

COMMENTARY

USP General Chapter <797> Pharmaceutical Compounding— Sterile Preparations

The *United States Pharmacopeia 27* and *National Formulary 22 (USP 27-NF 22)*, also known as *USP-NF 2004* lists a new general chapter, “Pharmaceutical Compounding—Sterile Preparations” (<797>), in which radiopharmaceuticals are explicitly included under the definition of compounded sterile preparations (CSPs) (1). Chapter <797> was previously titled “Sterile Drug Products for Home Use” (<1206>).

Enforceable Guidance

According to *USP 27-NF 22*, general chapters numbered from <1> to <999> include general requirements for tests and assays, whereas general chapters that are informational are numbered from <1000> to <1999> (2). Chapter <1206> was renumbered and renamed in order to “provide better enforceable guidance to qualified health care professionals who compound sterile preparations” as stated in the commentary section of *USP 27-NF 22* (3). The USP decision to make such a revision (i.e., converting a non-enforceable <1206> to an enforceable <797> status) was the result of 2 actions (3):

1. After the enactment of the Food and Drug Modernization Act (FDAMA), which was signed by President Clinton on November 21, 1997, the FDA published a concept paper (available at www.fda.gov/cder/fdama/difconc.htm) pertaining to FDAMA section 127 on Pharmacy Compounding that recommended <1206> as the standard to be used in the preparation of compounded sterile products.
2. After a meeting held on July 13, 2002, the FDA Advisory Committee on Compounding recommended that <1206> be recognized as the national standard for compounded sterile preparation techniques and practices.

In April 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) posted an announcement titled “Compliance with New USP-NF Chapter on Compounding Sterile Preparations” on the Web site of the Joint Commission Resources, an affiliate of JCAHO (4). This news release indicated that the JCAHO was surveying compliance with <797> as of the same date of the Web

announcement (4). Starting July 1, 2004, JCAHO analysts will address these requirements during surveys of organizations that compound sterile products (4).

“The new requirements match extremely well with our 2004 standards but are more detailed,” explains Darryl Rich, PharmD, associate director for surveyor management and development at the JCAHO. “Compliance with the USP-NF Chapter 797 will certainly help organizations comply with our standards in the area of sterile medication preparation and infection control” (4). Thus, JCAHO encourages organizations to comply with the requirements as stated in <797> by immediately evaluating their current practices in light of the new USP general chapter and implementing appropriate changes (4). According to a national survey conducted in 2003 and cited in the April 2004 JCAHO announcement (4), only 5.2% of hospitals were in compliance with guidelines similar to <797>.

Revision of <797>

There is no doubt that the practices and standards described in <797> for compounding sterile preparations will serve to prevent patient death and/or injury. However, to ensure that the practice of preparing sterile radiopharmaceuticals will not be overburdened and/or limited by various impractical or restrictive criteria and standards as listed in <797>, the nuclear medicine community should be aware of the contents of this important document, as well as its potential implications for our profession.

Our community unfortunately missed the opportunity to voice our concerns and suggestions about <797> during the USP public review and comment period. It is, therefore, fortunate that USP standards are under a constant state of revision. The USP establishes standards for drugs through a rigorous peer-review process conducted by the Council of Experts and expert committees, as well as through a review-and-comment process that is open to the general public. A request for revision may come from any interested entity or individual.

The project of revising <797> was assigned to the USP Parenteral Products—Compounding and Preparation Expert Committee. The committee chair and staff liaison

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for the aforementioned committee are David W. Newton, PhD, and Claudia C. Okeke, associate director, respectively.

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*Chair, SNM Committee on Pharmacopeia**

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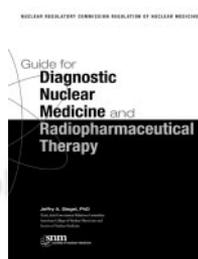
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1. Pharmaceutical compounding—sterile preparations. USP <797>. In: *First Supplement to The United States Pharmacopeia*, 27th rev.; and *The National Formulary*, 22nd ed. Rockville, MD: United States Pharmacopeial Convention, Inc.; 2004:3121–3138.
2. General Notices and Requirements. In: *The United States Pharmacopeia*, 27th rev., and *The National Formulary*, 22nd ed. Rockville, MD: United States Pharmacopeial Convention, Inc.; 2004: 1–12.
3. Commentary. In: *The United States Pharmacopeia*, 27th rev., and *The National Formulary*, 22nd ed. Rockville, MD: United States Pharmacopeial Convention, Inc.; 2004: xxxv–xxxvi.
4. Joint Committee on Accreditation of Healthcare Organizations. *Compliance with New USP-NF Chapter on Compounding Sterile Preparation*. Oakbrook Terrace, IL: JCAHO; 2004. Available at www.jcra.com/subscribers/perspectives.asp?durki=6952&site=10&return=6065. Accessed May 5, 2004.

Combined Guide to NRC Compliance Now Available

At the 51st Annual Meeting of the SNM in June, the Society will release *Guide for Diagnostic Nuclear Medicine and Radiopharmaceutical Therapy*, a new volume of guidance for compliance with Nuclear Regulatory Commission (NRC) requirements under revised 10 CFR Part 35. Author Jeffrey A. Siegel, PhD, Chair of the Joint Government Relations Committee of the American College of Nuclear Physicians and the SNM, noted in the book's foreword that "There is no question that licensees must comply with NRC regulations, but doing so by adopting regulatory guidance is not necessary. The NRC has clearly stated that its guidance for licensing under 10 CFR Part 35 is not intended to be the only means of satisfying requirements for a license." To that end, Siegel worked with NRC reviewers and with representatives from a number of professional medical organizations to review the regulations to provide specific guidance in meeting new risk-informed, outcomes-based requirements. The diagnostic portion of the volume appeared in 2003 under a separate cover. The combined volume now includes radiopharmaceutical therapy.

"This book is intended to serve as a useful bridge between the new regulations and practitioners who want to ensure continued compliance and maintain the security and safety of licensed materials in clinical and research settings," said Siegel. The book includes a complete "walk-through" of the regulations, focusing on radiation protection programs and implementation procedures necessary for compliance. "We have also attempted to point out procedures that may not be necessary or that may be necessary to establish the documented radiation safety



track record necessary for a licensee to unilaterally revise its radiation protection program to discontinue or modify certain components," said Siegel. "At a Glance" boxes throughout the book summarize the most important regulatory issues and pertinent regulations. The book may be used by diagnostic nuclear medicine and radiopharmaceutical therapy

practitioners in place of NUREG-1556, Volume 9, Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical License, issued by the NRC in October 2002 as guidance for licensing all medical by-product material under 10 CFR Part 35.

The NRC views this book "as providing focused information that may be useful to nuclear medicine professionals in understanding the applicability of NRC requirements to the medical use of by product material in diagnostic and radiopharmaceutical therapy settings, and as providing measures that practitioners in these settings may use to facilitate implementation of the revised rule."

"For all practitioners, the primary and paramount focus remains on the accurate, timely, and safe diagnosis and treatment of illness and disease," said Siegel. "Compliance with changing federal regulations and increased familiarity with the implications of these regulations will assure both practitioners and patients of adequate and effective radiation safety practices."

For information on purchasing the book, visit www.snm.org.