

What is a clean room?

As the name suggests, a 'clean room' is clean and has low levels of pollutants such as dust, microbes, aerosol particles, and chemical vapours. It is a 'contained space' where provisions are made to minimize the introduction, generation, and retention of particles inside the room, and control other environmental parameters such as temperature, humidity and pressure.



PC: Allied Cleanrooms

Why a Clean Room Environment is Important?

Certain industrial products are sensitive to particulates and get contaminated or destroyed in contact with pollutants, for example; medicinal/pharmaceutical products, semiconductor or electronic products, medical devices. Upcoming industries, such as nanotechnology and artificial intelligence (AI), also require clean room conditions.

Classification:

Depending on the level of contamination control required, clean rooms are classified by the International Standards Organisation (ISO) or British Standards (BS). It is based on the number and size of particles permitted per volume of air, classified from ISO Class 1 to 9.

The lower the ISO Class Number (i.e. the lower the size & concentration of the particles), the ‘cleaner’ the space.

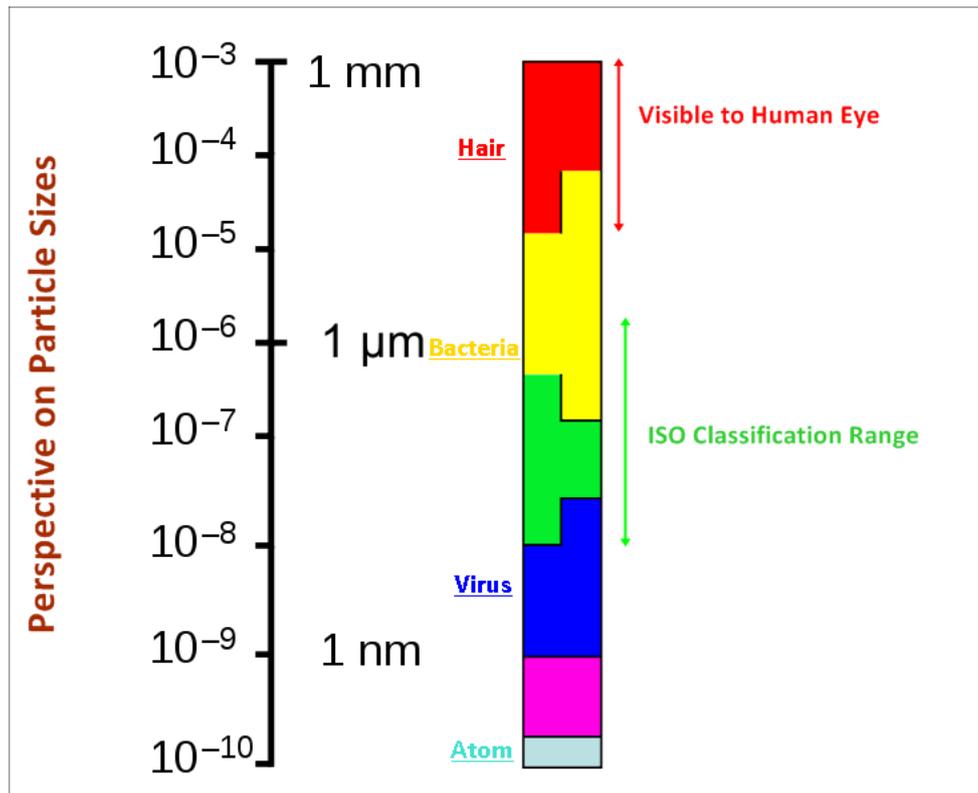
Table 1 — Selected airborne particulate cleanliness classes for cleanrooms and clean zones

ISO classification number (N)	Maximum concentration limits (particles/m ³ of air) for particles equal to and larger than the considered sizes shown below (concentration limits are calculated in accordance with equation (1) in 3.2)					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	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 Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level

Source: ISO.org

To put this in perspective;



The ambient air outside in a typical city environment contains 35,000,000 particles per cubic metre, 0.5 micron and larger in diameter. This corresponds to an **ISO Class 9** clean room which is at the lowest level of clean room standards.

An **ISO Class 5** lab cannot have more than 3,520 particles per cubic metre, 0.5 micron and larger in diameter.

In the UK, **BS EN ISO 14644-1:2015** covers the requirements for classified clean environments and guidelines related to air cleanliness, looking specifically at particle concentration.

Air Handling & Ventilation:

To achieve the required contamination control, both air handling and filtration are important.

The particle size is controlled by the High Efficiency Particulate Air (HEPA) filter that is used to trap particles that are 0.3 micron and larger in size (ISO Class 2-9). For lower particle size

Ultra Low Particulate Air (ULPA) (ISO Class 1) filters are used. All the air delivered to a clean room passes through HEPA filters.

Depending upon the ISO class desired, airflow type, airflow velocity and air changes are determined by always keeping positive pressure in the clean room.

Assuming a clean physical design, air flow determines the design cleanliness of a cleanroom. Cleanroom classes, ISO standards and Terra's general recommendations in terms of air-changes-per-hour are:

Class	ISO Average	Air changes/hour
100,000	ISO Level 8	5 to 48
10,000	ISO Level 7	60-90
1,000	ISO Level 6	150-240
100	ISO Level 5	240-480
10	ISO Level 4	300-540

Source: Terra Universal

Clean Room Design & Operation:

Many factors besides airborne particulate cleanliness must be considered in the design, specification, operation, and control of clean rooms and other controlled environments.

Personnel selected to work in clean rooms are required to undergo extensive training in contamination control theory. They enter and exit the cleanroom through airlocks, air showers and/or gowning rooms, and they must wear special clothing designed to trap contaminants that are naturally generated by the skin and body.

Bulb Laboratories work with specialist clean room suppliers to provide customised solutions to meet clients' exact requirements. Together we design and then deliver the bespoke solution including validation and certification to meet the regulatory compliance.

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