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COMMENT (20)
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From: Borges Roman, Jennifer
To: Ralph, Melissa; Blount, Barbara
Cc: DeJesus, Anthony
Subject: FW: NRC-2018-0230
Date: Friday, January 18, 2019 9:55:08 AM

FYI

From: Javier Villanueva-Meyer [mailto:javiervmeyer@gmail.com]
Sent: Friday, January 18, 2019 8:26 AM
To: Borges Roman, Jennifer <Jennifer.BorgesRoman@nrc.gov>
Subject: [External_Sender] NRC-2018-0230

Dear Mrs. Borges, Below are my comments regarding NRC-2018-0230

Are the current pathways for obtaining AU status reasonable and accessible? Yes, through ABNM and ABR board certification within the academic pathways.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Yes, there is no evidence for adverse effects.

3. Should the NRC develop a new tailored T&E pathway for these physicians? No, maintain existing pathway and enforce that pathway and guidelines are met. There is no need to separate pharmaceuticals by delivery method, type of radiation, preparation method or type of radiation. There is overlap in several categories and these are taught and encompassed in existing training. If anything the NRC should follow that existing pathways are completed.

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? Yes, should be the same. No need to develop limited AU status.

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals? Should be the same and not relaxed.

a. Describe what the requirements should include: maintain existing pathways.

b. Should a preceptor attestation be required for the fundamental T&E? If it meets existing rules.

c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? No, manufactures have commercial interest and patient safety conflicts of interest.

d. Who should establish and administer the curriculum and examination? American medical specialty boards (ABNM and ABR) following existing NRC guidelines.

e. Should AU competency be periodically assessed? By American medical specialty boards (ABNM and ABR).

B. NRC's Recognition of Medical Specialty Boards

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?
The NRC should recognize only ABMS medical specialty boards, namely ABNM and ABR, www.abms.org .

2. Are the current NRC medical specialty board recognition criteria sufficient? Yes.

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

Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? No. In my area, there are many AU nuclear medicine physicians and radiologists and radiation oncologists available to provide existing and new therapies. There is no shortage associated with the use of a specific radiopharmaceutical.

2. Are there certain geographic areas with an inadequate number of AUs? Not in Houston, Galveston, east and south Texas area.
3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? No.

4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and

development in nuclear medicine? No.

Should the NRC regulate the T&E of physicians for medical uses? No.

Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related? No.

How can the NRC transform its regulatory approach? As a practicing nuclear medicine physician with more than 25 years experience in the academic and private practice environments I believe the NRC should proceed with caution. New diagnostic and therapy procedures are available and I believe maintaining existing rules and make sure they are followed is best (do not relax or develop a new limited AU status) in the interest of patient safety.

Regards, Javier Villanueva-Meyer MD, Nuclear medicine physician