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ASHE Advocacy Alert



Hospitals being cited for compounding pharmacy issues

ASHE has received a number of reports that hospital compounding pharmacies are increasingly being cited for two easily avoidable conditions. As we get closer to the implementation of USP <800>, expected to become official on December 1, 2019, these issues may be a renewed focus of surveyors:

Integral Cove Base. Some compounding pharmacies have seamless flooring with integral vinyl covered bases. While seamless flooring is acceptable in these spaces, the cove base detail typically includes a cove base finishing cap. Flooring installations with a cove base finishing cap are being cited when found within the compounding environment because dust can settle on the cove base cap.

Engineering controls. Environmental monitoring and sampling is required in compounding areas for recertification of the primary and secondary engineering controls. Low- and medium-risk compounding areas need testing every 12 months, while high-risk compounding areas need testing every 6 months. There are two areas of concern for surveyors looking to ensure facilities meet the monitoring and sampling requirements. First, facilities must perform the monitoring and sampling at the intervals required by USP <797>. Second, hospital pharmacies, biomedical teams, and facility managers must work together to ensure that monitoring and sampling reports are handled appropriately. Reports should be reviewed and if failures are noted, necessary corrective actions must be made.

More information on the physical requirements for complying with USP <797> can be found in ASHE's monograph, Physical Environment Provisions of USP <797> "Pharmaceutical Compounding - Sterile Preparations," which is available for free to ASHE members. ASHE members also have free access to an On Demand recording, "USP 797/USP 800: Is Your Pharmacy Ready?"