction is identical to the process now employed by the ABR.

Determination of Validity of ABR Nuclear Radiology Certificates

Since many ABMS Member Board certificates (including those awarded by the ABR) no longer have expiration dates and because this section applies to all ABR certificates addressed in this letter, this issue is discussed below.

In summary, due to the additional documented training, experience, and examination requirements now in place, the ABR believes that the Nuclear Radiology subspecialty certification merits recognition for Authorized User Eligibility by the NRC under section 35.300. In fact, the NRC already has approved this process for acceptance of training and program director verification of training through the certification processes of the ABNM which recognizes completion of an ACGME-approved 1-year Nuclear Radiology Fellowship (in lieu of ACGME Nuclear Medicine Residency) along with Program Director attestation/verification of completion, including the NRC-required training and experience in parts 35.190, 35.290 & 35.390, leading to qualification for its certifying examination and ABNM Certificate in Nuclear Medicine. This would apply to certificates issued after July 1, 2014. The ABR respectfully requests that this recognition be granted.

Table 1. Nuclear Radiology Subspecialty Certificate Requirements:
Case Experience Requirements

REQUIREMENT	# of Cases
Cases of oral administration of less than or equal to 1.22 gigabequerels (33 millicuries) of sodium iodide I-131	10
Cases of oral administration of greater than 1.22 gigabequerels (33 millicuries) of sodium iodide I-131	5
Cases of parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 KeV	5

II. ABR CERTIFICATE IN INTERVENTIONAL RADIOLOGY AND DIAGNOSTIC RADIOLOGY (IR/DR) with the words "AU-eligible" appearing above the ABR seal: Request for NRC Specialty Board Certificate Recognition in 10 CFR 35.290, 35.392 & 35.394

The ACGME has approved a 5-year residency program combining training in diagnostic radiology *and* interventional radiology leading to qualification for a new ABR combined certificate in Interventional Radiology (IR)/Diagnostic Radiology (DR). These residents commit to a 5-year program including training in IR and DR as opposed to a 4-year DR program followed by a 1-year fellowship in interventional radiology. The ACGME program training requirements with respect to the NRC curriculum requirements in the DR portion of the training are identical to those in the stand-alone DR residency and may be found online at https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/415_interventional_radiology_2016.pdf.

In addition, the process of ABR verification of the required NRC training and experience through appropriate AU-preceptor attestations required for DR residents and the NRC-related content in the ABR diagnostic core and certification examinations are identical. Thus, no actual changes to the physician requirements or DR certification processes related to the NRC training and experience regarding the DR portion of the certificate have been made. Only the physical appearance of the certificate has changed to reflect the added training in Interventional Radiology. Given this equivalency of the underlying requirements and processes between the ABR Diagnostic Radiology and the Diagnostic Radiology/ Interventional Radiology certification processes, the ABR respectfully requests NRC Specialty Board Recognition of the Interventional Radiology/Diagnostic Radiology certificate with the words "AU eligible" appearing above the ABR seal for the same portions of the NRC regulations as recognized for the Diagnostic Radiology Certificate with "AU-eligible" above the seal (10 CFR 35.290, 35.392, and 35.394). This certificate will be awarded for the first time beginning in 2017. (A copy of the ABR Interventional Radiology/Diagnostic Radiology (IR/DR) certificate is attached/enclosed.)

Regarding the length of validity of the ABR Interventional Radiology/Diagnostic Radiology Certificate, please see below (section III).

III. ABR CERTIFICATE IN DIAGNOSTIC RADIOLOGY with the words "AU-eligible" appearing above the ABR seal: Request for removal of 4-year limitation of NRC Specialty Board Certificate Recognition

Current recognition of ABR's Certificate in Diagnostic Radiology for 10CFR 35.290, 35.392, & 35.394 reads as follows:

American Board of Radiology (ABR) certification process from June 2006 to July 2012 for the Diagnostic Radiology certificates with the words "AU eligible" appearing above the ABR seal; and from July 2012 forward for the Diagnostic Radiology certificates issued with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued from July 2012 forward *will initially be recognized for 4 years from the date of issuance.*

It was ABR's understanding that the initial limitation of recognition for 4 years from the date of issuance of the ABR Diagnostic Radiology "AU eligible" certificate was intended to allow the NRC to gain experience with the change from defined dates of certificate validity to validity dependent on "meeting the requirements of MOC" as well as with the ABR's online reporting of certificate validity which, as we stated in our letter of September 16, 2013, "is updated daily." In this respect, since NRC's recognition of this certificate, various organizations, credentialing bodies and presumably the NRC and Agreement State Agencies have used this system daily without incident and there have been no changes in the online verification process.

In addition, there were NRC's initial staff concerns regarding ABR's choice of language to report certificate validity online. There was particular concern over the apparent contradiction between "certified, meeting Maintenance of Certification (MOC) requirements" and "certified, not meeting MOC requirements." Since your letter of January 16, 2015 recognizing ABR's Diagnostic Radiology Certification process, ABR has adopted policy (below) to simplify determination of all our certificates' validity which we believe should dispel any confusion.

Validity of ABR Certificates

It is the policy of the ABR that all certificates are issued with a valid status and remain so, regardless of the current status of meeting MOC requirements on a given day of online reporting, as these statuses are remediable, and thus, the underlying certificates remain valid.

Diplomate certificates are only invalid if reported online as

- (1) inactive,*
- (2) expired,*
- (3) lapsed, or*
- (4) revoked.*

The above statuses indicating invalid status applies to all ABR certificates and are available through query of a diplomate's status, updated daily in real time, on the home page of ABR's website ("Check Board Certification"; www.theabr.org).

Given these clarifications of policy, we respectfully request that the 4-year limitation for recognition of ABR's Diagnostic Radiology certificates with AU-eligible above the seal be vacated and recognition be granted unless the above statuses are in force as reported on the ABR website.

ABR recognizes the importance to patient safety of the NRC's requirements for training and experience and the value of NRC recognition of ABR certificates to providing radioisotopic diagnostic and therapeutic care to patients. If there is any further information that you require of the ABR in order to accomplish the above requests, we will be pleased to comply.

Sincerely,



Valerie P. Jackson, M.D.
Executive Director

Enclosures:

ABR Nuclear Radiology Subspecialty Sample Certificate
ABR Diagnostic Radiology/Interventional Radiology Specialty Sample Certificate

cc: Donna-Beth Howe, PhD

The American Board of Radiology

*Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Radiation Oncology, the Association of University Radiologists,
the American Association of Physicists in Medicine, and the Society of Interventional Radiology,
the American Board of Radiology hereby certifies that*

John Doe, MD

*Has pursued an accepted course of graduate study and clinical work; has met certain standards
and qualifications, including passing the examinations conducted under the authority of
the American Board of Radiology, demonstrating to the satisfaction of the Board qualification
to practice; and is therefore awarded the Board's certification in*

Nuclear Radiology

a Subspecialty of

Diagnostic Radiology

AM Eligible



Certificate No. 00000

*Ongoing validity of this certificate is contingent upon
meeting the requirements of Maintenance of Certification.*

*This diplomate of the American Board of Radiology
is permitted to use the **ABR** mark to signify this certification.*

Monty J. Dinterman, MD
President

S. P. [Signature]
Secretary-Treasurer

Valerie J. Johnson, MD
Executive Director

ABR



Effective: September 1, 2016

The American Board of Radiology

*Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Radiation Oncology, the Association of University Radiologists,
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to practice; and is therefore awarded the Board's certification in*

Interventional Radiology/Diagnostic Radiology

AB Eligible

*Ongoing validity of this certificate is contingent upon
meeting the requirements of Maintenance of Certification.*

*This diplomate of the American Board of Radiology
is permitted to use the **ABR** mark to signify this certification.*

ABR



Certificate No. 000000

Milton J. Silberstein, MD
President

C. P. ...
Secretary-Treasurer

Valerie J. Johnson
Executive Director



Effective: September 1, 2016