

SUNSI Review Complete

Template = ADM-013
 E-RIDS=ADM-03
 ADD=Sarah Lopas, Carrie
 Crawford

As of: 5/15/19 7:05 AM Received: May 13, 2019 Status: Pending_Post Tracking No. 1k3-99w0-onri Comments Due: June 03, 2019 Submission Type: Web

PUBLIC SUBMISSION

COMMENT (5)
 PUBLICATION DATE:
 5/2/2019
 CITATION: 84 FR 18874

Docket: NRC-2018-0230

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0155

Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

Document: NRC-2018-0230-DRAFT-0160

Comment on FR Doc # 2019-08996

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General Comment

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 $^{223}\text{RaCl}_2$ 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.

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