TERRA UNIVERSAL.COM
Critical Environment Solutions

FS209E and ISO Cleanroom Standards

About Terra Universal:

Terra Universal is the global leader of Critical Environment Solutions®. We transform the world with innovative solutions that improve health, safety, performance, and yields.

Terra Universal designs, manufactures, customizes, and stocks comprehensive lines of cleanrooms, air filtration systems, pass-through chambers, desiccator cabinets, glove boxes, laminar flow hoods, and other cleanroom furnishings.

Since 1975, our mission has been to transform the world with innovative solutions that improve health, safety, performance, and yields.

Terra also operates Laboratory-Equipment.com offering carefully selected lines of laboratory instruments and equipment from sector-leading manufacturers such as Thermo Fisher.

Industries Served: Pharmaceuticals, Biotechnology, Medical Devices, Medical, Semiconductor, Electronics, Aerospace, Optics/ Photonics, General R&D, and other industries requiring precise control of environmental conditions.

Comparing FS209E and ISo 14544-1 Standards

Before global cleanroom classifications and standards were adopted by the International Standards Organization (ISO), the U.S. General Service Administration's standards (known as FS209E) were applied virtually worldwide. However, as the need for international standards grew, the ISO established a technical committee and several working groups to delineate its own set of standards.

FS209E contains six classes, while the ISO 14644-1 classification system adds two cleaner standards and one dirtier standard (see chart below). The "cleanest" cleanroom in FS209E is referred to as Class 1; the "dirtiest" cleanroom is a class 100,000. ISO cleanroom classifications are rated according to how much particulate of specific sizes exist per cubic meter (see second chart). The "cleanest" cleanroom is a class 1 and the "dirtiest" a class 9. ISO class 3 is approximately equal to FS209E class 1, while ISO class 8 approximately equals FS209E class 100,000.

By law, Federal Standard 209E can be superseded by new international standards. It is expected that 209E will be used in some industries over the next five years, but that eventually it will be replaced internationally by ISO 14644-1.

Airborne Particulate Cleanliness Class Comparison		
ISO 14644-1	**FEDERAL STANDARD 209E**	
ISO Class	English	Metric
ISO 1		
ISO 2		
ISO 3	1	M1.5
ISO 4	10	M2.5
ISO 5	100	M3.5
ISO 6	1,000	M4.5
ISO 7	10,000	M5.5
ISO 8	100,000	M6.5
ISO 9		

Airborne Particulate Cleanliness Classes (by cubic meter):						
Class	**Number of Particles per Cubic Meter by Micrometer Size**					
	0.1 micron	0.2 micron	0.3 micron	0.5 micron	1 micron	5 microns
ISO1	10	2				
ISO2	100	24	10	4		
ISO3	1,000	237	102	35	8	
ISO4	10,000	2,370	1,020	352	83	
ISO5	100,000	23,700	10,200	3,520	832	29
ISO6	1,000,000	237,000	102,000	35,200	8,320	293
ISO7				352,000	83,200	2,930
ISO8				3,520,000	832,000	29,300
ISO9				35,200,000	8,320,000	293,000

In cleanrooms, particulate concentration changes over time — from the construction and installation of equipment to its operational status. ISO delineates three cleanroom classification standards: as-built, at-rest and operational. As instruments and equipment are introduced and particulates rise, an “as-built” cleanroom becomes an “at-rest” cleanroom. When people are added to the matrix, particulate levels rise still further in the “operational” cleanroom.

ISO 14644-2 describes the type and frequency of testing required to conform to certain standards. The following tables indicate mandatory and optional tests.

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

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 14644-1 Annex B6
Containment Leakage	All Classes	24 Months	ISO 14644-1 Annex B4
Recovery	All Classes	24 Months	ISO 14644-1 Annex B13
Airflow Visualization	All Classes	24 Months	ISO 14644-1 Annex B7

Today, in addition to ISO 14644-1 and ISO 14644-2, eight other cleanroom standards documents are being prepared. Many are in the final voting stage and can be legally used in the trade (see chart).

ISO Document	Title
ISO 14644-1	Classification of Air Cleanliness
ISO 14644-2	Cleanroom Testing for Compliance
ISO 14644-3	Methods for Evaluating and Measuring Cleanrooms and Associated Controlled Environments
ISO 14644-4	Cleanroom Design and Construction
ISO 14644-5	Cleanroom Operations
ISO 14644-6	Terms, Definitions and Units
ISO 14644-7	Enhanced Clean Devices
ISO 14644-8	Molecular Contamination
ISO 14698-1	Biocontamination: Control General Principles
ISO 14698-2	Biocontamination: Evaluation and Interpretation of Data
ISO 14698-3	Biocontamination: Methodology for Measuring Efficiency of Cleaning Inert Surfaces

The USA source for ISO documents is:

Institute of Environmental Sciences & Technology (IEST)
5005 Newport Drive, Suite 506
Rolling Meadows, IL 60008-3841 http://www.iest.org
Phone: (847) 255-1561
Fax: (847) 255-1699

The source for FS209E documents at the General Services Administration is:

Standards Order Desk
Naval Publications and Forms Center
700 Robbins Avenue
Section D BLD4
Philadelphia, PA 19111
Phone: (215) 697-2667
Fax: (215) 697-2978

ISO and Federal Air Change Rates for Cleanrooms

A critical factor in cleanroom design is controlling air-change per hour (ACH), also known as the air-change rate, or ACR. This refers to the number of times each hour that filtered outside air replaces the existing volume in a building or chamber. In a normal home, an air-conditioner changes room air 0.5 to 2 times per hour. In a cleanroom, depending on classification and usage, air change occurs anywhere from 10 to more than 600 times an hour.

ACR is a prime variable in determining ISO and Federal cleanliness standards. To meet optimal standards, ACR must be painstakingly measured and controlled. And there is some controversy. In an appendix to its ISO 14644-1 cleanliness standard, the International Standards Organization addressed applications for microelectronic facilities only. (ISO classes 6 to 8; Federal Standards 1,000, 10,000 and 100,000.) The appendix contained no ACR standards for pharmaceutical, healthcare or biotech applications, which may require higher ACR regulations.

According to current research, case studies and experiments, using an ACR range (rather than one set standard) is a better guideline for cleanliness classification. This is true because the optimal ACR varies from cleanroom to cleanroom, depending on factors such as internal equipment, staffing and operational purpose. Everything depends on the level of outside contaminants trying to enter the facility versus the level of contaminants being generated on the inside.

The breadth of these ranges reflects how dramatically people and processes affect cleanliness. Low-end figures within each contamination class generally indicate air velocity and air change requirements for an as-built or at-rest facility—where no people are present and no contaminating processes under way. When there are people and processes producing contaminants, more air changes are required to maintain optimal cleanliness standards. For instance, some manufacturers insist on as many as 720 air changes per hour to meet Class 10 standards.

Determining the appropriate number of air changes for a particular application requires careful evaluation of factors such as the number of personnel, effectiveness of garbing protocol, frequency of access, and cleanliness of process equipment.

Rajan Jaisinghani, in his paper “Energy Efficient Low Operating Cost Cleanroom Airflow Design,” presented at ESTECH 2003, recommended the following ranges based on FS209E classifications:

FS Cleanroom Class	ISO Equivalent Class	Air Change Rate
1	ISO 3	360-540
10	ISO 4	300-540
100	ISO 5	240-480
1,000	ISO 6	150-240
10,000	ISO 7	60-90
100,000	ISO 8	5-48

Jaisinghani’s recommendations concur with other recent studies of ACR, which criticize some existing air rate standards (developed in the 1990s) as being unscientific because they are based on fans and filters inferior to today’s models. So when these older standards are applied, the resulting ACR is often too high. In fact, some studies have found that reducing the ACR (and its attendant air turbulence) can result in a cleaner atmosphere.

This was demonstrated in a study conducted by Pacific Gas and Electric (San Francisco) and the Lawrence Berkeley National Laboratory (Berkeley). The study measured air change rates in several ISO Class-5 cleanrooms and came to the conclusion that there is “no consistent design strategy for air change rate, even for cleanrooms of the same cleanliness classification.”

ACR rates have critical design implications, especially when considering desired cleanliness, fan size and lower energy costs. The PG&E/Berkeley study caused many designers to reduce fan sizes. In short, a lower ACR often resulted in cleaner air.

The study revealed three abiding principles:

- Lower air change rates result in smaller fans, which reduce both initial investment and construction cost.
- Fan power is proportional to the cube of air change rates or airflow. A 30-percent reduction in air change rate results in a power reduction of approximately 66 percent.
- By minimizing turbulence, lower airflow may improve cleanliness.

The study focused on Class-5 cleanrooms, concluding that an ACR range of from 250 to 700 air changes per hour is standard, but that “actual operating ACRs ranged from 90 to 625.” It added that all of these optimized cleanrooms were certified and performing at ISO Class-5 conditions with these lower ACRs. Finally, the study concluded that rarely does a Class-5 facility require an ACR of more than 300.

The study also found that the “[b]est practice for ACRs is to design new facilities at the lower end of the recommended ACR range,” with variable speed drives (VSDs) built in so that air flow adjustments can be made under actual operating conditions.

In his report “An examination of ACRs: An opportunity to reduce energy and construction costs,” Peter Rumsey, PE, CEM, essentially concurred with the PG&E-commissioned study by Berkeley. Rumsey issued a caveat, then brushed it aside by citing research subsequent to Berkeley’s: “Air cleanliness is a critical component of any cleanroom, far outweighing energy saving priorities. Designers and operators need evidence from others who have tried similar strategies in order to address the perceived risks of lowering air change rates.”

Rumsey then went on to cite studies done by International Sematech (Austin, Texas); the Massachusetts Institute of Technology (Cambridge, Mass.); Intel (Santa Clara, Calif.); and Sandia National Laboratories (Albuquerque, N.M.), which echoed the Berkeley study.

In summary, current research and thinking on air change rates indicate that some existing standards are too high and can be lowered while still meeting all ACR criteria.

Federal and ISO Ceiling Fan Coverage Specifications

Achieving the optimal air change rate requires proper ceiling fan coverage. The cleanest modular cleanroom incorporates filter/ fan units (FFUs) in every 2' x 4' (610 mm x 1219 mm) ceiling bay. This near-100% coverage provides a laminar flow of filtered air to quickly remove contaminants from the room, thus meeting FS209E standards for Class 10 and ISO Class 1 standards.

Such coverage, especially in a large cleanroom, can lead to higher energy consumption, thus increasing costs for both initial construction and ongoing operation. In most cases, a smaller percentage of ceiling coverage produces adequate cleanliness.

This table illustrates the percentage of ceiling coverage recommended for each cleanliness class, again as a range:

Class	Ceiling Coverage (Percentage)
SO 8 (Class 100,000)	5 – 15%
ISO 7 (Class 10,000)	15 – 20%
ISO 6 (Class 1,000)	25 – 40%
ISO 5 (Class 100)	35 – 70 %
ISO 4 (Class 10)	50 – 90%
ISO 3 (Class 1)	60 – 100%
ISO 1-2	80 – 100%

Federal and ISO Airflow Velocity Standards

In addition to ACR and ceiling coverage, the third factor integral to maintaining cleanliness is fan-generated air speed. Again, higher airflow velocity results in a "cleaner" cleanroom. The term "ventilation efficiency" refers to the speed of filtered air passing through the cleanroom in addition to the number of air changes per hour (ACH or ACR).

An earlier chart showed a range of recommended air change rates (ACRs) for different classes of cleanrooms. Ranges are given because as-built and at-rest facilities require a smaller ACR than an operational cleanroom, where both people and equipment are actively engaged. Non-operational cleanrooms are found in the lower range; operational cleanrooms higher.

Combining all three factors—ACR, ceiling coverage and airflow velocity—results in the following table:

Class ISO 146144-1 (Federal Standard 209E)	Average Airflow Velocity m/s (ft/min)	Air Changes Per Hour	Ceiling Coverage
ISO 8 (Class 100,000)	0.005 – 0.041 (1 – 8)	5 – 48	5 – 15%
ISO 7 (Class 10,000)	0.051 – 0.076 (10 -15)	60 – 90	15 – 20%
ISO 6 (Class 1,000)	0.127 – 0.203 (25 – 40)	150 – 240	25 – 40%
ISO 5 (Class 100)	0.203 – 0.406 (40 – 80)	240 – 480	35 – 70%
ISO 4 (Class 10)	0.254 – 0.457 (50 – 90)	300 – 540	50 – 90%
ISO 3 (Class 1)	0.305 – 0.457 (60 – 90)	360 – 540	60 – 100%
ISO 1 – 2	0.305 – 0.508 (60 – 100)	360 – 600	80 – 100%

Before deciding on the appropriate velocity and air changes for your application, Terra Universal recommends careful evaluation of factors such as number of personnel, effectiveness of garbing protocol, access frequency and cleanliness of process equipment. Once the required air change figure is established, the number of required FFUs can be determined using this formula:
No. of FFUs = (Air Changes/Hour ÷60) x (Cubic ft. in room÷ 650*)

**CFM output of a loaded FFU*

Meeting Class 100 standards using the low-end air change recommendation (240/hour) inside a 12' x 12' x 7' (3302 mm x 3302 mm x 2134 mm) cleanroom, with 1008 cu. ft. of volume, requires 6 FFUs. To meet the same standard using the high-end air change recommendation (480/hour) requires 12 FFUs.

Positive Pressure

Cleanrooms are designed to maintain positive pressure, preventing “unclean” (contaminated) air from flowing inside and less-clean air from flowing into clean areas. The idea is to ensure that filtered air always flows from cleanest to less-clean spaces. In a multi-chambered cleanroom, for instance, the cleanest room is kept at the highest pressure. Pressure levels are set so that the cleanest air flows into spaces with less-clean air. Thus, multiple pressure levels may need to be maintained.

A differential air pressure of 0.03 to 0.05 inches water gage is recommended between spaces. In order to ensure that pressure differentials remain constant when doors are opened, or other events occur, control systems must be in place.

Laminar and Turbulent Air Flow

ISO 5 (Class 100) and cleaner facilities rely on unidirectional, or laminar, airflow. Laminar airflow means that filtered air is uniformly supplied in one direction (at a fixed velocity) in parallel streams, usually vertically. Air is generally recirculated from the base of the walls back up to the filtering system.

ISO 6 (Class 1,000) and above cleanrooms generally utilize a non-unidirectional, or turbulent, airflow. This means the air is not regulated for direction and speed. The advantage of laminar over turbulent airflow is that it provides a uniform environment and prevents air pockets where contaminants might congregate.