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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

Please see the attached file giving my comments on NRC-2018-0230. Thank you for opening this for discussion and taking and considering everyone's comments.

Attachments

Concerning NRC-2018-0230

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As an individual with 25 years' experience in this profession, training in large hospitals and working for a company that provides service in small and medium sized hospitals across the country (my region of which I manage covers 5 states), I believe I have a little working knowledge. I also possess two mid-level provider degrees, one as a Radiologist Assistant (RA) and one as a Nuclear Medicine Advanced Associate (NMAA). Additionally, I have been an RSO for close to 20 years.

I published a paper a few years ago addressing the very issue of radiologists becoming fewer in number leaving more work to be done by the remaining radiologists. However, while it is true that the number of radiologists is decreasing and the workload is increasing, it is also true that every hospital I know of has a radiologist, while not every hospital has access to an oncologist. In other words, to say that the availability is diminished to the point that we should let other physicians receive limited AU status because of lack of availability I do not feel is valid. I also do not feel that granting AU status to nuclear pharmacists is prudent based on their lack of education as well. I have many friends who are nuc pharms who are excellent at what they do, compounding radiopharmaceuticals and dispensing them, but they would admit immediately and freely that they have no true understanding of biodistribution and certainly not altered biodistribution secondary to pathology. I don't believe I am qualified to speak to the number of hours of T and E that should be required, except I don't believe it should be shortened necessarily. I understand the concept of limited AU being less training time than full AU but I also understand that radiation safety and practices don't change much just because you are using a few isotopes instead of many. The principles and understanding required to handle and use a few are essentially the same, with a few exceptions, as what is required to handle most. And as far as competence required instead of T and E, I am not sure how you would measure competence. Competence isn't just knowing what to do in "normal practice" situations, it's knowing what to do in instances that don't follow the book. While anyone can fail at this, successful navigation comes through a deep understanding rather than a superficial knowledge.

One alternative I will offer is the possibility of granting AU status to Nuclear Medicine Advanced Associates (NMAA). I understand this sounds self-serving since I hold this credential, but I am simply speaking from what I know. NMAA credentials are given through the NMTCB which is already recognized by the NRC to be a legitimate entity that promotes safe and effective use of RAM. NMAAs have extensive training that I believe exceeds the requirements already set forth by the NRC for AU status with the exception that NMAAs are not MDs. All other requirements are exceeded as far as hours of T and E, etc., and NMAAs are tested already on a working knowledge concerning not only radiation safety, but general pharmacology, biodistribution, pathology, patient assessment, anatomy and physiology, etc. The NMAA has a very well rounded and extensive understanding of these things and more, and actually gets more T and E than most if not all the radiology residents get in their training (NMAAs train extensively for two years in this area alone beyond their NMT certification, whereas rad residents' time is split among several modalities including ultrasound and MRI that don't even employ any form of radiation). Additionally, NMAAs are required to work under the direction of a radiologist. In essence, you have a highly qualified individual working under the direction of another highly qualified individual taking care of patients and their needs. Granting AU status to NMAAs however, frees up the attending radiologists more to take care of other cases while the NMAA is doing all the paperwork that

is tying the hands of the radiologists currently, causing what appears to be a lack of access. Trying to keep this short, this would improve access by increasing availability even when the radiologist is busy elsewhere, without decreasing the expertise requirements, and actually maybe increasing them in some cases. This is a win win for the patient and medical community alike. Such a move would not only help therapy patients but would have a positive impact on the whole of our community, diagnostic and therapeutic alike. Please understand, this is not a move to block someone else from taking jobs, etc. It is my deep-seated belief of what is best for patient care. Whether NMAAs are ever granted AU status or not, I just do not condone lessening current standards to create a limited AU license. While I admit some of NRC guidelines may seem a little archaic to current conditions and practices, I feel that lessening requirements to grant even limited AU status would be counterproductive to the NRC's mission and all they have worked to obtain through the years. I understand fully that some of these seeking limited AU status would educate themselves far above requirements and perform an excellent service to their patients. I also understand others would meet the minimum requirements to get such status, and then use it to their personal monetary gain without regard to true patient care. I also understand this can be said of any group, including those already possessing AU status. However, it is the NRC's responsibility to consider all of this when making their decision for what is best for the safety of our patients and our country. Please consider all that is required of an NMAA and their qualification for AU status as an option to this perceived crisis. I would also encourage others seeking even limited AU status to show just cause in lowering the already simple guidelines required for such status. I do not feel the NRC is asking too much currently.

I debated about broaching this subject, but I'm going to call out the elephant in the room. A similar thing has taken place with cardiologists already. There are some cardiologists that have their limited AU status so they can read stress tests. A few of these perform the tests at the hospital and read the studies there. Most of them use this to perform stresses at their office. I myself have worked in these offices. I have never found that this improved patient care. Many offices were backlogged as much and often times more than the local hospital. However, what I have seen is patients that have trouble with the test waiting on an ambulance to come pick them up from the clinic to drive them across town to the hospital's ER because the clinic wasn't equipped to deal with the complications that arose during the test. Therefore, while many talk about doing it for better patient care, better accessibility to health care, and better services, it really amounts to doctors making more money and sometimes putting the lives of their patients at risk. Given that many of these new therapies require the radiologist (AU) to be present with the patient during administration due to possible reactions, etc., and the fact the radiologist primarily works in a hospital, would it be wise to do them in a clinic with an oncologist instead of at a hospital where they are equipped to deal with such issues? While a few oncologists may perform them at a hospital, most will not. If not, then is it really about availability and what is best for patients? Or is it about something else? I understand it is sort of outside the NRC's governance to decide what venue is acceptable to perform medical services, but I believe consideration should be given to the motives driving this request. It is easy for someone to say they can do as good a job as someone else, and maybe that is true in 90% of cases. But when someone starts with "well lower the expectations so I'm a shoe in" we are headed for trouble, and not just for the remaining 10%.

Thank you for taking time to consider my opinions.

Blaine Norton, MIS, RRA, RT(R), CNMT, NMAA, RSO