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Submitter Information

Name: J R
Address: United States,
Email: jrajendran@hotmail.com

General Comment

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Attachments

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To Whom It May Concern:

The following is a submission of my comments and opinions that are based on my observations and 43 years (22 years including Primary Radiation Oncology internationally) of medical practice (21 years primarily in Nuclear Medicine in the US) as well as active participation in organized medicine and scientific discussions and presentations. I am privileged to have the unique experience in Radiation Oncology and Nuclear Medicine. My professional activity during these years includes not only clinical practice in all aspects of the respective specialties (primary and adjunct) but also academic role as a Physician Scientist, participating in Radiopharmaceutical research using Radiation dosimetry, National organized medicine (the specialty's College and the Society). I am an AU and have personal experience and extensive expertise in all radiopharmaceuticals (RPs) used for therapy in the University and Federal Healthcare setting and participated in leading radiation safety efforts at the respective institutions with great respect for the pivotal role played by the NRC, who should be considered as facilitators and not simply as 'regulators'. Let us remember that systemic RP therapy is not the same as systemic chemotherapy and Radiation Oncology's growth and expansion as a specialty is as a result of its practice model and independence.

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.

A 1: Yes, they are. Per my assessment, the current training satisfies all of the public needs in medical diagnosis and therapy, without any evidence for untoward backlogs in facilities performing relevant services. In fact, there is sufficient manpower 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 Radio Pharmaceutical therapy (RPT) were to come into practice. Being ready for the future does not equate to abandoning intuitive reasoning or adding unreasonable control. There is a need to strike the balance if our patients are to benefit.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.

A 2. Yes, they are. The new radiopharmaceutical therapies that are expected to be introduce into medical practice in the near future will be based on theranostic principles and require imaging-based dosimetry calculations for personalization of therapy with RPs. It will move us away from an empirical approach for treating patients to one that will focus greatly on personalized approach using sophisticated imaging, dosimetry and RP prescription. Training & experience (T&E) will have to follow suit in the future to be effective yet reasonable. Based on this projection, our specialty is preparing to educate the experienced AUs in furthering their knowledge of RP-image-based dosimetry.

3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged.

*A 3. No, NRC should develop an inclusive approach rather than a tailored approach for T&E pathways based only on physician specialty. The broader organizational values of NRC express "**Service**: to the public, and others who are affected by our work; **Commitment:** to public health and safety, security and the environment and **Excellence:** in our individual and collective actions, high quality, continuously improving". Current regulations of NRC have been thoughtfully developed based on these*

key principles and evolved over the several decades and to fulfill these in keeping with US specialty medical boards expectations. Public health and environmental safety are the primary determinants of these regulations that have established the US as a leader and a role model for the world. We should always be looking for ways to improve health care and look for ways to be more efficient in an uncompromising yet more practical manner. Simplifying T&E requirements may sound like an easy solution, but it cannot be overemphasized that several specialties have learned to coexist in a synergistic manner for the common good of our patients. Let us consider the role of NRC not simply as a regulator but as a viable facilitator, looking to strike a synergy for the growth and development of the medical field.

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: A limited AU status should not be introduced solely for increasing the number of AUs available in the community. We need to be looking for ways to strengthen the manpower in existing practicing specialties rather than opening the practice to a wider group of practitioners. Lowering the bar may not be the answer. Reducing T&E should not be a driving force just for the sake of this aim. AU status based on a specific radiopharmaceutical is like splitting the specialties on the basis of say a specific "antibiotic" or a "cardiac" drug with the hope of increasing the work force. It will have a negative impact on the specialty itself that will challenge any specialty.

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?

a. Describe what the requirements should include:

i. Classroom and laboratory training—What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [*Note:* The topics currently required in the regulations to be included in the classroom and laboratory training and work experience are listed in 10 CFR 35.390, 35.392, 35.394, and 35.396.]

ii. Work experience—What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?

iii. Competency—How should competency be evaluated? Should a written and/or practical examination by an independent examining committee be administered? Provide a rationale for your answer.

b. Should a preceptor attestation be required for the fundamental T&E? Provide a rationale for your answer.

c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

d. Who should establish and administer the curriculum and examination? Provide specific group(s). [Some options are: NRC, medical specialty boards, medical professional societies, educational professional groups, and NRC in collaboration with any or more of the aforementioned groups.]

e. Should AU competency be periodically assessed? If so, how should it be assessed, how often, and by whom?

<u>This paragraph contains general observations to a wider discussion and is not provided in support or against the specific discussion point above #5:</u> T&E should not be structured that would in any way limit the scope of the specialty of Radiation Medicine. periodic assessment of competency for AUs is welcome but should not be onerous to the AUs – overseen by institutional committees under the purview of NRC and specialty boards. In as much as the drug manufacturers have excellent expertise, there can be a potential for perceived COI and the possibility of introducing bias, independent agencies should be the ones to provide attestation. The

manufacturers, academia and practitioners of the field of Radiation Medicine are allies and should work together under the 'guidance' of NRC.

B. NRC's Recognition of Medical Specialty Boards

The NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit website (*https://www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html*). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

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?

A1: These boards seem to have the optimal collective expertise and knowledge base within respective specialties to provide minimal T&E for recognition for medical uses under 10 CFR 35.300.

2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

A2: Yes, the current criteria are sufficient and well established.

C. Patient Access

The NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.

A1: There is no apparent shortage of the number of AUs for medical uses under 10 CFR 35.300. This opinion is broadly 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. (http://snmmi.files.cmslus.com/Theranostics%20Consensus%20Conference_Nov%209.pdf).

2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.

A2: National medical organizations, such as the American College of Radiology, the Society of Nuclear Medicine and Molecular Imaging can be queried for that type of data.

3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.

A3: Having optimal regulations on AU's T&E does not result in limited patient access. In fact, these regulations by ensuring public and patient safety improves patient confidence and thus patient access.

4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

A4: No they do not. Successful clinical research depends on maintenance of regulatory compliance which is the hallmark of any research program – not only for the safety of patients but also reproducibility.

D. Other Suggested Changes to the T&E Regulations

In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the general public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1.Should the NRC regulate the T&E of physicians for medical uses?

A1: Yes, NRC must continue to take the lead to regulate and guide the T&E of physicians for medical uses. This provides for the best system of checks and balances in RP therapy coming on the heels of vast expertise and knowledge base.

2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

A2: No, not to my knowledge.

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?

A3: NRC should continue to monitor the changing field of RP therapy as it enters the more sophisticated stage of theranostics, which will be more heavily based on image-guided personalized dosimetry. The ability to perform such dosimetry may need to be part of T&E criteria. NRC has been known to participate and collaborate with national medical societies such SNMMI to share its knowledge with the members of the society. This is very important towards forming a synergy in maintaining common goals.

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