## **CLEANROOM ORIENTATION**





### **OVERVIEW**

- > What is the Cleanroom?
  - Early History, Purpose, and Maintenance
- Cleanliness Classes
- > Types of Contamination
- Operating Procedures: Pre-entry Protocol
- > Entrance Courtesies
- The Need for Gowning
- Cleanroom Garments
- Gowning Procedures
- Proper Behavior in the Cleanroom
- De-gowning Procedures



### **OVERVIEW**

- Utility Chase Entrance Procedure
- Support Equipment
  - Wet Benches
  - > Specialty Gas Hook-ups
  - > Chillers
- Emergency Protocol
- > Emergency Equipment
- Safety Equipment (PPE)
- Spill Response Procedures
- Polices and Procedures Enforcement
- Governance
- Cleanroom Penalties

This orientation is only a supplement for the SEB Cleanroom Manual. It is no substitution for the Cleanroom Manual. Please see the Cleanroom Manual for more information and details.

# Early History & Development

- First cleanrooms found in hospitals
- WWII, 1<sup>st</sup> Industrial cleanrooms. Improved bombsights, guns



> 1960's , Sandia Laboratories, developed 1<sup>st</sup> unidirectional laminar air flow cleanroom technology , still used today in microlabs

### WHAT IS A CLEANROOM?

- Sealed room in which the concentration of airborne particles are controlled to specified limits.
- Need to continually eliminate contaminants from the air that are generated by people, processes, facilities, and equipment.
  - The level to which particles must be held to a minimum depends upon the standards required by the facility and the processes undertaken within the facility.





## PURPOSE OF A CLEANROOM

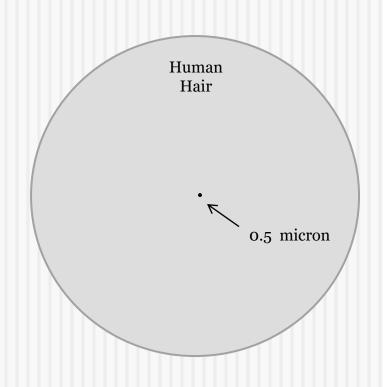
- \* A controlled environment that allows essential products to be manufactured
- Necessary in the nanotechnology, pharmaceutical, medical device, and biotechnology businesses.
  - Requires an <u>unpolluted</u>
     environment to assure potentially
     harmful contaminants are not
     present in construction of products





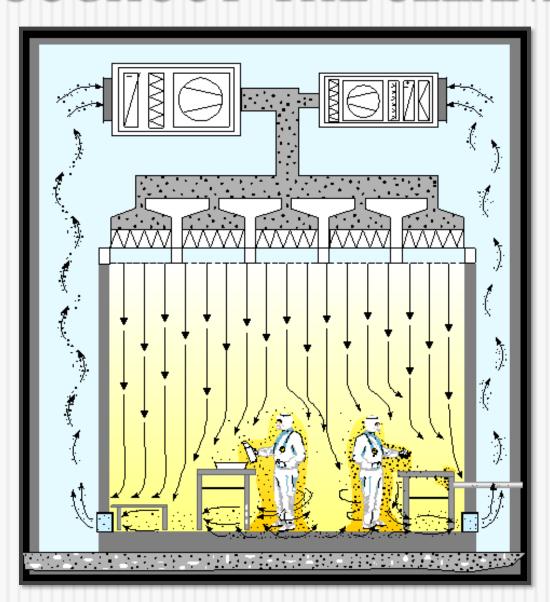
### HOW A CLEANROOM STAYS CLEAN

- In order to control contamination:
  - Air flow rates and direction, pressurization, temperature, humidity, specialized filtration, and sources of particles are tightly controlled.
  - HEPA (High Efficiency Particulate Air) Filters within the ceiling filter particles as small as 0.3 microns with a 99.97% minimum particlecollective efficiency.





### MOVEMENT OF AIR FLOW THROUGHOUT THE CLEANROOM

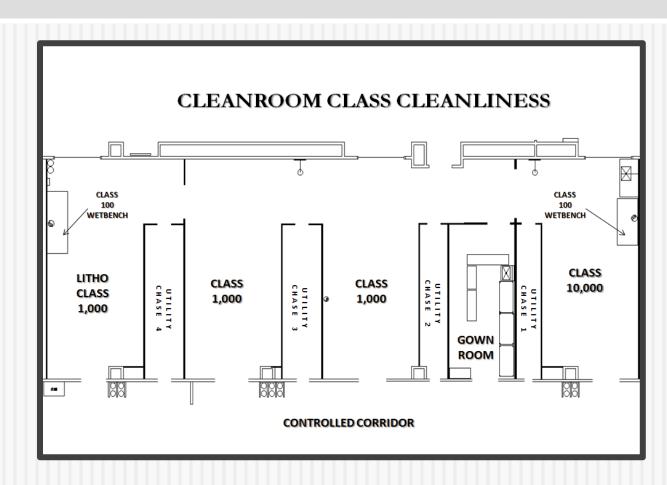




### CLEANLINESS CLASSES

# There are three cleanliness classes in our Cleanroom:

- Class 10,000 East portion
- Class 1,000 West and central portions
- Class 10 Wet benches located in East and West portions





### TYPES OF CONTAMINATION

- > Particle contamination
  - > Dust
  - Corrugated containers/paper
  - > Skin and dandruff
  - > Foot borne dirt from shoes
  - > Equipment-generated
- > Chemical contamination
  - > Ions and non-volatile residues
    - > Sodium from hands
    - > Ions from rust
    - > Off gassing from welding residue
    - > Out gassing from hydrocarbon residues



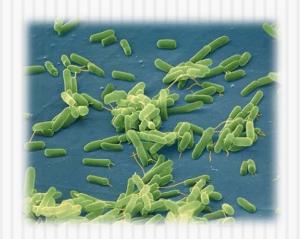


### TYPES OF CONTAMINATION

- Biological contamination
  - > Viable organisms
  - > Bacteria
  - > Viruses
  - > Pyrogens
  - > Spores
    - > The smallest is 1-2 microns in size



- > Normal talking (saliva) 2 to 3 feet
- > Coughing (saliva/lung tissue) 4 to 6 feet
- > Sneezing (200 mph) 10 to 15 feet







# OPERATING PROCEDURES: PRE-ENTRY PROTOCOL

#### Access to the Cleanroom

- > The main entrance is located in the controlled corridor on the first floor of the SEB.
- > Users must have a proximity card in order to enter into the gownroom.
- > The cleanroom is open 24/7/365.
- > The buddy system is strongly advised.

#### > Visitors

- > Permission from the Lab Manager, Principal Investigator, or SEB Assistant Director must be given.
- > Must always be escorted by a cleanroom qualified user.
- > Escorter is responsible for ensuring the visitor follows the facility protocol, policies, and procedures.

### PRE-ENTRY PROTOCOL

- > Bringing Items into the Cleanroom
  - All items brought into the cleanroom must undergo a coarse-cleaning in the controlled corridor, then an ultracleaning in the cleanroom.
  - Packaged items that are specific for the Cleanroom must be opened in the cleanroom with cleanroom scissors.
  - > Items on a campus cart must undergo a coarse-cleaning and must then be transferred onto a cleanroom cart outside in the controlled corridor. Once in the cleanroom, an ultracleaning must be completed on the items on the cleanroom cart.



### PRE-ENTRY PROTOCOL

- Pre-gowning Principles
  - > A daily bath/shower with regular shampooing is recommended
  - > Minimal use of cosmetics, hair products, colognes and perfumes
  - > Users should not smoke within 45 minutes of use of the cleanroom
  - > If special equipment set-up is required, consult the SEB Assistant Director at 5-2020.
  - > Before entering gownroom, remove all outerwear and place in provided lockers in service corridor.







### ENTRANCE COURTESIES

- > Users must document their name on the IN/OUT Board when entering and exiting.
- > Only authorized users may enter the cleanroom unescorted.
- Remove cartons and packaging material *before* taking materials into the cleanroom.
- > If you are not sure if it belongs in the cleanroom, ask before you bring it in.
- Do not bring in tools with wood, rust, oil, peeling paint, etc.
- > Only cleanroom paper or plastic-laminated paper will be allowed in the cleanroom. Cleanroom paper taken out of the cleanroom may be brought back into the cleanroom.
- Maintain personal hygiene, especially that of the hands, face, and hair. Do not apply cosmetics, colognes, and perfumes in the cleanroom and gowning areas.
- > ANYONE who is physically ill, especially with respiratory disorders, may NOT enter the Cleanroom.
- > Keep hair and ears covered with a hood or cap.





## THE NEED FOR GOWNING

- Maintain the cleanliness of the facility
- Contamination of the facility by exposure to human skin, hair and outerwear must be eliminated to promote a reasonable research environment and maintenance of the cleanroom
- Particles can destroy the ability of researchers to fabricate sterile devices and can lead to costly maintenance if not properly contained





### **CLEANROOM GARMENTS**

#### Required attire includes:

- **✓Shoe covers**
- **✓** Bouffant
- **√**Face-mask
- **✓** Coverall
- **√Hood**
- **✓Shoe booties**
- **✓ Cleanroom gloves**
- **✓** Safety eyewear



### **GOWNING PROCEDURES**

- In the controlled corridor, remove outerwear and unnecessary items and place them in a locker.
- 2) Confirm positive differential pressure.

\*Contact SEB Assistant Director if in alarm at 5-2020.

- 3) Write name on IN/OUT Board.
- Swipe into the gown room using your proximity card.
  - \*Before entering the door, be sure to step on the sticky mat THREE times.
- Put on shoe covers located just inside the entrance of the gowning room. Shoe covers must be worn at all times while in the gown room.







### **GOWNING PROCEDURES**

- Put on face mask and bouffant. Bouffant is required to protect the hood and contain hair in the hood.
- 6) If your gown was already assembled, retrieve your gown from the hanger.

**For new users:** Please get your gown by stopping by the stockroom with an IDR. Cost is ~\$7.00. Label your coverall, hood, and shoe booties with the date it was assembled and last name

\*Only keep gown for approx. two weeks of use (~14 working days).







### **GOWNING PROCEDURES**

- 7) Carefully put on a hood.
- 8) Inspect the coverall of your gown.
- 9) Put on your cleanroom coverall.
  - \*Make sure it does not touch the ground
- Put on booties as you transition over the bench from the dirty to clean side.

\*Booties should only be worn on clean side of the gowning room or in the cleanroom

- 11) Put on Cleanroom gloves
- 12) Put on safety eyewear
- 13) Confirm your gown is assembled properly in front of gownroom mirror.
- 13) Step on sticky mat THREE times upon entrance into the cleanroom.

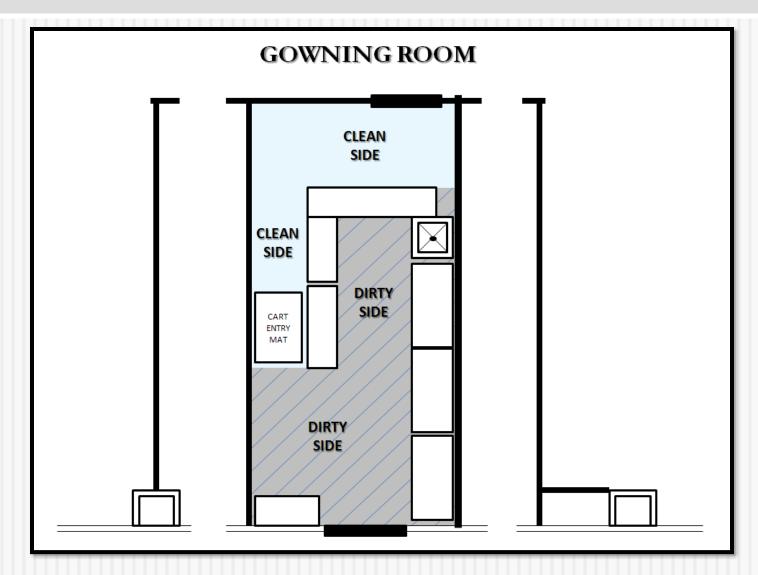








## **GOWNING ROOM**





### PROPER BEAHVIOR IN CLEANROOM

- Minimize the amount of materials stored. Excess storage in the cleanroom is not permitted. There is a shelf in the cleanroom opposite the gownroom with sealable totes for your work.
- > No paper in any form will be torn or mutilated within the cleanroom
- > If you are using a piece of equipment, you **MUST** get the permission of the PI who owns the equipment before use.
- > If you are not sure how a piece of equipment works, ask before you use it.
- > Use only cleanroom approved materials in the cleanroom.
  - > Cleanroom paper, notebooks, ball-point pens, and tape
- > Pencils, erasers, and retractable pens shall not be used within the cleanroom.
- Minimize traffic through the gown room and controlled corridor.



### PROPER BEAHVIOR IN CLEANROOM

- > Obey signs in the Cleanroom and on equipment.
- When working with acids or solvents, wear chemical resistant nitrile or neoprene gloves
- > Do not dump solvents down the drains. Use the solvent waste bins located at the wet benches.
- > Be considerate by not touching or messing up someone else's work.
- > Dilute acid mixtures with large amounts of water when disposing down the hood sinks.



### PROPER BEAHVIOR IN CLEANROOM

- Personal items such as combs, cigarettes, matches, tissues, and similar particle-shedding products SHALL
  NOT be exposed in the cleanroom.
  - > Cell phones must always be attached on the outside of the gown, or must be kept in a gown pocket.
- Do not wear jewelry (except plain wedding bands), watches, and pierced ear studs.
- Report adverse changes in environmental conditions to the SEB Assistant Director at 5-2020.
- > ALWAYS clean your bench and equipment with Cleanroom wipes when done at your station.



### HABITS TO AVOID IN CLEANROOM

- > Unfastening cleanroom garments and removing items from beneath the cleanroom garments.
- Using hydrocarbon-based aerosol cans or oil pumps (this is **strictly** prohibited).
- > Unregulated use of equipment that may expel particles.
- > Coughing or sneezing persistently.
- > Bringing wooden tool boxes or wooden-handled tools into cleanroom.
- > Combing or brushing hair within the cleanroom or gowning area.
- > Scratching exposed skin areas, or touching one's face or skin with gloves.
- Walking rapidly, or moving unnecessarily, including running, horseplay or any other fast motions is prohibited
- > Wearing torn or soiled cleanroom garments.
- > Wearing cleanroom garments outside of the cleanroom.
- Entering the utility chases in gowning garments when un-gowned staff are within.

# CLEAN UP PROTOCOL AND EXIT COURTESIES

- > If you turn it **ON**, remember to turn it **OFF**.
- Do not remove dedicated items from the cleanroom without the Cleanroom Manager's permission.
- Any materials you plan on taking out of the lab with you should be bagged.
- > If you think you may have accidentally interfered with someone's work or equipment, please try to find out whose it is and what to do about it.
- > If you make a mess, you are responsible for cleaning it up.
- Return everything to its original condition, or leave conditions better than you found them.



### **DE-GOWNING PROCEDURE**

- 1. Enter the gownroom from the cleanroom.
- 2. Remove safety glasses and place them back on the rack.
- 3. Remove gloves and discard.
- 4. Remove shoe covers as you transition over the bench one leg at a time.
- 5. Remove hood.
- 6. Remove facemask and bouffant and discard.
- 7. Remove coverall.
- 8. Hang up garment (hood, shoe booties, and coverall)
- Dispose of shoe covers outside the gown room upon exiting.



# CLEANROOM UTILITY CHASE ENTRANCE PROCEDURE

#### ENTRY OUTSIDE OF THE CLEANROOM

- Entrance into the utility chases from outside of the cleanroom should only be used by SEB Staff or the cleanroom staff.
- Un-gowned SEB Staff, Cleanroom Staff, or Facilities Maintenance (escorted by SEB Staff), must enter only from the controlled corridor OUTSIDE of the cleanroom. They are required to step on the sticky mat and don shoe booties while in the chase. When they are finished with their work, they must exit the same way they came in—through the door that leads into the controlled corridor.

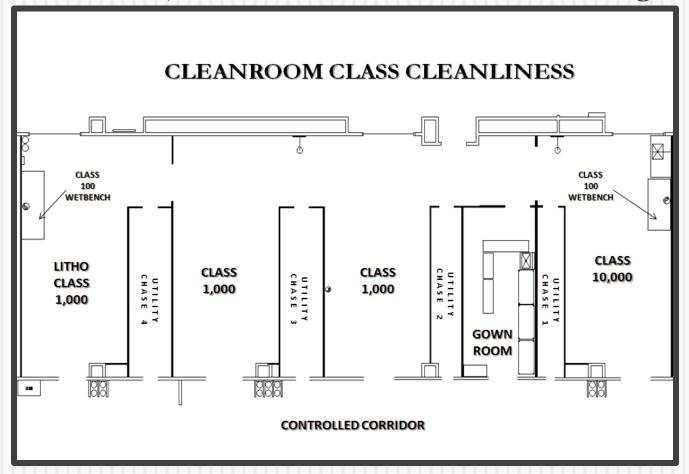
#### ENTRY FROM INSIDE THE CLEANROOM

Entry from inside the cleanroom is permitted. Users may enter fully gowned to turn on or adjust equipment. A gowned individual should never be in the utility chase with a un-gowned individual. When returning to the cleanroom, step three times on the sticky mat before reentry.



### **CLEANROOM INFRASTRUCTURE**

DOOR INTERLOCKS, AIR BALANCE, RETURN AIR HANLDERS, HUMIDIFIERS, RETURN FANS, MODULAR WALL SYSTEM, FILTERS. Use caution not to damage.





# SUPPORT EQUIPMENT

#### > WET BENCH

The Class 10,000 polymer and stainless steel wet benches are used to create a cleaner environment to work in. With the HEPA filter and fans it can become a Class 100 working environment or better. The open front area allows for clean laminar air to flow across the work surface while offering full access for operation. This flow captures particles and fumes and directs fumes through the exhausted slots at the rear of the station's work surface and out through the facility exhausts.

#### > SPECIALTY GAS HOOK UPS

No tanks are allowed in the cleanroom. There are tank stalls for specific gases outside of the cleanroom in the controlled corridor. There are gas manifolds that carry the gas from the tanks into the cleanroom to adjustable valves on the cleanroom walls.

#### > CHILLERS

Non-refrigerated, water-to-water (WW) systems are designed to remove process heat and discharge it to an auxiliary water supply, such as the centrally-chilled building water. These WW systems are ideal where water temperature to the application can be maintained within 3°C (5°F) of the auxiliary water-supply temperature



### **EMERGENCY PROTOCOL**

#### **EMERGENCY SHUT-OFFS AND EVACUATIONS**

- > An emergency shut-off may be required at some point in the event of the following situations:
  - > A large chemical spill
  - > Electrical fire
  - > Chemical fire
  - > Smoke
- \*\*Contact the SEB Assistant Director, RMS, or the Help Desk if this emergency situation is required.
- \*\*Do not try to clean up a large chemical spill. If the chemical spill is extremely noxious, immediately evacuate the cleanroom without degowning.



### EMERGENCY PROTOCOL

### **EMERGENCY EVACUATIONS**

- > If the building fire alarm sounds within the cleanroom:
  - > Set down your work in its place.
  - Make your way to the nearest cleanroom emergency exit.
  - Do not take the time to degown.
  - Proceed to the outside of the building.
  - You may degown outside and dispose; a new gown will be assembled at no cost to you.



# EMERGENCY EQUIPMENT

#### **Safety Showers**

 Purpose: To chemically decontaminate a person and their clothing

#### Eye Wash Station

- Purpose: To mitigate a chemical splash in the eyes
- > Location:
  - > #1 In the East Class 10,000 cleanroom along the North wall.
  - > #2 In the Central Class 1,000 cleanroom along the North wall
  - > #3 In the Litho Class 1,000 cleanroom along the North wall



# EMERGENCY EQUIPMENT

### > Halotron Fire Extinguishers

- Purpose: Used for small fires by those who are trained to use them
- Location: Each bay on wall



### First Aid Kit, Chemical Spill Kit

- Purpose: Used for small abrasions or burns; Chemical Spills
- Location: Central Utility Chase 1159A





# SAFTEY EQUIPMENT

#### > Gownroom:

> <u>Safety goggles</u>: must be worn at all times when in the cleanroom.

#### Wet benches:

- > <u>Face shields</u>
- > Chemical resistant gloves
- > <u>Heat resistant gloves</u>
- > <u>Apron:</u> Chemically-resistant, are to be worn when working with hot and/or strong acids, bases, or HF



### SPILL RESPONSE PROCEDURES

### Spill Response Kit

- Located in the center utility chase.
- Contains the following items necessary to combat a spill:
  - > absorbent spill dam
  - > absorbent pillows
  - > acid neutralizer
  - > caustic neutralizer
  - > Hydrofluoric ointment (calcium gluconate 2.5%)
  - > pH paper
  - > two pair of acid gloves
  - > respirators with acid gas cartridges
  - > two pair of vapor-resistant goggles
  - > trash bags



# POLICIES AND PROCEDURES ENFORCEMENT

#### > Who?

The cleanroom is managed by a committee representing 2 members of CoE, 2 members of CoS, and 1 member of SEB who serves as chair.

#### > Why?

- > To ensure the safety of the cleanroom users
- Protect the equipment in the cleanroom
- Create an environment in which many different research groups can co-exist
- Cleanroom users are expected to:
  - Police themselves
  - > Encourage and assist one another in adhering to the policies
  - > Flagrant or repeat offenders will be penalized, typically through suspension or expulsion from the cleanroom.
    - > The penalties are defined in the Cleanroom Penalties



## **CLEANROOM PENALTIES**

- > The following violations may result in suspension from the cleanroom for **ONE week** or worse:
  - > Unlawful use of any cleanroom equipment without being an authorized user for the equipment
  - Allowing a user to enter the cleanroom behind you when he/she has not swiped his/her marlok card
  - > Not wearing proper safety equipment at the fume-hood
  - > Not following proper gowning and degowning procedures
  - Removing supplies and/or equipment from cleanroom without permission
  - Choosing not to follow any of the procedures and courtesies stated in the Cleanroom Users Protocol



## Cleanroom Tour

- > Construction
- > Commissioning
- > Certifications
- > Specialty Systems
- > Gowning Demonstration

# QUESTIONS?



