



# OKLAHOMA

## State Board of Pharmacy

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### STERILE COMPOUNDING COMPLIANCE ISSUES

Retail pharmacies which compound sterile drug products under an OSBP **Parenteral Permit** must be compliant with both the USP standards and the rules and regulations of the Board. In 2009, the OSBP promulgated rules regarding sterile and non-sterile compounding which were approved legislatively and by the governor. The compounding rules were posted on the Board website at that time and have been in the OSBP Law Book since 2010.

It is imperative that pharmacists-in-charge and pharmacists who compound or supervise compounding technicians be familiar with the rules and regulations regarding compounding, and most specifically sterile compounding, which are located in OSBP rules sections 535:15-9 and 535:15-10. The pharmacist-in-charge and the pharmacy must define the risk-level of the drugs which are being compounded. Risk levels have been defined by the FDA & OSBP. Policies and procedures for compliance with OSBP rules and regulations must be written and available at the pharmacy for review by Board compliance officers.

The Board has reviewed deficiencies noted in several FDA and Board of Pharmacy inspections. These deficiencies appear to be some of the most frequently cited under the sterile compounding rules and regulations:

### STERILE COMPOUNDING TOP 12 ISSUES

1. The written policy and procedure manual must be current, precise, and explain in detail the processes used to compound sterile drugs. There may be multiple “standard operating procedures” to cover different aspects of sterile compounding in the policy and procedure manual.
2. Determination of the “risk level” of the sterile products being compounded must be made and the appropriate policies and procedures for that risk level implemented. Risk level determination information is found in chapter 535:15-10-54.
3. Written policies and procedures are required to document the method by which “Beyond Use Dates” (BUD) are established for each sterile drug product. Default “BUD information is found in chapter 535:15-10-61 and is also available in the chart in “Appendix A USP <797> Beyond Use Date Limits Chart” located at the end of chapter 525:15-10. When extended BUDs are used for sterile compounded medications, written policies and procedures outlining the routine testing for sterility and endotoxins prior to release of the product are required in conformance with Board of Pharmacy rules for sterile drug compounding. Documentation of the testing is required. Any BUD beyond the USP default dates will require documentation of stability-indicating analytical methods. Assignment of long BUDs (such as several months) would require

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documentation of testing to determine the effectiveness of anti-microbial preservatives through the BUD is required.

4. Sterilization techniques must be verified. Filter sterilization processes must be supported by documentation. Autoclave sterilization techniques must be supported by documentation. For example, each batch of autoclaved compounded preparation needs to have some form of acceptable indicator included in the run to confirm proper performance of the autoclave.
5. Documentation of adequate initial AND current training of persons who are performing sterile compounding procedures must be detailed, complete and available for review. The P&P manual must detail the initial and continuing training requirements. There must be documentation that the training detailed in the P&P has been completed and is current. The training records of personnel performing sterile compounding should include documentation of proper training prior to the person compounding sterile preparations. In addition, records of ongoing training should also be documented.
6. Clothing worn while compounding sterile drug products must be appropriate. The P&P manual should detail the clothing requirements. This should include sterile gloves, non-shedding gowns, hair and shoe covers, and other appropriate items. In addition, the clothing must be worn appropriately: sleeves down, gown buttoned, hair cover applied appropriately, etc.
7. Drug product containers such as vials and stoppers must be sterilized and pyrogen free to assure they are suitable for sterile drug compounding. Documentation from the manufacturer that the containers are sterile and pyrogen free, or written procedures and documentation of sterilization and pyrogen removal processes, is required.
8. Written policies and procedures for sterilization of equipment and utensils are required. Documentation of the procedures being followed is required.
9. Sterile Isopropyl Alcohol must be used whenever Isopropyl alcohol is utilized for cleaning or sterilization purposes.
10. Industrial detergents approved for such use must be used for cleaning equipment, utensils and drug containers. Non-shedding mops and other cleaning equipment, gowns, hair and shoe covers, etc., must be used.
11. When household dishwashers or dishwashers without a final purified water rinse cycle are used for cleaning, the policy and procedure manual should reference the methods used for sterile rinsing and depyrogenation after the dishwasher cycle has completed. Autoclaving or dry heat sterilization or separate depyrogenation at high temperature heat MAY be appropriate methods. Each pharmacy must establish their own policies and procedure.
12. Those pharmacies compounding drugs for animals should review the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), the FFD&C Act and FDA regulations in 21 C.F.R. Part 530.

**Please review *Part 3. Good Compounding Practices for Sterile Products [535:15-10-50]* of the Law Book for the full requirements of sterile drug compounding.**

**The Law Book is available on line at <http://www.ok.gov/OSBP/Rules/index.html> in PDF format and is keyword searchable to make it easier to look up specific sections of the rules and regulations.**