Smith Seckman Reid, Inc.

Hospital Engineering
TRENDS

Pharmacy Used for Compounding

by: Rick Wood, PE

On July 1, 2004, Joint Commission on Accreditation of Healthcare Organizations began requiring compliance with USP-NF 797, which mandates that sterile compounding be done in a an ISO Class 5 (Federal Standard 209E Class 100) environment. There are three ways to meet this requirement:

1. Use Laminar Air Flow Workstations, designed and manufactured to maintain this cleanliness level.
2. Provide an ISO Class 5 (Federal Standard 209E Class 100) clean room.
3. Use barrier isolators, which are enclosed, positive pressure envelopes or cabinets with glove ports and view ports and are used for preparation of sterile compounds.

The rooms containing Laminar Air Flow Workstations or barrier isolators should be an ISO Class 8 (Federal Standard 209E Class 100,000) room (2003 ASHRAE Applications, page 16.8).

The owner and the architect are to decide if the compounding will be done in a Laminar Air Flow Workstation, a barrier isolator or a Class 5 clean room. The owner or the pharmacy equipment consultant will specify the Laminar Air Flow Workstation or barrier isolator, which is not part of the building HVAC system.

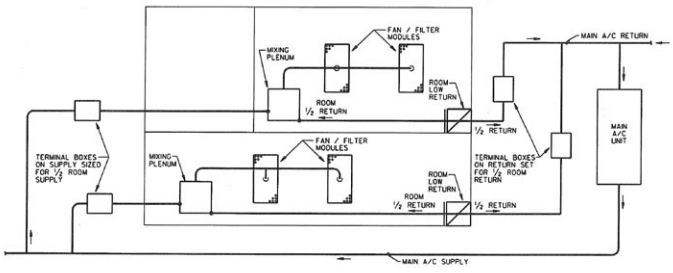
A Case Study

A large non-profit hospital in Nashville, Tenn., recently underwent a renovation of the pharmacy area, including the sterile compounding areas. Three clean rooms were added in a portion of the building, which was built in 1986. Laminar Air Flow Workstations were to be used, so the ambient conditions needed to meet Class 8 cleanliness standards but the existing HVAC system did not have the capacity to provide either the air changes or the filtration needed to maintain such standards.

In order to provide the clean room status, ceiling mounted fan/filter modules were used to increase the circulation within the spaces. These units fit in a 2 feet by 4 feet grid (although they must be supported from the structure, not the grid) and supply air into the space through HEPA filters at the ceiling. The units were sized to maintain approximately 30 air changes per hour of circulation within the space.

Because the cooling load of the spaces did not warrant 30 air changes per hour of cold supply air (and because the existing A/C unit could not provide the high cfm), the system was designed to re-circulate approximately half of the return air back to the main A/C unit and half of the room return back to the fan/filter module. A mixing plenum was provided to mix room return air and new cold supply air from the main A/C unit and then supply this mix of air to the fan/filter units.

Diagram 1: *AC Layout Chart*



In order to balance the return air, a terminal volume box was installed on the return line to the A/C unit to limit the amount of air returned. (The volume box goes on the return branch to the A/C, instead of the fan/filter module, because the A/C unit has stronger negative pressure in the return system and would pull more return air if not for the terminal box. Because the box is pressure independent, it will compensate for pressure uctuation in the A/C return system and help ensure constant return quantities to the fan/filter mixing plenum.) *See diagram 1.*

The fan/filter ceiling units provide the necessary cleanliness conditions within the spaces as intended and the mixing plenum avoids overtaxing the A/C system for unnecessary cfm. The ceiling units are a little louder than anticipated, although not objectionable – some sort of sound blanket on the outside of the unit (above the ceiling) might be desirable, as well as possibly some sort of sound attenuation inside the module (to attenuate the fan noise).

Two manufacturers of ceiling mounted fan/filter units are Precision Air HEPA-Vent FP and American Air Filter FM2-LE.

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Glossary of terms used in Compounding Pharmacies

Aseptic – Free from disease producing microorganisms.

ASHP – American Society of Health-System Pharmacists.

Barrier isolators – Enclosed, positive pressure envelopes or cabinets with glove ports and view ports and are used for preparation of sterile compounds.

Compounding – Preparation, mixing, assembling, packaging and labeling of a drug or device.

Federal Standard 209 – Previously used Federal Standard (cancelled November, 2001) that specified airborne particulate cleanliness classes in clean rooms. The quantity of particulates depended on the size of the particle but the familiar class numbers (Class 1, Class 10, Class 100, etc) came from the number of 0.5 micron particles in a cubic foot of air.

ISO – International Standards Organization (or International Organization for Standardization) ISO Standard 14644-1 lists particulate cleanliness classes similar to the Federal Standard 209. ISO Class 3 is equal to FS 209 Class 1, ISO Class 5 equals FS 209 Class 100, ISO Class 8 equals FS 209 Class 100,000.

JCAHO – Joint Commission on Accreditation of Healthcare Organizations.

USP – United States Pharmacopeia, a non-profit organization that develops standards for preparation, distribution and handling of pharmaceutical drugs.

Design Guidelines

SPECIAL CODES

JCAHO – Beginning July 2004, JCAHO will survey hospital pharmacies for compliance with USP -797, "Pharmaceutical Compounding - Sterile Preparations."

ARCHITECTURAL REQUIREMENTS

ISO Class 5 (Federal Standard 209E Class 100) room – Provide adjacent anterooms, gowning and degowning rooms, air locks arranged so that aseptic prep room is surrounded by less clean areas; provide seamless vinyl oors, cleanroom type ceiling grids and light fixtures.

ISO Class 8 (Federal Standard 209E Class 100,000) room – Provide an ante area but not physically separated; provide clean room type ceiling grids and light fixtures; may also need gowning and ante rooms.

HVAC System Guidelines

ISO CLASS 5 (FEDERAL STANDARD 209E CLASS 100)

Air change rate – 80 to 120 ACH

Pressurization – .05 in. w.c. between spaces of different ISO Classes HEPA supply at ceiling: 99.97 percent with gel seals at ceiling grid; size for average face velocity of 90 fpm. The sheer volume of air will result in ceiling diffusers taking most, if not all, of the ceiling.

Low returns – The volume of air will result in several low wall returns. Perforated oors are not recommended due to problems with cleaning and consequences of spills.

ISO CLASS 8 (FEDERAL STANDARD 209E CLASS 100,000)

Air change rate – 30 to 40 ACH

Pressurization – .05 in. w.c. between spaces of different ISO Classes

HEPA supply at ceiling – 99.97 percent filters are recommended; ASHRAE does not require them; some publications indicate that HEPAs are "good practice;" best if located at the ceiling instead of at the air handling unit, since this results in cleanest supply air and will result in less filter size than if located at the air handling unit.

Low returns – Provide low wall returns as needed.

Air change rates listed above are a compilation of several listed publications. The May/June 2001 issue of International Journal of Pharmaceutical Compounding recommends 40 to 60 ACH for Class 8 and 80 to 100 ACH for Class 5 rooms. An article in August 2001 ASHRAE Journal recommends at least 20 for less stringent rooms, presumably a Class 8, and 30 to 160 for Intermediate rooms, Class 5. ASHRAE Applications, Chapter 16, states that there are "no minimum air change requirements for facilities manufacturing pharmaceutical compounds" but also suggests a minimum of 20 ACH. Also in that chapter is a section on semiconductor clean rooms, Table 2, which associates 25 to 45 ACH, for 8 feet and 10-feet ceilings, for Class 8 rooms.

Pressurization should be monitored. Pressure relationships can be statically balanced (passively maintained) if there are few variables and these variables can be controlled (for example, compensation for filter loading). Otherwise, it is best to actively measure room pressure differentials and modulate exhaust or return air to maintain pressure differential setpoint.

Temperature – Maintain 70 F+/- 2 or 3 F in the spaces.

Humidity – 40 to 50 percent rh; if humidification is needed, a separate steam-to-steam humidifier should be used. No chemical treatment chemicals or amines should be introduced into the rooms.

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