

Institute of Environmental Sciences and Technology

IENT-RP-CC003.5

Contamination Control Division

Recommended Practice 003.5

Garment System Considerations for Cleanrooms and Other Controlled Environments



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IN THIS EDITION: Garments used in cleanrooms are essential to the success of maintaining a clean environment to protect products and processes. Poor implementation of a garment program results in a degraded cleanroom and can potentially cause adulteration of product. This IEST Recommended Practice has long been recognized as the industry document that covers all aspects of managing a cleanroom garment program, from selection of the proper materials and garment construction to proper care and laundering. IEST-RP-CC003 Appendices are the go-to resource for testing garments for cleanliness, performance, and construction. This RP is referenced in cleanroom standards and documents worldwide including the ISO/Technical Committee 209 Cleanrooms and associated controlled environments' ISO 14644 cleanroom series.

This 2023 update includes:

- A newly developed section on establishing an Arc-Rated (Flame Retardant) garment program in response to recent regulatory attention to this subject.
- All Supplements are now incorporated into the main document to ensure that users of the RP have all garment program information in one centralized document.

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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) addresses the gowning of personnel as an important aspect of cleanroom contamination control. It provides non-mandatory guidance for the selection, specification, maintenance, and testing of apparel and accessories appropriate for use in non-aseptic and aseptic cleanrooms and other controlled environments.

Included with this RP are the following supplements as Appendixes:

- APPENDIX A. *Recommended Garment System Configurations Applicable to Various Air Cleanliness Environments*, which identifies garment system configurations for different classes of air cleanliness
- APPENDIX B. *Guide to Measuring Cleanroom Garments*, which provides recommended garment measurement specifications
- APPENDIX C. *Recommended Requirements for Garments That Protect in Short Duration Fire and Arc Flash Hazards*, which provides considerations for adapting flame resistant (FR) garments for use in cleanrooms or other controlled environments
- APPENDIX D. *Testing*, which provides test recommendations and methods that allow for meaningful evaluation of the efficacy of garment system contamination control procedures
- APPENDIX E. *Bibliography*

1.2 Limitations

This RP does not prescribe design or performance requirements for garments, or control limits for specific cleanroom applications, such as food processing. It does not address personal protection or health and safety requirements as related to cleanroom apparel and accessories. Limitations, applicability, precision, and interpretation of data obtained from recommended testing as presented in Appendix D should be considered.

2 REFERENCES

The cited editions of the following documents are incorporated into this RP to the extent specified herein. Users should apply the most recent editions of the references.

2.1 American Association of Textile Chemists and Colorists (AATCC)

AATCC Test Method 22: Water Repellency: Spray Test

AATCC Test Method 118: Oil Repellency: Hydrocarbon Resistance Test

AATCC Test Method 127: Water Resistance: Hydrostatic Pressure Test

2.2 Association of the Nonwoven Fabrics Industry (INDA)

INDA Standard Test Method: IST 80.8—Alcohol Repellency

2.3 ASTM International

ASTM D737: Standard Test Method for Air Permeability of Textile Fabrics

ASTM D2261: Standard Test Method for Tearing Strength of Fabrics by the Tongue (Single Rip) Procedure (Constant-Rate-of-Extension Tensile Testing Machine)

ASTM D3776: Standard Test Methods for Mass per Unit Area (Weight) of Fabric

ASTM D3786/D3786M - 09: Standard Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method

ASTM D3884: Standard Guide for Abrasion Resistance of Textile Fabrics (Rotary Platform, Double-Head Method)

ASTM D3885: Standard Test Method for Abrasion Resistance of Textile Fabrics (Flexing and Abrasion Method)

ASTM D5034: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

ASTM D5035: Standard Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method)

ASTM D6193: Standard Practice for Stitches and Seams (supersedes FED-STD-751A)

ASTM E96/E96M-05: Standard Test Methods for Water Vapor Transmission of Materials

ASTM E284: Standard Terminology of Appearance

ASTM F50: Standard 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.

ASTM F51/F51M-20 Standard Test Method for Sizing and Counting Particulate Contaminant in and on Clean Room Garments

2.4 Institute of Environmental Sciences and Technology (IEST)

IEST-RP-CC005: Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments

IEST-RP-CC027: Personnel Practices and Procedures in Cleanrooms and Controlled Environments

IEST-RP-CC032: Flexible Packaging Materials for Use in Cleanrooms and Other Controlled Environments

IEST-RP-CC052: Understanding, Identifying and Controlling Electrostatic Charge in Cleanrooms and Other Controlled Environments

IEST-STD-CC1246: Product Cleanliness Levels and Contamination Control Program

2.5 International Organization for Standardization (ISO)

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

ISO 14644-2: Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

2.6 Occupational Safety and Health Administration (OSHA)

OSHA 29 CFR 1910.1200: OSHA Standard for Hazard Communication, Subpart Z, Toxic and Hazardous Substances

OSHA 29 CFR 1910.1030: OSHA Standard for Bloodborne Pathogens, Subpart Z, Toxic and Hazardous Substances

2.7 SAE International (SAE)

SAE ARP 901A: Bubble-Point Test Method

2.8 Technical Association of the Pulp and Paper Industry (TAPPI)

TAPPI T425 om-06: Opacity of paper (15/d geometry, illuminant A/2°, 89% reflectance backing and paper backing)

2.9 Sources and Addresses

AATCC

American Association of Textile Chemists and Colorists
1 Davis Drive, P.O. Box 12215
Research Triangle Park, NC 27709
USA
www.aatcc.org

ASTM International

American Society for Testing and Materials
100 Barr Harbor Drive
West Conshohocken, PA 19428

USA

www.astm.org

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www.ient.org

INDA

Association of the Nonwoven Fabrics Industry

1300 Crescent Green, Suite 135

Cary, NC 27511

USA

www.inda.org

ISO

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

IENT

1827 Walden Office Square, Suite 400

Schaumburg, IL 60173-4277

USA

www.ient.org

Outside U.S.: Documents available from representative ISO member body organization

OSHA

Occupational Safety and Health Administration

U.S. Department of Labor

200 Constitution Avenue, N.W.

Washington, DC 20210

USA

www.osha.gov

SAE

SAE International

400 Commonwealth Drive

Warrendale, PA 15096-0001

USA

www.sae.org

TAPPI

TAPPI Press

15 Technology Parkway South

Norcross, GA 30092

USA

www.tappi.org

3 TERMS AND DEFINITIONS

aseptic cleanroom

A cleanroom operated using a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens.

body box

A test chamber used to simulate the particle filtration of the clothing and the particle release of the person under real wear conditions.

calendered fabric

A form of cloth produced by a process of flattening fabric filaments resulting in a smoother, tighter fabric surface.

CSM

Chlorosulphonated Polyethylene Rubber (previously known as Hypalon®) is a form of flexible boot sole that has both good radiation resistance and high coefficient of friction.

cleanroom

A room in which the concentration of airborne particles is controlled by means of air filtration and airflow management, and which is constructed and operated in a manner designed to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters, such as temperature, humidity, and pressure, are controlled.

containment

The ability of a garment set to restrict the migration of potential contaminants from inside the garment set to the ambient environment.

contaminant

Any unwanted substance present in or on a material or surface within a cleanroom.

controlled environment

The environment in which parameters such as temperature, pressure, humidity, contaminant level, and so forth are controlled within specified limits.

coveralls (also known as jumpsuit)

A one-piece, loose fitting, full-length garment that covers the body, generally from the neck to the wrists and ankles.

denier

A unit of measure used to describe synthetic and silk fibers, based on a mass in grams per 9,000 meters of length.

entrapment

An accumulation of foreign material in hidden features of cleanroom garments that is difficult to remove by common methods.

fiber

A solid object, typically in the form of a thread or filament, having an aspect (length-to-width) ratio of 10 or more.

filament

A fiber or group of fibers long enough to be observable without magnification, typically 100 µm or more in length.

findings

Nonfabric elements used in the construction of, or as attachments to, cleanroom garments.

Examples: snaps, belts, straps, bindings, buckles, and zippers and other closures

float

The matrix of intersecting yarns described by the number of consecutive vertical yarn strands crossed by the number of consecutive horizontal yarn strands, interlocking the warp and weft of a woven fabric.

frock

A three-quarter-length garment employing a military collar design and a full front closure with snap adjustment at the neck opening; intended to cover the arms and torso, and meet the knees of the wearer; generally used in cleanrooms of less critical air cleanliness classifications.

garment set

A complete assemblage of body coverings specified for a particular cleanroom application.

garments, cleanroom

Specially designed items of clothing that are worn to prevent or reduce the dispersion of contaminants that may be shed or released by cleanroom personnel.

Examples: coveralls, footwear, shoe covers, gloves, and head covers.

gowning system (also known as *garment system*)

A set of specified articles of apparel and accessories, together with specifications governing their donning, use, doffing (removal), reprocessing or replacement, and storage, as well as specifications related to the way in which they interact with equipment, fixtures, and facilities.

Gram-positive bacteria

Bacteria that retain the purple color of the crystal violet dye when treated with Gram's staining technique.

knit fabric

A fabric made by interlacing threads in a series of interconnected loops.

laminated fabric

A fabric manufactured from two or more layers of different materials, bonded together to create a single multilayer structure exhibiting a beneficial blend of the properties of the individual layers.

legging (also known as *upper*)

The upper fabric area of a cleanroom boot, which extends over the pant leg or over the ankle and calf of the coverall.

non-aseptic cleanroom

A cleanroom having no requirements regarding the presence of microorganisms.

nonwoven fabric

A flat, flexible, porous sheet structure produced by interlocking layers or networks of fibers or filaments (bonded together thermally, mechanically, or chemically) or by perforating films.

opacity

The capacity of a fabric to inhibit the passage of light and prevent visual recognition of images, as related to personal modesty.

particle

A minute portion of matter with defined physical boundaries, usually between 1 nm and 1mm in size.

pass-through washer

A washing machine with two doors, which provides for the loading of soiled garments outside of the cleanroom and removal of cleaned garments inside of the cleanroom.

permeability

The quantitative measure of the ability of a material to transfer mass (solid, liquid, or gaseous) through its pores under the influence of a pressure gradient.

placket (also known as *zipper placket*)

A strip of material that completely covers the outside surface of a closed zipper.

porosity

The ratio of the combined volume of all of the pores in a material to the overall volume of the material.

processing

The cleaning and packaging of cleanroom garments to meet required cleanliness specifications.

raglan sleeve

A sleeve attached to a modified armhole with slanted seams extending from underarm to neck (see Figure 5).

safety data sheet (SDS)

A document prepared by a chemical or material manufacturer, describing the composition, reactivity, properties, and hazards of a chemical or material along with recommended safeguards for handling, storage, and use.

serge

The process of overcasting the raw edges of a piece of fabric with long, slanting widely spaced stitches meant to prevent raveling.

set-in sleeve

A sleeve attached to an armhole of a garment with a vertical seam (see Figure 5).

snood cap (also known as *snood*)

A net or fabric bag worn to hold the hair at the back of the head, and tied behind the head.

tumble dryer

A drying system that tumbles a bulk quantity of damp garments in a rotating drum that is fed by filtered, heated air.

tunnel dryer

A drying system in which garments are hung separately on a continuous conveyor that moves them through a tunnel supplied with heated, filtered air moving at a speed sufficient to dry the garments before they emerge into the cleanroom.

warp

A series of yarn filaments that extend lengthwise in woven fabric.

weft (also known as *woof* or *filling*)

A series of yarn filaments that are woven crosswise through the warp in woven fabric.

woven fabric

A cloth made on a loom by interlacing warp (vertical) and weft (horizontal) yarn filaments.

4 BACKGROUND AND PURPOSE

The design phase of any contamination control program should consider the effects of contamination from all sources. Personnel and their activities are one of the major sources of contamination. Therefore, specification and use of an appropriate gowning system is essential in limiting the elements of human-generated contamination from reaching and affecting product or processes in the cleanroom.

This RP is intended to assist the end user, system designer, supplier, and processor in defining required performance criteria, test methods, and procedures for gowning system use and maintenance, as well as in developing a quality control plan for the apparel and accessories that may be included in the system. The RP identifies garment-related factors that may influence the performance of cleanrooms. This RP covers selection, construction, material characteristics, performance, laundering, maintenance, validation, and documentation, as well as test methods that can be used in evaluating relevant properties for cleanroom applications.

5 PRODUCT CONSIDERATIONS

This section describes types of fabrics and relevant properties and methods of testing of the materials used in cleanroom garments, as well as the design and construction of appropriate configurations and special features of such garments.

5.1 Fabrics

Various types of fabrics are used in the construction of garments and accessories to be worn in cleanrooms and other controlled environment areas. Fabric selection is based on the specific degree of contamination control required in the area, as well as other factors, including cost, comfort, and durability. Characteristics of fabrics, threads (continuous filament polyester fibers), and other materials used in apparel and accessories may affect the performance of the gowning system.

Fabric types can be divided into three primary categories:

- Woven
- Knit
- Nonwoven

Each type of fabric has specific advantages and disadvantages and is available in a variety of forms.

Fabrics chosen for evaluation should be cleanable by available methods and should be compatible with chosen sterilization technology.

Fabrics containing natural fibers, such as cotton, linen, and wool are non-compatible cleanroom fabrics. They will shed particles and fibers and should not be used.

5.1.1 Woven fabrics

a) General

Woven fabrics are typically used in the construction of garment systems, including body coverings, head coverings, and footwear, for use in all classifications of controlled environments. In addition, some woven fabrics are used in facial coverings.

The yarns used in the manufacture of woven fabrics intended for use in cleanroom garment systems are typically made of continuous, multifilament polyester. The number, size, shape, and texture (bulk) of these yarns can be varied to impart different properties to the fabric.

Woven fabrics are produced on looms and are formed by the intersecting and interlacing of perpendicular sets of yarns, one of which runs the length of the fabric and the other of which crosses the fabric from edge (or selvage) to edge. These sets of yarns are called:

- *Warp* (long, or length, direction of the fabric)
- *Filling or weft* (short, or cross, direction of the fabric)

The float of a fabric is determined during weaving. This characteristic is the result of crossing a given number of consecutive vertical strands of yarn with another number of consecutive horizontal strands of yarn (e.g., 1×1 , 2×1 , 2×2 , 3×2 , etc.). The float can produce a visual pattern known as the weave design. The weave design not only affects the way a fabric looks, but it also affects the physical properties of the fabric. Weave design, yarn density, and filament selection play a critical role in determining the following properties of a fabric:

- Thickness
- Weight
- Flexibility and drape
- Hand (feel to the touch)
- Filtering and barrier properties
- Comfort
- Strength and durability

b) Types of weave designs and fabrics

1) Plain weave fabric or taffeta—

The most basic of weave designs, in which yarns pass over and under adjacent yarns in a 1×1 float pattern. A plain weave is capable of being the tightest, lightest, and thinnest of the fabric weaves. Even tighter weaves may be attained through calendaring (see section 5.1.1b3).

2) Twill weave fabric—

In a twill weave, the warp yarns pass over, under, or over and under two or more adjacent weft yarns. The fabric surface usually exhibits a diagonal pattern. Common twill floats are 2×1 , 2×2 , and 3×2 . Longer floats typically allow fabric to be more flexible and therefore softer to the touch, but usually also cause the fabric to be thicker and have greater permeability. A herringbone weave is a twill variation. Twills and other loosely constructed woven fabrics are recommended for less critical environments.

3) Calendered fabric—

A woven fabric may be calendered by being pressed under high heat and pressure to soften and flatten the filaments. The calendaring process reduces the space between the filaments, thereby reducing pore size, increasing filtration efficiency, and decreasing permeability. The resultant reduction in permeability, i.e., moisture vapor transmission rate (MVTR), should be assessed, since it may cause discomfort to those wearing the garments.

NOTE: Although calendering reduces air permeability, experience has shown a small decrease in MVTR due to calendering when comparing MVTR of the same fabric before and after calendering.

4) Laminated fabric—A woven fabric may also be laminated to a film or membrane to further reduce its permeability and to control shedding of fibers and particles.

NOTE: Calendered fabric and laminated fabric are typically used in more critical environments.

c) Special treatments

In controlled environments where electrostatic discharge (ESD) is a concern, woven fabrics may contain conductive or static-dissipative monofilament or multifilament yarns in a stripe or grid pattern. In some instances, woven fabrics may also contain durable, topical, chemical finishes designed to do the following:

- Provide splash protection
- Improve soil release
- Reduce static
- Control microbial growth

It is important that the end user thoroughly evaluate the relative advantages and potential disadvantages of the various treatments or fabric modifications to ensure a selected treatment or modification will not adversely affect the user's product or process.

d) Effects of processing

Garments made of woven polyester fabrics can be laundered and reused many times and, when required, can usually be sterilized by a variety of techniques, including steam and ionizing radiation (gamma-ray [cobalt 60] or high-energy, electron-beam [E-beam]). Ethylene oxide (EtO) is not recommended as a sterilization technology for polyester because outgassing (or offgassing) of residual EtO after sterilization is difficult to control.

Repeated launderings may have an effect on some chemical and mechanical fabric finishes and treatments. Care should be taken to follow the manufacturer's recommended fabric care practices to maximize the useful life of a garment set.

5.1.2 Knit fabrics

a) General

Knit fabrics are generally characterized by their stretch, flexibility, and lightness. Multifilament polyester yarns similar to those used in making woven fabrics are the primary yarn of choice in making knit fabrics. While it is possible to produce a fairly tight and rigid knit fabric, the innate characteristics of knit fabrics do not provide a stable filtration medium for body-covering garments. Accordingly, knit fabrics are not recommended for use in cleanrooms.

Knit fabrics are produced on knitting machines and are formed by the interlacing of a series of yarn loops known as:

- *Wales* (column of loops lying lengthwise in the fabric)
- *Courses* (rows of loops running across the fabric)

b) Types of knit configurations and uses

1) Warp knits—

One basic variety in which the yarns generally run lengthwise with one or more yarns per needle.

2) Weft knits—

Another variety in which a continuous yarn runs crosswise in the fabric, forming all of the loops in a course. Weft knits are an effective method for terminating collars and cuffs of cleanroom garments. Weft knits are also used in T-shirt-type applications.

3) Laminated knits—

A laminated knit is a barrier fabric produced by laminating a synthetic film or membrane to one side of a knit fabric.

c) Special treatments

Knit fabrics may be treated with many of the same finishes as woven fabrics. Knit fabrics may also be specified to contain conductive or static-dissipative monofilament or multifilament yarns for use in ESD-sensitive areas. In warp knits, the static-dissipative pattern created by the conductive or static-dissipative yarns is typically diamond-shaped or hexagon-shaped.

d) Effects of processing

Garments made from polyester knits may be processed and sterilized as discussed in section 5.1.1 d). Consideration should be given to heat and sterilizing effects on the garments or knitted features as they pertain to the user's requirements.

5.1.3 Nonwoven fabrics

a) General

A third fabric type used in the construction of cleanroom garment systems is nonwoven fabric. Produced directly from synthetic fibers or filaments by a variety of processes, nonwoven fabrics are commonly referred to by the type of process used to create them. Nonwoven fabrics may be used alone or as substrates with nonporous or microporous films in laminate structures. Nonwoven fabrics run the gamut from loosely organized bonded strands to tightly arranged films and membranes. Many cleanroom garments made from nonwoven fabrics are thought of as single-use or limited-reuse products.

The fibers or filaments typically used in nonwoven fabrics for cleanroom environments are the following:

- Polypropylene (a polyolefin)
- Polyethylene (a polyolefin)
- Polyester

NOTE: A polyolefin is any long-chain synthetic polymer composed of at least 85% (by weight) of ethylene, propylene, or other olefin units.

b) Types of nonwoven fabrics and their uses

1) Spunbonded or thermal bond—

A commonly available nonwoven fabric typically made from polypropylene in a relatively open structure and used in bouffant caps, shoe covers, etc. Due to the structure of spunbonded or thermal bond fabrics, this type of nonwoven fabric does not demonstrate high barrier performance, i.e., high filtration efficiency and splash resistance. Spunbonded and thermal bond nonwovens have limited use in the critical environments of the electronics, biotech, and pharmaceutical industries. They may provide sufficient barrier properties for some types of medical device manufacture and other areas where lesser barrier properties are adequate. Spunbonded fabrics are made from continuous filaments, which increase strength and reduce lint propagation.

2) Flash spun—

A nonwoven fabric made of high-density polyethylene continuous fibers and used for coveralls and aprons. Flash spun nonwovens have barrier properties and are splash-resistant to water. Flash spun nonwoven fabric is the most common fabric for disposable cleanroom garments.

3) Melt blown—

A nonwoven fabric made from continuous polypropylene microfibers and used in composite structures of many types of face masks because of its high filtration efficiency and repellency. Melt blown nonwoven fabric does not have adequate strength to be used alone for garments.

4) Spunbonded/melt blown/spunbonded (SMS)—

A laminate (sandwich) structure made from polypropylene continuous fibers and used in coveralls, aprons, etc. SMS fabrics offer barrier properties and comfort and can be used in areas where improved barrier properties are required.

5) Film laminate—

A spunbonded layer laminated to nonporous films. This laminate demonstrates particle, blood, and chemical barrier characteristics, but often lacks air and moisture permeability.

6) Microporous film laminate—

A laminate made from a spunbonded layer and a microporous film for improved barrier properties. This laminate is splash-resistant and is a blood barrier. Microporous film laminate is optimal for use in surgical areas and critical environments.

c) Special treatments

Many nonwovens can be sterilized by a variety of techniques and treated for antistatic properties.

d) Effects of processing

Cleanroom garments made of a spunbonded polyolefin are usually intended for limited use (considered to be disposable). Spunbonded polyolefin garments should be laundered and processed before use; however, repeated laundering is not recommended. In addition, spunbonded polyolefin garments are not compatible with repeated ionizing radiation sterilization techniques because the degradation of physical properties is too great; repeated ionizing radiation results in unacceptable garment degradation (particulation) as well as fabric deterioration (garment tendency to fall apart when donned). Accumulated ionizing radiation sterilization of no greater than approximately 50 kGy for disposable (one-time-use) garments has been found to be acceptable. Fabrics made of spunbonded polyolefins may be stabilized with the use of certain additives included during the fiber-forming process to provide greater compatibility with the repeated ionizing radiation sterilization process.

5.2 Material Properties and Testing

Depending on the specific application, evaluation of fabrics intended for use in cleanrooms may include tests for the following:

- Cleanliness and cleanability
- Electrostatic properties
- Biological properties
- Durability
- Comfort
- Opacity
- Particle filtration efficiency (see D1.1)
- Microbial penetration (see D2.6)
- Chemical compatibility
- Fluid resistance

NOTE: Not all test methods are applicable to all fabric types; results of a given test on different fabrics may not necessarily provide direct correlation for comparative purposes.

5.2.1 Initial cleanliness

Newly manufactured garment systems will be inundated with unwanted contamination (particles, fibers, etc.) and should be processed or laundered to a defined cleanliness standard before initial use (see section 6).

5.2.2 Electrostatic properties

The potential for a material or fabric to acquire and release an electrostatic charge, during use, is intrinsic to its physical composition and surface characteristics. An electrostatic charge can affect the product, process, or environment by discharge or induction, or both. Methods for evaluating the ESD properties of fabrics are presented in *IEST-RP-CC052*.

NOTE: ESD properties of these materials could change after exposure to wash and dry cycles.

5.2.3 Biological properties

Characteristics of materials and fabrics that control microorganisms by one or more mechanisms (such as barrier properties, durable or nondurable chemical treatments, or antimicrobial properties) are inherent in the physical composition of the material. Testing of various fabrics and materials can provide useful information for comparative evaluation.

5.2.4 Durability

The durability of a material is relative to the specific use of an article made of that material. Certain properties of the component fabric and materials may provide information on wear characteristics under laboratory or simulated conditions. This information may be helpful in comparative evaluation, but the true durability of an article can be measured only under real-use conditions over a significant amount of time. In addition, apparel system components and construction should be compatible with the intended method of sterilization over the expected life of the garment. A sample garment should be sterilized and then evaluated for degradation. Some durability tests include the following:

- Abrasion resistance according to *ASTM D3884* and *ASTM D3885*
- Tensile strength according to *ASTM D5034* and *ASTM D5035*
- Tearing strength according to *ASTM D2261*
- Hydraulic bursting strength according to *ASTM D3786/D3786M - 09*

5.2.5 Comfort

The matter of comfort is relative to the specific use of an article and to the individual who will use it. However, determination of certain properties of the component fabric and materials may provide information on relevant characteristics under laboratory or simulated conditions. This information may be useful in a comparative evaluation, but comfort can only be measured under real-use conditions over a significant amount of time. Some tests that can be used to provide information about the comfort of an article include the following:

- Equivalent pore diameter test (see B1.2)
- Air permeability according to *ASTM D737*
- Water vapor transmission rate according to *ASTM E96/E96M-05*
- Basis weight according to *ASTM D3776*

5.2.6 Opacity

Consideration should be given to the opacity (the resistance to light transmission or the opposite of transparency) of the fabric or material and its relationship to the wearer's inner apparel. Opacity measurement tests can be performed according to *ASTM E284* or *TAPPI T425 om-06*.

5.2.7 Chemical compatibility

The effect of certain chemicals on cleanroom garments during use and laundering is an essential consideration in the evaluation of cleanroom apparel. The fabric should be tested using the chemicals to which the apparel will be exposed during use. The laundry personnel should be aware of the limitations of the fabric and use appropriate wash solutions. Cleanroom fabrics are designed to contain particles, fibers, and other contaminants to protect the cleanroom environment from the wearer. It is reasonable to assume that any fabric that will deteriorate in the presence of chemicals may also be a hazard to the wearer. Thus, the user should inspect the cleanroom apparel for any possible fabric damage due to chemical exposure under use conditions. Use of appropriate protective sleeves or armguards, aprons, and the like will help protect the garment and the wearer.

5.2.8 Fluid resistance (applicable to both woven and nonwoven fabrics)

Fluid resistance tests include the following:

- *AATCC Test Method 127*
- *AATCC Test Method 22*
- *AATCC Test Method 118*
- *INDA Standard Test Method: IST 80.8*

5.3 Design of Apparel

The design of a gowning system should align with specified cleanliness control standards. Cleanliness control standards for cleanrooms and other controlled environments are defined in a variety of ways. Typically, particulate cleanliness control is defined either in relation to the airborne concentration of particles of given sizes, the type of control, or the degree of product cleanliness.

The primary purpose of cleanroom apparel and accessories is to contain particles and control microorganisms (in biological applications) generated by the wearer, thereby protecting the product or process. However, certain characteristics of the apparel and accessories may influence the performance of the gowning system.

A functioning cleanroom garment system acts as a filter. Garment closures should be designed in conjunction with other components of the garment system (boots, gloves, hood, and facemask) to minimize or eliminate particle release at the interfaces and the main garment closure. The same filter assembly should permit transfer of body moisture through the garment to establish an acceptable level of comfort for the wearer. For example, typical design characteristics of acceptable cleanroom coveralls include such features as raglan sleeves, military collars, static-dissipative knit cuffs, and single front zippers. Double-needle stitching should be used throughout the construction of the garment (see section 5.4.2b and c). Other garment system components include snug-fitting, flat-top hoods with open faces and snaps for attaching facial or beard covers, if needed, and a pair of boots with appropriate sole material, typically about 45 cm to 50 cm (18 in. to 20 in.) in height.

Various alternatives are available, including double-zipper front closures, shoulder zipper closures, recessed knit cuffs with encapsulated elastic wrist enclosures, tunneled elastic across the back of the waist area, bouffant-topped hoods, one-piece hood/facial systems, and front or back zippers for boots.

NOTE: When working with a woven fabric, design options are limited only by the imagination; however, there is a significant cost penalty associated with an over-designed garment system. See sections 5.4 through 5.10 for further details.

5.4 Construction of Apparel

The design and construction of an item of apparel should conform to all applicable health and safety ordinances and codes, as well as to performance requirements.

5.4.1 Sewing thread

Sewing thread should be synthetic, continuous, multifilament, and compatible with the fabric cleaning and sterilization process. Silicone and other lubricants or bonding agents, often used in the sewing process, should be assessed for compatibility with the end user's contamination requirements.

5.4.2 Seams

A seam is a joint consisting of a sequence of stitches uniting two or more pieces of material and is used for assembling parts in the production of sewn items (see *ASTM D6193*).

a) Edge seams

Before stitching any seams, the edges of each separate fabric panel or component used in assembling cleanroom garments should be properly prepared to eliminate the possibility of loose threads, frayed edges, or seam separation, which may add to contamination. Raw edges of each fabric panel or component may be prepared as follows (see Figure 1):

- Overlocked for an overedge or "edge finishing" stitch (serged), type EFd-1.

- Heat-sealed for a fused, beaded edge. Other sealed seams include ultrasonically welded, serged and taped, and heat-sealed (seams are bonded through the application of heat, pressure, and a special heat-activated adhesive used with nonwoven fabrics).

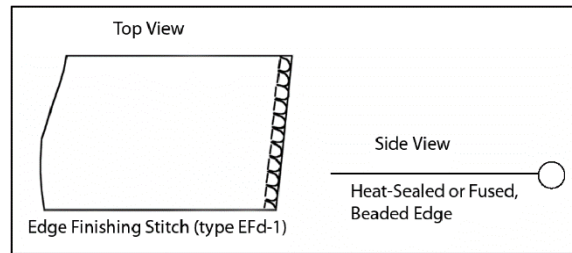


Figure 1. Edge finishing stitch and heat-sealed or fused, beaded edge.

b) Joining seams

Joining seams connect panels of fabric or join various components of a garment together. The choice of joining seams, in cleanroom garments, is important in the overall effectiveness of the garment set to avoid free-air passage from the inside of the finished garment to the outside of the finished garment. The types of joining seams recommended for the construction of cleanroom garments are *bound* and *lapped* (see Figure 2). Examples of how joining seams may be used include the following:

- Joining a zipper to a front panel of a body covering
- Joining a knit cuff to a sleeve of a body covering
- Joining a leg inseam to panels of a coverall leg
- Joining a sleeve to the body
- Joining a collar to the neck opening

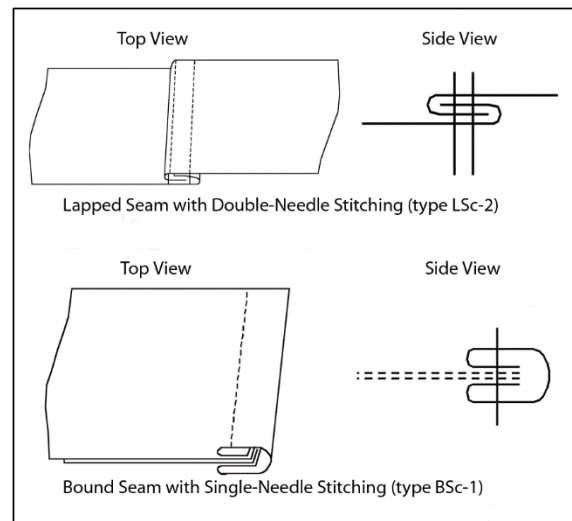


Figure 2. Lapped seam with double-needle stitching and bound seam with single-needle stitching.

c) Finishing seams

Finishing seams are used to hem wrist openings, leg openings, a frock bottom opening, a hood bottom opening, etc. The fabric edge should be turned under, folded back over the body of the fabric, and stitched. The turned and folded portion of the seam should be stitched to the body of fabric with one or more rows of stitches (see Figure 3).

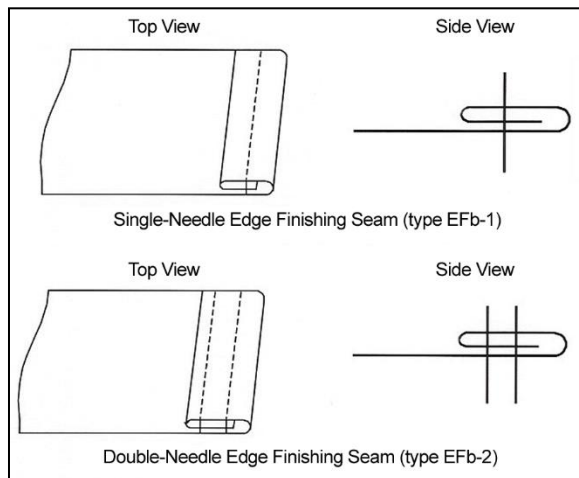


Figure 3. Single-needle edge finishing seam and double-needle edge finishing seam.

5.4.3 Entrapment areas

Entrapment areas are stitched features of the garment that can trap unwanted contamination and debris. Certain construction techniques and features added to basic cleanroom garments may serve as entrapment areas, such as pockets, pager tabs, belts, pleats, fold-over collars, folded or trough cuffs, unnecessary seams, sewn-on emblems, sewn-on logos, and pen tabs. These types of features should be avoided.

5.4.4 Findings

Findings are pockets, linings, zippers, and other sundry and supplementary items used in the manufacture of garments. Findings and the materials from which they are constructed should be compatible with the type of cleaning and sterilizing processes required by the end user's application. They should be installed on the garment in a way that minimizes the entrapment or release of contamination while in use. Findings include the following:

- Grippers or snaps—should be post-and-socket type stainless steel or plastic.
- Polyester tape that has been fuse-cut.
- Grosgrain or sateen ribbon.
- Zippers—100% filament polyester tape with a non-coated slider and stop and non-plated teeth. Closed bottom may be considered, depending on the application. Static-dissipative coveralls should be constructed with a plastic zipper. Hook and loop (e.g., Velcro) type closures are not recommended as they pose a significant risk of trapping contamination.
- Fly stiffeners (or “inner liners”)—should be cut from 100% polyester fabric with a crisp finish (250 denier) and used to fill zipper fly placket.
- Elastic—construction should consist of braided elastic (latex or suitable equivalent) having a calendered finish; width should be considered to achieve the desired fit.
- Straps—should be made of a continuous filament polyester denier; width should be considered. Straps should be flexible and nonabrasive. The ends of the straps should be heat-sealed and be nonabrasive.
- Boot buckles—should be made of a polymer material and are to have a male/female-type attachment.

- Knit cuffs—should be made out of a continuous filament polyester material. May also be made with static-dissipative, carbon-suffused fibers.
- Bungee cords with slide-lock—should be made with a non-particulating or non-fiber-producing material (plastic or polymer construction). Typically used at the top of boot leggings as a closure and also used on the inside of coveralls to allow for a more form-fitting look.
- Labels, loops, and badge tabs—not recommended. If label printing is necessary, it should be done using a heat sublimated label or with a non-particulating material that should be sewn down on all sides so as not to generate particulating fibers.

5.4.5 Garment sizes

Garments are generally available in generic sizes by letter; however, the end user needs to be aware that sizes usually vary among manufacturers. Garment measurement specifications can be found in Appendix B provided. To ensure a correct fit, sizing samples are used in advance of ordering additional stock. Color-coding of tags and straps is often employed for visual size identification.

5.4.6 Wrist cuffs and leg cuffs

Cuffs are available in knit, elastic, elastic with thumb loop, snap, or open varieties, or any combination of these designs (see Figure 4). The type of cuff used is application-specific.

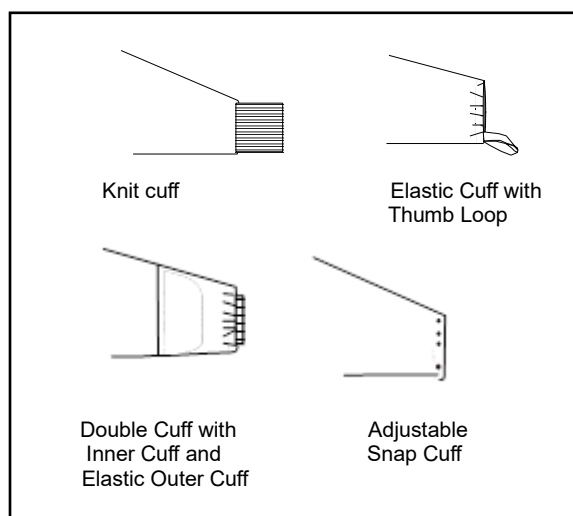


Figure 4. Cuff configurations.

Knit cuffs provide a comfortable, snug fit around the wrist or ankle. However, due to the porous nature of a knit fabric, cuffs made of this type of material are not an effective barrier. In addition, elasticity will fatigue over the life of the garment through normal wear and tear as well as exposure to gamma irradiation or autoclave sterilization. Knit cuffs are available in 100% polyester or static-dissipative varieties (also called electrostatic-dissipative). Static-dissipative cuffs include polyester-based conductive filaments or filament fibers as part of the knit construction.

Elastic cuffs provide ease while donning or doffing garments. Thumb loops may be added to the wrist cuff, which will help to keep the wrist cuff tucked inside the glove cuff. Elastic will fatigue over the life of the garment. In addition, exposure to gamma irradiation and autoclave sterilization will further deteriorate the elastic.

Snap cuffs are adjustable to the individual wearer. If gloves are worn, care should be given when snapping the cuff so as not to snag the glove in the snap.

Generally, leg openings on coveralls have either adjustable-snap or elastic cuffs. Ensure that leg openings will accommodate the variety of shoes or boots that will be worn by the end user's employees.

5.4.7 Sleeves

Sleeves are available as raglan or set-in design styles (see Figure 5). Raglan sleeves offer more freedom in sizing a variety of individuals and allow for improved mobility.

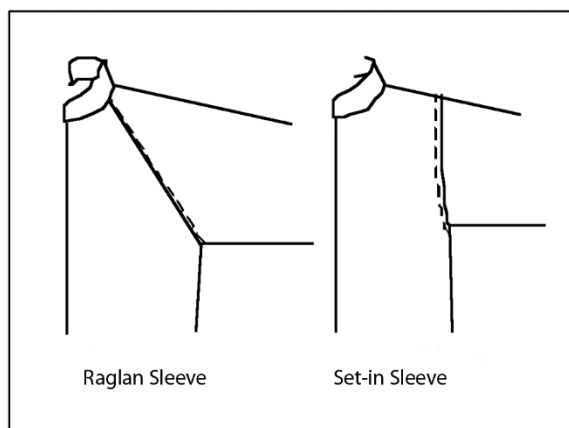


Figure 5. Raglan and set-in sleeves.

5.5 Inner Suits or Building Suits

Inner suits or building suits are generally two-piece top and bottom sets worn under coveralls. The suits should be made of lightweight, comfortable, low-shedding fabrics to reduce particle generation (as compared to particle shedding caused by fabrics used in street clothing such as cotton, wool, flannel fabrics, etc.). Dark fabric is suggested for modesty. The variety of top include: V-neck opening, snap closure, or pullover. Short or long sleeves acceptability is application dependent. The suit bottoms may have elastic or a drawstring at the waist. Ankle closures may vary depending on the application or preference of the end user.

5.6 Hair Covers

Hair covers should be of a bouffant style, lightweight, and elasticized (see Figure 6). Hair covers are worn separately or in conjunction with hoods or other head coverings and should contain loose hair. Hair covers are generally made from nonwoven, disposable fabrics.

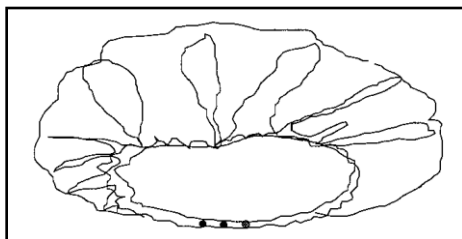


Figure 6. Bouffant-style hair cover.

5.7 Head Coverings

The purpose of head coverings is to contain and control particulate and microbial contamination generated by the wearer's clothing, head, face, and neck.

5.7.1 Snood caps

Snood caps should be designed to adequately cover the forehead, providing enough room to permit hair to be tucked neatly inside the rear of the snood cap. Adjustment at the nape of the neck is either by means of a tie string or elastic (see Figure 7).

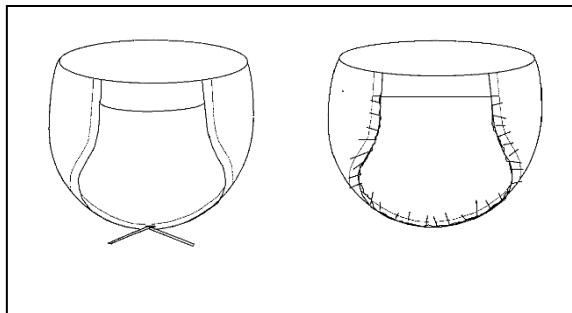


Figure 7. Snood caps.

5.7.2 Hoods

Hoods are coverings designed to fit over the head and generally cover all but the facial area (see Figure 8). Hoods should fully cover the head to contain and control migration of hair and particles. Hoods should either be closed by snaps in the front bib or be of a pullover style. The front and rear bibs of the hood should fit into the coverall or frock and not pull out of the garment when the wearer's head moves; i.e., it should be long enough to fit securely inside the outer garment. Snaps, ties, elastic, or combinations thereof should be used at the nape of the neck to provide a snug fit to the wearer's head. Although a pullover, full-face-opening design is preferable, other options include an eyes-only opening, a snap or zipper front, mesh ear panels, built-in face masks, eyeglass slots, and bouffant-style crowns. Full-face-opening designs should have snap sockets available to accept optional facial covers or masks as described in section 5.7.3.

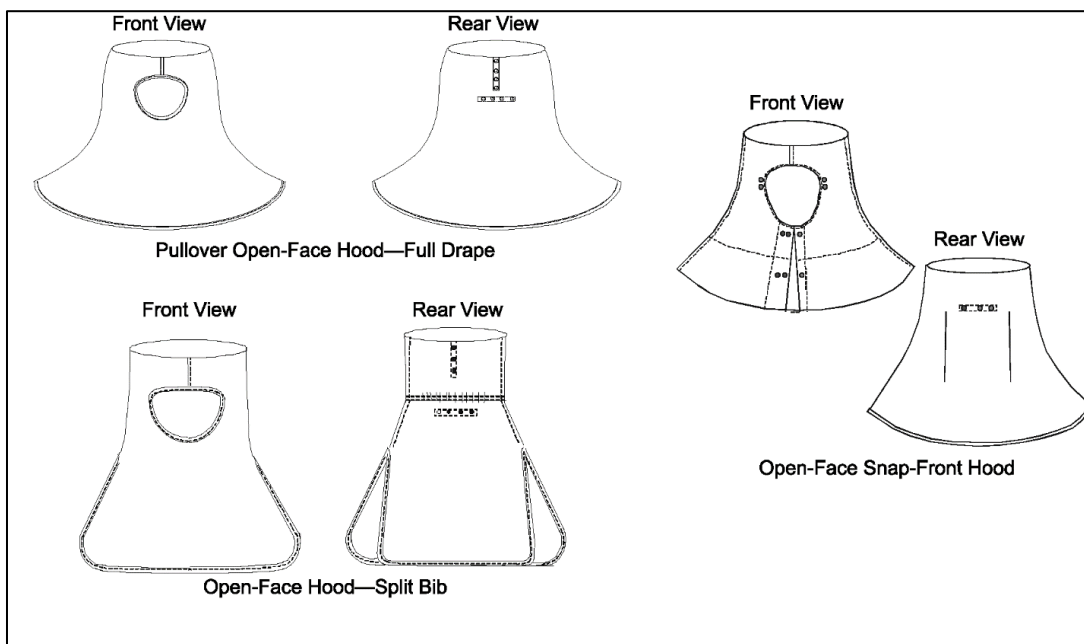


Figure 8. Hoods.

5.7.3 Facial covers or masks (as required)

Facial covers generally extend from under the eyes to the neckline and from ear to ear. Facial covers are usually contained within the head covering or hood. Facial covers are constructed from a variety of fabrics (disposable or launderable) and in a variety of designs. The choice of a specific material and style will be dictated by the end user's protocol and critical process or regulatory requirements.

5.8 Body Coverings

The purpose of body coverings is to contain and control particulate and microbial contamination generated and released by the wearer's body or clothing. Entrapment areas are unacceptable and should be avoided.

5.8.1 Frocks

A frock is a three-quarter-length garment employing a military collar design with a full front closure with snap adjustment at the neck opening (see Figure 9). A frock is designed to cover the arms and torso and minimally extends to the knees of the wearer. Frocks are generally used in cleanrooms of less critical air cleanliness classifications. The front closure is to consist of a full-length separating zipper to prevent contamination generated by the wearer's clothing from escaping into the work area. Frocks are to be devoid of pockets, pen tabs, and other entrapment areas. In non-critical applications, snaps may be acceptable on frocks, such as in lab coats (see section 5.8.4). The most common wrist closures on frocks consist of knit cuffs, a series of snaps for adjustment, or elastic at the wrist.

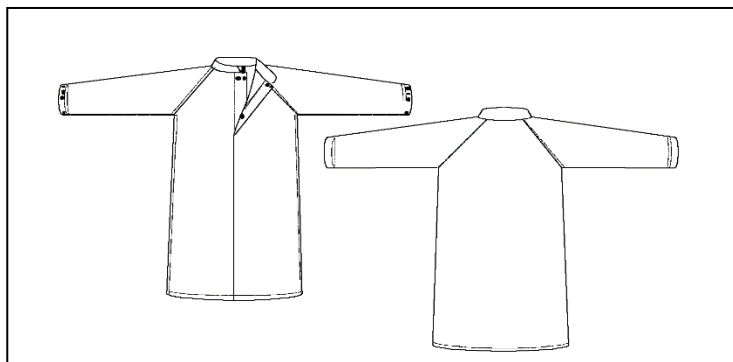


Figure 9. Frock.

5.8.2 Coveralls

Often called a bunny suit or jumpsuit, coveralls are a one-piece garment covering the entire body from the neck to the wrists and ankles (see Figure 10). Coveralls configured with attached hoods and booties are available but less common. A full-length, one-slider zipper to the base of the neck opening accomplishes front closure. A placket (zipper covering) with inner liner front may be desirable. The inner liner will allow the placket to lie flat over the zipper, thereby allowing for improved coverage and less likelihood of snagging the zipper in placket fabric. The diameter of the leg should be large enough for typical shoes, sneakers, and boots to slide easily through the opening without snagging and fit comfortably into the legging of the cleanroom boot. A series of snaps positioned in a vertical pattern below knee level at the back or sides of the legging can be used to secure the upper of the boot to each leg of the coveralls.

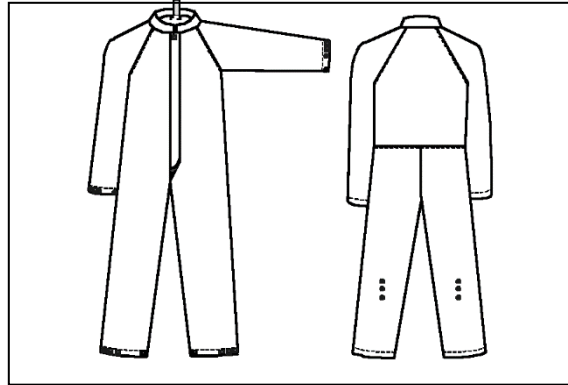


Figure 10. Coveralls.

5.8.3 Two-piece outer garments

Tops and bottoms used as outer garments should be designed for sufficient overlap between the two pieces to ensure full body coverage. The top can be designed as a pullover or front with zipper or snap closure. Sleeves may be designed with either adjustable snap closures at the wrists, elastic in the wrist hem, or knit cuffs. Bottoms may be designed with an elastic waist or may have a zipper closure as well. Ankle closures are to consist of adjustable snaps, knit cuffs, or elastic in the hem.

5.8.4 Lab coats

Lab coats are not recommended for use in a cleanroom or controlled environment. Lab coats are generally designed with a lapel collar, snap or button closures, one to three pockets, and set-in sleeves.

5.8.5 Smocks

Smocks are not recommended for use in a cleanroom environment but may be acceptable in certain controlled environments, such as surgical theaters. A smock is generally a wraparound, robe-style garment that ties at the back or side.

5.9 Footwear

The purpose of footwear is to contain and control street soil and other particles generated or carried in by the wearer's feet and shoes. Some footwear is designed with conductive soles, heel straps, or other conductive materials that help to mitigate ESD risks associated with charge accumulation on the body of the wearer.

5.9.1 Shoe covers

Shoe covers are designed to contain contamination and should be high enough to cover the shoe (see Figure 11). The foot opening should be made with elastic to ensure a snug fit to the wearer's shoe. The sole of the shoe cover should consist of a skid-resistant material compatible with the environment. The shoe cover may include a snap adjustment at the back or a strap across the front of the foot for additional adjustment.

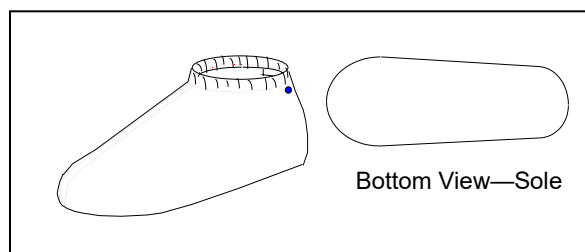


Figure 11. Shoe cover.

5.9.2 Garment boots

Garment boots are a covering for the foot and lower portion of the leg, consisting of a sole and legging (see Figure 12). Generally, boots are worn over shoes and are available in a variety of lengths and styles. If street shoes are worn, they should be as clean as possible before placing any cleanroom footwear over them. Disposable shoe covers (typically made of spunbonded polypropylene with nonskid soles) may be worn over street shoes to minimize contamination of the cleanroom boots.

The designs used for leg openings provide for various means of adjustment, including the use of elastic, snaps, zippers, and combinations thereof. The upper part of the boot, known as the legging, should be high enough to cover the pant leg and may stop above the calf. The height of the legging or upper can be anywhere from 30 cm to 50 cm (approximately 12 in. to 20 in.). The top hem should provide snaps, elastic, or some form of snap-tab arrangement for adjustment purposes. The fit around the calf should have enough slack to avoid restriction of circulation for the wearer. The diameter of the boot opening should also be large enough to accommodate a wide variety of shoes and boots that may be worn in the cleanroom.

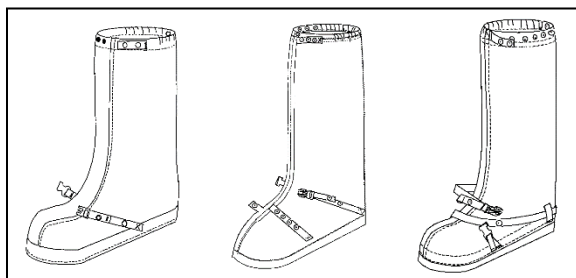


Figure 12. Boots.

Proper sizing and fit of soles should be a top priority when selecting boots. The design selected should ensure a snug fit to the wearer's shoe. A strap arrangement is to be used to properly secure the boot sole to the wearer's foot for comfort and safety. Strapping systems range from a one-strap or double-strap design to a gladiator-style design. Boot straps are to be adjustable. The free ends of straps may be a trip hazard and should be secured to the boot.

Soles may be constructed of various materials, such as skid-resistant vinyl, synthetic rubber, or a composite material. Soles should be compatible with the application environment. The cleanroom flooring may dictate the type of sole material to be used.

5.9.3 Building shoes

Dedicated employee-specific shoes called *building shoes* are available. Building shoes are made from cleanroom-compatible materials that eliminate the need for launderable or disposable boots or covers as described in sections 5.9.1 and 5.9.2. Building shoes are to be made of materials compatible with an appropriate cleanroom laundering process. Their use is limited to less critical environments.

5.10 Apparel Accessories

Apparel accessories are frequently required to provide control over contamination of the environment or product. This includes, but is not limited to, gloves, eyeglasses, face shields, seals and tapes, helmet systems, and wristbands. Any gowning accessories required should not contribute to, or permit the increase of, contamination.

6 PROCESSING CONSIDERATIONS

The objective of this section is to describe general considerations for the garment cleaning process (see Figure 13). The purpose of cleaning is to restore the garment to acceptable performance for its intended application.