

INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY

Contamination Control Division Recommended Practice 027.2

IEST-RP-CC027.2

Personnel Practices and Procedures in Cleanrooms and Controlled Environments

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Personnel Practices and Procedures in Cleanrooms and Controlled Environments

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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) provides a basis for establishing personnel procedures and the development of training programs for cleanrooms and other contamination controlled environments.

1.2 Limitations

This RP does not provide the specialized information needed for operations requiring control of living microbial contaminants.

A wide range of design options, equipment, protocols, and procedures can be combined to accomplish contamination control objectives consistent with the application. This document details many of those options, but it is up to the user to determine the suitability and applicability to his or her requirements.

2 REFERENCES

The following documents are incorporated into this RP to the extent specified herein. Users should apply the most recent editions of the references.

2.1 International Organization for Standardization (ISO)

ISO 14644-1 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness

ISO 14644-5 Cleanrooms and associated controlled environments—Part 5: Operations

2.2 Institute of Environmental Sciences and Technology (IEST)

IENT-RP-CC003: Garment System Considerations for Cleanrooms and Other Controlled Environments

IENT-RP-CC005: Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments

IENT-RP-CC007: Testing ULPA Filters

IENT-RP-CC018: Cleanroom Housekeeping—Operating and Monitoring Procedures

IENT-RP-CC026: Cleanroom Operations

IENT-STD-CC1246: Product Cleanliness Levels And Contamination Control Program

2.3 Sources and addresses

IEST

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ISO

In the U.S.: Documents available from
IEST
1827 Walden Office Square, Suite 400 |
Schaumburg, IL 60173 USA
www.iest.org

Outside the U.S.: Documents available from representative ISO member body organization

3 TERMS AND DEFINITIONS

building shoes

A dedicated pair of shoes worn by cleanroom personnel within the defined areas of the change room, cleanroom, and peripheral support areas to limit tracking in external contamination on street shoes.

building suit

An undergarment made of 100% polyester or other synthetic fabrics, normally similar to a two-piece jogging suit with either a pullover or zip-up top. It is worn over personal underwear and under the cleanroom garment.

change room

A facility contiguous to the cleanroom to provide for the control of the passage of personnel; donning, doffing, and storage of apparel; and storage of related supplies.

class (airborne particulate)

The cleanliness class as defined by ISO 14644-1.

cleanroom

A room in which the concentration of airborne particles is controlled and which contains one or more clean zones.

comfort suit

See *building suit*.

contaminant

Any unwanted substance present in or on a material or any surface within a clean zone.

contamination

The result of the addition of contaminants to a material or to any surface within a clean zone.

controlled environment

An environment in which parameters, such as temperature, pressure, humidity, and contaminant level, are controlled within specified limits.

doffing or degowning

The act of removing cleanroom garments in a controlled manner to prevent damage and unnecessary contamination of the garments.

donning or gowning

The procedures followed while putting on the garment system in a precise, prescribed order and manner to avoid compromising the cleanliness and functionality of the contamination controlling protective garment system.

donning gloves

An extra pair of gloves worn to protect gowning system components from coming into direct contact with

the hand to prevent the transfer of skin oil and flakes. May be worn over work gloves during gowning or used alone for gowning and replaced by work gloves after completion of the gowning procedure.

electrostatic discharge (ESD)

The transfer of electrostatic charge between two bodies that have different electrostatic potentials.

garments, cleanroom

Specially designed items of clothing that are worn to prevent or reduce the dispersion of contaminants that may be shed or released by personnel. Examples of such apparel include coveralls, footwear, shoe covers, gloves, and head covers.

garment system

The entire set of clothing and consumable items used to enclose the wearer and contain sources of human-borne and human-generated contamination. These items include beard covers, bouffants (hair nets), face masks, hoods, garments (including coveralls, shirts, pants, frocks or smocks), cleanroom shoes, safety shoes, shoe covers, cleanroom boots (or booties), glove liners, and gloves.

HEPA (high-efficiency particulate air) filter

An extended-medium, dry-type filter in a rigid frame, when tested at rated airflow having a minimum particle collection efficiency of 99.97% for 0.3- μm mass median diameter particles of DOP when tested in accordance with MIL-STD-282.

housekeeping, cleanroom

Maintenance or cleaning performed to preserve the specified cleanliness of a cleanroom.

micrometer (μm)

A unit of measurement of length equal to one millionth of a meter (approximately 0.00003937 inch).

particle counter, airborne

An instrument for continuous counting of airborne particles larger than a given threshold size. The sensing means may be optical, electrical, aerodynamic, etc.

pre-gowning

The required procedures between entering the building and entering the change room to begin the gowning procedure.

processing, garment

Procedures performed to meet cleanliness and usability specifications for apparel and accessories for use in a controlled environment.

shoe cleaner, mechanical

An electrically operated device that contains rotating or oscillating brushes and a vacuum collection system.

When a shoe or boot is placed into the device and slowly moved fore and aft, the brushes help to remove dust and dirt from the tops, bottoms, and sides of the shoe, while the vacuum system collects and contains the dirt.

shoe cover

A disposable or reusable cover worn over street shoes within defined boundaries of the change room, cleanroom, and support area to minimize the transfer of contamination from street shoes.

tack mat

A disposable or washable floor mat with a sticky surface which, when stepped upon, removes particles from the portion of the shoe or boot sole with which it comes in contact.

ULPA (ultra-low-penetration air) filter

A throwaway, extended-medium, dry-type filter in a rigid frame, having a minimum particle-collection efficiency of 99.999% (that is, a maximum particle penetration of 0.001%) when tested in accordance with the methods of IEST-RP-CC007.

wipe-down station

A facility provided in a change room for the cleaning of materials that are going to be brought into the cleanroom.

4 BACKGROUND AND PURPOSE

Most cleanrooms need people to perform tasks associated with the operations being performed. Even fully automated operations require personnel to tend or service automated systems. People and their street clothing generate contamination, therefore an effective contamination control system should be adopted to minimize the risks to the product, process yields, or the cleanroom environment. Also, because activities within the cleanroom can carry in, generate, stir up, or transfer contamination from place to place within the cleanroom, a system of operational protocols should be developed, enforced, and monitored to maintain the proper controls. ISO 14644-5 identifies the basic requirements for addressing these operational issues. These normative requirements should be addressed to assure a minimally thorough operational cleanroom program.

This RP serves as a guide for developing a program to manage contamination caused by or associated with the people, processes, and tooling in the cleanroom. Contamination may be generated by the people or the activities they perform, or may be transported into the clean environment with the materials brought into it.

Programs for the control of personnel-generated contamination are complex. In this document, the subjects often overlap. In some areas, there is deliberate redundancy between two sections. The reader will find the most specific and detailed information under the topic heading for a particular subject. However, related subject areas are included in the general discussions when these subject areas are pertinent to or have an effect on the main topic. References to sections of this document that provide more thorough coverage are included.

This RP provides a general description of the elements essential to a contamination control program as well as specific procedures for minimizing human-sourced contamination. The rationale behind the procedures and elements is discussed. The intent is to inform the user while assisting with the preparation of components of the program. This document specifies commonly accepted procedures and recommendations, and also points out considerations that should be made for a thorough and successful program.

Because there is a wide variety of degrees of cleanliness for cleanrooms (and differences in potential contaminants from which clean environments should protect products), some aspects of the procedures will be too stringent for some applications, while insufficient for others. A program should be expected to have a significant amount of individuality. What works well for one company or industry may not be acceptable in others because of factors such as local culture, facility constraints, large work forces, and government regulations.

The user is responsible for choosing the elements and degree of compliance that best suit the specific situation. In some cases, the advice of a contamination control consultant may be sought.

The science of contamination control is continuously evolving. Users are encouraged to find improved methods for controlling contamination appropriate for their needs and to share these with the contamination control community.

It is helpful to use data or experiments to evaluate whether a procedure is necessary or effective. Test methods are beyond the scope of this document.

It should be noted that there are several references available that provide a thorough background on contamination control theories, practices, and considerations. These references may be found in the text of this document and should be consulted when the user requires more detailed information.