ENGINEERED AIR BALANCE

USP 797/800 for Healthcare Pharmacies: What the TAB Firm Must Know

CxEnergy / AABC TAB Seminar
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Learning Objectives

1. Understand the role of USP standards in the design and testing of hospital pharmacies
2. Understand ISO room classifications and how they apply to hospital pharmacies
3. Understand Biological Safety Cabinet (BSC) classifications
4. Understand unique Testing, Adjusting and Balancing requirements for hospital pharmacies
5. Understand the coordination required between the TAB Firm and the Pharmacy Certifier

U. S. Pharmacopiel Convention (USP)

1. Scientific Non-profit Organization
2. Develops standards for identity, strength, quality and purity of medicines, food ingredients and dietary supplements.
3. USP's drug standards are enforced by the US Food and Drug Administration (FDA)
4. USP standards are used in more than 140 countries
5. USP-797: *Pharmaceutical Guidelines in Compounding Sterile Preparations (CSP)*
6. USP-800: *Hazardous Drugs – Handling in Healthcare Settings*

USP 797 – Facility Design and Environmental Control

ISO Classes: What do they mean?

ISO 14644-1 Class	FS 209E Class	ACH Rate	0.1 Micron	1 Micron
1		>750	10	
2		>750	100	
3	1	>750	1,000	8
4	10	500-600	10,000	83
5	100	150-400	100,000	832
6	1,000	60-100	1,000,000	8,320
7	10,000	25-40		83,200
8	100,000	10-15		832,000

USP 797 – Facility Design and Environmental Control

Facility Requirements

1. Space Temperature should be 68 deg. F or cooler
2. HEPA filtered supply air shall be introduced at the ceiling with return grilles (positive pressure rooms) mounted low on the wall
3. Ceiling mounted return grilles are not recommended
4. Return grilles should not be obstructed by equipment and arranged to allow clear flow paths from supply to return.
5. Rooms are to be equipped with Room Pressure Monitors

USP 797 – Facility Design and Environmental Control

Facility Requirements (contd.)

1. Compounding and Viral Rooms should be ISO 7 at minimum 30 ACH and -0.01” w.c. differential to adjacent spaces
2. Ante Rooms adjacent to negative ISO 7 rooms must be ISO 7 at 30 ACH and not less than +0.02” w.c. to the General Pharmacy
3. Ante Rooms adjacent to positive ISO 7 rooms may be designed as ISO 8 rooms
4. Clean Rooms should be ISO 7 at 30 ACH and minimum +0.02” w.c. to +0.05” w.c. to adjacent spaces
5. Any positive room must be the same ISO class as the adjacent room

USP 800 – *Hazardous Drugs – Handling in Healthcare Settings*

Facility Requirements

1. Introduced in February 2016
2. Positive ISO 7 Buffers change from +0.02” to +0.05” w.c. to constant +0.02” w.c.
3. Minimum +0.02” w.c. to be maintained to adjacent spaces
4. Negative ISO 7 Compounding or Viral rooms change from minimum -0.01” w.c. to a range between -0.01” to -0.03” w.c.
5. Having a maximum requirement of +/- 0.05” w.c. can cause problems with room pressure monitors and nuisance alarms.

Biological Safety Cabinets (BSC)

Classifications

1. IIA2 (Recirculating Cabinet)
   - Not connected to building exhaust
   - Not measured by the TAB Firm
   - Contributes to the ACH rate for the room with localized filtration
2. IIB1 (Partial Recirculation Cabinet)
   - Connected to building exhaust (typically 70% of filtered supply airflow)
   - Exhaust airflow is measured by the TAB Firm
   - Static pressure requirement is typically less than -1.0” w.c. for loaded condition
3. IIB2 (Full Exhaust Cabinet)
   - Connected to building exhaust (100% of filtered supply airflow)
   - Exhaust airflow is measured by the TAB Firm
   - Static pressure requirements can exceed -2.0” w.c. for loaded condition

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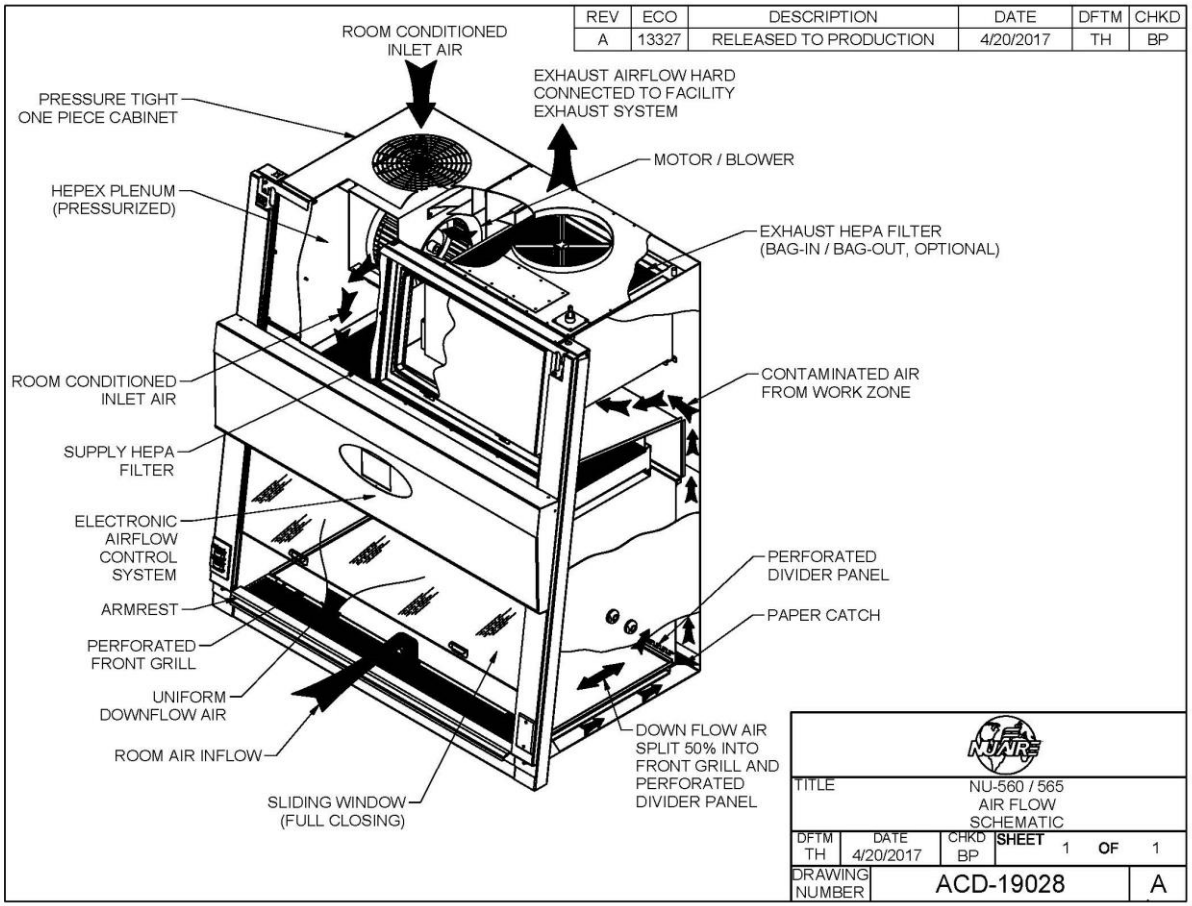
Biological Safety Cabinets (BSC)



Biological Safety Cabinets (BSC)

Concurrent Balance Value (CBV)

1. Ducted exhaust airflow vs. the cabinet airflow as measured by the Certifier
2. Caused by differences in measurement techniques

Criteria	3’ IIB2	4’ IIB2	6’ IIB2
Certification Exhaust	496 CFM	754 CFM	1100 CFM
Concurrent Balance Value	546 CFM	785 CFM	1250 CFM
Duct Static Pressure	1.5” w.c.	1.7” w.c.	1.8” w.c.

1. Nuaire Labguard NU-430-300/400/600 Product Data

Biological Safety Cabinets (BSC)

Testing Considerations

1. Ensure shipping material has been removed from supply inlet
2. Verify decontamination exhaust damper (if equipped) is fully open
3. Verify adjustable sash is set to the operating height
4. Verify design airflow is scheduled for the Concurrent Balance Value (CBV) or equivalent depending upon the manufacturer
5. If served by a terminal unit / venturi valve, measure static pressure at cabinet connection and ensure sufficient system capacity for filter loading
6. Traverse must be within +/- 5% of the CBV or equivalent

Testing, Adjusting and Balancing - Hospital Pharmacies

Pre-Balancing Activities

1. Understand the individual room classifications and clarify design intent with the Engineer of Record or the Owner
2. Understand the types of Biological Safety Cabinets (BSC) in each room and how these affect the overall ACH rates
3. Verify the anticipated HEPA filter differential pressure at loaded conditions – is system capacity sufficient?
4. What is required to adjust airflows for terminal units / venturi valves as well as Fan Filter Units (FFU)>
5. Verify Room Pressure Monitor ranges, alarm settings, calibration features, etc.

Testing, Adjusting and Balancing - Hospital Pharmacies

Balancing Activities

1. Measure each room and calculate room volume for ACH rates
2. Traverse each ducted BSC and adjust exhaust airflow to appropriate setpoint according to the manufacturer's recommendations
3. Measure and adjust supply airflows to HEPA grilles / FFUs
4. Adjust airflows to set room pressures according to the design criteria AND Owner's requirements
5. Verify Room Pressure Monitor calibration and alarming
6. Coordinate with the Certifier and make appropriate airflow adjustments to satisfy their requirements (2nd Trip??)

Testing, Adjusting and Balancing - Hospital Pharmacies

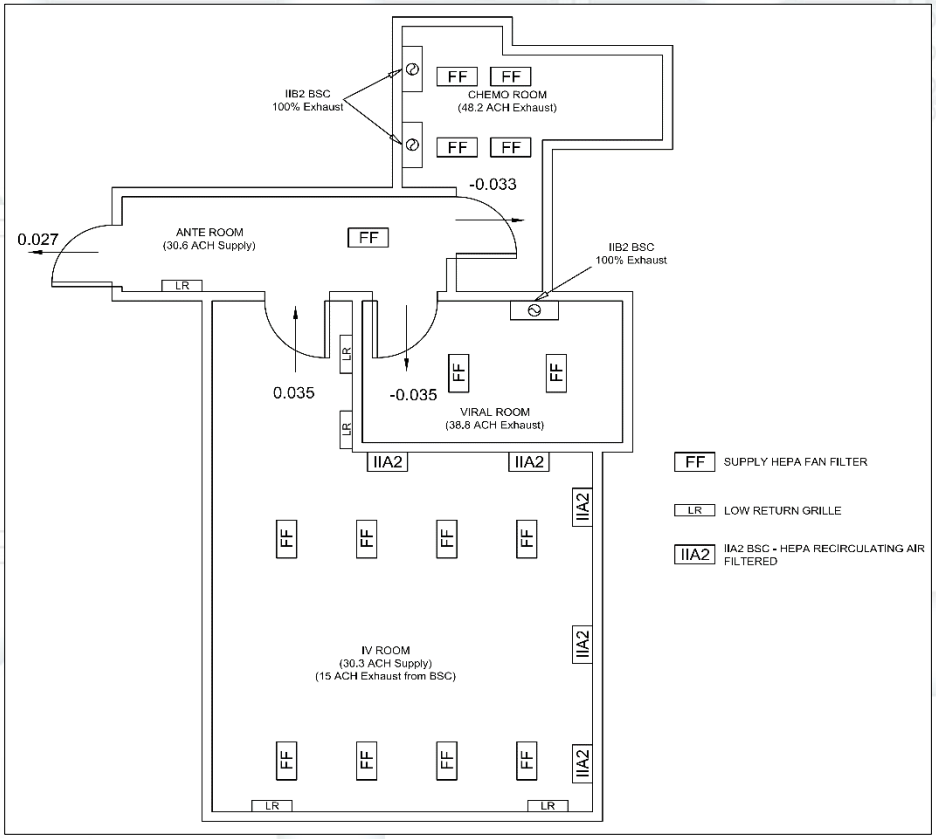
Coordination with Certifier and Pharmacy Manager

1. Areas of Interpretation
   - In negative rooms, the ACH rate may be calculated from the supply airflow (ie. CETA-CAG-003-006 methodology)
   - While the certifier may pass a room that exceeds +/- 0.05” w.c. pressure, the Pharmacy Manager may interpret to the letter of USP
2. Coordination Considerations
   - Ask what is expected ahead of time from both the Certifier and Owner’s personnel
   - Plan to make a return trip for airflow adjustments based upon the certifier’s findings or to correct pressure changes thereafter
   - Plan to address nuisance alarming and follow up to ensure satisfactory operation of the facility

Testing, Adjusting and Balancing - Hospital Pharmacies

Hospital Pharmacy Example

1. Ante Room
   - Positive to General Pharmacy, Chemo and Viral
   - Negative to IV Room
   - FFU Supply / Low Returns
2. Chemo and Viral Room
   - 100% Exhaust – IIB2 BSCs
   - Negative to Ante Room
3. IV Room
   - IIA2 BSCs (15 ACH Recirculating)
   - FFU Supply / Low Returns



Testing, Adjusting and Balancing - Hospital Pharmacies

Hospital Pharmacy Example

Room Type	Room Volume ft^3	ACH		DP (" WC)			Airflow (CFM)			
							Supply		Exhaust / Return	
		Required	Actual	Required	Actual	BAS	Design	Actual	Design	Actual
Chemo	2112	30	48.2	-0.01	-0.033	-0.040	1340	1245	1640	1700
Viral	1456	30	33.8	-0.01	-0.035	-0.040	550	495	820	820
IV	7133	30	30.3 (1)	0.02	0.035	0.031	1800	1820	1600	1390
Ante	1800	30	30.6	0.02	0.027	0.028	450	920	700	105

(1) 15.3 ACH HEPA filtered supply air plus 15 ACH HEPA filtered recirculated air (IIA2 BSCs)

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Testing, Adjusting and Balancing - Hospital Pharmacies

Hospital Pharmacy Example

Lessons Learned

1. Ante Room designed for 15 ACH; re-designed to meet 30 ACH ISO 7 requirement
2. Viral Room does not have sufficient supply airflow to meet ACH rates if calculated from supply airflow

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Conclusion

1. Be proactive and review the design; coordinate with the design team and Owner as needed to meet USP requriements
2. Plan to make multiple trips for TAB activities (2-3 trips)
3. Coordinate with the Certifier and Pharmacy Manager to ensure the TAB activities meet their expectations
4. Adjust final airflows to set room ACH rates / pressures according to the design criteria AND Certifier’s / Owner’s requirements

QUESTIONS

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