

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON. D.C. 20555-0001

May 8, 2017

The American Board of Radiology ATTN: Valerie P. Jackson, M.D. Executive Director 5441 E. Williams Circle Tucson, Arizona 85711-7412

SUBJECT: AMERICAN BOARD OF RADIOLOGY, REQUEST FOR ADDITIONAL

INFORMATION REGARDING RECOGNITION OF NEW BOARD

CERTIFICATES AND MODIFICATION OF THE CURRENT

RECOGNITION OF CERTIFICATION IN DIAGNOSTIC RADIOLOGY

Dear Dr. Jackson,

I am writing in response to your letter dated September 26, 2016, requesting initial NRC specialty board recognition of two American Board of Radiology (ABR) certification processes (i.e., for certification in Nuclear Radiology and in Interventional Radiology and Diagnostic Radiology) not currently recognized, and modification of the current recognition of ABR Certification in Diagnostic Radiology. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the information provided regarding your request. In order to continue our review, please provide the following information:

- With regards to your request for initial NRC recognition of the ABR's Nuclear Radiology Certificate with the "AU-eligible" designation above the seal for 10 CFR 35.190, 35.290, and 35.300:
 - a. Please provide an explanation of whether your request for recognition under 10 CFR 35.300 is for recognition under 10 CFR 35.390. [Note: The training and experience requirements in 10 CFR 35.396 (Training for the parenteral administration of unsealed byproduct material requiring a written directive) only apply to radiation oncologists and not nuclear medicine or radiology physicians. The parenteral administration requirements for nuclear medicine and radiology physicians are in 10 CFR 35.390.]

Additionally, your letter indicates that the graduates of the Nuclear Radiology training pathways are also currently recognized by the American Board of Nuclear Medicine (ABNM). Please note that the certification for Nuclear Radiology will not be recognized based on NRC's recognition of ABNM. The NRC's recognition of the ABR sub-specialty certification processes will be independently based on the information provided that describes the ABR's processes to determine that its diplomates meet all of NRC's requirements. These processes should not be dependent on another recognized medical specialty board.

- b. We reviewed the Accreditation Council for Graduate Medical Education (ACGME) requirements for Graduate Medical Education in Nuclear Radiology, and noted that the following training and experience criteria in 10 CFR 35.190, 35.290, 35.392, and 35.394, are not included:
 - i. Classroom and laboratory training in "Mathematics pertaining to the use and measurement of radioactivity."
 - ii. Work experience under the supervision of an authorized user involving:
 - Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - Calculating, measuring, and safely preparing patient or human research subject dosages;
 - Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
 - Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
 - Administering dosages radioactive drugs (uptake, dilution, and excretion; imaging and localization; and therapeutic) to patients or human research subjects; and
 - 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.

Please confirm and provide documentation that your requirements include the criteria listed above.

- c. Page 2 and 3 of your letter references the "examination covering the NRC-prescribed training and experience". Please confirm that this is the board certification examination as required by 10 CFR 35.190, 35.290, and 35.390.
- d. Your letter references "Nuclear Radiology Certificate" throughout. Please confirm that this phrase refers to the Nuclear Radiology Board Certification.

- e. Page 2 of your letter states in part that "all eligible candidates for Nuclear Radiology subspecialty certification must meet ACGME program training and experience requirements which meet or exceed the NRC requirements." Please note that the ACGME requirements do not necessarily meet the NRC requirements as described in Item 1.c. and 2. of this letter. Please confirm that each candidate has training and experience in all of the topics listed in NRC's regulations.
- 2. We reviewed the Accreditation Council for Graduate Medical Education (ACGME) requirements for Graduate Medical Education in Interventional Radiology, and noted that the following training and experience criteria in 10 CFR 35.290, 35.392, and 35.394, are not included:
 - a. Classroom and laboratory training in "Mathematics pertaining to the use and measurement of radioactivity."
 - b. Work experience under the supervision of an authorized user involving:
 - i. "Administering dosages of imaging and localization radioactive drugs to patients or human research subjects" and
 - ii. "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."

Please confirm and provide documentation that your requirements includes the criteria listed above.

3. The NRC recognizes that it is common to see training processes that involve web-based and online training. This web-based and online training may be provided during structured in-house training or by external courses. It is the responsibility of the ABR to verify that applicants have the appropriate training and experience and the hours required, and as such, the ABR needs to ensure that individuals that are being board certified are also getting the required laboratory training, which is in addition to supervised work experience. Further, once an hour is counted towards classroom training, laboratory training, or supervised work experience, it cannot be used again for another category, i.e. an hour cannot be counted more than once in the total number of hours of training and experience in accordance with 10 CFR 35.190, 35.290, and 35.390.

Please address how the ABR verifies the hours earned and the topics covered while participating in web-based and online training meet the ABR criteria.

 Please describe the ABR validation process for candidates for ABR Certification in more detail. Specifically, describe how you verify that candidates meet the specific requirements in 10 CFR 35.190, 35.290, and 35.390 for the Nuclear Radiology candidates, and in 10 CFR 35.290, 35.392, and 35.394 for the Interventional Radiology / Diagnostic Radiology candidates. [If you depend on a preceptor statement as the sole documentation that a candidate meets the training and experience requirement, the validation process should include review of documentation that forms the basis of the preceptor statement.] This process should verify that:

- a. If any of the training was web-based and online, the hours and topics are accurately accounted for.
- b. The candidate has the classroom training, laboratory training, and the supervised work experience for all the topics listed in the regulations.
- c. The candidates have the minimum total hours required in the regulation and that each hour in the total number of hours has not been counted more than once.
- d. Supervised work experience is provided by the appropriate authorized user.
- e. If appropriate, the clinical case work for the oral administration of sodium iodide 1-131 is completed.
- 5. With regards to your request for removal of the 4-year limitation of the NRC Specialty Board Certification Recognition, please note that the NRC cannot remove the 4-year limitation because NRC and Agreement State regulators need to accurately determine an individual's certification status. However, the NRC will clarify on the NRC website that after the 4-year period, the ABR web site needs to be checked to ensure that the individual is still certified. Additionally, in reviewing the ABR web site, staff noted a "Status" column that mostly includes the word "Valid." Will the NRC and the Agreement States be able to use this column and the word "Valid" to determine the board certification status of the individual? If so, please confirm whether this is a new system that replaces what was described in your letter dated September 26, 2016 (i.e. diplomate certificates are only invalid if reported as inactive, expired, lapsed, or revoked) so that the NRC and Agreement States could use the ABR web site to ensure that an individual is still certified.
- 6. Please provide updated copies of your "Nuclear Radiology a Subspecialty of Diagnostic Radiology" and "Interventional Radiology/Diagnostic Radiology" certification certificates marked with "NOT VALID." This ensures that what is posted on the NRC website cannot be modified and presented as official board certifications.

In your response, please note any proprietary information in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." For further information or for questions, please contact Maryann Ayoade at (301) 415-0862 or via e-mail at Maryann.Ayoade@nrc.gov or Dr. Donna-Beth Howe of my staff at (301) 415-7848 or via e-mail at Donna-Beth.Howe@nrc.gov.

/RA Douglas Bollock for/

Daniel S. Collins, Director Division of Material Safety, State, Tribal, and Rulemaking Programs Office of Nuclear Material Safety and Safeguards **SUBJECT**: AMERICAN BOARD OF RADIOLOGY, REQUEST FOR ADDITIONAL INFORMATION REGARDING RECOGNITION OF NEW BOARD CERTIFICATES AND MODIFICATION OF THE CURRENT RECOGNITION OF CERTIFICATION IN DIAGNOSTIC RADIOLOGY May 8, 2017

ML17089A328

OFC	NMSS/MSTR	NMSS/MSTR	NMSS/MSTR	NMSS/MSTR	NMSS/MSTR
NAME	MAyoade	DHowe	DBollock for MFuller	DBollock	DBollock for DCollins
DATE	04/11/17	05/8/17	05/3/17	05/08/17	05/8/17

OFFICIAL RECORD COPY