

Implications of USP 797 in the Nuclear Cardiology Lab

The revised version of General Chapter 797—an enforceable chapter of the US Pharmacopeia (USP)¹—was created in an effort to reduce patient infection rates and to better protect hospital and clinical staff by recommending protocols and conditions for handling and preparing pharmaceutical products.

The USP Convention sets US standards for ensuring drug quality, but is not an enforcement agency.¹ Other agencies, most likely at the state level, will be responsible for deciding which specific recommendations of USP 797 to enforce for compliance.¹ The revised chapter addresses the requirements for the preparation and handling of compounded sterile preparations (CSPs), which generally include most pharmacologic stress agents and radiopharmaceuticals, and is more encompassing than the Food and Drug Administration (FDA) definition of drug compounding and what constitutes compounded drugs.¹ Federal and state laws govern procedures that apply when drugs are administered to patients; USP 797 does not apply to drug administration.¹ Also note that USP 797 applies to practitioners rather than to drug manufacturers, making it an unusual though not unique USP general chapter.¹

USP 797 focuses narrowly on CSPs and defines best practices in handling, measuring, and preparing drugs for administration. Since most drugs used in the nuclear cardiology lab are supplied in vials and transferred to syringes, or supplied as prefilled, unit-of-use syringes, the focus here will be narrowed to those USP 797 recommendations that may apply to the preparation of vial- and syringe-based pharmacologic stress agents, product preparation areas, air-quality environments, and best practices leading up to actual patient administration of the products being described.

PREPARATION AREA RISK LEVELS

Most pharmaceutical products used in a nuclear cardiology laboratory (including pharmacologic stress agents) require no compounding per se. Manufacturers supply them as ready-to-use formulations, requiring weight-based dose calculation and transfer of the individualized dose from a vial to a delivery system (usually an infusion pump syringe).

According to USP 797, only a “low-risk compounding” environment is necessary for the following procedure:

“Single-volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers.”¹

Low-risk-level preparations involving aseptic manipulations can be performed under International Organization for Standardization (ISO) Class 5 or better air-quality conditions,¹ defined as an environment with 100 particles per cubic foot or less.¹ The use of a laminar flow hood may be necessary to achieve this level of air quality.²

RESPONSIBILITIES

For drugs prepared for administration, the compounding personnel:

“...are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. These performance responsibilities include maintaining appropriate cleanliness conditions and providing labeling and supplementary instructions for the proper clinical administration of CSPs.”

A special case applicable to nuclear laboratories involves separating the use of personal protective equipment (eg, syringe shields) from patients and in compounding areas.

Broadly defined, laboratory personnel are responsible for dosing accuracy (measurement), which, if doses are calculated according to a weight-based dosing formula, includes accurately weighing the



patient, calculating the recommended dose, and transferring the dose to a pump syringe if a pump infusion system will be used to deliver the drug to the patient.

IMMEDIATE-USE PROVISION

This provision is “intended only for those situations where there is a need for emergency or immediate patient administration of a CSP.”¹ This applies to “preparation of diagnostic agents”¹ under low-risk-level CSPs. It may be interpreted, therefore, as applying to radiopharmaceuticals used in myocardial perfusion imaging and ancillary products (such as pharmacologic stress agents) that may be required to help produce clinically evaluable results in patients who are unable to perform to an adequate level of exercise stress.

SINGLE-DOSE CONTAINER

Needle-punctured, single-dose containers (bags, bottles, vials, and syringes) should be used within 1 hour if opened in air-quality conditions below the minimal standard of ISO Class 5. Any remaining contents should be discarded¹ to remain compliant with best-practice procedures as described in USP 797.

Single-dose containers are defined in USP 797 as:

“...a single-unit container for articles intended for parenteral administration only. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.”¹

CONCLUSION

Best practices as presented in USP 797 apply both to individual healthcare practitioners and healthcare institutions. Therefore, the combined accuracy, measurement, and preparation area provisions can be interpreted as applying to departments within hospital settings, freestanding clinics, and the healthcare professionals who perform the procedures.

Likewise, it can be inferred that the recommendations apply to infusion pump syringes, accurately assessing patient weight, dose calculations based on patient weight, air-quality standards, and the 1-hour provision prior to patient administration.¹

With single-dose containers, ease of use and safety precautions are built-in to enhance pharmacy operations. Fewer steps from preparation to administration help reduce the chance of error. Quality assurance is built into the product preparation process, saving time and decreasing risk.³ Compliance with USP 797 and the Joint Commission may be simplified.

The website www.USP.org is a valuable resource to help achieve compliance, and includes a section on potential fines and penalties for noncompliance. An institution’s legal counsel can best interpret USP 797 and legal ramifications. Additional factors related to USP 797 compliance may also apply to those institutions and clinics that adopt the recommendations presented in the chapter, such as: overall waste reduction (“bio”) waste; less radiologic (“hot”) waste of supplies exposed during administration; and potential reduction of labor and materials.

New products supplied from manufacturers (eg, unit-dose, needleless, prefilled syringes) may offer exemptions to certain USP 797 provisions. In addition, they have the potential to generate less waste, require less preparation, reduce labor demands, and eliminate the need for air-quality-control capital investment.

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References

1. The United States Pharmacopeia. *USP <797> Guidebook to Pharmaceutical Compounding—Sterile Preparations*. Rockville, MD: United States Pharmacopeial Convention; 2008.
2. Joint Commission. *Hospital Accreditation Standards 2012*. Oakbrook Terrace, IL: Joint Commission Resources, Inc.; 2012.
3. Bates DW, Cousins DD, Flynn E, et al. Consensus development conference statement on the safety of intravenous drug delivery systems: balancing safety and cost. *Hosp Pharm*. 2000;35:150-155.