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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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Submitter Information

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General Comment

To Whom It May Concern:
I submit my opinions that are based on 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.
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. Current AU eligible physicians who are undertilized.
Q 2. Are the current pathways for obtaining AU status adequate for protecting public health and safety?
A 2. Yes, they are. Patient safety, appropriate care and affordable care all require adequate training as a minimum. With the introduction of new therapies current pathways should be more rigorous than they currently 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. Rather they should be extended. Please see (https://www.nrc.gov/docs/ML1610/ML16109A042.pdf).
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. There is no need for such. Sufficient safety has not been demonstrated for such a pathway, while the contrary had been suggested numerous times.
Q 5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
A 5. There should be no limited AU status.

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. None.
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. Nuclear medicine physicians are underutilized. Please see the recent report from the American Board of Nuclear Medicine to the NIH at the recent Theranostics Consensus Conference on November 8-9, 2018, as presented by Dr. Iagaru (http://snmmi.files.cms-plus.com/Theranostics%20Consensus%20Conference_Nov%209.pdf).
Q 2. Are there certain geographic areas with an inadequate number of AUs?
A 2. Not that I am aware of. If such do exist better utilization of existing AUs through a consultation for actions to resolve it should be sought from the relevant National medical organizations, such as the American College of Nuclear Medicine, etc.
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. 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, as far as I know.
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. Maintain or expand on the existing training and certification requirements. Continue to monitor the changing field of RP therapy as it evolves. Use evidence based medicine and consultation with exiting AU and relevant National medical organizations to develop personalized medicine that helps patients while providing adequate protection for all. Having a limited status AU may end up with more inexperienced users who may not receive sufficient training to ensure safe delivery of the radiopharmaceutical or provide safety to patients, family members or the public.