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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0001

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

COMMENT (135)
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Office of Nuclear Materials Safety and Safeguards

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

Re: Docket ID NRC-2018-0230-0001, Training and Experience Requirements for Different Categories of Radiopharmaceuticals

I have received NRC's letter regarding relaxation of training rule for use of radiopharmaceuticals in therapy. As an experienced nuclear medicine physician for over 30 years with radiology background, I have strong concern. I have worked and treated hundreds of patients in major medical center with various radioactive pharmaceuticals following appropriate evaluation, correlative imaging and use of radionuclide imaging and dosimetry prior to therapy. Treating patients with radiopharmaceuticals by AUs needs especial training, understanding and evaluating patients prior to radionuclide therapy. At academic centers, we are interested in patient safety and patient access to quality care. We provide the most up to date therapies and also educate our trainees well so they can provide similar therapies for others in the future. It is noted that the initial analysis of the number trainees who are expected to become authorized users presented at the Society of Nuclear Medicine and Molecular Imaging annual meeting this past June was in error, greatly underestimating the number of AUs in the United States. In fact, there are adequate authorized users in our institution and in Philadelphia and southeastern Pennsylvania.

Our primary concern regarding potentially relaxing the requirements for training is that of

patient safety and community. As with some other specialties, training may come from industry and may not be as robust as participating in a formalized training program. This is problematic as at least one industry professional has referred to $^{223}\text{RaCl}_2$ as just an alpha particle which would indicate to us that this individual is not well-versed in the radiation safety considerations for alpha particles.

By new pharmaceuticals being on the horizon for therapeutic reasons, I strongly suggest keeping the therapy in a safe environment by physicians who are trained by strict rules and not relaxing the criteria. Additionally, I am concerned that many unnecessary therapies in patients with inadequate preparation will not only help out patients but may harm them.

There should be no limited AU status as no need nor had sufficient safety been ever demonstrated for such a pathway, while the contrary had been suggested numerous times.

Hence, the question is presumptive and not applicable in my opinion.

Your strong consideration to keep the current criteria and state of training in order to keep radionuclide therapies under competent and well trained specialties is very much appreciated.

Regards,