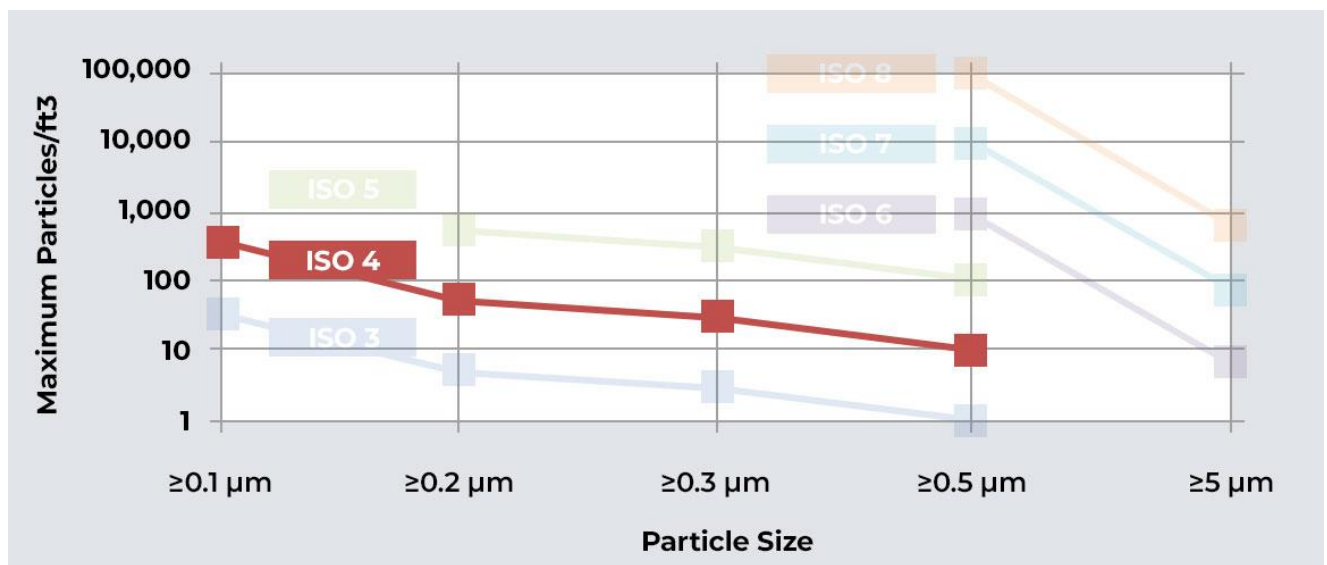


## ISO 4 Cleanroom Specifications

ISO 4 or Class 10 Cleanrooms are an ultra-clean stringently controlled cleanrooms utilized primarily for nanotechnology, semiconductor, and control zones within biotechnology and pharmaceutical applications for filling lines or other critical points.

### U.S. Federal Standard 209E Cleanroom Standards\*



| Maximum Particles / ft <sup>3</sup> |            |           |           |           |       |                 |
|-------------------------------------|------------|-----------|-----------|-----------|-------|-----------------|
| ISO                                 | ≥0.1 μm    | ≥0.2 μm   | ≥0.3 μm   | ≥0.5 μm   | ≥5 μm | Class           |
| ISO 3                               | 35         | 7         | 3         | 1         |       | Class 1         |
| <b>ISO 4</b>                        | <b>350</b> | <b>75</b> | <b>30</b> | <b>10</b> |       | <b>Class 10</b> |
| 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   |

## Filtration & Particle Control

- Focused measurement of particle sizes greater than 0.5 $\mu$  and less than 5.0 $\mu$
- Ultra-Low Particulate Air (ULPA) Filtration efficiency: 99.9995% at 0.12 microns. Final filtration is performed at the air entry point of the cleanroom, and is commonly performed by terminal HEPA modules, HEPA FFU (fan filter modules), or Plenum modules depending on the application.
- 352 PPC (particles per cubic meter) at 0.5 $\mu$
- Environmental parameters such as temperature, humidity, lighting levels, noise criteria, vibration, static control, and outgassing are often driven by the requirements of the specific process being performed in the cleanroom.
- Uses higher air velocities, air changes, and high-efficiency particulate air / ultralow particulate (ULPA) filter coverage on ceilings or on walls
- Max Particles: 10 per cubic foot of air at 0.12 microns

## Airflow & Air Change Rates per Hour (ACPH)

- Laminar unidirectional airflow or mixed air flow patterns are required for ISO 4 cleanrooms. Airflow is only a vertical flow from the ceiling to the floor, returning for conditioning and filtration through low wall returns, or more commonly raised access flooring (RAF) perforated tiles.
- Laminar Air Flow-Unidirectional airflow pattern is required
- Typical air changes: 300-540 air changes per hour
- Ceiling coverage: 50-90%

## 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 4 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 utilize plenum modules, or in smaller room spans gasketed grid or flush grid systems within integral lighting.
- Flooring systems for ISO 4 are raised access flooring with perforated tiles for nanotechnology applications. Biotechnology and pharmaceutical applications utilize resinous flooring systems, but usually within enclosures (i.e. RABs, Downflow booths). 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 return or Raised Floor

## Recommended Gowning & Housekeeping

- Required gowning requirements: full bunny suit with head cover, beard cover, foot coverings, often with face shields and personnel exhalation filtration, 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 5 airlock) prior to entering the ISO 4 Cleanroom or zone.

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

## **ISO 4 Testing Required (ISO 14644-2)**

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- 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