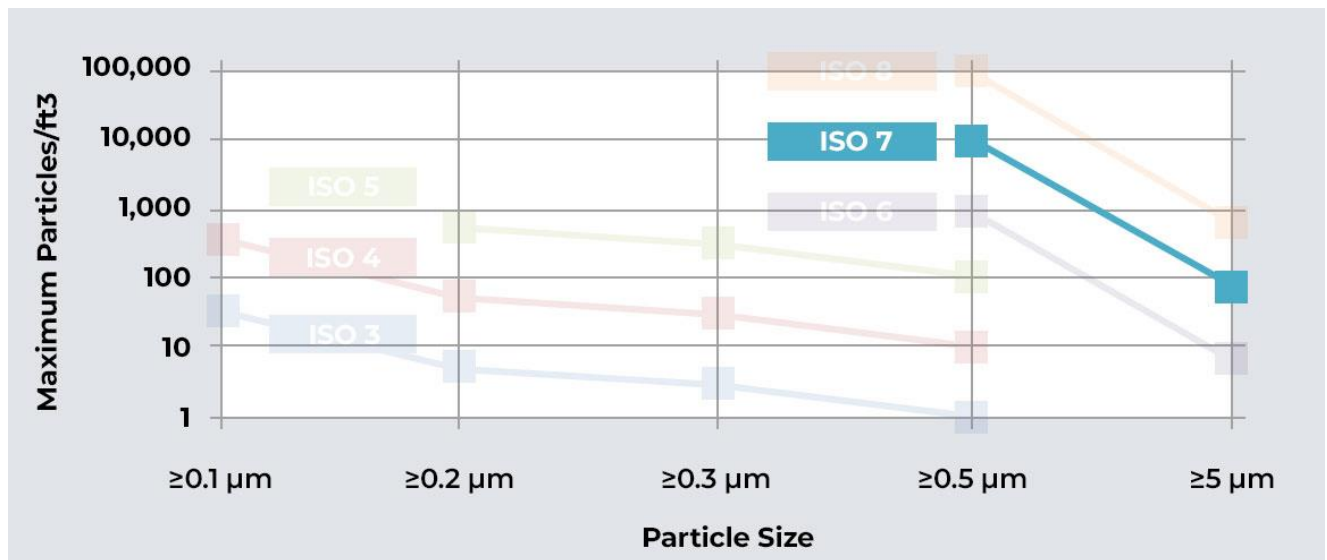


ISO 7 Cleanroom Specifications

ISO 7 or Class 10,000 Cleanrooms are the broadest classification usage of cleanrooms across a variety of industries and application types. ISO 7 Cleanrooms are utilized in biotechnology, pharmaceutical, nanotechnology, compounding, and various cleantech manufacturing applications such as ion lithium battery, solar, medical device, film/packaging, nutraceuticals, and certain packages foods.

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 7 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.
- 352,000 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)

- Non-unidirectional airflow or mixed air flow patterns typically used. Airflow is most commonly a vertical flow from the ceiling to the floor, returning for conditioning and filtration through low wall returns.
- Typical air changes: 60-90 air changes per hour
- Filtration ceiling coverage: 15-20%, with a randomized array with filtration located over the highest control areas.

Architectural Finishes

- Low wall air returns.
- 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 7 conditions depending on the application of the cleanroom. Biotech and pharmaceutical applications require walkable or panelized ceiling systems to promote monolithic washable surfaces, and access to maintain lights and filter media from the top side of the ceiling without breaching the certified and validated space. 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.
- Flooring systems most commonly a resinous floor system, or heat sealed vinyl flooring system, with specific 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.

Recommended Gowning & Housekeeping

- 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 8 airlock) prior to entering the ISO 7 Cleanroom

- No particle generation materials are allowed past material or personnel airlocks such as cardboard, pallets, paper, dry erase boards, etc.

ISO 7 Testing Required (ISO 14644-2)

- Particle Count Test: maximum time interval 12 months, test procedure ISO 14644-1 Annex A
- Air Pressure Cascade: maximum time interval 12 months, test procedure ISO 14644-1 Annex B5
- Airflow: maximum time interval 12 months, test procedure ISO 14644-1 Annex B4
- While the above criteria can be tested and certified on a 12 months interval basis, it is recommended to be done on an every 6 months schedule.