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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: Irene Virgolini

Submitter's Representative: Irene Virgolini

Organization: World Association of Radiopharmaceutical and Molecular Therapy

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General Comment

Please accept this response on behalf World Association of Radiopharmaceutical and Molecular Therapy (WARMTH)

Irene Virgolini
 President - WARMTH
 See attached file(s)

Attachments

WARMTH NRC Response



WARMTH

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OF RADIOPHARMACEUTICAL
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May Ma

Office of Administration

U.S. Nuclear Regulatory Commission

Washington, DC 20555

Re: Docket ID NRC-2018-0230; Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Dear Ms. Ma:

The "World Association of Radiopharmaceutical and Molecular Therapy" (WARMTH) is the only worldwide organization founded to promote the use of radionuclide molecular therapy, and of the relatively novel paradigm of 'Theranostics.' Our membership represents over 400 radiopharmaceutical therapy professionals from 65 countries.

The Nuclear Regulatory Commission (NRC), the United States' regulatory agency responsible for the safe use of radiopharmaceuticals in nuclear medicine, has called for the opinion of stakeholders and the public regarding its proposal to create an alternative pathway for non-nuclear medicine physicians to be considered as limited authorized users who will be capable of administering radionuclide therapies. This proposal was borne out of a perceived fear for a shortage of board-certified nuclear physicians to administer these therapies in the future.

Radionuclide therapy with unsealed radioactive sources is a rapidly evolving field of medicine, and many agents are likely to receive regulatory approval for routine clinical use in the coming years. The dynamic nature of this field, therefore, requires that individuals who will be administering these treatments be grounded in the essential background knowledge necessary for safe handling and use. A safe practice of nuclear medicine therapy entails the understanding and mastery of a diverse but related subject including physiology, radiopharmacy, tumor biology, oncology, medical physics, and radiation biology. In addition, a thorough knowledge of radiation protection and dosimetry ensure the safety of the patients being treated, the general public and the environment. Treatment, in most cases, requires hybrid imaging to select patients for therapy, for confirmation of delivery of the therapeutic agent to the disease sites, for estimating radiation dose to off-target tissues/organs and for response assessment during follow-up. This knowledge requirement for hybrid imaging buttresses the point that a physician that would be authorized to carry out patient treatment be equally vast in this knowledge domain. The advent of alpha particle therapy has rendered our unique specialised knowledge of radiobiology paramount since alpha particles kill very effectively and we must achieve stable accurate tumor localisation. The diverse knowledge required for our patients' safety and the safety of the community at large therefore indicates that would-be authorized user, limited or otherwise, be adequately trained for a sufficient time to ensure mastery. The level of proficiency required for a safe practice cannot be achieved in 700 hours (as currently required) and not in the proposed shorter length of training and experience.



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The envisaged shortage of authorized user in the future is also not based on facts. This misconception is borne out of a perceived decline in the accredited nuclear medicine training programs and nuclear medicine trainee in the US. The ABNM has adequately responded to this perceived decline as being due to a rise in the number of trainees who are specializing via the dual training pathway of combined nuclear medicine and radiology. These trainees are counted as diagnostic radiology residents in a diagnostic radiology program creating a fear of a decline nuclear medicine training programs and residents in training, and consequently, a future shortage of nuclear medicine physicians to carry out radionuclide therapies.

A well-trained nuclear medicine physician can supervise many therapy administrations in a day. It is therefore essential to make a concerted effort within the US and beyond in creating the capacity, infrastructure and otherwise, necessary to increase the number of patients that can be treated at any particular facility at a time. Reducing the requirements for supervised training and experience will create a large number of poorly-skilled physicians that will create more harm than benefit for the patient and the practice at large. Unsafe administration of radionuclide therapies by individuals without the requisite skill will quickly make this treatment option fall out of favor. Effort should also be geared towards ensuring a stable supply of radionuclide for diagnosis and treatment.

Sincerely,

Irene Virgolini
President
WARTMH