NRC Regulation of Accelerator Products

The eagerly anticipated U.S. Nuclear Regulatory Commission (NRC) draft rulemaking on naturally occurring and accelerator-produced radioactive material (NARM) was released for public comment on July 28. Titled "Requirements for the Expanded Definition of Byproduct Material," the rulemaking would revise the Atomic Energy Act of 1954 definition for "byproduct material," add a definition for "discrete source," amend existing regulations to include radium-226 and certain accelerator-produced radioisotopes, and modify the regulatory framework to account for these new materials.

The ACNP/SNM Joint Government Relations Committee's NRC Task Force has been actively involved in the public NARM rulemaking process since the passage of the Energy Policy Act of 2005. The task force is currently analyzing the proposed NARM regulations and will submit comments before the close of the public comment period on September 11. Of principal concern to the task force is that the rulemaking be written with patient access to radiopharmaceuticals in mind.

The NRC will hold a public meeting on August 22 in Las Vegas, NV, to solicit verbal comments from interested members of the public. To view more information about this meeting and/or the NARM rulemaking in general, please visit the NRC Web site at: http://ruleforum.llnl.gov/cgi-bin/rulemake?source=narm&st=prule or the SNM Web site at www.snm.org/GovernmentRelations.

USP General Chapter <797> Proposed Revisions

At this writing, efforts are underway by the SNM Radiopharmaceutical Sciences Council Committee on Pharmacopeia and SNM leaders to develop draft comments in response to the recent revisions of U.S. Pharmacopeia (USP) General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.

Hugh Cannon
SNM Director of Public Affairs

Prior to the June 16 USP Compounding Stakeholder Forum meeting, SNM submitted a written statement—cosigned by the Nuclear Pharmacy Section of the American Pharmacists Association, the Council on Radionuclides and Radiopharmaceuticals, and the National Association of Nuclear Pharmacies—containing 4 general requests regarding the proposed revisions of <797>. Essentially, SNM and its allies:

(1) Called for refining the definitions of compounding, preparation, and dispensing;
(2) Requested that the USP refrain from prescriptive requirements on methods to achieve desired competencies and outcomes;
(3) Requested that for adaptability, the USP substitute the word "should" for the word "must" used throughout the text; and,
(4) Asked for a cost evaluation by the Office of Management and Budget.

SNM expanded on these four concepts with detailed recommendations prior to the close of the public comment period on August 15. The SNM comments may be viewed online at http://interactive.snm.org/index.cfm?PageID=5466.

To download and view the proposed revisions of USP <797>, please visit the USP Web site at www.usp.org/USPNF/pf/generalChapter797.html ✳