

657—13.20(124,155A) Sterile preparation of hazardous drugs. Hazardous drugs shall only be prepared for administration under conditions that protect pharmacy personnel in the preparation area.

13.20(1) Storage and handling. Policies and procedures shall identify appropriate storage and handling of hazardous drugs to prevent contamination and personnel exposure.

13.20(2) Caution labeling and distribution. Preparations containing hazardous drugs shall be labeled on the primary container and placed in an overwrap bag that is also properly labeled. Prepared doses of dispensed hazardous drugs shall be labeled and distributed in a manner to minimize the risk of accidental rupture of the primary container. Proper labeling shall include any necessary precautions.

13.20(3) Preparation area. All hazardous drugs shall be compounded in a vertical flow Class II or Class III biological safety cabinet or in a compounding aseptic isolator containment and control device with biohazard control capabilities.

a. It is preferable for the ISO Class 5 BSC or CAI to be placed in a contained environment, physically separated from other preparation areas, where air pressure is negative and where the ISO Class 5 BSC or CAI is appropriately vented to the outside of the building.

b. If the pharmacy compounds fewer than five preparations per week in a BSC or CAI and uses a closed system vial transfer device to compound the preparations, the BSC or CAI may be located in a positive pressure room.

13.20(4) Protective apparel. Personnel compounding hazardous drugs shall wear appropriate protective apparel in accordance with documented procedures. Protective apparel may include disposable, nonshedding coveralls or gowns with tight cuffs, face masks, eye protection, hair covers, double gloves, and shoe covers.

13.20(5) Techniques. Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for processing sterile preparations.

13.20(6) Training required. All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before personnel prepare or handle hazardous preparations and shall be verified and documented for each person at least annually.

13.20(7) Waste. Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.

13.20(8) Spills of hazardous drugs. Written procedures for handling both major and minor spills of hazardous drugs shall be developed, maintained, implemented, and adhered to. The procedures shall be maintained with the policies and procedures required in rule 13.6(155A).