

The 3 Most Important Parts of Creating a Cleanroom

The meticulous planning and flawless execution required can make the cleanroom design process seem daunting, to say the least.

However, like any major undertaking, a detailed plan is key.

In this piece, we will explore the [43](#) key phases of cleanroom design and construction: [process requirements](#), classifying, designing, and testing.

1. [Process Requirements](#)

[Your process is the key driver in defining what level of classification is needed in the cleanroom. There are two major functions of a Cleanroom, one to keep particles and contamination out and two if the process requires hazardous substances to keep those hazards from getting out of the Cleanroom.](#)

[Once you defined at a high level if you are keeping contamination in or out of the room then the level of classification. In looking at your process you want to optimize the amount of space at the cleanest classification as these spaces become more expensive to operate in the long term with additional air changes, cleaning and disinfection requirements.](#)

[With clear process requirements the next three phases are straight forward.](#)

2. [Cleanroom Classification](#)

Your cleanroom's class will be defined by ISO 14644-1 classification which is set by the concentration of particles, from 0.1 microns to 0.5 microns.

The ISO standard 14644-1 (ISO 5, 6, 7, 8) replaced the Federal Standard 209 classification (Class 100; Class 10,000; Class 100,000) in 1999. However, some organizations continue to utilize the Class 100; Class 10,000; and Class 100,000 terminology.

Here is how they compare.

ISO Standard 14644-1	Federal Standard 209
ISO 3	1
ISO 4	10

ISO 5	100
ISO 6	1,000
ISO 7	10,000
ISO 8	100,000

[Insert table showing ISO level and class 100 etc level with number of allowable particles.](#)

2. Cleanroom Design

You will begin with a project plan to map out the required products and processes, as well as every stage of the installation.

This will include defining:

- 1) A process equipment list and their requirements
- 2) Peak and average demand expectations for each utility and environmental control system
- 3) A contamination control concept for each zone
- 4) The anticipated flow and movement of:
 - a) Any and all personnel
 - b) Equipment
 - c) Raw materials
 - d) Finished goods
 - e) Waste

Airflow

Your Cleanroom's airflow patterns will be unidirectional (ISO Class 5 and cleaner) , non-unidirectional, or mixed.

Unidirectional airflow can be vertical or horizontal, with airflow relying on a filtered air supply and return inlets that are almost opposite air supplies.

Whereas **non-unidirectional airflow** cleanrooms utilize airflow outlets across multiple positions. Your filter outlets can be staggered at equal intervals or grouped together over the core process. Your final filter can be remote, to help avoid contamination ingress between filters and cleanroom.

The return air locations are not as important in non-unidirectional airflow. However, you will want to minimize dead zones.

Layout

Here are a few key considerations when mapping out your cleanroom's layout:

1. Keep the size to a minimum for logistic and financial reasons, before and after installation. If you require a large space, make sure it's divided and segregated as efficiently as possible.
2. Always prevent contamination transfer from one zone to another with an impervious barrier.
3. Also utilize airlocks, speech panels and intercoms □to prevent cross-contamination
4. Map out your changing rooms in three zones, separated by a physical barrier:
 - a. Entry: For the removal, storage, disposal and/or redonning of garments
 - b. Transition: Where the cleanroom's garments or equipment are stored, donned or removed
 - c. Inspection/access: For the inspection of the completed gowning and access to your cleanroom
5. Ceilings should be sealed with minimal penetration points
6. Walls needs to be protected with rubbing strips and protective bars. Also, utilize double glazing, with an airtight seal
7. When it comes to door placement consider push plates, automatic openings, and appropriate door-swing

Air Filtration Systems

Your cleanroom's classification, cleanliness and using condition will dictate your:

1. Filter elements
2. Gaskets
3. Sealants
4. Mounting frames
5. Clamping system
6. Housings

3. Cleanroom Testing

You will be required to perform an airborne particle count test to classify an installation

Other optional tests include:

- Airflow direction tests and visualization
- Air pressure difference tests
- Airborne particle count for ultrafine and/or micro-particles
- Airflow test
- Containment leak tests
- Installed filter system leakage test
- Recovery tests
- Temperature, humidity and electrostatic tests
- Particle deposition tests

We are Cleanroom Design Experts

Our company's roots began in 1983 in commercial heating and air conditioning and evolved over the years combined with our expertise in temperature and humidity control which helped us find our calling in cleanrooms in the late 1990s.

Today, Environmental Systems Corporation designs critical environments and builds cleanrooms to ISO 14644 4, 5, 6, 7 & 8 Requirements.

Ready to discuss your project? Click here to [contact us anytime](#).