

# PUBLIC SUBMISSION

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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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## Attachments

NRC

I am categorically opposed to the idea of expanding AU to other physicians outside the field of Nuclear Medicine as they would be less than minimally trained in the field of radiopharmaceutical use, especially for therapeutic delivery. I have viewed the comments on both sides of the argument, and would like to share why I think supporting this proposal is based on flawed premises, as well as some slightly different perspectives I offer against it.

As supporting arguments, it has been correctly stated by many that the delivery of such therapies requires a skill set as well as an understanding not found in any other training programs outside of Nuclear Medicine. Radiopharmaceuticals have principles straddling both chemotherapy and radiation therapy, and lead to some additional synergistic effects beyond either of those areas. Training AUs with limited scope exposes them to some of the ideas, but does not cover the depth required to fully understand and implement this field, and so anticipation of the response and complications from those synergistic effects is seldom understood by them. It is therefore vital that the physician delivering the radiopharmaceutical be well versed not only in the mechanics of giving such a therapy, but also its appropriateness in the context of the clinical status of the patient at that particular time, as well as how to individualize the therapies for the patient at a minimum for competency. Expanding AU status to less than minimally trained physicians AT BEST only prepares them for the 1st of the 3 requirements since training to deliver these agents would only require knowledge of the mechanics, and far from an intimate understanding of the therapy itself. Whereas one might consider that the other 2 reasons only negligibly impact the newer radiopharmaceuticals since their delivery is pretty standard across patients in the package insert, it is very important to realize that the companies involved in the drug development do so to keep it 'dumbed down' precisely so that as many physicians as possible with marginal competence could become familiar enough to perform the procedure, and also reduces hurdles to get FDA drug approval; however, this is at the significant cost of optimizing the radiopharmaceutical for the patient, which is something unique to the field of Theranostics. These radiopharmaceutical therapies are at the dawn of this field, allowing for personalized medicine, and are thus inherently tied to an imaging component as well. Those trained in other fields severely underappreciate that link beyond its diagnostic and staging possibilities, and hence grossly under utilize its potential. Despite their standard package labeling, the Nuclear Medicine community understands the potential is far greater. Many studies in Theranostics are beginning to show that moving beyond the standard procedure leads to better outcomes for the patients. For example, dosimetry is shown to have some importance, even though PRRT manufacturers claim that dosimetry is not needed. These studies are specific to Nuclear Medicine based techniques, again which are not covered in any other training granting AU status.

Medical societies outside Nuclear Medicine have tried to downplay the role of theranostics by downplaying key parts of the published literature in order to make it more feasible to get AU status, and then administer therapies in oversimplified indications. Current approaches should have a multidisciplinary approach to the evaluation and recommendations of different imaging and approaches, and Nuclear Medicine certainly welcomes that, but also provides its own unique expertise on how these procedures can be helpful. Yet, Nuclear Medicine has had to bring forth literature other societies tried to ignore before their recommendations came out which were much more self-serving.

It is also very important to remember one of the cornerstones of all therapeutic deliveries in the medical field: the person using the therapeutic modality must take complete ownership of all aspects centrally related to that therapy, and not rely on others to manage their own issues, even though they may be working in a multidisciplinary group in the care of the patient. The role of other experts is to provide support, but not core responsibility of the procedure's intricacies and complications. Supportive expert opinion is sought when the disease progresses beyond the ability of the therapeutic modality to deal with the issue. As an analogy, consider institutions where Interventional Cardiologists work on catheterization of complex patients, and in those cases are backed up by a Cardiothoracic Surgeon. If the procedure goes awry and beyond the ability of the Interventionalist to fix it, it becomes the domain of the Surgeon to alleviate the problem. Note that even though this is a multidisciplinary effort, at no time is there an expectation that the Surgeon provides a back-up to the catheterization procedure itself, but only its extreme complications. The expectation is that the Interventionalist is COMPLETELY competent in the attempted procedure, and does NOT require support to be walked through it by others in different areas (ie. pharmacists, technologists, nurses, etc.). Extending AU status to others is akin to having an incompetently trained Interventionalist with the expectation that ancillary staff can take care of the peripheral aspects, and then having someone analogous to the surgeon step in if problems arise that should be within the responsibilities of the administering AU, yet are handled by someone else. From personal experience seeing that happen with others as well as in other comments provided, in virtually all those scenarios the problem would not have arisen in the 1st place had it been addressed at an earlier stage in the delivery of care.

As also stated in other comments and publishing of recent opinion pieces, there are ALREADY sufficient trained AUs available, as well as additional ones who will become available at the completion of Nuclear Medicine training. One important limiting factor in the past has been that Nuclear Medicine continues to be a modality that primarily derives its financing from imaging procedures, and thus exists under Radiology departments. Being primarily diagnosis oriented, most of Radiology has undervalued the therapeutic aspects of Nuclear Medicine, instead opting for dual Radiology trained personnel to increase their diagnostic value, resulting in institutions with very few people who are trained and have an interest in therapeutic Nuclear Medicine. This has resulted in many Nuclear trainees either abandoning the field completely, or practicing in very limited circumstances. The financial paradigm is beginning to shift quickly with the arrival of newer radiotherapies. In the current medical model, the future role of these therapy experts is not outlined and how they would be integrated into the medical system. Admittedly, a part of the problem is currently that a lot of the Nuclear Medicine training programs are geared towards imaging, partly because that has been what the market (specifically Radiology) has required so far, and has been a glaring shortsightedness of the societies in the field. Nevertheless, even the minimal competency of these trainees still far exceeds that of others who would become AUs from outside the field. To get some of these Nuclear Medicine trainees at even a higher level of competency would require far less of an effort than to get an outside trainee to basic competency. As it is, there are actually several superiorly trained physicians in therapeutic Nuclear Medicine that could immediately fill the void until the newer trainees get up to speed.

There are arguments that AU status should be based on competency rather than temporal based training. I actually agree with that statement philosophically; however, the reality of so-called competency based training is that those in other fields who have acquired AU status have NOT received training as part of a focus of their CORE education, but rather as an ANCILLARY component. An example is a General Radiologist who can acquire AU status, have been trained in Nuclear Medicine as a PART of their general radiology, but are not SPECIALISTS in it. Furthermore, there are those who go on for Fellowships in Nuclear Radiology, and whereas they become better trained in therapies, it is clear that even in that group the significant majority are more versed in the imaging aspects, and are uncomfortable with the therapeutic portions. This is also true of other fields who have limited AU status. The result has been that a lot of incorrect uses of Nuclear Medicine procedures has arisen, ultimately resulting in major slashing of reimbursement. It should be noted that the majority of incorrect uses came from imaging, which causes a significant financial burden, as well as some harm to the patient, although the latter is much less significant than the former. When this moves into the therapeutic realm, the consequences of OVERUSE and HARM become much more dire! It is therefore easy to understand that given the complexity of appropriate use – especially in the therapeutic arena – the training must be competency AND temporal based. It is reckless to believe that even a partial AU status can achieve adequate competency if the temporal aspects are not present.

Many organizations are urging the NRC to ‘think out of the box’ to expand AU status, but has been rebutted as a bad medical practice as shown above. They are clearly thinking of current system as limiting the already trained AUs of filling in the needs. A part of the argument is that it fills a great need in rural and underserved areas. Rather, it is they who are short sighted and do not recognize the paradigm shift that is coming, and could rapidly fill these needs. I myself have explored the idea of becoming a ‘traveling AU’, where I would be able to travel to local and regional clinics that do not wish to send their patients to larger specialized institutions that are far away. An alternate thought would be to set up a small clinic in a region, and have patients come to that, again avoiding having to travel much longer distances to specialized institutions. In discussing this with companies at the time, there was great interest shown in supporting such an endeavor, but given that it was very early on, some of the feasibility was not known then. In fact, I know colleagues who have already used that model very successfully around the country, and who have had financial success with it. This paradigm avoids having to have physicians necessarily work under Radiology, which can concentrate on its own goals of imaging. It also significantly opens up private practice opportunities, which up until this point have become non-existent for Nuclear Medicine physicians without Radiology training. It is unfortunate that the specialty societies have not pursued such an endeavor, opting instead to set up ‘Centers of Excellence’ to centralize these treatments. Whereas this is a good idea insofar as training future physicians to perform these procedures, this has been extremely short-sighted in addressing the need of the medical system as a whole. Nevertheless, I still feel the Nuclear Medicine community is poised to be able to provide adequate AND competent AUs very quickly in ALL settings, and do so in a financially feasible fashion.

There are yet additional comments of allowing physician extenders (ie. NMAA) to be allowed to get AU status. I am actually supportive of that, but in a VERY limited sense. I would ONLY support

physician extenders, provided that they are strictly supervised by not just an AU, but one who is actually well trained in the aspects of therapeutic Nuclear Medicine, and not just as a part of their general training in clinical or imaging areas. Hence, the physician extender could administer the dosage and assess the patient, but any contract, initial workup, and complete ownership of the patient's care for targeted radionuclide therapies would still be with the primary AU. Recall, these therapies are actually theranostic, so understanding them is beyond just delivering them, but also an intimate understanding of information provided by their imaging. Therefore, I do NOT see the NMAA as an organization that would assist in filling the needs for AUs, but rather enhance the accessibility to well trained AUs already readily available.

One last aspect that has also been commented on is the reality that we live in an era of bioterrorism, and that it appears radioisotopes have already been used in assassinations in the world. The age of alpha particle therapy is already here, and careful delivery, use and discard procedures of these agents should be a paramount area of concern for all those involved in the field. Widely expanding AU status and placing it in the hands of people who are less than minimally competent in the area creates a significant issue with accounting for the appropriate handling of these agents. It is clear that no other field is currently geared to handle these issues as in Nuclear Medicine. Creating appropriate safeguards for people who are sub-optimally trained for all this is a hidden cost to the system that is not being stated by other groups.

Given all the concerns raised above, I would actually urge the NRC to make it MORE difficult to obtain an AU status! This will force the training and societal organizations to raise their standards and produce highly competent physicians who can handle both the medical and logistical challenges associated with these new emerging treatments. Many detractors would try and point out that would further exacerbate the problem of there being adequate AUs present, but given the paradigm changes in healthcare delivery from Nuclear medicine physicians, that should not be a problem. A great example already exists in the rest of the world outside North America, where Nuclear Medicine has been able to provide excellent and adequate service because of the high quality training they provide, with no impact on the immediate financial aspects; in fact, there is an advantage in the downstream costs of having Nuclear Medicine perform these procedures.

There will always be a few physicians trained in fields other than in Nuclear Medicine who would also be well versed with the core principles of Nuclear Therapeutics; however, it would be rash to open up the AU status to a large number of less than competent physicians in order to benefit from just a few good ones among them. I therefore urge the NRC to NOT expand the pool of AU users, as these people would be undertrained and costly to the system, especially when there are already AUs available that can easily fill in those needs almost immediately.