Cleanroom Garment Programs:

A Comparative Analysis of Launderable and Limited Use Solutions

Part 1: Selecting a Cleanroom Garment System

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About The Author

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Jan Eudy is a cleanroom/contamination control and microbiological subject matter expert with more than 30 years of industry experience in semiconductor, microelectronics, pharmaceutical, biopharmaceutical, medical device, food manufacturing, compounding pharmacies, aerospace and automotive.

As the corporate quality assurance manager for Cintas Corp., Jan oversaw research and development, directed the quality system and ISO registration at all cleanroom locations and supported validation and sterile services. During her time with the company, Jan also implemented and maintained the HACCP risk management program at all Cintas industrial laundries. She is also a Past President and Fellow of the Institute for Environmental Sciences and Technology **(IEST)**.

Selecting a Cleanroom Garment System

All cleanrooms and controlled environments are aware of the many possible sources of contamination to their products, processes and facilities. The most significant threat is also the threat that is easiest to control – the humans working in the cleanroom.

The recommended human containment level of a cleanroom is based on how critical the product is and how clean the processing areas are. One of the methods for reducing human sourced contamination in cleanrooms and controlled environments is through a complete cleanroom garment program.

Cleanroom apparel is designed to capture, entrain and prevent operator-generated particles from being dispersed into the controlled environment. Cleanroom garments capture numerous contaminants that are generated from the human body, including:

Viable particles such as bacteria, mold and yeast.

Non-viable particles such as hair, dead skin cells and dandruff.

Elements such as sodium, potassium, chloride and magnesium.

ESD-compatible cleanroom garments are recommended for certain microelectronic cleanrooms or environments with a heightened sensitivity to static. These garments can be flame retardant and designed to protect the cleanroom operator from arc flashes. ESD garments also protect sensitive products and processes from contamination like:

- **Static**
- **Electric currents**
- **Charges**

Disposable, limited-use cleanroom garments, also known as personal protective equipment (PPE), protect the cleanroom environment, the product and the personnel from external hazards such as:

- **Liquids**
- **Powders**
- **Biological agents**
- **Chemicals**
- **Radioactive materials**

Evaluating Cleanroom Garments

The fabric serves as the primary barrier in both types of cleanroom garments:

Disposable, limited-use

Reusable, launderable

Both types of garments undergo intensive testing to assess their durability, cleanroom compatibility, gamma compatibility and other characteristics.

Cleanroom garments are often evaluated through a variety of standardized test methods, many of which are outlined in IEST's Recommended Practice RP-CC003 (Garment System Considerations to Cleanrooms and Other Controlled Environments). Garment evaluations include:

- **Basis weight:** Determined by ASTM D3776: Standard Test Methods for Mass per Unit Area (Weight) of Fabric which describes the fabric thickness and determines strength and durability. Lighter fabrics can enhance operator comfort.
- **Grab Tensile (MD & XD):** Using test method ASTM D5034: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) and ASTM D5035: Standard Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method) to indicate the strength and durability of the fabric.
- **Trapezoidal Tear (MD & XD):** ASTM D1117: Standard Guide for Evaluating Nonwoven Fabrics includes the test method for determining the strength and durability of disposable, single-use nonwoven fabrics.
- **Mean Pore Size:** Also known as the average space, measured in microns, between the weaves of polyester that make up the fabric in a launderable garment. The number of particles emitted from the operator's skin and clothing can be reduced with a smaller pore size. The smaller the pore size, the more particles will be entrained. Some reusable fabrics are calendared (pressed between drum rollers) to reduce the pore size to 1µm, but over time, with extended use and excessive wash cycles, pore size can increase tenfold and affect cleanroom compatibility. Mean pore size is measured though a number of methods. The microscopic method is simple and effective but limited to evaluating pore sizes greater than 5µm. A specialty "porometer" device is recommended for measuring pores less than 5µm.

- **Particle Filtration Efficiency** for launderable fabrics can be determined via particle penetration tests as described in IEST-RP-CC003.4 Section B1: Filtration Efficiency-Fabrics. Similar to mean pore size, filtration efficiency tests validate a material's ongoing suitability for encapsulating operator-generated particles and contaminants, helping to determine the useful life of a reusable fabric. The fabric's ability to filter particles is measured and reported as a "percent retention" in this evaluation method. For disposable materials, such as facemasks, particle filtration efficiency can be evaluated by *ASTM F2299: Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres*. This test similarly evaluates the effectiveness of specific fabrics in filtering out particles.

- **Moisture Vapor Transmission Rate (MVTR):** Measured according to ASTM E96/E96-05: Standard Test Methods for Water Vapor Transmission of Materials, MVTR determines the amount of water (in grams) that passes through one square meter of fabric in 24 hours. Higher MVTR values enhance operator comfort by reducing moisture build-up, which can otherwise lead to increased humidity and heat between the fabric and the body.

- **Air permeability:** Using test method ASTM D737: Standard Test Method for Air Permeability, the fabric is evaluated for its ability to allow air to pass through 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 product. Lower air permeability reduces the risk of transferring contamination from the garment to the product or process by minimizing airflow between the garment and the environment.

- **Bacterial Filtration Efficiency:** ASTM F2101: Standard Test Method for Evaluating the Bacterial Filtration Efficiency, tests the bacterial filtration efficiency of fabrics. This measurement indicates the garment's ability to entrain bacteria.

- **Splash resistance:** The ability for the fabric to resist absorbing liquids. This allows the operator to be better protected from spills in the cleanroom environment. Splash resistance is determined by:

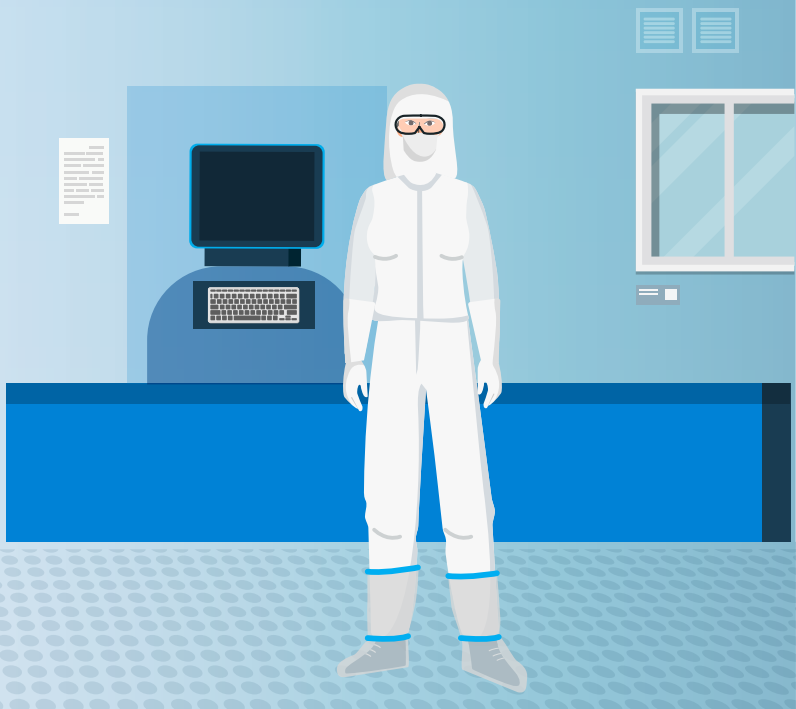
  - *The AATCC Test Method 22:* Water Repellency: Spray Test measures the ability of a fabric to resist wetting. Fabric performance may be enhanced with agents other than polyester. This becomes another layer of protection between the operator and the environment. Fabrics designed to have higher hydrostatic values will allow less particles to pass from operator to product.

  - *The AATCC Test Method 127:* Water Resistance: Hydrostatic Pressure Test 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.

- **Static decay and surface resistivity:** Tested using ANSI/ESD SMT 2.1-2018: ESD *Association Standard Test Method for the Protection of Electrostatic Discharge Susceptible Items – Garments -Resistive Characterization*. Performed to document that the fabric is static dissipative. Fabrics outside of the static dissipative range of 1 X 105 to 9.99 X 1010 ohms/square may cause an electrical discharge and subsequent product failure.

All fabric testing should be performed over time and with exposure to gamma radiation (if applicable). The results should remain consistent with the original findings and material specifications, demonstrating the long-term durability and stability of the cleanroom fabric's characteristics.

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, and the application of gamma radiation and autoclaving the garments (if sterilizing is a requirement for the material).



Types of Garment Programs

Cleanroom garment programs should be designed for the specific processes and products produced in the cleanroom or controlled environment. Cleanroom garment programs can be:

Fully disposable, limited-use cleanroom garments.

Fully reusable, launderable cleanroom garments and launderable cleanroom undergarments.

- **Customer-owned goods (COGs)**, or purchased garments, which are either self-maintained or managed by a cleanroom garment laundry provider.

- **Leased/rented** garments from a cleanroom garment laundry provider.

Combination of limited-use and launderable cleanroom garments.

- **Launderable undergarments**, like scrubs, may also be used as a substitute for operator streetwear in conjunction with other limited-use/launderable outer garments.

When determining what kind of cleanroom garment program is best for your cleanroom, it's important to consider:

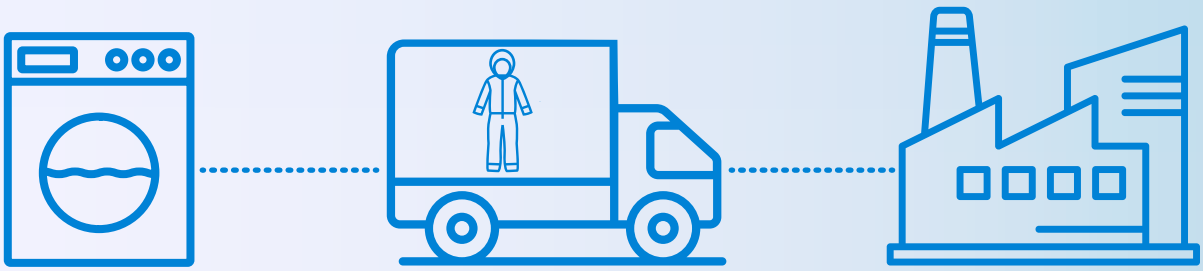
- the ISO cleanroom classification
- the products being manufactured
- the processes being performed
- the number of operators wearing cleanroom garments
- the environmental impact of disposing of limited-use garments vs. laundry water and energy use.

It's important to note that specialized recycling programs are available for the disposal of limited-use garments in an environmentally friendly manner for common garment materials (polypropylene, polyethylene, etc.). The availability and feasibility of such recycling options may depend on location but should be considered as part of the overall cleanroom garment management strategy.

Limited-Use Garments

Disposable, limited-use cleanroom garments are recommended when their advantages align with operational needs. For example:

- **Limited Personnel:** When the cleanroom has a small number of operators (usually fewer than 10), it's more economical to use disposable garments because most cleanroom garment laundry service contracts include minimum weekly charges over a long-term contract period.
- **Shift and Usage Fluctuations:** If the number of operators and/or shifts in the cleanroom is not consistent, committing to laundry service minimum requirements can be cost prohibitive.
- **Training Periods:** Newly hired cleanroom operators should wear disposable garments during training.
- **Hazardous Substances:** Disposable garments should be used in cleanrooms where operators are working with hazardous liquids, powders, toxic drugs, radiopharmaceuticals, biologicals, or chemicals. Cleanroom laundries will not accept garments contaminated with these substances.
- **Staining and Damage:** Many chemicals, dyes/inks and lubricants will stain or damage reusable, aunderable cleanroom garments and laundries will charge for any stains or damage to the reusable cleanroom garments.
- **Distance from Laundry:** When a cleanroom is located far from the cleanroom laundry facility, shipping costs and logistical challenges increase.
- **Contract Cleaning:** For facilities that use contract cleaning companies or cleanroom housekeeping personnel, managing additional logistics for reusable garments may be more complex.
- **Installation and Maintenance:** Frequent installation and maintenance of robotics, tools, or other manufacturing equipment may increase the risk of garment damage.



Launderable Garments

In other cases, laundered garments are recommended. For example:

- **High Volume of Operators:** When the cleanroom has large numbers of operators who work frequently, over many shifts, making the long-term investment in reusable garments can be more cost-effective compared to disposable options.
- **Consistent Usage:** Regular and predictable pattern of cleanroom use allows for efficient garment management and laundering processes.
- **Long-Term Cost Efficiency:** The total cost of ownership, including laundering and maintenance, may be lower over time compared to the recurring expense of limited-use garments.
- **Environmental Considerations:** If considering sustainability and reducing waste, reusable garments align with environmental responsibility goals by minimizing single-use waste.
- **Customization Needs:** Specialized garment features and customizations can be better managed through a reusable garment program. For example, if an operator is very tall and requires an unusual size.
- **Proximity to Laundry:** When the cleanroom is located within a practical distance from a cleanroom laundry service, it is more feasible to manage reusable garments without incurring excessive shipping costs or requiring excess garments in rotation.

Sterile Garments

If the cleanroom garments (launderable or limited-use) are gamma sterilized for use in certain life science controlled environments (i.e. pharmaceutical applications), they must be treated with an additional process and validated to a sterility assurance level of 10-6 SAL per ANSI/AAMI/ISO 11137: *Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices and ANSI/AAMI/ ISO 11137: Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose.*

The device bioburden analysis is performed per ANSI/AAMI/ISO 11737: Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of the Population of Microorganisms on Product. The VDmax sterility analysis is performed per ANSI/AAMI/ISO 11737: *Sterilization of Medical Devices – Microbiological Methods – Part 2: Test of Sterility Performed in the Validation of a Sterilization Process.*

Once the sterilization dose has been established, the contract gamma irradiator performs a dose mapping of the final packaged product. After gamma sterilization of each lot, the contract gamma irradiator will issue a Certificate of Processing that includes the minimum and maximum established dose and the minimum and maximum delivered dose. The cleanroom garment program supplier will then issue a Certificate of Sterility.

It is important to note that the sterilization process can cause accelerated wear on garment materials. This is less critical for disposable garments, as their use is limited, and more important when utilizing launderable garments, as the lifecycle can be significantly reduced.

Key Takeaways

There is no "one size fits all approach" in finding the right garment system. The decision should be based on factors including but not limited to cleanroom class, manufacturing processes and exposure, number of operators and shift consistency, geographic proximity to laundry service, and sterile requirements. There are many ways to best outfit an operator to reduce risk, increase yield and enhance compliance.