



Brief overview of the new ISO Standards in cleanroom – ISO 14644 Parts 1 & 2

by Mr Inderjit Singh

This article serves to provide an industry update on the new ISO 14644 Parts 1 and 2 Standards in Cleanrooms which will strongly impact the way cleanroom performance testing is to be conducted with respect to airborne particle counting.

The **Federal Standard 209E** has always been the industry standard, but now with the cancellation of the FS 209E, the ISO 14644-1 will no doubt gain popularity. Most, if not all companies will soon come to adopt it. Together with the ISO 14644-1 comes a follow-up standard, the **ISO 14644-2** which addresses the periodic testing and monitoring of cleanroom/clean zone.

How it started

In 1992, at the instigation of the **Institute of Environmental Sciences and Technology (IEST)**, the **American National Standards Institute (ANSI)** petitioned the **International Organization for Standardization (ISO)** to create a new technical committee that could set international standards that would find global acceptance. Thus the new technical committee, the **ISO/TC 209**, was established in May 1993 to draw up a total of 11 standards under the general title “**Cleanrooms and Associated Controlled Environments**”. Of the 11, the ISO 14644 Parts 1 & 2 were two that came into existence over the following few years.



ISO 14644-1 & ISO 14644-2

The Technical Committee ISO/TC 209 has officially released the 14644-1 and 14644-2 ISO documents to supersede the Federal Standard 209E. More companies and associations will be adopting ISO 14644-1 for the classification of airborne cleanliness levels (ISO 14644-1) and using ISO 14644-2 to specify monitoring protocol (or re-certification of cleanrooms) to demonstrate continued compliance.

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 0.1 μm to 5.0 μm are considered for classification purposes. This standard is a replacement of the Federal Standard 209E and there are several differences between the two standards. The notable differences or inclusions in ISO 14644-1 being:

- Units are only in metric now and concentration is only defined in particles/ m^3
- Classification is based on ISO Class 1 to ISO Class 9. Refer to **Table 1** for a comparison of ISO 14644-1 with Federal Standard 209E in terms of maximum concentration limits
- The reference unit is now 0.1 μm and not 0.5 μm
- The number of sampling locations is based on $N_L = \sqrt{A}$ (Where A = area of room in m^2 , N_L = no of sampling locations, rounded up to a whole number)
- Changes in the definitions of macroparticles ($> 5.0 \mu\text{m}$) and ultrafine particles ($< 0.02 \mu\text{m}$) and methods in measuring such particle sizes
- It is also mandatory to do pre-testing of certain parameters like velocity, pressure and leakage prior to performance of the airborne particle counting



Table 1: Comparison of Cleanliness Classification between FS 209E and ISO 14644-1 (ISO 14644-1, FS 209E)

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

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

This standard was formulated to specify requirements for the periodic testing of a cleanroom and/or a clean zone, in the *Operational* or *At-Rest* states, 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. This testing and monitoring requirement is something new altogether and has not been attempted to be defined in any prior standard or recommended practice previously.

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 is also stated and can range from between 6 months (\leq ISO Class 5) to 12 months ($>$ ISO Class 5), depending on the cleanliness classification. As for the airflow volume or velocity and the air pressure difference tests, these are based on a standard 12 months interval. In addition to these normative tests, other tests may also be optionally included and the suggested maximum time interval for these tests to demonstrate continued compliance should be no longer than 24 months.

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 could possibly be extended, provided that the results of the continuous or frequent monitoring remain within the specified limit(s). This is especially significant to users who have sophisticated monitoring systems in place throughout their cleanroom facility.

Conclusion

The ISO 14644 Parts 1 and 2 documents will no doubt catch on in due course and have attempted to globalize the protocol for airborne particle measurements. The ISO 14644:2 standard has especially addressed inexplicably the requirements for testing and monitoring to demonstrate continued compliance, though only in a brief document. However, the full impact of these two ISO standards 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. These standards can be purchased from the Institute of Environmental Sciences & Technology (IEST) at www.iest.org.

Editor's note: This article is written by Mr Inderjit Singh, Senior Project Manager with Cesstech (S). Inderjit has 12 yrs of experience in the field of contamination control and ESD & Static charge control in Cleanrooms. He is a NEBB (National Environmental Balancing Bureau) certified Cleanroom performance testing supervisor and a NARTE certified ESD Engineer (Certification #328).

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