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Docket: NRC-2018-0230

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0001

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Document: NRC-2018-0230-DRAFT-0069

Comment on FR Doc # 2018-23521

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General Comment

The ABNM strongly believes that the current requirement for 700 hours of supervised training and experience is the minimum necessary to qualify individuals to be authorized users, and should be obtained in an environment where classroom education and supervised experience are integrated into daily practice. Physicians must also demonstrate they have the required knowledge to be an authorized user by passing an objective, psychometrically valid examination. The attached letter explains the rationale for this position, and provides data showing that the NRC concern for a decline in patient access to care to be unfounded.

Attachments

ABNM comment Docket ID NRC-2018-0230



The American Board of Nuclear Medicine

A Member Board of the American Board of Medical Specialties

January 26, 2019

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Director, Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Collins:

The American Board of Nuclear Medicine (ABNM) is writing in response to your letter of November 2, 2018 regarding the training and experience requirements required for a physician to become an authorized user for medical uses under Subpart E, "Unsealed Byproduct Material—Written Directive Required," of Title 10 of the Code of Federal Regulations (10 CFR) Part 35, "Medical Use of Byproduct Material." We have read the SNMMI/ACNM joint response and concur; therefore we have sought to not duplicate their comments.

The ABNM sent a letter on July 31, 2018 to Christopher Palestro, M.D., Chair, Advisory Committee on the Medical Uses of Isotopes, expressing its strong belief that the current requirement for 700 hours of supervised training and experience should not be changed, and that reducing the minimum requirement for 700 hours of supervised training and experience for unsealed radioisotope therapy raises concern for patient and public safety. If anything, the numerous recently approved or under investigation targeted radiopharmaceuticals may require additional training beyond these 700 hours currently endorsed by various groups. Radiobiology and dosimetry for each newly approved unsealed radioisotope therapy are still debated and evaluated; therefore, future practice may become even more complex than currently envisioned.

The ABNM believes that the NRC concern for a decline in patient access to care to be unfounded, based on the number of ABNM initial certificates issued each year. In the July 31 letter, the ABNM reported that 43 new certificates were issued in 2016, and 49 in 2017. The ABNM issued 44 new certificates in 2018. The NRC also expressed concern for a decrease in the number of ACGME accredited Nuclear Medicine training programs. In 2017-2018, there were 75 residents enrolled in 41 programs. In 2018-2019, there are 79 residents enrolled in 40 programs. These data indicate stability of the future workforce.

The ABNM has issued 5,800 certificates since the board was incorporated in 1971.

ABNM Comment on Training and Experience to be an Authorized User

There are currently 3,577 active diplomates. According to 2016 data, there are ABNM diplomates in all 50 states and territories. The ratio of total U.S. population to the total number of ABNM diplomates is 79,853, with the lowest ratio in New York (52,795:1) and the highest ratio in Idaho (336,628:1). The distribution of ABNM diplomates is similar to the distribution of other medical specialists in the United States.

The ABNM strongly believes that the current regulations requiring 700 hours of supervised training and experience is the minimum necessary to qualify individuals to be authorized users. The risks to patients and the public from incorrect handling of radiopharmaceuticals are unlike risks from other medical procedures and thus require specific, careful and thorough training. Because events like spills and contaminations happen rarely but the management of which are critically important, practical experience dealing with these and other radiation safety problems requires a sufficiently long period of training to allow sufficient events. An authorized user is expected to be able to direct other individuals in the proper handling of radionuclides and handling these unexpected events. This responsibility requires training in an environment where classroom education and supervised experience are integrated into daily practice, as is the case in a nuclear medicine training program. The ABNM is very concerned that making the training and experience requirement less than 700 hours would result in physicians not having access to this critically important practical experiential component of training; meaningful participation is paramount in teaching safe medical practitioners and is the foundation for all medical education.

The ABNM believes that didactic education should remain a part of authorized user training, and the requirement for 200 hours of classroom and laboratory training in radionuclide handling techniques as part of the 700-hour requirement should not be reduced. Again, the important components of radiopharmaceutical handling are unique; there is little overlap with other areas of medical knowledge. Education should include radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, and radiation biology; adequate coverage of these topics in less than 200 hours is not feasible. The ABNM furthermore believes that physicians must demonstrate they have the required knowledge to be an authorized user by passing an objective, psychometrically valid examination. Preceptor attestation alone is insufficient. Physician assessment should remain the purview of the specialty boards.

In summary, there are no data to support the concern that there will be a shortage of authorized users limiting patient access to care, and no justification to reduce the current 700-hour training and experience requirement to be an authorized user. The knowledge required for authorized user status is unique and not overlapping with other areas of medical knowledge. There is very real concern that reducing current requirements will have an adverse impact on patient and public safety.

Sincerely,



George M. Segall, M.D.
Executive Director



Daniel A. Pryma, M.D.
Chair