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An Introduction to the Design of Clean and Containment Areas

The cleanroom is a modern phenomenon. Although the roots of cleanroom design and management go back more than 100 years and are rooted in the control of infection in hospitals, the need for a clean environment for industrial manufacturing is a requirement of modern society. The use of cleanrooms is diverse and shown in Table 1.1 is a selection of products that are now being made in cleanrooms, or require contamination control facilities.

It may be seen that the requirement for cleanrooms can be broadly divided into two. The first area is that in which inanimate particles (dust) are a problem and where their presence, even in submicron size, may prevent a product functioning or reduce its useful life. The second group requires the absence of microbe-carrying particles whose growth in the product (or in a hospital patient) could lead to human infection. It may also be seen that many of the examples given are recent innovations and this list will certainly be added to in the future, there being a considerable increase in the demand for these types of rooms.

Table 1.1 Some clean and containment room applications.

Electronics	Computers, TV tubes, Flat screens, Magnetic tape production
Semiconductors	Production of integrated circuits used in computer memory and control. Micromechanics Gyroscopes, Miniature bearings, Compact disc players
Optics	Lenses, Photographic film, Laser equipment
Biotechnology	Antibiotic production, Genetic engineering
Pharmacy	Sterile pharmaceuticals
Medical devices	Heart valves, Cardiac by-pass systems
Food and drink	Disease-free food and drink
Hospital	Immunodeficiency therapy, Isolation of contagious patients, Operating rooms

The application of cleanrooms has increased and diversified. As well as minimising the airborne contamination it may be necessary to contain dangerous or toxic contamination within the room. This is done by containment rooms.

Clean and containment rooms will be individually designed according to their application, but there are a number of basic similarities and design concepts that should be discussed before reading further chapters of this book. These concepts consider the special requirements of industries such as microelectronics, pharmaceuticals, medical devices and biotechnology.

What is a Cleanroom?

It is clear that a cleanroom is a room that is clean. However, a cleanroom now has a special meaning and it is defined in Federal Standard 209E as:

'A room in which the concentration of airborne particles is controlled and which contains one or more clean zones.'

and in ISO 14644-1:

'A room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimise the introduction, generation, and retention of particles inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary.'

Classification of Cleanrooms

Cleanrooms are classified by the cleanliness of their air. The method most easily understood and universally applied is the one suggested in versions of Federal Standard 209 (up to edition 'D'). In this standard the number of particles equal to and greater than 0.5 µm is measured in one cubic foot of air and this count is used to classify the room.

A classification of cleanrooms according to the older Federal Standard 209D is given in a simplified form in Table 1.2.

Table 1.2 A simplified Federal Standard 209D classification of cleanrooms.

Federal Standard 209 classification	1	10	100	1000	10000	100000
No. of particles/ft ³ - ≥0.5 µm	1	10	100	1000	10000	100000

This Federal Standard has now been superseded by a metric version (Federal Standard 209E) which was published in 1992. However, because of its simplicity and universal use, it will be many years before the older Federal Standard 209D classification is forgotten. It is also likely that Federal Standard 209D nomenclature will not be superseded by Federal Standard 209E but by the new International Organization for Standards (ISO) standard 14644-1.

The new ISO classification is based on the following equation:

$$C_n = 10^N \times \left[\frac{0.1}{D} \right]^{2.08}$$

where

C_n represents the maximum permitted concentration (in particles/m³ of air) of airborne particles that are equal to or larger than the considered particle size; D , and is rounded to the nearest whole number,

N is the ISO classification number, which shall not exceed the value of 9. Intermediate ISO classification numbers may be specified, with 0.1 the smallest permitted increment of N ,

D is the considered particle size in µm,
and 0.1 is a constant with a dimension of µm.

The above equation was chosen so that the class limits set by the Federal Standard at its standard reference point of 0.5µm coincide closely with those found in the ISO standard. This allows a harmonious transition from the previous cleanroom standards.

Reproduced in Figure 1.1 is the diagram given in the ISO standard, which shows the approximate class limits (maximum allowable airborne particle concentrations). These are for illustration purposes only, as the precise limits are determined by the equation. The ISO standard also gives a method by which cleanrooms can be specified in terms of ultrafine particles (smaller than 0.1 µm) or macroparticles (larger than 5.0µm).

Both the Federal Standard 209E and the new ISO standard are explained in much more detail in the next chapter of this book. Throughout this book the classification of cleanrooms will be given in terms of both the old Federal Standard 209D and the new ISO standard nomenclature.

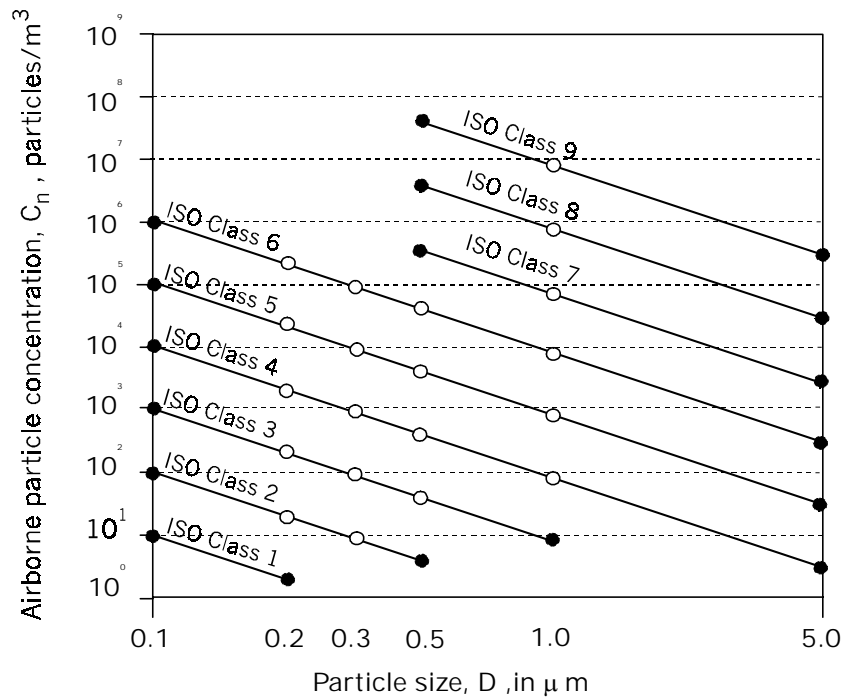


Figure 1.1. Graphical representation of ISO-class concentration limits for selected ISO classes.

It should be appreciated that the airborne contamination level of cleanroom is dependent on the particle-generating activities going on in the room. If a room is empty, very low particle concentrations can be achieved, these closely reflecting the quality of air supplied and hence the removal efficiency of the high efficiency filter. If the room has production equipment in it and operating, there will be a greater particle concentration but the greatest concentration will occur when the room is in full production. A classification of the room may therefore be carried out when the room is:

- as built: condition where the installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present,
- at rest: condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present,
- operational: condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon.

Class of Rooms Required by Different Industries

The required standard of cleanliness of a room is dependent on the task performed in it; the more susceptible the product is to contamination the better the standard. The following list (Table 1.3) gives an indication of the tasks carried out in different classifications of cleanrooms. These suggested classifications are only an indication of what might be used and care must be taken not to overdesign by providing cleaner than necessary rooms as this has a big influence on cost.

Table 1.3. Possible cleanroom requirement for various tasks carried out in cleanrooms.

Class 1	These rooms are only used by integrated circuit manufacturers manufacturing sub-micron geometries.
Class 10	These rooms are used by semiconductor manufacturers producing integrated circuits with line widths below 2 μm.
Class 100	Used when a bacteria-free or particulate-free environment is required in the

- manufacture of aseptically-produced injectable medicines. Required for implant or transplant surgical operations. Isolation of immunosuppressed patients, e.g. after bone marrow transplant operations.
- Class 1000 Manufacture of high quality optical equipment. Assembly and testing of precision gyroscopes. Assembly of miniaturised bearings.
- Class 10 000 Assembly of precision hydraulic or pneumatic equipment, servo-control valves, precision timing devices, high grade gearing.
- Class 100 000 General optical work, assembly of electronic components, hydraulic and pneumatic assembly.

Types of Clean Areas

Clean areas can be divided into four main types. These are shown in a diagrammatic form in Figures 1.2 to Figure 1.5 and are as follows:

Conventional. These cleanrooms are also known as turbulently-ventilated or non-unidirectional flow and are distinguished by their method of air supply. As can be seen in Figure 1.2, this is of the conventional type, the air being supplied by air supply diffusers or filters in the ceiling.

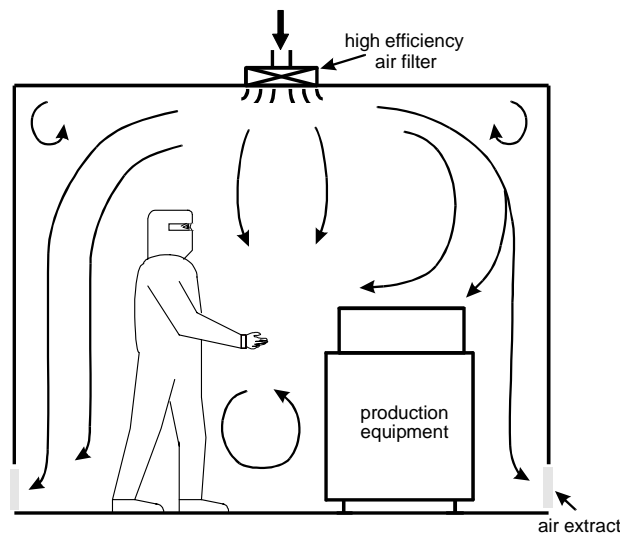


Figure 1.2 Conventional turbulently (nonunidirectional) ventilated cleanroom

Unidirectional flow. This was previously known as laminar flow. As can be seen from Figure 1.3, clean air is supplied from a bank of high efficiency filters and passes in a unidirectional manner through the room.

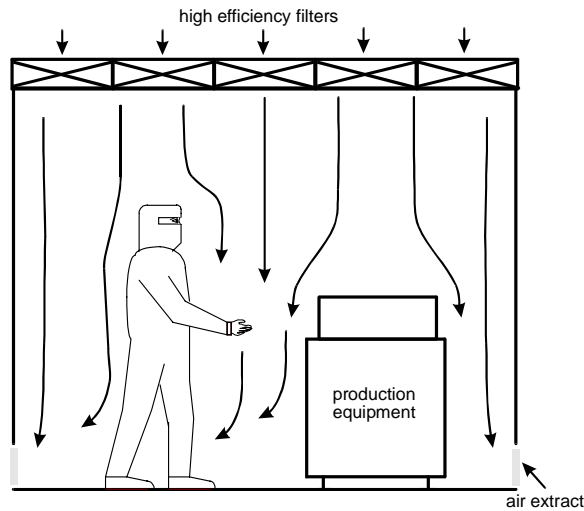


Figure 1.3 Vertical unidirectional flow cleanroom

Mixed flow. As shown in Figure 1.4, this type of cleanroom is conventionally ventilated but where the product is exposed to contamination, a unidirectional flow cabinet or workstation is used.

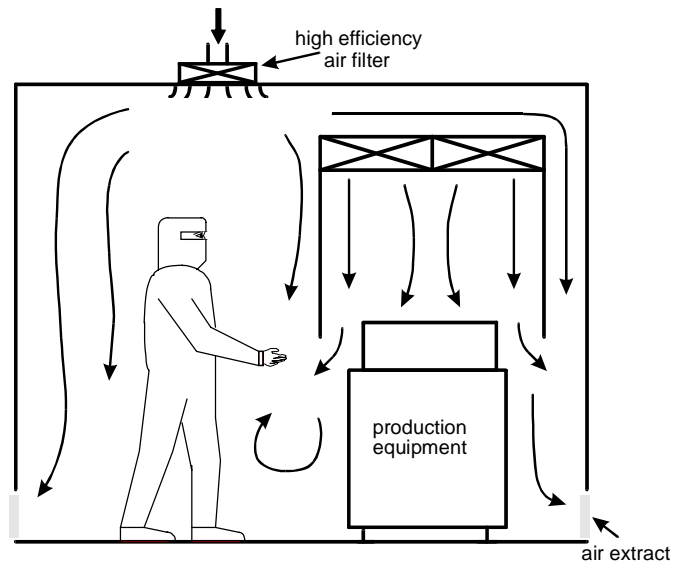


Figure 1.4 Mixed flow cleanroom

Isolators or microenvironment. These are used within a cleanroom to give the highest level of protection against contamination. In Figure 1.5 the isolator is shown to have a unidirectional supply of air but this may be a conventional turbulent-flow type. Similarly, gauntlets are shown, but half suits are also used.

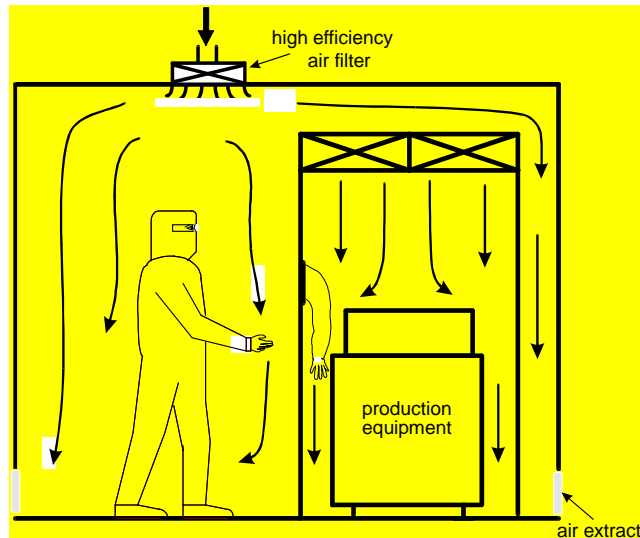


Figure 1.5 Isolator used to protect the critical production area

Conventionally Ventilated Cleanrooms

Shown in Figure 1.6 is a diagram of a simple conventionally ventilated cleanroom. The general method of ventilation used in this type of cleanroom is similar to that found in offices, shops, etc. in that air is supplied by an air conditioning plant through diffusers in the ceiling. However, a cleanroom differs from an ordinary ventilated room in a number of ways:

1. *Increased air supply:* An office or shop will be supplied with sufficient air to achieve comfort conditions; this may be in the region of 2 to 10 air changes per hour. A typical conventionally ventilated cleanroom is likely to have between 20 and 60 air changes per hour. This additional air supply is mainly provided to dilute to an acceptable concentration the contamination produced in the room.

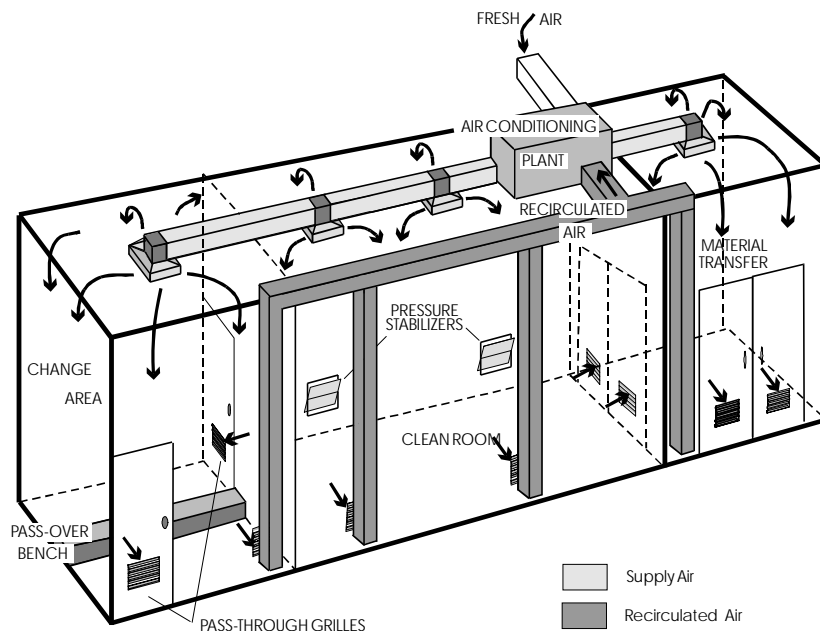


Figure 1.6. Conventionally ventilated cleanroom.

2. *High efficiency filters:* A cleanroom uses filters much more efficient than those used in offices etc. Cleanroom filters would normally be greater than 99.97% efficient in removing particles greater

than 0.3 μm from the room air supply. These filters are known as High Efficiency Particle Air (HEPA) filters although Ultra Low Particle Air (ULPA) filters, which have a higher efficiency, are used in microelectronic fabrication areas.

3. *Terminal air filters:* The high efficiency filters used in cleanrooms are installed at the point of air discharge into the room. In air conditioning systems used in offices, etc. the filters will be placed directly after the ventilation plant but particles may be induced into the air supply ducts or come off duct surfaces and hence pass into the room.
4. *Room pressurisation and pass-through grilles:* To ensure that air does not pass from dirtier adjacent areas into the cleanroom, the cleanroom is positively pressurised with respect to these dirtier areas. This is done by extracting less air from the room than is supplied to it, or by extracting the supplied air in adjacent areas. To achieve the correct pressure and allow a designed movement of air from the cleanest to the less clean rooms in a suite, pass-through grilles or dampers will usually be seen at a low level on walls or doors.

Another indication that the room is a cleanroom is the type of surface finish in a room. The room will be constructed of materials which do not generate particles and are easy to clean. Surfaces will be constructed so that they are accessible to cleaning and do not harbour dirt in cracks, e.g. coved flooring and recessed lighting.

The airborne cleanliness of a conventionally ventilated cleanroom is dependent on the amount and quality of air supplied to the room and the efficiency of mixing of the air. Generally speaking, a cleanroom will have sufficient air supply to achieve good mixing and the air quality of the room will therefore only depend on the air supply quantity and quality. It is important to understand that the cleanliness of a conventionally ventilated cleanroom is dependent on the volume of air supplied per unit of time and not the air change rate.

The cleanliness is also dependent on the generation of contamination within the room. i.e. from machinery and individuals working in the room. The more people in the cleanroom, the greater their activity and the poorer their cleanroom garments the more airborne contamination is generated. People moving about with poor cleanroom garments such as smocks or laboratory coats will generate, on average, about 2×10^6 particles $\geq 0.5 \mu\text{m}/\text{min}$, about 300 000 particles $\geq 5.0 \mu\text{m}/\text{min}$, and about 160 bacteria-carrying particles per minute. If people wear well designed clothing (coverall, knee-length boots, hood, etc.) made from tightly woven cloth the reduction of particles $\geq 0.5 \mu\text{m}$, $\geq 5.0 \mu\text{m}$ and bacteria-carrying particles will be about 50%, 88% and 92%, respectively. Little information is available about the generation of particles from machinery used in cleanrooms but this may account for hundreds to millions of particles $\geq 0.5 \mu\text{m}$ being dispersed per minute.

If the efficiency of the supply filters can be assumed to be close to 100% in removing the airborne contamination being considered, a rough approximation of the likely airborne cleanliness of a conventionally ventilated cleanroom (not a unidirectional flow one) can be achieved by use of the following equation:

$$\text{Airborne concentration} = \frac{\text{Number of particles (or bacteria) generated/min}}{\text{Air volume supplied* (ft}^3 \text{ or m}^3\text{/min)}}$$

(count/ft³ or m³)

*including that from unidirectional flow work stations.

Cleanrooms ventilated in this conventional turbulent manner may achieve conditions as low as ISO 6 (Class 1000) during manufacturing but are more likely to be ISO 7 (Class 10 000). To obtain cleaner rooms, greater dilution of the particles generated is necessary and this can be achieved by a unidirectional flow of air.

Unidirectional Airflow Cleanrooms

Unidirectional airflow is used when low airborne concentrations of particles of bacteria are required. This type of cleanroom was previously known as 'laminar flow' with a horizontal or vertical air flow at a uniform speed of between 0.3 and 0.45 m/s (60 to 90 ft/min) and throughout the entire air space.

The air velocity suggested is sufficient to remove relatively large particles before they settle onto surfaces. Any contaminant generated into the air can therefore be immediately removed by this flow of

air, whereas the conventional turbulently ventilated system relies on mixing and dilution to remove contamination. In a theoretical situation in an empty room with no obstructions to the airflow, contamination could be quickly removed to the exhaust by air velocities much lower than those mentioned above. However in a practical situation there are obstructions and people moving about. Obstructions will cause the unidirectional flow to be turned into turbulent flow and air vortices to be established around the obstructions. Movement of people will also turn unidirectional into turbulent flow. Higher contamination concentrations will be established in these turbulent areas. It is therefore necessary that the velocity is in the region of 0.3 to 0.45 m/s (60 to 90 ft/min) so that the disrupted unidirectional flow can be quickly reinstated and the contamination around the obstructions be adequately diluted.

Unidirectional airflow is correctly defined in terms of air velocity, the cleanliness of a unidirectional room being directly proportional to the air velocity. Air changes per unit of time should not be used with a unidirectional flow room as they are related to the volume of the room, which generally has no effect on the performance of the system.

The air volumes supplied to unidirectional flow rooms are many times (10-100) greater than those supplied to a conventionally ventilated room. They are therefore very much more expensive in capital and running costs.

Unidirectional flow rooms are of two general types, namely horizontal or vertical flow. In the horizontal system the air flow is wall-to-wall and in the vertical system it flows from ceiling-to-ceiling.

Shown in Figure 1.7 is a typical vertical flow type of cleanroom. It may be seen that the air is supplied from a complete bank of high efficiency filters in the roof and this flows vertically through the room and out through open gridded flooring. Air in this figure is shown to flow through the complete area of a floor but it is common to find rooms in which the air returns through grilles which are distributed about the floor. If the floor area is not too great, grilles can alternatively be placed at a lower level in the walls. The exhaust air is recirculated, mixed with some fresh make-up air, and supplied to the room through the high efficiency filters in the room ceiling. This type of room is further discussed in Chapter 3.

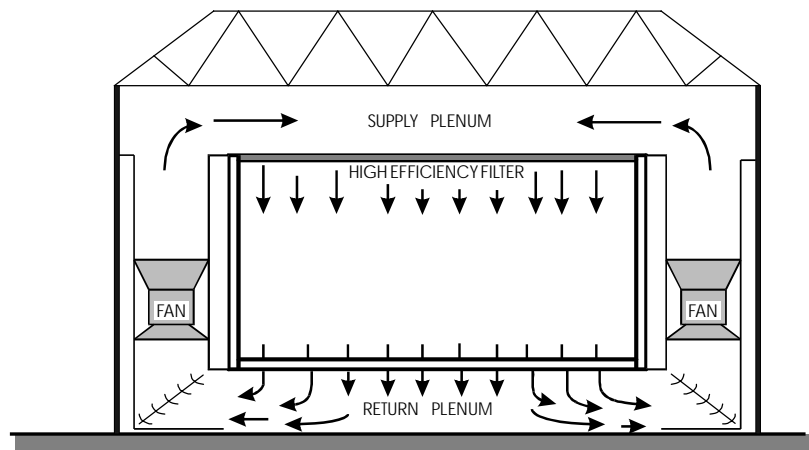


Figure 1.7. Vertical unidirectional flow cleanroom.

Most unidirectional cleanrooms are built in a vertical manner as particles generated within the room will be quickly swept down and out of the room. Less popular is the horizontal flow type of cleanroom, a typical example being shown in Figure 1.8.

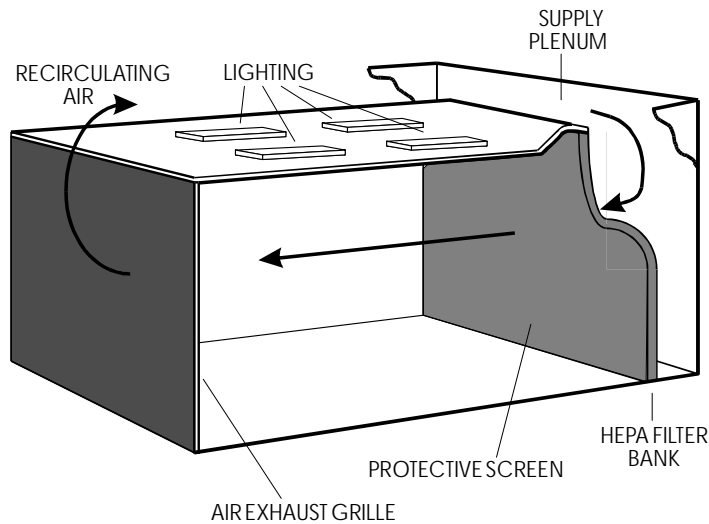


Figure 1.8 A horizontal flow cleanroom

This type of cleanroom is not so popular because any contamination generated close to the filters will be swept down the room and could contaminate work processes downwind. However as the area of a wall in a room is usually much smaller than the ceiling the capital and running costs are less. If the cleanroom can be arranged so that the most critical operations are close to the supply filters and the dirtier ones at the exhaust end, then this type of room can be successful.

Mixed Flow Rooms

This type of room is a conventional flow room in which the critical manufacturing operations are carried out within a higher quality of air provided by a unidirectional flow system, e.g. a bench. This mixed type of system is very popular as the best conditions are provided only where they are needed and considerable cost savings are available for use in this room. Shown in Figure 1.9 is a horizontal flow cabinet, this being one of the simplest and most effective methods of controlling contamination. In this bench the operator's contamination is kept downwind of the critical process. Also available are a variety of styles of vertical flow systems which may vary in size to encompass a person's manipulations or large pieces of machinery.

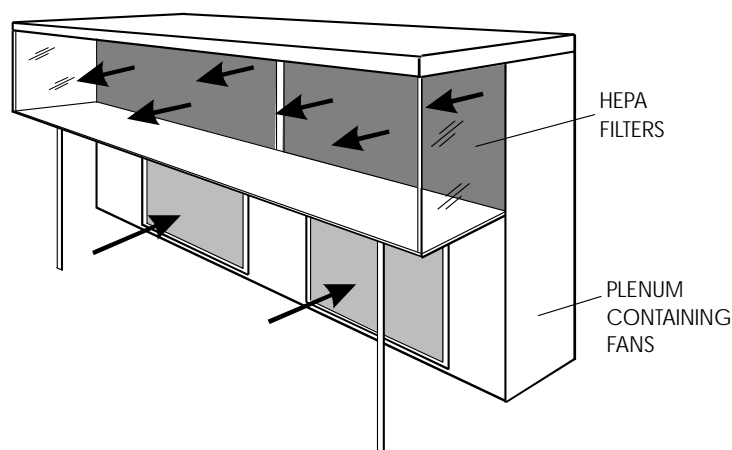


Figure 1.9 Horizontal flow cabinet.

Isolator or Minienvironments

Hazardous work with toxic chemicals or dangerous bacteria has been carried out for many years in glove boxes. Work on germ-free animals has also been carried out for decades in plastic isolators which prevented the entrance of micro-organisms. These contaminant-retaining and contaminant-

excluding systems do not principally depend on airflow for isolation but walls of metal and plastic. This principle of isolation clearly has excellent barrier properties and it has now been developed for use in modern cleanroom technology. In the pharmaceutical manufacturing area this technology is generally known as isolator or barrier technology, whereas in the semiconductor industry it is generally known as minienvironments.

Shown in Figure 1.10 shows the various components of an isolator. It may be seen that there is a physical barrier to outside contamination, and personnel either enter into half suits or use gauntlets to work at the clean processes within the isolators. The air within the isolator is sterile and particle-free having been filtered by high efficiency filters; this air is also used to pressurise the system and prevent the ingress of outside contamination. The containers and product cab enter and depart the isolator system through a sterilising tunnel, pass through tunnel or docking transfer device.

Another system, which is used in semiconductor manufacturing, is the SMIF (Standard Mechanical Interface Format) system. In this system silicon wafers are transported between machines in special containers which prevent the wafers being contaminated by the air outside. These containers, which contain the wafers, are slotted into the machine interface, the wafers processed and then loaded onto another container which can be taken to another machine and loaded into its interface. This system is further described and discussed in Chapter 3 of this book.

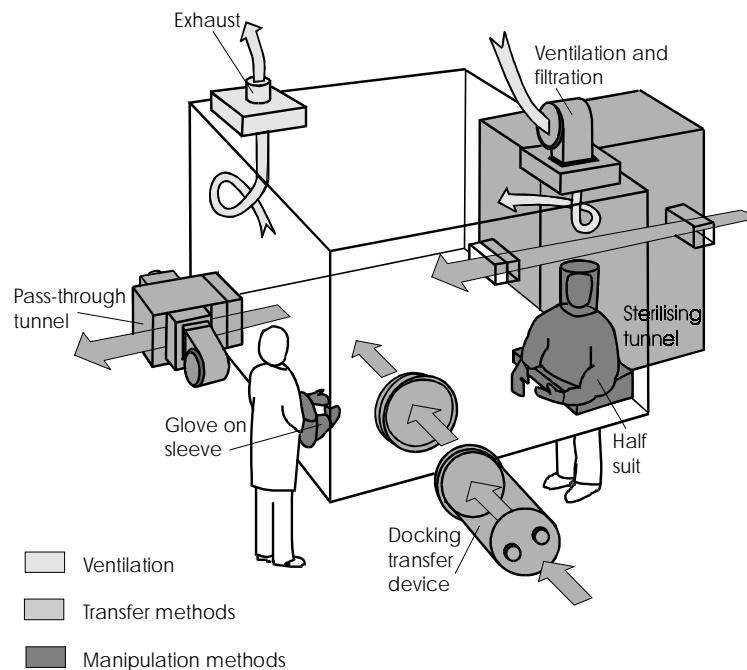


Figure 1.10. Various parts of an isolator.

CONTAINMENT OF CONTAMINATION

Cleanrooms are used to prevent contamination of articles produced in the room. However it is quite common to find that some manufacturing processes produce toxic chemicals or dangerous bacteria and these must be contained. This can occur, for example, in the pharmaceutical industry where highly active pharmaceuticals, such as hormones, must not reach the operator. Other examples are to be found in the biotechnology industry where rooms are required to contain the genetically engineered micro-organisms. Microbiological laboratories dealing with disease-producing micro-organisms require to ensure that the personnel working in them, or the people passing near them, are not infected.

The technology associated with the design of these containment rooms is similar to that used in cleanrooms and it is normal that containment rooms should also be cleanrooms. It is also common to find cleanrooms with containment cabinets within them. The design of containment rooms is also discussed in Chapter 6

Containment Rooms and Cabinets

Shown in Figure 1.11 is an example of a containment room that might be used for working with micro-organisms dangerous to the health of the personnel working there, or to anyone passing close to the room. It may be seen that clean air is supplied to the room but more air must be extracted from the room so that the room will be under negative pressure and air will always flow into the room. The air that is extracted must be filtered through a high efficiency HEPA filter before being discharged to the outside.

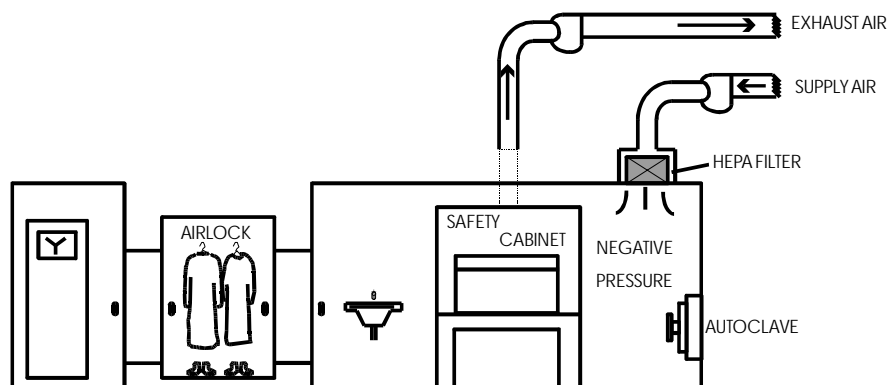


Figure 1.11. Containment room.

Within this room there will be a safety cabinet in which the micro-organisms are manipulated. In a room where there is not a very high risk a Class I or Class II cabinet is used. In a high-risk area a Class III cabinet would be used. Shown in Figure 1.12(a), (b) and (c) is a diagrammatic representation of these three types of cabinets showing their air flow and isolation principles. If the manipulation in the cabinet requires clean conditions then a Class II cabinet will be used, as this type is designed to give a flow of filtered air over the product while still ensuring that the flow of air is into the cabinet. To ensure satisfactory working of a class II cabinet, attention must be routinely given to the air flow balance and if especially clean conditions are not necessary a Class I cabinet may be chosen for its more stable airflow balance.

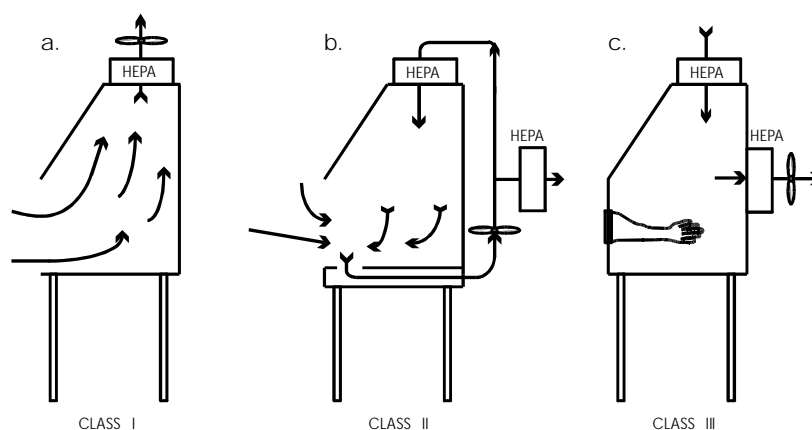


Figure 1.12. Containment cabinets.

Other features that may be seen in such rooms are the use of an airlock to allow people to pass in and out of the room. A pass-through autoclave may be available to allow for the sterilisation of contaminated material. Other containment rooms may be of a higher or lower standard, depending on the toxic, chemical, or microbiological hazard of the room. Less hazardous rooms would not use an airlock or pass-through autoclave and rely on the exhaust of a Class I cabinet, or fume cupboard, to create a negative pressure in the room. Rooms in which the hazard was high would contain the hazard

within a Class III type of cabinet and provide a shower area between the airlock and the room. In particularly hazardous situations, personnel would wear filtered air suits.

SUPPLY OF LIQUID AND GASES TO CLEANROOMS

To ensure that the product produced in the room is free of particles and microbial contamination, it is necessary to ensure that not only the air is free of contamination but that other gasses and liquids supplied to the room are also free of contamination. In pharmaceutical cleanrooms there is the requirement for large quantities of water used to make up pharmaceuticals and in semiconductor fabrication areas pure water is used to wash silicon wafers during the manufacture. The manufacture of semiconductors also requires the supply of various gases and these must be provided with extremely low levels of contamination. These topics are discussed in chapters 10,11 and 12 of this book.

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