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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

I would urge the NRC to use caution in reducing the requirements for AU status for therapeutic radionuclide-based agents. While the recent success of several new radionuclide-based therapy drugs for prostate cancer and neuroendocrine tumors has increased the clinical demand for these agents, with additional similar agents likely to gain approval in the future, the potency of these agents also creates a greater need for expertise and clinical experience in dosing and delivering these agent. Practitioners of broad radionuclide-based therapy mist be experienced in anticipating, identifying, and managing the toxicities of these powerful agents. Only the current training programs and certifications that assure sufficient training for broad application of unsealed byproduct material [for therapy] for which a written directive is required, namely the scope of practice covered by CFR 35.390, can provide assurance of an understanding of the dosing and toxicities for these potent new agents. Broadening the base of AUs to deliver these agents should be done by improving and expanding radionuclide-based therapy training, rather than by lowering AU training requirements. Currently, only nuclear medicine programs as well as radiation oncology and nuclear radiology program that include a nuclear medicine level curriculum for radionuclide therapy - can provide the level of training needed to assure safe and effective use of unsealed byproduct material under 35.390. Rather than lowering training standards for 35.390, I call on the NRC to maintain current training standards and urge current trainees and established practitioners needing therapy training at current 35.390 standards to leverage the substantial base of training programs that can provide the need level of expertise for safe and effective delivery of radionuclide-based covered under 35.390.

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