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From: Gerard, Stephen MD [mailto:StephenGerard@verity.org]
Sent: Tuesday, January 29, 2019 12:01 AM
To: Borges Roman, Jennifer <Jennifer.BorgesRoman@nrc.gov>
Subject: [External_Sender] Submission of Comment on Docket ID NRC-2018-0230

Dear Ms. Borges,

I am submitting my comment against the proposal to revise and/or weaken the current regulatory requirements to require 700 hours of training in Nuclear Medicine along with the current other training requirements detailed under CFR 35.390 in order to qualify for AU status for treating patients with unsealed radioisotopes, as described under CFR 35.300.

I have practiced Nuclear Medicine for ~30 years, half of this time at the San Francisco VA Medical Center, and the other half in my current community hospital. I have an accurate appreciation for the need to have properly and adequately trained practitioners who perform such treatments with unsealed radionuclides. Although the requirements for patient preparation and assessment vary among the growing list of different radioisotope treatment options, all of them require careful attention to standards of biodistribution, dosimetry, radiation safety for patients and other household residents, and for hospital staff. Compromising the requirements for medical performance and supervision of such treatment procedures will put patients at greater risk of medical errors, at a time when we have an urgent need to make significant progress on reducing the extent of medical errors being made. Simplifying such requirements, and creating a lesser burden of time and/or requirements in training, would be tantamount to cherry picking a list of some simpler general surgical procedures that could be performed by physicians assistants without the involvement of a licensed physician. We do not, and should not weaken the standards of training for such surgical procedures, because the risks of potential peri-surgical or post-surgical complications exist for all surgical procedures, regardless of their anticipated difficulty or complexity on the face of them. In such instances, the standard of care mandates that we maintain optimally-trained licensed surgeons to oversee and manage such surgical procedures, to assure the optimal outcome for our patients. The same consideration should apply for radiopharmaceutical therapeutic treatment. To weaken any such training requirements will unavoidably increase the risks of mistakes and

mismanagement associated with such radioisotope treatments, to the detriment of patient outcomes and to the quality of Nuclear Medicine practice.

Thank you for considering my comment against any proposals to weaken the training requirements for gaining AU status for radiopharmaceutical treatments as defined under CRF 35.300.

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