

# Classification vs Monitoring

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# Cleanroom Requirements, Certification and Monitoring Per Common Accepted Standards

Cleanroom Classification and class limits are established in ISO 14644-1 (see Table 1), while specifications for testing and monitoring to prove continued compliance are established in ISO 14644-2 (see Tables 2 and 3). Often there is confusion regarding the definitions of certification and monitoring. This article explains the differences between monitoring and certification.

A cleanroom is a modular environment where airborne contaminants, temperature, relative humidity, differential pressure, static electricity and other factors are under strict control. There are several levels of cleanliness, called classes, that can be applied to a cleanroom. When a cleanroom is certified to a specific class, the room performs to standards that meet or exceed the performance of that class under a specific occupancy status. Certification is the general means of checking the room for various parameters to guarantee that it is built to a specific set of requirements. The room is also periodically re-tested to those same parameters to ensure that nothing has changed.

Monitoring of a cleanroom is done to:

1. Ensure that the cleanroom parameters have not altered in any way. Everything in the construction and supporting equipment is 100% operational and is at the same performance level as it was when the room was certified.
2. Ensure that the process in the room is in control at all times.
3. Ensure that the cleanroom staff follows accepted procedures at all times.

ISO 14644-2 specifies that cleanroom particle classifications in areas cleaner than ISO class 5 require a maximum time interval of 6 months between demonstrations of compliance to ISO 14644-1. Areas less clean than ISO Class 5 require a 12 month maximum interval between demonstrations of compliance (see Table 2). In practice, the demonstrations of compliance may be conducted much more often than the maximum intervals specified in ISO 14644-2. If a cleanroom fails to comply with its assigned standard, the quality of all products or processes performed in that area since the last demonstration of compliance is questionable. The more often a demonstration of compliance is executed, the smaller the loss of time and materials in case of compliance failure.

If a continuous or frequent monitoring plan is established for airborne particles and air pressure differential, then the schedule of the particle counting certification testing may be modified. This monitoring plan shall be determined by a risk assessment based upon the type of facility, the possible causes of contamination and the impact of contamination on the product or process performed in the facility.

Experience with different tooling and facilities, as well as an understanding of the nature of particle generation, can greatly assist in making better choices about what and where particle monitoring should be performed.

**Note:** it is impractical and expensive to establish minimum monitoring points based solely upon the area of the room in square meters. This method works in certification, however, as coverage and testing guidelines must be established regardless of process and risk assessment. But in a monitoring program, risk assessment is extremely important to determining what and where to monitor.

The precise count levels required by ISO 14644-1 for each classification, by particle size, are given in Table 1.

**Table 1: Airborne Particulate Cleanliness Classes (by cubic meter)**

CLASS	Number of Particles per Cubic Meter by Micrometer Size					
	0.1 um	0.2 um	0.3 um	0.5 um	1 um	5 um
ISO 1	10	2				
ISO 2	100	24	10	4		
ISO 3	1,000	237	102	35	8	
ISO 4	10,000	2,370	1,020	352	83	
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7				352,000	83,200	2,930
ISO 8				3,520,000	832,000	29,300
ISO 9				35,200,000	8,320,000	293,000

ISO 14644-2 determines the type and frequency of testing required to conform with the standard. The following tables indicate which tests are mandatory and which tests are optional.

**Table 2: Required Testing (ISO 14644-2)**

Schedule of Tests to Demonstrate Continuing Compliance			
Test Parameter	Class	Maximum Time Interval	Test Procedure
Particle Count Test	<= ISO 5	6 Months	ISO 14644-1 Annex A
	> ISO 5	12 Months	
Air Pressure Difference	All Classes	12 Months	ISO 14644-1 Annex B5
Airflow	All Classes	12 Months	ISO 14644-1 Annex B4

**Table 3: Optional Testing (ISO 14644-2)**

Schedule of Additional Optional Tests			
Test Parameter	Class	Maximum Time Interval	Test Procedure
Installed Filter Leakage	All Classes	24 Months	ISO 14644-3 Annex B6
Containment Leakage	All Classes	24 Months	ISO 14644-3 Annex B4
Recovery	All Classes	24 Months	ISO 14644-3 Annex B13
Airflow Visualization	All Classes	24 Months	ISO 14644-3 Annex B7

The focus of the testing program is to monitor the performance of a facility in order to identify significant changes in efficiency. This process will ensure that changes can be addressed before they become a major source of contamination effecting productivity and yield.