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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~~ safety, health, and ~~health~~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]

[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.

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
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-CC020 Substrates and Forms for Documentation in Cleanrooms[5]~~
~~IEST-RP-CC022 Electrostatic Charge in Cleanrooms and Other Controlled Environments[5]~~
~~IEST-RP-CC026 Cleanroom Operations[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]
~~JACA Number 14C Guidance for Operation of Clean Rooms[7]~~
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[8]~~
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[8]~~
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)[8]~~
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)[10]~~

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~~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*—

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.
[5] 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.~~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 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.~~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), ~~36 rue de Stassart, B-1050, Brussels, Belgium, http://www.cenorm.be.~~Rue de la Science 23, B-1040, Brussels, Belgium.
[9] International Electrotechnical Commission, Case postale 131, 1211 Geneva 20, Switzerland.

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~~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:

(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.

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~~
Particle counts taken continuously	Required	Required	Required	Required	Optional	Weekly
~~Temperature and humidity recorded continuously~~	~~Required~~	~~Required~~	~~Required~~	~~Required~~	~~Opt.~~	~~Daily~~
Temperature and humidity recorded continuously	Required	Required	Required	Required	Optional	Daily
~~Wear gloves even when not handling products~~	~~Required~~	~~Required~~	~~Required~~	~~Required~~	~~Opt.~~	~~Opt.~~
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~~	~~Req.~~	~~Opt.~~
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

[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.

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.~~ 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,
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.

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.

4.1.7 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~~have minimal linting and ~~does~~do 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~~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,~~hardware, and the class of ~~cleanroom.In~~ cleanroom. In class 7 (FED-STD-209E class ~~10 000)~~ 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),~~ 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.~~JIS B9923, and JIS B9926.

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,