



Sterile Compounding Summary of Changes Between First and Second Working Drafts August 2015

The Pharmacy Quality Assurance Commission (commission) is sharing the second working draft of the sterile compounding rules for comment. The comment period runs through Wednesday, September 30, 2015. This memo summarizes the main changes between the first and second working drafts of the sterile compounding rules. Changes were made considering the comments the commission received on the first working draft.

First, the commission added a definition for “accountable pharmacist.” “Accountable pharmacist” took the place of “pharmacist-in-charge” in most rule sections and subsections.

Second, the commission clarified that the continuing education requirements for compounding are included in the existing number of required hours for continuing education. In other words, the continuing education hours for compounding are a portion of the continuing education hours already required.

Third, the commission added that beyond use dating for compounded or reconstituted products by a pharmacy must meet the United States Pharmacopeia/National Formulary.

Fourth, the commission added that clean rooms must be certified by an independent contractor according to the Controlled Environmental Testing Association Certification Guide for Sterile Compounding Facilities (CAG-003) every six months and whenever the room is altered or major service to the facility is performed.

Finally, the commission removed the following categories/ requirements regarding hazardous drugs from WAC 246-878-075. Instead, pharmacies and pharmacy personnel must follow all federal regulations and Washington State Department of Labor and Industries Chapter WAC 296-62 General Occupational Health Standards, and United States Pharmacopeia related to compounding hazardous drugs.

1. “Personal protective equipment shall be worn at all times when compounding hazardous drugs regardless of the PEC used to compound hazardous drugs.”
2. “All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel...”
3. Equipment used in the manipulation and compounding of hazardous drugs shall be used only with hazardous drugs.
4. Hazardous drugs – primary engineering control device.
5. Hazardous drugs – personal protective equipment.
6. Hazardous drugs – clean: deactivation, decontamination, cleaning and disinfection.
7. Hazardous drugs – spill control.
8. Transport.
9. Environmental quality control.



These are not the only changes the commission made based on the comments on the first draft. There are additional minor changes, including spelling and grammar changes. The commission greatly appreciates your comments and participation in the rulemaking process. Please send comments on the second working draft to SterileCompoundingRules@doh.wa.gov or by mail to Chris Humberson at the following address:

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