Committee on Pharmacopeia: Most Recent Proposed Revisions to USP <797>

Throughout the year, the Committee on Pharmacopeia (COP) of the SNM Radiopharmaceutical Sciences Council keeps members of the nuclear medicine community apprised of important news through the SNM Web site, periodic announcements, educational offerings at professional meetings, and articles in the pages of Newsline. This article reviews the most recent proposed revisions to the *United States Pharmacopeia* (USP) General Chapter <797>, titled "Pharmaceutical Compounding—Sterile Preparations." The entire text of these revisions is available at www.usp.org/healthcareInfo/pharmInfo/revisions797.html.

A public meeting hosted by the USP Expert Committee on Sterile Compounding was held at the USP Headquarters on November 15–16, 2005, in Rockville, MD, to discuss various issues related to these proposed revisions. Before this meeting, comments on proposed revisions to <797> were compiled and reviewed by the SNM COP, and the final version of comments was submitted to the USP on behalf SNM. A summary of our comments follows:

- The new definition for term "preparation" suggests that the "preparation" (or "compounded sterile preparation, CSP") may contain sterile "product(s)," which is (are) defined as commercially manufactured sterile drug(s) or nutrient(s) as per the proposed revisions to <797>. In order to ensure that <797> is consistent in its verbiage, COP suggested that the proposed definition for "preparation" be revised as follows:

  A preparation, or compounded sterile preparation, CSP, is a sterile drug or nutrient ~~prepared~~ **compounded** in a licensed pharmacy or other health care related facility pursuant to the order of a licensed prescriber, which may or may not contain sterile products.
- A radiopharmaceutical prepared with the use of a reagent kit ("cold kit") should not be considered as a "preparation" (i.e., "compounded sterile preparation, CSP"), as it is a commercially available drug, nor would it be considered a "product," since it is a commercially manufactured drug to be reconstituted using another commercially manufactured drug(s), rather than a single commercially manufactured drug. As such, COP would like to suggest that the definition of "product" be modified as follows:

  A product is a commercially manufactured sterile drug or nutrient **or a commercially manufactured sterile drug or nutrient that is to be reconstituted or combined with another (other) commercially manufactured sterile drug(s) in accordance with the manufacturer's labeling. Products have** ~~that has~~ been evaluated for safety and efficacy by the U.S. Food and Drug Administration, FDA. Products are accompanied by full prescribing information~~,~~ **and, when applicable, preparation information,** which is commonly known as the FDA-approved manufacturer's labeling or product package insert.
- One of the revised standards and clarifications pertaining to "product" as per the proposed revisions is the "use of sterile products is not subject to <797> unless their preparation, packaging, and storage deviates from their product package inserts, or their preparation requires sterilization (i.e., involves a high-risk level component)." This statement suggests that if there is any deviation from the package insert with regard to the preparation, packaging, and storage of a "product," then adherence to <797> would be required even if the aforementioned deviation (e.g., exceeding the recommended radioactivity limit, using an alternative heating or quality control method, etc.) does not affect the sterility status of the finished "product." Therefore, COP would like to recommend an alternative statement as follows:

  Use **and preparation** of ~~sterile~~ products is not subject to <797> unless their preparation, packaging, and storage deviates from their product package inserts **in such a manner that sterility of the final product could be potentially compromised,** or their preparation requires sterilization (i.e., involves a high-risk level component).

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