

Classification and Standard of Dust Free Work Shop

Definition of Classification and standard of clean room:

The development of dust-free workshops is closely linked with modern industry and cutting-edge technology. At present, it has been widely and maturely used in biopharmaceutical, medical and health, food daily chemical, electronic optics, energy, precision instruments and other industries. The dust-free workshop is divided into several grades, which are grade $1 \ge$ grade $100 \ge$ grade $1000 \ge$ grade $10,000 \ge$ grade $100,000 \ge$ grade $100,000 \ge$ grade $100,000 \ge$ grade $100,000 \ge$ grades, and different grades have different grade standards.

Air cleanliness level:

In the unit volume of air in the clean space, the grade standard is divided by the maximum concentration limit of particles greater than or equal to the considered particle size. In China, the dust-free workshop is tested and accepted according to empty state, static state and dynamic state, which conforms to "GB50073-2013 Clean Room Design Code" and "GB50591-2010 Clean Room Construction and Acceptance Code".

The cleanliness and the continuous stability of pollution control are the core standards for testing the quality of the clean room. The standard is divided into several grades according to factors such as the regional environment and cleanliness. Commonly used are international standards and domestic regional industry standards.

ISO14644-1 International Standard—Classification of Air Cleanliness:

Air Cleanliness	Maximum particle concentration limit greater than or equal to the size of the particle (number of air particles/cubic meter)						
Class (N)	0.1μm	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	1000	237	102	35	8		
ISO Class 4	10,000	2,370	1,020	352	83		
ISO Class 5	1000,000	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: Due to the uncertainty involved in the measurement process, it is required that no more than three valid concentration numbers be used to determine the grade level

GB50073-2013 National Standard- Air Cleanliness Level:

Air Cleanliness Class /Grade (N)	Greater than or equal to the maximum concentration limit of particle size in the table (pc/m2)						
	0.1μm	0.2μm	0.3μm	0.5µm	1.0μm	5.0μm	
1	10	2					
2	100	24	10	4			
3	1000	237	102	35	8		
4 (Grade 10)	10,000	2,370	1,020	352	83		
5 (Grade 100)	1000,000	23,700	10,200	3,520	832	29	
6 (Grade 1,000)	1,000,000	237,000	102,000	35,200	8,320	293	
7 (Grade 10,000)				352,000	83,200	2,930	
8 (Grade 100,000)				3,520,000	832,000	29,300	
9 (Grade 1,000,000)				35,200,000	8,320,000	293,000	

Approximate comparison table of cleanliness grades in various countries:

Pcs/M≥0.5μm	ISO 14644-1 (1999)	US 209E (1992)	US 209D (1988)	EEC c GMP (1989)	FRANCE AFNOR (1981)	GERMANY VDI 2083	JAPAN JAOA (1989)
1	-	-	-	-	-	-	-
3.5	2	-	-	-	-	0	2
10.0	-	M1	-	-	-	-	-
35.3	3	M1.5	1	-	-	1	3
100	-	M2	-	-	-	-	-
353	4	M2.5	10	-	-	2	4
1,000	-	M3	-	-	-	-	-
3,530	5	M3.5	100	A+B	4,000	3	5
10,000	-	M4	-	-	-	-	-
35,300	6	M4.5	1,000	1,000	-	4	6
100,000	-	M5	-	-	-	-	-
353,000	7	M5.5	10,000	С	400,000	5	7
1,000,000	-	M6	-	-	-	-	-
3,530,000	8	M6.5	100,000	D	4,000,000	6	8
10,000,000	-	M7	-	-	-	-	-



Dust-free workshop (clean room) grade description: The schema for class definitions is as follows:

Class X (at Y µm)

Where X is the grade of the clean room, such as 100 or 10000, etc., Y is the particle size such as $0.2\mu m$, $0.5\mu m$, etc., which can be selected multiple times. It means that the user stipulates that the particle content of the clean room must meet the limit of this level in these particle sizes. This can reduce disputes, here are a few examples:

Class 1 (0.1μm, 0.2μm , 0.5μm)

Class 100 (0.2μm, 0.5μm)

Class 100 (0.1μm, 0.2μm, 0.5μm)

In Classes 100 (M3.5) and Greater (Class 100, 1000, 10000...), generally just look at one particle size. In Classes Less than 100 (M3.5) (Class 10, 1....), it generally depends on the particle size.

The second trick is to specify the status of the clean room, for example:

Class X (at Y µm), At-rest

The supplier knows very well that the clean room must be accepted in the At-rest state. The third technique is to customize the upper limit of particle concentration. Generally, the clean room is very clean when As-built, and it is not easy to test the particle control ability. At this time, you can simply lower the upper limit of acceptance, for example:

Class 10000 (0.3µm <= 10000), As-built

Class 10000 (0.5μm <= 1000), As-built

The purpose of this is to ensure that the clean room still has sufficient particle control capabilities when it is in the Operational state.

