PUBLIC SUBMISSION

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

COMMENT (35)
PUBLICATION DATE:
10/29/2018
CITATION: 83 FR 54380

As of: 1/23/19 8:41 AM
Received: January 18, 2019
Status: Pending_Post
Tracking No. 1k3-97r4-zzsm
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-0032
Comment on FR Doc # 2018-23521

Submitter Information

Name: Kasey Nelson

General Comment

I propose to keep the T&E requirements as they currently are for authorized users and to add the nuclear medicine advanced associate (NMAA) as an AU. I am against relaxing the T&E requirements because doing so may adversely affect the safety and quality of radionuclide therapy by allowing physicians that are not trained as radiologists or nuclear medicine physicians to serve as authorized users. However, allowing the NMAA to become an AU will improve patient access, operational efficiency, and throughput without jeopardizing safety and quality because a NMAA operates under the supervision of a nuclear medicine physician or radiologist.

A NMAA is a physician extender currently working under the supervision of a nuclear medicine physician or radiologist to enhance patient care in the diagnostic imaging and radiotherapy environments. NMAAs have a high level of training in radiation safety, radiation biology, radiation physics, instrumentation, and radiation protection as required by the NRC. The NMAA is trained comparable to conventional physician extenders, and required to complete a graduate level program encompassing a didactic curriculum modeled after conventional physician extender programs, culminating in a Masters of Imaging Science Degree.

The NMAA is also required to complete a 24 month clinical internship. Based on nuclear medicine residency training, the NMAA must read required literature, including teaching files, and case studies. The NMAA must establish knowledge regarding normal radiotracer distribution patterns, including the appearance of disease processes, radiologic-pathologic correlation, and the associated differential diagnosis. The NMAA must calculate a minimum number of therapeutic doses and subsequent administrations depending on institutional availability. Via this training, the NMAA has met the qualifications required under 10 CFR 35.390 to become authorized users. By comparison, nuclear radiologists complete 24-28 months of specific nuclear medicine training, including radiology residency and nuclear medicine fellowship. Alternatively, diagnostic radiology

residency requires 16 18 weeks of nuclear medicine training, which also fulfills the minimum requirements for authorized user.

In summary, the NRC should consider the NMAA as candidates for authorized user designation for radioactive byproduct use encompassing, uptake, dilution, excretion, imaging and localization, and therapy.

Thank you,
Kasey Nelson, MIS, NMAA, CNMT