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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0001
Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Comment on FR Doc # 2018-23521

Submitter Information

Name: Emory Radiology

General Comment

See attached file(s)

Attachments

Emory Radiology NRC Response

EMORY

Emory University

Department of Radiology and Imaging Sciences

School of Medicine

Emory University Hospital
Suite D-112
1364 Clifton Road, NE
Atlanta, Georgia 30322
Tel: 404-712-5287
Fax: 404-712-7839

Carolyn Cidis Meltzer, MD, FACR
William P. Timmie Professor and Chair
Associate Dean for Research

January 28, 2019

Daniel S. Collins
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

Re: Docket ID NRC-2018-0230-0001, Training and Experience Requirements for Different Categories of Radiopharmaceuticals
January 25, 2018

Dear Mr. Collins:
Per recent communications in the American Board of Nuclear Medicine newsletter, *Tracers*, we have come to learn of the consideration of relaxing training requirements for authorized user status in favor of creating a "limited status" authorized user. As physicians in nuclear medicine and radiation oncology at an academic institution with an NCI designated National Comprehensive Cancer Center, we strongly oppose this action. At Emory, we are interested in patient safety and patient access to quality care. We provide the most up to date therapies and also educate our trainees well so they can provide similar therapies for others in the future.

It is noted that the initial analysis of the number trainees who are expected to become authorized users presented at the Society of Nuclear Medicine and Molecular Imaging annual meeting this past June was in error, greatly underestimating the number of radiation oncology trainees in the United States. Also, in Georgia, we do not have an authorized user shortage. At Emory, we are leading the way for combined nuclear medicine and radiology training that will ideally result in additional authorized users in the future who can provide therapies to patients.

We note that an existing pathway to AU status is already in existence with at least some endocrinologists fulfilling these requirements. It is curious to us why revising the *minimum* requirements that have been long-standing and time tested would be revised. Our primary concern regarding potentially relaxing the requirements for training is that of patient safety. As with some other specialties, training may come from industry and may

not be as robust as participating in a formalized training program. This is problematic as at least one industry professional who does not serve our area has referred to $^{223}RaCl_2$ as "just an alpha particle" which would indicate to us that this individual is not well-versed in the radiation safety considerations for alpha particles.

We expect additional radiopharmaceutical therapies to be introduced within the next few years. Many of these therapies are likely to be more complicated. Even more so, these may require a greater number of calculations, preparation and special considerations of administration. They will ideally be performed at centers of excellence, such as Emory. Having a "limited status" AU may end up with more inexperienced users who may not understand the necessary intricacies that would ensure safe delivery of the radiopharmaceutical or provide safety to family members or the public.
We strongly urge you to protect patient safety by maintaining the existing training and certification requirements.

Sincerely,

Carolyn Meltzer, M.D.
William P. Timmie Professor and Chair
Department of Radiology and Imaging Sciences

David Schuster, M.D.
Director, Division of Nuclear Medicine & Molecular Imaging
Department of Radiology and Imaging Sciences