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General Comment

I submit my opinions based on 11 years of continuous practice as a Nuclear Medicine physician (Board Certified in 2008) and Diagnostic Radiology (2006). My professional activity during those years includes not only clinical practice of Nuclear Medicine but also teaching and research at the San Antonio Military Medical Center. I am an AU and I have extensive experience in the use of therapeutic radionuclides . Below are my answers posed in the NRC-2018-0230.

A.1. The current pathways for obtaining AU status reasonable and accessible although with the advent of new therapeutic radionuclides, there will need to be specialized training for each therapeutic radiopharmaceuticals that is being approved which would be additional training on top the current training required to become an AU.

A 2. The current pathways are readily available for this AU and new training will need to be incorporated into these current pathways. The new radiopharmaceutical therapies that are expected to enter practice in the near future will required diagnostic scans prior to administration of the therapeutic agent and this will require specific calculations to determine a patient's individualized dose. AUs are currently doing this type of work with I-131 for thyroid cancer and a similar basis approach will be required for these new agents. Image-guidance and knowledge in the interpretation of the therapy planning diagnostic scans, primarily PET imaging, will be critical to the safe administration of these new radiopharmaceutical therapies.

The AU training & experience (T&E) will have to be greater in the future as the molecular-based radiopharamceuticals will require greater sophistication in prescribing. Based on this projection, our specialty is preparing to educate the experienced AUs in furthering their knowledge of radiopharmaceutical-image-based dosimetry. There will be a need to more involvement of radiopharmaceutical trained radiation physicists to calculate specific doses to the patient's organs and to assist AUs in determining the doses for each patient. I see that radiation physicists will work side by side with AUs, very similar to how they currently work with radiation oncologist in prescribing fields and doses with external beam therapy. AUs will have to have more education so that they will understand the technical terms of radiation physicists and so that both can communicate effectively with them. Radiation physicists will be particularly important which patients are given second and third doses to ensure that normal body organs have not exceeded their dose limits. The growing field of nuclear medicine is all getting more complex but at the same time, this complexity, if properly handled, will result in better patient therapy and better treatment of cancer.

A 3. No, NRC should not develop new tailored T&E pathways for various physicians. Experience with nuclear imaging and radionuclide therapy with I-131 will provide a strong basis for further work with new isotopes. Understanding of the physics of already approved isotopes will be vital for the understanding of new agents. Allow referring physicians to also be authorized users will generate a conflict of interest and could make these physicians overly anxious to use a specific therapy for which the rapid received limited certification.

A 5. Not in my opinion as I have stated above the general experience permits an understanding of the complexity of new agents and specific training in one specific category will not be enough to understand the intricacies of the whole field.

A 1. There are no other boards to the best of my knowledge that have expertise within respective specialty to provide minimal T&E for recognition for medical uses under 10 CFR 35.300.

A 2. Yes, the current criteria are sufficient as a starting point, although there may need to be more training in addition to the current training for specific therapies. I think it will be possible to incorporate more training into the current board certification to cover new therapies. Physicians will current board certification may need specialize training.

C. Patient Access

A1. There are no shortages of AUs for medical uses in any part of the country under 10 CFR 35.300? and AU T&E requirements do not unnecessarily limit patient access to procedures involving radiopharmaceuticals.

Q 4. Current NRC regulations on AU T&E requirements do not unnecessarily limit research and development in nuclear medicine. I speak from my own experience in research and the development and clinical translation of new radiopharmaceutical agents.

Thank for consideration of above. I would be glad to discuss any aspects of training and safety in nuclear medicine at any time in the future.