

**INSTITUTE OF
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**Contamination Control Division
Recommended Practice 003.3**

IEST-RP-CC003.3

**Garment System Considerations
for Cleanrooms and Other
Controlled Environments**

INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY

Arlington Place One
2340 S. Arlington Heights Road, Suite 100
Arlington Heights, IL 60005-4516
Phone: (847) 981-0100 • Fax: (847) 981-4130
E-mail: iest@iest.org • Web: www.iest.org



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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 nonaseptic and aseptic cleanrooms and other controlled environments.

1.2 Limitations

This RP does not prescribe design or performance requirements for garments, or control limits for specific cleanroom applications, such as gown 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 B should be considered.

2 REFERENCES

2.1 American Association of Textile Chemists and Colorists (AATCC)

AATCC Test Method 22: Water Repellency—Spray Test

AATCC Test Method 118: 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 of Nonwoven Fabrics

2.3 ASTM International

ASTM D737: 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: Standard Test Method for Hydraulic 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 E96: Standard Test Methods for Water Vapor Transmission of Materials

ASTM E284: Standard Terminology of Appearance

2.4 Federal Standard (FED-STD)

FED-STD-751A: Stitches, Seams and Stitching

2.5 Institute of Environmental Sciences and Technology (IEST)

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

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

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

IEST-STD-CC1246D: Product Cleanliness Levels and Contamination Control Program

2.6 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

2.7 Occupational Safety and Health Administration (OSHA)

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

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

2.8 Society of Automotive Engineers (SAE)

AS 9001: Aerospace Recommended Practices

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

TAPPI-T-425: Opacity of Paper

2.10 Sources and addresses

AATCC

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

ASTM International

American Society for Testing and Materials
100 Barr Harbor Drive
West Conshohocken, Pennsylvania 19428
USA
www.astm.org

Federal Standards

Federal Supply Service Bureau
Specification Section, Suite 100
470 East L'Enfant Plaza, N.W.
Washington, D.C. 20001
USA
www.gsa.gov

IEST

Institute of Environmental Sciences and Technology
2740 S. Arlington Heights Road, Suite 100
Arlington Heights, IL 60005-4516
USA
www.iest.org

INDA

Association of the Nonwoven Fabrics Industry
1300 Crescent Green, Suite 135
Cary, North Carolina 27511
USA
www.inda.org

ISO

In U.S., documents may be ordered from:
IEST
2340 S. Arlington Heights Road, Suite 100
Arlington Heights, IL 60005-4516
USA
www.iest.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, D.C. 20210
USA
www.osha.gov

SAE

SAE International
400 Commonwealth Drive
Warrendale, Pennsylvania 15096-0001
USA
www.sae.org

TAPPI

TAPPI Press
P.O. Box 102556
Atlanta, Georgia 30368-0556
USA
www.tappi.org

3 TERMS AND DEFINITIONS

aseptic cleanroom

cleanroom operated with strict controls designed to minimize the presence of microorganisms

body box

test chamber used to measure the containment properties of a garment set

calendered fabric

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

cleanroom

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

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

contaminant

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

controlled environment

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

coveralls (also known as jumpsuit)

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

denier

unit of fineness used to describe synthetic and silk fibers, based on a mass of 1 gram per 9,000 meters of length

entrapment

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

fiber

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

filament

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 their closures

float

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

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

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)

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

fabric made by interlacing threads in a series of interconnected loops

laminated fabric

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)

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

Material Safety Data Sheet (MSDS)

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

nonaseptic cleanroom

cleanroom having no requirements regarding the presence of microorganisms

nonwoven fabric

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

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

particle

minute portion of matter with defined physical boundaries, usually between 1 μ m and 1mm in size

pass-through washer

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

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)

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

porosity

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

processing

cleaning and packaging of cleanroom garments to meet required cleanliness specifications

raglan sleeve

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

serge

technique of sealing a raw edge of fabric by sewing the edge over onto itself to produce a smooth rise to the fabric prior to use in a garment

set-in sleeve

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

snood cap (also known as hood)

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

tumble dryer

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

tunnel dryer

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

series of yarn filaments that extend lengthwise in woven fabric

weft (also known as woof or filling)

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

woven fabric

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 noncompatible 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 in order 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 calendering (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