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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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Comment on FR Doc # 2018-23521

Submitter Information

Name: Holly Thompson

General Comment

January 28, 2019

Dear Nuclear Regulatory Commission,

Re: Docket ID NRC-2017-0230

I am a Nuclear Medicine Physician, double boarded in Nuclear Medicine and Radiology. I write this letter out of sincere concern for the proposed changes to the training and educational requirements for Authorized Users (AU).

The safe procurement, storage, calibration, patient selection, administration and disposal of radiopharmaceuticals are not trivial tasks to be taken lightly or performed occasionally by limitedly trained medical professionals. Safe radiopharmaceutical utilization requires exceptional attention to detail and an in depth knowledge of mathematics, radio-physics, material science, tumor biology, normal and compromised physiology, and extensive practice in sterile administration techniques. It requires advanced infrastructure (i.e. lead shielding, locked/secured labs, fume hoods, calibration and contamination instruments, waste storage) and a team of dedicated personal to include specialty trained physicians, medical physicist, and skilled nuclear technologist and nurses.

An AU needs extensive multidisciplinary training and experience to ensure appropriate and safe patient selection as patients typically have advanced cancer and have undergone multiple prior therapies which have altered their baseline physiology i.e. bone marrow reserve, liver, and renal function. As such, the systemic whole body administration of ionizing radiation places already sick patients at increased risks of grave side

effects whereby it is not uncommon for an AU to have to recalibrate a radiopharmaceutical dose or treatment schedule to best manage complications.

Additionally with new IV therapies; such as Lutathera, patients often experience nausea and vomiting during the procedure which can last 4-5 hours requiring supporting care and extensive experience in radiopharmaceutical contamination and containment techniques. Such level of training and experience cannot be acquired in a shortened or accelerated course nor facilitated by observing a handful of cases. As such I strongly oppose the proposal to reduce training and educational requirements for AU. In an era of new and more complicated radiotherapies, we should be striving to increase educational and competency requirements for Authorized Users, not reducing them.

The purported shortage of Authorized Users and distorted concern for reduced patient access is artificial. Radiotherapies, which are becoming more advanced (not simpler), should not be performed in rural centers with limited resources and education in radiopharmaceutical handling as complications do and will occur. Extensive training, educational requirements and infrastructure required for an AU to practice nuclear oncology is therefore self-fulfilling whereby centers adequately equipped to provide radiopharmaceutical therapies will have access to such specialized physicians and medical personal.

Fundamentally, I see no compelling reason to reduce our current standard for AU, which in reality is already a minimum standard. Perhaps instead our focus should be on supporting and confirming adequate competency of both current as well as future AU.

Thank you for your attention.

Sincerely,

Holly Thompson
Nuclear Medicine Physician
Northern California