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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

See attached file(s)

Attachments

To NRC_v3

We are reaching out in regard to the recent NRC initiative to consider relaxing authorized user training requirements in order to meet market demand. This initiative will allow physicians that are not trained as nuclear medicine physicians or radiologist to serve as authorized users. An obvious concern is that relaxed training requirements may adversely affect the quality and safety of radionuclide therapy.

We would like to propose an alternative to be considered, which may also help address the market demand without relaxing training requirements. Nuclear Medicine Advanced Associates (NMAAs) are physician extenders working under the supervision of nuclear medicine physicians and radiologists, who have a high level of training in radiation safety, radiation biology, radiation physics, instrumentation and radiation protection as required by the NRC. NMAAs operate under medical supervision of nuclear medicine physicians and radiologists. Thus, allowing NMAAs to become authorized users will improve operational efficiency and throughput without jeopardizing quality and safety.

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

Respectfully submitted,

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