FEDERAL STANDARD 209E FOR CLEANROOM - AN OBSOLETE DOCUMENT!

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ABSTRACT

The United States (U.S.) Federal Standard 209 (FS 209) was published by the Institute of Environmental Sciences and Technology (IEST), FS 209 was approved for use by the U.S. General Services Administration (GSA) in 1963, making it obligatory for organizations doing work for the United States government. FS 209 has been used widely as the de facto clean room standard in and around the world including in Malaysia, some countries completely adopted FS 209, while others made their own national version, similar to FS 209. Some made minor changes of the classes to comply with the metric system. Australia (AS 1386), France (AFNOR X44101), Germany (VDI 2083:3), Holland (VCCN 1), Japan (JIS-B-9920), Russia (Gost-R 50766), United Kingdom (BS 5295) are among the major national standards that referenced to FS 209.

The activities of the ISO Technical Committee ISO/TC209 *"Clean rooms and other associated controlled environments"* which started in 1993, has effectively and in reality made obsolete what is in FS 209. In addition ISO/TC209 offers broader domestic and international appeal. The ISO clean room standards will be known by their identifying number series, ISO 14644 and ISO 14698. ISO 14644-1 *"Classification of Air Cleanliness"* standard had became mandatory in the Europe Union (E.U.) since November 1999. In January 2000, the IEST submitted a formal request to the U.S. General Services Administration (GSA) to retire the standard, and the GSA officially did so on November 2001. It is coming to two year since its withdrawal, FS 209E is still widely used in Malaysia and around the region! The implications, salient and pertinent similarities and/ or differences between FS 209 and ISO 14644 shall be discussed in this paper.

INTRODUCTION

The last revision of the FS 209 is version E (FS 209E) : *Airborne Particulate Cleanliness Classes in Clean Rooms and Clean Zones* was published in 1992. FS 209E, has been a benchmark for contamination control industry lived and died by for more than 40 years, paving the way for worldwide harmonization by new cleanroom protocols from the International Organization for Standardization (ISO).

These ISO Standards specify classes of air cleanliness, specify which tests are required to prove compliance with these classes of air cleanliness and specify how often these tests must be conducted. For many of us, terms such as Class 100 and Class 10,000 are indelibly imprinted on our minds and in our speech. It will be hard to change and adjust to new terminology. However, how many of us today remember when cleanrooms used to be called "white rooms" and "grey rooms?" Twenty years from now who will recognize Class 100 and Class 10,000?

Bear in mind that the use of FS 209E is obligatory only for organizations doing work for the United States government. It is a voluntary standard for non-government commercial trade as a reference only per agreement between buyer and seller. This is significantly different from Europe and to businesses trading in Europe. Some people think the ISO standards are just another form of recommended practices (RPs), similar to those produced by the IEST and other organizations and are usually used as references per agreement between buyer and seller. This assumption is incorrect because ISO standards are directly impacted by ISO 9000 and/ or ISO 14000 certification criteria.

The direct impact of the ISO 14644 and ISO 14698 standards will hit first and hardest in the European Union (E.U.) and secondly to those doing business in or with E.U countries and businesses. The reason is paramount; for six months after formal publication of an ISO standard, the member nations of the E.U are required to rescind their own national standards in favour of the ISO standards. As such, the ISO standards will have the force of law in Europe. If you are an ISO 9000 and/ or ISO 14000 certified organization, you are required to use appropriate ISO standards as part of your certification. Therefore, the ISO 14644 and ISO 14698 standards will apply to your certification as they are published and as you are re-certified. This is another form of direct impact.

Too many cleanroom community people claim not to know about ISO 14644 and ISO 14698. They will affect your business, your profession and your job. Regulatory authorities in Europe and Asia are already using them, so if you do business in those parts of the world, you will be impacted immediately. The standards are not created to describe how a company must manage its cleanroom operations. Instead, the standards are in place to create a basic framework of cleanroom operation one that allows for the accurate apples-to-apples comparisons of cleanrooms operating in England, France, Malaysia and the United States or any ISO-participating country.

As the economy becomes increasingly global, having ISO 14644 and ISO 14698 in place allows worldwide buyers of components and products to have a single source for measuring supplier operations without having to understand the myriad country-specific standards that have held sway in the past.

DEFINITION OF CLEANROOM

The definition of cleanroom has been expanded in the ISO 14644 compared to FS 209E, the definition has include the specific internal environmental conditions. The definitions for both FS 209E and ISO 14644 are as follow;

> FS 209E Clause 3.5 Define cleanroom as *'A room in which the concentration of airborne particles is controlled and which contains one or more clean zones.'*
>
> ISO 14644-1 Clause 2.1.1 expanded the definition of a cleanroom to *'A room in which the concentration of airborne particles is controlled, <u>and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant parameters, eg temperature, humidity and pressure are controlled as necessary</u>.'*

CLASSES OF CLEANROOM

Gone from the new standards are Class 1, Class 10 and all the other familiar classifications of 209E. The new names are ISO Class N where N is a numerical number between 1 and 9, in increments of 0.1. As with 209, the class name tells the maximum allowed number of particles of a given diameter. In the ISO classifications, however, the maximum allowable concentration for a given class is 10^N, the concentration units are particles per cubic meter, and the reference particle diameter is 0.1 micron and larger -- quite different from 209E in which the Class number is itself the maximum allowable concentration of particles per cubic foot with a reference particle diameter of 0.5 micron. With the available filtration technology, 0.5-micron particles are not a significant problem anymore.

FS209E Table 1 : Airborne Particulate Cleanliness Classes

Metric	Imperial	0.1 µm		0.2 µm		0.3 µm		0.5 µm		5 µm	
M	Class	m^3	ft^3	m^3	ft^3	m^3	ft^3	m^3	ft^3	m^3	ft^3
1		350	9.91	75.7	2.14	30.9	0.875	10	0.283		
1.5	1	1,240	35.0	265	7.5	106	3.00	35.3	1.00		
2		3,500	99.1	757	21.4	309	8.75	100	2.83		
2.5	10	12,400	350	2,650	75.0	1,060	30	353	10		
3		35,000	991	7,570	214	3,090	87.5	1,000	28.3		
3.5	100			26,500	750	10,600	300	3,530	100		
4				75,700	2140	30,900	875	10,000	283		
4.5	1,000							35,300	1,000	247	7.00
5								100,000	2,830	618	17.5
5.5	10,000							353,000	10,000	2,470	70
6								1,000,000	28,300	6,180	175
6.5	100,000							3,530,000	100,000	24,700	700
7								10,000,000	283,000	61,800	1,750

ISO 14644-1 Table 1-Selected airborne particulate cleanliness classes for cleanroom and clean zones

Metric	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class	m3	m3	m3	m3	m3	m3
1	10	2				
2	100	24	10	4		
3	1,000	237	102	35	8	
4	10,000	2,370	1,020	352	83	
5	100,000	23,700	10,200	3,520	832	29
6	1,000,000	237,000	102,000	35,200	8,320	293
7				352,000	83,200	2,930
8				3,520,000	832,000	29,300
9				35,200,000	8,320,000	293,000

The footnote under Table 1 of ISO 14644, recognize the uncertainties related to the measurement process, as such it stipulate that the concentration data shall not be more than three significant figures in determining the classification level.

From footnote for Table 1 in FS209E which states concentration limits for intermediate classes may be calculated using;

$$\textbf{Particles/m}^3\textbf{=10}^M\textbf{ x (0.5/d)}^{2.2}$$

Where M is the numerical designation of the class based on SI units, and d is the particle size in micrometer, or

$$\textbf{Particles/ft}^3\textbf{=N}_c\textbf{ (0.5/d)}^{2.2}$$

Where N_c is the numerical designation of the class based on English (US customary) units, and d is the particle size in micrometer.

Whereas ISO 14644-1 Clause 3.2 allows the provision to calculate maximum permitted concentration of particles, C_n for each considered particle size.

$$C_n = 10^N \text{ x } (0.1/D)^{2.08}$$

where

C_n	:	Represent the maximum permitted concentration (in particles/m^3 of air) of airborne particles that are equal to or larger than the considered particle size; C is rounded to the nearest whole number.
N	:	Is the ISO classification number, which shall not exceed the value of 9. Intermediate ISO classification number may be specified, with 0.1 the smallest permitted increment N,
D	:	Is the considered particle size in µm, and
0.1	:	Is a constant with dimension of µm

COMPARISON BETWEEN 209E TO ISO 14644-1 CLASSIFICATIONS.

The following table compares FED STD 209E to the new ISO 14644-1 classifications.

Airborne Particulate Cleanliness Class Comparison

ISO 14644-1	FED STD 209E	
ISO Class	**English**	**Metric**
1		
2		
3	1	M1.5
4	10	M2.5
5	100	M3.5
6	1,000	M4.5
7	10,000	M5.5
8	100,000	M6.5
9		

Cleanliness classification levels defined by FS209E and ISO 14644-1 are approximately equal, except the ISO standard offers new class designations, a metric measure of air volume and adds three additional classes - two cleaner than Class 10 and one beyond than Class 100,000.

DIFFERENCE BETWEEN FEDERAL STANDARD 209E TO ISO 14644-1 CLASSIFICATIONS.

How then do the 209E and the ISO standards differ in describing a given cleanroom classification? Take Class 1 of 209E, allowing a maximum particle concentration of 1 particle per cubic foot. Rounded off, this concentration corresponds to 35 particles per cubic meter but the reference particle diameter is still 0.5 micron. How does one convert that concentration at 0.5 micron into an equivalent concentration at 0.1 micron? Table 1 of FS 209E offers a ready answer: 35 particles per cubic meter at 0.5 micron correspond to 1,240 particles per cubic meter at 0.1 micron. This conversion is based on a particle size distribution approximated by an inverse power law with an exponent of 2.2 (particle concentration [particle diameter] -2.2). Multiplying 35 by $(0.1/0.5)^{-2.2}$ =1,207 doesn`t quite yield 1,240 (the numbers in Table 1 of FS 209E do not represent exact power law behavior) but, accepting a concentration of 1,240 particles per cubic meter at 0.1 micron as a reasonable approximation of 1 particle per cubic foot at 0.5 micron, the corresponding ISO Class number becomes:

1,240 = 10N
$\log_{10}$ (1,240) = N
N = 3.09

By this conversion, Class 1 of 209E corresponds to ISO Class 3.1 as defined by ISO 14644-1.

An alternative conversion procedure appears in ISO 14644-1. Here the power law size distribution has an exponent of 2.08. The 35 particles per cubic meter at 0.5 micron correspond to 35 x $(0.1/0.5)^{-2.08}$ = 995 particles per cubic meter at 0.1 micron (or 1,000 particles per cubic meter by Table 1 of 1SO 14644-1) which rounds off to ISO Class 3.0.

Comparing Tables 1 from both standards shows that a simple relationship exists between the names used in the two classifying systems. The number appearing in the ISO Class name converts to the number appearing in the 209E Class name by simply moving the decimal point to either side of 1.0 the number of places equal to 3 minus the number appearing in the ISO Class name. For example,

ISO Class 1	Class 0.01	1 minus 3 = -2; move the decimal point 2 places to the left
ISO Class 2	Class 0.1	2 minus 3 = -1; move the decimal point 1 places to the left
ISO Class 3	Class 1	3 minus 3 = 0; no need to move the decimal
ISO Class 4	Class 10	4 minus 3 = 1; move the decimal place 1 place to the right
ISO Class 5	Class 100	5 minus 3 = 2; move the decimal place 2 place to the right
ISO Class 6	Class 1,000	6 minus 3 = 3; move the decimal place 3 place to the right
ISO Class 7	Class 10,000	7 minus 3 = 4; move the decimal place 4 place to the right
ISO Class 8	Class 100,000	8 minus 3 = 5; move the decimal place 5 place to the right
ISO Class 9	Class 1,000,000	9 minus 3 = 6; move the decimal place 6 place to the right

PARTICLE VERIFICATION

Neither standard requires that verification be conducted at the diameter of the reference particle. However, the particle diameter or diameters at which the verifying measurements are made must be within the size range defined for each class in Table 1 of each standard. And note that the class correspondences between the two standards strictly apply only when class verification measurements are made at the 0.5 micron particle diameter; that is, the limiting concentration of

FS 209E Class 1 corresponds to that of ISO Class 3 only at 0.5 micron. At 0.2 micron or 0.3 micron or other intermediate particle diameters at which class verification is allowed by either standard, the class limits will differ because of the differing power law dependencies assumed by each standard. For example, by FS 209E, 1,200 particles per cubic meter at 0.1 micron meets the concentration requirement for Class 1 but it does not meet the concentration requirement for ISO Class 3, which specifies a maximum of 1,000 particles per cubic meter. Admittedly the differences are small and may not often be important. Nonetheless, switching between the two standards will be complicated by such details. The prudent action is to switch to the ISO standard as soon as practicable.

CLASSIFICATION FORMAT

FS 209E Clause 4.4.1 Format for airborne particulate cleanliness classes, states that classes shall be expressed by using the format;

> **"Class X (at Y µm)"**, where
> X represents the numerical designation of the airborne particulate cleanliness class; and
> Y represents the particulate size or sizes for which the corresponding particle concentration (class) limits are specified.
>
> For example:
>
> "Class M2.5 (at 0.3µm and 0.5 µm)" describes air with no more than 1,060 particles/m^3 of size 0.3µm and larger, nor more than 353 particles/m^3 of a size 0.5µm and larger

ISO 14644-1 Clause 3.3 Designation, states that the designation of airborne particulate for cleanrooms and clean zones shall include;

1. the classification number, expressed as "ISO Class N",
2. the occupancy state to which the classification applies;
3. the considered particle size(s) and the related concentration(s), as determined by the classification equation (1) where each considered threshold particle size is in the range from 0.1µm through 5µm. (one or more, where diameter of one is 1.5 x diameter of next smaller particle)

> For example
>
> **"ISO Class 4; operational state; considered size: 0.2µm (2,370 particles/m^3), 1µm (83 particles/m^3)"**

SAMPLING LOCATIONS

Annex B of ISO 14644-1, labeled "normative" (meaning it`s a mandatory part of the standard rather than "informative"), defines the minimum number of required sampling locations with respect to the cleanroom area as:

$$N_L = \sqrt{A}$$ (Equation B.1 from Annex B of ISO 14644-1 Clause B.4.1.1)

N_L = the minimum required number of sampling locations
A = the area of the cleanroom in square meters

Whereas in FS 209E Clause 5.1.3.1 and 5.1.3.2, The minimum number of sampling locations depended on whether the airflow are unidirectional or non-unidirectional.

FS 209E Clause 5.1.3.1 states that the minimum number of sample locations required for verification in a clean zone with unidirectional airflow shall be lesser of (a) or (b);

(a) SI units : $N_L = A/2.32$
Where A is the area of the entrance plane in m^2

English units : $N_L = A/25$
Where A is the area of the entrance plane in ft^2

(b) SI units : $N_L = A \times 64 / (10^M)^{0.5}$
Where A is the area of the entrance plane in m^2, and M is the SI numerical designation of the class listed in Table 1 of FS209E.

English units : $N_L = A / (N_c)^{0.5}$
Where A is the area of the entrance plane in ft^2, and N_c is the numerical designation of the class, in English units, listed in Table 1 of FS 209E.
Ie N_C = the numerical classification of the cleanroom (NC = 10 for a Class 10 cleanroom, 1 for a Class 1 cleanroom, etc.)

FS 209E Clause 5.1.3.2 states that the minimum number of sample locations required for verification in a clean zone with non-unidirectional airflow shall be;

SI units : $N_L = A \times 64 / (10^M)^{0.5}$
Where A is the area of the entrance plane in m^2, and M is the SI numerical designation of the class listed in Table 1 of FS209E.

English units : $N_L = A / (N_c)^{0.5}$
Where A is the area of the entrance plane in ft^2, and N_c is the numerical designation of the class, in English units, listed in Table 1 of FS 209E.
Ie N_C = the numerical classification of the cleanroom (NC = 10 for a Class 10 cleanroom, 1 for a Class 1 cleanroom, etc.)

In FS 209E two expressions for N_L are equal when $N_C = 625$. For higher quality cleanrooms ($N_C < 625$), the first expression ($N_L = A/25$) yields the lesser value of N_L. When NC > 625, the second expression yields the lesser value. The minimum value of N_L according to FS 209E Clause 5.1.3.3 is 2 ; ISO 14644-1 allows N_L to take on the irreducible value of 1.

The equations show that N_L varies as the square root of cleanroom area by ISO 14644-1, while in FS 209E, N_L varies linearly with A. This difference becomes huge for large cleanrooms. Consider a cleanroom that is 100 square meters in area. The minimum number of sampling locations required by ISO 14644-1 is 10. For this same facility, FS 209E requires 44. (When A is in square meters, the N_L expression of FS 209E becomes $N_L = A/2.32$). For larger cleanrooms the differences become much larger. When A = 1,000 square meters, the ISO $N_L = 32$ and the FS 209E $N_L = 432$.

For lower quality cleanrooms, however, the differences are not as great or can even reverse in that FS 209E may require fewer sampling locations. At Class 100,000, for example, the second equation for calculating the minimum number of sampling locations required by FS 209E yields the lesser number; the 100-square-meter cleanroom considered previously requires only four sampling locations per FS 209E rather than the 10 required by ISO 14644-1. The minimum number of locations required by ISO does not depend on the cleanliness classification as it does in FS 209E.

MINIMUM SAMPLES PER CLEANROOM OR ZONES

Both FS 209E and ISO 14644 standards allow just one measurement to be made at any one location but specify a larger minimum number of measurements per cleanroom or clean zone. FS 209E requires a minimum of five (FS 209E Clause 5.1.3.3) individual measurements of particle concentration per cleanroom or clean zone. These five measurements can be divided in any manner between the minimum required two locations -- four at the first location and one at the second or three and two. ISO 14644-1 requires only three (ISO 14644-1 B4.3.4) individual measurements per cleanroom or clean zone. When only one location is required, these three measurements will, of course, be at that one location. This difference between the two standards in total minimum number of individual measurements per cleanroom or clean zone is relatively minor compared to the potential differences in the minimum number of required locations per cleanroom or clean zone, as pointed out in the preceding paragraphs.

MINIMUM SAMPLE VOLUME

The ISO standard also requires fewer sample locations as demonstrated above, especially as the cleanroom/area size increases; however, the ISO standard does require minimum one minute (ISO 14644-1 Clause B4.2.2) samples, whereas the FS 209E allows shorter samples, especially at smaller particle sizes.

For example, to certify an FS 209E Class 10 cleanroom (ISO class 4), with 250 square feet (7.08 square meters), classified at 0.3 micron with a 1 cfm flow rate particle counter, the required number of sample locations, sample volumes, and sample times would be as follows:

FS 209E Clause 5.1.3.1 states the lesser of (a) or (b) below;

(a) $N_L = 250/25$
$= 10$

(b) $N_L = A / (N_c)^{0.5}$
$= 250 / (10)^{0.5}$
$= 79.1$

FS209E requires 10 sample locations,

FS 209E Clause 5.1.3.4.1 states that each sample of air tested at each location shall be sufficient volume such that at least 20 particles would be detected;

Volume = 20 particles / [Class limit (particles/ volume) from Table 1 of FS 209E]

In addition the volume of air sampled shall not be less than 0.00283 m^3 (0.1 ft^3) and the result of the calculation of the sample volume shall not be rounded down.

Therefore, for the above cleanroom, the minimum volume per sample shall be

$= 20$ particles / [30 particles/ ft^3]
$= 0.67\ ft^3$

and a sample time of 41 seconds. This yields a total minimum sample time of 410 seconds and 10 equipment moves.

On the other hand, if the same cleanroom is certified using ISO 14644; using equation B.1 of ISO 14644-1 Clause B.4.1.1;

$$N_L = \sqrt{A}$$
$$= \sqrt{7.08}$$
$$= 2.66 \text{ say } 3$$

therefore, ISO 14644-1 requires 3 sample locations and from equation B.2 of ISO 14644-1 Clause B.4.2.1, the sample volume shall be;

$$= 20 \text{ particles} / [1020 \text{ particles}/ m^3] \times 1000$$
$$= 19.6 \text{ litres}$$

minimum sample volume (0.69 ft^3), but also a minimum sample time of one minute (ISO 14644 Clause B.4.2.2) yielding three samples of one cubic foot. This yields a total sample time of 180 seconds and three equipment moves.

UPPER CONFIDENCE LEVEL

Both Fed-Std-209E and ISO 14644-1 include the calculation of the 95 percent Upper Confidence Limit (UCL) as part of the statistical tests required to show that a given data set proves that a given cleanroom has demonstrated satisfactory compliance with its claimed cleanroom classification.

CONTINUED COMPLIANCE

FS 209E does not make recommendation nor stipulate requirement to demonstrate continuing compliance, ISO 14644-2, gives requirements for monitoring a cleanroom or clean zone to provide evidence of its continued compliance with ISO 14644-1. It determines the type and frequency of testing required for conformance with the standard. The following tables indicate which tests are mandatory and which tests are optional.

ISO 14644-2 Table 1 Schedule of testing to demonstrate compliance with particle concentration limits

Classification	Maximum Time Interval	Test method
<= ISO 5	6 Months	ISO 14644-1 Annex B
> ISO 5	12 Months	ISO 14644-1 Annex B

ISO 14644-2 Table 2 Schedule of additional tests for all classes

Test Parameter	Maximum Time Interval	Test procedure
Airflow volume or airflow velocity	12 Months	ISO 14644-1 Annex B.4
Air pressure difference	12 Months	ISO 14644-1 Annex B.5

ISO 14644 Table A.1 Schedule of optional tests

	Class	Maximum Time Interval	Test Procedure
Installed Filter Leakage	All Classes	24 Months	ISO 14644-3 Annex B.6
	All Classes	24 Months	
Airflow Visualization	All Classes	24 Months	ISO 14644-3 Annex B.7
Recovery	All Classes	24 Months	ISO 14644-3 Annex B.13
Containment Leakage	All Classes	24 Months	ISO 14644-3 Annex B.14

RECOMMENDED TESTS

FS 209E left it entirely to the seller and buyer to ascertain the types of tests to be carried out, it did not address the type of tests required. ISO 14644-3 dedicated the entire volume to "Metrology and test methods". ISO 14644-3 Clause 4.1 list appropriate recommended tests as listed below;

ISO 14644-3 Table 1 – Recommended tests for installations

Recommended test items	Clause for procedure (ISO 14644-3)	Clause for apparatus (ISO 14644-3)	Reference in ISO Standard
Airborne particle count for classification and test measurement of cleanrooms and clean air devices	B.1	C.1	14644-1 and 14644-2
Airborne particle count for ultrafine particles	B.2	C.2	14644-1
Airborne particle count for macroparticles	B.3	C.3	14644-1
Airflow test	B.4	C.4	14644-1 and 14644-2
Air pressure difference test	B.5	C.5	14644-1 and 14644-2
Installed filter system leakage test	B.6	C.6	14644-2
Airflow visualization	B.7	C.7	14644-2
Airflow direction test	B.8	C.8	
Temperature test	B.9	C.9	
Humidity test	B.10	C.10	
Electrostatic and ion generator test	B.11	C.11	
Particle deposition test	B.12	C.12	
Recovery test	B.13	C.13	14644-2
Containment leak test	B.14	C.14	14644-1 and 14644-2

As stated in the footnote of Table 1 (ISO 14644-3) the recommended tests listed above were not presented in order of importance nor the order in which test should be performed. It shall be based upon the requirement of a specific document or after agreement between the customer and supplier.

CONCLUSION

ISO 14644 adopts the metric system. This means that everything is based on orders of magnitude (powers of 10). This makes arithmetic conversions easy. No problems in going to or from cubic centimeters, milliliters, liters, cubic meters, etc. Compare that with navigating between inches and feet (12 inches = 1 foot, 144 square inches = 1 square foot, 1728 cubic inches = 1 cubic foot, etc.).

ISO 14644 recognizes a reference particle size of 0.1 micrometer compared to a reference particle size of 0.5 micrometer used in FS 209E. This is mainly attributed to the of shrinking geometries and increasing densities encountered in the microelectronics industry which have shifted their attention to particles well below the 0.5 micron level.

ISO 14644-1 retains the conversion formula between different particle sizes with slight modification from the FS 209E version. This makes it possible to readily convert the number of 0.1-micron particles per unit volume of cleanroom air to an equivalent number of 0.2- or 0.3- or 0.5- or 1.0- or 5.0-micron particles per unit volume. And although these particle sizes are the most commonly used, the formula can be used for any particle size of interest within this range. There is an exponent in the formula to describe cleanroom classification mentioned. The ISO 14644-1 document changes the value of this exponent from 2.2 to 2.08. While this may turn out to be useful and more accurate, however it is not earth shattering in its effects.

ISO 14644-1 adds three new cleanliness levels: two cleaner than the cleanest FS 209E level and one dirtier than the dirtiest FS 209E level. The relatively dirty new standard (ISO Class 9) will be useful for those industries just beginning to exert control over the number of airborne particles in manufacturing facilities, such as food and beverage, paint spray applications, consumer optics, plastic finishes, etc. And the two cleaner standards (ISO Classes 1 and 2) will be useful for the microelectronics people.

Both FS 209E and ISO 14644-1 are statistical procedures (and quite similar ones at that), they are susceptible to the effects of outliers but ISO 14644-1, explicitly recognizes this and provides a method of dealing with these under limited circumstances. FS 209E makes no mention of the subject.

The ISO 14644-1 is the first in a series of documents (ISO 14644 and the ISO 14698 series) whereas, by contrast, FS 209E was essentially a stand-alone piece of work.

The ISO 14644 standard changes the minimum number of sample locations required, for the cleaner classes (ISO Classes 5 and cleaner or equivalently, FS 209E Classes 100 and cleaner), the number of sample points required by ISO 14644-1 is reduced over that required by FS 209E.

ISO 14644-1 is not very different from FS 209E. The similarities between the two far outweigh the differences. And to be sure, this is probably the biggest selling point of ISO 14644. Anyone who understands FS 209E will recognize and understand ISO 14644-1.

Appendix A

ISO Document	Title	Published date	Content descriptions
ISO-14644-1	Classification of Air Cleanliness	1/5/1999	This International Standard covers the classification of air cleanliness in cleanrooms and associated controlled environments. Classification in accordance with this standard is specified and accomplished exclusively in terms of concentration of airborne particles and is limited to a designated range of considered particle sizes for determination of particle concentration limits.
ISO-14644-2	Specifications for Testing & Monitoring to Prove Continued Compliance with ISO 14644-1	15/9/2000	This part of ISO 14644 specifies requirements for periodic testing and monitoring 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 classification of a cleanroom or clean zone. Additional tests are also specified.
ISO-14644-3	Metrology and Test Methods	15/8/2002	This part of ISO 14644 specifies metrology and test methods for characterizing the performance of cleanrooms and clean zones. Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational. The test methods recommend test apparatus and test procedures for determining performance parameters. Where the test method is affected by the type of cleanroom or clean zone, alternative procedures are suggested. For some of the tests, several different methods and apparatus are recommended, so that different end-use considerations can be accommodated. Alternative methods not included in this part of ISO 14644 may be used if based on agreement between customer and supplier. Alternative methods do not necessarily provide equivalent measurements. The test methods may also be used or adopted for re-qualification or for periodic monitoring of the performance of a

			cleanroom or clean zone (here after referred to as an installation). This part of ISO 14644 is not applicable to the measurement of products or of processes in cleanrooms or clean zones.
ISO-14644-4	Design, Construction and Start-up	1/4/2001	This part of ISO 14644 specifies requirements for the design and construction of cleanroom installations but does not prescribe specific technological or contractual means to meet these requirements. It is intended for use by purchasers, suppliers and designers of cleanroom installations and provides a checklist of important parameters of performance. Construction guidance is provided, including requirements for start-up and qualification. Basic elements of design and construction needed to ensure continued satisfactory operation are identified through the consideration of relevant aspects of operation and maintenance.
ISO-14644-5	Operations	1/3/2001	This part of ISO 14644 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, this document is broad in application and does not address specific requirements for individual industries. Methods and programs for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference should be made to ISO 14644-2 and ISO 14644-3 for monitoring particles and ISO 14698-1 and ISO 14698-2 for monitoring microorganisms.
ISO-14644-6	Terms and definitions		
ISO-14644-7	Separative enclosures (clean air hoods, glove boxes,	1/3/2001	This part of ISO 14644 specifies the minimum requirements for the design, construction, installation, testing and approval of separative enclosures in those

	isolators, mini-environments)		respects where they differ from cleanrooms as described in ISO 14644-4 and ISO 14644-5.
ISO-14644-8	Molecular contamination		
ISO-14698-1	Cleanrooms and Associated Controlled Environments-Bio-contamination Control-General Principles And Methods	1/4/2003	This part of ISO 14698 describes the principles and basic methodology of a formal system of bio-contamination control (Formal System) for assessing and controlling bio-contamination when cleanroom technology is applied for that purpose. This part of ISO 14698 specifies the methods required for monitoring risk zones in a consistent way and for applying control measures appropriate to the degree of risk involved. In zones where risk is low, it can be used as a source of information. Application-specific requirements are not given. Neither is fire and safety issues addressed; for these, see regulatory requirements and other national or local documentation.
ISO-14698-2	Cleanrooms and Associated Controlled Environments-Bio-contamination Control-Evaluation & Interpretation of Bio-contamination Data	4/2003	This part of ISO 14698 gives guidance on methods for the evaluation of microbiological data and the estimation of results obtained from sampling for viable particles in risk zones for bio-contamination control. It should be used, where appropriate, in conjunction with ISO 14698-1.
ISO-14698-3	Measurement of the Efficiency of Cleaning Processes	1/1/1998	This part examines processing incorporating one or more of the following: rinsing, cleaning, dis-infection, combined cleaning and disinfection, biochemical action, and mechanical action.

References

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