Cleanrooms 101

During This Session, We Will:

- Learn - What is a Cleanroom
- Understand how we achieve the Level of Cleanliness.
- Discuss Cleanroom Design.
- Discuss the Certification Process.

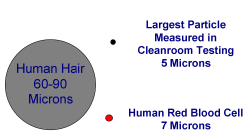
What is a Cleanroom?

A specially designed & constructed room in which; the air supply, air distribution, filtration of air supply, materials of construction, and operating procedures, are regulated to control airborne particle concentrations to meet appropriate cleanliness levels.

What is a "Particle"?

- A Particle is a very small discrete mass of solid or liquid matter, usually measured in microns.
- A micron is 1/1,000,000 of a metre.
- A human hair is 60 - 90 Microns.

Particle Size Comparison

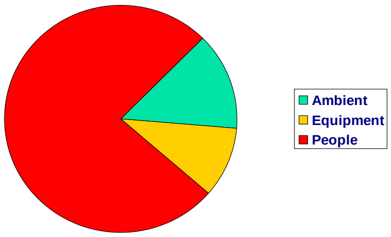


- An ISO Class 8 Cleanroom will have a maximum of 70 particles @ 5.0 Micron and a maximum of 100,000 @ 0.5 Microns / Cubic Foot
- (Actually measured in Cubic Metres in ISO)

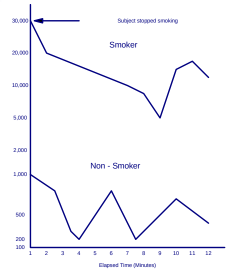
Cleanroom Classification Particles per Cubic Metre

ISO 14644	209E	0.5 Micron	5 Micron
3	1	35	N/A
4	10	352	N/A
5	100	3,520	29
6	1,000	35,200	293
7	10,000	352,000	2,930
8	100,000	3,520,000	29,300

Sources of Contamination



Smoking Particle Generation



- A typical smoker is expelling 10,000 to 20,000 0.03 µM particles 10 minutes after stopping. A non smoker generates less than 1,000.

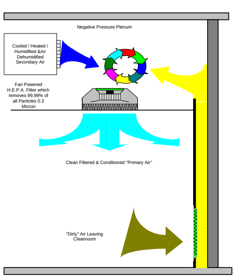
How do we Control Particles

- Isolation - Particles may be *isolated* by containing them at the source of generation.
- This is difficult as the Processes and Associates in the Cleanroom are the Largest Source of Contamination

How are Particles Controlled?

"It's time we face reality, my friends. ...We're not exactly rocket scientists."

How do we Control Particles?



- Dilution - Particles are captured by filtration, and the total space volume is diluted by clean air

HEPA / ULPA Filters

- This is a Ceiling Mounted HEPA Filter.
- High Efficiency Particulate Air Filters, range from 99.97% to 99.995% Efficient

ULPA Filters

- These are Ceiling Mounted ULPA Filters.
- These High Efficiency Particulate Air Filters are 99.9995% Efficient

Return Air Filter Grilles

- This is the method of Returning Air to the Negative Pressure Plenum

Typical Air Change Rates

ISO Class	Health Canada	US Fed Std. 209E	Air Changes Per Hour
4		10	720+
5	A	100	500-720
6	B	1,000	60-100
7	C	10,000	30-50
8	D	100,000	20-30

Particle Settling Velocities

Diameter (μm)	Feet / Minute	6' Drop
0.1	0.0006	7 Days
0.5	0.0020	50 Hours
1.0	0.0069	14.5 Hours
5.0	0.1530	39 Minutes
10	0.602	10 Minutes
100	48.82	7.4 Seconds

Where does Contamination Come From?

- Equipment, Material & Processes in the Cleanroom produce contamination.
- The largest single controllable source of contamination enters the Cleanroom with the Associates that work there.

Associate Contamination

0.5 Micron Particles / Minute	Street Clothing	Bouffant & Frock	Overall & Hood
Sitting	302,000	112,000	7,450
Swinging Arms	2,980,000	300,000	18,700
Twisting Upper Body	850,000	267,000	14,900
Walking	2,920,000	1,010,000	56,000

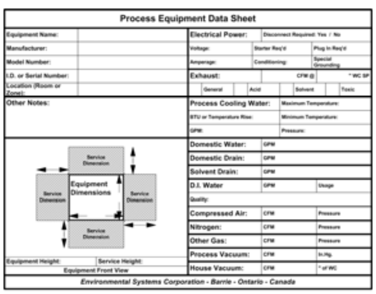
- Now that you know what a Cleanroom is, we will talk about design considerations.

Design Considerations
A Cleanroom Has Two Functions

- A Processing or Manufacturing Environment
- A Marketing Tool
- Design with both in mind

Design Considerations

- Start with the equipment requirements and use that information to produce an equipment matrix



Process Equipment Data Sheet

Equipment Name:		Electrical Power:	Disconnect Required: Yes / No	
Manufacturer:		Voltage:	Starter Req'd	Plug In Req'd
Model Number:		Amperage:	Conditioning:	Special Grounding
I.D. or Serial Number:		Exhaust:	CFM @	" WC SP
Location (Room or Zone):		General / Acid	Solvent	Toxic
Other Notes:		Process Cooling Water:	Maximum Temperature:	
		BTU or Temperature Rise:	Minimum Temperature:	
		GPM:	Pressure:	
Service Dimension / Equipment Dimensions / Service Dimension / Service Dimension / Service Dimension		Domestic Water:	GPM	
		Domestic Drain:	GPM	
		Solvent Drain:	GPM	
		D.I. Water	GPM	Usage
		Quality:		
		Compressed Air:	CFM	Pressure
		Nitrogen:	CFM	Pressure
		Other Gas:	CFM	Pressure
Equipment Height:	Service Height:	Process Vacuum:	CFM	In.Hg.
Equipment Front View		House Vacuum:	CFM	" of WC

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Design Considerations

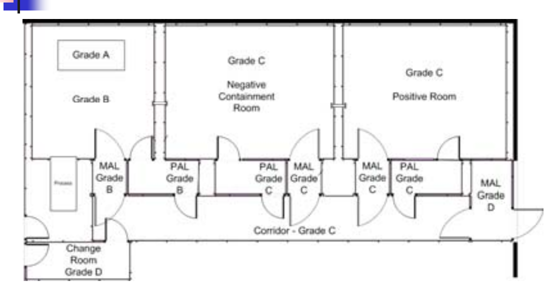
- Layout for process flow
- Can any of our equipment be installed outside the Cleanroom, with just the face in the Cleanroom
- Reduction in space saves cost.

Design Considerations

ISO Class	Health Canada	US Fed Std. 209E	Air Changes Per Hour
4		10	720+
5	A	100	500-720
6	B	1,000	60-100
7	C	10,000	30-50
8	D	100,000	20-30

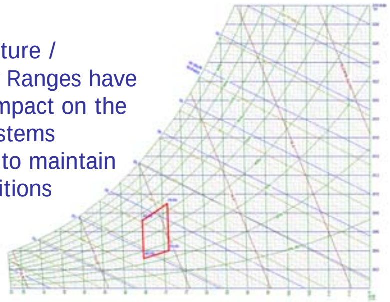
- Airflow rates are the way we maintain the required levels of particle control, the air changes come at a cost.

Design Considerations - Layout



Design Considerations

- Temperature / Humidity Ranges have a large impact on the HVAC systems required to maintain the conditions required



Design Considerations

- Room or Zone Classifications
- Typically in Pharmaceutical we look for an Ante Room between zones with a differential of 12.5 PA (0.05” WC) between different classifications, and 7.5 PA (0.03” WC) for the same classification

Design Considerations

- Don’t Skimp on the size of the Gowning Room
- You will require Storage for garments, gloves, etc.
- Where will you store cleaning equipment & supplies



Design Considerations

- Ceiling height, can be as low as 8’, however unless there process equipment requirements for more height, 9’ is the normal.



Design Consideration - Walls

- Drywall – Epoxy Painted
- Modular – Progressive
- Modular – Non Progressive



Design Consideration - Ceiling

- Drywall
- Gel Seal T Bar
- Panel Systems
- T Bar





Design Consideration - Floors

- Methyl Methcralate (MMA)
- Epoxy Resins
- Urethane
- Seamless Vinyl
- Vinyl Tile
- Raised Floors
- ESD

Design Consideration - Filtration

- HEPA / ULPA / SULPA
- Terminal
- Room Side Replaceable
- Bubble Tight Dampers
- Duct / AHU Mounted
- Bag In / Bag Out
- Fan Filter Units

Design Consideration – HVAC

- Largest Single Non Process Use of Energy is in your HVAC, Air Handling, Exhaust & Make Up Air Systems
- Component Selection is crucial as there are many factors to a complete “system”. Consider all component factors.
- Pressure Drop drives fan horsepower.

Design Consideration – Air Handling

- With large amounts of air required for recirculation, this can be handled by dedicated air handling systems, or by the use of Fan Filter Units.

Design Consideration - Exhaust

- Exhaust is the largest driver of energy cost, with our fluctuations in outdoor temperature we have large winter heating costs, and Summer conditions that rival the highest in North America.

Design Consideration – Make Up Air

- Make Up Air required for pressurization or to make up exhaust is a large component in the system energy cost.
- To maintain humidity levels within the controlled space cooling systems are sized for full system capacity that may only be a few hours per year.

Design Consideration - Electrical

Design Consideration - Process

Design Consideration - Ancillaries

- Air Showers
- Cleaning Materials
- Communication Systems
- Containment
- Gowning
- Pass Through's

Design Consideration - Portable

Cleanroom: Testing and Certification

HEPA Filter: High Efficiency Particulate Air Filter

- Rated at 99.97% efficiency minimum @.3 micron
- Scanned tested HEPA filter is 99.99% efficiency
- Gasket seal vs. Gel Seal
- Terminal HEPA vs. Ducted HEPA
- Fan Filter Modules

High Efficiency Particulate Air Filter

HEPA Housings: Gel Seal vs. Gasket

Primary Tests performed :

- Airflow Volume / Velocity Readings
- HEPA Filter Integrity Test
- Room pressure differential readings
- Particle Counts per ISO 14644-1

Airflow Volume / Velocity Readings

Velocity Profiles:

- For non-unidirectional room readings are taken 6 inches from the supply source at center of source
- For unidirectional rooms readings are taken 12 inches from the supply source. Divide the plane into equal sections and take multiple readings.
- Standard IES-RP-CC-006.3

Air Volume Readings:

- Air volume readings taken to calculate air changes per hour

Calculation :

Total Diffused Air Supply x 60 Divide by Room Volume (Cubic Feet) = ACPH

Installation tips:

- Ensure ductwork is clean of debris
- Important to not touch HEPA filter media
- Do not over tighten clamping system (gel seal)
- Ensure filter is 99.99% eff. (99.97%)
- Record model, and serial numbers

HEPA Filter Integrity Testing


HEPA Integrity Test

- Introduce aerosol into air system
- Measure upstream concentration to ensure minimum 10ug/L.
- Target upstream is > 20-40ug/L.
- Set photometer for determined upstream concentration
- Perform scan of filter face with probe at a scanning rate of 3m/min (10ft per min)
- Maximum repair 5% of area of filter

IES-RP-CC034.2 HEPA Integrity Test



Room Pressure Differential Readings.

- Correlation between room pressure and ACPH
- Differential between classes, 0.05” WC
- Magnahelic Gauge & Photohelic packages and configurations


Particle Counts per ISO-14644-1

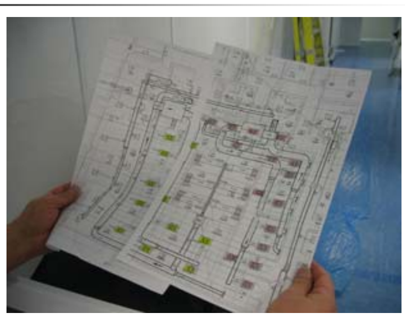
ISO Class	0.1 um	0.2 um	0.3 um	0.5 um	1 um	5 um
Class 1	10	2				
Class 2	100	24	10	4		
Class 3	1,000	237	102	35	8	
Class 4	10,000	2370	1020	352	83	
Class 5	100,000	23700	10200	3520	832	29
Class 6	1,000,000	237,000	102,000	35,200	8320	293
Class 7				352,000	83,200	2930
Class 8				3,520,000	832,000	29,300
Class 9				35,200,000	8,320,000	293,000

Sample Locations

- Determining the number of locations.
- Measure the area under consideration in square meters.
- Calculate the square root of that area.
- Ensure locations are distributed evenly throughout the area of the Cleanroom and positioned at the height of the work activity

Particle Counts per ISO 14644-1

Duct Layout Drawings



Additional Systems

Cleanroom Standards:

- IEST-RP-CC034.2 HEPA and ULPA Leak Tests
- IEST-RP-CC006.3 Testing Cleanrooms
- ISO 14644-1 Classification of air cleanliness

Institute of Environmental Sciences and Technology
2340 S. Arlington Heights Road, Suite 100
Arlington Heights, IL 60005-4516
Phone 847-981-0100 Fax 847-981-4130
Email iest@iest.org

Resources

- IEST - Recommended Practices & ISO Documents
  www.iest.org
- ISPE - Baseline Guides – Communities of Practice & So much More
  www.ispe.org

- ASHRAE – Handbooks
  www.ashrae.org

For More Information Contact:

Environmental Systems Corporation
122 Commerce Park Drive, Unit F
Barrie, Ontario, L4N 8W8, Canada
705 722 3220 / 1 866 565 7055

Vernon Solomon – 705 720 0030
vern@e-s-c.ca

David Hislop – 416 953 8691
david@e-s-c.ca

H.E.P.A. FILTER SERVICES INC.
 # 4 – 124 Connie Crescent
Concord, ON, L4K 1L7
905 669 1991 / 1 800 669 0037

Bruce Peat
bpeat@hepafilterservices.com

Danny Yee – Montreal - 514 871 9990
Danny.yee@qc.aira.com

Ottawa & Vancouver