#G-003c

Effective Contamination Control, Cleanroom Protocols, & Lab Safety

Presentation to LCI Cleanroom Users

dbryant@lci.kent.edu, 330-672-1583
bentley_wall@yahoo.com, 330-672-1525

External Resources

- **Cleanroom Technology: Fundamentals of Design, Testing, & Operation, W. Whyte, Wiley & Sons, 2001, ISBN 0 471 86842 6
- **Introduction to Contamination Control & Cleanroom Technology, Matts Ramstorp, Wiley-VCH, 2000, ISBN 3-527-30142-9
- Encyclopedia of Cleanrooms, Bio-Cleanrooms, and Aseptic Areas, Philip Austin, CRC Press, 2000, ISBN 0970113501
- Cleanroom Microbiology for the Non-microbiologist, David Carlberg, 1995, CRC Press, ISBN 0935184732 (2nd edition due Oct 2004)
- Cleanroom Design, W. Whyte, Wiley & Sons, 1999, ISBN 0471942049
- Trade Publications:
  - Cleanrooms Magazine, http://www.cleanrooms.com/
  - A2C2 Magazine, http://www.a2c2.com/
- **=source for many of images in presentation

Outline

- Introduction—Cleanroom definitions
- Facility design & layout principles
- Air flow
- Contamination & Measurement
- Cleaning & Materials Selection
- The user!!
- Protocols to improve control
- Safety Practices
- Conclusions

Things to Remember

- It is important for users to understand concepts behind clean processing
- Benefit from the experiences of others (standards, anecdotal information)
- Impact that a single user can have on overall process yield can be huge!

Historical Perspective

- Why Cleanrooms?
  - First cleanrooms were in hospitals to prevent disease transmission and infection in operating rooms (over 100 years ago!)
  - Valuable tool to prevent particulate and bio contamination
  - Most well known use is in semiconductor industry, but also essential in pharmaceuticals, flat panel displays, space program, photonics, life sciences, industrial (painting, assembly), etc.
  - Essential for LCDs because of coating processes, small cell gaps
  - Cleanroom itself is only part of the solution

Methods to Achieve Cleanliness

- Positive Pressure / Airflow
  - Keeps contamination out of the work area
  - Depends on clean air input
- Filtration
  - Development of effective filtration revolutionized industry
  - HEPA (High Efficiency Particulate Air) and ULPA (Ultra Low Particulate Air) Filters
- Materials Selection
- User Protocols
- Cleaning
- All are very important!

Definition of Clean Room / Area I

- In US, classes still referred to as defined by Federal Standard 209D

	Class limit (measured particle size) (equal to, or larger than the stated size, measured in micrometers)				
Class	0.1 µm	0.2 µm	0.3 µm	0.5 µm	5 µm
1	35	7.5	3	1	–
10	350	75	30	10	–
100	–	750	300	100	–
1000	–	–	–	1000	7
10000	–	–	–	10000	70
100000	–	–	–	100000	700

Definition of Clean Room / Area II

- Now superseded by ISO 14644-1; particles measured per cubic meter

	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO 1	10	2				
ISO 2	100	24	10	4		
ISO 3	1000	237	102	35	8	
ISO 4	10000	2370	1020	352	83	
ISO 5	100000	23700	10200	3520	832	29
ISO 6	1000000	237000	102000	35200	8320	293
ISO 7				352000	83200	2930
ISO 8				3520000	832000	29300
ISO 9				35200000	8320000	293000

Definition of Clean Room / Area III

- Conversion between standards:

USA Fed Std 209 D[1]	USA Fed Std 209 E[2]	Britain BS 5295[3]	Australia AS 1386[4]	France AFNOR X44101	Germany VDI 2083[5]	ISO 14644–1[6]	Japan JACA 24[7]
						1	1
				–	0	2	2
1	M 1.5	C	0.035	–	1	3	3
10	M 2.5	D	0.35	–	2	4	4
100	M 3.5	E	3.5	4000	3	5	5
1000	M 4.5	G	35	–	4	6	6
10000	M 5.5	J	350	400000	5	7	7
100000	M 6.5	K	3500	4000000	6	8	8
		M			7	9	–

1 Measured as number of particles ≥ 0.5 µm/ft^3
2 Measured as number of particles ≥ 0.5 µm/m^3
3 Measured as number of particles ≥ 0.5 µm/ft^3
4 Measured as number of particles ≥ 0.5 µm/m^3
5 Measured as number of particles ≥ 0.1 µm/m^3
6 Measured as number of particles ≥ 0.5 µm/m^3
7 Measured as number of particles ≥ 0.1 µm/m^3

Outline revisited

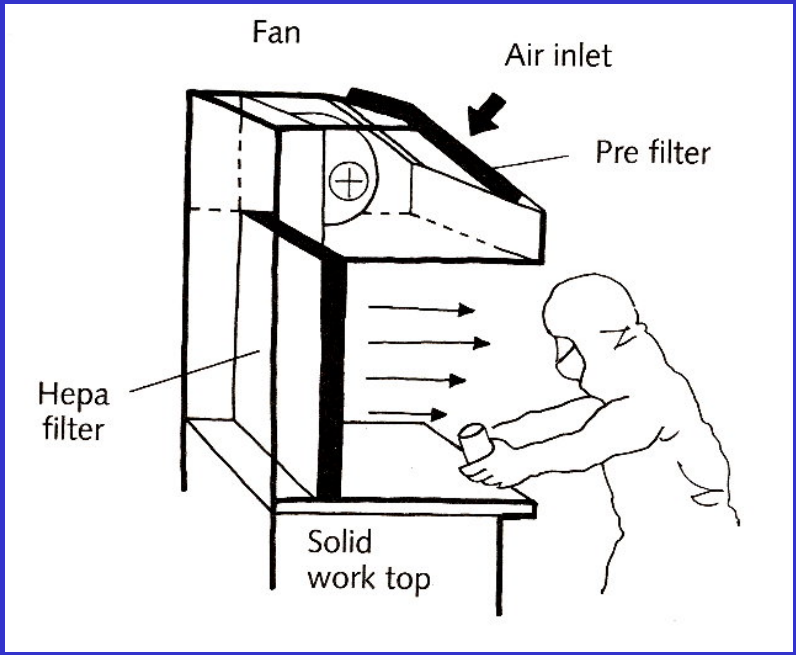
- Introduction—Cleanroom definitions
- **Facility design & layout principles**
- Air flow
- Contamination
- Measurement
- The user!!
- Protocols to improve control

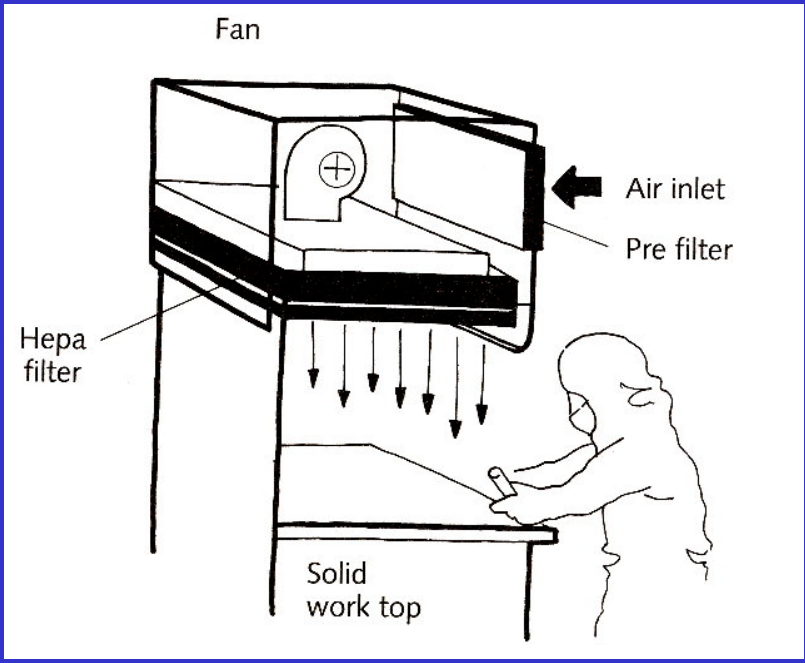
Facility Design

- Complete cleanroom created with centralized air handling or fan filter units
- Keeps entire room clean
- Requires complete gowning, careful materials and equipment selection to maintain class
- Costly, often unnecessary

Facility Design

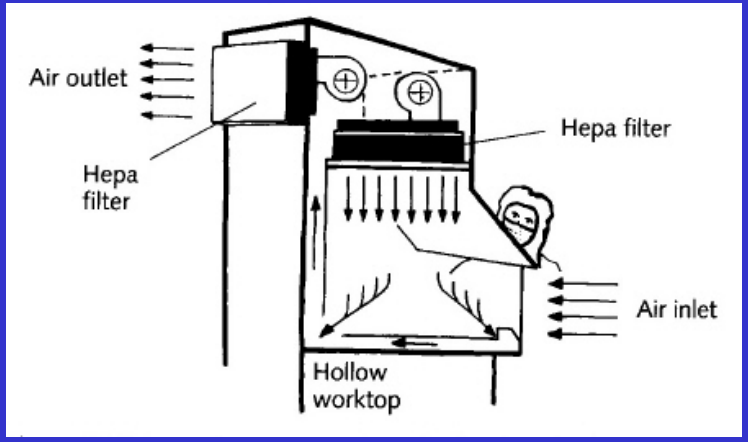
- Can use localized clean areas
- Clean Benches: Horizontal and Vertical Laminar Flow (HLF on left, VLF on right)

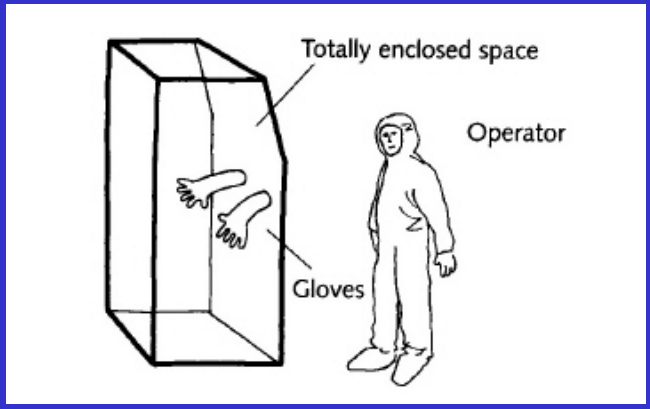




Facility design

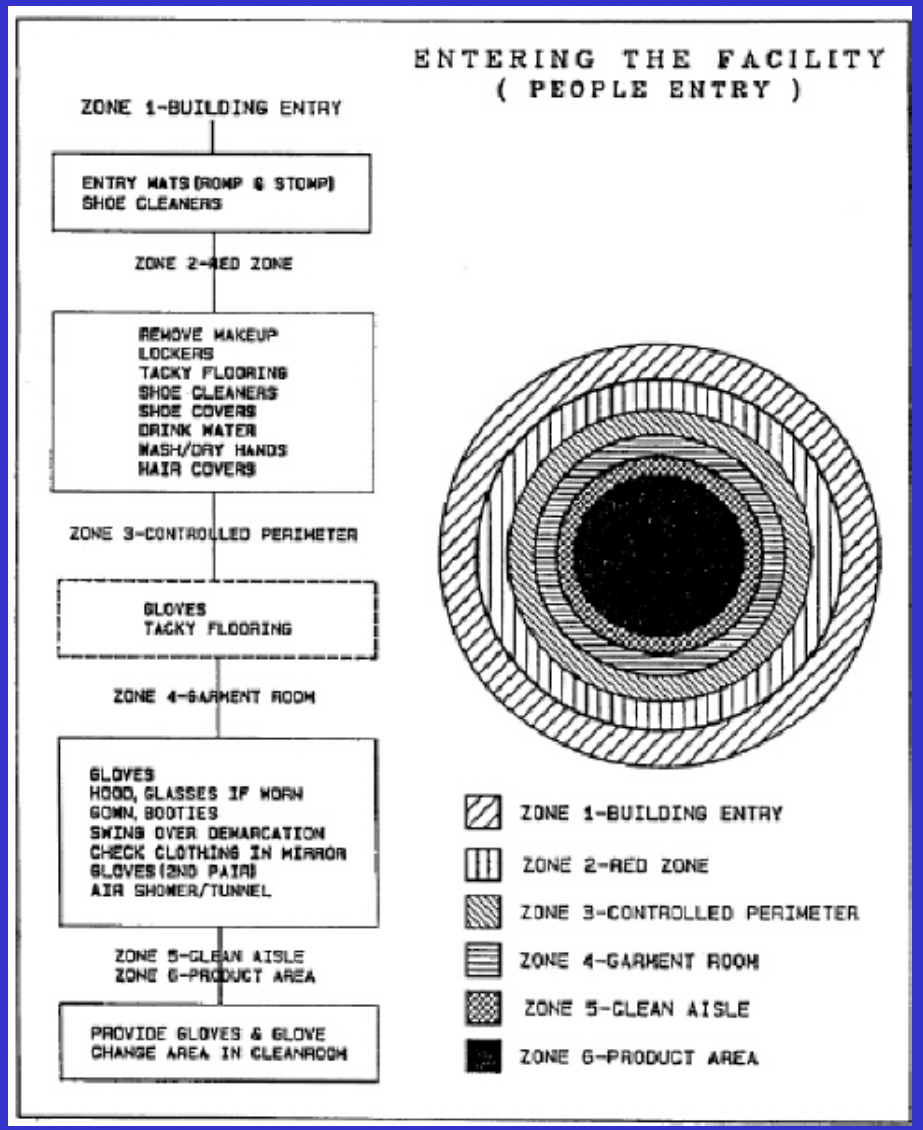
- Isolators, Glove boxes provide better protection from outside contamination





Contamination Control by Layout

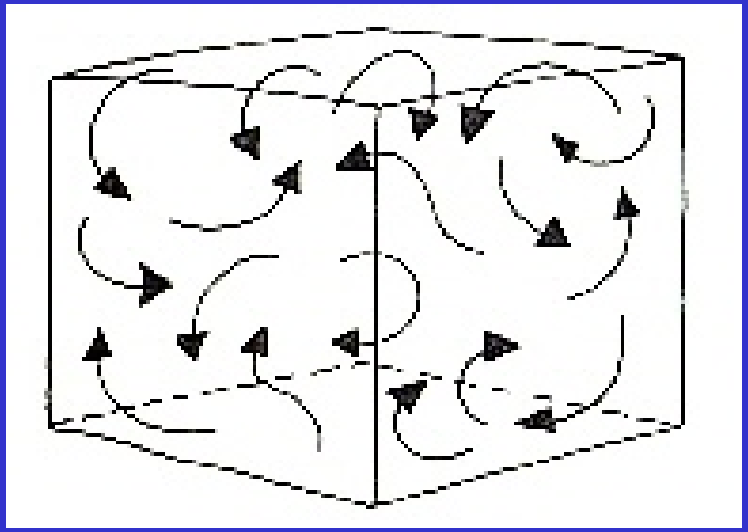
- Isolation between processes prevents cross contamination; separate rooms, air showers, door interlocks
- “Onion” concept: cleanest areas are inside, have to pass through successively cleaner areas to reach these areas



Outline

- Introduction—Cleanroom definitions
- Facility design & layout principles
- **Air flow**
- Contamination & Measurement
- Cleaning & Materials Selection
- The user!!
- Protocols to improve control

Air Flow & Turbulence

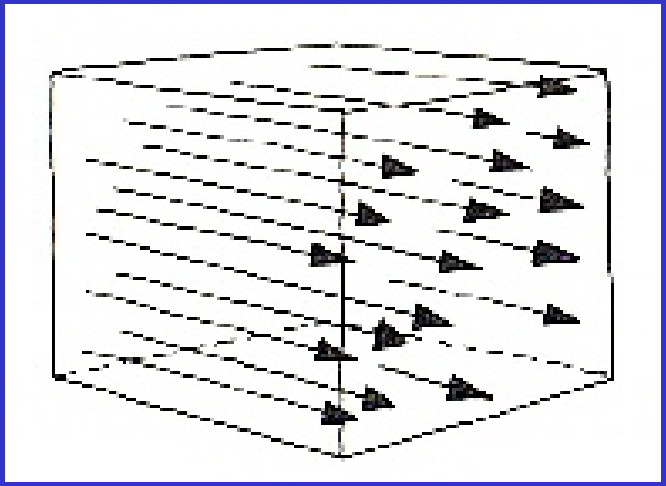


- Most airflow is turbulent—no clear relation between velocity vectors at different points

•Not optimal for contamination control!! Long path length for contamination to leave the room
•Particles can be trapped in eddies for long time

Laminar (Unidirectional) Air Flow

- Concept of laminar airflow
- In cleanrooms, often called uni-directional flow (UDF)



- Ideal for contamination control—shortest path to sweep particles out of clean areas; complete room air change in shortest period of time

How is this applied in cleanrooms?

- High level cleanrooms designed for laminar flow in most areas
- Cost means that for most, clean areas are some combination of laminar and turbulent flow
- Not always a simple tradeoff—with turbulent flow, require higher air velocities, which require larger air handlers ($$)

UDF More Important for Cleaner Areas

Class of cleanroom	Airflow type	Average velocity (ft/min)	Air changes/hr
ISO 8 (100,000)	N/M	1-8	5-48
ISO 7 (10,000)	N/M	10-15	60-90
ISO 6 (1,000)	N/M	25-40	150-240
ISO 5 (100)	U/N/M	40-80	240-480
ISO 4 (10)	U	50-90	300-540
ISO 3 (1)	U	60-90	360-540
better than ISO 3	U	60-100	360-600

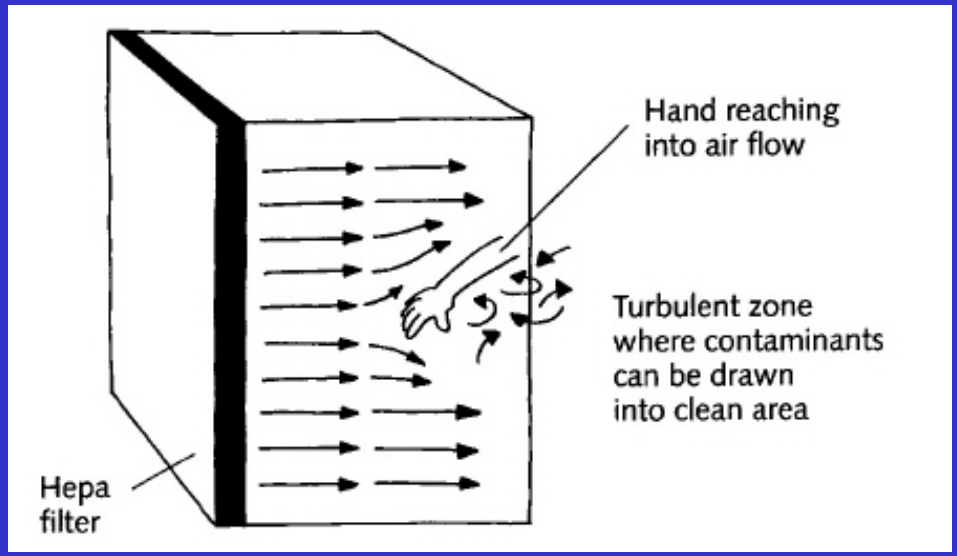
$$\text{Air changes per hour} = \frac{\text{Average airflow velocity}^{*} \times \text{room area} \times 60 \text{ min / hr}}{\text{Room Volume}}$$

* taken over the whole supply ceiling
N = nonunidirectional; M = mixed flow room ; U = unidirectional flow.

Practical Considerations for UDF

- Any objects in path of laminar flow will deflect airflow—this usually results in turbulence; USER BEHAVIOR HAS LARGE IMPACT

  •Most critical for laminar flow benches situated in non-clean areas; not as critical if located in larger clean area



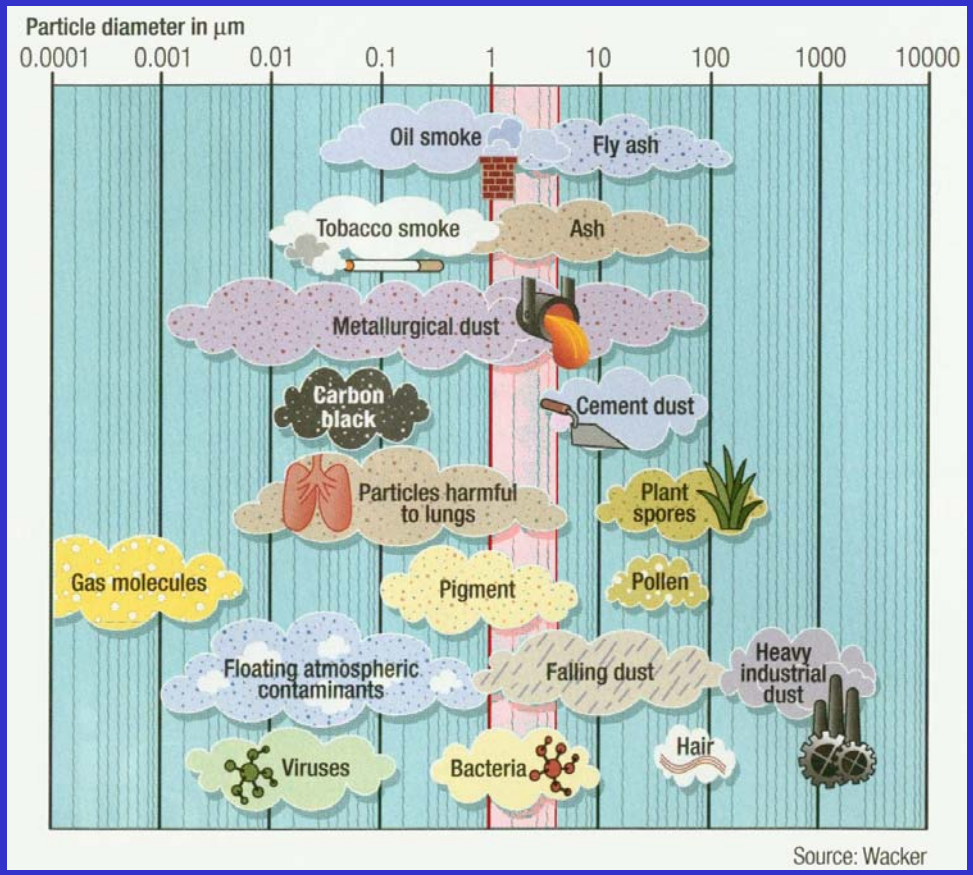
Outline

- Introduction—Cleanroom definitions
- Facility design & layout principles
- Air flow
- **Contamination & Measurement**
- Cleaning & Materials Selection
- The user!!
- Protocols to improve control

Types of Contamination

- Particulate—encompasses most contamination
- Chemical—films, vapors, etc.
- Biological—bacteria, viruses, etc.; for our purposes, treat as particles
- Similar concerns for rooms & equipment as for substrates

Airborne Contamination



From Cleanrooms Magazine, 2000

Invisible to naked eye below ~50um without special illumination

Particulate Contamination

- Biggest concern for LCI cleanroom users
- Basis for classification of cleanrooms
- Does include biological contamination as a subset of total particulates
- Many sources: personnel, equipment, etc.

Problem of Aerosols

- Generic term for particles that tend to remain airborne
- Small size of particles means that gravity has lesser effect; think cigarette smoke
- Can remain in turbulent eddy currents for long periods, not removed from room

Microbial Contamination

- Outer layer of human skin can host up to 1 million microorganisms per square cm
- Human saliva up to 1 billion per mL
- Bacteria is usually primary concern, but foreign organic matter, viruses, fungi, algae are all included here
- Cross contamination can be a big issue!!

Contamination Measurement

- Particulate contamination typically measured with laser particle counter
- Microbial contamination can be measured in several ways
  - Centrifugal sampler
  - Settle plate method
  - Contact plate method
  - Swabbing

How to Use Measurements

- Complementary to yield tracking
- Can use measurements to isolate problem areas
- Regular measurements can help to track changes, which can then be tied back to protocol, personnel, or material changes
  - Don’t depend upon room to maintain itself; verify!
- Possible to isolate culture lines responsible?

Reality

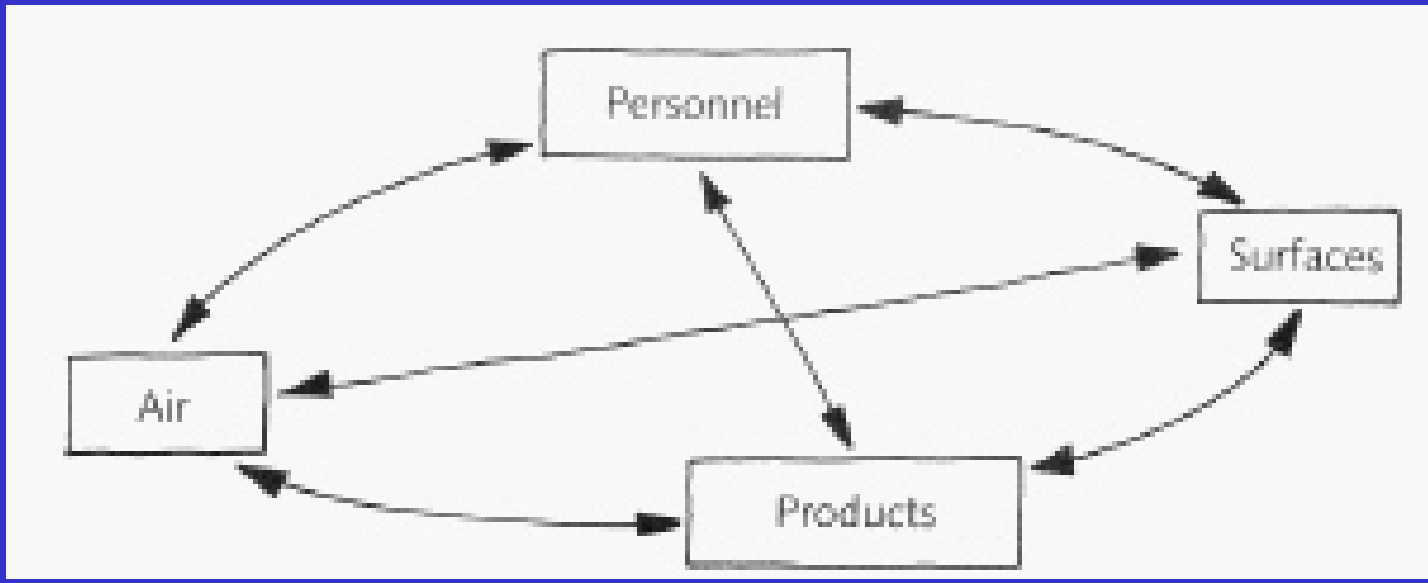
- In a perfect world, could monitor many points on a very regular basis
- In reality, this is usually not practical, due to personnel time and financial constraints
- Important to identify a realistic test & measurement program

Outline

- Introduction—Cleanroom definitions
- Facility design & layout principles
- Air flow
- Contamination & Measurement
- Cleaning & Materials Selection
- The user!!
- Protocols to improve control

Contamination Control and Its Relationships

- All sources of contamination and control are interrelated



Cleaning

- Critical to remove contaminants that cannot be removed by air handling
- Important to follow procedures appropriate to your application
- What is appropriate for one industry may not be appropriate for another
- Most important thing is to develop standard procedures and FOLLOW THEM

Surfaces are important

- The efficiency of these cleaning methods depends on the surface being cleaned
- Rough or pitted surfaces are more difficult to clean
- Sharp corners are difficult to clean
- Why are inside surfaces of cleanrooms smooth?

Vacuuming

- Dry and wet
  - Dry has low (<25%) efficiency for particles smaller than 10 microns (about .0005 inches)
  - wet uses liquids which result in greater force on the particles and hence better cleaning

Wet wiping

- Can be very efficient
- Liquid breaks some bonds between surface and particles and allows particles to float off
- Those adhering on surface can be rubbed off and retained in wiper.
- Must be careful not to redeposit particles
- Efficiency varies

Tacky rollers

- Efficiency depends of tackiness of roller, cleanliness of tacky surface and softness of roller are also very important

Cleaning liquids

- No ideal cleaning liquid
- Most facilities use DI water or isopropyl alcohol with disinfectant
- Water with surfactant and disinfectant may be used as well as alcohol-water solutions
- The choice depends on what works, cost, history, etc.

Materials Selection

- Choice of materials for supplies, equipment, gowning, etc. is important
- “Clean” materials can become dirty!!
- Look for easy-to-clean materials
- Triboelectricity can cause static problems, as can low humidity—this exacerbates contamination problems
- Biofilms!!

Outline

- Introduction—Cleanroom definitions
- Facility design & layout principles
- Air flow
- Contamination & Measurement
- Cleaning & Materials Selection
- **The user!!**
- **Protocols to improve control**
- Conclusions

Impact of the Cleanroom User

- Truth: Manufacturers can achieve similar yield results using cost effective flow hoods and isolation chambers as with full-blown central cleanrooms
- BUT: user behavior is much more critical in these areas!!!

Gowning at the LCI, I

- Put on plastic shoe covers (booties) over your shoes in the hallway
- If you wear boots or other heavy contaminating shoes, consider keeping a pair of sneakers in your office for use in the cleanroom
- Open door and enter cleanroom
- Log in on computer at entrance
- Put on gowning gloves

Gowning at the LCI, II

- Put on hairnet
- If using Class 10K south only, put on lab smock and proceed to usage area
- If using main cleanroom, proceed to gowning room
- Pick up an appropriately sized head cover and put on
- If previously in cleanroom, can use garment stored on hanger

Gowning at the LCI, III

- Pick up an appropriately sized coverall and put on, being careful to avoid allowing coverall to touch floor
- Tuck head cover into coverall before zipping up coverall
- Pick up an appropriately sized set of shoe covers and put on over plastic booties and coverall; snap shoe cover to back of pant leg and pull tight
- Put on second set of gloves, being careful to pull glove over cuff of coverall
- Put on safety glasses and proceed to air shower

Common Protocol Violations

- Not wearing Safety Glasses
- Improper gowning
  - zippers, snaps, masks
- Non-cleanroom materials in cleanroom
  - paper, cardboard, personnel items
- Not cleaning up after you are finished
- General conduct
  - Fast motions, incorrect carrying of materials
  - Remember laminar flow; minimize turbulence

Effect of the Cleanroom User

PEOPLE CONTAMINATE !

ACTIVITY	PARTICLES/MINUTE 0.3µm AND LARGER
MOTIONLESS - STANDING OR SEATED	100,000
WALKING ABOUT 2 MPH	5,000,000
WALKING ABOUT 3.5 MPH	7,000,000
WALKING ABOUT 5 MPH	10,000,000
HORSEPLAY	100,000,000

Activity and Particle Generation

Table 27. Relationship of activity to the number of particles shed from a human body

Activity	Number of particles generated (0.5 µm and larger per min)
Sitting or standing still	100000
Sitting, small movement of arms or head	500000
Sitting, moving arms, legs or head	1000000
Standing up	2500000
Walking slowly	5000000
Walking normally	7500000
Walking with speed (2.5 m/s)	10000000
Performing work-out	15000000–30000000

- User behavior has huge effect on particle generation (from Ramstorp)

General Cleanroom User Requirements I

- Minimize sources of contaminants
  - No smoking
  - No cosmetics
  - Avoid high particulate clothing, such as wool sweaters
  - Cover up! Uncovered skin can lead to more contamination

Activity and Contamination
(from Ramstorp)

Table 28. Sources of contamination and their effect on their environment

Contamination source	Size of generated particles (μm)
Rubbing a painted surface	90
Folding a piece of paper	65
Rubbing an epoxy-treated surface	40
Writing with a ballpoint pen on ordinary paper	20
Rubbing the skin	4
Activity	**In relation to normal breathing**
Brushing one's clothing	1.5–3
Stamping one's foot (without a shoe cover)	10–50
Stamping one's foot (with shoe cover)	1.5–3
Take a handkerchief from a pocket	3–10
Normal breathing	1
Breathing from a smoker (after 20 min)	2–5
Sneezing	5–20
Rubbing hands or face	1–2
Walking together (4–5 persons)	1.5–3
Normal walking	1.2–3
Sitting still	1–1.2
Clean air zone with micro-filter	0.01

Protocols to Improve Contamination Control

- Follow gowning procedures and restrict materials used in cleanroom
- An educated worker is essential to proper job performance; workers should be well versed in the how and why of their job

You as the User I

- Very important to think about each and every action you take:
  - How does this affect cleanliness?
  - Why do we do this the way we do?
  - Is there a better way to do it?
  - What will happen if I do not follow proper protocols?
  - You should know the answers to all of these questions!

You as the User II

- Cleanroom environment is very fragile!
  - Your actions have impact on other users
- Important to follow procedures EVERY TIME
  - Make sure fellow workers follow procedures as well; nothing wrong with pointing out mistakes
  - Be an active participant: keep an eye out for areas that can be improved

Minimalism is Good

- Bring only required materials into cleanroom; if it is not necessary to perform the task, it should not be there
- Personnel: only required personnel should be in the clean space
- Reduce clutter—do not store materials in clean areas unless they have to be there!

Repetition is Good

- Follow exact procedures every time
- Wipe down surfaces with cleanroom wipes before and after every usage
- Remember: this can seem tedious and unnecessary, but is essential to keeping the cleanroom maintained at its highest levels

Conclusions

- Contamination control is a continuous battle
- User behavior has a critical impact on contamination
- Proper procedures must be followed at all times
- Think about your actions! Be an active participant