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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 am writing to you about the requirements in Subpart of Title 10 of the Code of Federal Regulations Part 35 and the three ways a physician can be authorized to administer unsealed byproduct materials or radiopharmaceuticals requiring a written directive:

I am a Nuclear Medicine and CT Technologist who supervises the Nuclear Medicine Department for Dr. John Feller at Desert Medical Imaging, who owns three outpatient imaging and research facilities in the Palm Springs desert area. He is also my radiation safety officer and is on our current Radioactive Material License for 35.100 and 35.200. Dr. Feller has limited time reading and performing many procedures and therapies throughout the week. We have tried to get him proctored to no avail simply because he doesn't have the time, nor does other licensed physicians as well as their unwillingness to be responsible for take on the burden of doing such training. The other route on doing 700 hours of clinical and didactic training is just not feasible to obtain schedule wise as well as the know how on where to go for such training. Since Dr. Feller is not new to Nuclear Medicine and being on our RAM license already for nuclear medicine, seems that it would be an easy transition on being educated on 35.300. We definitely hope that the rules and regulations be changed so he and others can do some type of web, internet training/testing in the near future to qualify to apply and be approved for 35.300 licensing. We would then be able to provide many other services to help our patients, especially since we are a prostate cancer research and therapy facility. Currently, we have to send our patients out that have been with us for months or years even, to get the palliative therapy out here in the desert at the one place that provides Ra223 dichloride (Xofigo) that the patient would rather receive here with us since we are like family to them and been with us for their entire battle of prostate cancer. These stringent and

unrealistic regulations and requirements make it nearly impossible for our world renowned radiologist Dr. Feller who invented MRI Laser Focal Therapy for prostate cancer unable to provide the rather simple therapy of 6 injections of Xofigo. Seems like we can find a better solution for all involved and should.