VILAIR AAF
CLEANROOM SYSTEMS

Ultra-clean environments for the biopharma industry

Cleanroom requirements – ISO 14644-1 Class 7

Applications

Cleanrooms are defined as a room, or suite of rooms, in which the concentration of airborne particles is maintained within established parameters; and where other factors are controlled to within specified limits. These rooms are designed to provide control of various environmental factors including some or all of the following:

- Viable and non-viable airborne particles
- Air flow patterns
- Temperature and humidity
- Air pressure
- Containment of hazardous aerosols
- Operating procedures

Applications include the manufacture of biopharma products, sterile pharmaceuticals, electronics components, medical devices and implants; and the maintenance of sensitive aviation and avionics systems. GMP codes and specifications for many applications require that the critical process be performed in a Class 5 laminar flow cabinet installed in a Class 7 cleanroom.

Compliance requirements

- ISO 14644 Class 7 (AS 1386 Class 350) air cleanliness to be achieved in the cleanroom and an adjoining ante-room that acts as an air lock. Where installed, laminar flow units should provide ISO 14644 Class 5 (AS 1386 Class 3.5) conditions.
- Validation of the facility to Australian standards by a NATA-registered test laboratory.

HVAC system

Room air should be supplied by an external air conditioning system - preferably one dedicated to the facility. Partial recirculation of room air allows optimal energy utilisation. Sufficient fresh air should be supplied in accordance with ventilation codes; to balance leakage and exhaust air; and to maintain specified pressures. Unless otherwise specified, room temperature within the range of 16^0 C to 19^0C and relative humidity of 55% to 65% should be maintained. The type of cleanroom clothes may dictate some variation from these levels.

Class 7 cleanrooms with Vilair-AAF filtration system

Airflows

Only HEPA-filtered air should enter the cleanroom and ante-room from HEPA filters installed at the 'terminal 'point, i.e. in ceilings. HEPA filters should be proprietary cleanroom modules in purpose-designed ceiling frames. These modules are available in fan-assisted configuration with fan-speed control, or non-fan-assisted; and should operate at a velocity of > 0.4 m/s and < 0.6 m/s. The location of HEPA filters and return air grilles should create air movement from the designated ‘clean’ zone of the room to the ‘less-clean’ zone. Return air grilles should be at low level.

Room air-change rate

Air supply to the cleanroom should provide a room air-change rate of > twenty (20) per hour. Air cleanliness will be enhanced by higher air-change rates, e.g. > 30/h - typically, heat load calculations result in such a rate. When the doors are open, the supply-air volume should maintain an outward flow of air.

Room pressures

Cleanroom air pressure should be higher than that of the ante-room and the surrounding uncontrolled area. The pressure gradient between these zones should be ≥ 15 Pa. Typical values are:

Cleanroom:	30 Pa positive pressure
Ante-room:	15 Pa positive pressure

Suitable manometers should be installed outside the ante-room to indicate room pressures of the facility.

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Equipment and services – typical

The scope of the supply and installation requirement will depend on the nature of any existing facility; and that of the new development. Typical requirements are:

- Room construction or modification to create the required room configurations. Where existing walls are used to form all or part of the cleanroom, all joints and penetrations should be crevice-free and airtight. Exposed walls should have a smooth surface and be coated in epoxy, polyester, polyurethane or other durable plastics finish. If sandwich panel construction is used, wall panels should be pre-painted, self-supporting 1200 mm wide, 75 mm or 100 thick panels fitted into a powder-coated channel that is fastened and sealed to the floor. Panels should incorporate tongue and groove interlocking joints. All joints should be sealed with a fungicidal, flexible-setting compound. Plaster board and stud construction may offer a cost-effective alternative to sandwich panels if this meets facility operational, life-cycle and compliance needs.
- A dedicated HVAC system, including 415V electrical supply, cabling, ducting and controls; that is configured and sized to meet both existing requirements and identified future expansion.
- AAF®) *TM* (non-fan-assisted) or *FMII* (fan-assisted) HEPA filter modules for supply to cleanroom and ante-room. These units have the capacity to supply the required air volume for the proposed expansion of the facility.
- AAF panel, multi-pocket or rigid, extended-surface prefilters for the HVAC installation.
- If required, a pass-through hatch to allow materials transfer between rooms. These are typically of stainless steel construction with door interlocks.
- Dwyer Magnehelic gauges located at the ante-room entry to monitor room pressures.
- Validation of the facility confirmed by independent NATA-accredited testing and certification.

Australian and ISO cleanroom standards

The withdrawal of AS 1386 and the adoption of ISO 14644 will change classifications for air cleanliness as shown below.

AS 1386 Class	ISO 14644-1 Class
-	1
-	2
0.035	3
0.35	4
3.5	5
35	6
350	7
3,500	8
-	9

TGA and EU GMP define air cleanliness Classes A-D inclusive, with various zone classification requirements as ‘operational’ or ‘at rest’.

Our capability

Vilair-AAF is a specialist supplier of laminar airflow and containment equipment for high technology manufacturing. Our modular systems are engineered to meet the needs of any application that requires ultra-clean air or containment of hazardous aerosols.

Our aim is to provide highly cost-effective equipment solutions that meet stringent industry and government regulations. We have designed, manufactured and installed purpose-engineered systems for Australia’s leading manufacturers of pharmaceuticals and medical devices. As the Australian distributor for American Air Filters® (AAF) – the world’s largest air manufacturer of air filters - we have online access to world-class cleanroom technologies, research and support.

Vilair-AAF cleanroom products

- Laminar flow enclosures and workstations
- Dispensary & sampling containment booths
- AAF HEPA & ULPA filters and modules
- Cleanroom ceiling and lighting systems
- Clean garment-storage cabinets
- Pass-through hatches
- Air showers
- Absorption filter systems for odour control
- AAF and Vilair® filters for general ventilation and air conditioning

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