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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

I appreciate the opportunity to comment on behalf of CSA's Urology Division. CSA is a surgical multi-specialty group.

Our Urology Division has a robust advanced prostate cancer clinic and Xofigo (a radio-pharmaceutical in a patient ready dose) is an important treatment option for our patients. Our patients have few options for treatment outside a 4 hour automobile travel radius and many of them may not be able to travel for treatment that is not readily accessible due to socially determinate and economic barriers.

The original rule that outlined training and experience requirements was written before patient ready doses were available.

Urology regularly handles hazardous materials including BCG, Mitomycin C, Provenge and Gemcitabine. Safety is a priority in handling any hazardous material whether it be a bio-hazard, chemical or radioactive hazard. We have guidelines for all types of hazards and training is commensurate to duties with any hazardous material. We are able to safely administer these and other hazardous drugs while rendering high level, cost effective care by local physicians. Additional non radioactive training and experience would be unnecessary.

We think that the proposed 700 hours of training and experience would adequately train physicians for the full range of activities, however this would be excessive to handle and administer Xofigo. Training should be contingent upon the radio-pharmaceutical, its characteristics and its use.