Designation: E2312 – 11

Standard Practice for Tests of Cleanroom Materials[1]

This standard is issued under the fixed designation E2312; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice identifies test methods used to evaluate the properties of various materials and products used in cleanrooms and for cleanroom construction.

1.2 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E595 Test Method for Total Mass Loss and Collected Volatile Condensable Materials from Outgassing in a Vacuum Environment

E1216 Practice for Sampling for Particulate Contamination by Tape Lift

E1234 Practice for Handling, Transporting, and Installing Nonvolatile Residue (NVR) Sample Plates Used in Environmentally Controlled Areas for Spacecraft

E1235 Test Method for Gravimetric Determination of Nonvolatile Residue (NVR) in Environmentally Controlled Areas for Spacecraft

E1549 Specification for ESD Controlled Garments Required in Cleanrooms and Controlled Environments for Spacecraft for Non-Hazardous and Hazardous Operations

E1559 Test Method for Contamination Outgassing Characteristics of Spacecraft Materials

E1560 Test Method for Gravimetric Determination of Nonvolatile Residue From Cleanroom Wipers

E1731 Test Method for Gravimetric Determination of Nonvolatile Residue from Cleanroom Gloves

E2088 Practice for Selecting, Preparing, Exposing, and Analyzing Witness Surfaces for Measuring Particle Deposition in Cleanrooms and Associated Controlled Environments

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

E2217 Practice for Design and Construction of Aerospace Cleanrooms and Contamination Controlled Areas

F25 Test Method for Sizing and Counting Airborne Particulate Contamination in Cleanrooms and Other Dust-Controlled Areas

F51 Test Method for Sizing and Counting Particulate Contaminant In and On Clean Room Garments

F739 Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact

2.2 *IEST Standards:*[3]

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-CC020 Substrates and Forms for Documentation in Cleanrooms

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

2.3 *Others:*[4]

ANSI/AAMI/ISO 11137 Sterilization of Health Care Products Radiation Part 1

3. Terminology

3.1 *Definitions:*

3.1.1 *ESD*—electrostatic discharge, the transfer of electrostatic charge between bodies that have different electric potential.

3.1.2 *fiber*—particle having an aspect (length-to-width) ratio of 10 or more.

[1] This practice is under the jurisdiction of ASTM Committee E21 on Space Simulation and Applications of Space Technology and is the direct responsibility of Subcommittee E21.05 on Contamination.

Current edition approved Jan. 1, 2011. Published February 2011. Originally approved in 2004. Last previous edition approved in 2004 as E2312 – 04. DOI: 10.1520/E2312-11.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from Institute of Environmental Sciences and Technology (IEST), Arlington Place One, 2340 S. Arlington Heights Rd., Suite 100, Arlington Heights, IL 60005-4516, http://www.iest.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.3 *microorganism*—living organism of microscopic size capable of growth and reproduction. Examples include bacteria, yeasts, and molds.

3.1.4 *non-volatile residue (NVR)*—that quantity of molecular matter remaining after the filtration of a solvent containing contaminants and evaporation of the solvent at a specified temperature.

3.1.5 *outgassing*—evolution of volatile components from an item exposed to elevated temperature, normally in vacuum.

3.1.6 *particle*—small piece of matter with defined physical boundaries.

4. Summary of Practice

4.1 A number of tests for materials and products used in cleanrooms or to fabricate cleanrooms have been issued by various organizations such as ASTM and IEST. The purpose of this practice is to identify test methods used to determine the properties of various materials and products used in cleanrooms. A brief description and some of the features of the various tests are also given to aid interested users in selecting the test or groups of tests that have the ability to meet their needs for evaluating existing and candidate cleanroom products.

4.2 Table 1 lists the tests suggested to measure specific properties of various cleanroom materials and products. Where no test is presently listed it is probable that a test will be required and must be identified or developed if none exist at present.

5. Significance and Use

5.1 This practice is not intended to advocate or discourage use of any particular test method. It is intended for information only, and to provide a useful guide for further detailed study, test, and evaluation of cleanroom materials and products.

6. Hazards

6.1 Hazards can be present when using many of the referenced tests. Each of the referenced test methods warn of possible hazards and suggest means to minimize them. If toxic or other hazardous materials are identified, they must be handled properly per the reference documents.

7. Procedure

7.1 Table 1 lists the types of materials and cleanroom products of present interest and recommends the test methods to be used to evaluate these materials. Where several tests are listed, it is suggested that all of them be considered at least initially to evaluate the product and allow properties to be evaluated. Test results will provide relative values for the

TABLE 1 Test Methods—Tests of Cleanroom Materials and Products

Tests	Garments	Wipers	Gloves	Swabs	Documents	Tote Box	Cleanrooms, Surfaces
Particles	IEST RP003 Sect. 10.1-10.3	IEST RP004 Sect. 5.1-5.2 ASTM E1216 ASTM E2090 ASTM F51	IEST RP005 Sect. 7 ASTM E1216	IEST RP004 Sect. 5, 5.1-5.2	IEST RP020 Sect. 6, 7 ASTM E1216	ASTM E1216	ASTM F25 ASTM E1216 ASTM E2088 ASTM E1234 ASTM E1235
Extractable, NVR	IEST RP003 Sect. 10.4 ASTM E1549	IEST RP004 Sect. 6, 6.2 ASTM E1560 ASTM E1731	IEST RP005 Sect. 8 ASTM E1560 ASTM E1731	IEST RP004 Sect. 6-6.2 ASTM E1560	IEST RP020 Sect. 7.2	ASTM E1560	ASTM E1560
Microorganisms	None[A]	IEST RP004 Sect. 11, 13	None[A]	None[A]	NA	NA	None
Chemical Compatibility	ASTM E1549 ASTM F739	None	IEST RP005 Sect. 6.3	None	NA	None	None
Barrier	ASTM E1549	None	IEST RP005 Sect. 6.4	NA	NA	NA	None
Permeability	ASTM E1549	NA	IEST RP005 Sect. 6.6	NA	NA	NA	NA
Static, ESD	IEST RP003 Sect. 10.7 ASTM E1549	IEST RP004 Sect. 8	IEST RP005 Sect. 8	NA	NA	None	IEST RP022
Outgassing	IEST RP003 Sect. 9 ASTM E595 ASTM E1559	ASTM E595 ASTM E1559	ASTM E595 ASTM E1559	NA	NA	ASTM E595 ASTM E1559	ASTM E595 ASTM E1559
Heat Resistance	ASTM E1549	NA	IEST RP005 Sect. 6.1	NA	NA	NA	NA
Accelerated Aging	NA	NA	IEST RP005 Sect. 6.2	NA	NA	NA	NA
Design, Construction	IEST RP003 Sect. 9 ASTM E1549	NA	None	NA	None	None	ASTM E2217
Filter Efficiency	IEST RP003 Sect. 7.3	NA	NA	NA	NA	NA	ASTM E2217
Sorbancy	None	IEST RP004 Sect. 7	None	None	NA	NA	NA

[A] If microorganisms must be limited or controlled on garments, wipers, or gloves those products must be procured from a source that certifies cleanliness such as vendors and garment laundries that supply pharmaceutical cleanrooms (reference ANSI/AAMI/ISO 11137 Sterilization of Health Care Products Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices).

properties tested such as particle count per unit area, NVR per unit area or mass, or outgassing at a given temperature, typically at 125°C. No pass/fail values or minimum requirements are specified because there are no established values for cleanliness for any of the products that are listed. Users should rank materials for contamination generation potential and suitability for cleanroom use based upon test results and added factors such as conditions of use, consistency of test results, testing bias, and cost and availability of the products as-used in cleanrooms. It is normal for properties to vary somewhat from lot to lot, so it is important to test several lots to evaluate reproducibility of results and product consistency.

NOTE 1—If there is a specific interest in identifying or developing test methods for areas shown as having no tests at present, or that the test is Not Applicable, Committee E21 will consider any such suggestions.

7.2 Test methods as noted in the table are available from ASTM or IEST.

8. Report

8.1 The report should identify the material or product tested, the vendor, supplier or source, any part number or other identifying specification, the test or tests performed, and the actual test results.

8.2 The report also may compare test results for different lots from the same manufacturer or supplier, or for different types of products, and rank performance and test results. It also is useful to identify specific products or materials as being acceptable for use in particular types of facility or for specific uses or applications.

9. Precision and Bias

9.1 There is no precision or bias value possible for this practice. Many of the referenced documents do include precision and bias statements. They should be considered on an individual basis for each test method.

10. Keywords

10.1 cleanroom products; contamination control; gloves; materials evaluation; materials properties; material testing; product evaluation; product properties; product testing; test methods; wipers