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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

To Whom It May Concern:

My opinions echo that of many others in this field and are based on empirical observations and 20 years of personal practice within the relevant field of Nuclear Medicine, as well as active participation in organized medicine and scientific discussions regarding the future of my specialty. My professional activity during those years included not only the clinical practice in all aspects of the specialty but also academic teaching at the level of medical school (Indiana University) . I am an AU and have personal experience and extensive expertise in all radiopharmaceuticals (RPs) used for therapy.

Below are my answers (A) that follow the questions (Q) posed in the NRC-2018-0230.
A. Tailored Training & Experience Requirements
Q 1. Are the current pathways for obtaining AU status reasonable and accessible?
A 1. Yes, they are.
Q 2. Are the current pathways for obtaining AU status adequate for protecting public health and safety?
A 2. Yes, they are.
Q 3. Should the NRC develop a new tailored T&E pathway for these physicians?
A 3. No, NRC should not develop new tailored T&E pathways for various physicians.

There is another reason not to develop tailored T&E pathways for these physicians. These physicians would be basically the same ones who would routinely care for the same patients. It is my concern that ability to treat the patient with RPs by the same physicians who routinely care for them would remove an important additional safety layer of checks and balances.
Q 4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?
A 4. There should be no limited AU status as no need nor had sufficient safety been ever demonstrated for such a pathway, while the contrary had been suggested numerous times. Hence, the question is presumptive and not applicable in my opinion.
Q 5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
A 5. The question is presumptive and, I believe, that the basis for it is unsupported.
B. NRC's Recognition of Medical Specialty Boards
Q 1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?
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.
Q 2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?
A 2. Yes, the current criteria are sufficient.

C. Patient Access
Q 1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300?
A 1. No, there is none.
Q 2. Are there certain geographic areas with an inadequate number of AUs?
A 2. Not that I am aware of.
Q 3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals?
A 3. No, they do not.
Q 4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine?
A 4. No, they do not.
D. Other Suggested Changes to the T&E Regulations
Q 1. Should the NRC regulate the T&E of physicians for medical uses?
A 1. Yes, NRC must regulate the T&E of physicians for medical uses. This provides for the best system of checks and balances in RP therapy. Any practice associated with risks to patients should be regulated.
Q 2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?
A 2. No, I do not believe so.
Q 3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?
A 3. It should continue to monitor the changing field of RP therapy as it enters the more sophisticated stage of theranostics practice, which will be more heavily based on image-guided individual dosimetry. maging that concluded last week.

Respectfully submitted for consideration.