Cleanroom Risk Assessment Guide

Are Your Garments Working?

Cleanroom environments are constantly being surveyed for risks and potential scenarios where employees or sensitive products could be exposed or harmed. While there are many ways you can assess and quantify these risks, this guide reviews the stages of a cleanroom risk assessment with a special focus on the cleanroom garments used in these strategically controlled environments. Since humans are the biggest source of cleanroom contamination, it is critical to identify all possible risks associated with operators and technicians – including donning the correct garment.

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Potential Risks for All Cleanrooms

In the world of cleanrooms, there's one thing in common across many industries: risks that threaten the cleanliness of their cleanroom, the safety of their staff, and the integrity of their products, or research conducted within the environment.

Examples of Cleanroom Industries:

- Pharmaceuticals
- Microelectronics
- Medical devices
- Aerospace
- Life Sciences
- Food Safety

Many of these industries have overlapping contaminants, including static discharge, vibration, radiation, raw materials, and environmental microorganisms.

In the cleanroom industry, contaminants can skew data results and samples. What many industries have in common is a cleanroom that must be free of contaminants and surveyed for risks regularly. Humans account for 75-80% of particles found in cleanroom inspections. In this guide, we will look at the role cleanroom apparel plays in cleanroom risk assessments and how the correct product selection can mitigate contamination risks.

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Planning and Scoping of the Risks with Key Stakeholders

Communication is critical when it comes to the safety of your employees and the integrity of your cleanroom, so is the first step should be a conversation between risk managers and other members of management, QA, or stakeholders.

There are a few different conversations that need to be had before starting the four main stages of a risk assessment and you must consider environmental risks as well as employee risks.

According to many regulatory agencies, the members of the risk assessment team should do the following:

- Identify risk management goals and options
- Reach agreement on the scope and complexity of the assessment

Four Main Stages of a Risk Assessment

There are many different types of cleanrooms, from aseptic to septic and varying ISO classifications, but the stages of a basic risk assessment are largely the same:

1) Identify the risks

2) Determine who and what can be impacted

3) Conduct an exposure assessment with corrective actions required

4) Preventive actions/decisions/precaution

The pages to follow give greater detail on each stage as they pertain to cleanroom apparel, specifically garments, and highlight the impacts and vulnerabilities the garments you select can have on cleanroom and product integrity.

1. Identifying the Hazards

Hazard or risk identification is the process of determining the sources of potential contamination or risk to personnel within a cleanroom. When it comes to cleanroom PPE, common hazards must be evaluated for probability and severity for the cleanroom itself and staff. Below are some recommendations for identifying cleanroom apparel hazards in these categories.

Cleanroom Environment:

- Check manufacturers' dates and instructions on storage, including storage temperature and how individual packages are being sanitized before stocking.
- Verify whether garments are being donned and doffed correctly.
- Check your current garments (or future options) to determine if they have bound seams or serged seams.
- Take time to review the manufacture's product data, certification, and test results – just because something is sterile, doesn't mean it's particle free.

Personnel Health and Safety:

- Are the garments resistant to blood and body fluid penetration?
- Are the garments resistant to viral penetration and blood borne pathogens (BBPs)?
- Is your current PPE (or future considerations) latex and silicone-free?
- Does your PPE require chemical penetration resistance to oils, bleach, and other chemicals your staff encounters regularly?

2) Who and What Can Be Harmed and How?

Now that you've identified the risks in your cleanroom, focus on who or what is on the receiving end of these risks. Your PPE selection has a direct impact on four factors below:

Environment: Machinery, tools, various cleaning and processing chemicals, as well as your PPE, can impact your environment. Particle shed from cleanroom garments can not only add to the particle count in your controlled environment, but it can also contaminate your products.

Product: When cleanroom operators are working in electrostatic discharge (ESD)-sensitive cleanrooms, ESD from tribocharging can cause immediate or latent damage to product. Biological contaminants from employee skin shedding and spital can damage many products within the cleanroom.

Personnel: Not all employees working in the cleanroom environment are the same. It helps to identify groups of people and how you can best protect them.

Can your PPE selection limit or prevent these risks from contaminating your cleanroom, products, or processes?

- Some workers may have requirements where extra thought may be needed to ensure garments fit properly.
- Contractors, visitors, cleaning/sanitizing staff, and maintenance will need to be trained per cleanroom operating procedures.

Processes: When cleanroom processes are not followed properly, it can lead to contamination and harm to personnel. Identify the risks associated with your cleanroom processes, including whether your PPE is a contributing source of contamination.

- Is your PPE clean manufactured?
- Does your cleanroom apparel offer 99.999% bacterial filtration efficiency (BFE) and 99.999% particle filtration efficiency (PFE)?
- Does your current PPE resist blood and body fluid penetration, viral penetration, and blood borne pathogens?
- Various chemical spills or sprays can harm your staff without the proper PPE in place.

3) Exposure Assessment and Corrective Actions Required

After reviewing the risks, it's time to take corrective action. Modern cleanroom PPE should provide risk assessors with confidence in maintaining the integrity of the cleanroom and in their effort to minimize risks to products and to personnel within. Review the following garment-related solutions to minimize cleanroom risks:

- Clean manufactured garments offer significantly less viable and non-viable particles when compared to laundered garments or disposable garments that are not clean manufactured.
- Storm flaps and bound seams increase the level of protection for both products being created in the cleanroom from particle breakthrough, strikethrough, and liquid penetration.
- Thumb loops help secure coveralls and prevent exposure of skin.
- Chemical penetration resistance, as well as blood borne pathogens, blood, and body fluid penetration resistance, protect your employees from harm.
- Individual packaging with carefully folded PPE prevents excessive wrinkling and the potential for increased excursions and easy donning.
- PPE that has a smooth surface area is less likely to harbor a heavier particulate load.

4) Preventive Actions/Decisions/Precautions

In the final step of the risk assessment, it's time to take action based on your findings to eliminate the risks. There are several cleanroom garment-related preventative actions you can take.

Review ISO standards and IEST-recommended practices, as well as standard operating procedures established by your company, to ensure the current or selected garments meet or exceed those requirements.

- **Verify that your garments protect against liquid penetration**, blood borne pathogens, blood and body fluids, as well as microbiological contaminants.
- **If you are in an ESD-sensitive cleanroom industry**, particle shed, and anti-stat properties should be considered to prevent unwanted particle migration due to electro inductive forces.
- **Train and ensure** that your team is donning and doffing correctly in a manner that prevents contamination of your controlled environment and/or cleanroom.
- **Ensure that your vendor has a steady supply chain** and can promise consistent shipping. Running low on critical safety equipment that your team cycles through a few times daily is not acceptable and risks slowing down your processes.

- **Take comfort into consideration**. When your team is wearing comfortable cleanroom apparel, they are free to focus on the task at hand – not adjusting their garment – which risks excursions and contamination.

Importance of Clean Manufactured Garments

Clean manufactured sterile and non-sterile garments are beneficial in meeting the strict requirements of cleanroom industries and controlled environments.

The packaging must not contribute to the particle load on the garment. How a cleanroom garment is packaged is critical to the safety and integrity of your people and your controlled environment. It's not enough to have a clean and sterile manufacturing process, the packaging process must also be designed to:

- Reduce excursions
- Decrease gowning time and error
- Safeguard against contamination

Choosing clean manufactured garments for your cleanroom and/or controlled environment means maximum protection from unnecessary excursions during donning and foreign particle contamination.

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Prevent Cleanroom Apparel Associated Risks with CleanMax®

Protecting Your People and Your Cleanroom

With 40 years as an industry leader in workplace safety apparel, Lakeland Industries has extended our expertise to protect both your people and your cleanroom. CleanMax® PPE is made with a high-quality microporous laminate material that is light-weight and breathable but is impervious to liquids, harsh chemicals, and microorganisms.

Benefits of Choosing Lakeland CleanMax®

- Excellent comfort and protection
- Bound seams for added strength
- Folded for easier donning and less wrinkles
- PPE Cat 3 Type 5 & 6
- All sterile Cleanmax® garments are sterilized to a level of 10^{-6} SAL
- All garments meet IEST-RP-CC003 Category I Particle Cleanliness
- Smooth surface area prevents harboring of microscopic particles
- Clean manufactured sterile and non-sterile configurations are both clean processed and ready for use in ISO Class 5 – 8 cleanrooms
- Inherently static dissipative

Lakeland is here to provide risk assessors comfort by manufacturing cleanroom garments that mitigate the many risks we've reviewed in this guide. With sterilization and certifications accessible on every garment, superior packaging when compared to others in the industry, and a company-owned clean manufacturing chain to ensure consistent supply, CleanMax® is the clear choice for many organizations with a cleanroom and/or controlled environment.

Quick Selection Guide: Who Should Use CleanMax®?

Confidence in your cleanroom starts with understanding how to select the right disposable apparel for your unique needs. Part of the benefit of working with Lakeland is ongoing access to our team of cleanroom industry experts. In just a few minutes, we will work with you to determine the type of garment required for your application and environment and discuss how we can help you protect your team effectively with clean manufactured garments.

Applications for CleanMax® Cleanroom Apparel:

- Clean sterile
- Aseptic or terminally sterile cleanroom environments
- ISO Class 5-8 Cleanroom
- Sterility assurance level of 10^{-6} SAL
- ISO Class 5-8 or below non-aseptic cleanrooms

Apparel	ISO 8	ISO 7	ISO 6	ISO 5 Non-Sterile	ISO 5 Sterile (Aseptic)	ISO 4	ISO 3
Hair Cover	R	R	R	R	R	R	R
Barrier Gloves	AS	AS	AS	AS	R	R	R
Facial Cover	AS	AS	AS	R	R	R	R
Hood	AS	AS	AS	R	R	R	R
Frock	R	R	AS	AS	NR	NR	NR
Coverall	AS	AS	R	R	R	R	R
Shoe Cover	R	R	AS	AS	NR	NR	NR
Boot	AS	AS	R	R	R	R	R

Chart shows Lakeland garments relevant to ISO 5. Recommendations from IEST-RP-CC003. R = Recommended, NR = Not Recommended, AS = Application Specific

Tracking the Sterility Certificates of Your Cleanroom Garments Shouldn't Be a Difficult Task

You only want the best for your cleanroom, so don't be afraid to ask for the data. Not only should you insist on clean manufactured garments for your cleanroom, but it should also be easy for you to see the data supporting the sterility of your garments.

At Lakeland, we make it easy for you to see and access the chain of custody for garment sterility. In fact, it's as easy as 1-2-3.

1. **Locate the QR code** for you garment (it can be found on the garment tag, the individual package, and on the box used for shipping.)

2. **Scan the QR code** to access the Lakeland website database.

3. **View and print** your sterility certificate as needed.

Look for the Red Indicator Dot

Quickly assess the sterility of your garments with a gamma indicator dot, which acts as a visual indication that the product has been exposed to gamma radiation. Lakeland CleanMax® Sterile offers individually-wrapped garments with an expiration date and a self-adhesive, nontoxic indicator sticker that changes from yellow to red upon exposure to a validated dose of gamma radiation.

Quickly assess the sterility of your garments with a gamma indicator dot...

Moreover, each case is also equipped with a date of irradiation and a sterility indicator to ensure that, upon arrival, your garments meet the necessary sterility requirements for your cleanroom classification.

Contact Us/ Request a Consultation

Take the first step toward proven protection with Lakeland CleanMax® clean manufactured garments for cleanrooms and/or controlled environments.

Receive a free consultation and vendor list provided by a Lakeland representative.

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#AskForLakeland

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