



IV Automation and Compliance with The Joint Commission



INTRODUCTION

IV compounding receives a great deal of attention from the Medication Management Standards of The Joint Commission. From a risk point of view, this is appropriate since these doses pose the highest risk in terms of their immediacy of action, relative irretrievability (that is, they cannot be easily removed from the body once administered) and need for sterility.

Literature suggests this area is worthy of additional attention. Both the American Society of Health-System Pharmacists (ASHP) and the United States Pharmacopeia (USP) have described best practices for production of compounded sterile products (CSPs). However, research shows that compliance with these best practices, as measured by providers themselves, is less than 5%, that an average of 15% of CSPs are still prepared by nurses in patient care areasⁱ and that contamination rates for CSPs prepared in pharmacy IV rooms can be as high as 5%.ⁱⁱ

While The Joint Commission does not inspect to these standards, it specifically cites USP <797> (the chapter on sterile compounding practices) as a *best practice* and demands that institutions consider these practices and develop a reasonable plan for their implementation.ⁱⁱⁱ

USP is considered a significant standard of practice and is subject to FDA inspection and enforcement. Hospitals may face tort liability for failure to comply as well.^{iv}

Irrespective of USP <797>, The Joint Commission requires that CSPs be prepared in an area that is relatively isolated, is as clean as possible and provides ISO Class 5 (Class 100) or better airflow.^v This generally does not describe the medication preparation rooms on most nursing units. The result is that The Joint Commission generally prefers having the pharmacy issue CSP doses to patient care areas in ready-to-administer formats.

Both nationally, and by most State Boards of Pharmacy, USP <797> is recognized as best practice; therefore any such preparation on a patient care area needs to be performed under the same conditions that would be present in a pharmacy.

PHARMACY DOSE PREPARATION

Regulatory compliance therefore argues heavily for all doses being sent from the pharmacy in ready-to-administer format, which requires the pharmacy to prepare, or purchase and distribute, each dose in such format. Commercially available ready-to-administer formats are useful for drugs with doses that do not vary significantly, but tend to be very expensive. For pediatrics, oncology and other patient-specific dosed medications, commercially prepared doses are not available; therefore, representing significant amounts of pharmacy labor.

Commercial ready-to-use formats also complicate Bar Code Medication Administration (BCMA) systems in that such systems are generally not architected to permit a mixture of commercial and pharmacy-prepared doses, which result in an over-labeling requirement.

PHARMACY AUTOMATION

Another significant area of interest in medication management is the operating room. Traditional practice in this area has caregivers drawing up medications in syringes and leaving them unlabeled with verbal instructions to other caregivers about the contents of the syringes. The Joint Commission correctly recognizes that this practice creates significant opportunity for medication errors with significant, potentially deadly sequelae.

Automation offers potential solutions. Compounding devices, such as the IntelliFill® i.v., can prepare specifically labeled, ready-to-administer doses, thus eliminating medication admixture in patient care areas.

The IntelliFill i.v. also produces significantly cleaner doses because it removes the most significant source of contamination, human manipulation, and fills syringes in an ISO Class 5 (Class 100) environment. IntelliFill i.v. mandates environmental monitoring activities, proper garbing and materials handling that vastly improve compliance with USP <797>.

Automation, such as IntelliFill i.v., can be used to address medication management for the OR as well. Ready-to-administer doses in case-specific packaging provides the nurse or anesthesiologist with medications already drawn up in syringes and appropriately labeled to identify the contents of each syringe.

SUMMARY

Pharmacy automation can provide significant benefits for regulatory compliance, as well as ensuring safe ready-to-administer doses for caregivers. Automated systems, such as the IntelliFill i.v., address both the USP <797> requirements for compounded sterile products and The Joint Commission best practices for medication management.

IntelliFill i.v. is manufactured for Baxa Corporation by FHT, Inc.

ⁱ Pederson, Craig A et al, *ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration—2005*, **Amer J Health-Sys Pharm** 63 pp327-345 (Feb 2006)

ⁱⁱ Trissel, Lawrence A et al, *Using a medium-fill simulation to evaluate the microbial contamination rate for USP medium-risk-level compounding*, **Amer J Health-Sys Pharm** 62:3 pp 285-288

ⁱⁱⁱ MM8.10 EP#2

^{iv} Rich, Darryl S, JCAHO, NIOSH, and State Boards of Pharmacy: *Expectations for 2006, USP Chapter <797>: Steps to Compliance in 2006* (<http://symposia.ashp.org/797steps>)

^v MM4.20