

Hood Certification

Pharmacies use primary engineering controls (PEC) or hoods to provide ISO 5 classified environments in which to compound all non-immediate or non-emergency preparations. The most common PECs used are laminar airflow workbenches (LAFWs), compounding aseptic isolators (CAIs), biological safety cabinets (BSCs), and compounding aseptic containment isolators (CACIs). Every PEC must be tested to determine if it meets operating standards and maintains an ISO 5 classified environment. A facility must certify any new PEC and continue to certify the PEC every 6 months. A PEC must also be certified when it is moved or 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 PECs 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 follow the garbing and gowning requirements of the facility in order to access PECs. Equipment brought into clean rooms or into a PEC should be cleaned and disinfected according to the facility's policies and procedures.

To verify operating standards the certifier will leak test the PECs' HEPA filters. Many certifiers will also repair small leaks or replace filters. The air flow inside the hood will be tested to determine if it is unidirectional and of sufficient velocity to sweep particles away from the compounding area and maintain unidirectional airflow. The certifier will perform a smoke study to check for turbulence and stagnant air in the critical compounding area. The smoke study must be performed under dynamic conditions meaning compounding conditions. Many compounders are hesitant to compound during certification. To create dynamic conditions compounders could perform media fill tests.

To certify the PEC as an ISO Class 5 environment the certifier will perform a nonviable particle count of particles 0.5 micron or larger. To certify as ISO Class 5 the PEC will not have more than 3520 particles per cubic meter of air. This test must also be performed under dynamic conditions to show that the ISO Class 5 environment is maintained when compounding.

Depending on the type of PEC other tests might be performed. BSCs are tested to NSF International standards which require additional air handling tests. The ante chambers in CAIs and CACIs are particle tested.

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