

657—13.28(155A) Cleaning, maintenance, and supplies. The pharmacy shall have appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations.

13.28(1) Supplies and equipment. Required supplies and equipment shall include, but may not be limited to, the following:

a. Appropriate attire including nonshedding coveralls or gowns, head and facial covers, face masks, appropriate gloves, and shoe covers.

b. A sink with hot and cold running water, with bactericidal soap available for the purpose of hand and forearm scrubs, which shall be located convenient to the area used for compounding sterile preparations but outside the buffer area.

13.28(2) Documented procedures. Documented procedures shall include, but not be limited to, the following:

a. Specific cleaning procedures and frequencies for each compounding area involved.

b. Identification of the individual responsible for completing each procedure.

c. A list of approved cleaning agents for each procedure.

d. A written plan and schedule for the evaluation of airborne microorganisms in each controlled air environment (e.g., LAFW, barrier isolators, buffer area, and anteroom).

e. Equipment calibration, annual maintenance, and monitoring of proper function of equipment, apparatus, and devices used to compound sterile preparations.

f. An appropriate cleansing and garbing procedure. Coveralls and gowns may be hung outside the entry in the buffer area and reused for one shift, provided the coveralls and gowns are not visibly soiled and have not been worn during the compounding of hazardous drugs.