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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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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 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 number of authorized users presented at the SNMMI annual meeting this past June was also 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 also leading the way for combined nuclear medicine and radiology training which will ideally result in additional authorized users in the future who can provide therapies to patients.
We also note that an existing pathway to AU status is already in existence with some endocrinologists fulfilling the existing requirements. It is curious to us why revising the minimum requirements which 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 Radium-223 as just an alpha particle which would indicate to us that this individual is not well-versed in the radiation safety aspects of alpha particles.

We expect additional radio-pharmaceutical 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 which would ensure safe delivery of the radio-pharmaceutical or provide safety to family members or the public.

We strongly urge you to maintain the existing training and certification requirements.

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