NRC Advisory Committee on Medical Uses of Isotopes Spring Meeting

The Nuclear Regulatory Commission (NRC) held the spring meeting of its Advisory Committee on Medical Uses of Isotopes (ACMUI) on April 3 and 4 in Rockville, MD. The committee discussed several issues of importance to the nuclear medicine community, including changes to 10 CFR Part 35, ^{68}Ge/^{68}Ga generator licensing guidance, and training and experience (T&E) requirements.

10 CFR Part 35

Lisa Dimmick, NRC Medical Radiation Safety Team Leader, provided a brief update on the status of 10 CFR Part 35, to which changes became effective on January 14, 2019. NRC incorporated many of SNMMI's recommendations into these changes. Major new elements are related to: permanent implant brachytherapy medical event reporting and notification, naming of associate radiation safety officers on a medical license, generic T&E changes for all individuals, and requirements for molybdenum breakthrough measurement frequency and reporting of failed generators. NRC plans to offer public webinars to educate stakeholders on these changes.

^{68}Ge/^{68}Ga Pharmacy-Grade Generator Licensing Guidance

ACMUI member Megan Shober provided a brief update on current and proposed revised ^{68}Ge/^{68}Ga generator licensing guidance. As currently written, the 2017 guidance specifically names the Eckert & Ziegler brand of generator, includes a designated breakthrough limit, describes steps to take if a generator has not been eluted within 48 hours, requires notification to the NRC Operations Center if an eluate exceeds breakthrough levels, and requires wipe tests each day of use. Proposals under consideration for guidance revision include making generator language brand neutral, removal of reconditioning requirements for generators not eluted within 48 hours, and revising breakthrough reporting requirements (e.g., pertaining to "multiple" failures). NRC intends to release the revised guidance in the coming months.

Training and Experience Requirements

Darlene Metter, MD, ACMUI member, provided an update to the NRC Commissioners on T&E requirements for all modalities. An ACMUI subcommittee was formed in 2016 with the charge to periodically review T&E requirements in 10 CFR 35 subparts D (35.190, 35.290) and E (35.390, 35.392, 35.394, 35.396) and to make recommendations on needed or proposed changes in these requirements. During the spring 2018 ACMUI meeting, the subcommittee had noted 2 concerns:

1. The approval of ^{177}Lu-DOTATATE for treatment of somatostatin receptor–positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut. The ACMUI believed these broad indications to treat the second-most-common gastrointestinal tumor might result in a high demand for ^{177}Lu-DOTATATE.
2. The waning number of nuclear medicine physicians in the United States. The subcommittee recommended that an alternate Authorized User (AU) pathway be considered and also identified several specific tasks to be accomplished in exploring a limited AU pathway.

During the year between the 2018 and 2019 spring meetings, the subcommittee gathered information and reported on the results of their research.

Regarding the potential AU shortage, the ACMUI subcommittee noted 2 pathways under 10 CFR 35.390 to address the AU shortage: (1) Board certification (American Boards of Nuclear Medicine, Radiology, or Osteopathic Radiology) in nuclear medicine or radiation oncology; and (2) an alternative pathway that would include 700 hours of T&E (with 200 lab hours in basic radionuclide handling techniques in the medical uses of unsealed byproduct material requiring a written directive) in a redesigned diagnostic radiology program (with 16 months of nuclear medicine in a 48-month diagnostic radiology residency) or a nuclear radiology residency.

The ACMUI subcommittee identified individuals who, under these pathways, would be eligible in 2018 and 2019:

- 2018–2019 AU 35.390 pipeline: 921 (graduate totals including Pathways 1 and 2);
- 2019 graduates: 269 (graduate totals including Pathways 1 and 2); and
- 2018 American Board of Nuclear Medicine: 3,591 practicing AUs.

The ACMUI Subcommittee also reviewed the Limited-Scope Authorized User pathway. Dr. Metter reported that radionuclide therapy is the highest risk and highest impact of all nuclear medicine procedures. The subcommittee believes that all individuals must have a basic level of training and experience necessary to protect public health and safety and the equivalent level of procedural competency. Appropriate training would include basic knowledge of topics in 35.390, and, because of the complexity of these topics, any category would include nearly all of 35.390. As such, the subcommittee recommended against a limited-scope AU pathway.

The final ACMUI conclusions and recommendations on T&E included:

(Continued on 22N)

TABLE 1 (Continued)

United States		
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- The ACMUI strongly supports the current AU pathways for 35.390, which protect the public's health and safety;
- No objective data support the existence of an AU shortage;
- The ACMUI does not recommend a limited-scope AU pathway for unsealed byproduct material for which a written directive is required; and
- The ACMUI unanimously agrees that if the NRC pursues a limited-scope AU pathway, the AU candidate must attest to the acquisition of 35.390 topics and skills by successfully completing a formal competency assessment with continued formal periodic reassessment to maintain his or her limited-scope AU status.

In a statement released on April 25, the SNMMI noted agreement with the ACMUI on the importance of patient and public safety but also emphasized the need to ensure access to quality care. SNMMI has provided feedback to NRC and the ACMUI on this topic. The most recent comments were submitted in January 2019. The next ACMUI public meeting will be held in fall 2019.

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