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Chapter <797> Pharmaceutical Compounding—Sterile Preparations

In recent years, there have been isolated published reports of patient injury and death related to improperly compounded sterile preparations (CSP's). These reports have prompted state, federal, and professional organizations to examine the adequacy of the current framework of standards pertaining to CSP's. The United States Pharmacopeia Convention (USP) convened an expert committee to consider revisions to the USP chapters that would apply to all health care practice settings that prepare sterile products for medical use. The result of their work is USP <797>, "Pharmaceutical Compounding — Sterile Preparations," which officially became enforceable January 1, 2004.

The stated intent of USP <797> is "to prevent harm and fatality to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins, large content errors in the strength of correct ingredients, and incorrect ingredients in CSP's. The introduction to USP <797> notes that "sterile compounding requires cleaner facilities, specific training and testing of personnel in principles and practices of aseptic manipulations; air quality evaluation and maintenance; and sound knowledge of sterilization and solution stability principles and practices." The document states further that, "injections for administration into the vascular and central nervous systems pose the greatest risk of harm from nonsterility and large errors in ingredients."

USP Chapter <797> is currently enforceable by the FDA. State boards of pharmacy, medicine, and nursing have either adopted it into statute and regulations or are considering whether it should be adopted. JCAHO has also incorporated this chapter into their standards. <797> has generated many concerns in pharmacies and health care facilities because of its

many new and difficult requirements, and its new enforceable status. Radiopharmaceuticals are considered a preparation or a compounded sterile product according to this chapter. Because of shielding requirements and other considerations unique to preparing radiopharmaceuticals, total compliance with <797>, as written, by nuclear pharmacies and nuclear medicine departments is not feasible.

The SNM committee on Pharmacopeia together with the SNM Radiopharmaceutical Sciences Council communicated concerns to the USP Sterile Compounding Committee (SCC) in the fall of 2004. As a result of comments from SNM and other organizations and individuals, the SCC met and approved proposed revisions to <797>.

The following proposed revisions that may affect radiopharmaceutical preparations were reproduced from the summary prepared by Dr. David Newton, who serves as the chair of the SCC. His complete summary of the proposed revisions can be assessed at the USP Web site @ www.usp.org/standards/proposed797Revisions.html

1. Definitions to differentiate preparations from products.

A PREPARATION, or compounded sterile preparation, CSP, is a sterile drug or nutrient prepared 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 PRODUCT is a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA.

STERILE COMPOUNDING pertains to all pre-administration manipulations of CSP's, including preparation, storage, and transport, but not to administration of CSPs to patients. Sterile compounding differs from nonsterile compounding primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components, and the achievement of sterility when compounding with unsterile ingredients and components. 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).

2. Exemption for “immediate use” (this exemption was honored by the JCAHO in 2004):

Three or fewer sterile products may be prepared in worse than ISO Class 5 air when there is no direct contact contamination, and administration begins within 1 hour and is completed within 12 hours of preparation.

3. Hazardous drugs:

This new section addresses safety precautions and practices when hazardous drugs (i.e., those that can cause abortion, allergy, birth defects, blisters, burns, cancer cytotoxicity, genetic damage, infertility, irritation sensitivity, vital organ toxicity, or other adverse effects) are ingredients in CSPs. This section refers PET compounding to USP <823>, and it contains a statement about safe practices for all other radioactive sterile compounding. Currently official <797> requires positive pressure for all sterile compounding, but that is wrong for compounding radioactive and other hazardous drugs.

4. Physical inspection:

Direct visual inspection of highly sensitive CSPs is not required based on maintaining radiation exposures As Low As Reasonably Achievable (ALARA).

5. Storage and Beyond Use Dating:

Technetium-99m/Molybdenum 99 generator systems shall be stored and eluted (operated) under conditions recommended by their manufacturers and applicable state and federal regulations.

References

1. Hung JC. Exemption of radiopharmaceuticals from <797> from the SNM Committee on Pharmacopeia. J Nucl Med. 2004;45(10):13N,14N,16N
2. The United States Pharmacopeial Convention, Inc. Website. Available at www.usp.org/standards/proposed797Revisions.html.

FDG PET Approved for Cervical Cancer Staging

The Centers for Medicare and Medicaid Services has determined that there is sufficient evidence to conclude that FDG PET is reasonable and necessary for the detection of metastases during the pre-treatment management phase (i.e., staging) in patients with newly diagnosed and locally advanced cervical cancer with no extra-pelvic metastasis on conventional imaging tests, such as CT or MRI. Use of FDG PET as an adjunct may more accurately assist in the non-invasive detection of para-aortic, pelvic nodal involvement and other metastases in the pre-treatment phase of disease. The following conditions must be met:

- Pathologic diagnosis of cervical cancer prior to PET FDG scan being performed
- Reported results of other imaging procedures (e.g., CT or MRI) and
- Negative conventional imaging tests for extra-pelvic metastasis

Clinical Nuclear Medicine Video Tapes

For our customers' benefit, Radiopharmacy keeps a variety of teaching and educational materials on hand. One such item is “Clinical Nuclear Medicine 2001”, a series of videos covering a range of nuclear medicine topics. There is no charge for use of the videos. However, we would ask that videos be returned within one week to allow for use by others.

The series has nine programs containing 18 hours AMA/PRA category 1 CME credit. Below is a listing of the programs:

Program 1

- 1 Spectrum of PET Imaging
Alan D. Waxman, M.D.
- 1 Multimodality Approach to the Solitary Pulmonary Nodule
Martin P Sandler, M.D.
- 1 Overview of Nuclear Oncology
Alan D. Waxman, M.D.

Program 2

- 1 Sentinel Lymph Node Detection in Breast Cancer & Melanoma
Naomi P. Alazraki, M.D.
- 1 Fusion Imaging: SPECT/CT SPECT/SPECT, FDG/CT
Naomi P. Alazraki, M.D.

Program 3

- 1 The use of Bone Scanning in Benign & Malignant Disease
Ronald L. Van Heertum, M.D.
- 1 Bone Mineral Densitometry
Naomi P. Alazraki, M.D.
- 1 The ACR Nuclear Medicine Accreditation Program: How it Works; What it Means
Ronald L. Van Heertum, M.D.

Program 4

- 1 Dual Head Coincidence Imaging and Functional Anatomical Mapping
Martin P. Sandler, M.D.
- 1 Functional Brain Imaging
Alan D. Waxman, M.D.
- 1 Radiopharmaceuticals: A Look to the Future
Mark J. Carvlin, Ph.D.

Program 5

- 1 Lung Scanning: Interpretation & Current Thinking in an Era of Spiral/Helical CT
Ronald L. Van Heertum, M.D.
- 1 Radionuclide Therapy: Graves' Disease, Thyroid Cancer, Bone Pain Palliation & Lymphoma
Andrew T. Taylor, M.D.
- 1 Thyroid-Parathyroid Imaging
Martin P. Sandler, M.D.

Program 6

- 1 Renal Scintigraphy: Quality Control, Obstruction, & Renovascular Hypertension
Andrew T. Taylor, M.D.
- 1 Renal Scintigraphy: Case Reviews
Andrew T. Taylor, M.D.

Program 7

- 1 Gated SPECT: Interpretation and Reporting
Daniel S. Berman, M.D.
- 1 The Cost Effectiveness of PET Myocardial Perfusion Imaging with PET and Rubidium-82
Michael E Merhige, M.D.
- 1 Diagnosis and Prognosis Using Gated SPECT of Patients With Suspected Coronary Artery Disease
Daniel S Berman, M.D.

Program 8

- 1 FDG PET vs. FDG SPECT for Detecting Hibernating Myocardium
Jack A Ziffer, Ph.D., M.D.
- 1 Using PET with Rubidium-82 to Guide Coronary Disease Reversal with Aggressive Management
Michael E. Merhige, M.D.
- 1 Non-invasive Cardiac Imaging: Evaluation of Diagnostic Utility and Cost Effectiveness
Jack A. Ziffer Ph.D., M.D.

Program 9

- 1 Risk Assessment and Diagnosis of Patients with Acute Chest Pain Syndromes
Jack Ziffer, M.D.
- 1 Gated SPECT: Clinical Benefit of Combining Perfusion and Function Assessment
Daniel S. Berman, M.D.
- 1 Advances in PET Perfusion Imaging: Toward A Complete Study in Under 30 Minutes
Michael E. Merhige, M.D.

Technologist Job Line

Numed, Inc. Is looking for a Full Time or Part Time Nuclear Medicine Technologist to rotate between Wash General Hospital in Mt. Carmel, IL and Lawrence County Memorial Hospital in Lawrenceville, IL. Contact Blaine Norton at 618-847-8221.

If you have questions about anything in the “Monthly Scan” don't hesitate to call us at

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