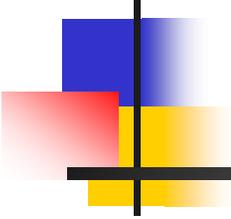
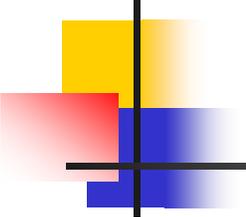


ASSESSMENT OF BIOAEROSOL REDUCTION METHODS IN STEM CELL TRANSPLANT UNITS AT A UNIVERSITY HOSPITAL



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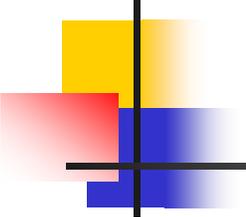
INTRODUCTION

- Fungal Spores Present a Risk of Opportunistic Infections
 - Both exogenous and endogenous sources
- Control Essential to Safety of Immunocompromised Patients
 - *Aspergillus* sp. represent greatest “exogenous” risk



ENGINEERING CONTROLS FOR A PROTECTIVE ENVIRONMENT

- Long Recognized Infection Control Tool
- New JCAHO Expectation
 - Manage airborne infection risk
- New CDC Environmental Infection Control Guidelines



RATIONALE FOR CURRENT INVESTIGATION

- Validate Performance of Current Controls
- Compare Bioaerosol Levels in Nursing Units Employing Different Control Measures
- Contribute to the Design of a New Transplant Unit



PATIENT UNITS INVESTIGATED

- “Standard” Intensive Care Unit
- Adult Stem Cell Transplant Unit
- Pediatric Stem Cell Transplant Unit
- All have Different Engineering Controls
- Viable Spore Sampling Methodologies
 - Thermo Andersen cascade impaction sampler
 - Mattson-Garvin slit-to-agar sampler

ENGINEERING CONTROL MEASURES FOR STUDY UNITS

Control Measures	ICU	ATU	PTU
Air handling unit (95% efficient filtration)	+	+	+
Air changes per hour in patient rooms (designed)	6	12	12
Point-of-use supply HEPA-filtration in patient rooms	-	-	+
Point-of-use supply HEPA-filtration throughout unit	-	-	+
Recirculation HEPA-filtration in each patient room	-	+	+
Recirculation HEPA units in unit hall	-	-	+
Pressure gradient established throughout unit	-	+	+
Continuous electronic monitoring of HVAC system	-	-	+
Airflow monitor at doorway of each patient room	-	- *	+
Enter unit through airlock	-	+	+ #

+ indicates that the control measure is available

* static pressure indicator installed within the patient room

indicates an interlocked airlock



RESULTS - FUNGAL SPORES

- Nine Fungal Genera Isolated
- No *Aspergillus* sp. Isolated from Patient Rooms in the Stem Cell Transplant Units
- Significantly Lower Spore Counts in Patient Rooms
- Use of All Engineering Controls Resulted in Significantly Lower Spore Counts

COMPARISONS OF MEAN SPORE CONCENTRATIONS FOR PATIENT ROOM SAMPLE LOCATIONS

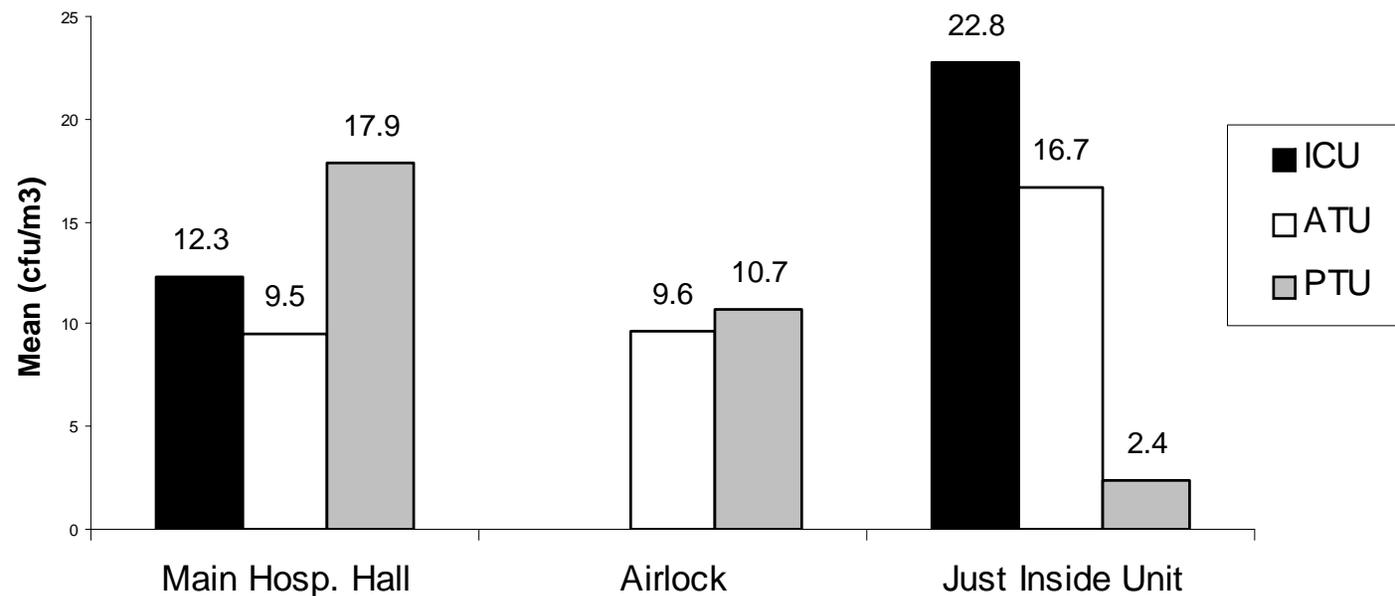
	Mean (cfu/m ³)	SD	Satterthwaite t-value (df)	p-value
ICU				
Bedside vs. Outside Rm.	6.41 14.42	5.29 12.88	3.86 (55.4)	0.0003
ATU				
Bedside vs. Rm. Entry	2.61 4.34	3.57 4.15	2.50 (115)	0.014
Bedside vs. Outside Rm.	2.61 9.67	3.57 10.84	4.86 (71.5)	<0.0001
Rm. Entry vs. Outside Rm.	4.34 9.67	4.15 10.84	-3.58 (77.7)	0.0006
PTU				
Bedside vs. Rm. Entry	1.31 1.59	2.47 2.86	0.7(177)	0.49
Bedside vs. Outside Rm.	1.31 2.94	2.47 3.59	2.88 (76.7)	0.005
Rm. Entry vs. Outside Rm.	1.59 2.94	2.86 3.59	-2.31 (85.9)	0.02

MEAN CONCENTRATIONS OF *ASPERGILLUS* SP. AND TOTAL VIABLE SPORES

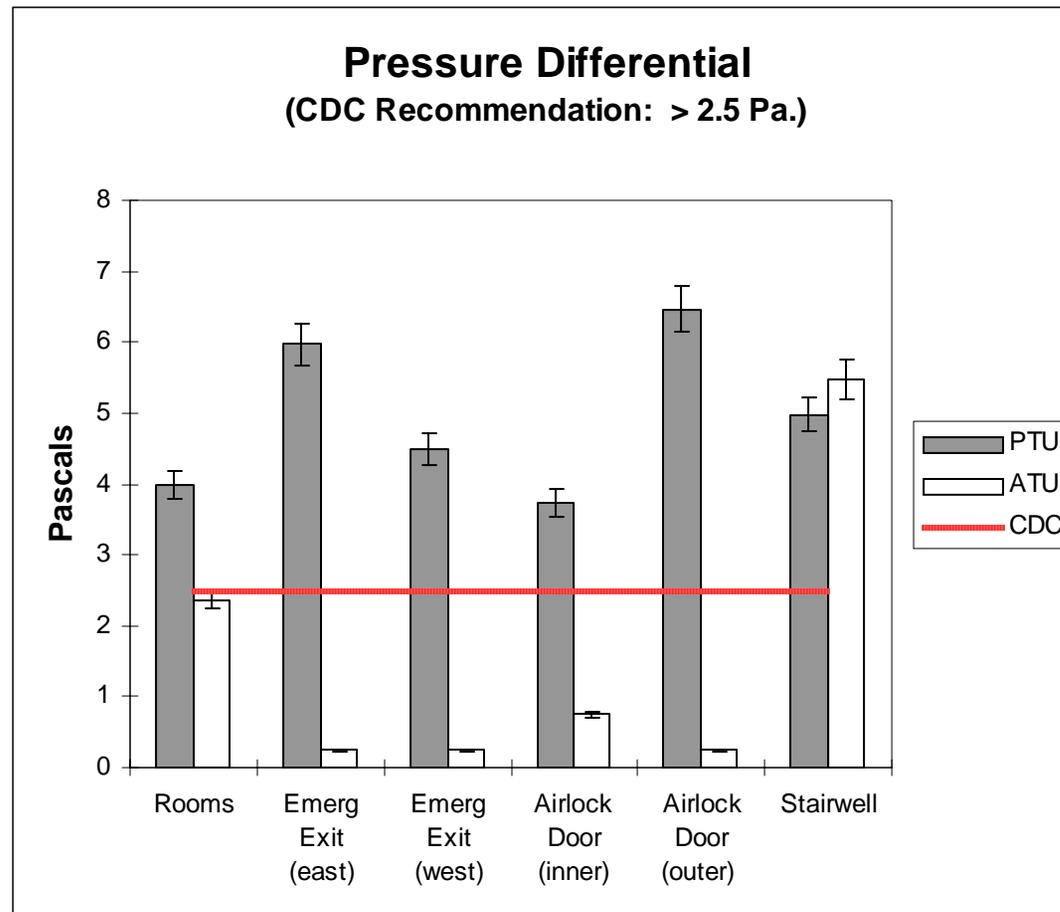
		N	Positive for <i>Aspergillus</i>	Percent Positive	<i>Aspergillus</i> Conc. (cfu/m ³)	SD	Total Viable Spore Conc. (cfu/m ³)
Unit Hall	ICU	44	15	34.0	0.8	1.15	14.42
	ATU	61	7	11.0	0.3	0.92	9.67
	PTU	47	2	4.3	0.1	0.49	2.94
Rm. Entry	ATU	59	0	0.0	0.0	0.00	4.34
	PTU	84	0	0.0	0.0	0.00	1.59
Bedside	ICU	51	7	13.7	0.3	0.83	6.41
	ATU	68	0	0.0	0.0	0.00	2.61
	PTU	84	0	0.0	0.0	0.00	1.31
Airlock	ATU	18	1	5.6	0.2	0.82	16.5
	PTU	31	1	3.2	0.1	0.43	19.5
Stairwell	*	30	17	57.0	2.8	3.2	60.8

VIABLE SPORE CONCENTRATIONS AT UNIT ENTRANCES

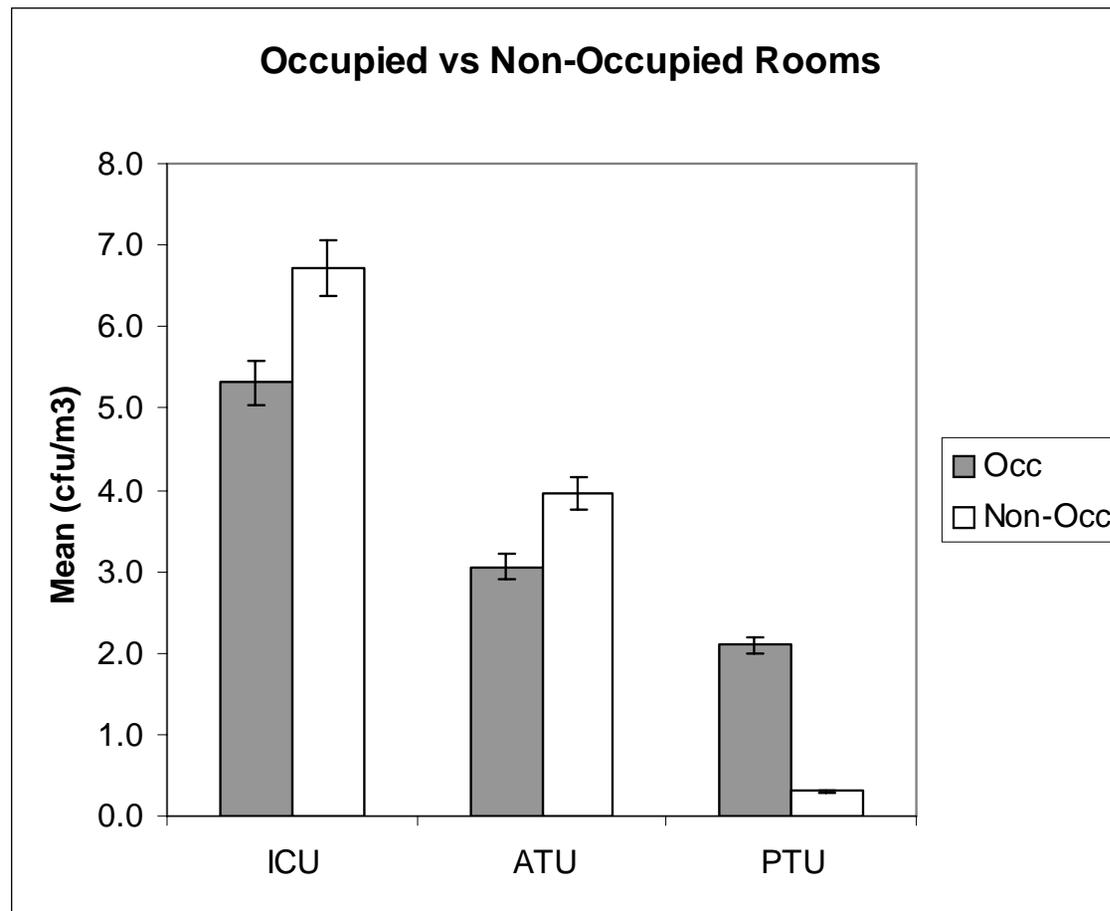
Unit Entrance Data

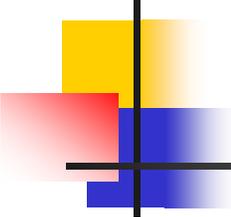


PRESSURE CHANGE READINGS TAKEN AT VARIOUS UNIT DOORWAYS



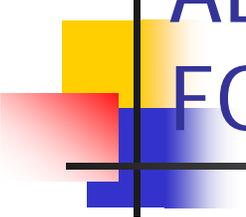
MEAN SPORE CONCENTRATIONS IN OCCUPIED VERSUS UNOCCUPIED ROOMS





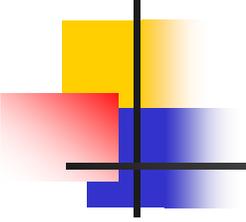
ENGINEERING CONTROLS FOR REDUCING BIOBURDEN

- Airlock with Interlocking Doors
 - Prevent simultaneous openings
- HEPA Refiltration Units to Manage “Endogenous” Sources of Fungal Spores
- Directional Airflow from Patient Breathing Zone of Room Entry
- Directional Airflow at >2.5 Pascals
- Isolate Nursing Units from Stairwell Contaminants



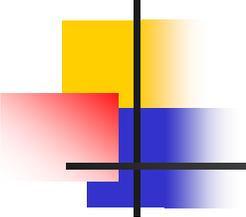
ADDITIONAL ENGINEERING CONTROLS FOR REDUCING BIOBURDEN

- Based on Previous Studies and Experience
 - Point-of-use HEPA filtration of supply air
 - >12 air changes per hour
 - Centralized monitoring of filtration and pressurization
 - Pressure indicators at patient rooms
 - No carpets and reduced horizontal surfaces



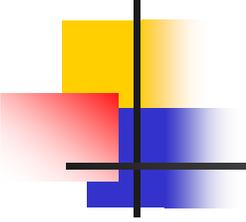
ADDITIONAL APPLICATIONS OF BIOAEROSOL CONTAINMENT CONTROL PRACTICES

- Human Tissue Processing Areas
- Tissue Culture Facilities
- Production Pharmacies



HUMAN MATERIAL “PROCESSING” LABORATORY

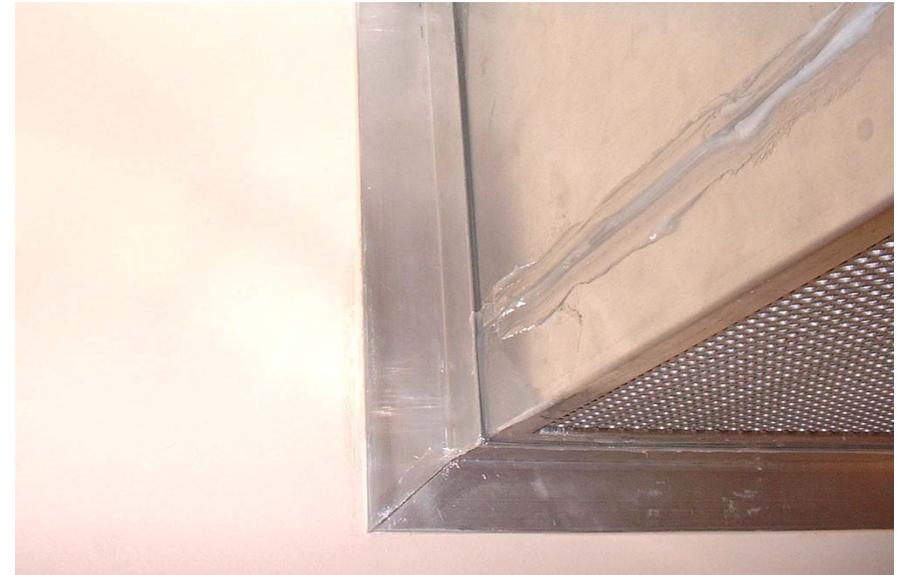
- FDA Regulations – 21 CFR parts 210, 211, 600, and 610
 - Non-prescriptive so address the “intent”
 - Assure patient safety (asepsis)
 - Protect the “critical area” where sterile product may be exposed to:
 - Environmental contaminants
 - Personnel/process “shedding”



ENGINEERING CONTROLS ASSESSED

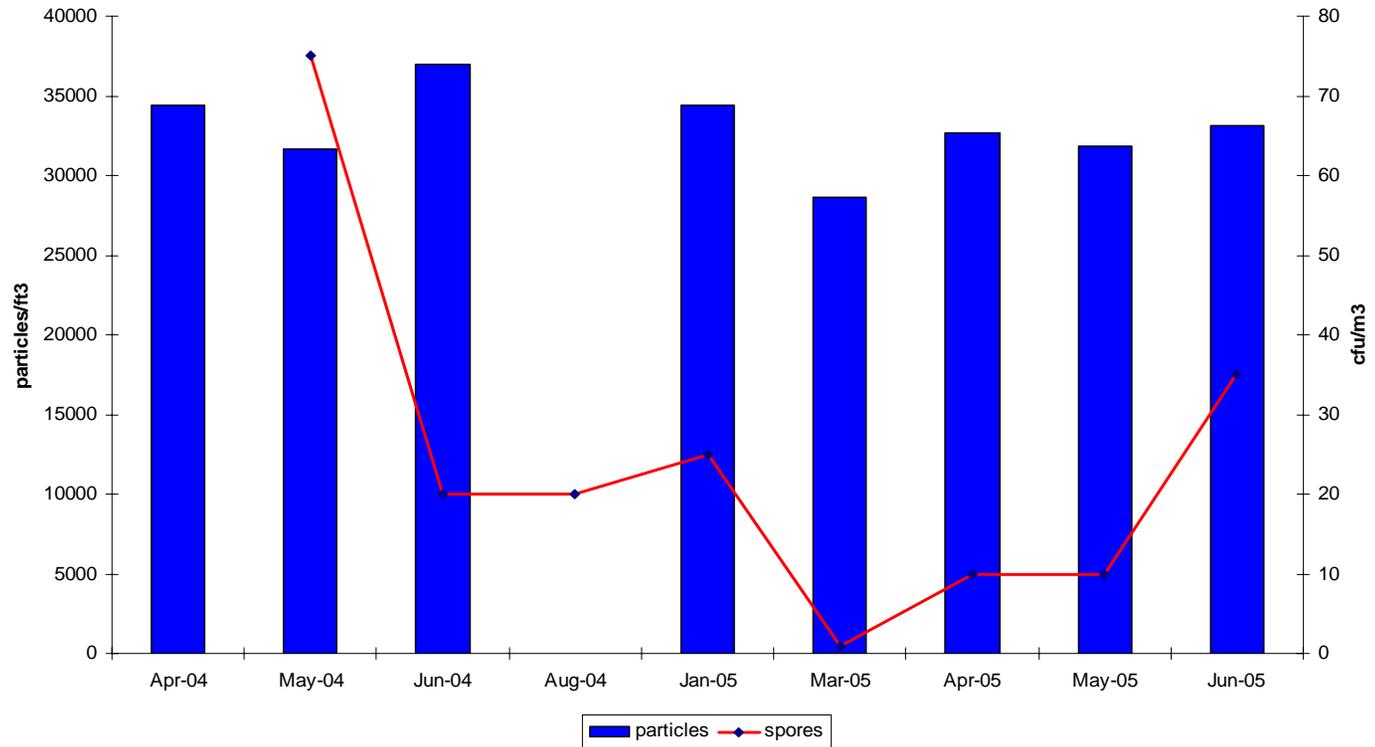
- Airlock
 - Not available at the laboratory
 - Isolated location reduced the need?
 - Considering for other more “open” laboratories
- Directional Airflow from Critical Area to Room Entry
- Directional Airflow at >2.5 Pascals
- Terminal Filtration

"SEALED" HEPA FILTER HOUSING



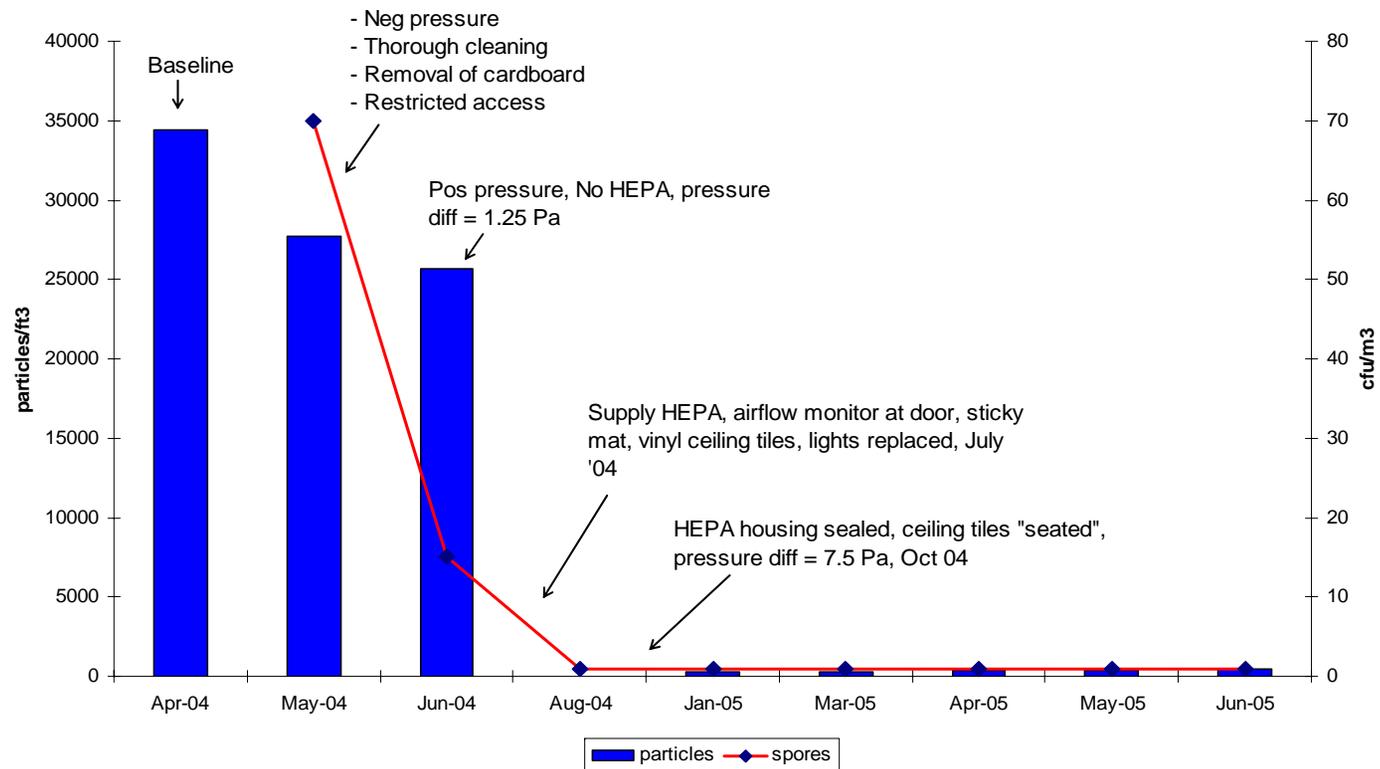
CONDITIONS IN THE ADJACENT "UNPROTECTED" ENVIRONMENT

Fungal Spore Concentrations and Particle Counts **Outside Lab #1 Near Door**



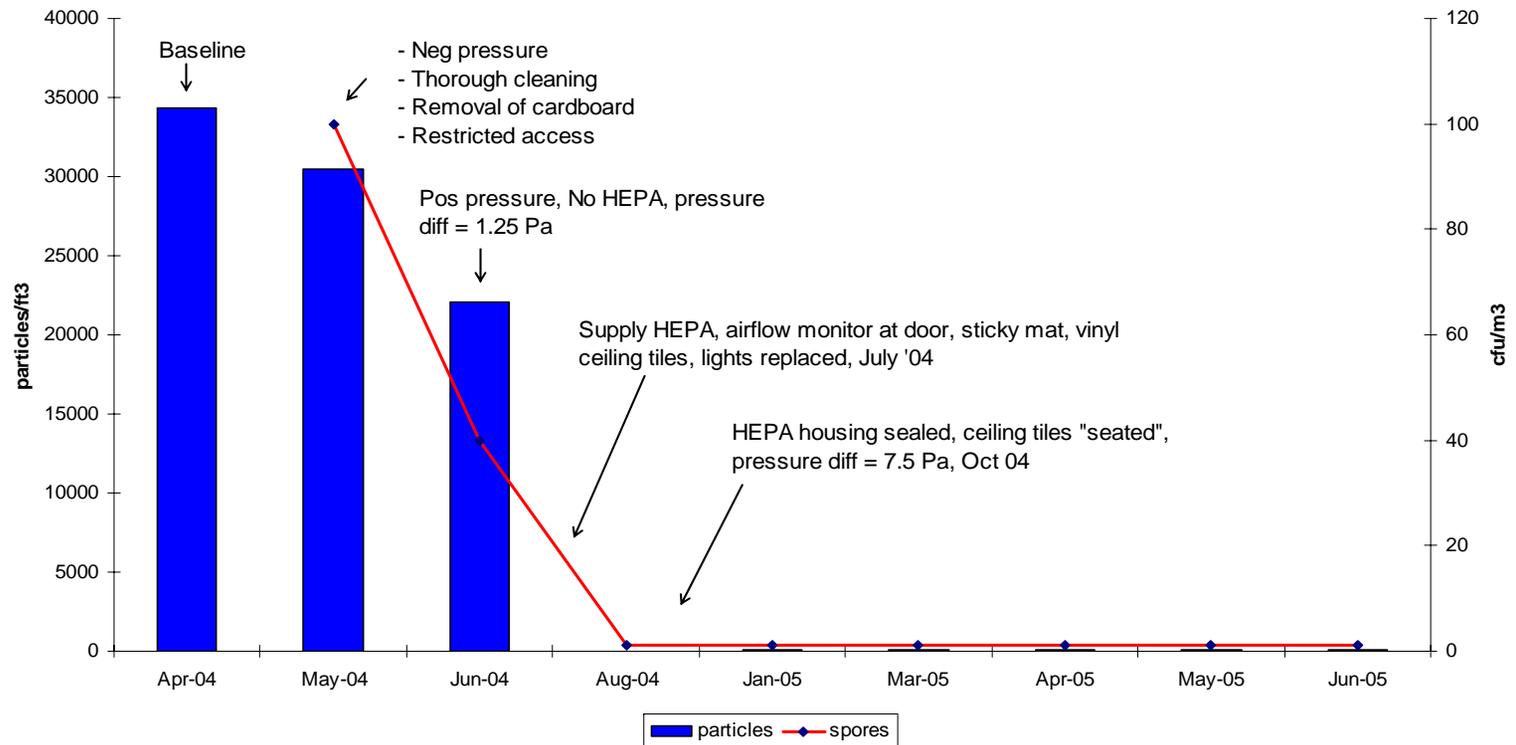
IMPACT OF "CONTAINMENT" ENGINEERING IN A GMP/GLP LABORATORY

Fungal Spore Concentrations and Particle Counts Inside Lab Near Door of Lab #1



IMPACT OF "CONTAINMENT" ENGINEERING IN A GMP/GLP LABORATORY

Fungal Spore Concentrations and Particle Counts in the "Critical Area" of Lab #1



CONFIGURATION OF "CRITICAL" AREA



“VALIDATION” MONITORING IN THE CRITICAL AREA

