Understanding Cleanroom Manufacturing

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Cleanrooms

- What is a Cleanroom?
- Cleanroom Classification
- Controlling the Environment For Contamination Control
- Appreciation for defects
- How to gown up to go into a clean room
- Safety precautions
- Clean room materials: tacky mats, special paper, fiberless clothing, etc

Cleanroom Definition Per ISO 14644-1

What is a Cleanroom?

- ‘A room in which the concentration of airborne particles is **controlled**, and which is constructed and used in a manner to minimize the **introduction**, **generation** and **retention** of particles and microbes inside the room and in which other relevant **parameters**, e.g. temperature, humidity and pressure are controlled as necessary.’

- 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

How Clean Does It Have To Be?

- Cleanrooms are classified according to the degree of cleanliness required of the entire manufacturing process
- Upon receiving a classification, the room must be maintained to meet the specifications for:
  - Cleanliness
  - Temperature
  - Humidity
  - Pressure
  - Number of air changes per hour
  - Air flow rate (CFM)

Manufacturing Environment (1)

Two operation states of Clean Areas

– Classified in terms of airborne particles

Grade	At rest		In operation	
	maximum permitted number of particles/m^3			
	0.5 - 5.0 µm	> 5 µm	0.5 - 5.0 µm	> 5 µ
A	3 500	0	3 500	0
B	3 500	0	350 000	2 000
C	350 000	2 000	3 500 000	20 000
D	3 500 000	20 000	not defined	not defined

"At rest" - production equipment installed and operating

"In operation" - Installed equipment functioning in defined operating mode and specified number of personnel present

Comparison of classifications

WHO GMP	US 209E	US Customary	ISO/TC (209) ISO 14644	EEC GMP
Grade A	M 3.5	Class 100	ISO 5	Grade A
Grade B	M 3.5	Class 100	ISO 5	Grade B
Grade C	M 5.5	Class 10 000	ISO 7	Grade C
Grade D	M 6.5	Class 100 000	ISO 8	Grade D

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

Examples of ISO Classifications For Industries

ISO 4:

- High Speed Video Duplication
- Glass Lamination

ISO 3:

- Compact disk manufacturing
- Optical Manufacturing

ISO 2:

- Semiconductor Manufacturing

ISO 1:

- Latest wafer and chip manufacturing
- Hard disk manufacturing

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

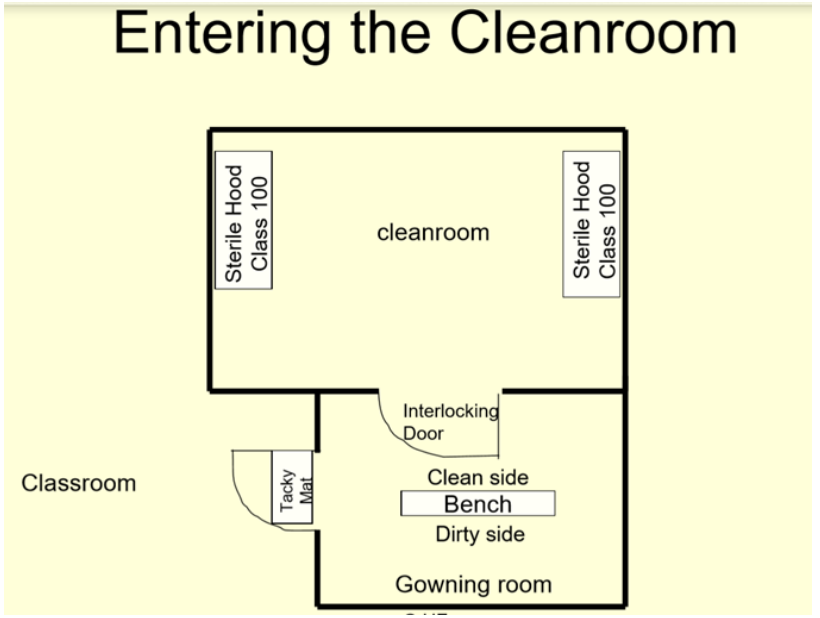
USA Fed Std 209 D[1]	USA Fed Std 209 E[2]	Britain BS 5295[3]	Australia AS 1386[4]	France AFNOR X44101	Germany VDI 2083[5]	ISO 14644–1[6]	Japan JACA 24[7]
						1	1
				–	0	2	2
1	M 1.5	C	0.035	–	1	3	3
10	M 2.5	D	0.35	–	2	4	4
100	M 3.5	E	3.5	4000	3	5	5
1000	M 4.5	G	35	–	4	6	6
10000	M 5.5	J	350	400000	5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

Cleanroom Basics: Controlling the Environment

- Environmental Control
  - Atmospheric Conditions: Positive air pressure
  - Entrance and Exits- tacky mats to trap dirt
  - Materials and Supplies: Must be cleanroom compatible
  - Cleaning and Maintenance- regular and thorough

- Personnel Control
  - Activity: follow cleanroom protocols
  - Personal Hygiene: proper attire and cleanliness
  - Gowning: follow guidelines and regulations



Controlling Contamination:

Air Quality

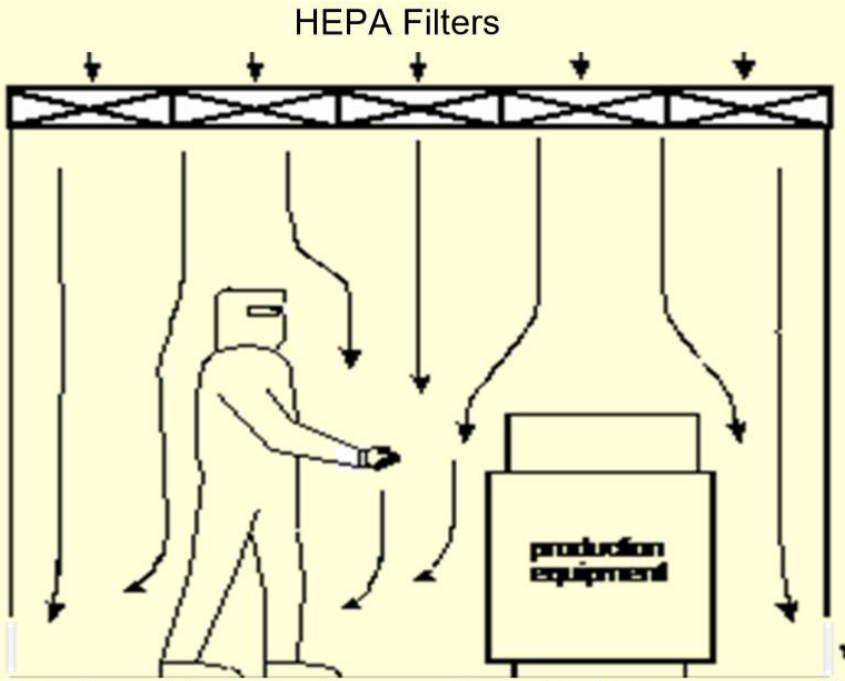
- Filtration
  - Pre-filtered in air handling units
  - HEPA (High Efficiency Particulate Air) filtered prior to entering cleanroom. Removes 99.99% of particles (typically 0.3um).
  - Air is not recycled
- Temperature
  - Maintained to reduce microbial growth (viruses, spores, fungi, bacteria)
- Humidity
  - Effects static, and growth of microbes

} Employee Comfort

Class 10,000 Specifications: Temperature 72 +/- 2.5°F, Humidy 45+/- 5%

Laminar Flow

Air flows with uniform velocity in parallel layers, with no disruption between the layers.



ate Air: HEPA

Why Laminar Flow?

- Non-turbulent air flow, reduces the possibility of contamination caused by the movement of particles
- “Scrubs” the room with air flowing from ceiling to floor

CLEANROOM ARCHITECTURE

- Interlocking door system
  - Door to “dirtier” area must be closed before door to “clean” area can be opened.
  - Personnel must come in and out of the cleanroom through the gowning room. buffer zone.
  - An open, non-air locked door can add billions of particles per cubic ft

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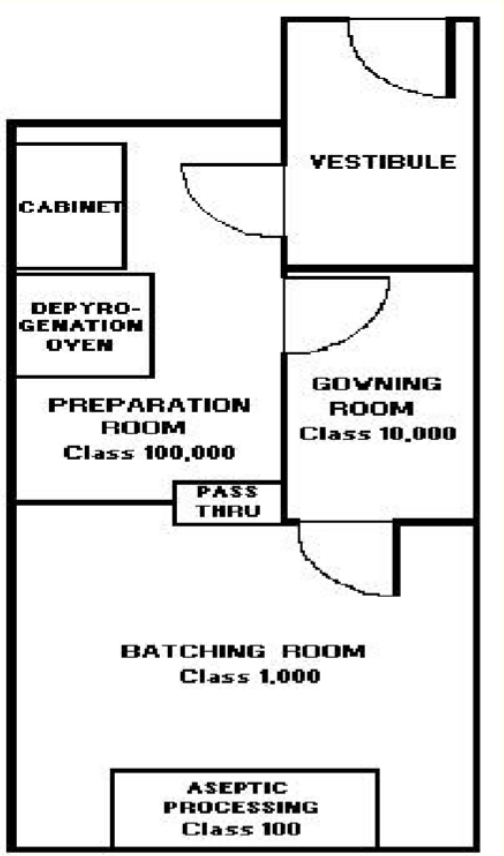
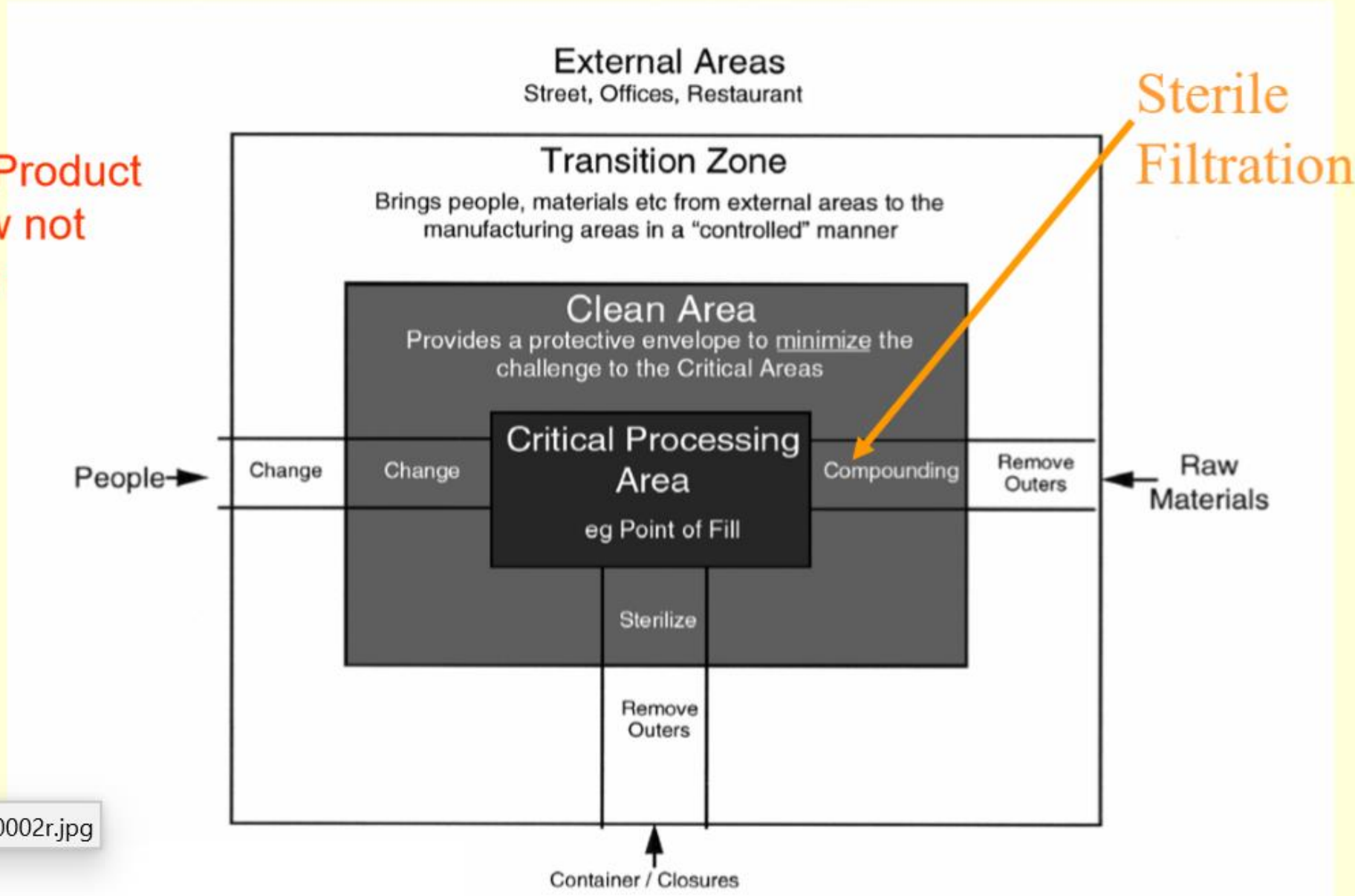


Cleanroom Architecture

- Elimination of spaces and crevasses that trap particles:
  - Recessed lighting and vents
  - “Coved” floor
  - Covered light switches
  - Specialized furniture (wheels, low particle emitting, stainless steel)
  - Epoxy paint on walls and floors

Nested Zones

Note: Product outflow not shown



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Sources of Contamination in Clean room (1)

1. **Personnel**
   - Skin flakes and oil
   - Cosmetics and perfume
   - Spittle
   - Clothing debris (lint, fibers etc.)
   - Hair

2. **Facilities**
   - Walls, floors and ceilings
   - Paint and coatings
   - Construction material (sheet rock, saw dust etc.)
   - Air conditioning debris
   - Room air and vapors
   - Spills and leaks

3. **Equipment / Tool Generated**
   - Friction and wear particles
   - Lubricants and emissions
   - Vibrations
   - Mops and dusters

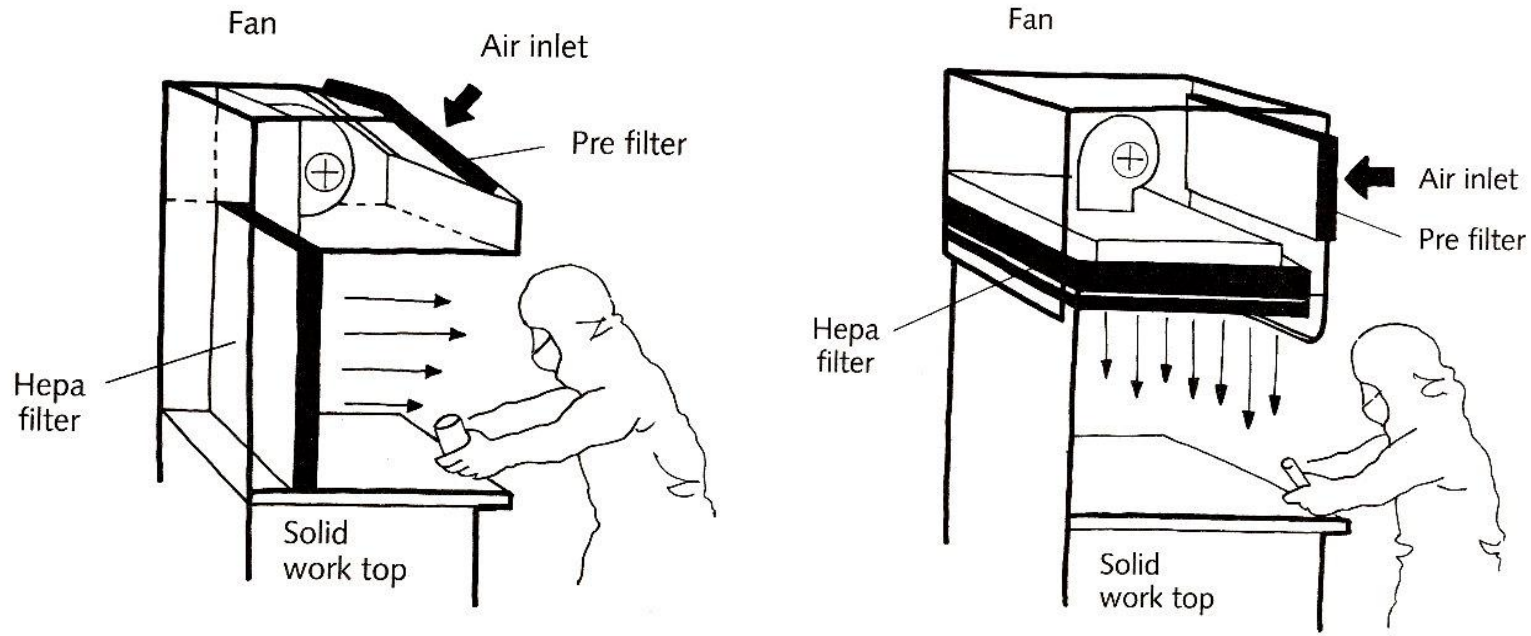
4. **Fluids**
   - Cleaning chemicals

5. **Product**

Microorganisms:
Viruses
Bacteria and
fungus

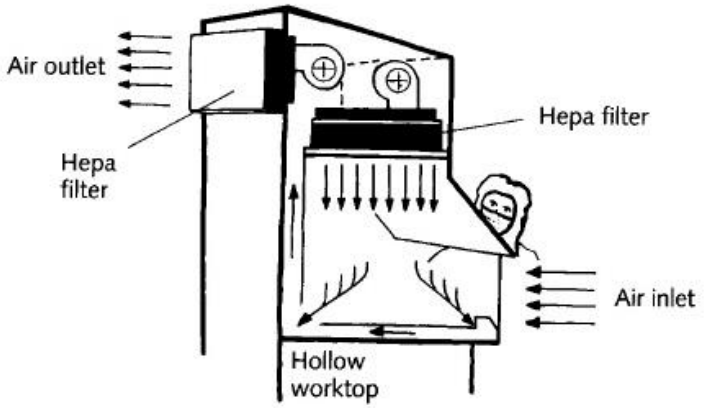
Facility Design

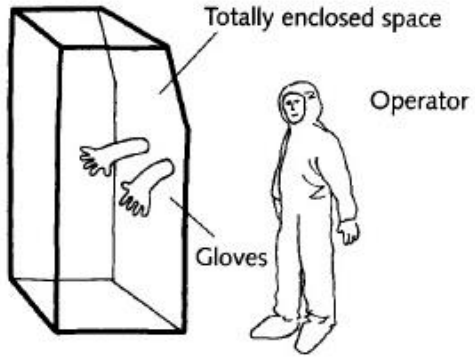
- Can use localized clean areas
- Clean Benches: Horizontal and Vertical Laminar Flow (HLF on left, VLF on right)



Facility design

- Isolators, Glove boxes provide better protection from outside contamination





Minimizing particles

- Only approved cleanroom paper.
- Only approved ball point pens for writing
- Use of paper or fabric towels are prohibited

-Two surfaces rubbing generates billions of particles per cubic ft.

-Equipment should be specialized for cleanroom use (brushless centrifuges)

Clean?

- When can the cleanroom be cleaned?
  - Need to work around production schedule
- How frequently does it need to be cleaned?
  - Depends on use
- What is clean and how is it measured?

Cleaning the Cleanroom

- Cleaning is the essential element of contamination control.
  - Disinfectants filtered
  - Mops/Buckets autoclaved
  - Disinfectants rotated every two weeks
  - Only cleanroom approved wipers allowed
  - Clean top to bottom, cleanest area to dirtiest

Cleanroom Regulations

- No personal items such as jewelry, keys, watches, matches, lighters and cigarettes
- No eating, smoking or gum chewing inside any cleanroom
- No cosmetics such as lipstick, eyeshadow, eyebrow pencil, mascara, eye liner, false eye lashes, fingernail polish, hair spray, mousse, or heavy use of aerosols, after-shaves and perfumes
- Approved skin lotions are sometimes allowed to reduce skin flaking

Particle Characteristics

- 50 μm particles are visible to the human eye
- Average human hair is 100 μm in diameter
- How long does it take for a particle to fall to the ground?
  - 33 s for a 10 μm particle
  - 48 min for a 1 μm particle
- Humans generate ~10^5 particles per minute (fully gowned) and motionless
- Humans can generate ~10^6 particles when walking in a cleanroom!

Actions Prohibited In Cleanrooms

- Fast motions such as running, walking fast or horseplay
- Sitting or leaning on equipment or work surfaces
- Writing on equipment or garments
- Removal of items from beneath the cleanroom garments
- Wearing tor or soiled garments
- Allowing hands to touch anything other than product-related work

Sources of Contamination in Clean room (2)

Among the Several sources (Area ceilings, walls; materials, Equipment) the largest cause of contamination in a clean room are personnel.

1. **Standing or sitting with no movement** results in shedding **100,000 particles/minute** 0.3 microns or larger.

2. **Sitting or standing, light head, hand and forearm movement** results in shedding **500,000 particles/minute**, 0.3 microns & larger.

3. **Sitting or standing, average body and arm movement , toe tapping**, results in shedding **1,000,000 particles / minute**, 0.3 microns & larger.

5. **Walking**

   5a. **Slow walking** (2 mph), results in shedding **5,000,000 particles/minute**, 0.3 microns & larger.

   5b. **Average walking** (3.57 mph), results in shedding **7,500,000 particles/minute**, 0.3 micron & larger.

   5c. **Fast walking** (5 mph), results in shedding **10,000,000 particles/minute**, 0.3 microns and larger

6. **Climbing stairs**, results in shedding **10,000,000 particles/minute**, 0.3 microns and larger.

It is important that each of us understand how our personal hygiene and habits affect the Cleanroom's cleanliness.

HUMANS IN CLEANROOMS

(The biggest source of contamination)

PEOPLE ACTIVITY	PARTICLES/MINUTE (0.3 microns 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

Sometimes you can tell — especially in the winter when your skin is dry or even now if we're inside and the heat's on the humidity's low. When you take off your socks or your clothes, sometimes you see this like just white cloud of dust. That's dead skin. In fact, most of the dust in your house is dead skin. So 30% of the soils that are on your clothes, you can see. These are food stains or things like that. And 70% are these body soils. So that's why we recommend you wash your clothes more frequently — because they may not look soiled.

Personnel Gowning

- Before entering a cleanroom all personnel must wash their hands and don cleanroom garb in the following order:
- Dedicated shoes or shoe covers over your shoes
- Head and facial hair nets or covers and facemasks that cover nose and mouth
- Safety glasses (with side shields if working with irritants)
- Wear a gown made of lint free non-shedding materials
- Wear sterile, powder free clean room gloves before entering the cleanroom

Must "Gown-In" prior to entering cleanroom

Minimum Gowning Requirements

	ISO Class 8	ISO Class 7	ISO Class 6	ISO Class 5	ISO Class 4
Hair Cover	x	x	x	x	x
Hood				x	x
Beard Cover	x	x	x	x	x
Face Mask		x	x	x	x
Frock	x	x			
Coverall			x	x	x
Shoe Covers	x	x	x	x	x
Boots				x	x

Non-Sterile Cleanroom Gowning Procedure

Step 1: Pre-entry

A

Bouffant/Hair Net
Be sure to contain all hair.

B

Shoe Covers
Contain all laces and tassels.

Step 2: Gowning

A

Gowning Gloves
Recommended for Class 100 and better.

B

Mask
Worn under hood. Bend nosepiece first for a snug facial fit.

C

Hood
Ensure snug fit and proper face/neck seal.

Step 3

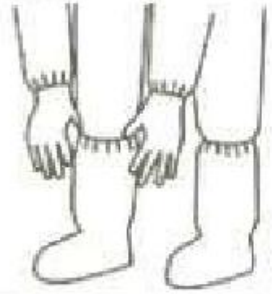
Coverall
Step into the coverall.

Be sure sleeves and upper garment do not touch bench or floor.

Tuck shoulder panels from hood inside coverall before zipping up.

Step 4

Boot Covers
Put on boots and pull boots (high-top shoe covers) over legs of coverall.

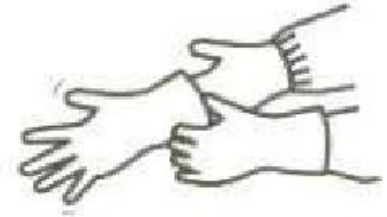


Step 5

Goggles
Wear goggles/safety glasses when eye protection or additional particulate control is desired.

Step 6

Second Sterile Gloves (optional)
For maximum particulate protection, place hem of glove over cuff of sleeve.



Ten Commandments of Good Safety Habits

(From OSHA https://www.safetymanualosha.com/the-ten...)

In most everything we do, we find a trick to make the process easier and faster. After we develop these tricks, they become work habits in our everyday activities.

Developing everyday safety habits can keep you injury-free all through the year.

Here are 10 safety habits to live by:

1. Set your own standards: *Don't be influenced by others around you who are negative. If you fail to wear safety glasses because other's don't, remember blindness you may suffer will be yours alone to live with.*
2. Operate Equipment Only if Qualified: *Your supervisor may not realize you have never done the job before. You have the responsibility to let your supervisor know, so the necessary training can be provided.*

Good Safety Habits: Continued

3. Respect Machinery: *If you put something in a machine's way, it will crush it, pinch it or cut it. Make sure all guards are in place. Never hurry beyond your ability to think and act safely. Remember to de-energize the power first before placing your hands in a point of operation.*
4. Use Your Own Initiative for Safety Protection: *You are in the best position to see problems when they arise. Ask for the personal protective equipment or additional guidance you need.*
5. Ask Questions: *If you are uncertain, ask. Do not accept answers that contain, "I think, I assume, I guess." Be sure.*
6. Use Care and Caution When Lifting: *Most spinal and muscle injuries are from overstrain. Know your limits. Do not attempt to exceed them. The few minutes it takes to get help will prevent weeks of being off work and in pain.*

Good Safety Habits: Continued

7. Practice Good Housekeeping: *Disorganized work areas are the breeding grounds for accidents. You may not be the only victim. Don't be a cause.*
8. Practice Good Housekeeping: *Disorganized work areas are the breeding grounds for accidents. You may not be the only victim. Don't be a cause.*
9. Practice Good Personal Cleanliness: *Avoid touching eyes, face, and mouth with gloves or hands that are dirty. Wash well and use barrier creams when necessary. Most industrial rashes are the result of poor hygiene practices.*
10. Be a Positive Part of the Safety Team: *Willingly accept and follow safety rules. Encourage others to do so. Your attitude can play a major role in the prevention of accidents and injuries.*

5 Common Cleanroom Hazards and How to Avoid Them

June 23, 2017 Trip Textoris

One of the biggest challenges associated with cleanrooms is the unpredictability of situations: things that may seem small, but can affect and contaminate a cleanroom. Here is a list from our team at Vernick & Associates of several common cleanroom hazards to try to avoid.

Exposed Communication Devices

Sometimes workers must have a communication device in the cleanroom, including a phone, pager, or radio. If communication devices are necessary, it's very important that they are never clipped to the outside of a worker's coveralls, since it could fall off and cause contamination. Instead, there are cleanroom fanny packs that can be used.

Incorrect Flooring

It's important that all equipment that the workers are using in the cleanroom are able to be securely grounded to the floor when the use of ESD carts, chairs, and shoe covers will be in play. If the wrong flooring is installed, you're at risk for contamination. Make sure to ask a cleanroom installation professional about the correct flooring for your specific cleanroom requirements.

Adjusting Furniture and Equipment

Even the smallest movement, such as shuffling a chair, can cause contamination. Other cases of contamination have involved something as tiny as picking up a sterile glove to use. This is why it's important for workers to keep movement to an absolute minimum while working inside the cleanroom.

Uncovered Electrical Sockets

Always seal electrical sockets. If this isn't done, it's a big invitation for contamination. Even insects can crawl through. Electrical sockets should all be carefully sealed, just as people seal them when small children are around.

Using Face Masks Incorrectly

CLEANROOM DOs & DON'Ts

DOs, before entering the Cleanroom:

- Enter only through the ante-room – no shortcuts.
- Walk across tacky mat to clean soles of your shoes.
- Wear shoe covers.
- Wear Cleanroom garments (bunny suit).
- Wear a bouffant cap & beard cover, as per requirement.
- Wear gloves, as per requirement.
- Wipe down any hand tools carrying.
- Wipe down any other items brought into the area.

DON'Ts, inside the Cleanroom:

- No wooden pallets, ladders or wood-handled tools.
- No cardboard boxes.
- No pencils or erasers – pens only.
- Never bring in unclean or rusty tools.
- No Food, No Drink, No Chewing Gum – ever.
- No cosmetics and jewellery.

DOs, Whenever leaving the Cleanroom:

- Exit only through the ante-room/personnel Air Lock – no shortcuts.
- Remove Cleanroom garments within the ante-room.
- Discard garments properly in bin only.
- Take your time – haste does make waste.

Conclusion

Clean areas:

- **Play a major role in the quality of pharmaceuticals.**
- **Design requires careful consideration of its intended use.**
- **Must be designed meticulously, by professionals.**
- **Must be treated as a critical system.**

Clean Room Safety and Procedures Manual from University of north Texas- review if time permits

References

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