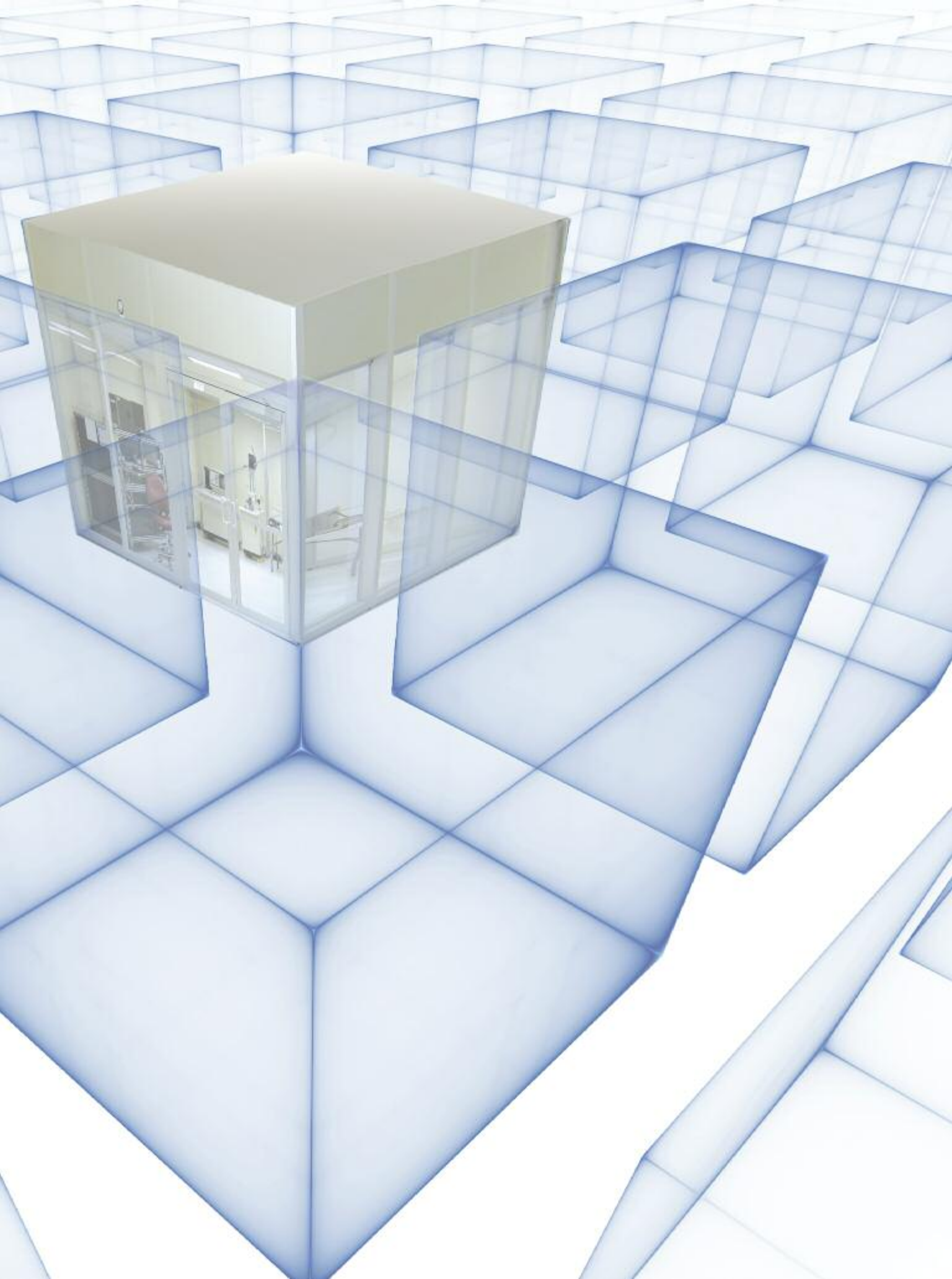
CONTROLLED Environments® MAGAZINE

CONTAMINATION CONTROL FOR LIFE SCIENCES AND MICROELECTRONICS

APRIL • 2010 VOL. 13 • NO. 4

Modular Cleanrooms for Business Startups and New Product Development

www.cemag.us



Modular Cleanrooms for Business Startups and New Product Development

Regulations, cost, location, size, performmance—how do you choose the right cleanroom?

Kevin Weist

Selecting a cleanroom for a new business or product is not a difficult process. There are many considerations and options, but focusing first on requirements will help make the decision-making process easier.

CLEANROOM SELECTION CRITERIA

Rules mandated by government regulations, ISO guidelines, or customer requirements are the first consideration in selecting the right cleanroom. For example, government regulation USP 797 outlines specific requirements for the manufacture of pharmaceutical products, and ISO 14644-5:2004 guidelines specify basic requirements for cleanroom operations. Most often regulations or customer specifications will dictate the cleanliness level or required rating, which provides a good starting point for choosing the right cleanroom.

Cost is an important consideration, especially if starting a new business or new product line. Prices can vary greatly from custom, fixed wall construction to modular, free-standing, soft wall or hard wall prefabricated cleanroom systems. Fixed wall rooms are typically most expensive, with soft wall rooms the least expensive. Additionally, size, shape, configuration, and accessories will affect the overall cost.

The location of the cleanroom site within the existing building structure, and the number of processes and workers in the cleanroom will determine the size and shape of the room.

In addition to meeting performance needs, many companies consider the visual aesthetics of a cleanroom very important, wanting to project a high-tech image with visual appeal to attract new customers.

ADVANTAGES OF MODULAR CLEANROOMS

Modular, free-standing cleanrooms have many distinct advantages over their fixed wall counterparts. Using modular rooms greatly reduces design, engineering, and construction time, thereby reducing costs. Since they are not an integral part of a larger structure, modular rooms can be taken down and moved to other facilities, or even sold as an asset. Fixed wall cleanrooms do not have this flexibility.

Expanding a modular cleanroom can be easily accomplished by taking off a wall and adding another module. The prefabricated design allows the room to be expanded, relocated, or reconfigured into a different shape or made into multiple smaller rooms.

All air handling and filtration equipment modules are built into the modular room ceiling. Hook-ups for electrical and plumbing are engineered in as part of the design.

The amount of time it takes to construct a modular room is much less than constructing a permanent walled structure. It can take several months to construct a fixed wall cleanroom because of the amount of design, engineering, and the various trades involved. However, a fairly sophisticated modular room can be constructed in a week or two. Onsite assembly of a modular cleanroom is also less disruptive to surrounding operations in comparison to their fixed wall counterparts.

Modular cleanroom systems offer potential tax advantages for businesses. They are not typically considered part of the building and can often be depreciated faster than built-in, fixed wall cleanrooms. Tax consultants can provide specific tax advantage information.

MODULAR, SOLID WALL CLEANROOM CONSTRUCTION CONSIDERATIONS

There are two basic types of modular, solid wall cleanrooms: recirculating and non-recirculating. Product and process requirements will determine which type of room is best suited for a company's needs.

Recirculating cleanrooms recirculate the air within the cleanroom and prevent it from mixing with outside air, allowing for better control of the temperature and humidity. Air is recirculated back to the high efficiency particulate absorbing (HEPA) filters located in the cleanroom's ceiling. This is accomplished by using air return chambers in the room's walls or through existing walls of the building. The recirculating cleanrooms will have less contamination loading on the HEPA filters because the system is recycling previously cleaned air. With less contamination loading, the filters will last longer and perform better.

Non-recirculating, sometimes called single pass rooms, draw in air from above the room into the ceiling HEPA filters. The filtered air is then blown into the cleanroom and exits through an approximate two-inch space located below the walls or through adjustable wall grills. Non-recirculating cleanrooms are less costly to construct than recirculating rooms due to the lack of return air ductwork.

CLEANROOM PERFORMANCE CONSIDERATIONS

Most businesses are aware of their cleanroom performance requirements because of customer, industry, or government specifications. These performance requirements identify the cleanroom class level required at a given state or condition. There are three levels of condition (states) for testing and characterizing the performance of cleanrooms: as-built, at-rest, and operational. Specific test methods for these three classifications are outlined in ISO 14644-3:2005.

Most cleanrooms are rated and sold in the as-built category—an empty room with the filter system running, but without workers and production equipment. However, adding workers and equipment will introduce contamination and affect the room rating. A cleanroom may be rated ISO 6 at rest, but at ISO 7 during operation (Table 1). To comply with performance requirements, the as-built empty room should be tested and benchmarked, followed by testing and documentation of the at-rest and operational states. If contamination in the at-rest or operational states is not in compliance, corrective steps need to be taken. These steps can range from examining the production process and number of workers in the cleanroom, to testing the room's air flow performance.

To ensure optimal cleanroom performance, air flow design and frequency of air changes should be evaluated. Cleanrooms are classified according to the number and size of particles permitted per volume of air in a specific amount of time. There is a relationship between cleanroom class ratings and the room's air changes per hour. For a cleaner room rating, more air exchanges become necessary. For example, a typical

Maximum Number of Particles in Air
(Particles per cubic meter)

ISO Class	Fed-Std 209E Class	Particle Size ≥ 0.1µm	≥ 0.2µm	≥ 0.3µm	≥ 0.5µm	≥1µm	≥ 5µm
ISO 1		10	2				
ISO 2		100	24	10	4		
ISO 3	(Class 1)	1,000	237	102	35	8	
ISO 4	(Class 10)	10,000	2,370	1,020	352	83	
ISO 5	(Class 100)	100,000	23,700	10,200	3,520	832	29
ISO 6	(Class 1,000)	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	(Class 10,000)				352,000	83,200	2,930
ISO 8	(Class 100,000)				3,520,000	832,000	29,300

Table 1

Recommended Air Changes and Ceiling Coverage

ISO Class	Air Changes Per Hour	Ceiling Coverage
ISO 1	500-750	80-100%
ISO 2	500-750	80-100%
ISO 3	500-750	60-100%
ISO 4	400-750	50-90%
ISO 5	240-600	35-70%
ISO 6	150-240	25-40%
ISO 7	60-150	15-25%
ISO 8	5-60	5-15%

Table 2

ISO 7 Class room will have 60-150 changes of air per hour, while an ISO 6 Class room will have 150-240 changes (Table 2).

All areas within a cleanroom should have similar air changes during each hour to ensure required performance. For example, a cleanroom with only one air return or exit, located at the opposite end of the room from the fan and filter, will produce stagnant air spots. This type of design causes air to flow almost horizontally across the room to the venting location, in a line-of-sight fashion. Areas of inadequate air movement retain higher levels of contamination. Adding or moving air returns will enable a more vertical and even air flow, improving overall air quality. The right balance of filter systems and air returns must be maintained to create positive air pressure inside the cleanroom. Positive air pressure produces an outward air movement, preventing the inflow of contaminants and assisting in expelling particles generated by workers and equipment.

Cleanroom air flow performance can be cost-effectively upgraded by adding fan-filter modules (FFM). For example, FFMs cover approximately 5-15% of an ISO 8 class cleanroom ceiling. Upgrading to an ISO 7 cleanroom requires 15-25% ceiling coverage, and covering 25-40% of the ceiling changes the room to an ISO 6 class (Table 2).

OPTIONS

To make a cleanroom fully functional, a variety of additional accessories, from lighting and doors to furniture and changing rooms, need to be considered. Accessories can be selected while working with the modular cleanroom company during the room design and specification phase.

Most cleanrooms have adjacent gowning areas where workers change into special garments, minimizing particulate contamination before entering the production area of the cleanroom. Some gowning rooms are equipped with air showers as a way to further reduce particulate contamination that might settle on the surface of a cleanroom garment. Some gowning rooms may have special benches for people to use while changing into boots, gloves, gowns, and masks.

Many companies may use the gowning room for transferring production material and equipment in and out of the clean environment. However, pass-through or double-door airlocks are more efficient and keep the introduction of particulate contamination to a minimum.

Specially produced cleanroom furniture and tools should be used because they are designed for low particulate generation. For example, tables are smooth and sealed so they don't shed particulates and can be easily wiped down.

SITE CONSIDERATIONS

The modular cleanroom location within a building is very important. Physical space, temperature/humidity, and cleanliness will affect selection decisions and overall project cost.

Most modular cleanrooms can be installed with as little as 25 inches of clearance over the inside clear height of the room on non-recirculating rooms, and about 30 inches with recirculating rooms.

A typical cleanroom should operate at about 66-70 degrees Fahrenheit to ensure a comfortable environment for workers wearing cleanroom garb such as lab coats, head coverings, gloves, and masks.

Non-recirculating cleanrooms work best when the space surrounding the cleanroom is air-conditioned. If supplemental air conditioning is necessary, it can be brought into the space above the cleanroom or directly into the HEPA filters, ensuring the room's temperature is cooler than the surrounding space.

Recirculating cleanrooms provide better temperature control between the interior cleanroom and the surrounding building space. The room air does not mix with the external air and only requires cooling to compensate for the internal heat load. Processes requiring humidity control will require special environmental control systems and are usually only available with recirculating cleanrooms. Typically, systems are made to just add or just remove humidity depending on the surrounding environment.

ON-SITE INSTALLATION

Installation of a modular, hard wall cleanroom is quick and easy. With modular systems everything is prefabricated at the factory, so specialists are not needed to assemble the room, just local trades or internal people.

It's not uncommon to start a project on a Monday and finish on Friday.

MAINTENANCE CONSIDERATIONS

Regular cleanroom maintenance is very straightforward and is needed to ensure cleanroom performance and certification.

Interior surfaces are wiped down daily on a regular basis or before each shift using a solution of deionized water and 10% alcohol. The cleanroom floors are routinely mopped as well. Vertical surfaces, such as walls can be cleaned less frequently depending on product requirements. All contact points such as door handles and user-operated equipment should also be wiped down on a daily or shift basis, again, depending on process requirements.

HEPA filters have a pre-filter that needs to be changed regularly—depending on loading. The HEPA filter modules are fairly maintenance free, but are required to be certified every year. Additionally, proper air flow and leak checks are usually part of the regular certification for a cleanroom.

Certification of a room can be performed by either internal personnel or external companies. Most companies prefer an external, third-party firm to perform the certification, providing them with an independent analysis. Customer or product requirements may require independent certification.

SUMMARY

Determining the right cleanroom for a new product or business requires balancing many selection aspects—from process requirements and cost, to performance and construction. The decision process is not complex, but a clear understanding of cleanroom requirements, regulations, operation, and available options will make cleanroom specification and design easier.

Kevin Weist *is a sales engineer with Clean Air Products of Minneapolis, Minnesota, and can be reached at kevinw@cleanairproducts.com.*