USP 797 MAY NOT BE AS DIFFICULT OR EXPENSIVE AS YOU MAY THINK

When *USP General Chapter <797> Pharmacy Compounding-Sterile Preparations* become official January 1, 2004. Few pharmacies were in compliance. Most pharmacies were aware of the requirements and many began to review the requirements and procedures so that compliance could become possible.

Since it's initial start up date of January 2004 numerous start and stop dates, extensions have been established. Individual states have adopted the USP <797>, some states have only partial participation and some states have taken no action. We suggest that you check with the State Board of Pharmacy to obtain the latest information pertaining to USP <797>.

USP <797> covers all aspects of compounding sterile preparations. If you do not already have a copy of <797> you should acquire a copy from U.S. Pharmacopeia whose web site you may access from our LINKS page.

AirScan Technologies, Inc., is a certification company specializing in the inspection and certification of clean air devices, biological safety cabinets and clean rooms. It is our desire that you find our web site informative and select our company to provide your <797> compliance inspection.

The following will address what we consider as a practical approach for compliance to USP <797>.

You must first determine your compounded sterile preparation (csp's) risk level. The three risk levels are low medium or high. The following low and medium risk level area's will be discussed first.

<u>Low and Medium Risk Levels:</u>

A properly maintained "clean zone" will work efficiently for a low or medium risk level. You must insure you arrange the clean air devices (hoods) in a manner so as not to influence each other. The clean air devices should be located away from high traffic areas, away from doors, and any air vents that may disrupt the air flow or intake of any clean air devices.

If you use a section of an existing room to prepare csp's then that area shall become a "clean zone". There shall be a distinct line on the floor or a barrier to mark the clean zone. The clean air devices shall be located within this designated area, only authorized personnel shall be permitted access. The other part of the room shall support the clean zone. This area should contain the hands free sink and the appropriate garments to be worn into the csp area. This sectioned room should be constructed of smooth, easy to clean material. There should be no cracks or gaps. If a drop in ceiling is used they should be smooth non-shedding type and they must be caulked in place. If ceiling self-powered ductless HEPA filters are used there must be an access door adjacent to the HEPA'S so pr-filters and airflow adjustments can be performed. It is suggested that room side replaceable (RSP) HEPA filter housing be utilized. The entire room should be positive pressure in regards to adjoining areas.

If you use a dedicated room as your clean room the same procedures for location of clean air devices and smooth surfaces and drop in ceiling shall apply. The adjoining room (ante-room) supports the clean room and contains the hands free sink and gowning garments to be worn before entering the clean room. The clean room should be under positive pressure in relation to the ante-room. The ante-room shall be positive pressure to the outside area. If self-powered ductless HEPA modules are used there should be access doors for changing pre-filters or adjusting airflow. RSP modules are recommended.

High Risk Level:

You must use a dedicated two-room facility. The same construction and placement of clean air devices as outlined for low and medium risk levels is applicable. Both rooms must be under positive pressure to the outside area. The ante-room shall contain a physical barrier and traffic or unauthorized entry must be strictly controlled.

Some of the Basics You May Already Have

Your laminar flow Clean Bench or Class II Biological Safety Cabinets probably already meet ISO Class 5 Environments. Normal operation of your clean air devices (Clean Benches, Biological Safety Cabinets) may clean your air to meet ISO Class 8 requirements, depending on room size. But keep in mind recent changes state controlled air, meaning you must utilize ceiling HEPA filters to condition and control the room incoming air. Check with your local contractors to see if a clean zone can be constructed within your facility or existing rooms can be modified. Check with your local engineering and air conditioning specialist to see if your existing air system will support your clean zone. Remember ceiling powered HEPA filters both ductless and with ducts can be installed. AirScan also works with companies who can provide a turn-key construction of either a softwall or hardwall clean zone.

Barrier Isolators:

Recently these items have been pushed as the answer to USP 797. The isolators are very similar in design to a Class III Biological Safety Cabinet. Manipulations are performed through gloves. This type of device has both benefits and drawbacks, and not all isolators qualify as a containment cabinet. We suggest you evaluate all your options. If you intend to work chemo preparation, you must do so in a separate designated area so serious consideration must be addressed for this concern. We suggest that you review *CETA Applications Guide for the use of Barrier Isolators in Compounding Sterile Preparation in Healthcare Facilities.* (Use our FAQ for a direct link to CETA)