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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

Thank you for the opportunity to comment.

As a healthcare professional, I have significant concern that any reduction to these training and experience requirements would put patients and the general public at risk.

Responsible, high-quality, safe administration of radionuclide therapy requires a physician who has fully mastered the nature of this type of therapy, including but not limited to its mechanism(s) of action and diagnosis and management of adverse effects, as well as safe handling of unsealed radioactive sources. At the very minimum, competency to do so requires an in-depth understanding of physics, instrumentation, and radiobiology pertaining to radiopharmaceuticals; the interaction of radiation with matter; nature and energy of radioactive emissions, radionuclide properties, radioactivity units, physical half-life calculations, bystander / cross-fire effects, waste management and dosimetry; and radiation safety considerations to ensure protection of the patient, personnel, and public at large.

This is not traditional chemotherapy. Radiopharmaceuticals do not have a durable shelf life, requiring understanding of judicious ordering practices (to avoid wasted doses) and management of a state-of-the-art hot lab with necessary equipment including shielding material, hoods, and dose calibrators. Waste management procedures vastly differ from those used for chemotherapy, with radiation safety surveys and concrete standard operating procedures in place for cases of spillage and emergencies, among other fundamental necessities. Management of radiation treatment-induced complications also significantly differs from traditional chemotherapy.

I find it irrational to assume that this level of expertise can be acquired in anything less than the current

training and experience requirement. Expert-level competency requires years of solid training, and I would not personally allow a family member to be treated by a practitioner without this level of competency. This is a serious risk to patient safety.

Please also refer to:

1. A recent editorial on this topic published in the Journal of Nuclear Medicine, with which I agree. (<http://jnm.snmjournals.org/content/60/1/1?etoc>)
2. Separate letters from professional societal organizations representing nuclear medicine (ABNM and SNMMI) in this regard.

Thank you.