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 10 and 11. Among the issues discussed were training and experience (T&E) requirements and the status of U.S. Pharmacopeia (USP) General Chapter <825> for radiopharmaceuticals.

T&E Requirements

NRC staff summarized information on feedback from an open comment period on potential changes to previously discussed T&E requirements in nuclear medicine. The following were among the comments highlighted: nuclear medicine and radiation oncology communities oppose any change to T&E and support the status quo; "nontraditional" physicians wish to treat patients with "patient-ready" radiopharmaceuticals, support tailored T&E, and suggest 80 h of T&E; the Organization of Agreement States (OAS) and some states oppose tailoring T&E; other states support the status quo; the OAS and some states suggest that the NRC and states should no longer review and approve T&E for physicians but, instead, should rely on other entities to credential Authorized Users (AUs).

Two options were proposed by NRC staff for consideration: (1) revise the T&E regulatory framework to remove prescriptive requirements, with the NRC and Agreement States no longer reviewing and approving T&E for AUs; and (2) maintain or enhance the existing T&E regulatory framework. (For more information see page 20 of the ACMUI agenda at https://www.nrc.gov/docs/ML1924/ML19247E282.pdf). Immediate next steps on this issue include a review of/comments on these options by the ACMUI T&E Subcommittee, with Agreement State review; an ACMUI Public Teleconference on the T&E Subcommittee comments; and finalization of an NRC paper on this issue by December 20.

SNMMI has already provided extensive feedback to NRC and the ACMUI on this topic, with the most recent comments submitted in July. These highlighted several issues: any reduction in current requirements will compromise the safety of patients, their caregivers, and family members; parenteral radionuclide therapy can be administered safely only by personnel with an extensive understanding of radiation physics, radiopharmacy, pharmacokinetics, dosimetry, and radiation biology, as well as the principles and practices of radiation safety; and there is no identified shortage of AUs, so there is no reason for a change in the current requirements.

USP General Chapter <825>

Nuclear pharmacist and ACMUI member Richard L. Green presented information on a range of items included in the new USP General Chapter <825>, first announced to the public on June 1. Chapter <825>, Radiopharmaceuticals–Preparation, Compounding, Dispensing, and Repackaging, provides uniform minimum standards for sterile and nonsterile radiopharmaceuticals for humans and animals as part of state-licensed activities. The new chapter had been proposed as a result of widespread recognition that the existing General Chapter <797> underserved the needs of the nuclear medicine and pharmacy communities and that specific standards based on the unique characteristics of radiopharmaceuticals should be created. This concern was addressed by the USP by inclusion of some standards for compounded sterile radiopharmaceuticals in the subsequent revisions of <797>, but many believed these to be inadequate. After seeking stakeholder feedback, the USP agreed to create General Chapter <825> specifically for radiopharmaceuticals. The new chapter was anticipated to go into effect on December 1.

Update: In an unexpected move less than 2 wk after the ACMUI meeting, the USP issued a statement on September 23 announcing a postponement of the chapter "until further notice." Several appeals filed after the June 1 announcement of the new chapter remain pending. The results of these appeals could affect General Chapters <795>, <797>, and <825>. USP's bylaws provide that the date by which conformance with a standard is required should be postponed while an appeal is pending. USP indicated that the following apply to compounding chapters currently under appeal: chapters <795>, <797>, and <825> will be postponed until further notice; none of these chapters will become official on the originally anticipated date of December 1; and regardless of the outcome of the appeals process, USP would not reestablish an official date for chapters <795>, <797>, or <825> without granting another 6-mo implementation period, at a minimum.