

# **INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY**

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## **Contamination Control Division Recommended Practice 026.2**

### **IEST-RP-CC026.2**

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## **Cleanroom Operations**

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# Cleanroom Operations

## IENT-RP-CC026.2

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# **Cleanroom Operations**

## **IENT-RP-CC026.2**

### **1 SCOPE AND LIMITATIONS**

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

#### **1.1 Scope**

Ancillary operations include:

- a) Preparation of supplies and materials
- 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-D3154-00 Standard Test Method for Average Velocity in a Duct (Pitot Tube Method)*

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

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

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

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

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

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

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

#### **2.2 Sources**

##### **ASTM**

American Society for Testing and Materials  
100 Barr Harbor Drive  
West Conshohocken, Pennsylvania 19428-2959 USA  
[www.astm.org](http://www.astm.org)

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Outside the US: Documents available from representative ISO member body organization

### 3 TERMS AND DEFINITIONS

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

#### **ancillary**

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**

A liquid that has the ability to aid in removing contaminants from surfaces, usually by dissolution, reducing surface tension, or neutralizing electrostatic charge, or by both reducing surface tension and neutralizing electrostatic charge.

Cleaning agents can also be disinfectants. To be acceptable for use in cleanrooms and other environmentally controlled areas, cleaning agents should be chemically and physically compatible with the process or product, or both, and should not themselves contribute measurably to the overall burden of contamination.

#### **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.

#### **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.