

TripleAir Guide to Cleanrooms ISO 8 to ISO 5

Clean Room Classification (ISO 8, ISO 7, ISO 6, ISO 5)

Clean rooms are classified according to the cleanliness level of the air inside the controlled environment. The clean room class is the level of cleanliness the room complies with, according to the quantity and size of particles per cubic meters of air. The primary authority in the US and Canada is the ISO classification system ISO 14644-1.

This ISO standard includes these clean room classes : ISO 1, ISO 2, ISO 3, ISO 4, ISO 5, ISO 6, ISO 7, ISO 8 and ISO 9. ISO 1 is the "cleanest" class and ISO 9 is the "dirtiest" class. Even if it's classified as the "dirtiest" class, the ISO 9 clean room environment is cleaner than a regular room. The most common ISO clean room classes are ISO 7 and ISO 8. The Federal Standard 209 (FS 209E) equivalent for these ISO classes are Class 10,000 and Class 100 000.

The old Federal Standard 209E (FS 209E) includes these clean room classes : Class 100,000; Class 10,000; Class 1,000; Class 100; Class 10; Class 1. This standard was replaced in 1999 by ISO-14644-1. It was withdrawn in 2001, but it is still widely used.

Clean rooms must also follow industry-specific and regional standards. For example, EU GMP (A-B-C-D).

Clean room levels and layouts

Depending on the class of cleanroom system you would like to reach, it is important to allow for enough square footage. This is critical not just for the clean zone, but also for the airlocks/gowning room which prevent the migration of particles from outside into the clean space.

The rule of thumb is that you should not skip over more than one class when you move towards a cleaner room (for example, from ISO 7 to ISO 6, not from ISO 8 to ISO 6), as illustrated below. In reality, however, you can reach a cleaner class with fewer airlocks than described below with the appropriate air changes per hour.

This depends on the process taking place inside the cleanroom, the size of the cleanroom, the number of people working inside, the equipment inside, etc. Seek the help of a cleanroom expert who can create the optimal layout for your particular needs.

Clean Room Filtration and Lighting Technology

TripleAir Technology are suppliers of high quality HEPA and ULPA filtration, ceiling grid systems and luminaires for the clean room industry. We offer fully integrated ceiling solutions for projects and cleanroom facilities.

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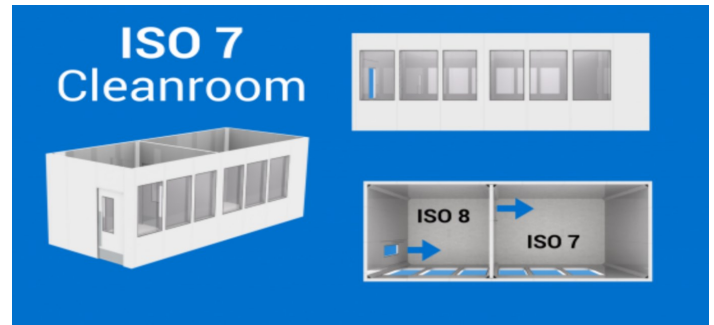


ISO 8 Cleanroom (Class 100,000 Cleanroom)

Let's assume that an unclassified space (office or lab) is ISO 9. In this case, you can directly enter an ISO 8 cleanroom, without an airlock. Depending on the production process inside the cleanroom, however, you may have to add a gowning room.

ISO 8 zone 15–25 air changes per hour

Non-unidirectional air flow



ISO 7 Cleanroom (Class 10,000 Clean room)

This is one of the most common classes of cleanrooms. If you need an ISO 7 cleanroom, you should consider having an ISO 8 airlock/gowning room prior to entering the ISO 7 room. The air changes per hour will vary in both rooms as described below.

ISO 7 zone 30–60 air changes per hour

ISO 8 zone 15–25 air changes per hour (ante-room)

Non-unidirectional air flow

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ISO 6 Cleanroom (Class 1,000 Cleanroom)

In theory, for an entire room to reach ISO 6 air cleanliness, you need to enter the cleanroom via an ISO 8 (ante-room), then go through an ISO 7, to finally get into the ISO 6, as shown in the image.

In reality however, you can reach an ISO 6 cleanroom with 1 (recommendation is 2) airlock. Again, it depends on the size of the room, the process taking place inside the cleanroom, the number of people working inside, the equipment inside, etc.

Unidirectional air flow is sometimes recommended to reach ISO 6 classification. For a room of less than 4–6mtrs in width (depending on the activities taking place inside the cleanroom), air returns can be positioned on the side of the walls instead of in the floor. Installing air returns in the floor is more expensive.

ISO 6 zone 90–180 air changes per hour

ISO 7 zone 30–60 air changes per hour

ISO 8 zone 15–25 air changes per hour (ante-room)



ISO 5 Cleanroom (Class 100 Cleanroom)

In theory, for a classified room (not just below a LAFW hood) to reach ISO class 5 air cleanliness, you need to enter the cleanroom via an ISO 8 (ante-room), then go through an ISO 7, followed by an ISO 6 to finally get into the ISO class 5 cleanroom.

In reality, however, you can reach an ISO 5 cleanroom with 2 or 3 airlocks. The optimal layout depends on the process taking place inside the cleanroom, the size of the room, the number of people working inside, the equipment inside, etc.

In addition, an ISO 5 or class 100 clean room needs to use **unidirectional air flow**. Unidirectional air flow cleanrooms use much more air than non-directional air flow cleanrooms. High efficiency filters are installed across the entire ceiling.

The filtered air sweeps down the room in a unidirectional way, at a velocity generally between 0.3 m/s and 0.5 m/s, and exits through the floor, removing the airborne contamination from the room. Cleanrooms using unidirectional air flow are more expensive than nonunidirectional ones, but can comply with more stringent classifications, such as ISO 5 or lower.

ISO 5 zone 240–360 air changes per hour

ISO 6 zone 90–180 air changes per hour

ISO 7 zone 30–60 air changes per hour

ISO 8 zone 15–25 air changes per hour (ante-room)

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Comparison between selected equivalent of FS 209E and ISO 14644-1

ISO 14644-1	FS 209E
ISO 3	Class 1
ISO 4	Class 10
ISO 5	Class 100
ISO 6	Class 1,000
ISO 7	Class 10,000
ISO 8	Class 100,000

Clean room classification particle concentration

The basis of clean room standards is the micrometer, or micron for short (μm), which is the size of the particles to be filtered. As stated before, clean rooms are classified by how clean the air is, according to the number of particles and size of particles per volume of air. The clean room classification table below shows the maximum concentration limits (particles/ m^3 of air) for particles equal to and larger than the considered sizes shown.

Some classifications do not require certain particle sizes to be tested because the respective concentrations are too low or too high to be tested, but they should not be zero.

ISO CLEAN ROOM STANDARDS AND THE FS 209E EQUIVALENT

ISO Class	Maximum Particles/ m^3						Particles/ ft^3	FS 209E Equivalent
	$\geq 0.1\mu\text{m}$	$\geq 0.2\mu\text{m}$	$\geq 0.3\mu\text{m}$	$\geq 0.5\mu\text{m}$	$\geq 1\mu\text{m}$	$\geq 5\mu\text{m}$	$\geq 0.5\mu\text{m}$	
ISO 1	10							
ISO 2	100	24	10					
ISO 3	1,000	237	102	35			1	Class 1
ISO 4	10,000	2,370	1,020	352	83		10	Class 10
ISO 5	100,000	23,700	1,020	352	832	29	100	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	1,000	Class 1,000
ISO 7				352,000	83,200	2,930	10,000	Class 10,000
ISO 8				3,520,000	832,000	29,300	100,000	Class 100,000
ISO 9				35,200,000	8,320,000	293,000		

** Old FS 209E classes were calculated in cubic foot of air, whereas ISO classes are in cubic meter of air.

HOW TO READ THE CLEAN ROOM CLASSIFICATION PARTICLE COUNT GRAPH

ISO Class	Maximum Particles/ m^3						Particles/ ft^3	FS 209E Equivalent
	$\geq 0.1\mu\text{m}$	$\geq 0.2\mu\text{m}$	$\geq 0.3\mu\text{m}$	$\geq 0.5\mu\text{m}$	$\geq 1\mu\text{m}$	$\geq 5\mu\text{m}$	$\geq 0.5\mu\text{m}$	
ISO 7				352,000	83,200	2,930	10,000	Class 10,000

For ISO 7, particles smaller than 0.5 microns ($\geq 0.1\mu\text{m}$, $\geq 0.2\mu\text{m}$, $\geq 0.3\mu\text{m}$) are not taken into consideration. The concentration of particles of $\geq 0.5\mu\text{m}$ and above should be below 352,000, for particles of 1 micron and above 83,200 or lower and for particles of 5 microns and above 2,930 or lower.

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Cleanroom classification and air changes per hour

Air cleanliness is achieved by passing the air through HEPA filters using low principles such as laminar flow. The more often the air passes through the HEPA filters, the fewer particles are left in the room air. The volume of air filtered in one hour divided by the volume of the room gives the number of air changes per hour.

The number of air changes per hour according to the ISO class

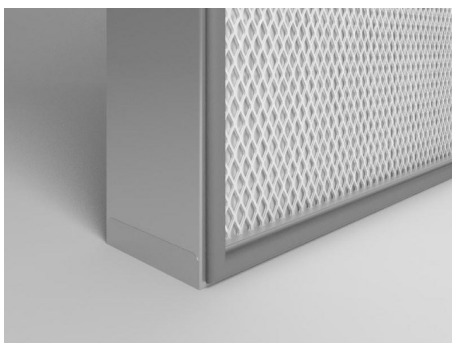
ISO Class	Average number of air changes per hour
ISO 5	240–360 (unidirectional air flow)
ISO 6	90–180
ISO 7	30–60
ISO 8	10–25
Conventional building	2–4

The above-suggested air changes per hour are only a design rule of thumb.

They should be computed by an HVAC cleanroom expert, as many aspects must be taken into consideration, such as the size of the room, the number of people in the room, the equipment in the room, the processes involved, the heat gain, etc.

Disclaimer

This article will help you understand the basic differences between an ISO 5, ISO 6, ISO 7 and ISO 8 cleanroom as per ISO 14644. Please note that this information is only provided for educational purposes. The definitions in this article are oversimplified in order to assist with understanding. This article will not help you decide which cleanroom classification you must reach. If help is needed in this respect, seek the advice of an expert in your industry (pharmaceutical, medical devices, sterile compounding, electronics, etc.).



TripleAir Technology Ltd
(Sales, Engineering & Manufacture)
41A Colbourne Crescent,
Nelson Park Industrial Estate,
Cramlington, England,
NE23 1WP.
T +44(0)1670 739394
E info@tripleairtechnology.co.uk

TripleAir Technology BV (Sales & Production)
P.O. Box 2204, 7801 CE, Emmen
Columbusstr. 30, 7825 VR, Emmen,
The Netherlands
T +31(0)591 630607 F +31(0)591 631099
E info@tripleair-technology.com

tripleairtechnology.co.uk