

Institute of Environmental Sciences and Technology

IENT-RP-CC004.4

Contamination Control Division
Recommended Practice 004.4

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 inherent wiper cleanliness and function.

Appendix A provides additional guidance based on common usage and collective experience, including a table to assist users in selecting wipers that may be suitable for certain applications or environments.

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.

Any guidance regarding wiper usage, or suitability for an environment, shall be considered general in nature, and it remains the sole responsibility of the user to determine and confirm suitability for their applications and fitness for use of any specific wiper.

This RP does not purport to address safety problems associated with its use. It is the responsibility of the user to consult and establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to the use of this RP.

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 American National Standards Institute (ANSI)

ANSI/AAMI/ISO 11737-1:2018 Sterilization of Health Care Products–Microbiological Methods–Part 1: Determination of a Population of Microorganisms on Products for Sterilization

2.2 American Society for Testing and Materials (ASTM)

ASTM D1193-06(2011): Standard Specification for Reagent Water

ASTM E548-94e1: Standard Guide for General Criteria Used for Evaluating Laboratory Competence

ASTM E2090-12: Standard Test Method for Size-Differentiated Counting of Particles and Fibers Released from Cleanroom Wipers Using Optical and Scanning Electron Microscopy

ASTM F25/F25M-09(2015): Standard Test Method for Sizing and Counting Airborne Particulate Contamination in Clean Rooms and Other Dust-Controlled Areas

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

ASTM F312-08(2016): Standard Test Methods for Microscopical Sizing and Counting Particles from Aerospace Fluids on Membrane Filters

2.3 EOS/ESD Association, Inc.

ANSI/ESD STM11.11: Surface Resistance Measurement of Static Dissipative Planar Materials

2.4 Institute of Environmental Sciences and Technology (IEST)

IEST-RP-CC013.3:2012: Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments

IEST-RP-CC022.2: Electrostatic Charge in Cleanrooms and Other Controlled Environments

2.5 International Organization for Standardization (ISO)

ISO 14644-1:2015: Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness

2.6 Semiconductor Equipment and Materials International (SEMI)

SEMI C10-1109: 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
1899 L Street, NW, 11th Floor
Washington, DC 20036
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Fax: 202-293-9287
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

EOS/ESD Association

EOS/ESD Association, Inc.
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ISO

In the U.S., documents may be ordered from:

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

SEMI

Semiconductor Equipment and Materials International
673 South Milpitas Blvd.
Milpitas, CA 95035, USA
Tel: 408-943-6900
Fax: 408-428-9600
Web: www.semi.org

3 TERMS AND DEFINITIONS

extrinsic sorbency

The sorbent capacity of a wiper expressed per unit area of the wiper material (e.g., mL/wiper or mL/m²). This measure is most useful for comparing the liquid holding capacity between different materials of the same area or size (such as two wipers of the same size).

fiber

An object typically defined as having a length greater than 100 µm and an aspect ratio of at least 10:1.

generated particles

See entry below particle

intrinsic sorbency

The sorbent capacity of a wiper expressed per unit mass of the wiper material (e.g., mL/g). This measure is most useful for comparing the liquid holding capacity inherent to materials.

non-shedding, low-lint, or lint-free wiper

A wiper exhibiting few, if any, fibers or other contamination, *visible without magnification*, which is separate from, or easily removed from the wiper material in a dry condition.

NOTE: Although there is no such thing as a contaminant-free wiper, materials containing natural fibers (e.g., any cotton, or cellulose content of 65% or more) are generally not considered to meet this definition.

particle

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

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.

releasable particles

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

releasable particles

See entry below particle

sorption

A physical or chemical mechanism whereby a fluid is taken up by a solid surface (as distinct from *absorption*, 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 both distinct characteristics are described in section 9.

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

Section 5 describes the 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 laboratory practices and procedures.

Section 6 specifies and clarifies the sample size and the reporting convention to be used when following the methods contained in this Recommended Practice (RP). The purpose of this change from previous versions of this RP is to make the reported results more relatable for the user (e.g., characteristics per wiper, rather than per square meter), and to improve consistency and reliability of both test results and reporting between various organizations and manufacturers that test wipers.

Section 7 describes the test for enumeration of particles and fibers releasable from a wiper. The number of particles and fibers that may 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 such particles. The method of sample preparation and method of enumeration are described.

Section 8 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 8.1— one a short-term test and the other an exhaustive extraction. Section 8.2 provides guidelines for use when the quantitative analysis of specific constituents is required. Non-specified extractable matter is covered in section 8.1, while organic compounds and inorganic constituents are described in sections 8.2.1 and 8.2.2, respectively.

Section 9 describes tests for sorbency capacity and sorbency rate.

Section 10 describes test methods for sampling and quantifying bioburden on wiping products. Sterile apparatus and aseptic techniques are required to perform these tests.

This RP offers rational and germane tests to determine the cleanliness 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 this RP 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, and non-volatile residues (NVR), etc.] is performed, but without the sample. As a general rule, the system blank value should comprise no more than 10% 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 should be conducted in a similar clean environment unless impractical.

d) Handling of samples

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

e) Calibration and validation (see also ASTM E548-94e1 and IEST-RP-CC-013.3)

Laboratories should determine a proper time interval for instrument calibration. Instrument or system calibration should be conducted using reference standards. Equipment performance should be verified at least once a year and after any major service of the equipment. Laboratories should also set operating limits for each analytical instrumentation system or equipment component.

f) Detection limits

Where feasible, measurement of method detection limits should be performed by using regression analysis of calibration data. Details are included in SEMI C10-1109. Ion determinations are performed using analytical equipment for which calibration data of each analyte can be obtained. Thus, detection limits for each ion type can be established.

g) Recovery studies for soluble species

To develop confidence in the performance of a proposed test method, it is good practice to dose one or more test samples intentionally with known amounts of the appropriate analyte, then perform a recovery study by measuring and quantifying the analyte using the proposed test method. A high percentage recovery for a given analyte signifies high confidence in the proposed test method.

h) Numerical analysis

Where feasible, replicate analysis should be performed, and the mean and deviation reported.

An important attribute of tests that measure a product property is the power of the test to distinguish between product categories with respect to the property in question; that is, the ability to distinguish between one part or lot and another. This subject is treated in an easily understood manner in References [1] and [3] and in comprehensive detail in Reference [2]. These references show that the statistical error associated with the measurement process stands in the way of discriminatory power.

The Percent Gage R&R is the statistic most commonly used as a measure of the discriminatory power of a test that employs a variable gage (as distinct from an attribute gage). A Percent Gage R&R calculation is recommended as part

of the validation of tests performed on wipers. For an introduction to attribute gages see Reference [1], page 81. Percent Gage R&R is defined as

$$\text{Percent Gage R\&R} = 100 \times \frac{\sigma_m}{\sigma_t} \quad (1)$$

where:

σ_m is the standard deviation associated with the measurement of the property in question

σ_t is the total standard deviation including variation in the product itself and variation arising from the act of measurement

Each product stream has its own Percent Gage R&R with respect to a particular property measured. Because of this, some practitioners use the description “Process Measurement Index (PMI)” for Percent Gage R&R. When the Percent Gage R&R is small enough, the test is suitable for quality control of the process or product stream for which it has been estimated. If all users of a test are having difficulty achieving acceptable Percent Gage R&R values, it may indicate the test is not suited for its intended purpose.

Accordingly, Percent Gage R&R (PMI) is recommended as an appropriate and useful part of the validation process for tests done on wiping materials used in cleanrooms and other controlled environments and for ongoing validation and test applicability.

Guidelines for the evaluation of observed Percent Gage R&R values are:

Percent Gage R&R <10: good

10 < Percent Gage R&R <30: usually adequate

Percent Gage R&R >30: measurement system needs improvement

Full details on how to apply the Percent Gage R&R statistic in test validation can be found in References [1–3].

i) Reporting

A summary report on the analysis should include the following information:

- Date of analysis
- Date of report
- Analyst’s name
- Report writer’s name
- Lot number or other sample identification information
- Measurement type
- Equipment specifics
- Sample preparation specifics
- System blank values
- Test values
- Detection limits
- Numerical analysis

6 SAMPLE SIZE AND REPORTING RESULTS

In the past, reporting of wiper test data included a variety of units of measure, creating confusion among users when comparing values from product literature of different manufacturers. Such confusion often distorts the true impact of any given wiper to an application or environment.

All of the methods detailed in this RP have been designed to use a 23 cm × 23 cm (9 in. × 9 in.) nominal size wiper. Testing wipers that are larger or smaller than this defined sample size will result in differing results that are typically non-linear in nature. As an example, in the case of particle and fiber testing, larger or smaller wipers than defined experience different physical forces in the extraction process and thus the particle and fiber release will be different, often with significant effects on the results.

It should be understood that the 23 cm × 23 cm (9 in. × 9 in.) nominal wiper size represents the majority of the wipers manufactured for use in cleanroom and other critical environments. The use of this defined wiper size will provide information relevant to the majority of wiper usage and applications.

When practical, for those intending to use wipers that are larger or smaller than the defined standard sample, wiper test samples made from the same material and processes may be obtained from the wiper manufacturers or suppliers. Ideally, such test samples would be processed together with the non-standard wipers of interest. Such “witness wipers” for testing should be 23 cm × 23(±)0.13 cm [9 in. × 9(±)0.5 in.]. The standard-sized wiper is tested to represent the characteristics of products of a different size.

For all tests detailed in this RP, a wiper of nominal 23 cm × 23(±)0.13 mm [9 in. × 9(±)0.5 in.] must be used. Additionally, all reporting of data resulting from the use of these methods must be in terms of “per wiper” to best reflect the impact of a given wiper to an application or environment.

If a wiper of any size different from the defined size is to be tested using the methods proscribed in this RP, all resulting data must be annotated indicating the wiper size actually tested.

7 TESTING FOR PARTICULATE AND FIBER CONTAMINATION

Unlike the testing of wiping materials for other contaminants, there is no discrete answer to the question of how many particles a wiper can potentially contribute to an environment. Wipers have a finite number of particles on their surfaces. However, wipers can also be the source of another category of particles, those that are not already present on the wiper’s surfaces but are brought into existence by imparting mechanical energy to the wiper. Particles that already exist on a wiper’s surface are referred to as *releasable particles*. Those brought into existence by imparting mechanical energy to the wiper are termed *generated particles*.

This model for viewing particles and wiping materials is equivalent to postulating the existence of characteristic “stress-strain” curves for wipers. If cumulative particles per unit area of wiper are plotted versus cumulative energy per unit area, then the curve for any wiper should increase in response to the administration of mechanical energy. The shape of the curve shows the propensity of the wiper to both release and generate particles. Initially, as the wiper is immersed in the proper wetting test liquid, the most readily releasable particles are removed from the wiper. As energy is applied, releasable particles that are more tightly bound to the surface are removed, and with a continued increase in energy, generated particles are created on the wiper and transferred to the test solution.

This RP recommends a practical method to determine one point on the curve, which is intended to strike a balance between the two types of particles. The orbital shake method using a square pail (section 7.1.3) imparts energy to the wiper from the orbital action and from the deformation of the wiper as it strikes the interior surfaces of the pail. As there is no single answer to the number of particles that a wiper will shed, this RP provides a sample preparation technique that strives to model representative stresses that a wiper would experience in use and that are consistent with methods proscribed by previous versions of this RP.

The particle tests described herein reference ASTM Standards D1193, F25, F311, F312, and E2090, and ISO 14644-1:2015.

Section 7.1 describes in detail the technique for removing particles and fibers from the wiper, while section 7.2 provides techniques for counting the particles and fibers once they are removed from the wiper.