

PHARMACY DESIGN GUIDANCE UPDATE ON COMPLIANCE WITH USP CHAPTER 797 “PHARMACEUTICAL COMPOUNDING - STERILE PREPARATIONS”

A. GENERAL:

This Pharmacy Design Alert is being issued based on current provisions of USP Chapter 797 (USP<797>) on “Pharmaceutical Compounding – Sterile Preparations” issued in December 2007, and supersedes the previously issued Design Alert FM-181A-DA-124 dated February 23, 2006. The purpose of the Pharmacy Design Alert is to provide a guidance to VA and VHA Facilities and Services to facilitate compliance with USP <797> provisions regarding architectural, environmental and physical standards required for compounding sterile drug preparations. It is not intended to replace or supersede any existing VA/VHA policies in place.

B. ISSUES:

USP issued its revised version of Chapter 797 (<797>) with a number of changes clarifying issues related to physical infrastructure such as mechanical, electrical and architectural items for both sterile compounding and hazardous sterile compounding of drug products. The Joint Commission (JC) has announced its intent to begin surveying healthcare facilities for compliance with the provision of USP Chapter 797 (USP<797>) entitled “Pharmaceutical Compounding - Sterile Preparations”. The JC considers USP <797> a valuable set of guidelines based on contemporary consensus-based safe practices that describe a best practice for establishing safe processes in compounding sterile medications. USP <797> is considered to be an official minimum standard for compounding sterile medications and it is therefore enforceable by the Food and Drug Administration (FDA), state boards of pharmacy and other regulatory agencies. As such, USP <797> is an enforceable requirement that mandates procedures and processes for sterile drug compounding (mixing) of pharmaceuticals in a clean room environment. USP <797> establishes International Organization for Standards (ISO) requirements for acceptable clean room airborne particulate concentrations and assessment procedures.

NIOSH has jurisdiction over the standards for drugs requiring separate preparation areas for personnel safety.

C. BACKGROUND:

USP is an independent organization that establishes standards for drugs and drug preparations. JC has adopted USP <797> for its inspection of sterile drug compounding areas in healthcare facilities. This has a significant impact on the design of pharmacy clean rooms and perhaps other spaces as well. VA’s Pharmacy Benefits Management (PBM) Services at VACO formed a USP 797 Work Group to provide consultations and technical guidance for VHA facilities to plan implementation of the USP <797> provisions and to meet JC requirements.

DESIGN
ALERT

Most VA pharmacies that prepare sterile compounding of pharmaceuticals also prepare hazardous drugs. Like sterile non-hazardous pharmaceuticals, sterile hazardous pharmaceuticals should also be prepared in a sterile environment. In this Design Alert, pertinent requirements for both hazardous and non-hazardous clean rooms are provided as related to compounding of sterile drug products.

D. DEFINITIONS:

1. Clean Room (also known as the Buffer Room) is a space in which the concentration of the airborne particles is controlled to meet a specified cleanliness class. For hazardous and non-hazardous clean rooms, mentioned below in Paragraph E with the recommended Option 2, the required level of cleanliness is ISO (International Organization for Standards) Class 7. Class 7 clean room limits the maximum concentration of particles to 10,000 particles per cubic feet (352,000 per cubic meter of 0.5 microns or larger).

2. Anteroom is a space leading into and out of the hazardous or non-hazardous clean rooms. This is a transitional space in which activities, such as, hand hygiene, garbing procedures, and staging of components and other activities are performed. While the ISO classification of the anteroom serving the hazardous clean room shall be same as the clean room, that is, ISO 7, the ISO classification of the anteroom serving the non-hazardous clean room shall be ISO 8 (or ISO 7, if the architectural design in place incorporates a common anteroom for both hazardous and non-hazardous clean rooms).

Anterooms are transition spaces, which ensure direction of airflow and help maintain the required pressure relationships. Non-hazardous clean rooms should be maintained at 0.02-inch to 0.03-inch positive pressure with respect to their anterooms, which, in turn, should be maintained at 0.02-inch positive air pressure with respect to the adjoining circulation spaces. Hazardous clean rooms should be maintained at 0.02-inch negative pressure with respect to their anterooms, which, in turn, should be maintained at 0.02-inch positive air pressure with respect to the adjoining circulation spaces.

Use of the anterooms prevents large swings in temperature. Each anteroom shall be equipped an automatic hand washing basin. Anteroom serving hazardous clean room should also be equipped with an eyewash station.

For the hazardous clean rooms, anterooms can be used for storing the hazardous drugs so that the use of a dedicated storage room can be avoided.

3. Primary Engineering Control (PEC): This is an ISO Class 5 space or a device in which (Compounded Sterile Preparations (CSPs)) take place. While the choice of the ISO 5 device is left to the discretion of the pharmacists using the facilities, the following two devices are recommended:

3.1 Biological Safety Cabinets (BSC): Use of these cabinets is recommended for the hazardous clean rooms. These are vented cabinets meant of the protection of personnel, products, and environment. Air drawn by the BSC should be exhausted outdoors after passing through HEPA filters, integral or duct-mounted external, by a dedicated exhaust fan.

3.2 Laminar Airflow Workstation (LAFW): Use of these devices is recommended for the non-hazardous clean rooms. These devices can be 100% re-circulatory type.

3.3 CAI (Compounding Aseptic Isolator): This is a form of isolator designed for maintaining aseptic environment within itself. Air exchange into and out of the isolator shall be done through HEPA filters.

3.4 CACI (Compounding Aseptic Containment Isolator): This is form of CAI, designed to provide worker protection from exposure to unacceptable levels to drug exposure. 100% exhaust of the air is required while dealing with hazardous substances. Air exchange into and out of the isolator shall be done through HEPA filters.

4. Air lock: A small room or space (“pass-through” chamber or window) between two rooms of different air pressure, with interlocked doors (one tightly closed at all times) to prevent loss of pressure in the higher pressure room.

Refer to USP 797 Pharmacy Design Briefing Document @ <http://vaww.ceosh.med.va.gov>, for helpful information listed under Pharmacy Safety for ISO Class 5, Class 7 and Class 8 Clean rooms.

E. DISCUSSION:

USP 797 describes three risk levels defined by the complexity of the pharmaceutical compounding process, namely Low, Medium and High Risk Level compounding, all of which require that work involving the sterile pharmaceutical compounding shall take place under ISO Class 5 conditions within a buffer area that should be ISO Class 7 with appropriate air conditioning and humidity controls in place in the buffer area environment. These standards are to be exemplified in every category. Class 5 environments require hundreds of air changes of HEPA filtered air, stringent gowning and masking requirements, Anteroom etc. The Class 5 environment is achievable in four ways:

Option 1: Provide a Class 5 Clean Room.

Option 2: Provide a Class 5 environment in a Primary Engineering Control (PEC) defined above. Locate this device in ISO Class 7 buffer room and protect the integrity of the clean room requirement by providing an ISO Class 7 anteroom for the hazardous clean room, and an ISO Class 8 anteroom for the non-hazardous clean room.

Option 3: Perform all sterile pharmaceutical compounding within a Compounding Aseptic Containment Isolator (CACI) for Low Risk Levels.

Option 4: Consider use of a portable clean room.

F. Recommendations:

1. Determine the risk level of compounding typically performed within the pharmacy (Low, Medium or High) and the volume of work to be accomplished at peak periods. The medical centers can perform this essential task with guidance from the VHA USP 797 Workgroup and Chief of Pharmacy. Consider Options 1-4 for their impact on ventilation and architectural issues:

a. Option 1, ISO Class 5 clean rooms will be a very difficult option to follow, primarily due to the severe operational difficulties associated with gowning, masking, scrubbing, very high rate of air changes and the high cost of the HVAC and architectural features. More importantly, if the air handling system fails, it will not be possible to continue to use the space for sterile compounding until the system is back up again.

b. Option 2, Class 7 clean rooms would be easier to construct and maintain than option 1 from an HVAC standpoint requiring on the order of minimum 30 air changes per hour which may include 15 air changes per hour from an ISO Class 5 air-re-circulating device, and not hundreds. To simplify the HVAC system design, VA has opted to supply all 30 air changes per hour from the environmental air-handling unit and not use a secondary -, dedicated air-circulating unit as stipulated in USP <797> pages 27-28. See the attached room data sheets for HVAC design parameters. The room however, must be able to maintain the defined particle count during peak operations. Architectural features however, will still apply such as monolithic, cleanable surfaces, with anteroom and gowning, masking scrubbing etc. Also, if the air handling system fails it would still be possible to continue use the space to maintain ISO Class 5 environment within the operating PEC device.

- c. Option 3, the least impacted option could be the use of CACIs, where a surrounding clean room environment and air lock and ante room are not required. However, it may not be possible to perform all procedures in these enclosures.
 - d. Option 4: A portable clean room would cost in the range of \$40,000 - \$80,000, but would be less than a total physical renovation or new addition of a space.
2. For the hazardous clean room, the ISO Class 5 PEC device should be BSC (Biological Safety Cabinets) NSF Class II (Laminar Flow), Type B2, with 100 percent exhaust to outside.
 3. A DX (Direct Expansion) system for cooling should not be used. Use of chilled water is more effective in providing accurate environmental control. While it is preferable to provide emergency power for the heating, ventilating and air-conditioning system including all exhaust fans serving the clean rooms and support area, at least the dedicated exhaust fan serving the BSC cabinet should be on emergency power.
 4. Air locks and Anterooms: The use of air locks and ante rooms should be carefully planned. The medical center staff may consider provision of an air lock in addition to an ante room where they expect a high volume of compounding in the clean room, otherwise use of an ante room should be sufficient to maintain pressure in the clean room.
 5. Pass-through Chamber: Depending on the size and space availability in the clean room and volume of compounding done, the medical center may consider provision of a pass-through window to facilitate passing out of compounded drugs without having pharmacy personnel frequently go in and out of the clean room through an ante room. The pass-through window should be big enough to facilitate the passage of compounded sterile products or materials and have a tight seal between the clean room and the pharmacy area and should have two access doors. To prevent direct exposure from the clean room to the pharmacy area, both doors should not open at the same time. Provide door interlocks limiting doors to being open.
 6. HEPA with pre-filters should be accessible for service from outside the Clean Room.
 7. See the attached AHU and Room Data Sheets for details of the exhaust air system.
 8. Location of outside air intake is critical. The intake should not be located near plumbing vents, animal room exhausts, generator exhausts, loading docks, automobile entrances, driveways, passenger drop offs, cooling towers, incinerator and boiler stacks and any other item that may degrade the quality of air. There should be separation of at least 30 feet between the air intakes and exhaust air outlets. Perform a dispersion analysis based on the actual configuration of the pharmacy area, surrounding facilities, and prevailing wind directions etc. to establish, if a separation of more than 30 feet is required.
 9. Monitor room temperature, relative humidity and pressure via monitoring devices in the Clean Rooms on a continuing basis.
 10. Provide monolithic and cleanable walls, floors and ceilings.
 11. Do not provide floor drains and sinks in the Clean Room.
 12. Operate the dedicated biological safety cabinets exhaust system around the clock.
 13. The external lens of any lighting fixture must be smooth and cleanable.
 14. The doorway into the buffer zone or clean room must be of sufficient size to move LAFWs in and out of the buffer zone when required.

15. Seal all wall openings, slots, piping and electrical conduits and other penetrations to minimize air leakage from the clean room.
16. Provide hand hygiene facilities in the ante room and touchless controls to the extent possible to avoid recontamination of hands. Consider items such as automatic controls for entrance door between the Anteroom and the clean room. The controls should be on emergency power. Provide electronic devices or photo sensors with time delays for light switches and towel dispensers with electronic sensors. The electronic sensors should be in front of the faucets facing the user to allow water to be run long enough to come to temperature before immersing hands.
17. Provide clothing hooks in the ante room on the way to the Clean Room.
18. Review material shown under 'REFERENCES' below.
19. Appendix 1 and 2: The attached AHU Data Sheet and Room Data Sheets, taken from the 2008 HVAC Design Manual for Hospital Projects are somewhat modified to avoid repetition of the information appearing in the text of the design alert, and references to the chapters in the Design Manual are not readily available here. A dedicated AHU for the pharmacy area can serve other areas, such as, controlled substance vault, prescription receiving and filling assembly etc. While the focus of this Design Alert is on the hazardous and non-hazardous drug preparation areas, requirement for other areas associated with pharmacies is also attached for information purposes only.

G. REFERENCES:

1. <http://www.ashp.org/sterileCpd>
2. <http://vaww.ceosh.med.va.gov>
3. United States Pharmacopeia General Chapter <797> 'Pharmaceutical Compounding – Sterile preparations'; The United States Pharmacopeia, Second Supplement to USP 31 – NF 26, Rockville, MD; United States Pharmacopeia Convention: 2008: 1-61.
4. PBM Website for VHA USP 797 Workgroup
5. Technical Information Library (TIL): Access HVAC Design Manual for Hospital Projects @ <http://www.va.gov/facmgt/standard> for ventilation requirements for Bio-safety Class II Cabinets. Refer to Paragraph 3.7 'Biological Safety Cabinet (BSC) – VA Type H12 in the Manual.
6. ASHRAE Journal September 2004, Article" Understanding Pharmaceutical Clean Room Design".
7. Under Secretary for Health Information Letter 'Airborne Particle Assessment of Pharmaceutical Clean rooms'.
8. Under Secretary for Health Information Letter 'Microbiological Assessment of Pharmaceutical Clean rooms'.
9. Frequently Asked Questions (FAQS) Regarding USP <797>, VHA USP 797 Workgroup.

H. CREDITS:

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APPENDIX 1:

PHARMACY SERVICE - AIR HANDLING UNIT

AHU Data Sheet	
Air Handling Unit Type	<ul style="list-style-type: none"> • Variable Air Volume (VAV) • Note 1
Inside Design Conditions	Room Data Sheets
Minimum Outside Air	Chapter 2 of HVAC Design Manual for Hospital Projects
Minimum Supply Air Changes per Hour	Room Data Sheets
Return Air	Room Data Sheets
Economizer Cycle	ASHRAE 90.1 - 2007
Air Balance	Room Data Sheets
Filtration	<ul style="list-style-type: none"> • Pre-Filters, MERV 8 rating • After Filters, MERV 14 rating • Final-Filters, MERV 17 rating • Note 2
Cooling Source	Use chilled Water from the central chiller plant Note 3
Heating Source	<ul style="list-style-type: none"> • Use high pressure steam from the central boiler plant as the primary source for generating heating hot water and producing “clean steam” for winter humidification. • Use medium pressure steam from the central boiler plant for unit mounted pre-heat coils.
General Exhaust System(s)	Required
Special Exhaust System(s)	Room Data Sheets
Heat Recovery System	ASHRAE 90.1 - 2007
Additional Energy Conservation Measures	To meet the mandated goal of 30% additional energy conservation above ASHRAE 90.1 – 2004, evaluate the use of desiccant dehumidification system to reduce the dew point temperature of the incoming outside air
Emergency Power	Required
<p>Note 1: The HVAC system design criteria are based on the latest (December, 2007) publication of the USP (The United States Pharmacopeial Convention) Revised Bulletin <797> Pharmaceutical Sterile Preparations. A dedicated air-handling unit is not required to serve the hazardous and/or non-hazardous clean rooms so long as any air-handling unit serving these spaces can meet all requirements outlined in the AHU Data Sheet and the Room Data Sheets.</p> <p>Note 2: Locate the final filters (third bed) on the downstream side of the individual air terminal units serving each hazardous and non-hazardous clean room. Oversize the final filters to minimize the pressure drop. For remaining rooms, terminal HEPA filters are not required.</p> <p>Note 3: Dedicated chiller is required if chilled water is not available year-round</p>	

PHARMACY SERVICE – ROOM DATA SHEETS

Non-Hazardous Clean Room – Room Data Sheet

PHARMACY SERVICE – ROOM DATA SHEETS

Description: The following introductory information is provided for the non-hazardous clean rooms. The room comprises three segments:

1. PEC (Primary Engineering Control) is a device or a space that provides ISO Class 5 environment for compounding of drugs. **Selection of the PEC shall be done by the VA Pharmacy Department.** Generally a laminar airflow work bench (LAFW) is used as the PEC device. The room air need not be exhausted outdoors.

Note that USP <797> General Chapter allows the use of a CAI (Compounding Aseptic Isolator) or CACI (Compounding Aseptic Containment Isolator) for Low-Risk Level CSPs (Compounded Sterile Preparations) even without the use of Class 7 Clean Room, provided “non-hazardous and radiopharmaceutical CSPs pursuant to a physician’s order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended by in the manufacturer’s package insert whichever is less. See USP <797> for the Low-Risk Conditions.

2. Buffer area is the space in which the PEC is physically located. This is the clean room where activities such as preparation and staging of components used for drug preparation take place. Buffer area is maintained at ISO Class 7 by supplying HEPA filtered air in a unidirectional manner from the suspended ceiling.

3. Anteroom is an ISO Class 8 or better area, which serves as a transient place to maintain the integrity of buffer area. This space also handles personnel hygiene and garbing of the personnel. Physical separation between the anteroom and buffer area is a wall with doors. Only one set of doors will be able to open at any given time to avoid disruption of the air pressure gradient.

PEC and Buffer Room (Non Hazardous Clean Room) – Room Data Sheet

Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 68 F [20 C] Dry-Bulb Temperature (maximum) 55% Relative Humidity ● Heating Mode 68 F [20 C] Dry-Bulb Temperature (minimum) 40% Relative Humidity <p>Note 3</p>
Minimum Supply Air Changes per Hour	<ul style="list-style-type: none"> ● 30 - CV Required ● Note 1
Return Air	Permitted
Exhaust Air	Not required with 100% re-circulatory ISO Class 5. Specific configurations of the BSC cabinets may require exhaust from the room air to outdoors. Co-ordinate exhaust air volume and system configuration per manufacturer’s recommendations.
Individual Room Temperature Control	Required
Room Air Balance	Positive (+) with respect to the Anteroom Note: 2

PHARMACY SERVICE – ROOM DATA SHEETS	
Room Noise Level	NC 40
<p>Note 1: Air changes listed above must be able to limit the concentration of the airborne particles. Provide more air changer per hour, if required, to maintain ISO Class 7 particulate count.</p> <p>Note 2: Provide outside air as required to maintain the specified pressure differential.</p> <p>Note 3: Room level humidity control is not required.</p>	

Anteroom (Non Hazardous Clean Room) – Room Data Sheet	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 68 F [20 C] Dry-Bulb Temperature (maximum) 55% Relative Humidity ● Heating Mode 68 F [20 C] Dry-Bulb Temperature (minimum) 40% Relative Humidity <p>Note 2</p>
Minimum Supply Air Changes per Hour	<ul style="list-style-type: none"> ● 20 - CV Required ● Note 1
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	<ul style="list-style-type: none"> ● Positive (+) with respect to circulation space ● Negative (-) with respect to Buffer room
Room Noise Level	NC 40
<p>Note 1: Air changes listed above must be able to limit the concentration of the airborne particles. Provide more air changer per hour, if required, to maintain ISO Class 8 particulate count.</p> <p>Note 2: Room level humidity control is not required.</p>	

Hazardous Clean Room – Room Data Sheet
<p>Description: The following introductory information is provided for the hazardous clean rooms. The room comprises of three segments:</p> <p>1. PEC (Primary Engineering Control) is a device or a space that provides ISO Class 5 environment for compounding of drugs. Selection of the PEC shall be done by the VA Pharmacy Department. Generally, a Biological Safety Cabinet (BSC) Class II B2 is used as the PEC device through which the air is exhausted outdoors after passing over the duct-mounted HEPA filter. The HEPA is an integral to the BSC unit, and additional in duct HEPA is not needed.</p> <p>2. Buffer area is the space in which the PEC is physically located. This is the clean room where activities such as preparation and staging of components used for drug preparation take place. Buffer area is maintained at ISO Class 7 by supplying HEPA filtered air and establishing unidirectional flow.</p> <p>3. This room can also be used to store hazardous drugs provided adequate storage space is available. Otherwise a separate room is required to store hazardous</p>

PHARMACY SERVICE – ROOM DATA SHEETS

drugs. This room should be ventilated @ minimum 12 air changes per hour with negative pressure. Exhaust from this room should be connected to the special exhaust system serving the buffer room and ante room.

4. Anteroom is an ISO Class 7 or better area, which serves as a transient place to maintain the integrity of buffer area. This space also handles personnel hygiene and garbing of the personnel. Physical separation between the anteroom and buffer area is a wall with doors. Only one set of doors will be able to open at any given time to avoid disruption of the air pressure gradient.

5. See USP <797> for additional requirement for lighting and ceiling surfaces, caulking, etc.

PEC and Buffer Room (Hazardous Clean Room) – Room Data Sheet

Inside Design Conditions	<ul style="list-style-type: none">● Cooling Mode 68 F [20 C] Dry-Bulb Temperature (maximum) 55% Relative Humidity● Heating Mode 68 F [20 C] Dry-Bulb Temperature (minimum) 40% Relative Humidity Note 2
Minimum Supply Air Changes per Hour	● 30 - CV Required
Return Air	Not Permitted
Exhaust Air	100% Note: 1
Individual Room Temperature Control	Required
Room Air Pressure	● Negative (-) with respect to the Anteroom
Room Noise Level	NC 40
Note 1: All air supplied to the buffer room shall be exhausted outdoors without in duct HEPA filters in a manner to avoid facility entrainment and building wake effect. BSC or equivalent ISO Class 5 device shall be served by a special exhaust system without additional in duct HEPA filters in accordance with the manufacturer's recommendations. Buffer area and Anteroom below shall be exhausted outdoors through another special exhaust system but without HEPA filters	
Note 2: Room level humidity control is not required	

Anteroom (Hazardous Clean Room) - Room Data Sheet

PHARMACY SERVICE – ROOM DATA SHEETS	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 68 F [20 C] Dry-Bulb Temperature (maximum) 55% Relative Humidity ● Heating Mode 68 F [20 C] Dry-Bulb Temperature (minimum) 40% Relative Humidity Note 1
Minimum Supply Air Changes per Hour	● 30 - CV Required
Return Air	Not Permitted
Exhaust Air	100% See Buffer Room Above
Individual Room Temperature Control	Required
Room Air Balance	Positive (+) with respect to Hazardous Clean Room Positive (+) with respect to Circulation Space whose room pressure is assumed as neutral (0)
Room Noise Level	NC 40
Note 1: Room level humidity control is not required	

Controlled Substance Vault and Secured Dispensing Receiving Area – Room Data Sheet	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 70 F [21 C] Dry-Bulb Temperature (maximum) 50% Relative Humidity ● Heating Mode 75 F [24 C] Dry-Bulb Temperature (minimum) 35% Relative Humidity ● 5 F [2.8 C] Dead-Band See Note 1 <ul style="list-style-type: none"> ● .Room Humidity shall be 40% if this room is served by the same AHU serving the clean rooms above.
Minimum Supply Air Changes per Hour	6 - VAV Permitted
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	Neutral (0)
Room Noise Level	NC 40
Note 1 Room level humidity control is not required	

Dispensing, Pre-Packing and EXTEMP – Room Data Sheet

PHARMACY SERVICE – ROOM DATA SHEETS	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 70 F [21 C] Dry-Bulb Temperature (maximum) 50% Relative Humidity ● Heating Mode 75 F [24 C] Dry-Bulb Temperature (minimum) 40% Relative Humidity ● 5 F [2.8 C] Dead-Band <p>Note 1 Room Humidity shall be 40% if this room is served by the same AHU serving the clean rooms above.</p>
Minimum Supply Air Changes per Hour	6 – VAV Permitted
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	Neutral (0)
Room Noise Level	NC 40

Note 1 Room level humidity control is not required

Drug Information Service – Room Data Sheet	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 70 F [21 C] Dry-Bulb Temperature (maximum) 50% Relative Humidity ● Heating Mode 75 F [24 C] Dry-Bulb Temperature (minimum) 35% Relative Humidity ● 5 F [2.8 C] Dead-Band <p>Note 1 Room Humidity shall be 40% if this room is served by the same AHU serving the clean rooms above.</p>
Minimum Supply Air Changes per Hour	4 - VAV Permitted
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	Neutral (0)
Room Noise Level	NC 40

Note 1 Room level humidity control is not required

EXTEMP Repacking and Compounding – Room Data Sheet	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 70 F [21 C] Dry-Bulb Temperature (maximum) 50% Relative Humidity ● Heating Mode 75 F [24 C] Dry-Bulb Temperature (minimum) 35% Relative Humidity

PHARMACY SERVICE – ROOM DATA SHEETS	
	<ul style="list-style-type: none"> ● 5 F [2.8 C] Dead-Band <ul style="list-style-type: none"> • . Room level humidity control is not required • . Room Humidity shall be 40% if this room is served by the same AHU serving the clean rooms above.
Minimum Supply Air Changes per Hour	6 - VAV Permitted
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	Neutral (0)
Room Noise Level	NC 40

Medicine Assignment and Stat Counter – Room Data Sheet	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 70 F [21 C] Dry-Bulb Temperature (maximum) 50% Relative Humidity ● Heating Mode 75 F [24 C] Dry-Bulb Temperature (minimum) 35% Relative Humidity ● 5 F [2.8 C] Dead-Band <p>Note 1 Room Humidity shall be 40% if this room is served by the same AHU serving the clean rooms above.</p>
Minimum Supply Air Changes per Hour	6 - VAV Permitted
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	Neutral (0)
Room Noise Level	NC 40
Note 1 Room level humidity control is not required	

PHARMACY SERVICE – ROOM DATA SHEETS	
Prescription Receiving, Filling/Assembly – Room Data Sheet	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 70 F [21 C] Dry-Bulb Temperature (maximum) 50% Relative Humidity ● Heating Mode 75 F [24 C] Dry-Bulb Temperature (minimum) 35% Relative Humidity ● 5 F [2.8 C] Dead-Band <p>Note 1</p> <ul style="list-style-type: none"> ● . Room Humidity shall be 40% if this room is served by the same AHU serving the clean rooms above.
Minimum Supply Air Changes per Hour	6 – VAV Permitted
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	Neutral (0)
Room Noise Level	NC 40

Note 1 Room level humidity control is not required

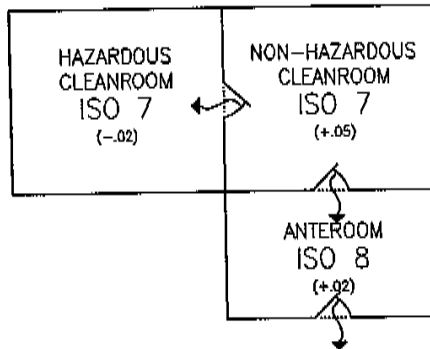
Unit Dose and Ward Stock – Room Data Sheet	
Inside Design Conditions	<ul style="list-style-type: none"> ● Cooling Mode 70 F [21 C] Dry-Bulb Temperature (maximum) 50% Relative Humidity ● Heating Mode 75 F [24 C] Dry-Bulb Temperature (minimum) 35% Relative Humidity ● 5 F [2.8 C] Dead-Band <p>Notes 1 and 2</p>
Minimum Supply Air Changes per Hour	6 - VAV Permitted
Return Air	Permitted
Exhaust Air	Not Required
Individual Room Temperature Control	Required
Room Air Balance	Neutral (0)
Room Noise Level	NC 40

Note 1: Room level humidity control is not required:

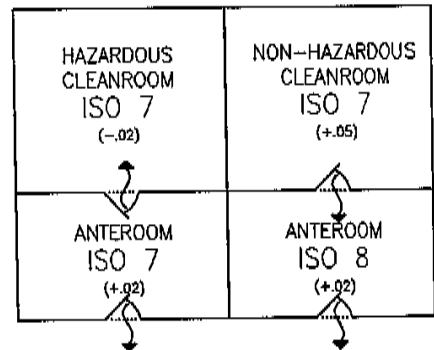
Note 2: Room humidity shall be 40% if this room is served by the same AHU serving the clean room above.

HVAC DESIGN MANUAL
APPENDIX 6-A / PHARMACY
FIGURE 6A-1
FEB 2008

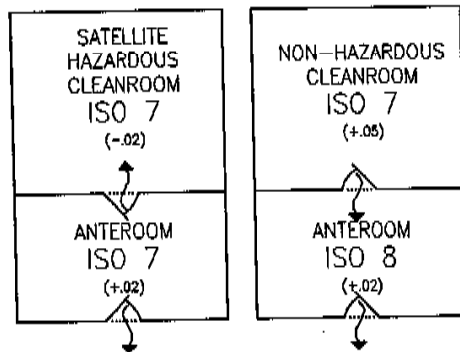
SKETCH A



SKETCH B



SKETCH C



SWING DOORS SHOULD BE GASKETED AND HINGED TO OPEN AGAINST POSITIVE PRESSURE FOR PERSONEL SAFETY AND MAINTAINING PROPER PRESSURE RELATIONSHIPS.

	AIR FLOW DIRECTION TO BE MAINTAINED.
	DIRECTION OF DOOR SWING
(±.0X)	MINIMUM PRESSURE TO BE MAINTAINED (IN INCHES OF WATER GAUGE), AND MONITORED

PHARMACY COMPOUNDING AREAS

Not to Scale

6-A66

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00CFM1A-DA-132