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General Comment

See attached file(s)

Attachments

Required T & E for AUs to provide RN Therapy BG 1.25.2019

January 25, 2019

Daniel S. Collins
Director, Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
Rockville, Maryland

Mr. Collins:

The following comments are submitted as my own opinions, as a Nuclear Medicine physician and Radiologist.

I believe the following is necessary for physicians to practice high quality, safe and effective radionuclide therapy:

Physicians need to master the previously submitted curriculum, which would include mastery of physiology and pathophysiology, tumor biology, oncology, and multidisciplinary patient management. It is essential that these physicians are dedicated to the practice of NM and have a though understanding of nuclear medicine, including evaluating relevant diagnostic nuclear medicine imaging studies (especially including hybrid imaging studies).

For an expert precision/targeted approach, these therapies require molecular-level diagnosis, evaluation of the desired target(s), evaluation of possible targeted therapies, including proper sequences if multiple therapies are given, and follow-up after treatment, including consideration of further therapies. Dosimetry is likely to be critically important.

Understanding the mechanisms of action of these targeted radionuclide therapies is critical, which involve systemic delivery of these therapeutic radionuclides that will deliver targeted effects to malignant lesions while sparing normal tissue.

The above requires a thorough understanding of radiation physics and radiobiology (including radiation units, half-life calculations NM instrumentation, and interaction of radiation and tissue). It also requires a thorough understanding of the radiopharmaceuticals used, the types and energies of radioactive emissions, and possible bystander and cross-fire effects of therapy.

Other important considerations include radiation safety (of patients, staff and the public), radiation surveys for detection of contamination, how to respond to spills or emergencies. Considerations regarding ordering radiopharmaceuticals (and therefore availability), radiopharmaceutical handling in the radiopharmacy (hot lab), and waste management are important.

All of the above can be obtained with specific training in radionuclide therapy during residency or fellowship training, but almost certainly would be impossible to obtain without such training.

Answers to the Specific Questions:

1. Are the current pathways for obtaining AU status reasonable and accessible? – **Yes.**
2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? – **Yes.**

3. Should the NRC develop a new tailored pathway? – **No.**
4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300? – **Yes.**
5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals? – **Requirements should remain the same.**

B. What certification boards other than those already recognized by the NRC should be considered? – **None.**

These radionuclide therapies are complicated, and newer radiopharmaceuticals will be developed for use in the near future. Use of current and new radiopharmaceuticals will require extensive knowledge, experience and skill. There is a great potential for benefit to patients with these therapies. However, substandard practice has the potential to produce great harm to patients. Risk of harm to patients is increased if training and experience requirements are reduced.

I believe that evaluation of Authorized Users that is competency-based would be best. Examinations to document sufficient knowledge is a recommended process. These examinations can be provided by the certification boards, ABNM and ABR. Maintenance of certification is suggested, as new therapies are expected to be introduced in the next several years. Accreditation of laboratories providing radionuclide therapy is suggested. Such an accreditation process is currently being planned by SNMMI. Proficiency testing of laboratories/department providing these therapies, where the labs/departments can document satisfactory receipt, handling of radiopharmaceuticals and knowledge and skill of the physicians can be documented. I believe that SNMMI would be able to provide such proficiency training.

Therefore, I recommend that the NRC maintain current training and experience requirements for provision of radionuclide therapies by all authorized users.

Sincerely,

Bennett S. Greenspan, MD, MS