Fabric and Garment Testing for Cleanrooms, Flame Resistance, and Sterlization Compatibility

by Jan Eudy

I am trying to better understand the fabric and garment testing requirements specific to cleanroom apparel in the sterile and nonsterile cleanroom segments, globally. What are the specific tests for fabric and garments? What do the results mean to the end-user?

I always recommend turning to Institute of Environmental Sciences and Technology (IEST) documentation for current information on a cleanroom subject. The IEST published the latest revision of IEST-RP-CC003.3, "Garment Considerations for Cleanrooms and Other Controlled Environments" in 2003. It outlines all aspects of cleanroom garment systems, including the recommended components and construction of cleanroom garments and testing of the cleanroom reusableapparel used in cleanrooms.

FABRIC TESTING

The tests performed on non-woven fabrics manufactured in the U.S. are similar to the tests performed on all woven fabrics manufactured worldwide. Some fabrics are calendared, which means they are treated with heat and pressure.Calendared fabrics feel lighter and are softer to the operator's skin.

Some of the most common tests and the standards applicable to those tests are:

• Weight	ASTM-D-3776
• Thickness	ASTM-D-1777
• Grab Tensile	ASTM-D-1682
• MVTR	ASTM-E-96B
• Air Permeability	ASTM-D-737
• Pore Size	Coulter porometer
• Abrasion tests	Wyzenbeek/Taber
• Suter Hydrostatic	AATCC-127
• Spray Rating	AATCC-22

• Flammability	ASTM F-1506, 16CFR Part 1610 or NFPA 70E
• Surface Resistivity	ASTM-D-257 or AATCC-76
• Static Electricity Decay	FTM 4046
• Bacterial Filtration Efficiency	Modified Ford Peterson Method

What these test results indicate to the end-user:

Weight: Heaviness in ounces when one square yard is measured. A lighter fabric contributes to operator comfort.

Thickness: Measurement of fabric width in millimeters. A lower thickness is preferred because thickness directly correlates to weight.

Grab Tensile: Measures the durability of the fabric by measuring the breaking strength of the yarns.

Moisture Vapor Transmission (MVTR): Describes the amount of water in grams that passes through one square meter of fabric in 24 hours. More moisture passing through the fabric translates to more comfort for the operator. Moisture build-up causes the operator to feel hot because of the increase in humidity between the fabric and the body.

Air Permeability: The ability of a fabric to allow air to pass through it, which is quantified by a volume:time ratio per area. Air flow in heating and cooling processes, such as the cooling process of the body, contains contaminants that can be transferred to the product. The lower the permeability or transfer of air from within the garment to the outside, the lower the contamination to the product.

Mean Pore Size: Describes the average size, in microns, of spaces between the weave of polyester in fabric. Particles emitted from the operator (from skin and clothing) can be reduced with a smaller pore size.

Wyzenbeek Abrasion: Measures the abrasion resistance of a fabric by rubbing the fabric against a wire screen.

Taber Abrasion: Measures the abrasion resistance of a fabric by rubbing the fabric with abrasive wheels.

Suter Hydrostatic: Measures the amount of pressure in centimeters of water needed to force three drops of water through any fabric. This test relates to the pore size of the fabric. Fabrics designed to have higher hydrostatic values will allow less particles to pass from operator to product.

Spray Rating: Measures the ability of a fabric to resist wetting. Fabric performance may be enhanced with agents other than polyester. In the case of the Integrity series, a thin film of Teflon molecularly bonds with the polyester threads. This becomes another layer of protection between the operator and the environment. Fabrics designed to have higher hydrostatic values will allow less particles to pass from operator to product. This protective layer reduces absorption of liquids and qualifies this fabric as splash resistant. Optimum spray ratings are between 80 and 100 (maximum) because these fabrics absorb little to no water when sprayed (hydrophobic).

Flammability: Refers to special cleanroom flame-retardant fabrics and garments below.

Water Impact: Method of testing splash resistance or the ability for fabric to resist absorption of liquids measured in grams of liquid penetrating fabric. The lower the mass of liquid allowed through the fabric, the better protected the operator will be from spills in the cleanroom environment.

Static Electricity Decay: Quantifies the ability of a fabric to reduce an electrical charge, measured over time. The less time it takes a fabric to reduce an electrical charge of 500 volts to 50 volts, the better its performance in a cleanroom environment. Static electricity in the working environment due to instrumentation, movement, etc. can cause two forms of product failure. Charged particles around the operator will migrate and cause particle contamination, and a charge will reach a critical point and then discharge from the operator to the product in the form of a spark.

Surface Resistivity: Quantifies the resistance of a fabric to pass an electrical charge through it measured in Ohms from point to point. The resistivity of a garment must be within the electrostatic dissipative range which is 105 ohms/sq. to 1011 ohms/sq. Within the ESD range of 105 ohms/sq. and 1011 ohms/sq., any electrical charge will be broken down to 0 volts over a small period of time and no electrical charge will enter the product. Fabrics outside this range may cause electrical discharge and product failure.

Bacterial Filtration Efficiency: Assesses the ability of the fabric to contain viable particles.

Additionally, some cleanroom fabric manufacturers have developed “in house” test methods, such as testing for the presence or absence of an antimicrobial if the fabric has an antimicrobial agent suffused within the weave. A fabric with an antimicrobial agent controls the growth and transference of living particles to an operation. A general decrease in microbial population, cleaner (on

particulate level, due to a reduction in the number of living particles), and less bioper-meation of microbes through the pores of the garment will result with the addition of an antimicrobial agent. The efficacy of the antimicrobial is directly proportional to the durability of the antimicrobial agent in the fabric.

GARMENT TESTING

The most important, universal specification for cleanroom apparel is that it is appropriate to protect the cleanroom process or product manufactured in the cleanroom and that it is always worn correctly.

There are many associations worldwide that recommend tests for non-woven and disposable products, including INDA (United States), EDANA (Europe), and ISO (international). However, none of these groups sets criteria for material consideration in cleanrooms. For example, the Gelbo test is a method described in INDA IST 160.1 1995, EDANA Method 220.0 1996, and ISO 9073-10-2003 (each method being slightly different but with the same basic approach), yet none of these tests contains specifications for cleanroom apparel for use in certified cleanroom classifications. Members of the IEST working group 3 are evaluating and creating recommendations for cleanroom non-woven garments for the IEST-RP-CC003.4 revision.

HELMKE TUMBLE TEST

Only IEST-RP-CC003.3 recommends that apparel used in cleanrooms meet Category I particle cleanliness derived from the Helmke Tumble test. The classification table describes cleanliness categories in size ranges of 0.3 microns and0.5 microns.

Both the ISO 9073-10-2003 and IEST-RP-CC003.3 documents stress ranking of all results to create more reproducible data. The IEST-RP-CC003.3 Working Group performed a statistical, round-robin Helmke Tumble test in 1999 and established the ranking of woven cleanroom garments (medium coverall, frock, or five hoods) into categories I, II, and III at both 0.3 and 0.5 microns per cubic foot minute of air cumulative.1

ADDITIONAL PARTICLE TESTING METHODS

There are other recommended tests for cleanroom apparel listed in IEST-RP-CC003.3. In addition to the Helmke Tumble test, which tests a cleanroom garment for the cumulative number of particles 0.5 micron and greater per cubic foot of air per minute, the particle dispersion test (body box test) specifically addresses the particle filtration containment of the full garment system in a 100% HEPA- (or ULPA-) filtered environment. The releasable large particles test, similar to the method outlined in ASTM F-51 Appendix X1, evaluates the fabric of the cleanroom garment microscopically (100) for fibers and larger particles (5 microns and greater). The microbial penetration test assesses the garment fabrics ability in preventing penetration of both viable and non-viable particles. The combination of the results of all these tests provides a comprehensive evaluation of the barrier and shedding propertiesof the cleanroom fabric or garments.

ESD TESTS

A cleanroom fabric or garment that contains a conductive yarn in a stripe or grid pattern is tested for its ability to dissipate static electricity. Conductive yarn reduces any electrical charge and attraction between particles around the operator. Particles [living (viable) and non-living (nonviable)] are small and will be affected by electrical fields created by operator movement. An electrical field will cause a particle to be charged and move toward oppositely charged particles. Particle movement is reduced if the electrical field is reduced. Beltron is the most frequently used cleanroom-/gamma-compatible conductive thread. Conductive thread is woven in a grid or stripe patternto dissipate static electricity.

The most common ESD tests required for cleanroom fabric and apparel are:

• Static Electricity Decay	FTM 4046
• Surface Resistivity	ASTM-D-257
• Surface Resistance @ 50%	RH ESD STD 2.1

Additional ESD testing may be specified in the scope of work in a customer'scontract based on the protection of the product or process in the cleanroom.

TESTING FOR RESIDUAL ELEMENTS

There are some applications that are sensitive to residual elements if present in the cleanroom garment items. Extraction tests can be performed to determine the qualitative presence or absence of anions or cations, nonvolatile residues, volatile residues, silicone, or antibiotics and if residual elements are present in the cleanroom garment items, the concentration can be determinedin subsequent quantitative analysis.

DEVICE BIOBURDEN/AAMI STERILITY TESTS

All cleanroom materials used in sterile cleanroom applications must have a quarterly dose audit test performed and be validated for sterility assurance levels using ANSI/AAMI/ISO 11137 – 2006 Parts 1, 2, 3, if the sterilizationmethod is gamma or e-beam radiation.

Typically, an FDA-regulated manufacturer that is producing a product in an aseptic cleanroom with a final product sterility level of 10-6SAL will specify that all materials required during the manufacturing process be validated and certified sterility to 10-6SAL. However, an FDA-regulated, terminally sterilized, non-implantable medical device manufacturer in a non-sterile cleanroom may specify that all cleanroom materials used in the process be validated and certified sterility to 10-3SAL.

It is in the best interest of the cleanroom materials manufacturer to reduce the average device bioburden levels during the manufacturing process to in turn reduce the level of gamma radiation required to terminally sterilize the product to the sterility assurance level required by the customer. It is also most cost effective to radiate the manufactured materials to the same sterility assurance level. Therefore most suppliers of sterile cleanroom materials validate their processes to deliver sterile clean-room reusable or disposable materials at 10-6SAL (sterility assurance level) to serve a broader, universal market. ANSI/AAMI ST67:2003 "Requirements for Products Labeled "Sterile" addressesrecommendations for garment sterility.

TEST METHODS FOR ETO/STEAM STERILIZATION

The preferred sterilization method for apparel in the U.S. is gamma sterilization based on validation using the ANSI/AAMI/ISO standards mentioned above. However,all the components used in the manufacturing of the cleanroom apparel must be compatible with the sterilization method chosen as well as be cleanroom compatible. Presently, gamma sterilization is the most cost effective method of sterilization for cleanroom materials. However, cleanroom apparel may be validated andsterilized using E-beam sterilization using the same ANSI/AAMI/ISO standards.

Cleanroom apparel may be sterilized using ETO. Sterility validation is performed using ANSI/AAMI/ISO 11135:1994.

Cleanroom apparel used in the United Kingdom and Europe may also be steam sterilized. However, steam sterilization of cleanroom apparel causes shrinkage and wrinkling of the reusable garment system. Sterility validation of steam sterilization is performed per ANSI/AAMI/ISO 11134:1993 for industrial facilities or ISO 13683:1997 for health care facilities.

TESTING OF FLAME RETARDANT FABRIC AND GARMENTS

Traditional flame resistant clothing is constructed of flame retardant treated cottons or an inherently flame resistant material, like DuPont Nomex®fiber. These garments will shed particles that will compromise the integrity of the cleanroom and contaminate the products and processes in the cleanroom. The FDA regulated industries mandate that if these garments are worn in a sterile cleanroom environment, they must be validated for sterility compatibilityas well as cleanroom compatibility.

NFPA 70E

Compliance to NFPA 70E in cleanroom environments requires that all personnel working on electrical equipment operating at greater than 50V wear arc-flash protective garments to prevent injury. Polyester is specifically prohibited under any circumstances when exposed to live electrical parts operating at greater than 50V. The automotive industry has been using cleanroom FR garments meeting ASTM F1506 for workers exposed to electric arc for several years in their cleanrooms and recently the pharmaceutical and semiconductor

industrieshave begun wearing these clean-room FR garments in their manufacturing cleanrooms.

CLEANROOM FLAME RESISTANT FABRIC

Dupont's filament Nomex®is used to create the flame-resistant characteristic in fabrics for cleanroom applications. Normal woven Nomex®yarn generates particles in the cleanroom; however, the filament Nomex®used in clean-room FR fabrics uses the same Nomex®chemical structure in a filament form to replace the fibrous forms used in most Nomex®fabrics. In most of the FR cleanroom fabrics filament Nomex®and carbon yarn is combined and woven into fabric. This resulting fabric is flame resistant, clean-room compatible,and static electricity dissipative.

CONSTRUCTION OF CLEANROOM FLAME-RESISTANT GARMENTS

Typical cleanroom garments constructed of cleanroom FR fabric meet NFPA 70E Category 1. Seam construction of cleanroom FR garments must comply with IEST-RP-CC003.3 (i.e., 100% Nomex®filament thread for sewing, serging of all rough edges and flat-feld seams, etc.) to assure cleanroom compatibility, durability of the seams, and encapsulation of particles. All other components (i.e., zippers with protective tape, protective snaps, tunnelized neoprene wrist closures, etc.) in the garment must be cleanroom compatible and flame resistant as well. Flame-resistant cleanroom garments must meet ASTM F1506 and be labeledas such to meet NFPA 70E.

VALIDATION OF CLEANROOM FR GARMENTS

The validation of the cleanroom flame-resistant garment system includes all the results of the tests performed to confirm cleanroom compatibility, gamma compatibility, and flame resistance. Testing of cleanroom FR garments must be performed to validate arc-flash resistance per ASTM F 1959 to determine the arc rating. The sterility of the garment per ANSI/AAMI/ISO 11137-2006 over time must be validated in the FDA-regulated industries as well as thedurability of flame resistance after many exposures of gamma radiation.

ADDRESSING THE COMPROMISE OF CLEANROOM PROTOCOL AND FLAME RESISTANT PROTECTION

The specifications of cleanroom compatibility, sterility compatibility, and flame resistance (both HRC Categories 1 and 2) characteristics are clearly defined by industry standards. Constant research and development of flame-resistant fabrics and the construction of flame-resistant cleanroom garments is being conducted by fabric and garment manufacturers worldwide and new dual-layer systems are available now that offer cleanroom compatibility, sterility compatibility,HRC 1 and 2 compliance, and wearer comfort.

A more in-depth presentation of this information and discussion of fabric and garment tests will be performed by a panel of industry experts at a technical session at ESTECH 2007, the annual technical meeting of the Institute of Environmental Science and Technology, April 29 – May 2, 2007 at Indian Lakes Resort,Bloomingdale, IL. Register on-line at www.iest.org.

References

1. "Improving the Repeatability and Reproducibility of the Helmke Drum Test Method" and "The Size Distribution of Particles Released by Garments During Helmke Drum Tests", Journal of the IEST 44, no.44 (Fall2001).

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