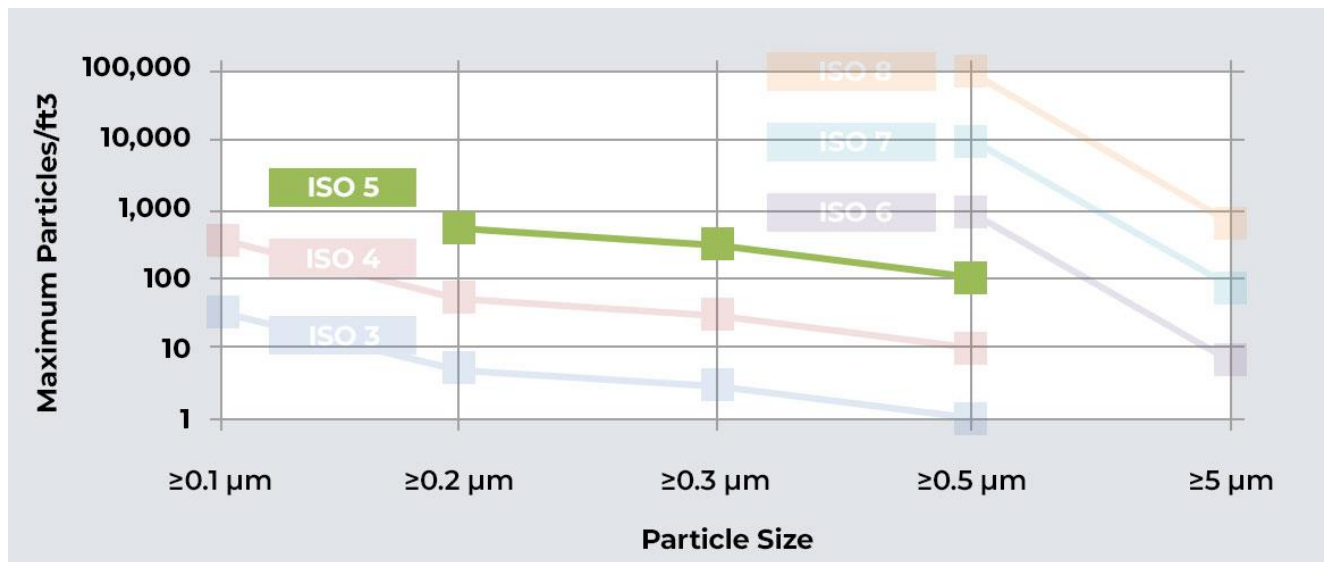


ISO 5 Cleanroom Specifications

ISO 5 or Class 100 Cleanrooms are an ultra-clean stringent classification of cleanrooms across a narrower cross section of industries and application types. ISO 5 Cleanrooms are utilized in biotechnology, pharmaceutical, nanotechnology, and various cleantech manufacturing applications such as fine chemical, ion lithium battery, solar, active medical devices, and high-end film / packaging.

U.S. Federal Standard 209E Cleanroom Standards*



Maximum Particles / ft ³						
ISO	≥0.1 μm	≥0.2 μm	≥0.3 μm	≥0.5 μm	≥5 μm	Class
ISO 3	35	7	3	1		Class 1
ISO 4	350	75	30	10		Class 10
ISO 5		750	300	100		Class 100
ISO 6				1,000	7	Class 1,000
ISO 7				10,000	70	Class 10,000
ISO 8				100,000	700	Class 100,000

Common ISO 5 Cleanroom Design Specifications and Considerations

Filtration & Particle Control

- Focused measurement of particle sizes greater than 0.5 μ and less than 5.0 μ
- High Efficiency Penetration Air (HEPA) Filtration efficiency: 99.99% at 0.3 microns
- Final filtration is performed at the air entry point of the cleanroom, and is commonly performed by terminal HEPA modules or HEPA FFU (fan filter modules) depending on the application.
- 35,200 PPC (particles per cubic meter) at 0.5 μ
- Environmental parameters such as temperature, humidity, lighting levels, noise criteria, static control, and outgassing are often driven by the requirements of the specific process being performed in the cleanroom.

Airflow & Air Change Rates per Hour (ACPH)

- Unidirectional airflow is utilized due to the stringent nature of a stable ISO 5 cleanroom area. Airflow is vertical flow from the ceiling to the floor, returning to conditioning and filtration through low wall returns or raised access (perforated) flooring.
- Typical Air Changes: 240-480 air changers per hour (ACPH)
- Ceiling coverage: 35-70%
- Filtration Ceiling coverage is 35-70%, with a uniform array across the span of the cleanroom.
- Unidirectional airflow pattern typically used

Architectural Finishes

- Wall systems: modular purpose-built wall systems depending on the application of the cleanroom. Biotech applications require non-shedding systems, with monolithic seams and coving to remove 90° angles, allowing wet washed down or VHP fogging to achieve sterile requirements. Nanotechnology and other non-sterile cleanroom types utilize non-shedding systems and are regularly dry wiped or vacuumed.
- Ceiling systems: purpose-built ceiling systems are utilized for ISO 5 conditions depending on the application of the cleanroom. Biotech and pharmaceutical applications often require plenum module ceiling system to achieve both proper filter coverage and lighting levels. Nanotechnology and other non-sterile applications commonly utilize gasketed grid systems with non-shedding blank ceiling tiles where devices such as filtration or lights are not populated, or utilize plenum modules.
- Flooring systems range from resinous flooring systems, to heat welded vinyl flooring system, or raised access flooring with perforated tiles. Each system can provide attributes depending on the application (i.e. chemical resistance, coving, static control, rolling weight loading / impact resistance, non-slip).
- Miscellaneous architectural features to include types of doors, viewing windows, glass walls, pass-thrus, sprinkler heads / fire suppression, Wi-Fi / network access, security cameras, and access control devices.
- Air returns: Low wall returns or raised flooring (perforated tiles)

Recommended Gowning

- Recommended gowning requirements: head cover, goggles, beard cover, lab coat, foot coverings or booties and gloves suitable to the task (i.e. vinyl, latex, nitrile)
- Gowning room: separate (typically a lesser pressure and one classification less stringent; i.e. ISO 6 or ISO 7 airlock) prior to entering the ISO 5 Cleanroom
- No particle generation materials allowed past material or personnel airlocks such as cardboard, pallets, paper, dry erase boards, etc.

ISO 5 Testing Required (ISO 14644-2)

- Particle Count Test: maximum time interval 6 months, test procedure ISO 14644-1 Annex A
- Air Pressure Cascade: maximum time interval 6 months, test procedure ISO 14644-1 Annex B5
- Airflow: maximum time interval 6 months, test procedure ISO 14644-1 Annex B4