Designation: E2352 – 19

Standard Practice for Aerospace Cleanrooms and Associated Controlled Environments—Cleanroom Operations[1]

This standard is issued under the fixed designation E2352; 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 specifies basic requirements, procedures, and practices for operating aerospace cleanrooms and controlled environments and precautions associated with the facility and equipment used.

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D737 Test Method for Air Permeability of Textile Fabrics

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

E2042 Practice for Cleaning and Maintaining Controlled Areas and Clean Rooms

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

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

F50 Practice for Continuous Sizing and Counting of Airborne Particles in Dust-Controlled Areas and Clean Rooms Using Instruments Capable of Detecting Single Sub-Micrometre and Larger Particles

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

F318 Practice for Sampling Airborne Particulate Contamination in Cleanrooms for Handling Aerospace Fluids (Withdrawn 2013)[3]

2.2 *Government Standards:*[4]

Federal Standard 209E Airborne Particulate Cleanliness Classes in Cleanroom and Clean Zones (cancelled Nov. 29, 2001)

NASA-STD-6001, Test #7 Flammability, Odor, Offgassing and Compatibility Requirements and Test Procedures for Materials in Environments That Support Combustion

[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.

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[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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

2.3 *Other Technical Society Standards:*

IEST-RP-CC003 Garments Required in Cleanrooms and Controlled Environments[5]

IEST-RP-CC004 Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments[5]

IEST-RP-CC005 Cleanroom Gloves and Finger Cots[5]

IEST-RP-CC018 Cleanroom Housekeeping—Operating and Monitoring Procedures[5]

IEST-RP-CC027 Personnel Practices and Procedures in Cleanrooms and Controlled Environments[5]

IEST-RP-CC0016 Recommended Practice for the Rate of Deposition of Nonvolatile Residue in Cleanrooms[5]

IEST-STD-CC1246 Product Cleanliness Levels – Applications, Requirements, and Determination[5]

JIS B9923 Methods for Sizing and Counting Particle Contaminants in and on Clean Room Garments[6]

JIS B9926 Test Methods for Dust Generation from Moving Mechanisms[6]

2.4 *International Standards:*

ISO 14644-1 Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness[7]

ISO 14644-2 Cleanrooms and Associated Controlled Environments—Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1[7]

ISO 14644-3 Cleanrooms and Associated Controlled Environments—Part 3: Metrology and Test Methods[7]

ISO 14644-4 Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction, and Start-up[7]

ISO 14644-7 Cleanrooms and Controlled Environments—Part 7: Separative Devices[7]

ISO 9237 Textiles—Determination of Permeability of Fabrics to Air[7]

EN 1149-1 (1994) Protective Clothing—Electrostatic Properties—Part 1 Surface Resistivity (Test Methods and Requirements)[8]

CEI IIEC 1025:1990 Fault Tree Analysis (FTA)[9]

3. Terminology

3.1 *Definitions:*

3.1.1 *airlock*—intermediate room or area that is normally ventilated and used to minimize the transfer of airborne contamination from one area to another; the airlock is maintained at a lower air pressure than the cleanroom and a higher pressure than the outside area.

3.1.2 *changing room*—room where people using a cleanroom may change into or out of cleanroom clothing.

3.1.3 *cross-over bench*—bench that is used as an aid to changing of cleanroom clothing and which provides a barrier to the tracking of floor contamination.

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

3.1.5 *non-unidirectional airflow*—air distribution where the supply air entering the room mixes with the internal air by means of induction.

3.1.5.1 *Discussion*—This type of air distribution results in dilution of the particle concentration.

3.1.6 *operational*—condition where the installation is functioning in the specified manner, with the personnel present and working in the manner agreed upon.

3.1.7 *operator*—person working in the cleanroom performing production work or carrying out process procedures.

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

3.1.9 *personnel*—persons entering the cleanroom for any purpose, but typically operators.

3.1.10 *stationary equipment*—large equipment that cannot be easily moved.

3.1.11 *unidirectional airflow*—air flow which has a singular direction of flow and may or may not contain uniform velocities of air flow along parallel lines; formerly known as laminar airflow.

4. Requirements

4.1 *Operational Systems:*

4.1.1 *General*—The air cleanliness class required shall be determined before the facility is certified or used initially. Operations may be performed in a controlled area if the products are not sensitive to contamination, or if they will be cleaned adequately during later steps. Normally operations will be performed in a cleanroom of at least class 8 or cleaner per ISO 14644-1 (class 100 000 or cleaner per FED-STD-209E).

4.1.2 A set of risk factors, appropriate for the use of the specific cleanroom, shall identify the areas where there is a risk of contamination to the process. Improper control of the critical elements of an operational cleanroom can pose a risk to the cleanliness of the cleanroom and the quality of the product. A risk assessment must be done and plans formulated to remedy out-of-control situations. A method for monitoring these risks shall be instituted so that action can be taken when conditions are outside of specifications. The following list identifies some of the risks that may prove important. Cleanroom parameters including heating, ventilation and air conditioning, pressure differential, temperature, humidity, air change rates, and filters, are discussed in ISO 14644-2, ISO 14644-3, and ISO 14644-4.

4.1.2.1 Table 1 gives the recommended air cleanliness class, personnel practices, and operational controls for different types of cleanroom and controlled area operations. Examples of methods used for determining and managing these factors include:

[5] Available from Institute of Environmental Sciences and Technology (IEST), 1827 Walden Office Square Suite #400, Schaumburg, IL 60173, info@iest.org.

[6] Available from Japan Industrial Standards (JIS), 1-3-1 Kasumigaseki, Chiyoda-ku, Tokyo, 100-8901, Japan.

[7] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[8] Available from European Committee for Standardization (CEN), Rue de la Science 23, B-1040, Brussels, Belgium.

[9] International Electrotechnical Commission, Case postale 131, 1211 Geneva 20, Switzerland.

TABLE 1 Minimum Requirements for Air Cleanliness Classes and Operations Constraints

Operation or Controls	Class 4	Class 5	Class 6	Class 7	Class 8	Class 8.5
Wear garments including hair and beard covers	Required	Required	Required	Required	Required	No beard or hair covers
Enter via ante room with air shower or air lock	Required	Required	Required	Optional	Optional	No
No cosmetics or similar products worn	Required	Required	Required	Required	Required	No
Sanding, grinding, machining prohibited	Required	Required	Required	Controlled	Controlled	Controlled
Particle counts taken continuously	Required	Required	Required	Required	Optional	Weekly
Temperature and humidity recorded continuously	Required	Required	Required	Required	Optional	Daily
Wear gloves even when not handling products	Required	Required	Required	Required	Optional	Optional
Pre-clean all equipment before entry, verify clean	Required	Required	Required	Required	Required	Optional
Clean working surfaces twice daily	Required	Required	Required	Required	Daily	No
Remove trash and waste daily	Required	Required	Required	Required	Preferred	No
Personnel trained and certified for cleanliness level	Required	Required	Required	Required	Required	Required

(1) HAZOP (HACCP Principles and Applications, per HACCP Principles and Applications),[10]

(2) HACCP (Hazard Analysis Critical Control Point),

(3) FMEA (Failure Mode Effects Analysis) per CEI IIEC 1025, FMEA: Failure Modes and Effect Analysis,[11] and Failure Mode Effect Analysis: FMEA from Theory to Execution,[12,13]

(4) FTA (Fault Tree Analysis) per EN 1149-1, and

(5) Evaluation of sensitivity of the products and equipment in the cleanroom or controlled area to the effects of contamination, and the ease and cost of cleaning those products and removing contamination products.

4.1.3 A system for training and certifying personnel in cleanroom procedures is required. Provide a method for monitoring compliance to procedures. All personnel must be trained and certified with regard to their responsibilities and how those responsibilities affect the clean environment. Personnel shall be recertified every two years. The training should ensure that each of the following groups of personnel is educated and trained appropriately: operators, technicians, engineers and scientists, supervisors and managers, facilities personnel, contractors, field service personnel, and visitors.

4.1.3.1 Records shall be maintained to provide evidence that all personnel have received proper training in the following areas:

(1) How the cleanroom works (design, airflow, equipment used, and air filtration),

(2) Cleanroom standards,

(3) Sources of contamination and how to avoid or control them,

(4) Hygiene and permitted and prohibited personal care products,

(5) Cleaning operations and handling of products,

(6) Cleanroom clothing and changing procedures,

(7) Maintenance procedures,

(8) Cleanroom testing and monitoring,

(9) Proper behavior in a cleanroom,

(10) Work processes and technologies employed,

(11) Safety and emergency responses, and

(12) Corrective actions if there are operational failures such as exceeding allowed particle counts or temperature.

4.1.3.2 Different types of personnel require training in different areas. For example, visitors need not be trained in maintenance, testing, monitoring, or corrective actions. Failure to properly train anyone entering, using, or maintaining the facility will compromise the effectiveness of the cleanroom.

4.1.4 Courses taken and passed for certification must be identified. A concise, comprehensive system that documents the training progression and level of each individual should be used. Each job and set of jobs or responsibilities should be identified by the management team. This system should be easily accessible to management and periodically reviewed. Basic documentation should include course contents, personnel identification information, training and certification dates, and schedules for retraining at future intervals.

4.1.5 A set of procedures shall be documented to describe how the cleanroom systems are to be operated, maintained, repaired, and monitored. See ISO 14644-4. Factors that may influence the operation or environmental quality of the cleanroom may include the following:

4.1.5.1 Entry, exit, and movement procedures for equipment and personnel,

4.1.5.2 Installation of equipment,

4.1.5.3 Cleaning techniques and methodology,

4.1.5.4 Contamination generation from personnel or equipment operation,

4.1.5.5 Generation of heat, humidity, and electrostatic charge,

4.1.5.6 Service, maintenance, and repair of equipment and facilities,

4.1.5.7 Cleanliness of process materials and utilities delivery systems,

4.1.5.8 Testing and monitoring the facility,

4.1.5.9 Routine environmental contaminating factors (airflows, airborne particles, outgassing, hazardous gas, vibration, electrostatic charges, and molecular contamination),

4.1.5.10 Personnel and material flow,

4.1.5.11 Emergency and planned shutdowns,

4.1.5.12 Facility expansion and modification,

4.1.5.13 Frequency of monitoring the results,

4.1.5.14 Compatibility and selection of fabrication and environmental control equipment,

4.1.5.15 Waste and trash disposal,

4.1.5.16 Storage of equipment and supporting supplies in the cleanroom,

[10] *HACCP Principles and Applications*, edited by Merle D. Pierson and Donald A. Corlett, Jr., Chapman & Hall, New York, NY, 1992.

[11] Palady, P., *FMEA: Failure Modes and Effect Analysis*, PT Publications, Inc., West Palm Beach, FL, 1995.

[12] Stamatis, D. H., *Failure Mode Effect Analysis: FMEA from Theory to Execution*, American Society for Quality, Milwaukee, WI, 1995.

[13] Kletz, T.A., *Hazop and Hazan: Identifying and Assessing Process Industry Hazards*, Hemisphere Pub, Washington, DC, 1992.