

Clean Room Certification

Many pharmacies in Kentucky compound sterile preparations in a segregated compounding area often within an isolator. This article pertains to those facilities with clean rooms consisting of ante and buffer areas and the certification requirements for those rooms. Requirements for hood certification can be found in a separate article.

Clean rooms are designed to provide cleanliness of the compounding area and protect compounded preparations from air, moisture, or touch contamination. Clean rooms consist of an ante and a buffer area. The ante area is entered from the general pharmacy area and is the area in which compounders garb, gown and perform hand hygiene. The compounder enters the buffer area from the ante area. The buffer area is where the primary engineering control or hood is located and compounding occurs. The ante and buffer areas must be tested to verify that they meet operating standards and maintains the necessary ISO classification. A facility must certify any new clean room and continue to certify the clean room every 6 months. The clean room must also be certified after construction and when it is altered, when there are identified problems with end products or staff technique and in response to issues with compounded preparations such as patient infections.

The pharmacy must have a qualified certifier test the clean room to CETA guidelines or similar. These guidelines are available at

<http://www.cetainternational.org/reference/cetaasepticcompoundingcertificationguide.pdf> . The equipment used by the certifier must be calibrated. Certifiers must following the garbing and gowning requirements of the facility in order to access the room. Equipment brought into the clean room should be cleaned and disinfected according to the facility's policies and procedures.

The ante area must be certified as either an ISO Class 7 or an ISO Class 8 space. The ante area must be ISO Class 7 if it is connected to a hazardous compounding buffer area. The buffer area must be certified as an ISO Class 7 space. The certifier will perform a nonviable particle count of the areas testing for particles of 0.5 micron or larger. To certify as ISO Class 7 the buffer or ante area may not have more than 352,000 particles per cubic meter of air. To certify as ISO Class 8 the ante area may not have more than 3,520,000 particles per cubic meter of air.

The clean room must be supplied with HEPA filtered air introduced into the area from the ceiling. The certifier will leak test all HEPA filters supplying air to the ante and buffer areas and identify any requiring repair or replacement. The certifier will also test to determine if the areas have adequate airflow by testing the number of air exchanges per hour (ACPH). ISO Class 7 areas are required to have at least 30 ACPH and ISO Class 8 areas are recommended to have at least 20 ACPH. In buffer areas with a recirculating hood, the outside air supplied to the buffer area must still account for 15 ACPH (for a total of at least 30 ACPH). These are minimums for air exchanges; the areas may require more depending on the number of personnel inside the clean room and processes performed.

The certifier will also verify that the areas operate under an air cascade from the buffer area through the ante area and out into the general pharmacy area. In clean rooms in which there is complete physical separation of the ante area from the general pharmacy and the buffer area

from the ante area through the use of walls, doors, and pass-throughs, the areas must have a positive differential pressure of at least 0.02 inch water column between the buffer area and ante area and between the ante area and general pharmacy. Hazardous compounding buffer areas require a negative pressure differential. The requirements of hazardous compounding buffer areas will be discussed in another article. In clean rooms without complete physical separation between the areas, the certifier will verify an air flow velocity of at least 40 feet per minute from buffer area into the ante area. This incomplete separation is only allowed in facilities performing low and medium risk nonhazardous compounding.

Many certifiers will also perform viable air sampling and surface sampling for pharmacies. The requirements of these programs will be discussed in later articles.