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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

The training and experience already set for AU should remain the same. The safe and effective use of radiopharmaceuticals is not something to be taken lightly. In fact ensuring that the training and experience is actually happening is something that should be looked at.

With the new radiopharmaceuticals coming out it is more critical now than ever to have the required training, and possibly additional periodic competency in place. It would be a serious injustice to patients to decrease the requirements. Developing new tailored T & E would do nothing but decrease the quality of care the patients will receive.

T & E for limited AU: should have the same training

If you decide to separate out based on category the education and training should be based on the potential harm to the patient, family, and public.

The qualifications of the supervising individual should remain the same.

The preceptor attestation should definitely be required and investigated to be sure the person signing the attestation understands what they are attesting to.

Allowing the radiopharmaceutical manufacturers to provide the preceptor training is a bit of a slippery slope. If that is decided then there should be strict oversight of this practice. Remember the radiopharmaceutical manufacturers focus is to sell the product.

The curriculum and examination should be established by the medical specialty boards in conjunction with the NRC.

Periodic assessment is a great plan. Things continue to change and this would ensure safety.

The boards recognized by NRC are sufficient.

There is not a shortage of AU's. Keep in mind our therapies are not something that need to happen on an emergent basis. Patients having to travel a bit to get the required therapy is no different than patients traveling for specialized surgeries or procedures.

As far as geographic areas and lack of AU's the sentence above would apply.

The NRC regulations on AU T&E requirements is NOT limiting patient access. There is a lot involved with setting up these therapies to ensure quality and safe patient care. This has nothing to do with the NRC regulations on AU T&E.

I am not versed in the research aspect so will not comment.

The NRC should ABSOLUTELY regulate the T&E of physicians for medical uses. Without oversight the safety of both patients and the public would be compromised.

I believe all requirements in the NRC's T&E are required for safety.