U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes

Subcommittee on Training and Experience for All Modalities

Draft Report
Submitted on April 28, 2023

Subcommittee Members:
Hossein Jadvar, M.D., Ph.D. (Nuclear Medicine Physician; Chair)
Ronald Ennis, M.D. (Radiation Oncologist; term ended 3/17/2023)
Richard Harvey, Ph.D. (Radiation Safety Officer)
Darlene F. Metter, M.D. (Diagnostic Radiologist)
Megan L. Shober (Agreement State Representative)
Melissa C. Martin (Medical Physicist, Nuclear Medicine)

NRC Staff Resource: Maryann Ayoade

Subcommittee Charge:

The T&E Subcommittee was re-established in 2022 by Dr. Darlene Metter, Chair of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), with expanded charges to:

- Identify any potential impacts of ABR's request to terminate NRC recognition and other inactive boards identified during the staff's evaluation of specialty boards and provide recommendations to mitigate any potential impacts.
- Review and evaluate the NRC's current board recognition criteria and provide any recommendations for action.

The Subcommittee reviewed the relevant literature (see reference section) and met virtually several times to discuss the charge and propose several considerations in consultation with the NRC staff. The Subcommittee reported on the first charge above during the ACMUI meeting and the Commissioner's meeting in December 2022. The second charge was further discussed during early 2023. The Subcommittee's conclusions for both charges are included in this document.

Introduction:

The American Board of Radiology (ABR, founded in 1934 as a non-for-profit organization and a member of the 24 certifying boards within the American Board of Medical Specialties, ABMS) announced in March 2022 that the board will no longer include Authorized User-Eligible (AU-E), Radiation Safety Officer-Eligible (RSO-E), and Authorized Medical Physicist-Eligible (AMP-E) designations on their certificates for all NRC-recognized ABR certification processes (for all specialty areas) starting on January 1, 2024, for individuals seeking authorization on NRC or Agreement State radioactive materials licenses:

1. AU-E designation for Diagnostic Radiology (DR), Interventional Radiology/Diagnostic Radiology (DR/IR), and Radiation Oncology (RO) certificates;
2. RSO-E designation for Diagnostic Medical Physics and Nuclear Medical Physics certificates; and
3. AMP-E for Therapeutic Medical Physics certificates.

Prior to 2005, the ABR did not provide AU/RSO/AMP–Eligible designations on their certificates. During 2005-2023, after receiving NRC recognition, these designations were an option for candidates. The ABR provided the following reason for the decision to discontinue including these designations on the certificates (https://www.youtube.com/watch?v=hkRc9JzP2oA):

- Not aligned with the core ABR mission ("to certify that our diplomates demonstrate the requisite knowledge, skill, and understanding of their disciplines to the benefit of patients"); diverts limited resources,
- ABR has never issued AU status; most radiologists are not (and do not need to be) AUs,
- ABR merely passed along documentation of T&E and direct (alternate) pathway to becoming AU exists,
- AU requirement for 700h T&E in nuclear radiology is an ACGME ("residency") requirement,
- DR/IR (Form A - checklist related to the RC 80-h curriculum; Form B - I-131 documentation), RO (2-page verification form) need not to be submitted to ABR,
- Radioisotope Safety Exam (RISE) questions will not be scored separately,
- Trainees and programs should continue to keep T&E documentation,
- T&E documentation needed for 16-m embedded NM-DR pathway and NR fellows to sit for NR CAQ exam,
- T&E documentation needed for Radiation Oncology for AU status designation,
- "ABR change is more cosmetic than substantive".

The ABR indicated that from 2024, the candidates should provide the relevant T&E documentation through their employers directly to the NRC or Agreement States in order to add the employee to the employer's Radioactive Material (RAM) license.

<u>Subcommittee Specific Comments</u>:

<u>Charge</u>: To identify any potential impacts of ABR's request to terminate NRC recognition and other inactive boards identified during the staff's evaluation of specialty boards and provide recommendations to mitigate any potential impacts.

The subcommittee reviewed a number of relevant articles (see references), gathered data from few states, and asked the ABR's Executive Director, Dr. Brent Wagner, to

participate live with discussions and answer the subcommittee's questions. The following conclusions were reached:

1) There may be, at in least in the short term, challenges with attaining AU status since AU-E designation on certificates was a rapid proof of AU eligibility and with the ABR's decision, the burden of proof is being placed on the applicants, preceptors, and training program directors to provide relevant documentation. It is plausible that in some cases the preceptors may be deceased or unwilling to sign off T&E documentation if there is >7 years window (per requirement in 10 CFR 35.59), or if the preceptor was not initially involved with applicant's T&E.
2) Despite the concern expressed in item 1 above, the sampled environmental data indicated that, for example, in Wisconsin, only a minority of AU licenses were granted through ABR AU-E designation on board certification (majority were through the alternate pathway). The 2020-21 ABR data indicated that 67% of DR, 79% DR/IR, 97% of RO certificates had AU-E designations. The percentages for AMP-E and RSO-E were almost 100%. However, despite these high percentages of designations, it was unclear how many individuals holding AU-E designations on their certificates actually applied for and were declared AU, although it is presumed that the conversion fraction is relatively small.
3) In California, it was estimated that it takes approximately 4 hours per license amendment for documentation evaluation by the regulator and that there was no significant time difference in the evaluations of the ABR AU-E certificates and the alternate pathway. As for benchmark reference, SECY-20-0005, Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material 10 CFR Part 35 (ML19217A318) cost-benefit analysis, the time spent per applicant for documentation evaluations were 15 hours for NRC, 11 hours for Agreement Sates, and 5 hours for licensees.
4) There was no credible indication that other NRC-recognized entities will follow the ABR's decision. Of note, the following boards are either dissolved or inactive and are currently listed on the NRC-recognized specialty board certifications webpage as no longer recognized by the NRC:
    a. Certification Board of Nuclear Endocrinology
    b. American Osteopathic Board of Nuclear Medicine
5) The subcommittee suggested that further discussions may be appropriate within the annual meetings of the Association of University Radiologists (AUR), Society of Chairs of Academic Radiology Departments (SCARD), Society of Chairs of Academic Radiation Oncology Programs (SCAROP), and Association of Program Directors in Radiology (APDR).
6) The subcommittee recommends publication of the subcommittee recommendations (approved by the ACMUI) in the AUR flagship journal, Academic Radiology.

Charge: To review and evaluate the NRC's current board recognition criteria and provide any recommendations for action.

The subcommittee discussed the current NRC board recognition criteria as outlined in "NMSS Procedure MSST-70-03, Revision 2: Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards" (ML20351A389), "2022 Evaluation of NRC-Recognized Specialty Boards" (ML22125A247), and NRC Form 313A (AUT): Authorized User Training, Experience, and Preceptor Attestation – for uses defined under 35.300 [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396] (ML12164A741). It was also noted and discussed that per the NRC final rule "Medical Use of Byproduct Material – Medical event definitions, Training and Experience, and Clarifying Amendments" published in the Federal Register on July 16, 2018 (83 FR 33046):

"Training and experience requirements are amended in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC has determined that certification by a specialty board, coupled with meeting the recentness of training requirements, is sufficient to demonstrate that an individual seeking authorization on a license has met the T&E requirements and has the requisite current knowledge and, therefore, additional attestation by a preceptor is unnecessary. Individuals who are not board certified will still need to obtain a written attestation; however, the language of the attestation is modified. Additionally, residency program directors will be allowed to provide these written attestations."

It was agreed that board recognition criteria as described in these documents are sufficiently comprehensive and detailed. The Subcommittee does not recommend any changes to the NRC board recognition criteria.

References:

What you need to know about the recent ABR decision related to authorized user eligibility. https://orbitcme.com/blog/what-you-need-to-know-about-the-massive-abr-decision-on-authorized-user-eligibility/

Baldwin JA, et al. All you need to know as an authorized user. Am J Roentgenol 2015; 205:251-258.

10 CFR 35.50 – Training for radiation safety officer and associate radiation safety officer.
10 CFR 35.51 – Training for an authorized medical physicist
10 CFR 35.55 – Training for an authorized nuclear pharmacist
10 CFR 35.59 – Recentness of training
10 CFR 35.190 – Training for uptake, dilution, and excretion studies
10 CFR 35.290 – Training for imaging and localization studies

10 CFR 35.390 – Training for use of unsealed byproduct material for which a written directive is required
10 CFR 35.392 – Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
10 CFR 35.394 – Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than or equal to 1.22 gigabecquerels (33 millicuries)
10 CFR 35.490 – Training for use of manual brachytherapy sources
10 CFR 35.690 – Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Respectfully Submitted on April 28, 2023
Training and Experience for All Modalities Subcommittee
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)