

Abstract

The new ISO Documents, viz, 14644 Parts 1 and 2 have already been officially released by the Technical Committee ISO/TC 209 : Cleanrooms and Associated Controlled Environments . Recently with the official cancellation of the Federal Standard 209E, more and more companies and associations will be adopting these standards for the classification of airborne cleanliness classes (ISO 14644-1) and using the second part ISO 14644-2 to specify monitoring protocol (or re-certification of cleanrooms) based on the cleanliness classes . This paper outlines the main differences between the ISO 14644-1 and the Federal Standard 209E and also explains briefly on the relevant tables and the recommended monitoring or re-certification protocol of ISO 14644-2 .

Scope of ISO Documents 14644 Parts 1 and 2

A. ISO 14644-1 : Classification of Air Cleanliness

ISO 14644-1 covers the classification of air cleanliness in cleanrooms and associated controlled environments exclusively in terms of concentration of airborne particles . Only particle populations having cumulative distributions based on threshold (lower limit) sizes ranging from 0.1µm to 5µm. are considered for classification purposes . See Table 1 below for the cleanliness classification .

ISO Classification Number (N)	Maximum concentration limits (particles/m ³ of air) for particles equal to and larger than the considered sizes shown below (concentration limits are calculated in accordance with equation (1) in 3.2)					
	0.1µm	0.2µm	0.3µm	0.5µm	1.0µm	5.0µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

NOTE : Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level

Table 1 : Selected Airborne Particulate Cleanliness Classes for Cleanrooms and Clean zones (Extracted from Table 1 : ISO 14644-1)



B. ISO 14644-2 : Specification for Testing and Monitoring to prove continued compliance with ISO 14644-1

This part of International Standard ISO 14644 specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

These requirements invoke the test described in ISO 14644-1 for the classification of the cleanroom or clean zone. Additional tests are also specified, to be carried out based on the requirements of this International Standard. Optional tests, to be applied at the user's discretion, are also identified.

This part of ISO 14644 also specifies requirements for the monitoring of a cleanroom or clean zone (installation) to provide evidence of its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness

ISO 14644:1 vs FS 209E

This document was prepared to address the same scope and tasks as Federal Standard 209E, ie, Classification of Air Cleanliness . Most users are very familiar with FS 209E having used it day in and day out . The best way therefore to understand this new ISO 14644-1 is to point out the major differences in this standard as opposed to FS 209E . The matrix on the next page highlights the essential differences between the two standards .

Sub Sections	ISO 14644-1	FS 209E
Units	All units are in metric	Units are in English (US customary) and Metric
Particle range	0.1µm, 0.2µm, 0.3µm, 0.5µm, 1.0µm, 5.0µm	0.1µm, 0.2µm, 0.3µm, 0.5µm, 5.0µm (No 0.1µm classification)
Classification	Class ISO 1 to ISO 9	Class M1 to M7
Units of concentration	Particles / m ³	Particles/ft ³ or Particles/m ³
Reference particle size for classification	0.1µm – see Table 2	0.5µm – see Table 2
Classification Number / Formula	$C = 10^N \times (0.1/D)^{2.08}$ C = concentration in particles/m ³ N = cleanliness class, D = particle diameter in µm	$C = 10^N \times (0.5/D)^{2.2}$
Classification designation	1 or more where diameter of one is 1.5 times diameter of next smaller size ($D_2 \geq D_1 \times 1.5$)	1 or more and No restriction on particle diameter

Sub Sections	ISO 14644-1	FS 209E
Sampling Location	$N_L = \sqrt{A}$ Where A = area of room in m ² N _L = no of sampling locations N = cleanliness class	<i>Unidirectional Airflow</i> Lesser of (a) or (b) (a) A/2.32 or (b) A x 64/√10 ^N <i>Non-Unidirectional Airflow</i> A x 64/√10 ^N
Measurement Method	DPC for 0.1 to 5 μm CNC for ultrafine particles Optical Microscope for macroparticles	DPC (=OPC, CNC) + optical microscopy
Restrictions on sample locations	1 location is possible but need to sample at least 3 times	Minimum of 2 sampling locations need to be taken and a minimum of 5 samples in total
Ultrafine particles	Particles ≤ 0.1 μm	Particles ≤ 0.02 μm
Macroparticles	Information on particles ≥ 5 μm	Not considered
Isokinetic sampling	Not required	Required
Pretest conditions	Prior to airborne cleanliness class measurement, the following tests need to be performed : <ul style="list-style-type: none"> • Airflow volume or velocity tests • Air pressure difference test • Containment leakage test • Installed filter leakage test 	No such requirement
Single Non random value	If the 95% UCL calculation fails to meet the specified cleanliness class, due to a single non-random “outlier” value, this outlier value may be excluded from the calculation	No such provision

Cleanliness Classification	No of Particles per m ³					
	0.1µm	0.2µm	0.3µm	0.5µm	1.0µm	5.0µm
ISO Class 1	10	2				
-	-	-				
ISO Class 2	100	24	10	4		
-	-	-	-	-		
ISO Class 3	1 000	237	102	35	8	
1	1 240	265	106	35.3	-	-
ISO Class 4	10 000	2 370	1 020	352	83	
10	12 400	2 650	1 060	353	-	-
ISO Class 5	100 000	23 700	10 200	3 520	832	29
100	-	26 500	10 600	3 530	-	-
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
1 000	-	-	-	35 300	-	247
ISO Class 7				352 000	83 200	2 930
10 000				353 000	-	2 470
ISO Class 8				3 520 000	832 000	29 300
100 000				3 530 000	-	24 700
ISO Class 9				35 200 000	8 320 000	293 000
-				-	-	-

*Table 2 : Comparison of Cleanliness Classification between FS 209E and ISO 14644-1
 (Top and in black : ISO 14644-1, Bottom and in Blue : FS 209E)*

ISO 14644-2

General

This standard was formulated to specify requirements for the periodic testing of a cleanroom and/or a clean zone as there were several questions raised over the years which addressed the need for a re-certification protocol after initial commissioning of a cleanroom or clean zone .

Normative tests and Time Interval

This standard establishes the schedule for testing of the airborne particle count, the airflow volume or velocity test and the air pressure difference tests – all these tests being normative in the standard . The maximum time interval for the airborne particle count to demonstrate compliance can range from between 6 mths to 12 mths, depending on the cleanliness classification – see table 3 below . As for the airflow volume or velocity and the air pressure difference tests, these are based on a standard 12 mths interval – see table 4.

Classification	Maximum Time Interval	Test Method
≤ ISO Class 5	6 months	Annex B in ISO 14644-1:1999
> ISO Class 5	12 months	Annex B in ISO 14644-1:1999
NOTE : Particle count tests will normally be performed in the operational state, but may also be performed in the at-rest state in accordance with the designated ISO classification		

Table 3 : Schedule of testing to demonstrate compliance with particle concentration limits (Extracted from Table 1 in ISO 14644:2)

Test Parameter	Maximum Time Interval	Test Procedure
Airflow Volume ^a or velocity test	12 months	ISO 14644-3:-, clause B.4
Air pressure difference ^b	12 months	ISO 14644-3:-, clause B.5
NOTE : These tests may normally be performed in either the operational or at-rest state in accordance with the designated ISO classification		
^a Airflow volume may be determined by either velocity or volume measurement		
^b This test will not apply to clean zones which are not totally enclosed		

Table 4 : Schedule of additional tests for all classes (Extracted from Table 2 in ISO 14644:2)

Other Optional Tests

The standard also states that the user can specify other optional tests to be performed at a suggested maximum interval of 24 mths, to ensure compliance . The recommended optional tests include :

- Installed filter leakage test
- Airflow visualization test
- Recovery test
- Containment leakage test

The test procedures and protocol will be found in the relevant sections of ISO 14644:3 Metrology and Test methods which is not available yet even in the draft stage .

Technical Bulletin

Brief Explanation of ISO 14644 - Parts 1 & 2



Exception to Monitoring Interval and Re-qualification

If the cleanroom or clean zone is equipped with instrumentation for continuous or frequent monitoring of the airborne concentration and air pressure differential, the maximum time interval as stated in tables 3 and 4 can be extended, provided that the results of the continuous or frequent monitoring remain within the specified limit(s) .

If any of the parameters fail, then remedial action will have to be immediately taken and re-qualification undertaken . As stated in the standard, re-qualification will have to be undertaken after any of the following :

- Completion of remedial action implemented to rectify an out-of-compliance condition
- A significant change from the current performance specification, such as a change in the operational use . The significance of a change should be determined by agreement between the customer and the supplier .
- Any significant interruption of air movement which affects the operation of the installation . The significance of an interruption should be determined by agreement between the customer and the supplier .

Examples where re-qualification will be required (but not limited to) include :

- When there is a change in the layout of the process and equipment in the cleanroom
- When cleanroom walls are taken apart and the cleanroom extended
- When there is a change in the layout of the cleanroom filters (perhaps filters are re-located or additional filters are installed)

Documentation

Besides this the standard also covers the need for a written monitoring plan for the various parameters and specifies the documentation required . The documentation includes the need for a submission of a comprehensive report along with a statement of compliance or non-compliance with the specified tests

CONCLUSION

The ISO 14644 Parts 1 and 2 documents will no doubt catch on in due course and have attempted to globalise the protocol for airborne particle measurements . The ISO 14644:2 standard has especially addressed, inexplicably, the requirements for monitoring to demonstrate continued compliance, though only in a brief document . However the full impact of these two ISO standards (ISO 14644:1 and ISO 14644:2) will only be realized with the release of the ISO 14644 Part 3 which establishes the test methods involved in the testing of cleanroom and clean zones .

REFERENCES

1. Whyte, W "Cleanroom Design", Wiley, Second Edition, October 1999.
2. ISO 14644:1 - Classification of Air Cleanliness, 1999
3. ISO 14644:2 - Specification for Testing and Monitoring to prove continued compliance with ISO 14644-1, 2000
4. Federal Standard 209E : Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones, 1992