

INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY

Contamination Control Division Recommended Practice 004.3

IEST-RP-CC004.3

Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments

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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) describes methods for testing wipers used in cleanrooms and other controlled environments for characteristics related to both cleanliness and function.

1.2 Limitations

No recommendations are made for the construction, packaging, or laundering of wipers, or for the determination of such physical characteristics as strength or resistance to abrasion.

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 ANSI

ANSI/AAMI/ISO 11737-1: Sterilization of medical devices – microbiological methods – Part 1: Estimation of population of microorganisms on products

2.2 American Society for Testing and Materials (ASTM)

ASTM D1193-99e1: Standard Specification for Reagent Water

ASTM E548-94: Standard Guide for General Criteria Used for Evaluating Laboratory Competence

ASTM E2090-00: Standard Test Method for Size-Differentiated Counting of Particles and Fibers Released from Clean Room Wipers Using Optical and Scanning Electron Microscopy

ASTM F25-68(1999): Standard Test Method for Sizing and Counting Airborne Particulate Contamination in Clean Rooms and Other Dust-Controlled Areas Designed for Electronic and Similar Applications

ASTM F311-97(2002): Standard Practice for Processing Aerospace Liquid Samples for Particulate Contamination Analysis Using Membrane Filters

ASTM F312-97(2003): Standard Test Methods for Microscopically Sizing and Counting Particles from Aerospace Fluids on Membrane Filters

2.3 ESD

ESD STM11.11-2001: Surface Resistance Measurement of Static Dissipative Planar Materials

2.4 Institute of Environmental Sciences and Technology (IENT)

IENT-RP-CC013-86T: Equipment Calibration or Validation Procedures

IENT-RP-CC022.1: Electrostatic Charge in Cleanrooms and Other Controlled Environments

2.5 International Organization for Standardization (ISO)

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

2.6 SEMI

SEMI C10-0998: Guide for Determination of Method Detection Limits

2.7 Other References

1. Automotive Industry Action Group. 2002. *Measurement Systems Analysis*. 3rd Ed. Detroit, MI: AIAG.
2. Wheeler, D.W. and R.W. Lyday. 1998. *Evaluating the Measurement Process*. 2nd Ed. Knoxville, TN: SPC Press Inc.
3. Rudisill, J.F. and E.E. Burch. 1999. *Quality Management & Measurement Systems*. Clemson, SC: Quality Associates of Clemson.

2.8 Sources and Addresses

ANSI

American National Standards Institute
25 West 43rd Street
New York, NY 10036, USA
Phone: 212-642-4900
Fax: 212-398-0023
Web: www.ansi.org

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

ESDA

Electrostatic Discharge Association
7900 Turin Road, Bldg. 3
Rome, New York 13440-2069, USA
Phone: 315-339-6937
Fax: 315-339-6793
Web: www.esda.org

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ISO

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www.ient.org

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

SEMI

Semiconductor Equipment and Materials
International
1401 K Street NW, Suite 601
Washington DC 20005, USA
Phone: 202-289-0440
Fax: 202-289-0441
Web: www.semi.org

3 TERMS AND DEFINITIONS

generated particles

Particles that are not already present on the surface of a wiper, but that are generated in response to imparting mechanical energy to the wiper.

particle

A solid or liquid object that, as a general rule, measures from 0.001 μm to 1000 μm in size.

releasable particles

Particles that are already present on the surface of a wiper and are readily releasable from it by wetting it with a liquid, but without imparting mechanical energy to the wiper.

sorption

A physical or chemical mechanism whereby a fluid is taken up by a solid surface (as distinct from *adsorption*, which occurs within pores and capillaries as well as on surfaces).

4 BACKGROUND AND PURPOSE

Tests for wiping materials can be divided into two broad categories, one concerned with function, the other with contamination.

The most important functional characteristic of wipers may be their ability to sorb liquids. Two separate characteristics related to sorbency are relevant: capacity (how much liquid a wiper can sorb) and rate (how fast the wiper can sorb the liquid). Tests for these distinct characteristics are described in section 8.

Tests for contamination (or cleanliness) can be listed almost without end. However, the consensus in high-technology industries is that particles, non-specified extractable matter, and individual ionic constituents are the most important contaminants.

Section 5 describes recommended laboratory practices that should be followed when testing wiping products. These practices are designed to promote the

quality and validity of all laboratory measurements using standard practices and procedures.

Section 6 describes tests for enumeration of particles releasable from a wiper. The number of particles that can be released from a wiper is maximized when the wiper is immersed in a liquid that will properly wet the fiber surfaces. Thus, testing wipers in a wetted condition is the most efficient way to enumerate these particles. Two methods of sample preparation and two methods of enumeration are described.

Section 7 describes tests for the quantitative analysis of unspecified matter extractable from wipers. Two procedures for extracting and quantifying general extractable matter are described in section 7.1, one a short-term test, the other an exhaustive extraction. Section 7.2 provides guidelines for use when the quantitative analysis of specific constituents is required. Non-specified extractable matter is covered in section 7.1, while organic compounds and inorganic constituents are described in sections 7.2.1 and 7.2.2, respectively.

Section 8 describes tests for sorbency capacity and sorbency rate.

Section 9 describes test methods for sampling and quantifying bioburden on wiping products. Sterile apparatus and aseptic techniques are required to perform tests.

This RP does not categorize wipers according to their suitability for particular applications. Rather, it offers rational and germane tests to determine those characteristics of wiping materials generally acknowledged to be important. The results of these tests permit the quantitative assessment of the merits of wiping materials according to the mix of properties considered important in relation to their intended use.

5 RECOMMENDED LABORATORY PRACTICES

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.

NOTE: This RP does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

Recommended laboratory practices include:

a) System blank

Where feasible, a system blank should be performed to ensure the cleanliness of all equipment, apparatus, reagents, and materials associated with a given measurement. In a system blank, the measurement of the analyte (the characteristic to be measured, such as particles, ions, NVR, etc.) is performed, but without the sample. As a general rule, the system blank value should comprise no more than 15% of the test sample value.

b) Sampling and analysis

The sample taken for analysis should be large enough to produce reasonable accuracy and precision for a given measurement. Where feasible, the sample size should be large enough that the measured value of the analyte is at least twice the detection limit for the measurement (see also section 5f). If that is not possible and the sample measures below the detection limit, then the sample is reported as “below detection limit” (zero indicates no quantity found with a perfect measurement tool, therefore “below detection limit” should be used rather than zero). Also, where feasible, the sample size should be large enough that the test sample value is 7× higher than the system blank (section 5a).

At least three representative samples should be secured for analysis from the same production lot. Also, each sample should be labeled with date, lot number, and measurement type to provide an audit trail if needed.

c) Environment

All sample preparation work on samples and system blanks for particles and ions should be performed in an environment that prevents contamination of the analyte of interest. The environment may include an ISO Class 5 at 0.5 µm clean hood or cleaner environment. Test for sorbency, residues, and bioburden shall be conducted in a similar clean environment unless not practical.

d) Handling of samples

To avoid extraneous contamination, where applicable, all samples should be handled using pre-cleaned clean-room gloves (vinyl preferred over latex), tweezers, and forceps in an environment described in section 5c.

e) Calibration and validation (see also *ASTM E548* and *IEST-RP-CC-013-86T*)

Laboratories should determine a proper time interval for instrument calibration. Instrument or system calibration should be made with reference standards. Equipment performance should be verified at least