

NRC Advisory Committee on Medical Uses of Isotopes Fall Meeting

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The Nuclear Regulatory Commission (NRC) held the fall meeting of its Advisory Committee on Medical Uses of Isotopes (ACMUI) on September 20 and 21. The ACMUI typically has public meetings each year during the spring and fall and holds public teleconferences as needed. At the fall meeting, ACMUI members and NRC staff discussed several topics of importance to the nuclear medicine community, including training and experience (T&E) requirements, nursing mother guidelines, and compounding of sterile and nonsterile radiopharmaceuticals.

Training and Experience Requirements

ACMUI member Darlene Metter, MD, provided an update on T&E requirements for all modalities. As previously reported (*J Nucl Med.* 2018;59[5]:7N), an ACMUI subcommittee has been reviewing T&E requirements in 10 CFR subparts D (35.190, 35.290) and E (35.390, 35.392, 35.394, 35.396) and preparing recommendations for/against changes in these requirements. During the March 2018 ACMUI meeting, the subcommittee noted 2 concerns: (1) Potential results of 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 could result in a high demand for ^{177}Lu -DOTATATE. (2) The decreasing numbers of nuclear medicine physicians in the United States. As a result, the subcommittee recommended that an alternate Authorized User (AU) pathway be considered and identified several areas that must be explored before such a pathway could be created. These include but are not limited to assessing: feasibility for certain categories of radiopharmaceuticals, how these categories should be defined, appropriate T&E requirements, and appropriate methods for measuring competency (e.g., number of hours or objective assessments).

In addition, NRC staff reported that after the 2017 10 CFR Part 35 revision, the NRC had tasked staff with investigating the feasibility of a limited AU pathway specifically for radiopharmaceutical therapy. NRC staff conducted limited outreach in April and May of 2018 and concluded that

additional information gathering would be necessary. NRC staff plan to post a *Federal Register* notice with questions, hold public meetings/webinars, send letter/emails, and create newsletter articles. Stakeholders will include licensees, regulators, medical specialty boards, patient health organizations/advocacy groups, trade organizations/industry groups, medical professional societies, medical specialty training/fellowship organizations, and the medical oncology community. NRC staff also plan to evaluate a possible AU shortage, review medical and radiation safety events, and gather international benchmark information.

Specific questions to be included in the *Federal Register* notice will address: establishing tailored T&E requirements for radiopharmaceutical uses requiring a written directive; assessment of knowledge, skills, and abilities; and patient access. NRC staff plan to analyze all public comments and information, continue to engage the ACMUI, and determine whether changes to current T&E requirements are warranted.

Nursing Mother Guidelines

Metter also provided an update on the progress of the Nursing Mother Guidelines Subcommittee. The group's charge was to review radiation exposure from diagnostic and therapeutic radiopharmaceuticals, including brachytherapy, to the nursing mother and child. The subcommittee presented its draft report during the February 1, 2018, public ACMUI teleconference. The report's recommendations focus on: nursing interruptions with specific radiopharmaceuticals, radiation exposure to the nursing child, and nuclear medicine department signage.

Compounding of Sterile and Nonsterile Radiopharmaceuticals

ACMUI member Richard L. Green, RPh, BCNP, provided a brief update on the latest activities within the U.S. Pharmacopeia (USP). The USP currently has Chapter <797> on Pharmaceutical Compounding—Sterile Preparations and the proposed General Chapter <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging open for public comment. SNMMI submitted comments during November.