

ASK JAN:



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BASIC CLEANROOM PROTOCOL

Can you please recommend a basic protocol program for cleanrooms?

Yes. Most basic protocol programs for cleanrooms are based on the Institute of Environmental Science and Technology (IEST) recommended practices for contamination control and the ISO 14644 series of international standards for cleanrooms and associated controlled environments. The focus of any protocol program is to protect the integrity of the cleanroom and the products and processes in the cleanroom from the people working in the cleanroom. Whereas contamination may be due to the product, processes, or equipment in the cleanroom, the people working in the cleanroom exercise the greatest control over the cause of and elimination of contamination. Therefore, all protocol programs address the functionality of the cleanroom, the behavior of the people working in the cleanroom, and the cleaning and maintenance of the cleanroom.

The basic components of a balanced cleanroom protocol program are:

- The facility design and cleanroom floor-plan
- Cleanroom gowning requirements and procedures
- Personnel behavior within the cleanroom environment
- Cleanroom supplies – correct types and usage
- Cleanroom housekeeping
- Continuous improvement and assessments (audits and trending test results)

FACILITY DESIGN

Initially, one must understand the design, layout and certification of the cleanroom. IEST-RP-CC012.2, “Considerations in Cleanroom Design” is an excellent document to reference for understanding the design and functions of various components in cleanrooms (i.e., air flow, room pressures and particle management, etc.). Appendix B, “Sample cleanroom construction protocol” provides protocol guidance to cleanroom construction employees during the four levels of cleanroom construction. This IEST

recommended practice supports ISO 14644-4, “Cleanrooms and associated controlled environments – Part 4: Design”. Since 1999, cleanrooms have been certified to ISO 14644-1, “Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness” and ISO 14644-2, “Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove compliance with ISO 14644-1.

CLEANROOM GOWNING PROCEDURES

After the cleanroom has passed certification, cleanroom personnel must don the required cleanroom apparel applicable to the classification of the cleanroom. IEST-RP-CC003.3 contains a chart of recommended gowning configurations and frequency of change of garments based on the Air Cleanliness Classes of ISO 14644-1. Many cleanroom operations require the cleanroom personnel to change from street clothes to 100% polyester building suits or tech suits to reduce the amount of particle contamination in the cleanroom environment. The garment system selected must meet the specifications for the cleanroom applications. Facility requirements for changing areas, lockers, in-use garment storage, soiled garment storage, garment inventory storage, and internal inventory transit must be defined. Additionally cleanroom garment laundering and other garment management services must be defined and subcontracted.

Gowning procedures begin at home with daily bathing or showering, shaving, brushing of teeth and hair, and application of non-silicone containing skin moisturizers to reduce skin flakes. All make-up, hair gels, hair sprays, perfumes, aromatic after-shave lotions, or body lotions are not Cleanroom compatible and therefore unacceptable to wear to work. At work, all employees must wash hands before entering the cleanroom and after eating and/or using the toilet. Cleanroom compatible hand cream may be applied prior to gowning.

Gowning procedures may vary depending upon cleanroom applications; however the gowning sequence is basically similar to:

Donning Sequence

1. Wash and dry hands.
2. Enter non-sterile gowning area.
3. Put on bouffant. Assure all hair is entrained under bouffant.
4. Walk over tacky mat to remove excess soil from shoes.
5. Put on disposable shoecovers.
6. Put on first set of "donning" gloves.
7. Walk to gowning area.
8. Don hood. Touch only inside of the hood. Slide hood from cleanroom bag.
9. Completely cover bouffant. Fit snugly with vertical and horizontal snaps in back of hood. Don facemask.
10. Don coverall. Do not let it touch the floor or walls. Grasp inside neck of coverall and slide coverall from cleanroom bag. Allow coverall to unfold. Unzip zipper to the full length. Begin rolling coverall backwards into a tube gathering the sleeves inside the roll. Gather up one leg. Place foot in one leg and pull up to thigh. Do the same with the other leg. Pull coverall up to waist. Begin unrolling top of coverall. Slide in one arm and roll coverall over back and shoulders. Slide in other arm. Zip up coverall. Snap at collar and ankles.
11. Don boots. Place hand on inside of boot top. Remove one boot from cleanroom bag. 12. Put on boot and step to "cleaner" side of gown area. Place hand inside of other boot top. Remove other boot from cleanroom bag. Put on boot and step to "cleaner" side of gown area. Pull up boot tops. Snap around calf area and snap to back of coverall.
13. Don goggles or shield.
14. Either remove donning gloves or put on second pair of gloves over first pair. Roll gloves over cuffs of coverall sleeves.

Doffing

Reverse the above procedure. Place disposable items in trash. Place reusable coverall, hood, and boots in proper receptacle. Place goggles in separate receptacle. Exit gowning area. In cases of emergency evacuation, personnel are instructed to immediately leave the cleanroom without doffing cleanroom garments.

After donning cleanroom garments personnel may walk through air showers or other pressurized, interlocked air locks to protect the integrity of the cleanroom from cross-contamination of lesser cleanroom areas.

PERSONNEL BEHAVIOR

Meticulous hiring practices for cleanroom personnel include screening potential operators for physical characteristics such as: smoker hiring policy, overweight or obese personnel, facial hair, sensitivity to heat, cold and humidity, and seasonal allergies including skin allergies.

Also, when evaluating personal skills and language skills, the human resources department must also evaluate potential cleanroom candidates for mental characteristics such as claustrophobia. Recommendations for personnel behavior in the cleanroom are found in IEST-RP-CC027.2, "Personnel, Practices and Procedures in Cleanrooms and Controlled Environments". This recommended practice addresses factors in hiring personnel to work inside the cleanroom. Certain cleanroom industries:

- do not allow smokers to work inside the cleanroom because the residual tar and nicotine will stain the face-masks and residual smoke particles may redeposit on the product or the process. Smoking is not allowed inside the manufacturing facility including all cleanroom areas. Smokers release particles for at least one-half hour after smoking one cigarette.
- require the removal of all facial hair or at minimum, the complete encapsulation of facial hair in beard covers or masks.
- require demonstration that the personnel can work inside the cleanroom comfortably and efficiently.

Just as all operators are thoroughly trained in occupational skills and knowledge of the product being produced and all aspects of the production process, cleanroom operators must be trained in the unique practices and behavior required for working in the cleanroom environment. Training personnel for working in the cleanroom environment is mandatory for all personnel regardless of frequency of entry and job classification. Testing and certification of cleanroom operators and subsequent observation of operators after training assures that the training has been implemented and is effective. Records of initial and refresher training must be kept. A thorough and comprehensive training program detailing all aspects of the cleanroom will empower the cleanroom operators to control the degree of contamination during the production process.

As mentioned earlier, any activity by the cleanroom operator generates millions of viable and non-viable particles. Therefore, it is imperative to limit talking and actions in the cleanroom to only those required for the manufacturing of the product. Running, horseplay and other non-professional activities are not permitted. Other behavioral requirements include but are not limited to:

- Nothing is allowed inside the cleanroom complex which is not required in the cleanroom manufacturing process. This includes personal items such as jewelry or keys, cosmetics, tobacco or matches in any form, and food or drink in any form. Hair may not be combed in the cleanroom gowning area.
- Only cleanroom compatible ball-point pens are allowed inside the cleanroom for recording data on cleanroom compatible paper and clipboards.
- While working in the cleanroom, avoid mannerisms such as scratching head or rubbing hands. Cleanroom

personnel may not access the inside of the cleanroom uniform.

- The use of facial tissues is prohibited in the cleanroom. If one must use a cleanroom compatible non-linting tissue, it must be used only in the gowning area and disposed appropriately in waste receptacle.
- All doors must remain closed when not entering or exiting. Emergency doors may be alarmed with a visual and audible alarm to enforce compliance.
- If there are any changes such as skin irritations, open sores, or respiratory infections, the personnel should be reassigned to non-cleanroom duties.

CLEANROOM SUPPLIES AND STORAGE

Garments may be stored inside the cleanroom gowning area as well as the many cleanroom consumable supplies to support the cleanroom operators and the processes inside the cleanroom. Cleanroom supplies should be stored in cleanroom packaging until use. All chemicals and supplies used to clean the cleanroom should also be stored in original cleanroom packaging until use. Used mops and mop heads should be properly disposed after use. It is recommended that the cleanroom supplies storage area be ventilated under vertical unidirectional air flow. Prior to introduction of any supplies into the cleanroom storage areas, proper wipe down of the exterior packaging should be performed.

CLEANROOM HOUSEKEEPING

An integral piece of the cleanroom management program is cleaning of the cleanroom. IEST-RP-CC018.3, "Cleanroom Housekeeping" details aspects of proper cleaning of the cleanroom, selection of cleaning materials, equipment, and cleaning agents as well as auditing the cleaning of the cleanroom. A documented and controlled cleanroom cleaning program should be established and maintained to ensure the integrity of the cleanroom environment. Selection of cleanroom cleaning materials, equipment, and cleaning agents should be appropriate to the type of cleaning required (i.e., aseptic versus non-aseptic cleanrooms). All cleaning agents and subsequent cleaning protocols should be validated to assure efficacy of cleaning.

CONTINUOUS MONITORING FOR EFFICACY

Monitoring and auditing the cleanroom management program assures that the documented procedures and protocols are understood, implemented and effective at all levels within the cleanroom manufacturing process. The audit program should provide documented and impartial evidence that the cleanroom management program is robust and reproducible. Tracking and trending this data will show shifts in the program which can be addressed prior to compromising the entire Cleanroom protocol program.

SUMMARY

The execution of the various tasks discussed in the basic protocol program is summarized in IEST-RP-CC026.2, "Cleanroom Operations" which is a supporting document for ISO 14644-5, "Cleanrooms and associated controlled environments – Part 5: Operations". Appendices A-F provides information on the various operations in the cleanroom from garmenting and behavior to entry, cleaning and movement of equipment.

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