



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 in 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) at www.iest.org.

Defining a Cleanroom and Controlled Environment

A **cleanroom** is 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, such as temperature, humidity and pressure are controlled as necessary.

A **controlled environment** is a building, cell, room or other enclosed area in which the air supply, exhaust, personnel practices and housekeeping maintenance are controlled.

Contamination is any material substance or energy that is unwanted or adversely affects the product.

Common Contaminants found in Controlled Environments and Cleanrooms:

- Particles: Solid (dust), or 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, Gowning Rooms, and 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 "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 and/or discardable shoe covers. We also suggest the use of sticky mats to clean the shoe soles. The sticky mat will pick up gross contaminants from the shoe soles.

Once in the gowning 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 sticky 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, or by carrying them in.



Type 316 Stainless Steel Gowning Room Furniture

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 bodies have varied bacterial counts. Bacteria is classified into two categories; **Transient** and **Resident**.

Resident bacteria is attached to deeper layers of skin, and is more resistant to removal.

Transient bacteria is found on superficial layers of skin, and is easier to remove with hand washing.

- Research has shown that automatic hand washers do not show any increase in the quality or frequency of hand washing when used.
- There is a lack of scientific information to help impact or improve hand hygiene. Therefore, the goal is to educate workers so that they can better perform appropriate hand hygiene. Poor hand hygiene is the leading cause of assorted infection in healthcare settings.
- There are a few major issues that contribute to poor adherence to recommended practices:
 - Males and physicians are less likely to follow procedures.
 - Sinks are inconveniently located, or there is a shortage of sinks.
 - Workers are often too busy to practice appropriate hand hygiene.
 - Belief that glove use prevents the need for hand hygiene.
- Fingernail and artificial nails are a an area of concern. It is possible that chipped nail polish may increase the number of organisms on the fingernail, although there is no scientific data to back up that assertion.
- The **CDC** (Centers for Disease Control and Prevention) **Glove Policy** states that 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 with 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.
- These recommendations are not for food processing. The CDC guidelines are strongly recommended or suggested for implementation.

Recommendations for Hand Washing & Hand Antisepsis

Highlight of Indications for Hand Washing and Hand Antisepsis

The required specified by the CDC is that 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 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 and fingers until dry.
- When washing hands with soap and water, wet hands first with water, apply the amount of product recommended by the manufacturer to hands, and 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, as 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 manufacturer (usually 2-6 minutes).
- When using an alcohol based surgical hand scrub, follow manufacturer 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.

Selection of Hand Hygiene Agents

- Use products that have a low irritancy potential.
- Solicit input from employees regarding 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 the manufacturer 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 the manufacturer regarding effect the hand lotions, creams or alcohol-based product may have with persistent use.

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, as there is no scientific data.

Performance Indicators

- Periodically monitor and record adherence.
- 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 regarding artificial fingernails.

Basics 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.
- Garments should have 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.
- Garments should be loose-fitting to eliminate abrasion against the clothing underneath.
- Garments should not have pockets, belts, or pleats.

Gowning Room Discipline

- Before entering the gowning room, remove all make up such as lipstick, blush, eye shadow, eye liner, mascara, powder, and any other cosmetic that is applied on the face or neck area.
- No personnel wearing perfumes or aftershaves should be allowed in the cleanroom.
- Hair combing should not allowed in the gowning 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 gowning 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 sticky mat to remove contaminants from street shoes.
- Street shoes are to be removed outside the gowning room. Place street shoes in a shoe rack.
- Put on slipper and enter into the gowning room.
- Remove slipper in gowning room and place on a rack.
- Put on hair net or hood to 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 that the hood is tucked underneath the coverall before zipping up the jumpsuit.
- Take the designated footwear for the cleanroom (shoe cover or cleanroom boots) from the storage racks and slip on over the feet.
- Ensure the legs of the jumpsuit are tucked into the footwear.
- Check to make sure that no hair is sticking out.
- Check to make sure the face mask covers the nose and chin.
- 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.

Non-Sterile Cleanroom Gowning Procedure

Step 1: Pre-entry



Bouffant Cap

Be sure to contain all hair.



Shoe Covers

Contain all laces and tassels.



Step 2: Gowning



Gowning Gloves

Recommended for Class 100 and higher.



Mask

Worn under hood. Bend nose-piece 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.



Recommended procedure changes for USP 797 environments.

Personnel must don garb in the following order;

- Dedicated shoes or shoe covers.
- Head and facial hair covers and face masks.
- 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, and prior to donning sterile, powder-free gloves, personnel must clean their hands with an alcohol-based surgical hand scrub per manufacturer recommendations.



Proper Working Procedures

- Walk slowly and avoid creating air turbulence.
- Anticipate your needs; gather all necessary materials, tools and supplies you will need to perform your job (such as cleaning solutions, wiping materials, assembly tools, testing tools and production forms, as well as actual process production materials).
- 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, or product carriers should enter the cleanroom in poly bags or packaging. No cardboard is allowed.
- 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.
- 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 that blocks 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.

Wiping Guidelines

1. Follow relevant site protocol (procedures for safety, contamination, etc.) and wear cleanroom gloves.
2. Fold wiper in mid-air into quarter folds (Figure 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, or far to near (Figure 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 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.

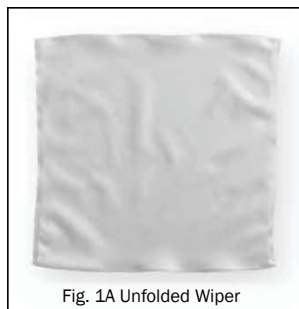


Fig. 1A Unfolded Wiper

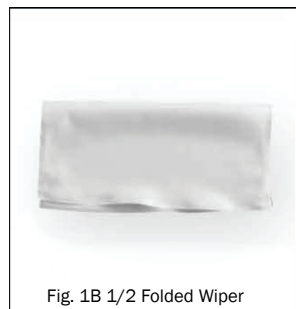


Fig. 1B 1/2 Folded Wiper



Fig. 1C 1/4 Folded Wiper



Fig. 2

Cleaning Procedures and Materials

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 a vinyl material. We suggest the use of a sealer. It is recommended it be used straight and can be applied with a chamois skin mop in very light coats. One (1) gallon should cover 600-700 sq. ft.
3. We recommend that cleanroom-approved detergent 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 the use of a stripper. The stripper should be applied and removed by mop only (no scrubbing machines are required). After the areas have been stripped properly, we suggest using floor sealer with five (5) parts water.
5. Scrub rags, rag mops and scouring powders should never be used in a cleanroom. Use only urethane sponges, urethane mops, stainless steel sponge mops, tacky roll mops or squeegees for large area cleaning. All sponge/urethane employed products should be thrown away before they begin to deteriorate.
6. Heavy-duty cleaning may require floor sealer, or 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
 - Cleanroom approved limited-lint wipes
 - Portable vacuums may be used in the cleanroom only if the exhaust is equipped with an absolute HEPA filter.
8. Floors will be damp mopped daily before normal work shifts with distilled water, and vacuumed dry.
9. Floors will be damp mopped weekly with distilled water and a cleanroom detergent, and vacuumed dry.
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 wiped 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 sticky mats shall be changed. Do not allow particle buildup on the sticky mats.