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EMPOWERING CONTROLLED ENVIRONMENTS

The Science Behind Cleanroom Particle Counting

Part 3 of 3

Particle Monitoring

Particle Monitoring-Essential Guide for Cleanroom Standards

The ISO Class 5 cleanroom allows only 3,520 particles per cubic meter at 0.5 microns. This strict limit highlights why particle monitoring plays a vital role in maintaining cleanroom standards. Most cleanrooms still don't practice continuous non-viable particle counting regularly.

Particle monitoring science helps maintain product safety and quality in regulated environments. The standards from ISO 14644, USP<797>, USP<800>, cGMP, EU Annex 1, and FDA 21 CFR Part 11 require cleanroom operators to meet specific requirements through proper monitoring protocols.

This piece will help you understand and implement particle monitoring strategies that work. We'll get into the science behind particle monitoring and classification requirements. You'll learn about continuous versus periodic monitoring approaches and find practical solutions to troubleshoot particle excursions. Our focus stays on improving your cleanroom operations with proper monitoring strategies.

Cleanroom Classification Requirements

The International Organization for Standardization (ISO) created complete standards for cleanroom classification through ISO 14644-1. This 2001 standard replaced the US Federal Standard 209E. Cleanrooms get their classification based on the maximum allowed concentration of airborne particles. The scale runs from ISO 1 (cleanest) to ISO 9.

Classification testing happens in three distinct phases:

- As-Built: Room complete with services connected, without equipment or personnel
- At Rest: Equipment operating but no personnel present
- Operational: Equipment functioning with specified personnel working according to procedures

These standards outline minimum requirements for monitoring cleanroom performance related to air cleanliness by particle concentration. On top of that, the standard requires annual testing for ISO Class 6 and above facilities. ISO Class 5 and below need testing twice a year.

A systematic process of risk assessment helps identify hazards and analyze risks from exposure. The monitoring plan needs to account for the required air cleanliness level, critical locations, and performance attributes that affect how well the installation works.

We use Class 5 for aseptic areas in pharmaceutical cleanrooms, Class 7 for surrounding areas, and Class 8 for support areas. Results that go beyond specified limits need investigation to find the cause and take corrective action. Teams can adjust monitoring frequency based on risk assessment results and steady compliance with acceptance limits.

Continuous vs. Periodic Monitoring

Cleanroom environments use two different types of monitoring: continuous and periodic monitoring. The original approach of continuous monitoring uses multiple particle counters that provide uninterrupted data flow during production. This system allows quick detection of contamination events and helps teams take swift corrective actions.

The EU GMP Annex 1, which became effective in August 2023, requires continuous monitoring for aseptic operations. Grade A ISO Class 5 environments must follow this requirement, while it's strongly recommended for Grade B ISO Class 7 areas. The system tracks several parameters like pressure differentials, airflow velocities, and particle counts immediately.

Periodic monitoring involves scheduled particle measurements at set intervals. Facilities determine the frequency based on risk assessment results to show ongoing compliance between classification tests.

Both monitoring types need appropriate alert and action limits. These limits must be based on:

- Historical sampling data
- Risk assessment findings
- Long-term trend evaluation

Continuous monitoring proves more effective than periodic sampling. The system provides complete data for trend analysis, allows quick operational adjustments, and supports root cause investigations. Continuous particle counting systems with proper alarms can detect problems like door seal gaps or malfunctioning air handling equipment.

Troubleshooting Particle Excursions

Cleanrooms need quick action and systematic investigation when particle excursions occur. We analyzed data integrity problems that come from contamination around sensor optics and mirrors, especially when cleaning operations leave inlets uncapped. Failed calibrations can be prevented by regular maintenance programs and sensor health checks instead of waiting for yearly calibrations.

Human personnel create more than 80% of cleanroom contaminants. The biggest contamination sources come from skin cells, cosmetics, and clothing fibers that need careful monitoring. Good gowning procedures and strict hygiene rules help reduce these risks.

The systematic investigation of excursions needs several vital steps:

- Verify sensor calibration and sampling methods
- Review recent maintenance records and cleaning procedures
- Get into personnel practices and gowning protocols
- Analyze environmental parameters like air pressure and flow patterns

Proper particle counting with configured alarms can spot problems like door seal gaps or faulty air handling equipment. Any excursions beyond class limits from a single sample need a full investigation in ISO 5 environments. The right location identification is vital because wrong data attribution leads to serious integrity problems.

Normal sensor operation needs more frequent tests beyond just regular calibration. Zero count filters and sensor health monitoring give us the quickest way to fix data integrity problems. Cleanroom operators can keep consistent environmental control and quickly fix any problems that deviate from set parameters through good maintenance and monitoring.

Conclusion

Particle monitoring is the life-blood of cleanroom operations that directly affects product quality and regulatory compliance. Cleanroom operators can maintain required cleanliness levels in a variety of ISO classes through proper classification protocols and testing phases.

Modern cleanroom operations need continuous monitoring, especially since the EU GMP Annex 1 mandate. This system helps detect and respond to contamination quickly and provides valuable data to analyze trends and optimize systems.

Your particle monitoring success depends on these crucial factors:

- Regular sensor maintenance and calibration
- Strict adherence to gowning protocols
- Quick investigation when issues arise
- Clear documentation of all procedures
- Detailed staff training

Cleanroom operators who understand these elements can maintain consistent environmental control while meeting tough regulatory requirements. REX Dynamics can help you create effective particle monitoring strategies for your cleanroom facility.

This scientific approach to particle monitoring, along with proper maintenance protocols and staff training, will give your cleanroom operations the edge to meet or exceed required

standards. Regulations continue to get stricter and quality requirements keep rising, so proper particle monitoring remains vital to product safety and operational excellence.

FAQs

Q1. Why are 0.5 micron and 5 micron particle counts important in cleanroom environments? Particle counts at these sizes are crucial because they represent potential contamination risks. Particles as small as 0.5 microns can carry bacteria, which is particularly concerning in sterile environments like pharmaceutical manufacturing. Monitoring these particle sizes helps ensure product safety and quality.

Q2. What are the key standards for cleanroom particle monitoring? The primary standard for cleanroom particle monitoring is ISO 14644. This standard provides guidelines for measuring, interpreting, and applying results of particle deposition or obscuration rates on vulnerable surfaces in cleanrooms. It also outlines methods for controlling contamination and reducing risk levels.

Q3. How are particles measured in a cleanroom? Particles in cleanrooms are typically measured using airborne particle counters. These devices use light scattering technology. As air enters the counter, it passes through a laser beam. The laser shines onto a photodetector, which measures the size and number of particles based on the scattered light.

Q4. What are the advantages of continuous particle monitoring over periodic monitoring? Continuous monitoring offers several benefits, including real-time detection of contamination events, comprehensive data for trend analysis, and the ability to make immediate operational adjustments. It also aids in root cause investigations and can identify potential issues like door seal gaps or malfunctioning air handling equipment more quickly than periodic monitoring.

Q5. How often should cleanroom classification testing be performed? The frequency of cleanroom classification testing depends on the ISO class of the cleanroom. For ISO Class 6 and above facilities, annual testing is required. ISO Class 5 and below cleanrooms need more frequent testing, typically biannually. However, the exact frequency can be adjusted based on risk assessment results and consistent compliance with acceptance limits.

This article is written by REX Dynamics. We empower controlled environments when it comes to consultation, design, installation, validation & servicing of environmental monitoring solutions. For further information please visit our webpage www.rexdynamics.se or contact us at info@rexdynamics.se