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## General Comment

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## Attachments

Edwin Palmer comments

I strongly oppose any reduction in current AU training and experience. Although the existing regulations have been in place for many years, time has shown that they provide adequate training for the safe administration of therapeutic radiopharmaceuticals. Under no circumstance should economic considerations outweigh the critical patient care issues surrounding radiation safety. Only substantial training, supervision, and experience can provide the background needed to administer these agents safely. In my 35 years of academic practice of nuclear medicine and nuclear radiology, I have organized and overseen the radiation safety training of hundreds of residents and fellows, and absolutely do not believe that any reduction of current requirements is warranted.

I further believe that much of the discussion about limitation to access misses the mark. Zevalin and Bexxar are not widely administered simply because there are other better treatment modalities, not because of a lack of authorized users. In my institution, we do vanishingly few Zevalin administrations, but treat many patients with radium-223 (Xofigo) and currently are currently struggling to keep up with the demand for Lutathera therapy of patients with neuroendocrine tumors. The difference here has nothing to do with availability of authorized users; it is simply a question of which agents currently fill the clinical need. The limitations in our ability to treat with Lutathera have nothing to do with authorized users, but rather with space and availability of infusion rooms.

Thank you for considering my comments.

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