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

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

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

2.2 *Government Standards:*[3]

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

2.3 *Other Technical Society Standards:*

IEST-RP-CC003 Garments Required in Cleanrooms and Controlled Environments[4]

IEST-RP-CC004 Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments[4]

IEST-RP-CC005 Cleanroom Gloves and Finger Cots[4]

IEST-RP-CC018 Cleanroom Housekeeping—Operating and Monitoring Procedures[4]

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

[4] 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.

IEST-RP-CC020 Substrates and Forms for Documentation in Cleanrooms[4]
IEST-RP-CC022 Electrostatic Charge in Cleanrooms and Other Controlled Environments[4]
IEST-RP-CC026 Cleanroom Operations[4]
IEST-RP-CC027 Personnel Practices and Procedures in Cleanrooms and Controlled Environments[4]
IEST-RP-CC0016 Recommended Practice for the Rate of Deposition of Nonvolatile Residue in Cleanrooms[4]
JIS B9923 Methods for Sizing and Counting Particle Contaminants in and on Clean Room Garments[5]
JIS B9926 Test Methods for Dust Generation from Moving Mechanisms[5]
JACA Number 14C Guidance for Operation of Clean Rooms[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/AWI 14644-6 Cleanrooms and Associated Controlled Environments—Part 6: Terms and Definitions[7]
ISO 14644-7 Cleanrooms and Controlled Environments—Part 7: Separative Devices[7]
ISO 7730 Moderate Thermal Environments—Determination of the PMV and PPD Indices and Specification of the Conditions for Thermal Comfort[7]
ISO 9237 Textiles—Determination of Permeability of Fabrics to Air[7]
ISO 11092 Textiles—Physiological Effects—Measurement of Thermal and Water-Vapour Resistance Under Steady-State Conditions (Sweating Guarded-Hotplate Test)[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]
CEI IIEC 812:1985 Analysis Techniques for System Reliability—Procedure for Failure Mode and Effective Analysis (FMEA)[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.

[5] Available from Japan Industrial Standards (JIS), 1-3-1 Kasumigaseki, Chiyoda-ku, Tokyo, 100-8901, Japan.
[6] Available from Japan Air Cleaning Association (JACA), Tomoe-Ya Building No. 2-14, 1-Chome, Uchi-Kanda, Chiyoda-ku, Tokyo, 101, Japan.
[7] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.
[8] Available from European Committee for Standardization (CEN), 36 rue de Stassart, B-1050, Brussels, Belgium, http://www.cenorm.be.
[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	Opt.	Weekly
Temperature and humidity recorded continuously	Required	Required	Required	Required	Opt.	Daily
Wear gloves even when not handling products	Required	Required	Required	Required	Opt.	Opt.
Pre-clean all equipment before entry, verify clean	Required	Required	Required	Required	Req.	Opt.
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

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:

(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—Part 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,

[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.

TABLE 2 Minimum Requirements for Frequency of Garment Changes

	Class 4	Class 5	Class 6	Class 7	Class 8	Class 8.5
Garments, Gowns	Each entry	Each entry	Daily	Every 3 days	Weekly	Weekly
Gloves, hand covers	Each entry	Each entry	Each entry	Each entry	Daily	Daily
Hair, beard covers	Each entry	Each entry	Each entry	Each entry	Daily	N.A.

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,

4.1.5.17 Contamination factors during use,

4.1.5.18 Fluid and gas purity supplied by delivery systems, and

4.1.5.19 Packaging materials and methods of packaging products.

4.1.6 Cleanroom mats and sticky flooring are used as a barrier to help control foot-borne contamination from entering the cleanroom. The size (particularly the length) and location of the mats/flooring are major factors governing the effectiveness for the removal of foot-borne contamination. Two major varieties of mats/flooring available include:

4.1.6.1 *Disposable*—Multiple layers of adhesive, plastic film with the sticky surface facing up. Layers are removed and discarded periodically as they get dirty.

4.1.6.2 *Reusable*—Resilient polymeric mat with a naturally sticky surface, to be cleaned when it becomes dirty. These polymeric mats reportedly have higher particle capture efficiency than disposable mats.

4.1.7 All activities that modify the cleanroom or that result in any change in contamination controls shall be planned to include all relevant personnel, including facility, manufacturing, and equipment engineers, contamination control engineers, process engineers, quality assurance engineers, manufacturing managers, and contractors. Any significant changes of facility operation or use may require requalification of the facility in compliance with Practice E2217, Practice E2042, ISO 14644-2, and ISO 14644-4. Modifications of concern include adding equipment or work benches, relocating equipment, adding or removing operations or functions, changes to mechanical equipment such as blowers or HEPA filters, relocating environmental monitors for particle counts, temperature, humidity, particle deposition, or NVR deposition may require retesting and recertification of the facility.

4.1.8 Establish and document a system that enforces safety and complies with all applicable regulatory requirements for operations and personnel in the cleanroom. Proper personnel training in safety requirements and procedures are essential. Management must implement and monitor effective systems to protect the health and safety of personnel. Good programs should include the following:

4.1.8.1 Readily available safety data sheets (MSDS) that describe hazardous materials,

4.1.8.2 Evacuation plans and practice evacuations,

4.1.8.3 An accident reporting system,

4.1.8.4 Suggestion feedback systems for personnel,

4.1.8.5 Appropriate monitoring of potentially hazardous conditions or materials,

4.1.8.6 Rapid response to emergencies by trained personnel,

4.1.8.7 Supporting documentation for all safety improvements and corrections and emergency responses,

4.1.8.8 Standard operating guidelines and plans for different types of incidents, and

4.1.8.9 Safe storage for hazardous materials in or near the cleanroom.

4.2 *Cleanroom Clothing:*

4.2.1 Cleanroom clothing shall protect the environment and products from contamination generated by the personnel and their clothing. To maximize this containment, the choice of barrier fabric, the clothing style and extent of coverage of personnel by the garment shall be controlled. The fabric used to manufacture cleanroom clothing should not create significant amounts of contamination and shall be made of fabrics and materials that has minimal linting and does not shed. Cleanroom clothing should be resistant to break-down and tearing. Garments should disperse the minimum of particles. Information on tests used to assess these properties is available Garments should comply with Test Method F51 or IEST-RP-CC003. Specification E1549 describes garment requirements for ESD controlled areas. Clothes worn under the cleanroom gowns should cover most of the body. Shorts or short skirts which expose bare legs are inappropriate under cleanroom garments. The cleanroom clothing worn will vary according to the product cleanliness and process requirements. It includes hoods, caps, coveralls, overboots, facemasks, and goggles or safety glasses. In controlled areas, class 8.5 (FED-STD-209E 300 000) or less stringent, wearing facemasks, goggles, and safety glasses is optional.

4.2.2 People disperse fragments from their skin and particles from their normal indoor clothing. This dispersion varies from person-to-person and from time to time but can be several million particles and several hundred bacteria-carrying particles per minute. The prime function of cleanroom clothing is to act as a body filter. It should be made from a fabric that filters the contamination, and be designed to enclose a person and prevent significant amounts of unfiltered body emissions from being dispersed into the cleanroom.

4.2.2.1 Personnel emit, through sneezing, coughing and talking, inert and microbe-carrying particles from the mouth, nose, and face. Touching transmits contamination from the hands to surfaces in the cleanroom. It normally is necessary to wear facemasks and gloves to minimize transmission of this contamination. Face masks are required to cover beards or facial hair. They are a barrier against saliva and contamination and are commonly used in cleanrooms. The masks can be surgical-style masks with elasticized straps and loops and the veils are snapped into hoods or permanently sewn into the hood at manufacture. Materials used are washable or disposable

fabrics. Care should be taken to select the proper material and style that is appropriate to the risk from emissions from the mouth.

4.2.3 The best design of cleanroom clothing completely envelops the person and has good closures at the wrist, neck, and ankle. The choice depends on operations being performed, the requirements of the hardward, and the class of cleanroom.In class 7 (FED-STD-209E class 10 000) or better cleanrooms, typical clothing includes a one-piece coverall, overboots, and a hood with yoke or skirt that tucks under the neck of the garment. In class 8 (FED-STD-209E class 100 000), cleanliness requirements permit clothing of lesser coverage. The minimum requirements for clothing worn in various cleanroom classes are shown in Table 1.

4.2.4 The frequency of changing into fresh clothing before entering the cleanroom shall be determined in accordance with the product and process cleanliness requirements. Table 2 provides the minimum requirements for the frequency of garment changes.

4.2.5 The necessary cleaning, processing, and packaging of clothing shall be defined so that the clothing and packaging are appropriate for the product or process. Personnel must wear hair and beard covers and garments that have acceptable ESD behavior, stability, and low levels of particulate generation, acceptable permeability, and low NVR when tested per Test Method D737, Specification E1549, IEST-RP-CC003.2, and JIS.

4.2.6 Reusable cleanroom clothing shall be cleaned at regular intervals, but not less than weekly, to remove contamination.

4.2.7 Cleanroom clothing shall be stored in closed cabinets or closets, or on racks in the changing room to minimize contamination. An area large enough to contain the spare clothing must be set aside for storage purposes. Lockers can be obtained for this purpose. These lockers should be placed on the cleaning schedule to ensure that they do not contribute to contamination. Several methods are effective for storing clothing. These may include the following:

4.2.7.1 Clothing racks inside lockers or closets,

4.2.7.2 Fixed and portable racks utilizing hangers,

4.2.7.3 Hooks mounted to walls or frames in the changing area or room; these can be in a locker or in the room, and

4.2.7.4 Bins or storage slots. Clothing elements may require physical separation when stored together in bins or slots. Launderable or disposable bags can be used to help avoid cross-contamination.

4.2.8 Cleanroom clothing (clean packaged or dirty) shall not be removed beyond the confines of the storage area and cleanroom or changing room except for laundering purposes. Cleanroom garments shall not be worn in uncontrolled areas or outside of the cleanroom and changing room.

4.2.9 Cleanroom clothing shall be put on and removed so that the spread of contamination is avoided or minimized. Dress from the top down, and do not drag cleanroom garments on the floor. Cleanroom personnel will change into cleanroom clothing in the changing area or airlock, before proceeding into a cleanroom. Minimize contamination of the cleanroom clothing while putting it on and removing it to ensure that contamination is not spread from the changing area. Several methods are acceptable depending on the design of the changing area and the cleanliness levels of the cleanroom. A preferred procedure is outlined below, but many variations exist.

4.2.9.1 Remove contamination from shoes by use of a shoe cleaner, cleanroom mat, or cleanroom flooring.

4.2.9.2 Remove unnecessary street clothing and store or hang it in provided lockers or on hangers.

4.2.9.3 Remove jewelry and so forth, if required (always in class 8 or cleaner).

4.2.9.4 Remove cosmetics and put on moisturizer, if required (always in class 8 or cleaner).

4.2.9.5 Put on hair cover.

4.2.9.6 Wash hands and put on suitable moisturizer, if applicable.

4.2.9.7 Select cleanroom clothing.

4.2.9.8 If required, put on gloves for handling cleanroom clothing.

4.2.9.9 Put on beard covering, if the operator has a noticeable beard or facial hair.

4.2.9.10 Put on coverall or gown.

4.2.9.11 Put on shoe coverings or special cleanroom shoes.

4.2.9.12 Gloves used for putting on cleanroom clothing can now be removed. Process gloves then can be put on.

4.2.9.13 Enter the cleanroom.

4.2.10 Cleanroom clothing will become contaminated during use. If clothing is to be reused, it shall be removed and stored in an anteroom or in a closet or closed cabinet to ensure that contamination is minimized. Package clothing to be laundered to minimize any additional contamination during transport to the cleaning facility. Laundering and operations must be carried out in a cleanroom with equal or better standards of cleanliness as where the clothing is worn. An effective cleaning process should be used. Cleaning procedures should be followed by sample testing at the laundry, for the appropriate type and level of contamination.

4.2.11 Cleanroom clothing shall be checked at regular intervals to ensure that it retains acceptable contamination control characteristics. See IEST-RP-CC027.1 and ISO 9237.

4.2.12 The design and construction of cleanroom clothing should minimize contamination in the cleanroom. Methods used include: all raw edges of the fabric should be interlocked, heat seared, or laser cut to prevent fraying. Seams are double needle stitched, bound, or taped to provide a good barrier and not produce fibers. Threads should be continuous monofilament. Zippers, clips and fasteners, and shoe soles should not shed, chip, or corrode, and should be able to tolerate multiple laundering.

4.2.13 The fabric used acts as a filter to prevent personnel-generated contamination from being dispersed into the cleanroom. Fabric effectiveness is related to the tightness of the fabric's weave or the effectiveness of the membrane barrier. The effectiveness of the weave can be tested by measuring the pore size and the efficiency of fabrics in removing particles, and by measuring air permeability. As air permeability decreases, pressure within the garment increases as personnel

move about. This can result in pumping of unfiltered air out through the closures of the cleanroom clothing.

4.2.14 The design of clothing should consider the type of cleanroom. There are two broad categories of clothing used in cleanrooms, that is, disposable (or limited use) and reusable. In general, disposable or limited use clothing usually is made from a non-woven materials and is used either once or a few times and then discarded. Reusable clothing is processed and laundered at regular intervals and is usually made from tightly woven synthetic fabrics. More critical applications may require the use of membrane barrier technology. Natural fabrics made from fibers such as cotton or blends with high percentages of cotton or wool would not normally be used in cleanrooms, as they easily break up and disperse contamination.

4.2.14.1 Cleanroom clothing should incorporate a large selection of sizes, to provide comfort and fit. To minimize the retention of contamination, no pockets, pleats, darts, or action backs should be used. Elasticized or knitted cuffs should not trap or shed contaminants and should not build up electrostatic charges. Pockets are either not provided or are limited in number. Garment closures should provide a tight yet comfortable closure. Other design parameters that should be considered are:

(1) Zipper material (for example, covered plastic zip-fasteners), type, and location,

(2) Placement and effectiveness of snap adjusters and stays,

(3) Sleeve construction (set-in or raglan),

(4) Collar style,

(5) Ability to don over various shoe or boot styles,

(6) Hood style (open or closed face, snap or pull-over),

(7) Passive or active adjustment and fit of hoods, and

(8) Type and placement of straps on boots.

4.2.15 The comfort of people working in the cleanroom must be considered whenever possible when choosing cleanroom clothing materials. Air and moisture permeability specifications of the fabrics under consideration can help in this determination. A simple but effective approach is to obtain a selection of suitable clothing of different fabrics and try them in the cleanroom. Feedback, solicited from personnel who will be expected to wear the clothing, may provide valuable information that will aid in the selection process. See Test Method D737 and ISO 9237 (1995).

4.2.16 Consideration shall be given to special (for example, chemical, physical, or ESD) properties of the clothing that may be necessary for specific applications. In some types of cleanrooms, for example, microelectronics, or rooms with flammable ordnance or explosive chemicals, the electrostatic charges that build up on the surface of clothing will be harmful to the components being manufactured or hazardous to operators. Fabrics are available that have static-dissipative threads, woven into the fabric, to conduct away the electrostatic charge. The effectiveness of a fabric to dissipate an electrostatic charge can be indirectly measured by checking the fabric's surface resistivity. In a more effective test, a static charge of known voltage level is applied to the fabric. Static dissipative performance can then be determined by the time it takes for the voltage to decrease by a given percentage of the original voltage. Static dissipation effectiveness can degrade over time, or after repeated washings, so it is important to verify adequacy of static dissipation of garments periodically.

4.2.17 Cleanroom gloves are required for anyone who handles any items in a cleanroom. They cover that part of the human body that is often closest to the product and critical surfaces. Properties of cleanroom gloves that should be considered depending upon the type of cleanroom in which they will be used are as follows: surface contamination, outgassing or offgassing, sterility, tactility, strength, comfort, fit as well as the method of packaging. Various tests can be performed to help in selecting the proper gloves. See Test Methods E595, E1559, and E1731, NASA STD-6001, Test #7, and IEST-RP-CC005.

4.2.17.1 Gloves can be constructed of latex, vinyl, or nitrile rubber and must be powder-free. Some glove materials cause rashes or discomfort for susceptible personnel and must be avoided. Undergloves, made from non-linting materials, may also be needed by some employees to provide comfort or isolation from glove surfaces that can cause, or aggravate, dermatitis.

4.3 *Personnel:*

4.3.1 Personal and other items not intended for cleanroom use shall not be allowed inside the cleanroom, unless approved. Jewelry normally is not allowed, but watches and rings usually are permitted. In general, items taken into the cleanroom should be limited to those needed to perform operations and functions and not be mainly decorative.

4.3.2 Personnel shall be instructed in hygiene-related issues that will prepare them for properly working in the cleanroom environment. Cleanroom personnel are expected to have good personal hygiene. They should minimize dandruff and use specially formulated skin lotion to replace skin oils after washing and showering, if necessary. Personnel should report problems associated with unusual skin shedding, coughing, allergic conditions which cause sneezing, itching or scratching or other problems such as flaking skin, dermatitis, sunburn or bad dandruff, a cold, flu or chronic coughing. Depending on the seriousness of the condition with respect to the process or product being produced, it may be necessary to relocate such personnel to work outside the cleanroom. Personnel who are coughing or sneezing should be excluded from cleanrooms until their health problems are resolved.

4.3.3 Smoking and tobacco products are prohibited. Jewelry, cosmetics, hair spray, and similar materials that can cause contamination problems shall be prohibited from cleanrooms but may be allowed in controlled areas. Cosmetics, talcum powder, hair sprays, nail polish, or similar materials are undesirable in a cleanroom. Cosmetics can generate particles or contaminate cleanroom clothing and are prohibited in cleanrooms, but may be worn in controlled areas.

4.3.4 Personnel shall be protected against hazards such as microbes, radioactivity, and chemicals. This can be done by the provision of containment cabinets, cupboards, or isolators. See ISO 14644-4 and ISO 14644-7. Suitable protective clothing such as eye splash shields, gloves, and aprons may be required.

4.3.5 Personnel shall receive safety training for all known health and safety risks associated with their work. Normal operation of cleanrooms often includes the use of hazardous or

toxic materials. Personnel should be protected from exposure to those agents. MSDS information shall be provided in each cleanroom and controlled area.

4.3.6 Cleanroom personnel shall be trained to conduct themselves in a manner that minimizes the possibility of contamination being generated or stirred up and transferred or deposited on or into the product. Personnel who are motivated can have a positive influence on the effectiveness of the cleanroom. Helpful coaching of one to another can improve conformance to personnel procedures. Also, empowering all personnel to report observed deficiencies in the cleanroom to authorized personnel may help identify unnoticed contamination sources for correction or repair.

4.3.6.1 Even though properly trained, personnel may fall into poor cleanroom habits. The actions of personnel should therefore be monitored to ensure that they adhere to correct cleanroom disciplines. Monitoring programs can be formal or informal depending on the level of empowerment given to each person on the cleanroom staff and the sensitivity of the products. Internal auditors can monitor the actions of those in the cleanroom based upon the written procedures. Reports would be issued to management on a regular basis detailing deficiencies and can be used for determining corrective actions that can be initiated. An effective program should positively influence all personnel to follow proper cleanroom procedures.

4.3.7 Cleanroom personnel should conduct themselves in a cleanroom in such a way as to minimize the possibility of contamination getting to the product. Minimum disciplines that should be considered are given below.

4.3.7.1 Doors should not be opened and closed quickly, not left open. When entering an airlock, the first door should be allowed to close before next one is opened. Personnel should be positioned correctly with respect to the product so that contamination dispersed from them neither falls onto the product nor is blown towards the product. In general, the correct air flow sequence should be: air supply to exposed product to personnel and then onwards to the general cleanroom area and hence to the air return or exhaust. Devise methods for moving or manipulating the product that minimize opportunities for product contamination. 'No-touch' techniques should be used where appropriate. Personnel should not support material against their body, or contamination may be transferred. Personnel should not talk when working close to the product. Do not allow anything to trail over the product. Facial or other personal wiping must be done outside the cleanroom. It may be permissible to do so in the changing area. Glove and garment surfaces can easily become contaminated. Personnel should not touch surfaces and transfer contamination to critical areas. A cleanroom wiper should be used as specified, and then discarded. All personnel movements should be deliberate and methodical. Overexuberant behavior should not be allowed. Contamination generation is proportional to personnel activity. The room should be kept neat and tidy. Products stored or left standing in a cleanroom should be protected from contamination and kept in an identifiable closed cabinet, container or unidirectional cabinet. Waste material should be collected frequently into easily identified containers and removed.

4.3.8 Emergency situations may arise and emergency response personnel, trained in all aspects of potential emergencies, can minimize the effects of mishaps that may occur. Procedures for the most common types of incidents should be documented and practiced. All employees should be trained for an orderly evacuation. If an evacuation is necessary, provisions should be made for the orderly return to the cleanroom once the situation is cleared. An emergency procedure for supplying fresh cleanroom clothing should be implemented. Retesting or recertification should be considered as necessary.

4.3.9 The number of personnel in a cleanroom should be limited. Normally only those personnel actively working or directly supporting the operations should be in the cleanroom. If there is a cleaner area within a cleanroom, such as a laminar flow bench operating at class 5 in a class 8 facility, personnel at the clean bench should be minimized.

4.3.10 Exit procedures for portable objects should be considered. Many items used by personnel are routinely removed when they leave the cleanroom. These items may include notebooks, pens, hand-tools, and other types of small portable equipment. These items should be protected from becoming contaminated through the use of approved plastic bags or other suitable means if they will be regularly reintroduced into the cleanroom. In addition, items may require cleaning before being reintroduced into the cleanroom. This will facilitate reentry to the cleanroom at a future time. The method for the removal of cleanroom clothing on leaving the cleanroom will depend on whether fresh clothing is used on each entry or whether they are to be reused. Cleanroom clothing that will be reused should be stored on hangers or inside cabinets in the anteroom and should not be worn in uncontrolled areas or outside of the anteroom or cleanroom. If fresh clothing is worn, discard the used clothing in a designated bin.

4.4 *Stationary Equipment:*

4.4.1 All equipment that is large enough to be relatively immovable is called stationary. Usually, extensive efforts are required to remove or relocate this equipment once installation is completed.

4.4.2 This equipment and its associated moving and rigging equipment shall be thoroughly cleaned before being transported into the cleanroom. When possible equipment to be used in the cleanroom should be manufactured under clean conditions and packaged for the requirements of the intended cleanroom.

4.4.3 All equipment should be checked for damage in transport and suspected or damaged goods should be isolated or protected outside the cleanroom pending appropriate actions. Shipping crates and packaging should be removed in the uncontrolled environment adjacent to the cleanroom. All cardboard and shedding materials should be removed outside of the controlled environment. When not pre-packaged, all equipment surfaces should be pre-cleaned prior to its entry into a cleanroom area. This is best done within the airlock or entry chamber.

4.4.4 Bringing equipment into the cleanroom should not cause contamination of the environment. Equipment entering a cleanroom that is operating "as built" or "at rest" should be

properly unpackaged and cleaned before entry. Failure to do so will require extensive clean-up afterwards. Special considerations must be made before bringing equipment into an "operational" cleanroom. Failure to do so will expose not only the cleanroom to contamination risks but may affect products in process. This will necessitate additional cleaning and may require the cleanroom to be requalified under ISO 14644-2.

4.4.5 If the equipment is so large that special installation procedures are required, then the area should be isolated from surrounding portions of the cleanroom or other controlled environments with temporary walls. Unpack the equipment in steps to control contamination entering the cleanroom. The airlock, or a temporary room built for this purpose and attached to the cleanroom, can be used for the removal of exterior film packaging materials and surface cleaning before cleanroom entry. Preparation should be performed in the order listed below:

4.4.5.1 The outer protective covering should be vacuumed, beginning at the top surface and then proceeding to the sides.

4.4.5.2 The protective cover should be wiped, using the appropriate cleaning agent.

4.4.5.3 The outer layer of packaging film should be slit at the top and peeled from the top to the bottom.

4.4.5.4 The bottom edge of the packaging film should then be lifted and joined to the sides of the packaging film.

4.4.5.5 These unpacking procedures, except for vacuuming, should be repeated for each additional layer.

4.4.5.6 All exterior surfaces of the equipment should be thoroughly cleaned.

4.4.5.7 All personnel should be properly gowned prior to entering the airlock.

4.4.5.8 All moving and handling equipment should be cleaned as described above.

4.4.5.9 The airlock should be cleaned before opening the doors to the cleanroom for transferring the equipment inside.

4.4.6 Large equipment should be dismantled (if possible) to a size that will enable safe entry via the anteroom, minimizing risk to personnel and the existing cleanroom. Physical damage and contamination can result when these large units come into contact with fixed surfaces and other tools. Any special equipment used for lifting, hauling, or positioning large equipment must be thoroughly cleaned before being allowed into the cleanroom. Often this equipment may not be designed or maintained for cleanroom use and should be thoroughly inspected for chipping and flaking surfaces or materials unsuitable for transfer into the cleanroom. These tools can often be made acceptable by means such as wrapping and sealing the tool with cleanroom- compatible plastic films and tape. Soft rubber wheels can be coated with cleanroom tape to avoid leaving trails of rubber or plastic particles on the flooring.

4.4.7 An effective way to install equipment is to isolate it from the rest of the cleanroom environment by surrounding it with a temporary isolation wall or partition. Enough room should be left around equipment to complete the installation and operation unhindered.

4.4.7.1 Access to this isolation area should be from a service aisle or other non-critical area, if possible. If this is not possible, take measures to minimize any effects of construction-generated contamination. Maintain airflow to the isolation area at a neutral or negative pressure to reduce the possibility of contamination being forced outside the work area.

4.4.7.2 A completely sealed isolation area should not be pressurized from within or the surrounding cleanroom can be contaminated. Clean-air supplies inside the isolated area must be deactivated. When entry to the isolated area is only accessible through an adjacent cleanroom, sticky mats should be installed to remove shoe-borne contamination. Once inside, disposable boots or shoe covers and coveralls may be required to avoid contaminating cleanroom clothing. These disposables must be taken off before leaving the isolated area.

4.4.7.3 Monitor the areas surrounding the isolated area to ensure that any contamination that may leak into the adjacent cleanroom areas is detected and removed.

4.4.7.4 Attach facility services such as electricity, water, gas, vacuum, compressed air, and waste piping. Care should be taken to ensure that fumes and debris generated are controlled and contained as completely as possible to avoid release to the surrounding cleanroom and to facilitate effective cleaning before removal of the isolation barriers.

4.4.7.5 Use accepted cleaning procedures to decontaminate the entire isolation area. All surfaces should be vacuumed, wiped, and mopped. This includes all walls, both fixed and portable, equipment, and floors, taking special care to clean areas behind equipment panels and under equipment.

4.4.7.6 Some internal preparation and preliminary performance testing of the equipment is now possible, but final acceptance may require full cleanroom conditions before final testing can be completed.

4.4.7.7 The isolation walls can now carefully be removed and filtered air sources returned to service if deactivated. This should be scheduled to minimize interruptions in the regular operation of the cleanroom. Particle measuring or testing also may be required.

4.4.7.8 Clean equipment interiors and critical processing chambers for use under normal cleanroom conditions. All surfaces involved in handling or coming into contact with the product should be wiped to achieve a desired cleanliness level. The cleaning procedure should be done by working from the top to the bottom of the equipment. If particles are disturbed larger particles will fall to the bottom of the equipment or to the floor.

4.4.7.9 Clean the outer surfaces of the equipment, working from the top to the bottom surfaces.

4.4.7.10 Surface particle checks should be performed of areas critical to product or process requirements. See Practice E1216.

4.4.8 Management must ensure that cleanroom support services consistently function as required. This includes clean and conditioned air systems, compressed air and gasses, water and other utilities, and other aspects required for standard cleanroom operation. Failure of any mechanical support system can seriously affect the cleanliness and operation of the cleanroom. Equipment maintenance, repairs, and calibration procedures shall be performed in such a way as to control and minimize contamination of the cleanroom.

4.4.9 Procedures relating to maintenance work and repairs shall be specified to control contamination. Unplanned downtime can adversely affect productivity and introduce contamination to the cleanroom. Perform ongoing equipment checks and do preventive maintenance to minimize contamination that may be caused by unanticipated equipment failures. Repair and maintenance procedures should minimize and contain contamination. Tests may be necessary to ensure that reactivated equipment is clean and in specification before being accepted for reuse.

4.4.10 Preventive maintenance schedules shall be established and timed to renew and replace components before the components become contamination sources. All personnel repairing and maintaining equipment in cleanrooms should follow the appropriate practices defined for the area, including wearing appropriate garments, cleaning the area and equipment after repairs are completed and verifying that the equipment and area are cleaned properly. Maintenance personnel should be trained in contamination control procedures.

4.4.11 Removing stationary equipment from the cleanroom often stirs up or loosens contamination from internal or other inaccessible surfaces that have not been routinely cleaned. This is especially true when the equipment must be disassembled before removal. Steps must be taken to isolate, clean, and contain such equipment before and during removal to avoid contaminating the surrounding cleanroom.

4.5 *Materials and Mobile Equipment:*

4.5.1 All materials, portable, and mobile equipment shall be appropriate for the level of cleanroom cleanliness and shall not compromise the product and process. Materials should be selected to protect a cleanroom from contamination. Only materials and portable equipment that are compatible with the cleanroom classification and use should be brought into the cleanroom. Outer contamination-generating packaging, such as wood, cardboard, paper, and other materials should be removed before entry to any part of the controlled or cleanroom environments. Inner plastic wrappers should not be removed at this time. Any interior packaging should be wiped, with appropriately moistened cleanroom wipers, to remove any gross contamination from the outer packaging before being carried into the controlled environment or specific area used for removing cleanroom packaging. Surfaces and moving parts should shed or generate as little contamination as possible. They should have unbroken, impervious, and clean surfaces. They should minimize generation of contamination by shedding and cutting. They should be supplied in suitable cleanroom packaging. They should be evaluated for compatibility with the clean room environment. They should be free from chemicals (for example, acid, alkali, organic). They must have acceptable anti-static properties and be low out-gassing when tested per Test Methods E595 or E1559.

4.5.2 Paper and paper products will contaminate the cleanroom. All documents should be printed on lint-free, cleanroom-compatible media or thermally laminated between plastic films. Information on the selection of such substrates is given elsewhere. Use of such media in the form of labels, logsheets, equipment repair manuals, reports, and notebooks should be controlled and kept to a minimum. Label adhesives should leave minimal residues when removed.

4.5.3 Writing instruments can become sources of contamination to the cleanroom, products, or processes. Pencils, erasers, and felt tipped pens should be avoided. Pens should be ballpoint style with inks that are permanent.

4.5.4 Wipers are used to remove surface contamination. Wiper characteristics vary, so products should be evaluated for specific applications in cleanrooms. See Test Method E1560 and IEST RP-CC-004. Some wipers are absorbent but shed particles; others don't shed but do not absorb. Consider the following characteristics when selecting wipers for cleanroom use:

4.5.4.1 Wiper material,

4.5.4.2 Solution or solvent compatibility,

4.5.4.3 Absorption rate of liquids,

4.5.4.4 Particle generation (both wet and dry),

4.5.4.5 Extractable molecular contamination or NVR, and

4.5.4.6 Packaging.

4.5.5 Materials that may be used to protect or package finished products made in the cleanroom, should be clean and compatible with the cleanroom. Selection should be based on particle generation, electrostatics, outgassing, and other concerns. Tapes that are used within the cleanroom should have adhesives that leave minimal residues when removed.

4.5.6 Items that can easily be transported into and out of the cleanroom can compromise the cleanliness of the cleanroom if they are not properly selected and handled. This includes consumable and disposable supplies, production and cleaning materials as well as hand tools and portable equipment.

4.5.6.1 Procedures shall be established to ensure that materials and mobile equipment entering the cleanroom are not contaminated. All bulk materials, equipment, and supplies should either be cleaned with suitable solvents before introduction into the cleanroom, or they should be pre-packaged and sealed. Any non-wrapped portable equipment requires careful cleaning and is discussed below.

4.5.6.2 A designated area, such as an airlock, should be used for final wiping procedures. The changing area should be avoided for this purpose to avoid contaminating cleanroom clothing. A working surface and wiping materials should be readily available in this location for the task of cleaning all outer surfaces of the object to be transported into the cleanroom. Outer wrappers on double-wrapped packaging can now be removed and placed in an appropriate rubbish receptacle. Final packaging should only be removed prior to use of the material or object.

4.5.6.3 Any portable equipment must be thoroughly cleaned before being allowed back into the cleanroom. Cleaning efforts should not overlook the surfaces of wheels that can transfer excess contamination directly onto the cleanroom floors. Sticky mats or flooring will help prevent this from occurring. Cleanroom personnel, correctly dressed in cleanroom clothing, may then carry such items into the cleanroom via the airlock. A clean cart (trolley) may be used to transport many items from the airlock into the cleanroom.

4.5.7 Procedures shall be established to control the quantities of materials stored in the cleanroom. Process materials

such as adhesives and coating should be limited to amounts reasonably expected to be used in a week or less. Consideration shall be given to shelf life limitations, when applicable. Materials that normally are refrigerated or frozen should be kept in freezers in the anteroom, not the cleanroom, if possible.

4.5.8 Materials stored in the cleanroom shall be subject to defined procedures and, where necessary, shall be held in protective storage or isolation. The risk of contamination, arising from the storage and subsequent use of materials, and portable or mobile equipment in the cleanroom, shall be considered.

4.5.9 Preliminary testing and auditing of materials and products used in cleanrooms should be performed as agreed upon between users and suppliers. Testing procedures performed by the supplier may be deemed sufficient for entry and use in the cleanroom. Additional testing may be required for some materials before being used in the cleanroom. Incoming inspection criteria and sampling methods should be fully documented. A secure storage location may be necessary to avoid unauthorized use while materials are waiting for acceptance. Test equipment and methods should be fully documented. Acceptance limits and authorized personnel should be identified for final approval or disposition of non-conforming materials. A procedure for communicating problems to the supplier should be instituted. The supplier should be expected to react with plans to improve its quality and avoid further shipment of non-conforming materials. The supplier should notify the user prior to making critical changes to approved materials or supplies used in the cleanroom.

4.5.10 All used and waste materials shall be collected and removed regularly. See Practice E2042. Waste materials shall be removed frequently and in such a manner that does not compromise the cleanliness of the product or process. Normally waste containers are emptied daily. Procedures for handling and removing hazardous materials shall conform to standards set by appropriate regulatory agencies.

4.5.11 Contamination generated by maintenance and moving of stationary equipment must be minimized as follows:

4.5.11.1 Portable equipment should be removed from the area whenever possible before making repairs to reduce the possibility of generating contamination.

4.5.11.2 Isolate equipment from the surrounding cleanroom operations before proceeding with major repairs or maintenance. Alternatively, take steps to ensure that all products under manufacture have been removed to a suitable location.

4.5.11.3 Adjacent cleanroom areas near the equipment being repaired should be monitored to insure that contamination is being effectively controlled.

4.5.11.4 Maintenance personnel should not come into contact with personnel doing manufacturing or processing.

4.5.11.5 Determine conditions before technicians lie or crawl under equipment to make repairs. Conditions caused by chemicals, acids, or hazards should be effectively neutralized before proceeding.

4.5.11.6 Protect cleanroom garments from contacting contamination from lubricating oils or processing chemicals. Avoid rips and tears from sharp edges. Either turn in for repair or discard if garments are contaminated or damaged.

4.5.11.7 Thoroughly clean all tools, boxes, and carts used for maintenance or repair work before they are exposed to the cleanroom environment. No rusted or corroded tools should be allowed.

4.5.11.8 Technicians should not set tools and spare, damaged parts, or cleaning materials on adjacent work surfaces used for product and process materials.

4.5.11.9 Clean as repairs proceed so that contamination does not build up.

4.5.11.10 Change gloves regularly so that they do not deteriorate and permit bare skin to touch clean surfaces.

4.5.11.11 If gloves other than cleanroom gloves (for example, acid, heat, or cut-resistant) are required, they should be either cleanroom compatible or covered with a pair of cleanroom gloves.

4.5.11.12 Use HEPA vacuums or external vacuum cleaners during all drilling or sawing operations. Maintenance and construction operations often require drilling or sawing. Special shrouds can be used to contain the tool and area being drilled or sawn.

4.6 *Cleanroom Operations:*

4.6.1 Class 8 or cleaner (class 100 000) facilities shall be operated at positive pressure of 0.25 mbars or greater, so that normal airflow is from the cleanroom to the surrounding uncontrolled areas. Positive pressure of 0.25 mbars or greater should be maintained. Temperature shall be maintained between 19 and 24°C ± 1°C (65 and 75°F) and 25 to 60 % RH, unless otherwise required by specification. Temperature and humidity should be measured and recorded whenever the facility is in use, or whenever products are stored within.

4.6.2 Particle counts shall be taken when the facility is operational and in use with operators at normal tasks. Sampling for particle counts should be done at least 0.50 m (20 in.) from the filter face.

4.6.3 Personnel shall observe all requirements for gowning, proper clothing and hygiene, and apparel as noted in 4.2.

4.6.4 Personnel shall be properly trained and possess a valid current certification to work in the specific class of facility, as noted in 4.3.

4.6.5 Any non-standard conditions or risks to products shall be reported promptly to management, and corrective actions taken at once so that the cleanliness and integrity of the products are preserved.

4.6.6 The number of personnel in a cleanroom should be minimized. Only those actively performing needed functions should be in the facility.

4.7 *Cleanroom Cleaning:*

4.7.1 Cleaning methods and procedures shall be specified and routinely followed to maintain cleanroom surfaces at acceptable cleanliness levels. Cleanrooms are designed to be as free from contamination as possible. Facility and maintenance operations, manufacturing processes, the presence and activity of personnel, and other factors, all may cause contamination to be generated and dispersed on surfaces in the cleanroom. Therefore, all surfaces should be cleaned adequately to prevent this from compromising the manufacturing process. Procedures should be specified to ensure that thorough and complete

cleaning operations are performed in a manner that is consistent with recommended cleanroom practices for the facility. See Practice E2042 and IEST RP-CC-0016. Cleaning should be avoided during manufacturing operations. If this is not possible, special cleaning procedures should be devised to minimize risks to products. These precautions include covering or segregating in-process hardware and temporary clean enclosures.

4.7.2 Personnel responsible for the cleaning operation shall be designated and receive specific training for accomplishing the task. See Practice E2042 and IEST RP-CC-0016. Cleaning personnel should be designated and trained for the cleaning program. Operators, with proper training, may be assigned to clean the work surfaces and areas that they use.

4.7.3 Evidence of effective maintenance requires a documented record involving all such activities. Problem diagnoses and parts replaced, as well as dates, times and personnel performing the maintenance should be documented. Cleaning schedules are defined at frequencies that ensure that specified cleanliness levels are maintained. Cleaning frequency and methods vary with the cleanroom cleanliness class, per Practice E2042. Regular removal of trash and waste is essential and also should be documented.

4.7.4 Appropriate contamination checks shall be carried out on a routine basis to ensure that the cleanroom is being maintained at specified levels. Particle counts for air shall be performed per Test Method F25 or Practice F50. Particle counts must be taken continuously in class 7 or cleaner facilities (Class 10 000 per FED-STD-209E) and weekly in class 8 facilities (Class 100 000 per FED-STD-209E). Particle counts must be taken at least weekly in class 8.5 facilities (Class 300 000 per FED-STD-209E). Surface sampling for particulate contamination shall be performed regularly per Practice E1216. NVR deposition on surfaces shall be determined per Practice E1234 and Test Method E1235. Practice F318 also is used for air sampling in cleanrooms where aerospace fluids are handled.

4.7.5 An assessment shall be made to identify any cleaning procedures that will place products or processes at risk during the performance of such cleaning tasks so that preparations are made to remove or cover work-in-process before cleaning begins.

4.7.6 Ceilings, diffusers, lamp fixtures, and other fixtures upstream of work areas should not be cleaned in the operational state but should wait for “at rest” conditions. Cleaning should proceed with vacuuming followed by wiping techniques. Some diffusers may require removal for washing or replacement. Lamp fixtures should be thoroughly wiped whenever bulbs are changed.

4.7.7 Cleanroom mats and sticky flooring must be cleaned or maintained on a regular basis during the normal workday. They should be serviced according to the manufacturer’s instructions, as frequently as needed. Mats with renewable surfaces should be cleaned frequently. After wet mopping, a rubber squeegee is used to pull contamination and water to the edge to be mopped dry. A wet vacuum with a squeegee head can also be used for this purpose. Mats with removable, sticky surfaces are cleaned by slowly peeling each of the four corners and rolling the film towards the middle of the mat until the layer is removed.

4.7.8 Cleaning solutions are used to aid in the removal of contamination from surfaces in the cleanroom. Some contaminants are dissolved or particles are floated off by the cleaning solution and others are pushed off through use of a wiper. After cleaning, certain finishes are also used to protect or preserve characteristics of surfaces in the cleanroom. These solutions and finishes should be as clean as required to meet the cleanliness requirements of the cleanroom. The filtration of prepackaged solutions should be considered. Types of cleaning solutions and finishes follow:

4.7.8.1 Filtered purified or deionized water has many desirable properties but pure water can corrode certain types of surfaces and may be ineffective in cleaning without the addition of a surfactant or disinfectant.

4.7.8.2 Surfactants and detergents are the most reasonably priced, nontoxic, nonflammable, and effective cleaning agents. However, non-ionic surfactants are generally preferred for cleaning cleanrooms, as this group is the least reactive and does not contain metallic ions.

4.7.8.3 Organic solvents can also be used for removing contamination on hard surfaces. Organic films are best removed with organic solvents or detergents (detergents tend to leave behind a film).

4.7.8.4 Synthetic sealers that are highly resistant to wear can be used on certain cleanroom floors. Antistatic floors require special care and sealers should not compromise the surface or electrical characteristics. Any sealing operations should only be done when the cleanroom manufacturing is stopped or during general maintenance periods. Specific cleanroom applications may require that certain surface treatments or finishes are applied to cleanroom surfaces, to provide characteristics that normally would not exist. These treatments may protect the products being produced in the cleanroom, but must be carefully considered. The use of surface treatments and finishes after cleaning should be avoided if possible. These treatments deteriorate with time and will compromise the cleanliness of the cleanroom. These treatments also can risk process or product contamination if not used or maintained properly. Surfaces that receive these treatments should be inspected regularly to ensure they do not compromise the cleanroom.

4.7.9 Special cleaning procedures and techniques shall be defined for instances when accidents or system failures occur that create contamination which places the cleanroom, products, processes, or personnel at risk. Emergency shutdown procedures and start-up procedures after unplanned shutdowns should be documented.

4.7.10 Records and procedures documenting the operation of the systems that provide and maintain the cleanroom should be readily available. The mechanical and electrical systems within the installation should have a clear set of operating and maintenance instructions. These instructions should describe procedures used to check and inspect all critical components prior to start-up. See ISO 14644-4.

4.7.11 Portable vacuum cleaners are constructed of stainless steel or plastic whose exhaust must flow through a HEPA or

ULPA filter before being allowed to escape to the surrounding environment. Vacuum cleaners capable of handling damp and liquid materials are also available for the cleanroom. Built-in vacuum cleaner systems employ a large, centralized vacuum pump, usually in a service area outside the cleanroom environment, that is connected by a system of plastic piping to wall outlets in each area of the cleanroom. Hoses, handles, and tools should be matched to the application and constructed of cleanroom compatible materials. Arrangements should be made for routine inspection and maintenance of all equipment used in the vacuum cleaning process. The HEPA or ULPA filters of the vacuum cleaning equipment should be tested or replaced, or both, on a regular basis to ensure that they do not become a source of airborne contamination in the cleanroom. A portable HEPA or ULPA vacuum cleaner shall have the filter after the motor, not before.

4.7.12 Cleaned clothing should be packaged in clean, non-shedding bags to avoid contamination during handling, storage, and distribution. It is recommended that storage should be in a controlled environment that is adjacent to or in the changing area. This allows better control of the inventory and reduces the risk of clothing being removed from the cleanroom environment and becoming soiled.

4.7.13 Used materials, byproducts, and other waste generated inside the cleanroom should be removed as soon as possible. A means for the collection, containment, and storage of wastes should be provided to protect the cleanroom from these contamination sources while waiting for removal. These criteria should be considered when selecting receptacles for collection of these materials:

4.7.13.1 Nature of the materials to be discarded or recycled,

4.7.13.2 Safety requirements,

4.7.13.3 Environmental hazards,

4.7.13.4 How they will be lined,

4.7.13.5 Floor space available,

4.7.13.6 How often they will be emptied (hence the size needed),

4.7.13.7 Material of construction, and

4.7.13.8 Cleanroom compatibility.

4.7.14 Clean containers can be used for transporting or isolating sensitive materials and products to and from the cleanroom, while waiting to be used or processed. Surface cleanliness and isolation characteristics should be consistent with the intended use of the enclosed materials. Entry procedures should be followed. Cleaning may be necessary to avoid contamination buildup during use. Special cleaning and verification of cleanliness may be required before reuse.

4.7.15 The use of computers for work in progress will eliminate the need for many sources of contamination, such as logbooks, log sheets, process documentation, writing implements, and others. Installation and use of computers and peripherals should be compatible with the classification of and intended location inside the cleanroom. Computers often employ internal cooling fans. Consideration should be given to how the exhaust air may affect the cleanroom and critical surfaces surrounding the computer. Methods may need to be devised to duct such exhaust air directly to air returns or through portable filtration units, depending on cleanliness requirements. Printers interfaced with such computers should be appropriately contained or isolated and exhausted in like manner. Printer maintenance should be performed carefully to avoid dispersal of residual contamination generated by the printing operation.

4.7.16 Hand tools, boxes, and maintenance equipment should be compatible with the cleanroom classification, products, stationary equipment, and processes with which they will come into contact. They should be kept clean and free from contamination of all kinds. Boxes or cases that contain tools and other repair or diagnostic equipment may be overlooked sources of contamination. They should be made of stainless steel or synthetic materials that resist or protect against the generation or transfer of contamination. Any use of molded inserts or dividers that can generate contamination such as open-cell foam, vinyl-covered wood, or pressboard (wood-chip board) should be avoided. Boxes should be thoroughly cleaned on a regular basis, with tools and instruments removed, to ensure cleanliness. Clean tools and instruments before replacing them inside the toolbox or case. Keep tool boxes and cases inside the cleanroom whenever possible. If removed from the environment, they should never be opened outside the cleanroom. Thorough external cleaning should be required before being allowed back inside. Carts and trolleys routinely used for transferring maintenance and other supplies into and out of the cleanroom must be thoroughly cleaned before re-entry.

4.7.17 Safety goods and equipment used in the cleanroom such as chemical gloves, aprons, face and arm shields, self-contained breathing apparatus, chemical absorbing pads, and fire extinguishers should be selected for their intended safety requirements as well as compatibility with the intended cleanroom.

4.7.18 Stored materials can become contaminated or ineffective if improperly stored while waiting to be used. Proper storage and controlled storage methods are critical to preserve their effectiveness. They should be stored in an environment that protects them from degradation and contamination. The accumulation of unused materials in the cleanroom presents a risk of contamination, if not properly stored.

4.7.18.1 Certain classes and types of waste materials must be stored in the cleanroom until specified limitations are reached. Often these limits are regulated by agencies or by recycling programs set up for the cleanroom. They also may require the use of specialized containers.

4.8 *Critical Surfaces*—Surfaces classified as critical are of concern during handling, manufacture, or production. They should be carefully protected when contamination can gain access to the product or process. Unidirectional airflow equipment, clean benches, or workstations usually help control the cleanliness of these surfaces. These surfaces are the most critical and should therefore be kept the cleanest.

4.8.1 All surfaces within the cleanroom that are not at the point of production or localized by unidirectional airflow are considered “general.” They should be cleaned on a regular basis to prevent transfer of contamination onto critical surfaces.

4.8.2 The classification of different kinds of cleanroom surfaces and the rate at which they become contaminated should be understood when setting up a cleaning program. Schedules should be specified to ensure that cleaning is performed frequently enough to maintain the required cleanliness of the cleanroom. The cleaning requirements should take account of the process and product within the cleanroom to determine which tasks need to be accomplished on a daily, weekly, or other periodic basis.

4.8.3 Preparing a cleaning program requires an evaluation of the processes and products found in the cleanroom and the types of surfaces and cleanliness requirements for those surfaces. First, classify all surfaces into critical, general, or other surfaces. Next, determine the best cleaning and surface treatment method for achieving the desired cleanliness level. Then determine the cleaning frequency required to maintain the desired cleanliness levels for each surface type. See Practice E2042 and IEST RP-CC-018.2 for details on cleaning operations and schedules. Some of the cleaning schedule will be executed by operators and some by cleaning staff. Daily cleaning is done at least once in a 24-h period. Many tasks may be allowed during working hours, such as trash removal, vacuuming, mopping floors, and wiping surfaces in changing areas, pass through, and common halls. Each room within the cleanroom may need a special written cleaning program depending on criticality of cleanliness to product or process concerns.

4.8.4 Air locks and changing areas should be cleaned at least daily. These areas can harbor high contamination levels, due to the high level of personnel activity. Therefore, cleaning is required more frequently than in manufacturing cleanrooms to control the cleanliness level and reduce the opportunity for contamination transfer. This will enhance the level of cleanliness within the general cleanroom areas. Thorough vacuum cleaning and mopping procedures described above should be implemented.

4.8.5 Surfaces not cleaned on a daily basis should be cleaned periodically. An appropriate frequency for these surfaces is given in Practice E2042 and IEST RP-CC-018.2. Special precautions may need to be taken to ensure product integrity during these procedures.

4.8.6 Cleaning during emergency situations requires procedures to ensure that work in progress, the process, and the cleanroom environment is not compromised in the case of a gross contamination event. Special tools and materials should be readily available to neutralize or control any hazardous situations that may arise. Events that may trigger special cleaning may include the following:

(1) Environmental incident (for example, utility failure, spill, major equipment failure, damaged or broken product, etc.),

(2) Failure of routine cleaning procedures resulting in contamination levels rising to unacceptable levels, and

(3) Monitoring has revealed that unacceptable contamination of the facility has occurred.

4.8.6.1 Work should be suspended in the area deemed at risk until acceptable levels of cleanliness are attained. This applies both to air class or cleanliness level and to surface contamination of the facility or of the products.

4.8.6.2 Products should be inspected to verify that they were not contaminated by the emergency conditions. If any products were damaged or contaminated, appropriate corrective actions must be taken and documented.

4.8.7 Cleanroom equipment, apparatus, or surfaces may require cleanliness testing after cleaning. Users are responsible for selecting appropriate cleanliness verification methods. See Practices E1216, E1234, E2088, and Test Method E1235 and IEST STD-CC-1246. An acceptable degree of cleanliness must be determined for each element or characteristic that will affect the products or processes in the cleanroom. The user must specify limits for tests performed. It is recommended that, when possible, limits be determined from actual measurements, using the test methods. Routine surface contamination checks should be defined and carried out to ensure that the specified levels are being maintained. Visual inspection techniques can be used to determine surface cleanliness. Visibly-clean surfaces demonstrate an absence of soiling that can be seen without magnification. It may be seen with or without the aid of high-intensity white light or ultraviolet light sources. Wiper-clean surfaces can be demonstrated by a clean wiper passed over a surface. This inspection aide detects visual contamination that may adhere to the wiper surface that may indicate that further cleaning is needed. Colored wipers are available from some suppliers and may be helpful detecting some forms of contamination. Other methods that may be considered include:

4.8.8 Upgrading the room into prescribed classification is done by removing all deposited and clinging dust from every surface (in order: ceilings, walls, equipment, floors) and verifying proper cleanliness. This is done by cleanroom cleaning which is performed by personnel specially instructed on regulations, routing and behavior. Method of cleaning includes wiping down surfaces with moistened wipers.

4.8.9 Verification of cleanroom classification is done by monitoring airborne and surface particles, air velocities, differential pressure, temperature, and humidity. Frequency of measurement depends upon the cleanroom class, but continuous monitoring and recording of temperature and humidity is normal and is recommended.

4.8.10 Daily and periodic cleaning is performed for the cleanroom, using a tailor-made cleaning program for the cleanroom, which accounts for the specific demands of the production process and the customer. Effectiveness of the cleaning is done by routine testing of critical operation parameters and by verifying cleanliness of products before they are removed from the cleanroom.

5. Keywords

5.1 aerospace cleanroom; cleanroom; cleanroom maintenance; cleanroom operation; cleanroom products; contamination; contamination control; controlled area; facility operation; personnel practices