



WHITEPAPER

WHAT TO KNOW WHEN CONSIDERING A CLEANROOM

16 considerations for planning your cleanroom project



Simplex Cleanrooms by Subzero Engineering

Planning a cleanroom starts with understanding what your product or process requires. Before comparing designs, consider the cleanliness requirements, workflow, equipment, facility conditions and future needs that will shape your project.

This guide outlines 16 considerations to help you evaluate cleanrooms and controlled environments—and prepare for a productive discussion with a cleanroom professional.

1. Define your application and requirements.

Better product quality and improved manufacturing yield are important reasons to invest in a cleanroom. Start by identifying the contamination risks that matter to your process, rather than selecting an enclosure or cleanliness class first.

Medical device manufacturing and packaging,

electronics, food preparation, aerospace and other applications can have different requirements. Obtain the applicable customer specifications and regulatory requirements, and involve your quality and engineering teams in defining the environment you need.

Start by identifying the contamination risks that matter to your process, rather than selecting an enclosure or cleanliness class first.

ISO—the International Organization for Standardization—classifies air cleanliness by the concentration of airborne particles at specified sizes. Lower ISO class numbers represent lower allowable particle concentrations at a given size, where that classification applies. For example, the ISO Class 6 limit at 0.5 micrometers is 35,200 particles per cubic meter for particles 0.5 micrometers and larger. This example is one classification limit, not a complete

room specification.^[1]

Define the required ISO class, relevant particle size or sizes, and the operating condition in which that class must be achieved. Identify any additional needs, such as microbial control or temperature and humidity control. An airborne particle classification alone does not establish sterility or compliance with every requirement of your application.^[1]

2. Understand how a cleanroom controls contamination.

A cleanroom combines an enclosure, filtration, managed airflow and operating procedures to limit contamination. The purpose of the space determines how these elements work together.

Positive pressure. For applications focused on protecting a product or process, a cleanroom may operate at a higher pressure than adjacent spaces. In a typical ceiling-supply arrangement, filtered air enters above the work area and leaves through designated return or relief openings. The resulting

outward airflow helps reduce entry of airborne contamination from surrounding areas. It does not eliminate the need to control doors, personnel and material movement.

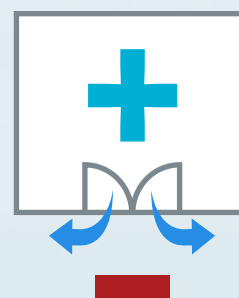
Negative pressure. A containment room operates at a lower pressure than surrounding spaces so air moves inward. The supply and exhaust system creates that pressure relationship—not a HEPA filter installed in reverse. Exhaust handling, filtration and other safeguards must be designed for the specific hazard. Biological hazards, hazardous chemicals and flammable or explosive materials require specialized assessment beyond the scope of this guide. Do not assume that a standard cleanroom enclosure is suitable for those applications.

The distinction is fundamental: positive pressure helps protect the space from surrounding contamination; negative pressure helps contain contamination within the space. This guide primarily addresses product-protection cleanrooms.^[3]

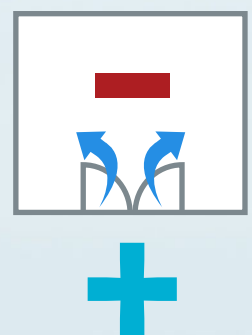
Filtration. Pre-filters remove larger airborne particles, while high-efficiency particulate air



Positive Pressure Room



Negative Pressure Room



(HEPA) filters provide finer particle removal. HEPA performance is described by efficiency under defined test conditions, not by a simple “smallest particle” cutoff. These filters capture particles both larger and smaller than a reference test size. Confirm the filter grade, rated performance, test method and installation requirements specified for your project.

A filter rating is not, by itself, proof that an installed room achieves its required cleanliness classification.
[1, 2]

3. Use ISO classifications when specifying air cleanliness.

ISO 14644-1 provides the classification framework for airborne particle concentration. You may also encounter legacy Federal Standard 209E class names in older drawings or specifications. The U.S. General Services Administration discontinued FED-STD-209E in 2001 in favor of ISO 14644-1.
[1, 4]

The following comparison helps interpret those older class names. It is a historical reference, not a substitute for the particle-size limits and testing requirements of the applicable ISO standard.

ISO CLASS	APPROXIMATE LEGACY FED-STD-209E CLASS
ISO Class 9	No comparable legacy class
ISO Class 8	Class 100,000
ISO Class 7	Class 10,000
ISO Class 6	Class 1,000
ISO Class 5	Class 100
ISO Class 4	Class 10
ISO Class 3	Class 1
ISO Class 2	No comparable legacy class
ISO Class 1	No comparable legacy class

Specify the ISO class, particle size or sizes, and occupancy state in project documents. Under ISO 14644-1, ISO Class 9 applies only to the operational state. The three occupancy states are explained in Consideration 5.
[1]

ISO classifications expanded the horizon for classifying clean space.”
—Richard Matthews, Filtration Technology, Inc.,
quoted in the original edition of this guide.

4. Design airflow around the process—not a rule of thumb.

Airflow helps dilute and remove airborne particles, but air changes per hour and airflow velocity do not determine ISO class on their own. Classification is established through particle-concentration testing under the specified conditions.
[1]

The airflow design should account for the work being performed, personnel, equipment, room volume, filtration and the location of supply and return openings.

Rather than assuming a universal air-change rate for each ISO class, develop the design around the application and verify the result.
[5]

Worktables, chairs and machinery can obstruct airflow or create areas where particles accumulate. Review the occupied layout—not just an empty floor plan—so air can reach critical work areas and leave through the intended path.



DESIGN FACTOR	WHAT TO CONSIDER
Air-change rate	The volume of filtered supply air delivered relative to room volume. Select the rate for the application; do not treat it as the ISO classification itself.
Airflow pattern and velocity	How air reaches the work area and carries particles toward returns or exhausts. Select an appropriate distribution pattern, not just a total airflow quantity.
Filtration	The filter specification and installed performance needed for the project.
Pressure relationships	The direction of airflow between adjacent spaces and whether the objective is product protection or containment.

5. Define the occupancy state for testing.

A cleanroom can be evaluated in three occupancy states. Agree on the required state or states before design and procurement, rather than assuming that a result for an empty room also describes production conditions. ^[1]

OCCUPANCY STATE	CONDITION BEING EVALUATED
As Built	The enclosure is finished and its building services are running. Production equipment, furniture, materials and people have not been introduced.
At Rest	Production equipment is installed and runs in the condition agreed for the test. No personnel are present.
Operational	The room and equipment function as specified, with the agreed number of personnel present and carrying out the defined activities.

Equipment, materials and people can add contamination and change airflow. Machinery that functions well outside a cleanroom may release particles or oil mist inside it; materials can also introduce other contaminants that require application-specific controls.

Where a process generates contamination, assess whether it needs local isolation, a separate enclosure or dedicated exhaust. A partition or curtain is not automatically sufficient; the complete arrangement must protect the surrounding operation.

Document the acceptance criteria, test methods, operating conditions and party responsible for testing. Do not assume manufacturer certification is included in every project. Agree on the scope, reporting and any requalification required after installation, relocation or significant changes. ^[1,5]

6. Choose a modular design that can adapt.

A modular cleanroom can allow you to expand, reconfigure or relocate the enclosure instead of replacing the entire installation as needs change. Ask which components can be reused and what additional work would be required for an expansion or move.

Consider more than wall panels. A larger or relocated room may also need changes to filtration, airflow, cooling, electrical services and other supporting systems.

Confirm those implications before relying on future expansion as part of the business case.



Where a mobile design is appropriate, a portable enclosure may isolate a specific process on the factory floor. For example, an injection-molding operation may need a locally controlled environment even when the surrounding facility does not. The required cleanliness level must come from the actual product and process requirements—not a blanket assumption about the application.

After setup or relocation, follow the agreed start-up and verification procedures. Running filters for a fixed period alone does not establish that the space meets its classification. ^[1, 5]

Discuss the financial treatment of the project with a qualified tax advisor. Do not assume that every modular cleanroom qualifies for the same depreciation period or deduction solely because it is modular. ^[6]

7. Plan for future space and capacity needs.

Consider how production volume, staffing, equipment and product requirements may change. Provide enough room for the work itself, material movement, gowning where needed, cleaning and access to equipment. Balance likely growth against the cost of building and operating more space than you currently need.

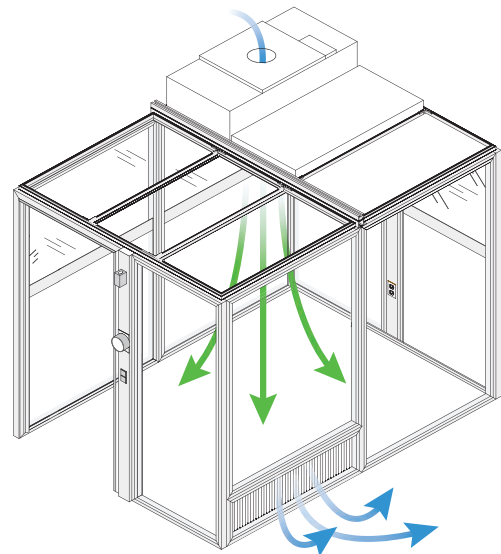
Identify where expansion could occur and whether the supporting systems can accommodate it. A clear growth plan is more useful than simply choosing the largest enclosure that fits.

8. Plan for air conditioning and environmental needs.

People, equipment and the cleanroom's air-handling systems contribute heat. Protective garments can also make warm conditions more uncomfortable. Plan for the expected maximum occupancy and equipment load, not just the number of people present on the first day.

Define the temperature range and any humidity requirements for the process. Select gowning requirements through the applicable contamination-control program and application requirements; an ISO particle class alone does not provide a complete garment specification.

Single-pass systems. Air passes through the cleanroom and leaves the enclosure rather than



In this example, filtered air enters above the work area and leaves through low-level openings, helping carry airborne particles out of the space. The supply, return and pressure arrangement must match the application.

being returned through a dedicated cleanroom recirculation path. Consider where that air goes and how its replacement affects the facility's conditioning load.

Recirculating systems. A portion of the air returns through a designed path for conditioning and filtration before re-entering the room. That path may use overhead ductwork, a ceiling plenum—the space above the cleanroom ceiling—or an air chase built into the wall system. The design must also address any required make-up air and exhaust.

Assess whether recirculation is appropriate for the process. Existing facility air conditioning may be useful, but its capacity and suitability must be confirmed. Include conditioning equipment, installation, controls and operating costs in the budget rather than applying a fixed percentage to every project. ^[5]

9. Involve a cleanroom expert early.

Bring a knowledgeable cleanroom professional into the project before the layout, budget and equipment decisions are fixed. Coordinate with your process, quality, facilities and safety teams so the enclosure is planned as part of a complete operating environment.

Use that early discussion to resolve airflow, testing, cleaning, personnel and material movement, utility connections and operating procedures.

Clarify who will design, supply, install, test and maintain each part of the system. An enclosure quote should not be assumed to include every service required to put the room into operation.



Clarify who will design, supply, install, test and maintain each part of the system.

10. Plan a clear process flow.

Map the route of materials from receipt through processing, assembly, packaging and exit. Where practical, arrange work in a clear sequence that reduces backtracking and unnecessary crossing of incoming materials, finished products, waste and personnel.

The goal is to support productivity while controlling contamination. Position equipment and furniture so they do not obstruct supply or return airflow, create difficult-to-clean spaces or restrict access.

11. Provide appropriate gowning and interior separation.

Determine whether the application requires a gowning area, an anteroom, airlocks or other separation between spaces. Design these features around personnel movement, contamination risk, pressure relationships and applicable requirements—not a universal rule tied only to an ISO class number. Interior separation can also help manage incompatible processes.

For example, transfer of material from a vitamin

B12 process into a vitamin C operation would be cross-contamination. Consider the movement of people, materials and air when deciding how those operations should be separated.

Specify the enclosure, doors, transfer points and procedures appropriate to the risk. A softwall curtain may be useful for some forms of separation, but should not be assumed to provide the containment or pressure control required for every application.

12. Allow sufficient overhead clearance.

Measure the available space above the proposed cleanroom and account for the fan-filter units, ductwork, ceiling construction and access needed for inspection, filter replacement and maintenance. An enclosure that fits beneath the building ceiling may still leave too little room to service its components.

Confirm the manufacturer's clearance and air-intake requirements for the actual equipment selected. Overhead needs can vary with the system and filter-access method. Record the approved dimensions on the project drawings; do not rely on a universal clearance figure.

13. Allow space around the enclosure for installation.

Plan enough working space around the enclosure to assemble panels, reach connections and perform maintenance. Review the installation sequence and any constraints created by nearby walls, columns or equipment.

Placing a cleanroom directly against an existing wall may help conserve floor space, but it can restrict assembly and future access.

Confirm whether the proposed system can be

installed and maintained in that arrangement. Coordinate the final layout with the site's access and safety requirements before ordering.

14. Require clear drawings, instructions and handoff documents.

The quality of installation affects cleanroom performance. Request approval drawings that show the plan, elevations, enclosure dimensions, doors, filters, lighting and relevant utility connections. The final documents should also identify the approved installation and maintenance clearances.

Installation drawings should make it easy to match panels and components to their intended locations. Clearly labeled parts and an organized assembly sequence reduce avoidable uncertainty on site. For large or critical installations, consider a contractor experienced in cleanroom construction.

Agree on the documents required at handoff, including operating and maintenance instructions, test reports within the contracted scope, and records of approved changes. Confirm responsibility for start-up, acceptance testing and training rather than assuming those tasks are included. ^[5]

15. Distinguish a cleanroom, a clean zone and general process isolation.

Cleanroom. A room designed and operated to control airborne particle contamination, with its air cleanliness classified under defined conditions.

Clean zone. A defined space with controlled and classified airborne particle cleanliness. It may be inside a larger cleanroom or established as a separate local environment; it does not have to be a fully enclosed room. A clean zone within a room may have

a more stringent classification, but that is not what defines every clean zone.

Specify the required classification and operating conditions for either a cleanroom or a clean zone. ^[1]

General process isolation. A barrier or enclosure may be used to limit dust transfer or separate activities without establishing an ISO-classified environment. That can be a suitable solution when classification is not required, but it should not be described as a classified cleanroom or clean zone without verification.

A historical project featured in the original guide used 300 linear feet of opaque vinyl curtain and two strip doors to separate manufacturing from inventory storage. The objective was to reduce dust on stored products, not to establish a verified ISO classification. Clearly defining that objective helps avoid specifying more—or less—than the application needs.

16. Document operating procedures and train the team.

Cleanroom performance depends on how the room is used, not just how it is built. Personnel are a significant source of contamination, and consistent procedures are essential to maintaining the intended environment.

Document the rules for entry and exit, gowning, material and equipment transfer, cleaning, maintenance and behavior within the room. Make sure employees, visitors and contractors receive the training relevant to their activities and follow the same applicable procedures.

Establish a monitoring and review program appropriate to the application. Define who checks

performance, what is recorded, how deviations are handled and when testing or requalification is needed. Revisit the procedures when staffing, equipment, processes or the enclosure change. ISO 14644-5 addresses cleanroom operations; industry-specific requirements may also apply. ^[7]

About Simplex Cleanrooms by Subzero Engineering

Subzero Engineering is the global leader in turnkey engineering solutions for industrial cleanrooms, data centers, and mission-critical environments.

Simplex Modular Cleanrooms and Separation Systems by Subzero Engineering is one of the most prominent names in modular cleanrooms, softwall curtains, strip doors, separation and process isolation. Subzero Engineering's Simplex cleanroom product line has set industry standards for over 40 years, and are engineered to optimize and protect contaminant-free environments.

Whatever the unique requirement, our team brings industry expertise and a proactive approach to solving even the most difficult isolation challenges.

We believe that no other organization can match our unique portfolio of critical infrastructure optimization technology + services.

Contact Subzero Engineering to discuss your cleanroom application, facility constraints and next steps.

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Gather the following information before your first project-planning discussion. Identify unknowns early so the project team can resolve them before design and procurement.

☐	Application and requirements. Product or process, contamination risks, customer specifications and applicable regulatory requirements.
☐	Cleanliness target. Required ISO class, particle size or sizes, occupancy state or states, and acceptance criteria.
☐	Layout and process flow. Room footprint and height, work sequence, material routes, entry points and separation needs.
☐	Equipment and personnel. Equipment dimensions, operating conditions, heat loads, expected occupancy and gowning needs.
☐	Environmental conditions. Temperature, any humidity limits, filtration, airflow, pressure relationships and exhaust needs.
☐	Facility readiness. Available services, supporting HVAC capacity, overhead access and installation and maintenance clearances.
☐	Future needs. Expansion, reconfiguration or relocation plans and the supporting capacity they may require.
☐	Budget and schedule. Enclosure, supporting systems, installation, start-up, testing, operating costs and required completion date.
☐	Responsibilities and handoff. Who designs, supplies, installs, tests and maintains the system, and what documents are included.
☐	Operating program. Training, cleaning, monitoring, maintenance, response to deviations and review after changes.

References and publication notes

This revised guide is based on the original eight–page “What to Know When Considering a Cleanroom” white paper supplied for the redesign. The references below support the technical and company–information updates.

[1] ISO 14644–1:2015. Classification of air cleanliness by particle concentration; see definitions in Clause 3 and classification provisions in Clause 4.

[2] U.S. Environmental Protection Agency. What is a HEPA filter? General filtration explanation, not a Simplex product specification.

[3] Centers for Disease Control and Prevention. Environmental Infection Control: Air, subsection on pressurization. Used for the basic pressure–direction distinction, not industrial design requirements.

[4] Institute of Environmental Sciences and Technology. IEST History, 1999 and 2001 entries: introduction of ISO 14644–1 and discontinuation of FED–STD–209E.

[5] ISO 14644–4:2022. Design, construction and start–up; public scope includes requirements definition, verification and life–cycle considerations.

[6] Internal Revenue Service. Publication 946, How To Depreciate Property. General reference only; no project–specific tax classification is asserted.

[7] ISO 14644–5:2025. Operations; public scope covers personnel, gowning, training, transfers, cleaning, maintenance and monitoring.

[8] Subzero Engineering. Simplex product–line overview and publicly listed main phone number.

Public sources checked October 7, 2026. These references support the editorial updates; project teams should use the applicable full standards, requirements and manufacturer documentation.

Important note

This guide provides an introduction to cleanroom planning. It is not a substitute for project–specific engineering, applicable standards, regulatory requirements or qualified professional advice. Work with a cleanroom professional and the appropriate project specialists to define, implement and verify the environment required for your application.

Original–edition acknowledgment

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