

# Delivering Radionuclide Therapies Requires Extensive Training and Competence: Send a Firm Message to the NRC and Your Representatives

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**T**he problem: The Nuclear Regulatory Commission (NRC) is the federal agency tasked with protecting public health and safety related to radiopharmaceuticals used in nuclear medicine. It is now considering creating alternate pathways for physicians without dedicated nuclear medicine training and board certification to become limited authorized users (AUs), specifically to administer radionuclide therapies.

**Why is this being considered?** The impetus for these contemplated changes is a presumed future shortage of AUs who can deliver radionuclide therapies because of current alternate pathway requirements specified in 10CFR Part 35.390 that supposedly may create a bottleneck. The current alternate pathway requires 700 hours of training and experience, which is equal to approximately 4 months of training. The NRC has now requested comments from a broad group of stakeholders, including professional organizations, physicians, patients, patient advocacy groups, and other interested individuals, to further discuss training and experience requirements for delivering radionuclide therapies. The deadline for the comment period is January 29, 2019.

**Who has an interest in further diluting requirements for practicing therapeutic nuclear medicine and theranostics?** Here is a simple suggestion: follow the money. There is evidence for significant pressure from the radiopharmaceutical industry, also at the political level, to create very broad distribution opportunities for new and emerging targeted radionuclide therapies. Recent transactions underscore the great business potential of theranostics. These therapies will create significant revenues. More AUs and more treatment sites likely result in more treatments. This is how markets work. This is not a bad thing as long as it does not compromise quality of care and patient safety.

At the same time, the NRC, the very entity that seriously considers this minimalistic training approach, is also a stakeholder. As a self-funded agency, the NRC has to support its operating budget, for example, for its medical program, with user fees (1). Increased AU licensure fees create a fiscal benefit for NRC's medical program. As a consequence, there is a direct incentive for the NRC to issue as many authorized user licenses as possible—this is, in our view, a perfect example of a conflict of interest that cannot be managed.

**Why the argument of an insufficient number of AUs is wrong:** Based on annually published American Board of Nuclear Medicine (ABNM) data and by conservative estimates, the current nuclear

medicine workforce consists of approximately 1,200 board-certified nuclear medicine physicians across the United States (2). Based on projections of future needs in radionuclide therapies, approximately 150 new theranostic centers across the United States would be needed to deliver approximately 150,000–200,000 treatment cycles/year (assuming 4 cycles/patient for up to 50,000 patients/year). Each of these sites would treat 1,000–1,250 patients/year or 5–7 patients/day. The current ABNM-certified workforce in the United States and the expected addition of new ABNM-certified physicians in the upcoming years of approximately 50–60 ABNM diplomates/year will easily meet this demand (2). The Advisory Committee on the Medical Uses of Isotopes, which has an advisory role to the NRC and comprises nuclear medicine physicians, radiologists, radiation oncologists, and radiation physicists among others, also refuted in its report from July 5, 2018, the assumption of shortage of authorized users (3). Thus, the argument of an AU shortage is simply not supported by data.

**Why extensive training and education is required to administer radionuclide therapies:** To provide high-quality and responsible care, a physician must master the nature of this type of therapy and understand its mechanisms of action: systemic delivery of ionizing radiation and conferring targeted damage at a cellular level from a nonsealed radioactive source. A relatively short and incomplete list of requirements to reach such competency includes an in-depth understanding of physics, instrumentation, and radiobiology pertaining to radiopharmaceuticals; the interaction of radiation with matter; and the nature and energy of radioactive emissions, radionuclide properties, radioactivity units, physical half-life calculations, bystander and cross-fire effects, and dosimetry. Radiation protection, largely a nonissue when it comes to diagnostic applications, is clearly a patient, personnel, and public safety issue in the context of radiotherapeutics. Considerations regarding the supply chain, because radiopharmaceuticals do not have a durable shelf life; judicious ordering of radiopharmaceuticals to avoid wasted doses; a state-of-the-art hot lab with necessary equipment including shielding material, hoods, and dose calibrators; and, finally, appropriate waste management, with radiation safety surveys and concrete standard operating procedures in place for cases of spillage and emergencies, are among other fundamental necessities. Even more



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specific to theranostics, advanced skills in nuclear hybrid imaging interpretation and a thorough understanding of the biologic half-life of specific therapeutic radiopharmaceuticals, target expression, target volume, and target heterogeneity prior to delivering therapeutic radionuclides are all among imperative aspects of a comprehensive training. Above and beyond, training needs to embed radionuclide diagnostics and therapeutics in a solid understanding of physiology, tumor biology, oncology, and multidisciplinary patient management. Can all of this be accomplished without training?

Management of side effects of treatment, which do exist, as well as integration and coordination of care all require real expertise not pseudotraining. It is absurd and grotesque to assume that this expertise can be acquired in 80 (= 2 weeks) or even 700 hours (= 4 months). This expert-level competency requires years of solid training. Would anyone send a family member to any treatment delivered by someone who had 2 weeks of training? Limited AU licenses would be akin to providing privileges to nononcologists to administer cytotoxic chemotherapies or immunotherapies after a 2-week course or to a nonsurgeon to perform complex laparoscopic surgery after 4 months of surgery training.

The NRC has abdicated its role as a protection agency for patients. Its policy in the past and current rulemaking considerations have been overreaching the commission's purview and defeat the very purpose of its existence, which is protecting public health and safety!

**What is the remedy?** The current NRC request for public comments is an opportunity to voice your disbelief of and opposition to this irrational proposal that puts patients and the public at risk. Nuclear medicine departments and divisions and all individual physicians need to embrace this opportunity to raise their concerns firmly and unapologetically.

Your comments must be posted by January 29, 2019. Follow this link to provide responses to NRC's questions: <https://www.regulations.gov/document?D=NRC-2018-0230-0001>.

Finally, the nuclear medicine leadership and community must reach out to congressional representatives to inform and warn them about this real danger for patient and community safety. Neither theranostics nor cytotoxic therapies or external-beam radiation can be delivered to cancer patients by poorly trained amateurs.

## REFERENCES

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