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Cleanroom Design in 10 Easy Steps

"Easy" may not be a word that comes to mind for designing such sensitive environments. However, that doesn't mean you can't produce a solid cleanroom design by tackling issues in a logical sequence. This article covers each key step, down to handy application-specific tips for adjusting load calculations, planning exfiltration paths, and angling for adequate mechanical room space relative to the cleanroom's class.

Many manufacturing processes need the very stringent environmental conditions provided by a cleanroom. Because cleanrooms have complex mechanical systems and high construction, operating, and energy costs, it is important to perform the cleanroom design in a methodical way. This article will present a step-by-step method for evaluating and designing cleanrooms, factoring in people/material flow, space cleanliness classification, space pressurization, space supply airflow, space air exfiltration, space air balance, variables to be evaluated, mechanical system selection, heating/cooling load calculations, and support space requirements.

STEP ONE: EVALUATE LAYOUT FOR PEOPLE/MATERIAL FLOW

It is important to evaluate the people and material flow within the cleanroom suite. Cleanroom workers are a cleanroom's largest contamination source and all critical processes should be isolated from personnel access doors and pathways.

The most critical spaces should have a single access to prevent the space from being a pathway to other, less critical spaces. Some pharmaceutical and biopharmaceutical processes are susceptible to cross-contamination from other pharmaceutical and biopharmaceutical processes. Process cross-contamination needs to be carefully evaluated for raw material inflow routes and containment, material process isolation, and finished product outflow routes and containment.

STEP TWO: DETERMINE REQUIRED SPACE CLEANLINESS CLASSIFICATION

To be able to select a cleanroom classification, it is important to know the primary cleanroom classification standard and what the particulate performance requirements are for each cleanliness classification. The Institute of Environmental Science and Technology (IEST) Standard 14644-1 provides the different cleanliness classifications (1, 10, 100, 1000, 10000, and 100000) and the allowable number of particles at different particle sizes.

For example, a Class 100 cleanroom is allowed a maximum of 3,500 particles/cu ft and 0.1 microns and larger, 100 particles/cubic ft. at 0.5 microns and larger, aand particles/cubic ft. at 1.0 microns and larger.

This table provides the allowable airborne particle density per cleanliness classification table:

ISO 14644-1 Cleanroom Standards							
Classification	Maximum Particles/m³						FED STD 209E Equivalent
	≥0.1µm	≥0.2µm	≥0.3µm	≥0.5µm	≥1µm	≥5µm	
ISO 1	10	2.37	1.02	0.35	0.083	0.0029	
ISO 2	100	23.7	10.2	3.5	0.83	0.029	
ISO 3	1,000	237	102	35	8.3	0.029	Class 1
ISO 4	10,000	2,370	1,020	352	83	2.9	Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1.0×10^6	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7	1.0×10^7	2.37×10^6	1,020,000	352,000	83,200	2,930	Class 10,000
ISO 8	1.0×10^8	2.37×10^7	1.02×10^7	3,520,000	832,000	29,300	Class 100,000
ISO 9	1.0×10^9	2.37×10^8	1.02×10^8	35,200,000	8,320,000	293,000	Room Air

Space cleanliness classification has a substantial impact on a cleanroom's construction, maintenance, and energy cost. It is important to carefully evaluate reject/contamination rates at different cleanliness classifications and regulatory agency requirements, such as the Food and Drug Administration (FDA). Typically, the more sensitive the process, the more stringent cleanliness classification should be used. This table provides cleanliness classifications for a variety of manufacturing processes:

Industrial Applications	
Application	Classification
Aerospace	ISO Class 5-7
Assembly of Touch Screen Membranes	ISO Class 7
Composite Materials	ISO Class 8
General Industrial	ISO Class 8
Isolation of Injection Molded Parts	ISO Class 7-8
Optical	ISO Class 5-7
Electronics	
Application	Classification
Semiconductor	ISO Class 5
SMT Assembly	ISO Class 7-8
Solar	ISO Class 5-7
Wafer Board	ISO Class 5
Consumables and Pharmaceuticals	
Application	Classification
E-Liquid	ISO Class 7-8
Food Packaging	No Classification
Nutraceutical Packaging	ISO Class 7-8
Pharmaceutical Compounding	ISO Class 7
Pharmaceutical Packaging	ISO Class 8
Sterile Compounding	ISO Class 5
Medical Devices	
Application	Classification
Device Reprocessing	ISO Class 7
Inplantable Devices	ISO Class 5
Medical Device Packaging	ISO Class 7

Some manufacturing process may need a more stringent cleanliness class depending upon their unique requirements. Be careful when assigning cleanliness classifications to each space; there should be no more than two orders of magnitude difference in cleanliness classification between connecting spaces. For example, it is not acceptable for a Class 100,000 cleanroom to open into a Class 100 cleanroom, but it is acceptable for a Class 100,000 cleanroom to open into a Class 1,000 cleanroom.

STEP THREE: DETERMINE SPACE PRESSURIZATION

Pressurization of classification spaces is essential in preventing contaminants from infiltrating into a cleanroom. It is very difficult to consistently maintain a space's cleanliness classification when it has neutral or negative space pressurization. What should the space pressure differential be between spaces? Various studies evaluated contaminant infiltration into a cleanroom vs. space pressure differential between the cleanroom and adjoining uncontrolled environment. These studies found a pressure differential of 0.03 to 0.05 in w.g. to be effective in reducing contaminant infiltration. Space pressure differentials above 0.05 in. w.g. do not provide substantially better contaminant infiltration control then 0.05 in. w.g.

Keep in mind, a higher space pressure differential has a higher energy cost and is more difficult to control. Also, a higher pressure differential requires more force in opening and closing doors. The recommended maximum pressure differential across a door is 0.1 in. w.g. at 0.1 in. w.g., a 3 foot by 7 foot door requires 11 pounds of force to open and close. A cleanroom suite may need to be reconfigured to keep the static pressure differential across doors within acceptable limits.

Air infiltration should not, of course, go from a dirtier cleanliness classification space to a cleaner cleanliness classification space.

STEP FOUR: DETERMINE SPACE SUPPLY AIRFLOW

The space cleanliness classification is the primary variable in determining a cleanroom's supply airflow. Looking at the table above, each clean classification has an air change rate. For example, a Class 100,000 cleanroom has a 15 to 30 ach range. The cleanroom's air change rate should take the anticipated activity within the cleanroom into account. A Class 100,000 (ISO 8) cleanroom having a low occupancy rate, low particle generating process, and positive space pressurization in relation to adjacent dirtier cleanliness spaces might use 15 ach, while the same cleanroom having high occupancy, frequent in/out traffic, high particle generating process, or neutral space pressurization will probably need 30 ach.

The designer needs to evaluate his specific application and determine the air change rate to be used. Other variables affecting space supply airflow are process exhaust airflows, air infiltrating in through doors/openings, and air exfiltrating out through doors/openings. IEST has published recommended air change rates in Standard 14644-4.

STEP FIVE: DETERMINE SPACE AIR EXFILTRATION FLOW

The majority of cleanrooms are under positive pressure, resulting in planned air exfiltrating into adjoining spaces having lower static pressure and unplanned air exfiltration through electrical outlets, light fixtures, window frames, door frames, wall/floor interface, wall/ceiling interface, and access doors. It is important to understand rooms are not hermetically sealed and do have leakage. A well-sealed cleanroom will have a 1% to 2% volume leakage rate. Is this leakage bad? Not necessarily.

First, it is impossible to have zero leakage. Second, if using active supply, return, and exhaust air control devices, there needs to be a minimum of 10% difference between supply and return airflow to statically decouple the supply, return, and exhaust air valves from each other. The amount of air exfiltrating through doors is dependent upon the door size, the pressure differential across the door, and how well the door is sealed (gaskets, door drops, closure).

We know the planned infiltration/exfiltration air goes from one space to the other space. Where does the unplanned exfiltration go? The air relieves within the stud space and out the top.

STEP SIX: DETERMINE SPACE AIR BALANCE

Space air balance consists of adding all the airflow into the space (supply, infiltration) and all the airflow leaving the space (exhaust, exfiltration, return) being equal.

STEP SEVEN: ASSESS REMAINING VARIABLES

Other variables needing to be evaluated include:

- ◊ Temperature: Cleanroom workers wear smocks or full bunny suits over their regular clothes to reduce particulate generation and potential contamination. Because of their extra clothing, it is important to maintain a lower space temperature for worker comfort. A space temperature range between 66°F and 70° will provide comfortable conditions. Check instrument and machinery heat load specs for their impact.
- ◊ Humidity: Due to a cleanroom's high airflow, a large electrostatic charge is developed. When the ceiling and walls have a high electrostatic charge and space has a low relative humidity, airborne particulate will attach itself to the surface. When the space relative humidity increases, the electrostatic charge is discharged and all the captured particulate is released in a short time period, causing the cleanroom to go out of specification. Having high electrostatic charge can also damage electrostatic discharge sensitive materials. It is important to keep the space relative humidity high enough to reduce the electrostatic charge build-up. An RH or 45% +5% is considered the optimal humidity level.
- ◊ Laminarity: Very critical processes might require laminar flow to reduce the chance of contaminates getting into the air stream between the HEPA filter and the process. IEST Standard #IEST-WG-CC006 provides airflow laminarity requirements.
- ◊ Electrostatic Discharge: Beyond the space humidification, some processes are very sensitive to electrostatic discharge damage and it is necessary to install grounded conductive flooring.
- ◊ Noise Levels and Vibration: Some precision processes are very sensitive to noise and vibration

STEP EIGHT: DETERMINE MECHANICAL SYSTEM LAYOUT

A number of variables affect a cleanroom's mechanical system layout: space availability, available funding, process requirements, cleanliness classification, required reliability, energy cost, building codes, and local climate. Unlike normal A/C systems, cleanroom A/C systems have substantially more supply air than needed to meet cooling and heating loads. Class 100,000 (ISO 8) and lower ach Class 10,000 (ISO 7) cleanrooms can have all the air go through the AHU. Looking at Figure 3, the return air and outside air are mixed, filtered, cooled, reheated, and humidified before being supplied to terminal HEPA filters in the ceiling. To prevent contaminant recirculation in the cleanroom, the return air is picked up by low wall returns. For higher class 10,000 (ISO 7) and cleaner cleanrooms, the airflows are too high for all the air to go through the AHU.

STEP NINE: PERFORM HEATING/COOLING CALCULATIONS

When performing the cleanroom heating/cooling calculations, take the following into consideration:

- ◊ Use the most conservative climate conditions (99.6% heating design, 0.4%
- ◊ drybulb/median wetbulb cooling deign, and 0.4% wetbulb/median drybulb cooling
- ◊ design data).
- ◊ Include filtration into calculations.
- ◊ Include humidifier manifold heat into calculations.
- ◊ Include process load into calculations.
- ◊ Include recirculation fan heat into calculations.

STEP TEN: FIGHT FOR MECHANICAL ROOM SPACE

Cleanrooms are mechanically and electrically intensive. As the cleanroom's cleanliness classification becomes cleaner, more mechanical infrastructure space is needed to provide adequate support to the cleanroom. Using a 1,000-sq-ft cleanroom as an example, a Class 100,000 (ISO 8) cleanroom will need 250 to 400 sq ft of support space, a Class 10,000 (ISO 7) cleanroom will need 250 to 750 sq ft of support space, a Class 1,000 (ISO 6) cleanroom will need 500 to 1,000 sq ft of support space, and a Class 100 (ISO 5) cleanroom will need 750 to 1,500 sq ft of support space.

The actual support square footage will vary depending upon the AHU airflow and complexity (Simple: filter,

heating coil, cooling coil, and fan; Complex: sound attenuator, return fan, relief air section, outside air intake, filter section, heating section, cooling section, humidifier, supply fan, and discharge plenum) and number of dedicated cleanroom support systems (exhaust, recirculation air units, chilled water, hot water, steam, and DI/RO water). It is important to communicate the required mechanical equipment space square footage to the project architect early in the design process.