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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

See attached file(s)

Attachments

Mark Tulchinsky

To Whom It May Concern:

I submit my opinions that are based on empirical observations and 30 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 (Penn State), National organized medicine (the specialty's College and the Society), as well as internationally (https://www.linkedin.com/in/marktulchinskyuniversity/). 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. The basis for my assessment includes the fact that all of the public needs in medical diagnosis and therapy are satisfied, showing no evidence for out-of-reasonable backlogs in facilities performing relevant services. In fact, there is a large buffer of AU eligible physicians who are currently practicing nuclear medicine, radiology and radiation oncology who can answer the demand for any additional AU needs if new RP therapy were to come into practice.

Q 2. Are the current pathways for obtaining AU status adequate for protecting public health and safety?

A 2. Yes, they are. The new radiopharmaceutical therapies that are expected to enter practice in the near future will be based on theranostic principles and require RP-imaging-based dosimetry calculations for personalization of therapy with RPs. The AU training & experience (T&E) will have to be greater in the future as the molecular-based RPs will require greater sophistication in prescribing. Based on this projection, our specialty is preparing to educate the experienced AUs in furthering their knowledge of RP-image-based dosimetry. There is no plausible circumstance that would project that the expertise or T&E required for new RPs would be any less than the ones currently required.

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. The reason I feel strongly regarding this answer is that experience in administering RP therapy for various indications build cumulative expertise that helps one solve quandaries posed by new RP therapies. If someone is trained in a limited area of a certain therapeutic RF application, they would not have a general and diversified experience that often helps in avoiding serious problems in unusual cases of RP therapy. In my understanding, the above question is considering physicians who are not involved in the supervision and performance of diagnostic imaging RP-based tests. That is also a significant hindrance to optimal T&E for practicing RP therapy. When one uses diagnostic RPs and therapeutic RPs, respective experience enriches one another, i.e. there is a cross-pollination of experience. In fact, NRC utilizes the services of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The only suggestions I have ever seen in all of the ACMUI reports are in favor of extending the T&E requirements – not to narrow (or tailor) them. As an example, see comments by Dr. Metter made during the Thursday, March 10, 2016 meeting (https://www.nrc.gov/docs/ML1610/ML16109A042.pdf). I strongly encourage you to re-examine transcripts of ACMUI reports.

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. Currently, when a patient with prostate cancer is sent for therapy with Ra-223 dichloride for a metastatic disease he would be consulted by the physician in Radiology, Nuclear Medicine or Radiation Oncology. Not every patient has a clear indication for an RP therapy. It is always better to have more than one opinion. The limited AU status would enable the same physician who usually cares for the patient also make this often equivocal decision about RP therapy. The limited AU would remove the current need for a second opinion by an AU physician, which is part of the system of checks and balances in RP therapy. This is not to denigrate our colleagues in oncology or to suggest that they are anything other than highly ethical physicians. The reality is that a bias of earning more by treating more is present in the medical practice. One instructive example of Michigan cancer specialist Dr. Farid Fata is useful to review (https://en.wikipedia.org/wiki/Farid_Fata). Dr. Fata had bullied or deceived 553 people into getting chemotherapy treatments at his own facilities that they didn't need, leaving the patients' insurance companies and Medicare stuck with $34 million in fraudulent and unnecessary claims. He pleaded guilty to 13 counts of health care fraud on September 20, 2014. If he had to send his patients to another physician for chemotherapy, this situation would have never been possible. The maintenance of checks and balances that is currently built into the practice of RP therapy would prevent any such abuse of radioactive materials. This safety mechanism would be removed by instituting tailored AU regulations that enable many to treat their own patients.

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. This opinion is shared by the most recent report from the American Board of Nuclear Medicine that was provided 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 there is such an area or areas, a consultation for actions to resolve it should be sought from the relevant National medical organizations, such as the American College of Radiology, the Society of Nuclear Medicine and Molecular Imaging, etc. This would be the most responsible approach without jeopardizing the safety of patients from downscaling regulatory criteria.

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. The ability to perform such dosimetry may need to be part of T&E criteria. I believe that NRC is doing its

best to keep up with the developments in RP therapy, which was evidenced by their presence at the Society of Nuclear Medicine and Molecular Imaging that concluded last week.

Respectfully submitted for consideration.