

PUBLIC SUBMISSION

SUNSI Review Complete
Template = ADM-013
E-RIDS=ADM-03
ADD=Sarah Lopas

COMMENT (32)
PUBLICATION DATE:
10/29/2018
CITATION: 83 FR 54380

As of: 1/15/19 10:30 AM Received: January 15, 2019 Status: Pending_Post Tracking No. 1k3-97p1-aykj Comments Due: January 29, 2019 Submission Type: Web

Docket: NRC-2018-0230

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Comment On: NRC-2018-0230-0001

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Document: NRC-2018-0230-DRAFT-0030

Comment on FR Doc # 2018-23521

Submitter Information

Name: Anonymous Anonymous

General Comment

As a physician specializing in Nuclear Medicine, it is with great worry that I read about the proposed changes to the training and experience requirement by the NRC.

The current requirements are already, in my opinion, insufficient. Treatments with unsealed radioactive sources are complex, and require an understanding of underlying physiology and physics. Understanding the underlying mechanisms of action of these therapies is crucial. Adequate knowledge of radiobiology, radiosafety, and expert knowledge of the instrumentation used is also paramount. Advanced skills in hybrid imaging is also a critical skills. Even the current requirements are clearly insufficient to provide expert knowledge in all these fields. It is ridiculous to assume that an even shorter training period could convey even a basic knowledge in all these fields, and I strongly fear that these proposed changes to training requirement will jeopardize patient safety and lead to unnecessary, avoidable, mistakes, by allowing what would amount to untrained personnel to administer these therapies. On the contrary, I believe that the NRC should strongly consider making the requirements more stringent, to ensure that these therapies are administered by trained experts, and to ensure the best outcome possible for all patients, and to guarantee patient safety.

Lastly, I should also point out that these proposed changes appear to be based on the issue of a "shortage" of trained personnel/authorized users. I believe that this is a non-issue. I am not aware of any lack of authorized user under the current guidelines, and the current training pathways are more than enough to provide the USA with an adequate volume of fully trained authorized users. This "shortage" does not appear to be based on any real data. Even if there was a shortage, compromising patient care, patient safety and the public's safety is not a solution.