JAN EUDY

Apparel Considerations for Clean Manufacturing

While humans are the most significant threat to contamination in a cleanroom, this type of contamination is also the easiest to control.

The cleanroom industry is acutely aware of the many possible sources of contamination that threaten cleanroom operations. The most significant threat is also the threat that is easiest to control–the humans working in the cleanroom.

One of the most significant methods for reducing human contamination in the cleanroom is through a complete cleanroom uniform program. Cleanroom apparel is designed to capture and entrain particles and not allow contaminants to be dispersed into the cleanroom environment. Apparel protects the environment from numerous contaminants that are generated from the human body, including:

- Viable particles such as bacteria and yeasts
- Non-viable particles such as hair, dead skin cells, and dandruff
- Elements such as sodium, potassium, chloride, and magnesium

Table 1. Table of Recommended Garment Configurations from RP-3.3

Apparel Type	ISO 8 (m6.5 or 100,000)	ISO 7 (M5.5 or 10,000)	ISO 6 (M4.5 1,000)	ISO 5 (M3.5 100)	ISO 5 (or M3.5 for Aseptic10)	ISO 4 (M2.5 or 10)	ISO 3 (M1.5 or 1)	ISO 1 and 2
Inner Suit	AS	AS	AS	R	AS	R	R	R
Hair Cover	R	R	R	R	R	R	R	AS
Woven Gloves	AS	AS	AS	AS	NR	NR	NR	NR
Barrier Gloves	AS	AS	AS	AS	R	R	R	R
Facial Cover	AS	AS	AS	R	R	R	R	AS
Hood	AS	AS	AS	R	R	R	R	AS
Powered Headgear	AS	AS	AS	AS	AS	AS	AS	R
Frock	R	R	AS	AS	NR	NR	NR	NR
Coverall	AS	AS	R	R	R	R	R	R
2 Piece Suit	AS	AS	R	R	R	R	R	R
Shoe Cover	R	R	AS	AS	NR	NR	NR	NR
Boot	AS	AS	R	R	R	R	R	R
Special Footwear	AS	AS	AS	AS	AS	AS	AS	AS
Typical Frequency of Change	2x/week	2x/week	3x/week	1x/day	Per Entry	Per Entry	Per Entry	Per Entry

It is important to note that because the human body produces these contaminants in such large quantities, the cleanroom apparel may be overwhelmed. Therefore, change frequencies and garment system configurations must be evaluated for the room cleanliness that you want to achieve.

The Institute of Environmental Sciences and Technology (IEST) published the latest revision of the recommended practice for garments, IEST-RP-CC003.3, "Garment Considerations for Cleanrooms and Other Controlled Environments." This document is a tremendous resource for determining the fabric, garment system, and garment configuration for your cleanroom application. This recommended practice provides guidance for the selection of fabric, garment construction, cleaning, and maintenance of cleanroom garments; and testing of cleanroom apparel and components for use in aseptic and non-aseptic cleanroom environments.

Evaluation of fabrics using ASTM and AATCC test methods at 1X, 50X, 100X

Over the years, the contamination control industry has evolved unique, innovative fabrics and apparel to encapsulate humans working in the cleanrooms, thereby protecting the product and the processes from possible deleterious contamination. There are several ASTM (American Society for Testing and Materials) and AATCC (American Association of Textile Colorists and Chemists) test methods to evaluate these new fabrics.

- The weight of the fabric determines its strength and durability; however a lighter fabric contributes to operator comfort. Additionally, the Grab Tensile and Tongue Tear tests give an indication of the strength and durability of the fabric.
- The pore size is an indicator of barrier efficiency. The smaller the pore size, the more particles that will be entrained. Therefore evaluation of the pore size is important to the evaluation of the fabric used in construction of the cleanroom garment.
- MVTR (Moisture Vapor Transmission Rate) evaluates the ability to move moisture through the fabric and translates to more comfort to the operator. Moisture build-up causes the operator to feel hot due to the increase in humidity between the fabric and the body.
- Air permeability is the ability of a fabric to allow air to pass though it, which is quantified by the volume-to-time ratio per area. Air flow in heating and cooling processes, such as the cooling process of the body, contains contaminants which can be transferred to the prod-

Table 2. IEST-RP-CC003.3 Cleanliness Classification Chart

Category	Garment Type	Particle emission rate, 0.3µm and larger	G particles/min 0.5µm and larger
I	1 Frock	Less than 1,700	Less than 1,000
I	1 Coverall	Less than 2,000	Less than 1,200
I	3 Hoods	Less than 780	Less than 450
II	1 Frock	1,700 to 17,000	1,000 to 10,000
II	1 Coverall	2,000 to 20,000	1,200 to 12,000
II	3 Hoods	780 to 7,800	450 to 4,500
III	1 Frock	17,000 to170,000	10,000 to 100,000
III	1 Coverall	20,000 to 200,000	12,000 to 120,000
III	3 Hoods	7,800 to 78,000	4,500 to 45,000

Note: The particle emission rates shown for each of the garments types are proportional to the respective areas of fabric involved. The areas of the garments considered in the preparation of the table are as follows:

Garment Type	Average area, m^2 (both sides)	Average area, ft≤ (both sides)
Frock*	4.63	49.8
Coverall*	5.99	64.4
Hood*	1.03	11.0

*Medium size garments

uct. The lower the permeability or transfer of air from within the garment to the outside, the lower the contamination to the product.

◗ There are several tests to determine the fabric's splash resistance or ability for the fabric to resist absorption of liquids. These characteristics allow the operator to be better protected from spills in the cleanroom environment.

◗ Static Decay and Surface Resistivity testing are performed to document that the fabric is static dissipative. Fabrics outside of the static dissipative range of 105 to 1011 Ohms/Square may cause an electrical discharge and subsequent product failure.

All testing of fabrics should be performed over time and exposure to gamma radiation. The results over time should not be significantly different from the original results; therefore demonstrating durability of the fabric characteristics over time.

These same tests may be used in the evaluation of the garment system (fabric and components of garments) to withstand chemicals used in the cleaning of the cleanrooms, the cleaning of the garments, the application of gamma radiation, and even in some cases, autoclaving.

Evaluation of seams and components via RP-3.3 recommendations

Currently all reusable cleanroom garments are constructed of 100% polyester and durable carbon threads and cleanroom-compatible snaps, zippers, and binding. These garment systems are lightweight, non-linting, economical, and control both non-viable and viable particle contamination. The IEST document details recommended seam construction and components for cleanroom garments.

Evaluation of ability of garment system to entrain particles using body box testing at 1X, 50X, 100X

All Cleanroom garment systems will deteriorate over time due to wear, wash/dry/wear cycles, and sterilization. The ability of the garment system as a barrier to contamination and its filtration efficacy is evaluated in a "Body Box" test. The "Body Box" is a mini-cleanroom. The particle cleanliness of the area is determined by typical room particle measurement with a particle counter and probe. This is the background. The operator inside the body box wearing the garment system performs a series of prescribed movements to the prescribed cadence of a metronome. The particle measurement during the prescribed movements determines the garment system's efficacy.

Evaluation of the cleaning of the garment system

The latest revision of IEST-RP-CC003.3 (Table 2) details recommended parameters for the cleaning of cleanroom garments and revised the performance of the Helmke Tumble test for particle cleanliness. This revised version has established test parameters that, when followed precisely, produce test results that are more robust, repeatable, and reproducible over various test laboratory settings. The Helmke Tumble test is specifically designed to test the particle shedding of a garment over time. This test evaluates the integrity of the garment as well as the cleanroom garment laundry's overall ability to render the garment item "particulately clean." The Helmke Tumble test evaluates particle shed at 0.3 microns and larger. The ASTM F51 test evaluates the same characteristics but at a larger micrometer particle (> 5 microns) and fibers. This test is less reproducible due to technician variability over various laboratory settings. Additionally, extraction testing can be performed to determine if residual elements and/or compounds are present in the cleanroom garments after cleanroom laundering.

Validating a Cleanroom Garment System Supplier

There are numerous steps involved in validating a cleanroom garment system supplier. These steps include:

◗ Complete an Installation Qualification that audits the garment-system supplier and evaluates their qualifying tests and testing results.

◗ Perform an Operation Qualification that includes a trial at the customer site and evaluation of the customer-qualifying tests and results.

◗ Conduct a Performance Qualification that includes evaluation of the performance of the fabric and garment system over time within the customer's cleanroom.

All of these steps are necessary to ensuring that your garment system meets your expectations and can fully service your apparel needs.

Jan Eudy is Corporate Quality Assurance Manager for Cintas Cleanroom Resources, 6800 Cintas Blvd, Cincinnati, OH 45262. She can be reached at 845-564-6550 or eudyj@cintas.com.