

CLEANROOMS



Class 100 (ISO 5) Cleanroom with Raised Floor (at rest)



CLEANROOM OPERATING & MAINTENANCE PROTOCOL

The following instructions should be adapted to achieve the maximum potential from a cleanroom facility. It is not intended that these instructions be used in all cleanrooms under all circumstances. These instructions should be used as a guide in total, or part, as needed to achieve the end results of individual cleanroom specifications.

Viewed this way, the cleanroom is a manufacturing tool enabling industry to economically produce, assemble, preserve and inspect a clean end product by controlling contamination, pressure, temperature and humidity. Specific uses and applications of ISO 14644-1 and 2 are the responsibility of users and specifiers. The International Standards for Cleanrooms and associated controlled environments, ISO 14644-1 Part 1: Classification of air cleanliness; and ISO 14644-2 Part 2: Specifications for testing and monitoring to proven continued compliance with ISO 14644-1. Copies of the ISO Standards are available for IEST (Institute of Environmental Sciences and Technology) web address: www.iest.org, or email: publicationsales@iest.org.

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DEFINING WHAT IS A CLEANROOM / CONTROLLED AREA

CLEANROOM: an enclosed area in which airborne particles(contamination) are limited, controlled and/or eliminated within that space. The ability of these particles to contaminate or cause a problem is in direct proportion to the size of the particles. A cleanroom is 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 inside the room, and in which other relevant parameters, ie. temperature, humidity and pressure are controlled as necessary.

CONTROLLED ENVIRONMENT: a building, cell, room or other enclosed area in which the air supply, exhaust, personnel practices and housekeeping maintenance are controlled.

CONTAMINATION: Any material substance or energy that is unwanted or adversely affects the product.

Common Contaminants found in Controlled Environments and Cleanrooms:

- Particles
 - Solid (dust), Liquid
- Bio Contamination
 - Bacteria, Fungi, Viruses, Etc.
- Electrical Charge

Particle size is measured in microns (25,400 equals 1"). A particle of this size becomes a source of contamination when it is allowed in a place or situation where it can damage the end product. The function of the cleanroom is to limit, as much as possible, the number of particles within the critical area.

The cleanroom deals with contamination in three (3) basic ways:

1. Preventing the entry of particulate contamination by filtration of the air entering the room.
2. Changing the air within the room with a frequency dependent on the classification of the room. These air changes purge the air of particulate generated within the room by personnel and procedure.
3. Providing an area and a specified procedure for cleaning of personnel, parts and equipment prior to their introduction into the room.

ENTRANCE ROOMS/GARMENT ROOMS/ANTE-ROOMS

A mistake often encountered in present day cleanroom facilities is the assumption that the garmenting area is not part of the cleanroom. This area is the transition point from the "dirty" to "clean", which means the section leading into the cleanroom should be at least as clean as the cleanroom itself.

The design should segregate street clothes from cleanroom garments to minimize contaminate carry-over, particularly along the floor. It must be pointed out that clothing, such as overcoats, boots and rubbers should be left as far from the room entrance as possible. At the entrance there should be a shoe cleaning device (suggest *Liberty's 2001TB*) and or/ discardable shoe covers. We also suggest the use of *Tacky Mats*® to clean to the shoe soles. The Tacky Mat® will pick up gross contaminants from the shoe soles.

Once in the garment room, watches, jewelry and any clothing not to be worn in the cleanroom should be stored on the "dirty" side. The personnel in special garments, then progress to the "clean" side of the room. The Tacky Mat® should be at the entrance of the cleanroom with a waste receptacle placed near it. Due to the "dirty" to "clean" transition, the garment room is a good path to bring items into the cleanroom, either using a pass thru, *Liberty's H100SS or H100PL series*, or by carrying them in.



Model H100 SS Stainless Steel Pass Thru

HAND HYGIENE

To understand different approaches for hand cleansing understanding of normal bacterial skin flora is essential. Normal human skin is colonized with bacteria. Different parts of the bodies have varied bacterial counts. In 1938 bacteria recovered from hands were divided into two categories, Transient and Resident.

Resident – attached to deeper layers of skin, more resistant to removal

Transient – on superficial layers of skin, easier to remove with hand washing.

- It also discussed that automatic hand washers do not show any quality or frequency of hand washing increased when used.
- The main issue that is apparent is that education is required. There is a lack of scientific information to impact or improve hand hygiene. There is a failure to perform appropriate hand hygiene. This is the leading cause of assorted infection in health care settings.
- Poor adherence to recommended practices, a few major issue:
 - o Males and Physicians less likely to follow practices
 - o Sinks are inconveniently located/shortage of sinks
 - o Often too busy
 - o Wearing gloves/beliefs that with glove use no need for hand hygiene.
- Fingernail and Artificial Nails are a main area of concern. Chipped nail polish may grow and increase the number of organisms on fingernail; again no scientific proof only assumed at this point. Fingernails overall show evidence that pose an infection hazard.
- CDC Glove Policy- states gloves can reduce the transmission of infection and bacteria. However, those who wear gloves are less likely to wash or clean their hands prior to putting on gloves.
- Alcohol based hand rubs may be a better option than traditional hand washing w/ soap and water or antiseptic hand wash. The alcohol rubs require less time, act faster and are less likely to irritate hands less than traditional hand soaps.
- Recommendations are not for food processing. THE CDC guidelines are strongly recommended or suggested for implementation. There are really no clear cut guidelines and no one mandating them.

RECOMMENDATIONS FOR HANDWASHING & HAND ANTISEPSIS

Highlight of Indications for Hand Washing and Hand Antisepsis

The only area that is required by the CDC is if hands are not visibly soiled, use an alcohol based hand rub for routine decontamination of hands. Decontaminate hands before having direct contact with patients.

Decontaminate hands before putting on gloves when inserting a catheter.

Decontaminate hands after removing gloves.

Before eating and after using a restroom, wash hands with a non-antimicrobial soap and water or with an antimicrobial soap and water.

Antimicrobial – impregnated wipes may be considered an alternative to hand washing hands with a non-antimicrobial soap. They are not as effective as alcohol based hand rubs or washing hands with an antimicrobial soap and water for reducing bacterial counts on the hands. The wipes are not a substitute for using an alcohol based hand rub or antimicrobial soap.

Hand Hygiene Technique

When decontaminating with an alcohol based hand rub. Apply product to palm of one and rub hands together, covering all surfaces of hands, fingers until hands are dry.

When washing hands with soap and water, wet hands first w/ water, apply an amount of product recommended by the mfg. to hands, rub hands vigorously for at least 15 seconds, covering all surface of hands and fingers. Rinse with water and dry thoroughly with disposable towel. Avoid using hot water, repeated exposure to hot water may increase the risk of dermatitis.

Surgical Hand Antisepsis

Remove rings, watches and bracelets before being a surgical hand scrub.

Remove debris from fingernails using a nail cleaner under running water.

An antimicrobial soap or an alcohol based hand rub with persistent activity is recommended before donning sterile gloves when performing a surgical procedure.

When performing and using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the mfg, usually 2-6 minutes.

When using an alcohol based surgical hand scrub follow mfg. instructions. Before applying the alcohol solution, pre-wash hands and forearms with a non antimicrobial soap and dry hands completely. After application of alcohol based product, allow hands to dry thoroughly before putting on sterile gloves.



#6395-57 Alcare ® Hand Germicidal

Selection of Hand Hygiene Agents

Products that are low irritancy potential.

Solicit input from employees – fragrance issues and skin tolerances. The cost of hand hygiene products should not be the primary factor for influencing a product selection.

Solicit input from mfg. regarding any known interactions between products used to clean hands, skin care and types of gloves used.

Do not add soap to a partially empty soap dispenser. This “Topping off” can lead to bacterial contamination of soap.

Skin Care

Provide employees with hand lotions or creams to minimize occurrence of irritants associated with hand washing.

Solicit information from mfg. regarding effect the hand lotions, creams or alcohol based product may have with persistent effects of the soaps being used.

Other Aspects of Hand Hygiene

Do not wear artificial nails or extenders when having direct contact with patients at high risk.

Keep natural nail tips less than ¼” long.

Wear gloves when contact with blood or other potentially infectious materials is possible.

Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient and do not wash gloves between uses with different patients.

No recommendations can be made regarding wearing rings in health care settings, an unresolved issue.

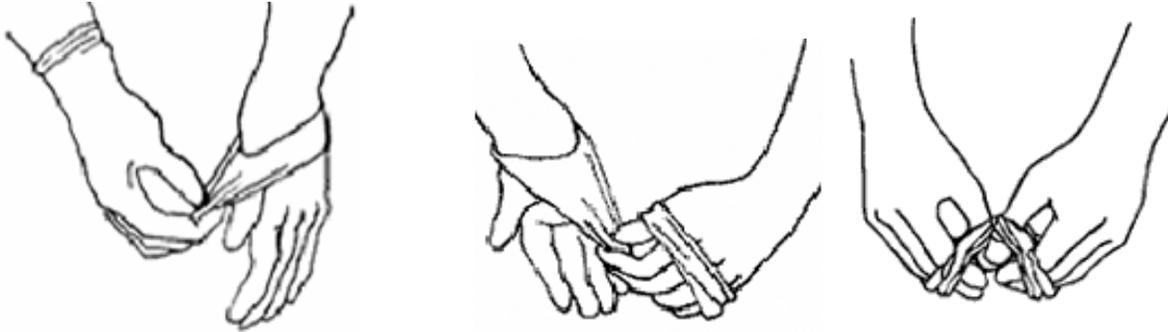
Performance Indicators

Periodically monitor and record adherence the number of hand-hygiene episodes performed by personnel/number of hand-hygiene opportunities.

Monitor the volume of alcohol based hand rub (or detergent used for hand washing or hand antisepsis) used for 1000 patient-days.

Monitor adherence to policies dealing with wearing artificial fingernails.

Do's and Don'ts of Glove Use



Grasp one of the gloves and cuff and pull it partway off. The glove will turn inside out. It is important to keep the first glove partially on your hand before removing the second glove. This protects you from touching the outside of either glove with your bare hands.

Leaving the first glove over your fingers, grasp the second glove near the cuff and pull it part of the way off. The glove will turn inside out.

It is important to keep the second glove partially on your hand to protect you from touching the outside surface of the first glove with your bare hand.'

Pull off the two gloves at the same time, being careful to touch only the inside surfaces of the gloves with your bare hands.

Dispose of the gloves by placing inside out in the trash.

Wash hands thoroughly.

Work from clean to dirty — this will help prevent contamination.

Don't touch your face or adjust PPE with contaminated gloves.

Change gloves when heavily soiled or if they are torn.

Discard gloves after use, never wash or reuse disposable gloves.

GOWNING PROTOCOL

Garment Design

Garment should produce little or no particulate emission. This requires the fabric or material to be stable, possessing a high ability to resist breakdown.

- Garments can be manufactured of woven and non-woven materials.
- A minimum of seams, seams must firmly envelop the raw edge of the material. Sewing threads should be of a non-filament materials and resist linting.
- Loose fitting to eliminate abrasion against the clothing underneath.
- Absence of pockets, belts and pleated areas.

Discipline within the Changing Room

- Before entering the changing room, remove all make up such as lipstick, blush, eye shadow, eye liner, mascara, powder, and/or any other cosmetic that is applied on the face or neck area.
- No personnel wearing perfumes or after shaves should be allowed in the cleanroom.
- No combing of hair is allowed in the changing room.
- Personnel shall wash their hands and face, if required. Hot air or lint-less wipes shall be used for drying. Do not use paper towels.
- No eating, drinking or smoking in the changing room.
- No gum chewing in the cleanroom.
- No jewelry should be worn.
- Do not enter cleanroom without complete cleanroom attire.
- Do not rub any exposed part of the face with a gloved hand. If this occurs, gloves must be changed out.
- Movements such as scratching the head, rubbing hands or similar type actions are to be avoided.

Gowning Sequence

- Walk on a Tacky Mat® to remove gross contaminants from street shoes.
- The street shoes to be removed outside changing room. Place street shoes in a shoe rack.
- Put on slipper and enter into the change room.
- Remove slipper in changing room and place on a rack.
- Put on head covering, (hair net, hood) assure that all hair is tucked under head covering.
- Secure face mask with band hood over ears. Pull bottom of face mask down completely under chin.
- Remove coverall all from sealed packaging. Assure the upper part of the jumpsuit does not touch the floor Put on the coverall, feet first and finally arms.
- Ensure the hood is tucked underneath the coverall before zipping up the jumpsuit.
- Take the designated shoe wear for the cleanroom (booties/shoe covers) from the storage racks and slip on over the feet.
- Ensure the legs of the jumpsuit are tucked into the booties.
- Check to make sure no hair is sticking out.
- Check to make sure the facemask has the nose and chin covered.
- Check to make sure that the hood is tucked underneath the jumpsuit collar.
- You can now take one glove at a time from the glove bin. Handle gloves only by the cuffs. Pull glove cuff toward upper arm. Cover cuff of sleeve with gloves.
- You may now enter the Cleanroom!
- Walk slowly and avoid creating air turbulence while in the cleanroom.

CLEANROOM GOWNING PROCEDURE

Non-Sterile Cleanroom Gowning Procedure

Step 1: Pre-entry



Bouffant/Hair Net
Be sure to contain all hair.



Shoe Covers
Contain all laces and tassels.



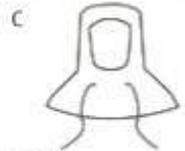
Step 2: Gowning



Gowning Gloves
Recommended for Class 100 and better.



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



Hood
Ensure snug fit and proper face/neck seal.



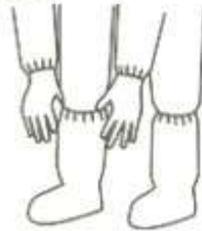
Step 3

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.



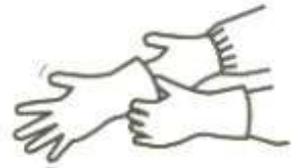
Step 5

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.



(Thanks to DuPont® for above Diagram)

Proposed 2006 change for <USP> 797 describe the sequence for gowning.

Personnel must don garb in the following order;

- Dedicated shoes or shoe covers.
- Head and facial hair covers and facemasks
- Eye shields are optional unless working with irritants.
- After this garb, personnel must clean their nails and wash their hands. Then they must dry with lint free disposable towels or an electric hand dryer.
- After hands are dry, personnel must don a non shedding gown.
- Once inside the buffer room, prior to donning sterile, powder free gloves, personnel must clean their hands with an alcohol based surgical hand scrub per mfg. recommendations.



WIPING GUIDELINES

Cleanroom Wiping Guide

1. Follow relevant site protocol (procedures for safety, contamination, etc.) and wear cleanroom gloves.
2. Fold wiper in mid-air into quarter folds (Fig. 1A–1C). This will produce several clean surface areas and allow better contact with the surface to be wiped.
3. When wiping, hold the wiper so that the folded edge is toward the area to be wiped. Hold the unfolded edges in your hand. Group the unfolded edges between thumb and forefinger.
4. Use either a pre-wetted wiper or a dry wiper moistened with an appropriate cleaning agent.
5. Wipe in one direction, overlapping wiped area by 10% to 25%.
6. Wipe from cleanest to least clean regions of the surface being wiped. Wipe systematically, for example, from top to bottom, far to near. (Fig. 2)
7. Keep track of which surfaces have been cleaned and which wiper areas are unused.
8. Always use the cleanest surfaces of the wiper. If re-wiping use a clean portion of the wiper, not the used wiper area.
9. Dispose of wipers according to site procedures.



Wiping Wet Spills

1. Identify the spilled liquid. Follow the Material Safety Data Sheet (MSDS).
2. Choose wiper and gloves that will not be degraded by the liquid.
3. For hazardous spills, wear two pairs of gloves and try to keep the gloves dry. Wear any other necessary protective gear.
4. Use dry wipers to wipe spills up immediately. Then clean the affected surfaces by following steps 1-9 in the "Cleanroom Wiping Guide" above.
5. Dispose of wipers according to site procedures.

(Thanks to ITW Texwipe for above diagram)

PROPER WORKING PROCEDURES

1. Walk slowly and avoid creating air turbulence.
2. Anticipate your needs, gather all necessary materials, tools and supplies you will need to perform your job. For example, cleaning solutions, wiping materials, assembly tools, testing tools and production forms, as well as actual process production materials.
3. Clean and inspect all incoming supplies, materials, equipment, tools, parts, carriers and carts (particularly the wheels). This involves looking for chipping, rusting and other signs of wear on metal tools and equipment. All outside packaging must be cleaned or removed from the supplies or materials prior to taking them into the cleanroom. When possible, supplies, materials, equipment, tools, product carriers, etc. should enter the cleanroom in poly bags/packaging. No cardboard can be allowed.
4. Wipe down your work area at the end of each shift to allow time for the room air to settle down before the next work shift begins.
5. Know your air flow patterns at your work area and organize your work space accordingly.
 - Do not block HEPA filtered air from reaching the product with either your body or equipment.
 - Do not pin or tape notes or instructions sheets on walls or equipment so as to block the HEPA filtered air flow.
 - Keep tools, equipment and supplies in appropriate containers or designated areas until needed. Make sure they are down-stream of the product and will not contaminate it.
 - During lunch, or long interruptions in the work cycle, and at the close of the work shift, be sure that all products, supplies and materials are stored or covered to protect them from contamination.
 - Wipe up any spills immediately.
 - Re-clean any object that becomes contaminated.
 - Never touch exposed skin with gloved hand.

MAINTENANCE IN THE CLEANROOM



Cleanroom Maintenance Kit What Every Cleanroom Must Have To Keep It Clean

The Liberty Cleanroom Maintenance Kit is essential to maintain cleanroom cleanliness levels. The kit includes The Tacky Mat® - the original contamination control dry mat created over forty years ago at Liberty Industries and the Tacky Roll Mop® in all its versions. The kit makes it easy to keep your clean- room clean!

- 1ea Cleanroom Maintenance Primer
- 1cs Tacky Mats®, 18" x 36"
- 1ea Tacky Roll Mop8 w/ 4 Refills
- 1ea Hand Held Tacky Roll Mop®
- 2ea Hand Held Tacky Roll Mop® Refills 1ea 3" Tacky Roll Mop®
- 6ea L-10 Sponges
- 1ea 14"Sponge Mop
- 3ea Sponge Mop Refills
- 1ea Cleanroom Bucket
- 1ea Hand Held Squeegee
- 1cs Econowipes
- 1ea Wet wipe/Canister 7" x 7"
- 1ea IPA 30/70 Solution 20 oz bottle
- 12 btl Spray Cleaning Agent
- 2gal Floor Sealer
- 2 gal Floor Cleaner/Stripper
- 2 gal Ceiling, Wall & Panel Cleaner

Procedures and cleaning materials to be used in cleanroom;

1. The essential aspect of janitorial services is that the introduction of non-cleanroom agents must be avoided. Many general cleaning agents in the janitorial field contain pine and or ammonia.
2. The floor covering used in the controlled areas is very often Armstrong Vinyl material. We suggest the use of *Liberty's J-73* as a sealer for this product. It is recommended it be used straight and can be applied with a chamois skin mop in very light coats, (1) one gallon should cover over 600-700 sq. ft.
3. We recommend that *Liberty's MIL-D-1679* in DI water solution (0.5% by volume maximum) be used for scrubbing floors, wall surfaces and benches. Rinse with clean water.
4. When an entire room area becomes worn and needs refinishing, we recommend *Liberty's J-75 Stripper* may be used. The stripper should be applied and removed by mop only (no scrubbing machines are required). After the areas have been stripped properly, we suggest the *Liberty's J-73 Sealer*, used to give five (5) parts water.
5. Scrub rags, rag mops and scouring powders should never be used in a cleanroom. Use only urethane sponges, *Liberty's LN-10* urethane mops *Liberty's 1214* stainless steel sponge mops, *Liberty's 6-300* Tacky Roll mops or squeegees for large area cleaning. All sponge/urethane employed products should be thrown away before they begin to deteriorate.
6. Extra heavy duty cleaning may require *Liberty's SS-660*, non -residue ceiling, wall and panel cleaner. It is water soluble and removes grease, oil and dirt from a variety of surfaces.
7. Other materials which can be used for cleaning area as follows:
 - Distilled water
 - Non residue forming detergents, *Liberty's SS-660*, *MIL-D-1679#* or *IPA 30/70*.
 - Cleanroom approved limited lint wipe, *Liberty's 8025 Econowipe*.
 - Portable vacuums may be used in the cleanoom only if the exhaust is quipped with an absolute HEPA filter, *Liberty's CRV 7347*, 4 gallon dry vacuum.
8. Floors will be damp mopped daily before normal work shifts with distilled water vacuumed dry.
9. Floors will be damp mopped weekly with distilled water and a cleanroom detergent and vacuumed fry.
10. Walls are to be vacuumed daily.

11. Walls are to be wiped with a damp sponge using distilled water and vacuumed weekly.
12. Walls are to be washed with distilled water and detergent and vacuumed dry, whenever necessary, to remove visible dirt deposits.
13. Windows are to be washed and wiped dry with lint free wipes, inside and out weekly.
14. Ceiling will be vacuumed daily.
15. Ceilings will be wiped with a damp sponge using distilled water and vacuumed dry, weekly.
16. Ceilings will be washed with detergent and distilled water and vacuumed dry, whenever necessary, to remove visible dirt deposits.
17. Overhead light troffers will be vacuumed as necessary to remove visible dirt deposits.
18. Overhand light lenses will be wipes with a damp sponge using distilled water and vacuumed dry, weekly.
19. All daily cleaning with the exception of the floors may be performed during normal work shifts.
20. Weekly cleaning by the custodial service shall be performed during hours when the cleanroom is not in normal use.
21. The Cleanroom supervisor will determine when the *Tacky Mats*® shall be changed. Do not allow particle build up on the *Tacky Mats*®.

Since 1953, Liberty Industries has been providing clients with a wide range of high quality supplies and accessories. We offer a huge selection of recognized national brand name accessories— everything from wipes, filters, roll mops, and mats to garments, tables and specialized furniture, vacuums and much more.

Visit our website to view our complete product line:
www.liberty-ind.com

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