

*Institute of Environmental Sciences and Technology*

## **IENT-RP-CC026.3**

Contamination Control Division  
Recommended Practice 026.3

# Cleanroom Operations



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# Cleanroom Operations

## IEST-RP-CC026.3

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# Cleanroom Operations

## IENT-RP-CC026.3

### 1 SCOPE AND LIMITATIONS

This Recommended Practice (RP) provides guidance for maintaining the integrity of the cleanroom or clean zone during ancillary operations.

#### 1.1 Scope

Ancillary operations include:

- a) Preparation of supplies and materials for entry into the cleanroom
- b) Modification of the facility
- c) Installation and repair of equipment

Procedures are given for verifying the cleanliness of the equipment, the workstation, and the area, following these ancillary operations.

#### 1.2 Limitations

This Recommended Practice does not address the effect of contamination from the equipment or facility upon the product under manufacture, nor does it specify limits of acceptance for operational conditions. It does, however, recommend standard terminology for specifying desired limits.

### 2 REFERENCES

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

## 2.1 Standards and recommended practices

*ASTM-D3154 Standard Test Method for Average Velocity in a Duct (Pitot Tube Method)*

*ASTM-F24: Standard Method for Measuring and Counting Particulate Contamination on Surfaces*

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

*IEST-RP-CC004: Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments*

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

*IEST-RP-CC012: Considerations in Cleanroom Design*

*IEST-RP-CC018: Cleanroom Housekeeping—Operating and Monitoring Procedures*

*IEST-RP-CC044: Vacuum Cleaning systems for use in Cleanrooms and Other Controlled Environments*

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

## 2.2 Sources

### ASTM International

American Society for Testing and Materials

100 Barr Harbor Drive

West Conshohocken, Pennsylvania 19428-2959 USA

Phone: 610-832-9500

Fax: 610-832-9555

[www.astm.org](http://www.astm.org)

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### ISO (National Standards)

International Organization for Standardization

In the USA, ISO 14644 documents available from:

IEST

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Fax: 847-981-4130

[www.iest.org](http://www.iest.org)

Outside the USA, documents available from representative ISO member body organization or  
ISO Central Secretariat  
1, ch. De la Voie-Creuse  
Case postale 56  
CH-1221 Geneva 20 Switzerland  
Phone: 41 22 749 01 11  
Fax: 41 22 733 34 30  
[www.iso.org](http://www.iso.org)

### 3 TERMS AND DEFINITIONS

The following terms have special meaning in the context of this Recommended Practice.

#### **ancillary operations**

Subordinate, subsidiary, auxiliary, or supplemental activities required to start up or maintain production or process activity.

#### **adhesion**

A molecular force that is exerted across the surface of contact between unlike liquids and solids, or solids and solids, and which resists their separation.

#### **airlock**

An intermediate room or area that is normally ventilated and used to minimize the transfer of airborne contamination from one area to another.

#### **clean zone**

A defined space in which the concentration of airborne particles is controlled to specified limits.

#### **cleanroom**

A room in which the air supply, air distribution, filtration of air supply, materials of construction, pressure gradients, and operating procedures are regulated to control airborne particle concentrations to meet established air cleanliness levels, as defined by *ISO 14644-1*.

#### **cleaning agent**

Any liquid that has the ability to aid in the removal of surface contamination, is compatible with the product and process, and does not contribute substantially to the contamination of the cleanroom.

#### **classes of air cleanliness**

Airborne particle concentration levels as defined by *ISO 14644-1*.

**contaminant**

Any unwanted substance present on a surface.

**contamination**

The act or result of deposition of contaminants on a surface.

**filter, high-efficiency particulate air (HEPA)**

An extended-medium, dry-type filter in a rigid frame, having a minimum particle-collection efficiency of 99.97% (i.e., a maximum particle penetration of 0.03%) for 0.3- $\mu\text{m}$  particles specified aerosol.

**filter, ultralow-penetration air (ULPA)**

An 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%) for particles in the size range of 0.1 to 0.2  $\mu\text{m}$ , when tested in accordance with the methods of IEST-RP-CC007.

**housekeeping maintenance**

Functions performed to preserve the specified cleanliness of a cleanroom or clean zone.

**modification**

Making of a limited change in something.

**particle**

A solid or liquid object that, as a general rule, measures from 1 nm to 1 mm.

**particle burden**

The number of particles in the relevant size range that can be found on a given surface.

**pass-through**

An opening in a wall between two rooms through which something (such as materials) may be passed.

**prep area (decontamination area)**

A preparation cleanroom or clean zone that typically is less clean than the operational cleanroom and in which preliminary cleaning procedures are performed.

**primary surface**

A surface that is in direct contact with the product.

**residue**

Any contaminant remaining on a surface after it has been cleaned.

### **secondary surface**

A surface that is not in contact with the product, but which indirectly affects the product.

### **viable particle**

A particle capable of reproduction.

## **4 BACKGROUND AND PURPOSE**

New cleanrooms and the production and service equipment they contain are installed and commissioned by specialists under controlled and near ideal conditions. Inevitably, however, routine maintenance, modifications, and replacements will be made to both the room and equipment during their operating life. All cleanroom operations, therefore, must be conducted in accordance with correct procedures if cleanroom integrity is to be maintained at all times.

This RP provides both general and detailed methods for the continuing operation of a cleanroom to assure its integrity and is intended for use as a basis for preparing standard operating procedures (SOP) for any cleanroom.

## **5 ANCILLARY OPERATIONS**

### **5.1 Considerations in planning and preparation for ancillary operations**

a) The proper planning and preparation of tasks that may be a source of contamination should include the procedures and precautions required to control (or limit) these risks. A detailed protocol should include the following considerations (refer to *IEST-RP-CC012*):

- Mission statement (purpose, goals, and implementation strategy)
- Collection and analysis of facts (parameters requiring control)
- Contamination control guidelines
- Life safety
- Environmental issues
- Personnel entry and exit requirements
- Critical material flows
- Security and access control
- Special requirements

b) Better maintenance of equipment and support facilities can often be achieved by providing easy access for repair and replacement purposes. Major service equipment should be located outside the process floor footprint. The extensive requirements of cleanroom facilities for support maintenance are often underestimated. In many cases, a separate cleanroom facility is required.

c) Redundancy in critical equipment or systems may be justifiable in cleanroom projects to ensure continuous operation and control of the room. Costs associated with redundant systems should be evaluated in relation to the risk of lost product and extensive cleanroom restart and qualification costs.

d) Flexibility to facilitate future expansion and change should be considered in the design of cleanroom projects. The following is a partial list of features that may enhance cleanroom flexibility:

- Additional air recirculation units to accommodate future increases of air volume
- Zone design that will facilitate the rearrangement of any zone with minimal interruption of adjacent zones or the total system
- Location of the distribution of services (such as utilities) in proximity to the equipment so that the desired level of access is facilitated
- Location of service mains outside the process floor and placement of branch connections to serve equipment, thus easing process line modification
- Location of support services outside the process floor

e) Certain ancillary operations, such as the following, may require certain precautions:

- Major work on the room structure (walls, floors, ceilings) requiring a total shutdown
- Minor work on the room structure that does not require a shutdown
- Equipment entry and installation (planned tooling or plug-in)
- Replacement of individually ducted HEPA or ULPA filters
- Replacement of HEPA or ULPA filters in a pressurized plenum system
- Lighting changeouts
- Equipment removal (decommissioning and exit procedures)

## 5.2 Service equipment and supplies for ancillary operations

All tools, equipment, and supplies used in the cleanroom should be clean (consistent with the requirements of the product and process) and, if applicable, sterilized or disinfected prior to entry into the clean-

room. Equipment designated for cleanroom service should be restricted to this use. Examples of such equipment and supplies may include but are not limited to those with the following characteristics:

#### 5.2.1 Vacuum cleaning systems

Vacuum cleaning systems may be central plant vacuum systems with attachments or portable vacuum cleaners with HEPA filtered exhaust (dry-wet, or dry type). Refer to *IEST RP-CC044*.

#### 5.2.2 Tacky rollers

Tacky rollers are cleaning tools, resembling a paint roller, which remove particles by means of a removable or renewable adhesive contact surface.

#### 5.2.3 Cleanroom wipers

Cleanroom wipers should be selected in accordance with the recommendations of *IEST-RP-CC004*. A dry wiper may be used with water or other cleaning agents or solvents as dictated by the cleaning application. Pre-saturated wipers—cleanroom wipers that are pre-packaged in a specified cleaning solution or solvent, may also be an option.

#### 5.2.4 Stepladders

Stepladders may be fiberglass-reinforced, plastic, aluminum, or stainless steel.

#### 5.2.5 Cleanroom apparel

Cleanroom apparel should be compatible with the product cleanliness requirements, the process being used to meet these requirements, and the cleanroom classification. Refer to *IEST-RP-CC003* and *IEST-RP-CC005*.

#### 5.2.6 Water

Water may be filtered tap, distilled, reverse osmosis, deionized, or other water suitable for injection.

#### 5.2.7 Cleaning agents

Cleaning agents that are aqueous (acid and alkaline, both with and without detergents and disinfectants) and those that are based on solvents. Cleaning agents that are dispersed as aerosols or sprays usually are not acceptable for cleanroom use because of the dispersion of particles, cross-contamination effect, electrostatic events, and safety of electronics.

**NOTE:** Toxic or corrosive substances require special handling precautions, tools, and disposal procedures.