Cleanroom Garment Programs:

A Comparative Analysis of Launderable and Limited Use Solutions

Authored by Jan Eudy,
Cleanroom and Contamination Control – Independent Subject Matter Expert

Table of Contents:

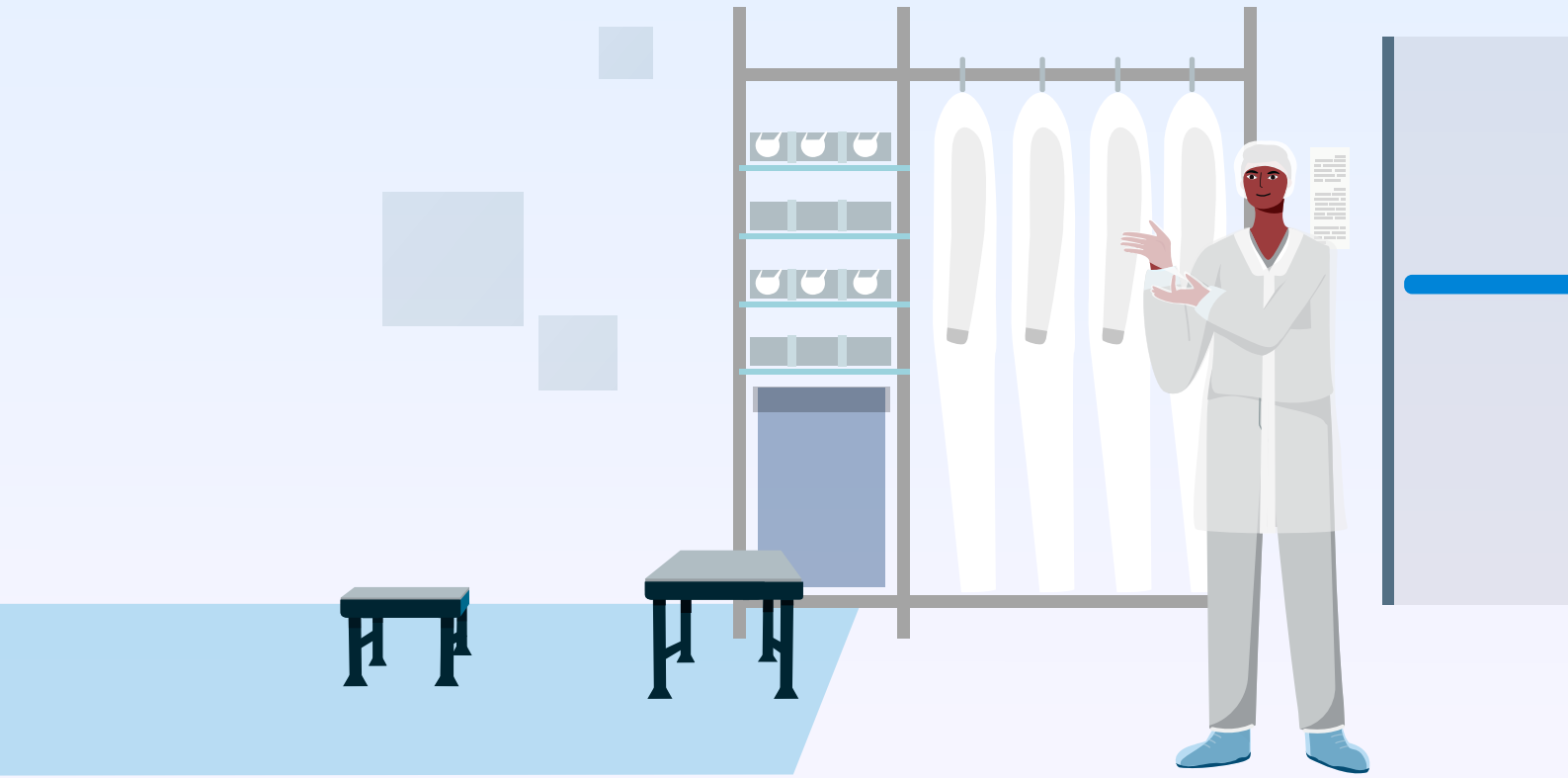
About The Author

Authored by Jan Eudy,
Cleanroom and Contamination Control – Independent Subject Matter Expert

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)**.

Part 1: Selecting a Cleanroom Garment System



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:

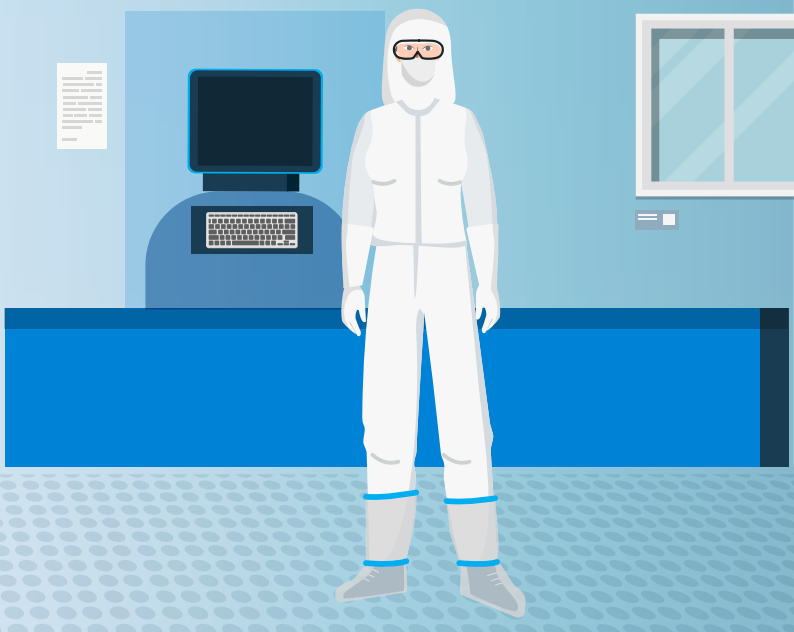
  - *The AATCC Test Method 22:* Water Repellency: Spray Test measures the ability of a fabric to resist wetting. Fabric performance may be enhanced with agents other than polyester. This becomes another layer of protection between the operator and the environment. Fabrics designed to have higher hydrostatic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

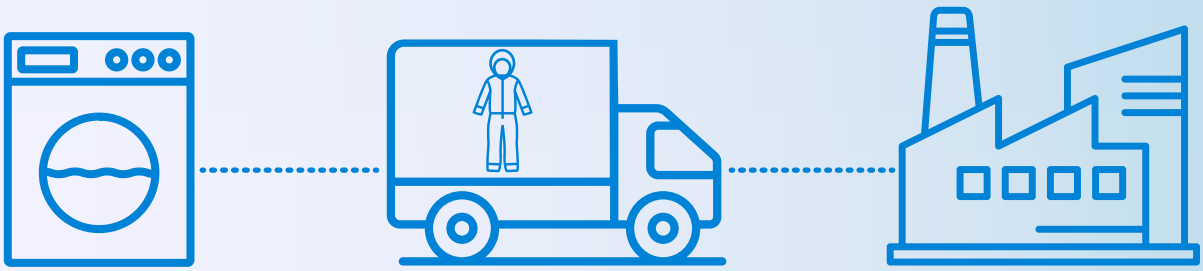
- the ISO cleanroom classification
- the products being manufactured
- the processes being performed
- the number of operators wearing cleanroom garments
- the environmental impact of disposing of limited-use garments vs. laundry water and energy use.

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.

Part 2: Managing a Launderable Cleanroom Garment Program

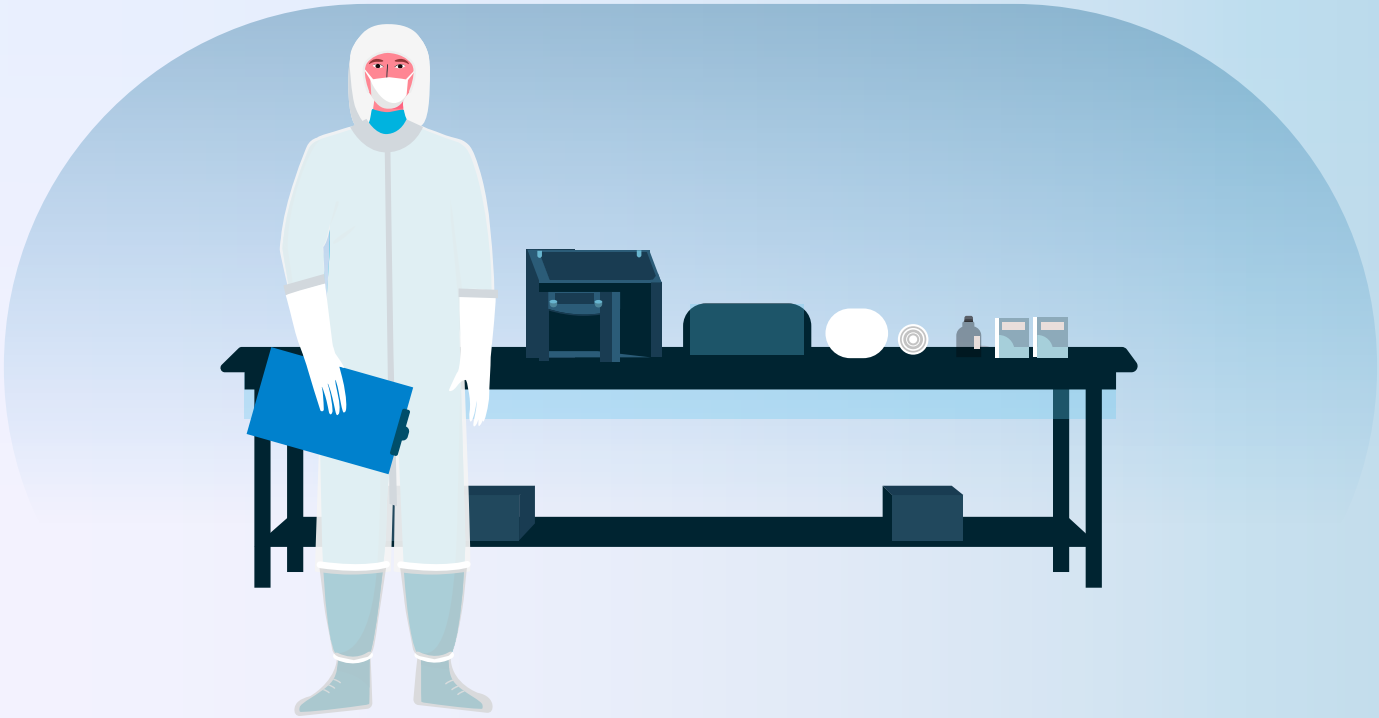
Managing a Launderable Cleanroom Garment Program

If utilizing a form of launderable apparel as part of a facility garment program, understanding the unique materials and styles, washing techniques, and ongoing material testing is critical to successfully managing the program for best outcomes.

Cleanroom laundry service providers should have a validated garment start-up program and be able to provide documentation of the garment styles, the fabrics and accessories (zipper, boot sole, sewing thread, etc.), number of launder cycles, laundry process and gamma sterilization doses (if applicable). It is recommended that end users regularly audit their cleanroom laundry provider and review the documentation of their Quality Management System (QMS). The QMS should contain standard operating procedures (SOPs) for every step in the cleanroom garment laundering and delivery process.

Most cleanroom garment laundry providers base their QMS on ISO 9001, *Quality Management Systems - Requirements and ISO 13485, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes* (which is harmonized with Code of Regulations - CFR Part 820, *Quality Systems Regulation)*. During an onboarding or audit, a review of the current Disaster Prevention/Response/Recovery Plan should be discussed to ensure regularly scheduled delivery of the cleanroom garments as agreed upon throughout the contract period.

A missed garment delivery could result in a facility shutdown and understanding the entire garment service process is a crucial part of mitigating risks.



Selecting a Garment Style

The type of cleanroom garment should be compatible with the level of contamination control and air cleanliness requirements of the environment. For example:

Coveralls with attached hood and boots feature a one-piece design with attached hood and boot/shoe covers. They are ideal for highly critical environments where complete operator coverage is required. Coveralls with attached hood and boots offer excellent protection against particulate contamination.

Coveralls provide full body coverage and may be paired with a separate hood and boot/shoe cover as needed. They are used in a range of cleanroom environments and are suitable for applications requiring stringent cleanliness levels.

Frocks are typically knee-length or mid-calf with snap or zipper closures. They have snap or cuff closures at the wrist and are typically used in ISO Class 7 or 8 Cleanrooms.

Smocks are typically knee-length or mid-calf, with an open back or tie closures. These are used in less critical environments where full-body coverage is not required, and comfort and ease of donning are more important than cleanliness.

Lab Coats, which are distinguished from frocks because they have pockets, are usually knee-length and include button, snap, or zipper closures. They typically feature cuffs and a collar and are mainly used in laboratory-type controlled environments with less stringent cleanliness requirements.

Aprons can be worn over other garments to provide additional protection to the front of the body. They are useful in environments where splashes or spills are possible, but full-body coverage is not required.

Sleeves can be worn over the arms of a coverall or frock to protect the lower arm areas from liquids.

IEST-RP-CC003, *Garment Considerations for Cleanrooms and Other Controlled Environments section 5.3 Design of Apparel* states that "the primary purpose of cleanroom apparel and accessories is to contain particles and control microorganisms generated by the wearer, thereby protecting the process and the product." Section 5.4 *Construction of Apparel* describes the sewing thread, and the seams used in the manufacture of cleanroom garments. Cleanroom garment manufacturers use guidelines in ASTM D6193: *Standard Practice for Stitches and Seams* for the number of stitches per inch and construction of seams. Section 5.4.3 describes the entrapment areas, which are additions to the cleanroom garment that are known to trap unwanted contamination and debris and therefore should be avoided in the manufacturing of cleanroom garments. Section 5.4.4 *Findings* describes the accessories that can be used in the manufacture of cleanroom garments. Appendix B, *Guide to Measuring Cleanroom Garments* assures the end-user that the reusable, launderable cleanroom garments manufactured will have the same measurements no matter what garment manufacturer is used.

Appendix A – Recommended Garment System Configurations Applicable to Various Air Cleanliness Environments describes the different garment styles used for ISO Class 3-8 cleanrooms and sterile ISO Class 5 cleanrooms, whether recommended, not recommended or application specific as well as suggested frequency of change.

Selecting a Garment Fabric

Launderable cleanroom garment fabrics are often made from a combination of polyester and carbon. Any carbon yarn must be cleanroom- and gamma-compatible. Carbon yarn is used to reduce any electrical charge and attraction between particles around the operator. Particles, both living (viable) and non-living (non-viable), are small and are affected by the electrical fields naturally created by operator movement. An electrical field will cause particles to become charged, attracting them to oppositely charged particles. Particle movement is reduced if the electrical field is reduced.

Conductive thread is woven in a grid or stripe pattern to dissipate this static electricity buildup. Cleanroom garments used in the life science industry typically have a carbon stripe pattern. The percentage of carbon in the cleanroom fabric is dependent on the dissipative fabric specifications of the customer.

IEST-RP-CC052, *Understanding, Identifying, and Controlling Electrostatic Charge in Cleanrooms and Other Controlled Environments Appendix D Cleanroom Garment Considerations for An Electrostatic Charge Control Program* describes the cleanroom garment fabrics, the dissipative fabric specifications, garment construction, garment failure mechanisms and garment testing.

Garments that limit electrostatic discharge (ESD) typically have at least a 5mm carbon grid pattern and should be tested on a routine basis after laundering cycles because their resistance properties can be affected by high temperatures, cleaning solutions and fabric softeners. Many garments can be effective after more than 100 laundered cycles if handled properly. Garments that become permanently stained or degraded by substances, especially those used in the electronics manufacturing process, may no longer provide the intended static dissipative characteristics and should be discarded and replaced.

Cleanroom garment launderers typically have a validated "core stock" of cleanroom garments in rotation. Validation documents provide information about the makeup of the garments, the initial testing of the fabric, any other components used in the manufacturing process, and test results after numerous launder cycles, gamma sterilizations and wear cycles.

IEST-RP-CC003, *Garment Considerations for Cleanrooms and Other Controlled Environments Appendix C – Recommended Requirements for Garments That Protect (In Short Duration) Fire and Arc Flash Hazards* describes the fabric, styles and manufacturing of arc flash and fire retardant, reusable, launderable cleanroom garments. Monofilament Dupont Nomex™ is the only National Fire Protection Association (NFPA) approved cleanroom garment yarn used to manufacture cleanroom garment fabrics that protect against fire and arc flash hazards.

Other launderable cleanroom garments are often made from synthetic materials such as:

- **High-density continuous filament polyester**
- **Combinations of high-density continuous filament polyester and ESD carbon yarns**
- **Spunbonded polyolefin like Tyvek®**
- **GORE-TEX®**
- **Nomex® such as Maxima® FR**

The cleanroom garment fabric type should be based on the end user's number of operators working in the cleanroom, the processes done inside the cleanroom, the number of cleanroom garments changed per shift/per day/per week and if the cleanroom garments are gamma sterilized.

Anti-Static **Liquid- Repellent** **Non-Linting**

The Garment Cleaning Process

Cleanroom operators should doff the garments and place them in a dedicated, covered, lined container to prevent further contamination in the gowning area. Boot and shoe covers should be placed in separate containers from frocks, coveralls and hoods. Any cleanroom garment item requiring stain removal, repair or replacement should be segregated and labeled. Depending on the type of laundry service agreement, a representative from the cleanroom garment laundry will retrieve all soiled garments during the delivery of the cleaned garments.

When the soiled cleanroom garments are received at the cleanroom laundry facility, they are scanned, sorted and inspected for damage. Any disposable items like shoe covers, bouffant caps, masks and gloves are separated from the reusable garment items and placed in a trash receptacle. Pens, badges and other items are segregated to be returned to the customer with the next clean laundered garment shipment.

Garments that require repair or replacement are removed from the load. Damaged garments will be repaired, if possible, and reunited with the garment inventory as soon as possible. When the wash loads are created and queued, boots are laundered separately from hoods, frocks and coveralls. Colored garments are separated from white garments. Undergarments are washed separately from outer cleanroom garments.

The interior of cleanroom garment washers is made from grade 304 stainless steel and designed with a pass-through chamber. Garments are loaded into the washers on "the soiled side" and unloaded in a certified ISO 3, 4, or 5 cleanrooms (depending upon end user requirement) on the other side.

Because polyester fabric is hydrophobic, it requires a special wash formula. To get the correct mixture of water, wash chemical and mechanical agitation, the wash load weight is typically 75% - 80% of the rated load weight of the washer. Each washer is programmed with several wash formulas. The wash cycle formula is computer-controlled to the amount and type of water dispensed, temperature of wash or rinse cycle, amount and type of wash chemical used and duration and mechanical action of each step of the wash formula. The initial decontamination step consists of filtered to at least 2.0 µm softened or reverse osmosis (RO) water, a filtered nonionic surfactant (detergent), and may contain additive chemicals to control microbial bioburden or removal of stains or heavy soiling.

During the rinse steps, filtered, softened or RO water is used to remove the wash chemicals thoroughly. There is a final 0.2µm filtered multi-megohm (as close to 18 megohm) deionized (DI) water rinse. During the decontamination step, the temperature of the water must reach 60°C or 140°F to meet CDC guidelines for the removal of microorganisms.

To reduce wrinkles and shrinkage, the temperature range of the rinse cycles should be gradually reduced to room temperature. Because human skin is slightly acidic, the final pH of the washed garment should test between pH 5.5 – 6.5. An alkaline pH of greater than 7.5 will cause skin irritation when the operator is wearing the cleanroom garment. Over time, a high alkaline pH will cause alkali hydrolysis of the polyester molecule and degradation of the cleanroom garment's fabric.

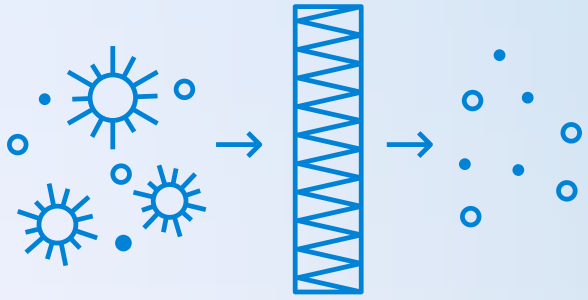
As part of the QMS Standard Operating Procedures for the maintenance, cleaning and calibration of the water system, the washer and the various wash formulas are created and documented. The efficacy of the water system is based on the water source, the maintenance, cleaning and calibration of the water system. The efficacy of cleaning of the garments is based on the maintenance, cleaning and calibration of the washer and calibration and dispensation of the wash chemicals.

Washed garments are then loaded into a one-pass HEPA or ULPA filtered, grade 304 stainless steel dryer inside the certified ISO 3, 4, or 5 cleanrooms. The dryers are underloaded to ensure completely dried garments. The drying temperatures are to be no higher than 60°C or 140°F and should be gradually reduced to room temperature over the duration of the drying cycle to avoid wrinkling, shrinkage or premature fabric degradation caused by excessive heat. The efficacy of continuing the particle removal in the drying process is based on the maintenance and calibration of the dryers.

When cleanroom garments are removed from the dryers, they are folded to be easily donned by the cleanroom operators. All identifying labels and inventory tracking mechanisms (barcodes, RFID tags, etc.) should be visible.

The packaging for cleanroom garments should be cleanroom- and gamma-compatible (if applicable) and sealed securely when the cleanroom garment item is placed inside the individual bag and residual air evacuated. The scanned, individually packaged cleanroom garments are sorted by size, color and type before being placed in labeled protective containers to be delivered to the customer. If necessary, the garments are sent to the contract gamma sterilizer for irradiation before being sent to the customer. The gamma radiation dose is validated to achieve a 10-6 sterility assurance level (SAL).

A schematic of the entire cleanroom garment laundry cycle is found in IEST-RP-CC003, *Garment Considerations for Cleanrooms and Other Controlled Environments Figure 13, The Garment Cleaning process.*



Testing Launderable Garments

All cleanroom garments should undergo continuous testing to ensure ongoing compatibility with the controlled environment over the lifecycle of the garment. Cleanroom laundry service providers should conduct several tests designed to evaluate the garment in both a "static" state and "in-process." At a minimum, these tests should assess cleanliness, efficiency and lifecycle, as well as electrostatic discharge (ESD) performance.

Common garment tests for evaluating cleanliness include:

- **The Helmke-Yeich (HY) Tumble Drum** test is widely used to provide evidence and assurance of the garment particle cleanliness after cleanroom garment laundering or manufacturing of disposable, single-use cleanroom garments. The Helmke drum test method is used to quantify dislodged particles (0.3µm, 0.5µm, 1.0µm, 3.0µm, 5.0µm and 10.0µm) from woven, nonwoven and coated fabric garments through the tumbling of the garments in a rotating drum attached to a discrete air particle counter over ten minutes. Table D2. *Helmke Garment Cleanliness Classification* in IEST-RP-CC003, *Garment Considerations for Cleanrooms and Other Controlled Environments* classifies the category level of particle cleanliness for a medium size frock or coverall or three hoods. Category 1 particle cleanliness is recommended for all cleanroom garments used in ISO Class 3-8 Cleanrooms.

- The ***ASTM F51 Alternative In-Plant Method for Particulate Sampling of Clean Room Garments*** may be used to measure particles greater than 5.0µm and fibers. This test is used only for fabrics with some porosity. During the test, the fabric is secured on a stainless steel, one square foot frame and vacuumed with an apparatus containing a 45-mm-diameter filter at a controlled constant volumetric flow rate. The filter is placed in a petri dish and particles greater than 5.0µm and fibers are microscopically enumerated at 100X magnification. Table D1. *Releasable Particle Garment Cleanliness in IEST-RP-CC003, Garment Considerations for Cleanrooms and Other Controlled Environments* classifies the maximum releasable particles and fibers per 0.1m2 of fabric as Class A, B, C, D, and E. Class "A" is recommended for all cleanroom garments.

  - ***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*** may also be used. This general method counts airborne particles in the controlled environment using an air particle counter (APC). In addition to ASTM F51 that tests the garment itself, testing the air inside the critical environment where garments are exposed can provide additional data. This method is especially useful in testing/monitoring during the folding and packaging process.

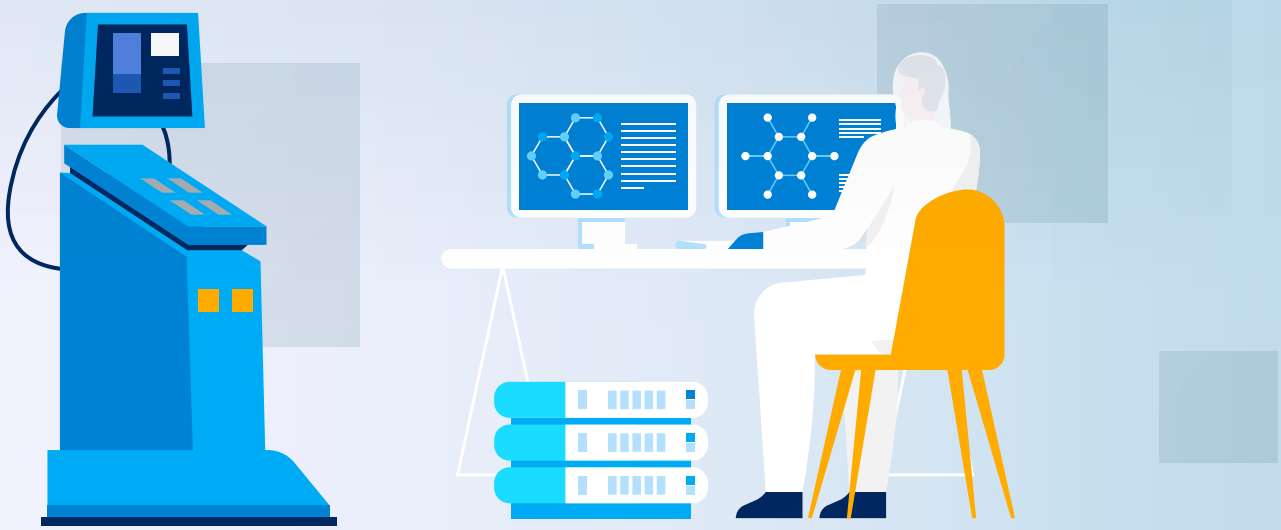
- The **Body-Box Test** assesses the particle dispersion, filtration efficiency and ability of the garment to serve as a barrier to contamination. The Body-Box is a small replica of a cleanroom environment. The air particle cleanliness of the Body-Box is determined by in-room air particle measurement procedures using an air particle counter and probe. The operator inside the Body-Box is wearing the garment while performing a series of prescribed movements to the prescribed cadence of a metronome. The particle measurement during the prescribed movements determines the garment's efficacy.

Common tests for evaluating garment filtration efficiency and lifecycle wear include:

- **Filtration Efficiency for Fabrics**, as outlined in **IEST-RP-CC003.4 Section B1**, involves clamping a section of garment to a holder and passing air with a known number of particles and sizes through it.

  In this particle penetration evaluation, the fabric's ability to filter particles is measured and reported as a "percent retention." Measuring filtration efficiency is crucial because a garment may pass its cleanliness specification in a static test, such as the Helmke-Yeich Tumble Drum, yet still be over-worn or over-washed. In such cases, it may no longer effectively trap particles in a controlled environment.

- **Mean Pore Size** measures a fabric's average pore size and can determine if the polyester weave has "degraded" and opened over time. This measurement serves as an indicator for a garment's lifecycle and ongoing efficiency. Mean pore size is essential because garment materials that pass other cleanliness tests might be "clean" but not effectively trap contaminants if their fabric weave has loosened due to wear, washing, and drying. For measuring fabrics with pore sizes greater than 5.0 µm, a microscope can be used to assess the fabric weave. For pore sizes smaller than 5.0 µm, a specialty porometer or similar apparatus is required.



Common tests for evaluating garment ESD characteristics include:

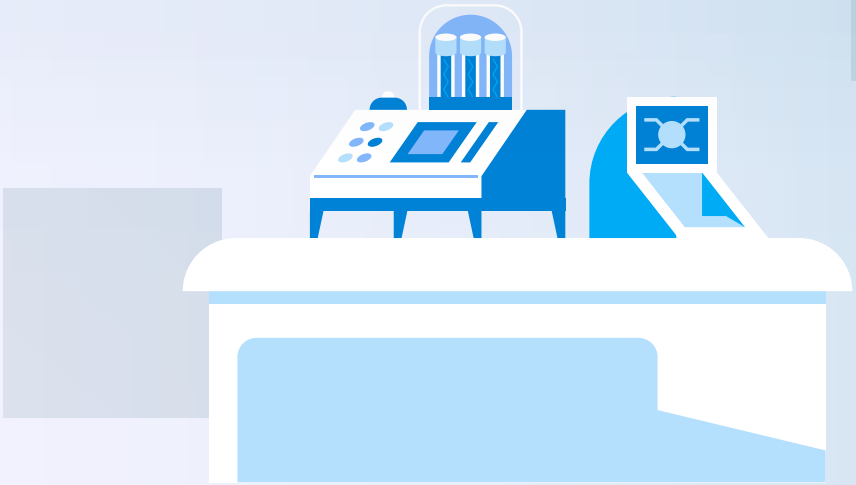
- **ANSI/ESD STM 2.1, *Garments – Resistive Characterization*** describes the point-to-point testing using five-pound weighted probes performed on ESD garments used in cleanrooms and other controlled environments.

  - **Category 1 ESD garments** consist of a carbon threaded grid matrix with no ground point. The ESD coat suppresses fields on the person and their street clothing. The test limit is < 1.0 X 1011 Ω.

  - **Category 2 ESD garments** consist of a carbon threaded grid matrix with a ground point. The ESD coat suppresses fields on the person and their street clothing and grounds the garment when tethered to a ground point. The test limit is <1 X 109 Ω. Some disposable, single-use and reusable, launderable cleanroom garments meet Category 1 and Category 2 ESD criteria. Category 1 and Category 2 ESD garments are typically worn in controlled environments or ISO 7 or 8 cleanrooms.

  - **Category 3 ESD garments** consist of a carbon thread grid pattern (5mm) woven into garment material to provide a path for static charge dissipation and field suppression. There is electrical continuity from the hood to coverall to boots and wrist cuffs in the Category 3 ESD Cleanroom garment system. The boot soles have sufficient conductivity to continuously transfer body and garment voltage to a conductive or dissipative floor which grounds the operator. The test limit is <3.5 X 107 Ω. Category 3 ESD garments are constructed to be worn in ISO 6 certified cleanrooms.

- **The Body Voltage or Walking Test** based on ANSI/ESD STM 97.2 *Footwear Flooring System – Voltage Measurement in Combination with a Person*, measures the volts generated by the body. An operator wearing a Category 3 ESD Cleanroom garment system walks a prescribed pattern on a floor. The test limit is < 100 Peak volts.



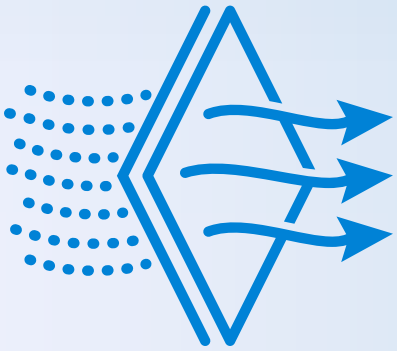
Each test outlined has its strengths and weaknesses, and no single test fully encompasses all aspects of a thorough evaluation. For example:

- The **Helmke-Yeich Tumble Drum** test is reliable for evaluating overall material cleanliness down to the smallest sub-micron particle size. However, it cannot determine whether the material is still effective as a filtration barrier after extended wash cycles. The results from this test are typically trended to evaluate that the cleanroom garment laundry process remains in control to achieve Category 1 particle cleanliness of every lot laundered. It should be noted that the Helmke Tumble Drum test does not assess releasable particles greater than 10.0 µm.

- **IEST's** "filtration efficiency" test or "mean pore size" evaluation is best suited for assessing the ongoing effectiveness of the material in encapsulating particles after repeated wash cycles. Over time, a garment's fabric will degrade and its effectiveness at capturing operator-generated particles will deteriorate. While the garment might still be "clean" after a laundry cycle, it could have surpassed its lifecycle and become a source of potential contamination A microscopic evaluation of the fibers and releasable particles 5.0 µm and larger can provide insights into hard water or wash chemical crystals that may not have been thoroughly rinsed from the garment. It may also show any colored fibers that have contaminated the garment during its lifecycle.

- Most tests currently in use are "static" and do not evaluate garments in use. The **Body Box** test better replicates an "in process" environment, resembling actual conditions and how the garment will be used in a controlled environment. However, results can be difficult to replicate and subject to deviation based on the test subject.

Understanding each test method and how to interpret the results are important in managing any type of laundry program.



Cleanroom Garment Laundry Specifications

During contract discussions, the end user of the cleanroom garments should provide the cleanroom laundry provider with all pertinent information regarding contamination control and quality requirements related to the cleanroom garments being processed. This information enables the launderer to determine the best approach to meeting the defined needs.

The end user should specify the following:

- Type of soil or chemical deposition that may appear on the garments.

  - All relevant safety data sheets (SDS) and documents must be supplied per OSHA 29CFR 1910.1200.

  - SDS and related documentation ensures the safety of laundering personnel and allows for an informed approach to effective soil removal and safe transportation of soiled cleanroom garments.

  - All biohazard materials and soils must be identified and properly handled per OSHA 29CFR 1910:1030.

- The specific details of when the cleanroom garment is beyond repair and must be replaced.
- The number and type of repairs that can be made to the cleanroom garment items by the cleanroom garment launderer.
- What level of indelible staining is acceptable.

  - This includes size, quantity and location.

- When the cleanroom garment requires replacement.

It is the end user's responsibility to prevent the cleanroom garments from becoming overloaded with soil, particles and fibers. This can be done through training of the cleanroom operators in proper gowning procedures and behavior in the cleanroom. Maintenance of the cleanroom and equipment should prevent garments from being torn or ripped by the cleanroom operator. The clean garments should be stored in a controlled environment until stocked in the cleanroom gowning area. There should be a sufficient inventory so cleanroom operators can change on a frequent basis and therefore not accelerate degradation of the cleanroom garments.

The end user's QMS should include SOPs for working in the cleanroom, donning and doffing the cleanroom garments and consumable items such as bouffant caps, gloves, shoe covers, goggles, etc. SOPs should also outline the maintenance and cleaning of the cleanroom, information about the equipment in the cleanroom, and how to enter and exit the environment. These SOPs should be the basis for the end user's training program and should be required for all employees that enter the cleanroom or controlled environments. All QMS should be regularly audited for continual improvement.

IEST-RP-CC003, *Garment Considerations for Cleanrooms and Controlled Environments* Section 6.2 describes the responsibilities of the end user of the cleanroom garments.

The cleanroom garment laundry provider's QMS should include SOPs for the routine, scheduled delivery of all processed cleanroom garments and accessories in quantities sufficient to accommodate the number of operators working in the cleanrooms, including emergency evacuations, outside contractors, testing personnel and the change frequencies of the cleanroom garments between the routine, scheduled deliveries. The cleanroom garment laundry should provide secure storage for cleaned garments and accessories, and secure storage of soiled garments. The delivery invoice should clearly state in detail what has been picked up and delivered for end customer internal usage and tracking purposes.

When selecting a cleanroom garment program, an audit of the supply chain should be conducted. Lot traceability to all components of the cleanroom garment should be available for each item. Cleanroom garments are Class 1 medical devices and are validated to ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes* (which is harmonized with the Code of Federal Regulations CFR Part 820: *Quality Systems Regulation).*

Past supply chain disruptions have severely affected the supply and demand of the raw materials used to make cleanroom products. These disruptions disproportionally affected cleanroom garment programs.

For critical cleanroom products required for facility operations, it is imperative that organizations review any cleanroom garment system thoroughly as part of supply chain redundancy and business continuity. This review should include the current Disaster Prevention/Response/ Recovery plan, an on-site audit, and review of the QMS.

Key Takeaways

While the washing of garments should be managed by the respective laundry service professionals, understanding the process is crucial for any user. This knowledge and familiarity with the process allows users to ask pertinent questions, confirm that the correct materials are selected, verify garment integrity, and ensure sustained performance over the lifecycle of the garment to meet facility and process specifications.

Part 3: Procuring Cleanroom Garments: Evaluating Ownership vs. Leasing Options

Procuring Cleanroom Garments: Evaluating Ownership vs. Leasing Options

When incorporating reusable garments is deemed the best fit for cleanroom operational needs, deciding whether to own or lease the garments themselves involves a complex evaluation of operational efficiency, cost implications, regulatory compliance, and logistical considerations.
Owning cleanroom garments (often referred to as a COGs, or Customer Owned Goods, program) involves a significant upfront investment in both the garments themselves and the resources required for their proper tracking, maintenance, and quality control processes. In contrast, leasing/renting garments offers a potentially lower initial cost and shifts all the burden of tracking and compliance to the service provider. Each approach has distinct advantages and challenges.

When going to the market to procure reusable cleanroom garments and evaluate options, it is essential to find a solution that meets the following basic criteria:

- **Supplier Reliability:** A dependable partner to address any performance issues experienced with other providers.
- **Supplier Responsiveness:** Prompt attention to any issues and effective resolutions to enhance service.
- **Efficient Implementation:** Quick and predictable timelines for initial garment program installation and future personnel additions.
- **Transparent Pricing:** Clear and manageable pricing with a detailed breakdown of invoice charges, including rental, repair, replacement, and other miscellaneous fees, as outlined in a comprehensive contract.
- **Garment Quality:** Focus on enhanced quality and performance of garments, including fabric, style, and functionality and consistent processing and garment testing.
- **Consolidated Services:** Preference for full consolidation and control of external resources, or preference for multiple suppliers and service contractors.

The next step in making a procurement decision involves outlining the variables unique to the cleanroom operation, including:

- The number of full-time, part-time and temporary cleanroom operators and any other personnel who will be accessing the cleanroom (contractors, cleaning crew, maintenance staff, etc.).

  - It is generally recommended to have a 3:1 inventory of non-sterile garments for operators – one on the back, one on the rack, one at the laundry. Sterile garment inventories may have a higher ratio.

  - Workforce variations and seasonality should also be considered.

- The number of shifts and hours garments will be worn in a scheduled cycle.

- The sizes of garments required, including for any contractors, technicians and maintenance personnel that may not be entering the cleanroom on a regular basis.

- Any possible product and process exposures to the operators working in the cleanroom.

- Proximity to a cleanroom garment launderer to assure regularly scheduled delivery of cleanroom laundered, reusable cleanroom garments.

- Department budget, including cost of the current program and the target cost for a new program.

Owning vs. Leasing Garments

Choosing between leasing or owning cleanroom garments depends on factors such as budget, control preferences, and operational flexibility. Each option has its trade-offs, and facilities should weigh these based on their specific needs and constraints.

Pros of Leasing

- **Cost Predictability:** Leasing garments typically provides predictable monthly or periodic costs, which can be easier to budget around.
- **Repair and Replacement:** Leasing contracts may include maintenance, repair, and replacement costs.
- **Quality Control:** If leasing from a laundry service provider, high standards for garment quality and cleanliness are followed to ensure compliance with industry regulations.
- **Client Experience:** Most laundry service providers offer inventory management, on-time delivery, and customized options for leasing programs.

Cons of Leasing

- **Contractual Obligations:** Leases come with service contracts that often include additional fees, penalties, termination terms, automatic renewals and more.
- **Program Visibility:** When a program leases and outsources everything to a garment provider and laundry service, there is less program control and visibility into service charges/damage fees/replacement costs/etc.
- **Dependency:** If the service provider fails to provide high-quality garments and timely delivery, there are risks for idle time, cleanliness issues, and even facility shutdowns.
- **Cross-Contamination:** If leased garments for multiple customers are washed in a single load, or transported in the same delivery truck, there may be risks of cross-contamination.

Tips for Managing a Leasing/Rental Program

Typically, when an end user is leasing cleanroom garments, the items are from the laundry provider's core stock program. The best practice in managing this type of "full service" garment program is to make sure the contract includes a dedicated employee resource from the service company who manages everything on-site from start to finish. This includes reviewing all invoicing charges line by line with every pickup and drop off, in addition to stocking/rotating clean garments, retrieving soiled garments, inspecting, and segregating garments for stains or damage. While this resource is an employee of the service company, they need to be intimately familiar with the site and report directly to the customer.

Pros of Owning

- **Asset Ownership:** Owning cleanroom garments can be considered an asset, providing financial reporting benefits and long-term cost savings
- **Customization:** Ownership allows for tailored garment solutions that meet the exact specifications of a cleanroom and the fit preferences of operators.
- **Full Control:** Facilities have complete process control over the garment quality, who does the laundering service, and maintenance. If managed properly by internal resources, there are cost benefits over the lifecycle of the garment.

Cons of Owning

- **Upfront costs:** The initial investment in purchasing garments can be significant.
- **Storage Requirements:** Owning garments requires adequate space for inventory management.
- **Depreciation:** Over time, fabric properties can change with "wear and tear." This leads to fabric degradation where the pore size of the fabric weave increases, and the bacterial filtration efficiency decreases compared to initial testing. If a facility owns garments, they must also budget for replacements at the end of a garment's useful life—typically after 100 wash cycles at minimum.
- **Obsolescence:** As technology and cleanroom standards continuously evolve, owned garments may become outdated or less effective, requiring additional investment.

Tips for Managing a Customer Owned Goods (COGs) Program

When an end user owns their cleanroom garments—either purchased from a specialty garment provider or purchased from a cleanroom laundry provider—they still need to be properly washed. Unless the end user owns the specialty equipment required for cleanroom-compatible washing and drying, they will still contract with a cleanroom garment laundry service provider for washing only. While there will be no ongoing rental or leasing cost, there will still be ongoing washing, delivery, service costs—understanding these cost structures, and who is responsible for tracking wash cycles, identifying damaged garments, and coordinating repairs are all important aspects of successfully managing this type of program.

Like managing a full-service rental program, a COGs washing program will need to include a dedicated employee resource from the service company who manages everything on-site from start to finish. This includes reviewing all invoicing charges line by line with every pickup and drop off. While this resource is an employee of the service company, they need to be intimately familiar with the site and report directly to the customer.

Contract Review

Regardless of whether garments will be rented and washed by a service provider, or customer owned and washed by a service provider, a service contract or agreement will still be required. When reviewing any form of agreement, be mindful of the different fee structures and common clauses that are standard in these types of agreements. Fully understanding the scope of these will result in a better partnership and improved outcomes.

- **Annual Price Increase**, commonly based on the annual inflation rate.
- **Term of Contract Agreement**, typically five years (if leasing) to pay off the initial investment of purchasing the cleanroom garments for the customer by the cleanroom garment laundry, typically fewer years if the contract is for washing services only
- **Exit Fees** are charged if the company ends the service contract for any reason before the defined term.
- **Evergreen Clauses** are common, with the term set to auto renew without defined advanced notice within a specified timeframe
- **Restocking Fees** are charged when the company returns cleanroom garments before termination of the defined contract term.
- **Repair Fees** are charged on any repairs made to every cleanroom garment.
- **Lost/Replacement Fees** are charged on any cleanroom garments that have been damaged beyond repair or lost. Oftentimes replacement fees are assessed at the "new" value of the garment, even if it is a fully depreciated garment at the end of it's lifecycle.
- **Labeling Fees** are charged because each garment item is labeled with a readable, bar code and/or RFID chip to control inventory.
- **Installation Fees** are charged at the initial installation of the cleanroom garment program and whenever new garments are installed in a current account.
- **Quality Testing Fees** are charged when a customer requires specific testing to be performed on a sampling of their garments.
- **Environmental Handling Fees** are often charged to comply with regulations.

- **Service Fees** are charged for scheduled delivery service by a dedicated representative of the cleanroom garment laundry service provider.
- **Fuel Surcharges** are established based on the current fuel costs and tolls.
- **On-Site Inventory Fees** are charged if the reusable, laundered cleanroom garments and consumable supplies are managed by a representative of the cleanroom garment laundry service provider on-site of the customer.

When entering any form of contract with a cleanroom garment service provider, it's important to consider the fee structure outlined in the contract, and require that all invoicing is broken down by line item—cost of leasing, cost of washing, cost of delivery, cost of repair, etc. This is oftentimes one of the most overlooked aspects when starting a new laundry program, and it is not uncommon for additional fees to range from 5%-25% over the initial budgeted cost of the program. If these fee structures are not budgeted for on the front-end, users will run into issues during the duration of the agreement. Depending on the size of the operation, these unbudgeted fees can add up to hundreds of thousands of dollars over the term of the agreement, and penalty fees have been observed more than a million dollars to end a contract early—both scenarios observed with a laundry contract case study by a US based pharmaceutical manufacturer.

Key Takeaways

The decision to own or lease cleanroom garments is not one with a universally correct answer. Both approaches have their distinct advantages and potential drawbacks, which vary depending on the specific needs and circumstances of each organization. Customer-owned cleanroom garments can offer long-term cost savings and greater control over garment management, but it also requires a significant initial investment and ongoing responsibilities. Leasing provides flexibility and reduces upfront costs, while shifting all responsibility for garment care and maintenance to the provider, yet it may come with higher long-term expenses and less control.

Ultimately, the choice between owning and leasing should be guided by a careful assessment of factors such as budget constraints, desired level of control, expected garment usage, and the importance of flexibility in the program. Cleanroom managers must weigh these factors against their operational goals and constraints to determine the most suitable option. By thoroughly evaluating their specific needs and priorities, organizations can make an informed decision that aligns with their strategic objectives and enhances their cleanroom operations.