

**Title 20—DEPARTMENT OF  
COMMERCE AND INSURANCE  
Division 2220—State Board of Pharmacy  
Chapter 2—General Rules**

**PROPOSED AMENDMENT**

**20 CSR 2220-2.200 Sterile Compounding.** The board is amending subsection (5)(C) of the rule.

*PURPOSE: This amendment removes the requirement that Risk Level 3 preparations must remain Risk Level 3 for the life of the preparation.*

(5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. All non-sterile equipment that is to come in contact with the sterilized final preparation must be sterilized before introduction in the buffer area or into the RABS. *[Once compounded, Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation.]*

*AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.010 and 338.140, RSMo Supp. [2018] 2020.\* This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992, effective Feb. 26, 1993. For intervening history, please consult the Code of State Regulations. Amended: Filed April 14, 2021.*

*PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five-hundred dollars (\$ 500) in the aggregate.*

*PRIVATE COST: This proposed amendment will not cost private entities more than five-hundred dollars (\$500) in the aggregate.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at [pharmacy@pr.mo.gov](mailto:pharmacy@pr.mo.gov). To be considered, comments must be received within thirty (30) days after publication of this rule in the **Missouri Register**. No public hearing is scheduled.*