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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0162
Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

Document: NRC-2018-0230-DRAFT-0201
Comment on FR Doc # 2019-10760

Submitter Information

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General Comment

July 3, 2019
Honorable Kristine Svinicki, Chairman
U.S. Nuclear Regulatory Commission
Office of Administration
Mail Stop: TWFN7A60M
Washington, DC 205550001
ATTN: Program Management, Announcements and Editing Staff
Re: Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive, Section 10 CFR Part 35.390(b)

Dear Chairman Svinicki:

I appreciate the opportunity to express my views. I am a nuclear medicine physician and diagnostic radiologist, with substantial experience in radiation safety and radiation protection over many years. I am a Past President of ACNP and SNMMI. However, I am not officially representing any society at this time, and the following opinions are my own.

I strongly recommend that the NRC keep the Status Quo for training and experience requirements for

Authorized Users. The most important objective is to maintain patient safety, and also to maintain safety of occupational workers and the general public. It is important to require that an Authorized User have sufficient training, skill and experience to not just provide radiopharmaceutical therapy, but also be able to handle problems and issues that may arise in any particular patient and prevent adverse outcomes. A reduction of the training requirements to 400 hours is arbitrary and may not be sufficient. All of the expert societies are opposed to reducing the requirements. This is not self-serving, it is to protect our patients.
I expect that a number of different therapeutic radiopharmaceuticals will be developed and introduced over the next few years. It does not make sense to have different regulations for each one of these. Authorized users need to have sufficient training, skill and experience to be able to administer these new radiopharmaceuticals as they are introduced into clinical practice. Tailored requirements for each new therapeutic radiopharmaceutical will be very difficult to establish and regulate.
I think a team approach, if the Authorized User is off-site, is a very bad idea. If a problem arises, there will be nobody on-site to properly address the problem. However, the idea of an Authorized Administrator (AA) is probably a reasonable idea. The Nuclear Medicine Advanced Associate (NMAA) is well-qualified to provide this service. However, I dont like the term, since administrator usually means something else. You could consider Authorized Administration Professional.
How should we assess Competency (Question 6)? Competency in my opinion means the AU should be 1) Board -Certified (ABNM -NM or ABR Radiation Oncology or ABR - Diagnostic Radiology with Nuclear Radiology training and certification), 2) Pass a radiation safety exam. ABNM and ABR could provide these. 3) The laboratory/department should be accredited, 4) There should be periodic (probably annual) proficiency testing. This can be accomplished by a lab exercise and a quiz that are graded.

Sincerely,

Bennett S. Greenspan, MD, MS

Attachments

NRC Comments Training and Experience Requirements BG 7.3.2019

July 3, 2019

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U.S. Nuclear Regulatory Commission
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I strongly recommend that the NRC keep the "Status Quo" for training and experience requirements for Authorized Users. The most important objective is to maintain patient safety, and also to maintain safety of occupational workers and the general public. It is important to require that an Authorized User have sufficient training, skill and experience to not just provide radiopharmaceutical therapy, but also be able to handle problems and issues that may arise in any particular patient and prevent adverse outcomes. A reduction of the training requirements to 400 hours is arbitrary and may not be sufficient. All of the expert societies are opposed to reducing the requirements. This is not self-serving, it is to protect our patients.

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