657—13.27 (124,126,155A) Physical environment requirements. The pharmacy shall have a designated area for compounding sterile preparations, with entry restricted to designated personnel. The area shall be used only for sterile compounding. The area shall be structurally isolated from other areas and shall be designed to avoid unnecessary traffic and airflow disturbances. The area shall be of sufficient size to accommodate at least one primary engineering control device and to provide for the storage of drugs and supplies under appropriate temperature, light, moisture, sanitation, ventilation, and security conditions.

13.27(1) *Requirement for primary engineering control device.* The primary engineering control device shall be capable of maintaining at least ISO Class 5 air quality in the area where critical objects are exposed and critical activities are performed. The device shall be capable of maintaining ISO Class 5 air quality during normal activity. A primary engineering control device includes, but is not limited to, a horizontal or vertical laminar airflow workbench or CAI.

13.27(2) *Placement of primary engineering control device.* The primary engineering control device shall be placed in a buffer area where HEPA filters are employed and the air quality is maintained at ISO Class 7. This area shall have cleanable, nonshedding, smooth surfaces; all junctures shall be coved; and all cracks and crevices shall be caulked. The ceiling shall be impervious and hydrophobic. The buffer area shall not contain any drains or sinks. Only the furniture, equipment, supplies and other material required for compounding activities to be performed shall be brought into the room. Such items brought into the room shall be cleaned and disinfected. Placement in buffer areas of objects and devices not essential to the compounding process is dictated by the measured effect of those objects and devices on the required environmental quality of air atmospheres and surfaces.

13.27(3) *Exception for placement of CAI.* The CAI shall be placed in an ISO Class 7 cleanroom unless the CAI meets each of the following conditions:

a. The CAI provides isolation from the room and maintains ISO Class 5 conditions when ingredients, components, and devices are transferred into and out of the CAI during the preparation process.

b. The manufacturer provides documentation verifying that the CAI meets the standard in paragraph *"a"* when the CAI is located in an environment inferior to ISO Class 7.

13.27(4) *Anteroom requirements.* Except for a CAI that meets the conditions specified in subrule 13.27(3) exempting the CAI from placement in an ISO Class 7 cleanroom, an anteroom or ante area shall be located adjacent to the buffer area and maintained at ISO Class 8 air quality. This area is to be used for unpacking and disinfecting supplies for storage and for hand sanitizing and gowning. If the sterile preparation area is to be used only for the compounding of low- and medium-risk preparations, the ante area shall be clearly demarcated for the compounding of low- and medium-risk preparations. If the sterile preparation area is to be used for the compounding of high-risk preparations, the ante area shall be physically separated from the buffer area.

13.27(5) *Delayed implementation.* A pharmacy whose sterile compounding area is in substantial compliance with the physical and structural requirements of this rule shall be authorized to engage in the compounding of sterile preparations pursuant to the practice standards established by this chapter and subject to the following:

a. Any pharmacy that commences, on or after July 11, 2007, new construction or remodeling of a pharmacy sterile compounding area shall comply with the physical and structural requirements of this rule.

b. Any pharmacy engaged in the compounding of sterile preparations shall, no later than December 31, 2010, complete any necessary changes or improvements to the sterile compounding area to ensure compliance with the physical and structural requirements of this rule.

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