

# **INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY**

---

## **Contamination Control Division Recommended Practice 018.4**

### **IEST-RP-CC018.4**

---

## **Cleanroom Housekeeping: Operating and Monitoring Procedures**

---

#### **INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY**

---

1827 Walden Office Square, Suite 400 |  
Schaumburg, IL 60173 USA  
Phone: (847) 981-0100 • Fax: (847) 981-4130  
E-mail: [iest@iest.org](mailto:iest@iest.org) • Web: [www.iest.org](http://www.iest.org)



**Documents**  
Document Sharing Hub

---

This Recommended Practice is published by the INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY to advance the technical and engineering sciences. Its use is entirely voluntary, and determination of its applicability and suitability for any particular use is solely the responsibility of the user.

This Recommended Practice was prepared by and is under the jurisdiction of Working Group 018 of the IEST Contamination Control Division.

Copyright © 2007 by the **INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY**

Second printing, July 2017

ISBN 978-0-9787868-3-0

**PROPOSAL FOR IMPROVEMENT:** The Working Groups of the INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY are continually working on improvements to their Recommended Practices and Reference Documents. Suggestions from those who use these documents are welcome. If you have a suggestion regarding this document, please use the online Proposal for Improvement form found on the IEST website at [www.iest.org/proposal/form.html](http://www.iest.org/proposal/form.html).

**INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY**

1827 Walden Office Square, Suite 400 | Schaumburg, IL 60173 USA

Phone: (847) 981-0100 • Fax: (847) 981-4130

E-mail: [iest@iest.org](mailto:iest@iest.org) • Web: [www.iest.org](http://www.iest.org)



---

# Cleanroom Housekeeping: Operating and Monitoring Procedures

## IENT-RP-CC018.4

### CONTENTS

#### SECTION

|   |                             |    |
|---|-----------------------------|----|
| 1 | SCOPE AND LIMITATIONS ..... | 5  |
| 2 | REFERENCES .....            | 5  |
| 3 | TERMS AND DEFINITIONS ..... | 6  |
| 4 | BACKGROUND .....            | 6  |
| 5 | PROCEDURES .....            | 7  |
| 6 | TEST METHODS .....          | 14 |

#### FIGURE

|   |                                        |    |
|---|----------------------------------------|----|
| 1 | RECOMMENDED WIPING SEQUENCE .....      | 10 |
| 2 | WALL-CLEANING STROKE METHOD .....      | 10 |
| 3 | FLOOR-CLEANING STROKE METHOD .....     | 11 |
| 4 | CLEANING CHECKLIST .....               | 13 |
| 5 | WIPING SUB-ASSEMBLY .....              | 18 |
| 6 | CAMERA AND UV LIGHT SUB-ASSEMBLY ..... | 19 |

#### TABLE

|    |                                                                      |    |
|----|----------------------------------------------------------------------|----|
| 1  | CLEANING FREQUENCY FOR ISO CLASS 5 CLEANROOM .....                   | 13 |
| 2  | APPLICATION OF TEST METHODS ACCORDING TO TYPE OF CONTAMINATION ..... | 14 |
| A1 | EFFECT OF PARTICLE SIZE ON ADHESION TO SURFACE .....                 | 24 |

#### APPENDIX

|   |                                     |    |
|---|-------------------------------------|----|
| A | PARTICLE ADHESION AND REMOVAL ..... | 23 |
| B | BIBLIOGRAPHY .....                  | 26 |

COPYING IS ILLEGAL



# Cleanroom Housekeeping: Operating and Monitoring Procedures

## IENT-RP-CC018.4

### 1 SCOPE AND LIMITATIONS

#### 1.1 Scope

This Recommended Practice (RP) provides guidance for maintaining a cleanroom at the level for which it was designed. This document is intended as a guide for establishing appropriate housekeeping procedures essential for the overall contamination control program of the cleanroom. In addition, test procedures are provided for use in establishing the frequency of housekeeping and monitoring the effectiveness of the housekeeping.

The test methods also are designed to help determine appropriate levels of surface cleanliness for specific cleanrooms.

#### 1.2 Limitations

This RP does not specify acceptance limits, but does provide standard terminology for specifying desired limits.

**NOTE:** References to “cleanroom” in this document are to be construed, where appropriate, as including clean zones and clean-air devices.

### 2 REFERENCES

The cited editions of the following documents are incorporated into this RP to the extent specified herein. Users are encouraged to investigate the possibility of applying the most recent editions of the references.

#### 2.1 American Society for Testing and Materials (ASTM)

*ASTM F24-04: Standard Method for Measuring and Counting Particulate Contamination on Surfaces*

#### 2.2 Institute of Environmental Sciences and Technology (IEST)

*IENT-RP-CC003.3: Garment System Considerations in Cleanrooms and Other Controlled Environments*

*IENT-RP-CC004.3: Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments*

*IENT-RP-CC005.3: Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments*

*IENT-RP-CC007.1: Testing ULPA Filters*

#### 2.3 International Organization for Standardization (ISO)

*ISO 14644-1:1999 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness*

#### 2.4 United States Pharmacopeia (USP)

*USP30-NF25: The United States Pharmacopeia and National Formulary*

#### 2.5 Sources and Addresses

##### ASTM

American Society for Testing and Materials  
100 Barr Harbor Drive  
West Conshohocken, PA 19428-2959 USA  
Phone: 610-832-9585  
Fax: 610-832-9555  
Web: [www.astm.org](http://www.astm.org)

## IENT

Institute of Environmental Sciences and Technology  
1827 Walden Office Square, Suite 400 |  
Schaumburg, IL 60173 USA  
Phone: 847- 981-0100  
Fax: 847-981-4130  
Web: www.ient.org

## ISO

In the US, documents may be ordered from:  
IENT  
1827 Walden Office Square, Suite 400 |  
Schaumburg, IL 60173 USA  
www.ient.org  
Outside the US: Documents available from represen-

tative ISO member body organization

## USP

United States Pharmacopeia  
12601 Twinbrook Parkway  
Rockville, MD 20852-1790 USA  
Phone: 301-881-0666  
Fax: 301-816-8148  
Web: www.usp.org

## 3 TERMS AND DEFINITIONS

### adhesion

The force exerted across a surface of contact between liquids and solids, or solids and solids, that resists their separation.

### classes of air cleanliness

The airborne particle concentration levels 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.

### cleanroom

A room in which the air filtration, air distribution, utilities, materials of construction, equipment, and operating procedures are specified and regulated to control airborne particle concentrations to meet appropriate airborne particulate cleanliness classifications, as defined by ISO 14644-1.

### clean zone

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

### contamination

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

## filter

A device used to remove particulate matter or impurities from a fluid (gas or liquid) flowing through it.

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

A throwaway, extended-medium, dry-type filter in a rigid frame, having a minimum particle-collection efficiency of 99.97% (that is, a maximum particle penetration of 0.03%) for 0.3- $\mu$ m particles of thermally generated dioctyl phthalate (DOP) or specified alternative aerosol.

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

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

### housekeeping, cleanroom

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

### particle

An object that is solid, liquid, or both, usually between 1 nm and 1 mm in size.

### particle burden

The number of particles in the relevant size range per unit area of surface.

### primary surface

A surface that is in direct contact with the product.

### residue

Any substance remaining on a surface after the surface has been cleaned.

### secondary surface

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

### surface contaminant

Any unwanted substance present in or on a surface.

### viable particle

A particle capable of reproduction; a living organism.

## 4 BACKGROUND

### 4.1 History

The methods and techniques presented in this RP originated from the initial meeting for this RP and from industry standards at that time. Some of the methods were based on studies that had been performed by universities and aerospace, semiconductor,

and pharmaceutical companies. Round-robin testing (industry testing of the methods by all classes and types of cleanrooms) was done for the initial publication of the RP.

Previous revisions added one floor and one wall cleaning technique. The proposal to add these techniques was based on particle removal efficiency studies published by the University of Arizona in Tucson and microbial removal efficiency studies published by Research Triangle Institute. The committee had direct oversight on the 25 companies that participated in the 6-month comparison testing of both wall and floor techniques. The results were reviewed, and the new methods were incorporated in the RP.

## 4.2 Particles on surfaces: adhesion and removal

Mechanisms by which particles are held to surfaces in a cleanroom include London-van der Waals forces (the dominant mechanism when surfaces are not wetted), electrostatic forces (which usually are small if the facility has been properly shielded), and capillary adhesion. Removal of particles is aided by the use of a liquid because such usage decreases the London-van der Waals forces by several orders of magnitude, dissipates electrostatic forces, and, if a surfactant is present in the liquid, decreases capillary adhesion through a lowering of surface tension.

Ionic surfactants alter surface electrical potentials and thus also can reduce electrical forces. Liquids also permit better coupling of the mechanical energy used during cleaning, as well as provide an opportunity for the removal of soluble contaminants through dissolution.

Individual submicrometer particles are extremely difficult to remove, and even an optimum cleaning procedure will not completely eliminate submicrometer particles from cleanroom surfaces (see Bowling, Appendix B). It is likely that only those particles larger than 5  $\mu\text{m}$  will be significantly affected by the cleaning procedures presented in this RP.

See Appendix A for a detailed discussion of particle adhesion and removal.

## 4.3 Validation of cleaning

If cleaning is being undertaken by or for a manufacturing process, where the control of viable organisms is critical (e.g. pharmaceutical, biologic, or medical devices manufacturing), the cleaning will probably be under the control of a regulatory agency such as the United States Food and Drug Administration (FDA), in which case the validation of cleaning is essential.

The formal FDA definition of such validation in *Guideline on General Principles of Process Validation* can be summarized as:

“Establishing documented evidence which provides a high degree of assurance that a specific [cleaning] process will consistently produce a product [result] meeting its predetermined specifications and quality attributes.”

Validation, usually undertaken as a project prior to full-scale operation, starts with the creation of a Validation Master Plan. Most often, the plan contains three sections: strategy, protocols, and evaluation. “Strategy,” or the design phase, sets out the objectives and specifies the results to be achieved. Results are specified as permitted residual limits. “Protocols” covers the implementation stage and specifies how the goals will be achieved. “Evaluation” describes the means and methods, either visual or sampling and analytical tests, that will be used to analyze the results of the process.

Sampling techniques should be able to collect contamination, the residues, in a form that is detectable by the analytical methods of choice. That choice will depend on the sampling site, the nature and properties of the residues, and the type of facility and its equipment.

# 5 PROCEDURES

## 5.1 Housekeeping equipment and supplies

All tools, equipment, and supplies used for maintaining the cleanliness of the cleanroom should be selected carefully for the intended cleanroom. Equipment should be constructed of non-shedding materials that can be easily maintained in a clean condition. Such materials may include reinforced plastic or fiberglass, powder-coated steel, anodized or hard-coated aluminum, stainless steel, or other approved materials. Equipment utilizing casters should have polyurethane or other non-marring wheel surfaces. If sterilization or disinfection is required then, equipment and tools should be constructed of stainless steel or other resilient materials.

The following sections list recommended supplies and equipment for use in housekeeping. It should be noted that this list is not all-inclusive. The responsible person should select equipment and supplies that are compatible with the cleanroom, cleanroom surfaces, the product, and related processes.

### 5.1.1 Vacuum cleaning system

A central plant vacuum (wet or dry) with attachments, or a portable vacuum cleaner with HEPA/ULPA-filtered exhaust and accessories.

### 5.1.2 Tacky roll mop

A cleaning tool, resembling a paint roller, that removes particles by means of a removable or renewable adhesive contact surface.

### 5.1.3 Mop bucket

A receptacle with a wringer or squeezing device made of plastic or stainless steel with single, dual, or triple compartments.

### 5.1.4 Wet mop

A mop that has a head constructed of foam, nylon, or low-linting material and handles constructed of stainless steel, aluminum, reinforced plastic, or an equivalent material.

In general, recommended laboratory practices are designed to promote the quality and validity of all laboratory measurements using standard practices and procedures. It is expected that users of IEST-RP-CC004 will follow recommended laboratory practices in the measurement of wiper characteristics.

### 5.1.5 Cleanroom wiper

Dry wiper—a cleanroom wiper selected in accordance with the recommendations of IEST-RP-CC004. The 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.

### 5.1.6 Stepladder

Common folding—constructed of non-contaminating materials such as aluminum, stainless steel, or fiberglass-reinforced plastic. Typical safety regulations prohibit the use of the top two steps. Generally, the user must hold onto the ladder with one hand while performing a cleaning task with the other. These ladders are generally the lightest types of stepladders and easiest to position in tight work areas.

Folding platform—similar to a common folding variety except that the frame extends beyond the uppermost step to provide a handhold. The uppermost step provides a wide, stable platform that allows the user to safely stand and work comfortably. These ladders are generally a little heavier than common folding ladders and have a slightly wider stance in tight work areas.

Fixed platform—a movable, rigid staircase with a platform and rails on top and casters or wheels for maneuvering into place. Locking mechanisms provide stability during ascent and descent. These ladders are generally the safest but least effective in tight work areas and are the most difficult to store when not in use.

### 5.1.7 Cleanroom apparel

Cleanroom apparel compatible with the cleaning agents and the cleanroom classification, as recommended in IEST-RP-CC003 and IEST-RP-CC005.

### 5.1.8 Water

Water, such as filtered tap, distilled, or reverse osmosis; deionized water; or water suitable for injection.

The water used in healthcare cleanrooms is delivered in one of two forms: purified water or water for injections (WFI). Water originates from the mains supply, as delivered by the water supply company, or from an artesian well, and is processed (purified) to specification per United States Pharmacopeia.

#### a) Purified water

Purified water represents the bulk of water used in cleanroom applications. The water purification process includes pre-treatment to remove gross impurities, which may then be followed by the reverse osmosis process or deionization, or both in sequence.

The test for the purity of water is chemical and depends on its conductivity, measured in micro Siemens per cm. The Total Organic Carbons content is another measure of purity. Dependent on the quality specified, purified water is mostly free of solid contaminants.

#### b) Water for injections

WFI is used in biotechnological and pharmaceutical manufacturing. The difference between purified water and WFI is that the latter must be free of viable organisms and pyrogens as well as solid contaminants.

WFI may be produced by deionization, or, frequently, for extra security, as a third stage in the purification process by distilling the already purified water.

#### c) Mains supply

Water feedstock from the water supply company is delivered in potable, or drinkable, form but is not required to be bacteria-free, pyrogen-free, or contamination-free.

### 5.1.9 Cleaning agent

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.

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

#### 5.1.10 Squeegee

A squeegee that has a blade made of a material that contributes minimal contamination. The squeegee should have a support and handle made of stainless steel or reinforced plastic or sealed with a durable, acceptable coating.

#### 5.1.11 Vacuum-controlled, steam cleaning systems

A cleanroom-compatible system that utilizes steam to clean surfaces. Steam is applied directly to the surface; contaminants are trapped and removed by a vacuum head to avoid escape to the cleanroom environment.

#### 5.1.12 Vacuum-controlled floor scrubbing systems

A cleanroom scrubbing system that utilizes rotating brushes to clean or buff cleanroom floors. A built-in vacuum system, enhanced by shrouds, traps any particle residue created by the cleaning action and removes it to a HEPA-filtered container.

#### 5.1.13 Contamination control mats and flooring

Mats, wall-to-wall or small area, that are placed strategically to remove and trap foot-borne contamination. When used in pharmaceutical and other healthcare manufacturing and cleanroom applications where control of viable organisms is critical, particular attention should be paid to drying the underside after mopping because microorganisms can readily breed in such damp areas.

Semi-permanent control mats—pads of adhesive-coated sheets of thin plastic film applied to the floor in a contamination-sensitive area. The top sheet is peeled off when contaminated, revealing the next clean adhesive surface.

Permanent control mats—thicker, compliant polymeric mats with a surface texture that naturally attracts foot-borne contamination. This type of mat should be cleaned routinely to remove trapped particles and restore the contamination-controlling surface finish.

### 5.1.14 Waste containers and liners

Waste receptacles should be relatively small and made from plastics, metal, or stainless steel with or without covers. If liners are to be used, they may be flexible bags or rigid liners. Choice of the receptacle and liner system should be evaluated for intended use and fire-prevention requirements.

#### 5.1.15 Dispensers

Plastic, coated-metal, or stainless steel bins or containers for disposable supplies such as wipes, gowning, or safety supplies that maintain those supplies in a clean, organized fashion. Dispensers should be designed and used in such a way as to allow the user to remove product without contaminating remaining product.

#### 5.1.16 Swabs

A head or bud of material, usually but not necessarily sorptive, attached to the end of a slender handle. Swabs are used for applying liquids to surfaces and for removing solids and liquids from surfaces.

## 5.2 Housekeeping procedures

The housekeeping practices recommended herein provide a comprehensive program for the removal and control of viable and nonviable contamination. It is recognized that not all of these practices are necessary for all cleanrooms.

Cleanrooms in which viable contamination is of primary concern may require different cleaning steps or a different sequence of steps.

In general, cleaning should begin in the areas requiring the most critical level of cleanliness and proceed toward areas of less critical requirements.

**NOTE:** Safety precautions should be followed during any housekeeping activity. Personal protective equipment may be required. Waste disposal procedures should follow all local safety codes and environmental requirements.

### 5.2.1 Ceilings

**CAUTION:** If an ionization system is present, it should be deactivated prior to cleaning the ceiling.

a) Ceilings in which HEPA filters are located adjacent to each other

Where HEPA filters are located adjacent to each other, only the grid/grill should be cleaned by dry vacuuming to protect the filter. Strokes used in vacuuming should follow the grid pattern in one direction only.