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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

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Thank you for the opportunity to comment. I am a diagnostic radiology resident completing concurrent training in nuclear medicine, hopefully leading to dual certification in Nuclear Medicine and Diagnostic Radiology.

I am surprised that any changes are being considered that would allow physicians without dedicated nuclear medicine training and board certification to become limited authorized users (AUs). Halfway through my final year of training at a large academic institution I am still learning something new every day in the clinic or reading room. I cannot imagine feeling prepared to face the possibility of using radiopharmaceuticals as an authorized user with any less training than what I will have completed by the end of this year.

I am also surprised at and concerned by the comments recommending allowing Nuclear Medicine Advanced Associates (NMAA) to become AUs. In most cases, mid-level practitioners/physician extenders work under the direct supervision of physicians. If a physician is supervising an extender as an AU, the physician should have the ability to perform the role of the AU, thereby obviating the need to delegate this critical task to an NMAA. If a physician does not have the ability to perform the role of the AU, he or she should not be supervising an NMAA in the AU role. I respect and appreciate that NMAAs have an important role in nuclear medicine practices but I do not think AU should be one of those roles.

On the surface, it sounds easy and beneficial to patients for non-nuclear medicine trained physicians to go through some sort of limited certification to administer parenteral therapies like Radium-223 that can provide so much benefit for patients. In reality, so much more goes into a therapy than what you would think for what appears to be a straightforward in-office procedure. If the preparation and treatment are not done correctly, there is a significant potential for harm to both the patient and the general public. The authorized user works with nuclear medicine technologists directly on the day of the therapy to ensure safe and correct administration; with the nuclear medicine pharmacy days in advance to order the correct dose and to confirm safe transportation of the radiopharmaceutical; with the referring provider days to weeks in advance to ensure the therapy is indicated and appropriate; with their own office staff on the day of the therapy and in advance to minimize potential harm to other patients; with the NRC or agreement state months to years in advance and constantly thereafter to ensure their office is in compliance, their practices are to standard, their training is up to date, and unnecessary exposure is as low as reasonably achievable. When things go right, it seems easy. When things go wrong, as they can despite best efforts, the authorized user must be able to fall back on the extensive experience he or she has gained through appropriate nuclear medicine training in order to protect the patient who is being treated, the nuclear medicine staff, and the general public.

I believe that the consideration for physicians without dedicated nuclear medicine training and board certification to become limited AUs AND the suggestion for NMAAs to become AUs are equally ill-advised. I hope the NRC will reconsider.