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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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ADD=Sarah Lopas

Name: Janice M. Campbell, PhD

General Comment

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Please see the attached comments to Docket 2018-0230.

Attachments

Comments to NRC T&E Changes Docket 18-0230

Beaumont

Beaumont Hospital, Royal Oak
3601 West 13 Mile Road
Royal Oak, MI 48073

January 25, 2019

May Ma
Office of Administration
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Docket ID NRC-2018-0230

Dear USNRC,

In response to your specific requests for comments:

A Tailored T&E Requirements
1) and 2) We believe that the current pathways for obtaining AU status are reasonable, accessible and adequate for protecting public health and safety. This opinion comes from decades of training Nuclear Medicine and Radiology Residents in the appropriate and safe use of radiopharmaceuticals for both diagnostic and therapeutic uses.

3) No, the NRC should not develop a new tailored T&E pathway. In fact, AUs should have a broader perspective and T&E in the use of a variety of diagnostic and therapeutic radiopharmaceuticals (RPs). Training in a limited area of only a certain therapeutic RP application would not provide a general and diversified experience that helps to assure patient safety and avoid potential problems.

We feel the T&E for AUs should be greater in the future, as the molecular-based RPs will require greater complexity and sophistication in administration. We feel there is no reason to expect that the expertise or T&E required for new RPs would be any less than the ones currently required.

Another reason against establishing a "tailored T&E" is the potential for bias or conflict of interest. The limited AU status would possibly enable the physician who cares for the patient to also make the decision about, and to administer the RP therapy. The proposed limited AU status would remove the current practice of consulting an AU physician (who evaluates the appropriateness of the RP therapy for each patient) to assure that the benefits outweigh the risks. This is part of the system of "checks and balances" in RP therapy.

B NRCs Recognition of Medical Specialty Boards
1) and 2) We feel that the boards already recognized by the NRC; (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], and Certification Board of Nuclear Endocrinology [CBNE]) are sufficient in their required training standards and adequate in their certification process for safe and competent authorized users.

C Patient Access

1-4) We have not experienced a shortage in the number of AUs for medical uses under 10 CFR 35.300. To our knowledge, there is a large number of AU physicians who are currently practicing (or are completing training in) nuclear medicine, radiology and radiation oncology. They can answer the demand for any additional AU needs, as new RP therapies are introduced into clinical practice. If there is a geographic area with perceived shortage of AU's, the job market forces should be able to correct it. In fact, due to recent changes in national treatment recommendations we have seen a decrease in patients utilizing radiopharmaceutical therapy.

D Other Suggested Changes to T&E

The current NRC rules provide for a performance-based approach that relies on the training and experience of the AUs, authorized nuclear pharmacists, authorized medical physicists and radiation safety officers. We feel that this approach has worked well and do not recommend any changes to the T&E regulations in 10 CFR part 35. Radiotherapy administrations regardless of the radionuclide type are clearly higher risk in terms of both patient safety and radiation public safety when compared to diagnostic applications. Therefore, authorized use of therapeutic radionuclides should always require additional training above the training required for diagnostic applications.

To provide high-quality and responsible care, a physician authorized user must understand the radiation physics, radiobiology, therapeutic mechanism of action, imaging interpretation before and after radiotherapy, expected tissue response and side effects of radiobiological effects. This expert level competency requires years of training which the current certification programs and T&E requirements assure.

Submitted on behalf of the following individuals:
Radiation Safety Committee Chair
Corporate Radiation Safety Officer
Corporate Nuclear Medicine Physicist
Director of Nuclear Medicine ACGME Residency Program
Diagnostic Radiology and Molecular Imaging Authorized Users