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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0162

Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

Document: NRC-2018-0230-DRAFT-0171

Comment on FR Doc # 2019-10760

Submitter Information

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General Comment

LIMITED AU FOR ALPHA- OR BETA-EMITTING RADIOPHARMACEUTICALS:

Tailored limited use for authorized users has been in place within code 35.392 and should be, based on this precedent, the foundation for a limited use code for radium 223.

392 is for I131 only with only 80 hours of T & E.

This code has been in existence for years and has been highly successful even though I 131 is a complex radiotherapy from a clinical, radiation safety and handling consideration.

Radium 223 is much less complex.

Radiation safety has worked well within 392 because of the system for NRC compliance consisting of radiation safety officers, nuclear medical technologist, regulators, hospital clinic administrators and authorized users.

Competency should not exceed the 80 hours of training, as per 35.392, but could include manufactures training certification.

This would acknowledge the current training for Radium that is supplied by Bayer pharmaceuticals which is the only training an authorized user and the entire Radiation safety team receives about this Alpha emitting radiopharmaceutical.

Manufactures training requiring end user certification is the most efficient path for current information and is in everyones best interest.