

CLEANROOMS

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1.0 SCOPE

This loss prevention data sheet covers construction and fire loss prevention and control recommendations applied to cleanrooms.

1.1 Changes

April 2020. Interim revision. Added equipment contingency planning and sparing guidance.

2.0 LOSS PREVENTION RECOMMENDATIONS

2.1 Introduction

Cleanrooms are used in the manufacturing, assembly and packaging of products, as well as in research activities, by a great variety of industries. Because of their critical role in providing a work space where contamination from particles and other airborne contaminants is limited, cleanrooms find applications in industries as diverse as electronics, semiconductors, automotive, pharmaceutical, biotechnology, healthcare, film, garments, food, space and military.

The range of occupancies and processes handled in cleanrooms varies from industry to industry. As they do, so do the style, arrangement and classifications of cleanrooms, as well as the range of possible exposures and hazards that can be encountered.

Most of the recommendations in this document are core recommendations that apply uniformly to all cleanrooms. These recommendations typically address construction and facility related issues, or general or human element issues. Examples include: site selection, cleanroom and building construction, air handling, smoke control, fume exhaust, power supply, automatic sprinkler fire protection, housekeeping, **equipment contingency planning, inspection, testing and maintenance programs, and operator training.**

However, this document also includes a number of recommendations that are occupancy-specific and apply only when the hazard being addressed by the recommendation is present in the cleanroom. These occupancy-specific recommendations typically involve issues related to the process going on inside the cleanroom. Examples of those are: use of ignitable and corrosive liquids, flammable or toxic gases, utilization of process equipment of combustible construction, need for sanitation or sterilization, and others.

2.2 Construction and Location

2.2.1 Site Selection

2.2.1.1 Locate cleanrooms and related support facilities, such as: utility buildings, waste processing buildings, chemical storage and delivery buildings, subfabs and other support facilities to avoid the following exposures:

- Exposures from other occupancies located within the facility.
- Exposure from natural catastrophes such as flood, windstorm, geological events, freezing weather, hail, etc. Cleanroom buildings and related support areas should not be located within any identified flood zone.
- Exposure from internal or external fire and explosion sources. This would include proposed adjacent occupancies, external adjacent structures, wildfire potentials, conflagration, etc.
- Liquid damage exposure from piping and other utility services, such as drainage systems and liquid delivery systems.
- Contaminant exposure to air intakes from adjacent exhaust systems and occupancies.

2.2.1.2 Locate cleanrooms and related support facilities at or above grade level to prevent exposures to flooding, sewer backup and other hazards that could expose below grade areas to loss.

2.2.2 Cleanroom Construction

2.2.2.1 Locate cleanrooms in a fire resistive or noncombustible building or area.

2.2.2.2 Separate cleanrooms from adjacent occupancies no greater than ordinary hazard, by minimum 1-hour rated construction. The exception to this would be the air showers (entry) between the cleanroom and the adjacent gowning area; construct these of noncombustible materials. Locate adjacent occupancies greater than ordinary hazard in separate buildings.

2.2.2.3 Where there are viewing windows provided in a cleanroom exterior wall, along an adjacent hallway, construct the hallway of noncombustible materials and use a rated assembly for the hallway wall opposite the windows.

2.2.2.4 Provide noncombustible, sealed, interior subdivision walls in cleanrooms to limit the spread of smoke and other contaminants in the event of an accident. In vertical unidirectional flow cleanrooms these subdivision areas should run from the underside of the roof to the cleanroom floor; where a return air space exists below the cleanroom floor, these subdivisions should extend to the return air floor. Where cleanrooms adjoin, use one-hour rated fire partitions.

2.2.2.5 Use noncombustible wall and floor panels, and interior finishing materials in cleanrooms. Where noncombustible materials cannot be used, use materials that are FM Approved per FM 4882 for use in cleanrooms or FM Approvals 4910 specification tested (4910-listed) to meet the FM Approvals Cleanroom Materials Flammability Test Protocol. (See Appendix A for definition of Approved.)

2.2.2.6. Tightly seal all utility penetrations in solid noncombustible floors with Approved fire stop materials.

2.2.2.7. Seal any penetrations through rated wall systems using Approved wall penetration fire stops.

2.2.2.8 Establish a semiannual inspection program to verify that all wall and floor penetrations are properly sealed and that the integrity of all subdivisions is maintained. Test all fire doors.

2.2.2.9 Use Approved HEPA (high efficiency particulate air) and ULPA (ultrahigh particulate air) filter modules in new cleanroom installations.

2.2.2.10 Use noncombustible or 4910-listed materials for all filter housing, louvers and ceiling grids.

2.2.2.11 Construct the roof above the cleanroom of the following materials, in descending order of preference:

a) Fire-resistive (e.g., reinforced concrete or protected steel frame)

b) Noncombustible (e.g., concrete over steel deck or steel frame)

c) Class I (e.g., insulated steel deck with limited above deck combustibles) provided with sprinkler protection.

Combustible construction, including gypsum board sheathed roof (one-hour rated per code), is not recommended.

2.2.2.12 Design roofs to meet all FM Approvals requirements regarding windstorm, drainage, hail, rain and snow loading for the area.

2.2.2.13 Do not locate non-related occupancies above cleanrooms. Use totally liquid-tight floors with adequate drainage and containment to a safe location whenever occupancies above the cleanroom have potential for liquid leak, such as fill tanks or HVAC equipment in cleanroom plenums.

2.2.2.14 Use noncombustible or 4910-listed materials for acoustical lining of air handling fan enclosures.

2.2.2.15 Avoid any liquid piping and fittings above cleanrooms. When liquid piping above a cleanroom cannot be avoided, locate and protect pipes to prevent water damage to the cleanroom in the event of a leak. Examples include re-circulation air handlers, drains and other piping (see Section 2.4.4, *Utility Piping and Liquid Damage Exposures*).

2.2.2.16 Use noncombustible insulating materials, such as mineral wool or expanded glass insulation, for all needed piping insulation.

2.2.2.17 Establish a comprehensive loss prevention program for new cleanrooms under construction (or existing rooms undergoing renovation) in accordance with Data Sheet 1-0, *Safeguards During Construction, Alteration and Demolition*.

2.2.2.18 Provide air locks between adjoining clean areas to minimize damage (contamination) in the event of fire or related hazard.

2.2.2.19 When services are provided through concealed spaces, run services beneath the cleanroom or in service corridors (if provided) and protect the concealed service spaces in accordance with applicable FM Global data sheets.

2.3 Utilities

2.3.1 Cleanroom Air Handling System

2.3.1.1 Do not connect the return air system of a cleanroom to another air-handling system within the building.

2.3.1.2 Locate makeup air fan intakes away from any potential sources of smoke or fumes, which could expose the cleanroom to contamination from a fire in the same, or in adjacent buildings or areas. Locate makeup air fan intakes remotely from exhaust stacks of smoke control systems and scrubbers. Have smoke and/or fume dispersion calculations performed whenever there are questions about the possibility of the makeup air intake becoming contaminated by a potential adjacent source of smoke or fumes.

2.3.1.3 Provide an Approved smoke detection system within the makeup and re-circulating air handler units (AHU), or close to them downstream. Arrange the smoke detection system to sound an alarm at a constantly attended location, and to shut down the air handler units upon alarm to prevent continued intake of contaminated air.

2.3.1.4 Provide an Approved air-sampling or linear beam smoke detection system within the return air path. When the cleanroom smoke control system is integrated with the area air-handling system, arrange these detectors as follows:

- To close dampers (upon alarm), stopping the flow of re-circulating (supply) air to the cleanroom and,
- To open dampers, diverting the flow of smoke/contaminant (exhaust) within the cleanroom to the atmosphere.

In all cases, arrange detectors to alarm at a constantly attended location.

2.3.1.5 Provide emergency manual control switches for both the makeup and re-circulating air fans. Install emergency switches outside the entrance area to the cleanrooms.

2.3.1.6 Use metallic noncombustible construction for the air-handling ductwork installed between the re-circulating air unit and the cleanroom filter modules (i.e., elephant trunks).

2.3.1.7 Provide at least one redundant fan of each type for the various air systems (n+1). This includes fans used for building make-up air, cleanroom air supply, and the various exhaust systems (scrubbed exhaust, general exhaust, calamity exhaust and other exhaust systems).

2.3.1.8 Connect the air handling system to an emergency power source through an automatic transfer switch arranged to keep the cleanroom under positive pressure in the event of a loss of utility power.

2.3.1.9 When the electrical power is provided by two or more utility sources, arrange the electrical feed to the cleanroom air handling fans to split the load between at least two sources: about half from one utility feeder, and the other from the second utility feeder. It also is preferable to supply adjacent fans from alternate feeders and MCCs (motor control centers) so that if one utility source is lost or one MCC fails, air flow can be maintained to all air zones of the cleanroom.

2.3.1.10 Arrange a ventilation system that handles more than one cleanroom classification so that the air flow pattern is from lower to progressively higher zones of contamination risk, i.e., from the zones where there is a lower risk of having a release and contaminating the air to the zones with higher risk of such incident.

2.3.1.11 Install air filters so that they are readily accessible for inspection, maintenance, and fire fighting.

2.3.2 Cleanroom Smoke Control Systems

2.3.2.1 Provide each cleanroom with means of removing smoke during a fire. This will minimize the spread of contaminants within the cleanroom. Smoke removal should be provided either by a dedicated smoke control system or by an arrangement of the cleanroom air handling or fume exhaust system, as described below. Base the selection of which smoke removal arrangement to use on Table 1 below. In addition, consider the following factors in selecting a smoke removal arrangement: the combustible loading present in the cleanroom, the type of construction used, the sensitivity of the process and contents to smoke and other non-thermal damage, the expected downtime for clean-up after an incident, and other relevant factors.

Typically, dedicated smoke control systems are a more efficient means of smoke removal, and are preferred for cleanrooms class 100 or less, and where moderate to large amounts of combustible material is present.

Table 1. Cleanroom Smoke Removal Arrangements (use in conjunction with Figs. 1-5)

IF the cleanroom is provided with	Then smoke removal is provided by a dedicated smoke control system; or by:
No room re-circulating air system (Fig. 1)	Fume exhaust system if duct construction is Type 1 or 2 (see below)
Partial re-circulating air system (Fig. 2)	Air handling or Fume exhaust system if duct construction is Type 1 or 2
High volume laminar flow re-circulating air system (Fig. 3) with return air duct	Air handling system with damper arrangement to divert return air to atmosphere
High volume laminar flow re-circulating air system with return air plenum (Fig. 3)	Dedicated system
A perforated raised floor and ducted return (Fig. 4)	Air handling system with damper arrangement to divert return air to atmosphere
A perforated raised floor and attic return air plenum (Fig. 4)	Dedicated system
A perforated raised floor, open waffle slab and ducted return (Fig. 5)	Air handling system with damper arrangement to divert return air to atmosphere
A perforated raised floor, open waffle slab and attic return air plenum (Fig. 5)	Dedicated system

Duct construction materials:

Type 1: Unlined ferrous metal (steel, stainless steel, galvanized metal, etc.)

Type 2: Approved fume exhaust and smoke control duct systems not requiring automatic sprinklers, fire dampers, or interrupters of any kind.

2.3.2.2 When indicated in Table 1, smoke removal can be integrated with the fume exhaust system when the fume exhaust system is also designed for smoke removal. In this case, the following applies:

- Noncombustible or Approved fume exhaust duct system is used for smoke removal. Do not use fire dampers or interrupters in duct systems (Figs. 1 and 2).
- Local operations (process equipment, exhaust hoods, etc.) and other locations susceptible to fire are designed for local removal of smoke.
- The exhaust system is arranged so that smoke goes directly from the fire to the exhaust inlets without exposing other areas.

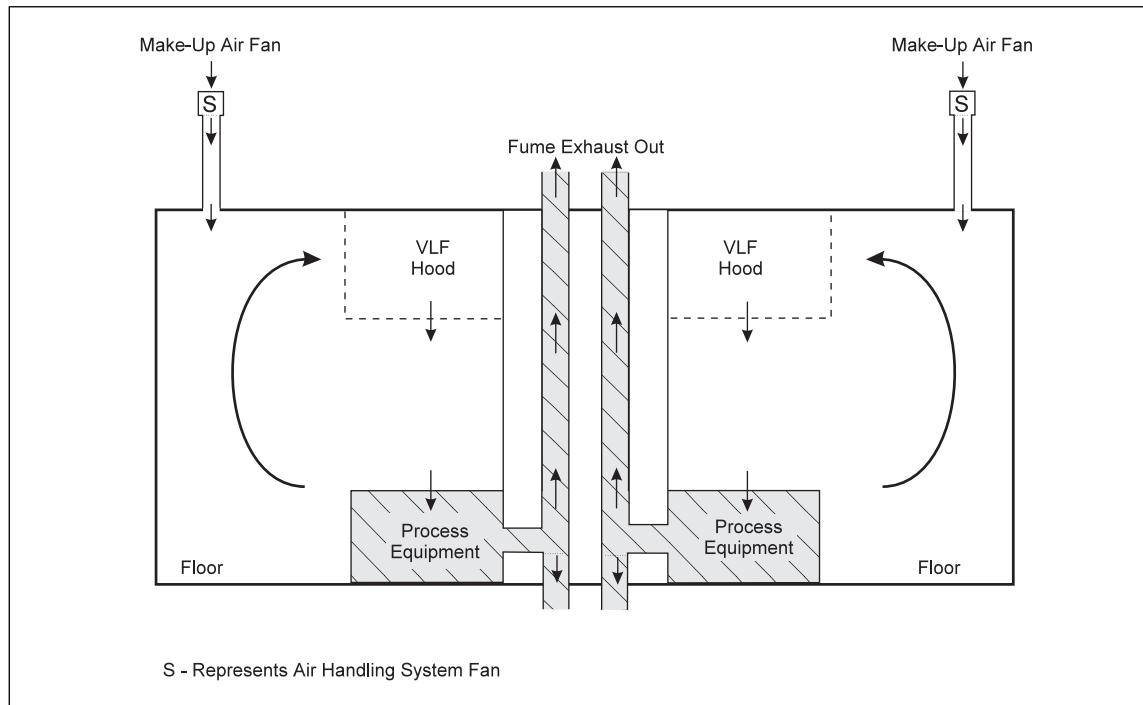


Fig. 1. Local return cleanroom.

Note: Figures 1 through 5 show vertical unidirection flow cleanrooms.

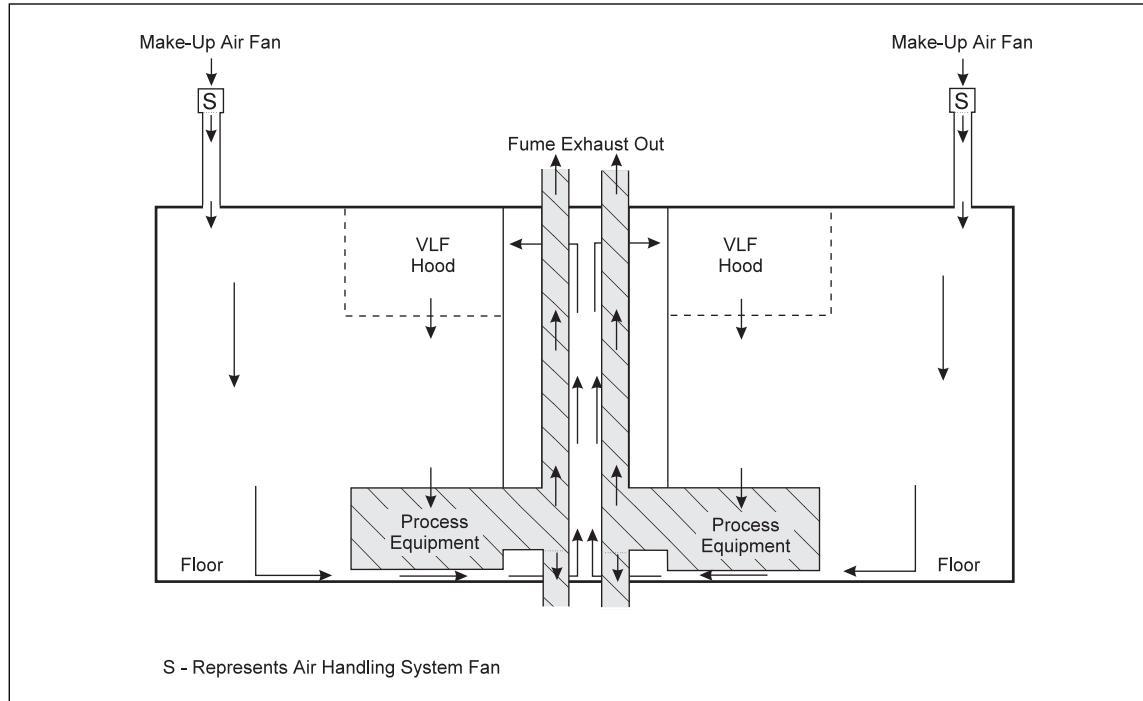


Fig. 2. Partial return cleanroom.

2.3.2.3 When indicated in Table 1, smoke removal can be integrated with the cleanroom air handling system when the cleanroom air is returned to the re-circulation air fan via ducts (Figs. 3, 4 or 5). In this case, the system should be arranged as follows:

- The system is designed and protected in accordance with Data Sheet 1-45, *Air Conditioning and Ventilating Systems*, and supplemented with the applicable recommendations listed below:
- When several cleanrooms are supplied with a central air handling system, the system is designed for the dual purpose of environmental protection and smoke control (Fig. 6). Upon the detection of smoke, this system automatically puts the fire area under 100% exhaust and simultaneously put the areas immediately adjacent to the fire area into 100% supply without resulting in damaging overpressures to separation walls. The intent of this smoke control concept is to prevent smoke infiltration to the cleanrooms adjacent to the one on fire, and to purge the fire area of smoke contamination. (Smoke control mode in each room is shown in Fig. 6.)
- When each room is served by an independent air handling system (Fig. 7), the system is designed and arranged to convert to smoke control mode in case of fire in any of the rooms. This conversion involves automatic closing of the supply damper and opening the exhaust damper in the room that contains the fire. In the adjacent rooms, the exhaust dampers are closed and the supply dampers opened (Fig. 7). (This creates a slight positive pressure in the non-involved rooms, thereby resisting smoke infiltration.)
- Supply and exhaust ducts serving one smoke zone do not pass through another smoke zone.
- The air handling system in the exposed area is designed to provide 100% outside fresh air to the areas adjacent to the fire. This will prevent smoke migration through openings and will pressurize adjacent areas to keep them clear during a fire.
- The outside fresh air intakes are located at floor level and opposite the exhaust outlets to lessen the possibility of drawing in smoke. A large height difference between the inlet and outlet provides greater reliability. This height difference should preferably be about 20 ft (6 m).

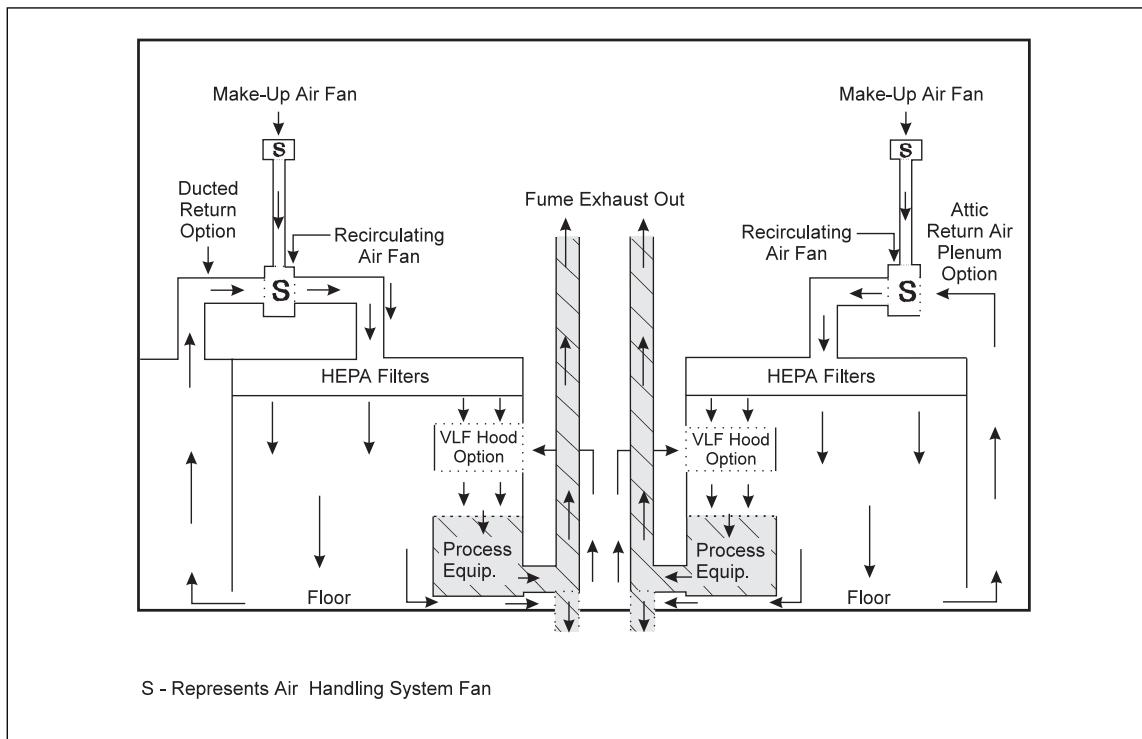


Fig. 3. Sidewall return cleanroom.

2.3.2.4 Arrange the smoke removal or control system for automatic activation either by a smoke detection system installed in the cleanroom or by the recommended smoke detection system installed in the return air path (see Section 2.3.1, *Cleanroom Air Handling System*). When the smoke control system is activated by a smoke detection system installed in the cleanroom, locate and space Approved spot type smoke detectors in accordance with Data Sheet 5-48, *Automatic Fire Detectors* and the Approval limitations for the detector.

2.3.2.5 Provide a secondary means of manual activation of the smoke removal or control system. Install manual controls in a clearly marked and accessible area outside the cleanroom.

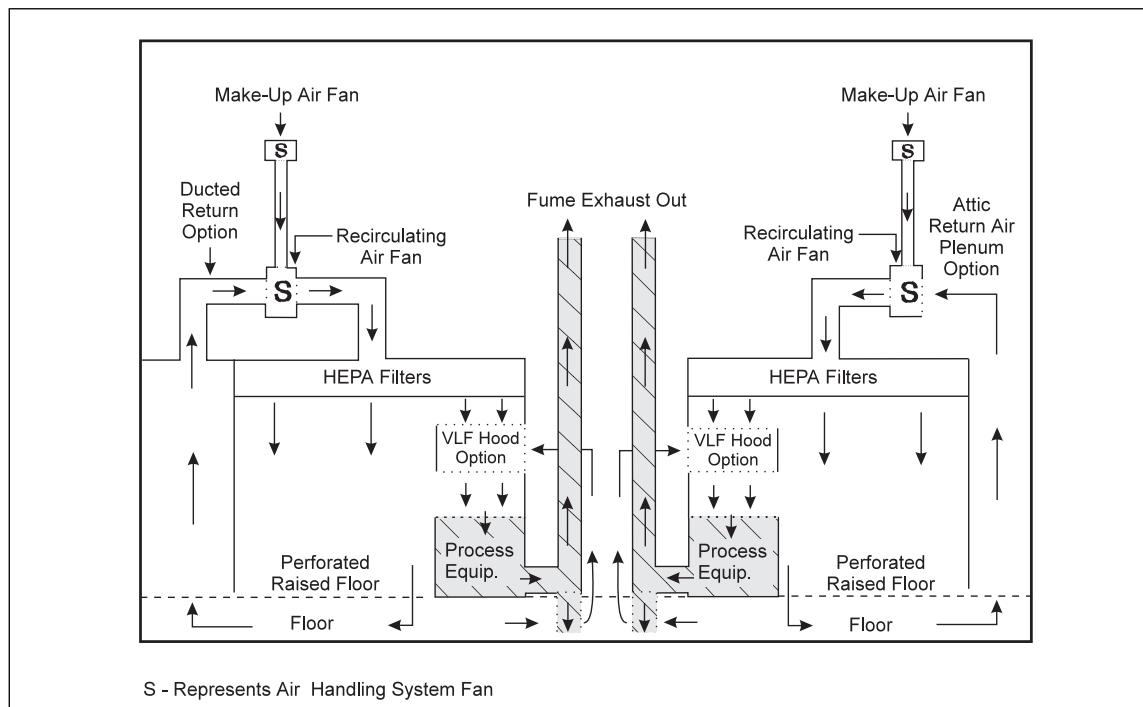


Fig. 4. Perforated raised floor cleanroom.

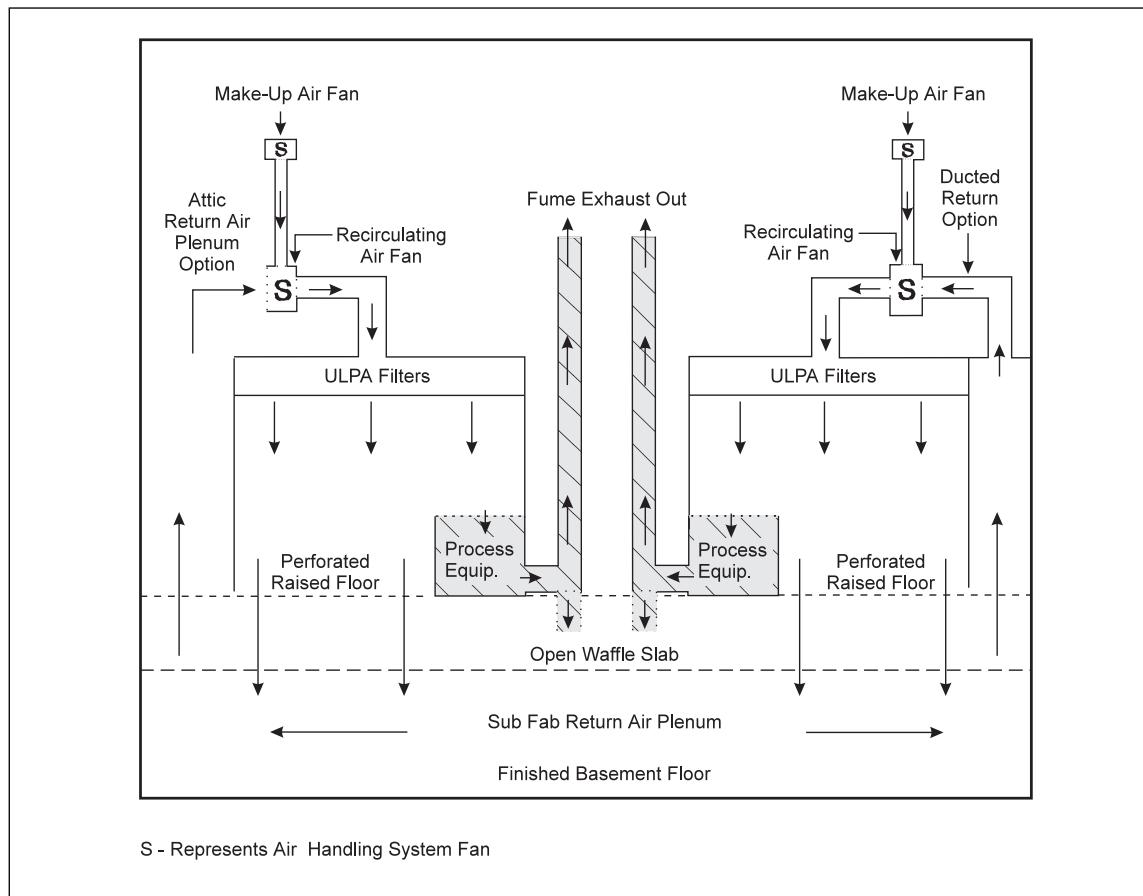


Fig. 5. Perforated raised floor and open slab cleanroom.

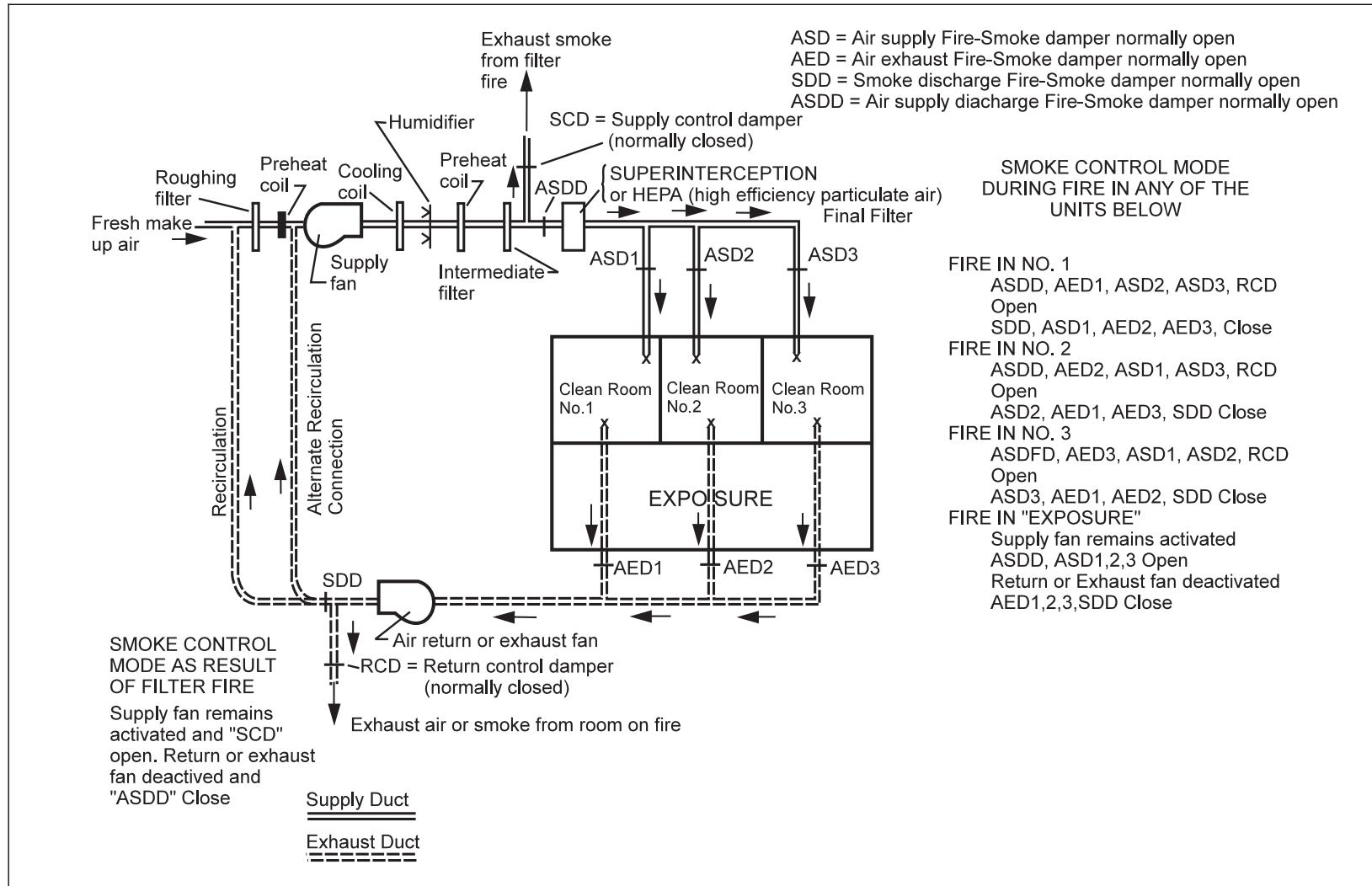


Fig. 6. Typical smoke control arrangement when a central air handling system is used to serve cleanrooms.

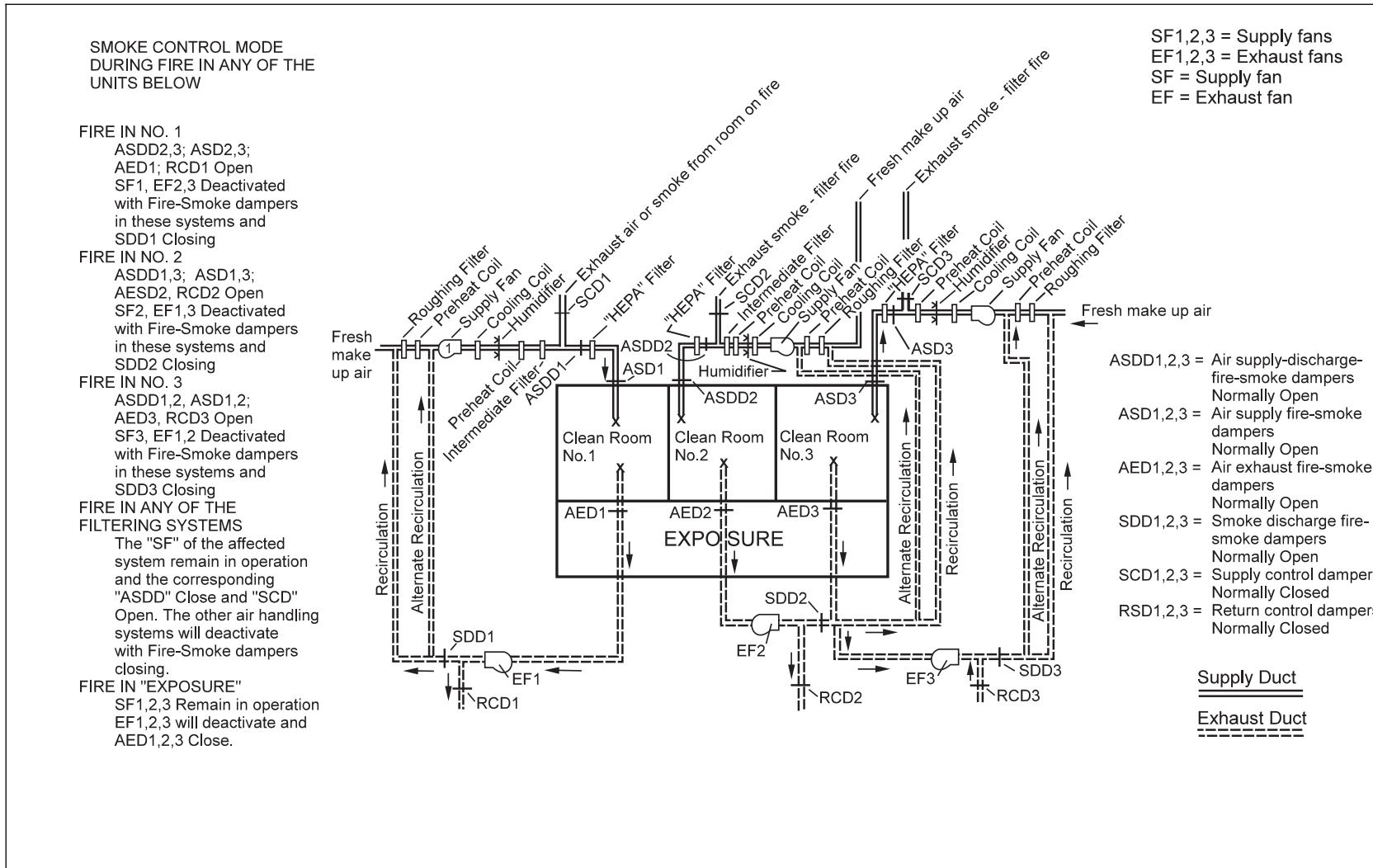


Fig. 7. Typical smoke control arrangement when an individual air handling system serves each room.

2.3.2.6 Where the cleanroom is arranged with the return air through service aisles (Fig. 3, 4 and 5), the ducted return air option is preferred.

2.3.2.7 Design smoke removal or control systems to limit infiltration of smoke and other contaminants to adjacent rooms or spaces. Design the system to clearly established goals, consistent with the type and class of cleanroom, the anticipated amount, types and arrangement of combustible materials in the cleanroom (fire loading of the cleanroom) as well as with the type and performance goals of available fire protection systems. Include the following performance information in system design goals:

- the maximum fire size for which minimum contamination is expected beyond smoke zones,
- gradient of contamination beyond the smoke zone expected for larger fires,
- amount, quality, impact and area of influence of filtered smoke.

Have the system designer provide data supporting the design of the system to meet the performance goals for the cleanroom.

2.3.2.8 In new facilities, perform a fully functional test of the smoke removal or control systems during mechanical system tests done near the end of the construction process including:

- a complete functional test of detection and control systems,
- activation of smoke removal fan and damper systems,
- verification of the performance of the smoke removal system using either sulfur hexafluoride (SF_6) or another tracer gas method.

Have the installing contractor provide written documentation and evidence of satisfactory completion of the test.

2.3.2.9 Perform a functional test of the smoke removal or control systems on an annual basis, including testing of all detection and control systems as well as dampers and fans in the system.

2.3.3 Fume Exhaust System

2.3.3.1 Use only Approved fume/smoke exhaust duct systems that do not require dampers or interrupters for new installations where corrosive products are exhausted. When such Approved exhaust duct systems are not specifically approved for use in cleanrooms (i.e., are not 4910-listed), use only ducts with noncombustible external surface.

2.3.3.2 Do not use Approved ducts for fume exhaust where liquids are expected to be exhausted with other fumes.

2.3.3.3 Do not allow liquids to accumulate within ducts Approved for fume exhaust. Provide low point condensate drains where condensate may accumulate in ducts used for fume exhaust.

2.3.3.4 Fabricate joints of Approved ducts in accordance with manufacturer's specifications.

2.3.3.5 For existing installations, where Approved duct systems are not used:

- a) Replace all PVC, polypropylene and combustible flexible ducts with Approved fume/smoke exhaust systems. Under heat, unapproved plastic materials may collapse and defeat any smoke/contaminant control design. Also, burning PVC develops corrosive fumes. If ducts cannot feasibly be replaced, they should be protected with automatic sprinkler protection in accordance with Data Sheet 7-78, *Industrial Exhaust Systems*.
- b) Provide automatic sprinkler protection inside all other nonmetal duct systems with diameters of 6 in. (150 mm) or larger. Automatic sprinklers should be designed and installed in accordance with Data Sheet 7-78.
- c) Replace or protect all other nonmetallic ducts with diameters less than 6 in. (150 mm).

2.3.3.6 Use noncombustible (unlined ferrous metal) or Approved ducts in new and existing installations where air and other non-corrosive products are exhausted. (For example, general exhaust and heat exhaust systems.)

2.3.3.7 Use noncombustible ducts for ignitable solvent exhaust. Do not use aluminum ducts because they are subject to early collapse under fire conditions.

2.3.3.8 Do not paint or coat the outside (exterior) surface of ducts that are Approved for use in cleanrooms.

2.3.3.9 Provide emergency power source for the fume exhaust system in accordance with the applicable electrical code. Design the emergency power to operate the exhaust system at not less than 50% of its normal flow.

2.3.2.10 Arrange process equipment handling different materials that can be ignitable, corrosive or can cause other type of contamination, to individually exhaust contaminant fumes. Alternatively, manifold similar elements together, if feasible, and exhaust them as a group to lessen the probability of contamination to other processes during normal operation or as a result of an accident. Do not allow oxidizer and organic substances to mix or collect within the fume exhaust system.

2.3.4 Electrical Power

2.3.4.1 Provide electrical power supply to cleanrooms from one or more reliable sources, per the appropriate electrical data sheets or occupancy standard.

2.3.4.2 Provide emergency uninterruptible power supply in accordance with Data Sheet 5-23, *Design and Protection for Emergency and Standby Power Systems*.

2.3.4.3 Install electrical equipment and wiring in accordance with NFPA 70, *National Electrical Code*. Use classified electrical equipment where needed.

2.3.4.4 In occupancies subject to frequent cleaning for sanitation, such as sterile areas, use electrical equipment that is IP rated for ingress protection against sprayed or splashed water (Ingress Protection (IP) codes IPX3 or IPX7; equivalent US Enclosure Type 6 & 6P).

2.3.4.5 Perform infrared thermal scans on processing equipment, particularly at the startup, during any new process equipment hookup, and on a routine annual basis. Perform infrared thermal scans of other electrical equipment inside cleanrooms in accordance with Data Sheet 5-20, *Electrical Testing*.

2.3.5 Waste Liquid Handling and Effluent Treatment Systems

2.3.5.1 Arrange waste liquid handling systems to divert the flow of any waste liquids, including water containing potentially hazardous materials, away from its source to a safe location outside the cleanroom.

- a) Arrange routine and emergency disposal of used or spilled chemicals via separate acid and solvent drainage systems connected to individual pieces of process equipment and work stations. Design and install ignitable liquid waste drains in accordance with Data Sheet 7-83, *Drainage Systems for Ignitable Liquids*.
- b) Empty solvents, acids or other contaminants into individual collection tanks remote from the cleanroom building. Design drainage systems so that no used ignitable, corrosive, or other contaminants are allowed to accumulate within the building.

c) Provide emergency drainage in accordance with Data Sheet 7-83, *Drainage Systems for Ignitable Liquids*.

2.3.5.2 Locate and protect effluent treatment systems in accordance with Data Sheet 7-7, *Semiconductor Fabrication Facilities*. Locate effluent treatment systems outside cleanrooms and related support areas, and arrange them to minimize the exposure to the surrounding occupancy.

2.3.5.3 Arrange and protect fixed bed absorbers as outlined in Data Sheet 7-2, *Waste Solvent Recovery*.

2.3.5.4 Arrange and protect fume incinerators as outlined in Data Sheet 6-11, *Thermal and Regenerative Catalytic Oxidizers*.

2.3.5.5 Locate scrubbers outside cleanrooms, arranged and protected as outlined in Data Sheet 7-7, *Semiconductor Fabrication Facilities*. In addition:

- Use only scrubbers built of noncombustible or 4910-listed materials.
- Provide automatic sprinkler protection to:
 - the inlet and exhaust openings of all scrubbers of combustible construction or with combustible fills. Design sprinkler protection for a minimum discharge flow of 25 gpm (95 l/min).
 - all combustible exhaust stacks.
- Locate exhaust stacks away from cleanroom air intakes. If necessary, have fume dispersion calculations conducted to confirm safe separation distances.
- Design the water make-up and drainage lines from the sump of the scrubber so that the drainage line capacity exceeds the water make-up capacity of the system.

2.4 Occupancy

2.4.1 Ignitable and Corrosive Liquid Storage, Handling and Dispensing

2.4.1.1 Store and dispense ignitable and corrosive liquids outside cleanrooms in locations designed in accordance with Data Sheet 7-29, *Ignitable Liquid Storage in Portable Containers* and Data Sheet 7-32, *Ignitable Liquid Operations*, as applicable.

2.4.1.2 Use a chemical transportation cart to transport chemicals from storage to cleanrooms.

2.4.1.3 Do not store excess chemicals within processing equipment. Limit the amount of chemicals within processing equipment strictly to the current production needs.

2.4.2 Process Gas Cylinder Storage and Handling

2.4.2.1 Store and protect process gas cylinders containing flammable, corrosive and toxic materials supplying cleanrooms in accordance with Data Sheet 7-50, *Compressed Gases in Portable Cylinders and Bulk Storage*. Where cut-off or detached rooms are used, separate these rooms from cleanrooms by Damage Limiting Construction (DLC) in accordance with Data Sheet 1-44, *Damage-Limiting Construction*.

2.4.2.2 Where flammable gases are used in process areas, provide Approved combustible gas detectors at the ceiling above the process and in the sprinklered ventilated cabinets. Arrange detectors to sound an alarm if a concentration at or above 25% of the Lower Explosive Limit (LEL) is detected, and provide an accessible emergency or automatic gas shutoff valve.

2.4.3 Process, Storage and Handling of Combustible Dusts

2.4.3.1 Arrange process, storage and handling of combustible dusts and of materials that produce combustible dusts in accordance with Data Sheet 7-76, *Prevention and Mitigation of Combustible Dust Explosions and Fires*.

2.4.3.2 Locate dust collectors outside the cleanroom and support facilities. Arrange and protect dust collectors per Data Sheet 7-73, *Dust Collectors and Collection Systems* and Data Sheet 7-76.

2.4.4 Utility Piping and Liquid Damage Exposures

2.4.4.1 Arrange piping and fittings for water (e.g., for domestic and high purity water systems, and water for HVAC systems) and non-process related liquid pipework (e.g., roof drains, scrubber drains, etc.) so that they are not located directly above or pass through cleanrooms. If this is unavoidable, provide leak containment and detection at probable leakage points (e.g., at equipment and valves) alarmed to a constantly attended location.

2.4.4.2 Provide shielding for water sensitive or high value equipment that may be exposed to water or process piping leakage.

2.4.4.3 Design chemical and gas distribution piping in accordance with appropriate recognized international standards (ANSI B31.3-1993, *Chemical Plant and Petroleum Refinery Piping*, should be used in the US).

2.4.4.4 Provide leak containment and detection to local chemical distribution systems. Arrange the detection system to alarm at a constantly attended location.

2.4.4.5 Arrange roof drainage systems to ensure that water from overflowing drains does not enter the cleanroom.

2.4.5 Housekeeping

2.4.5.1 Establish good housekeeping practices throughout the cleanroom, related support areas and fan attic plenum spaces. Do not allow combustible material to be stored within these areas. Keep these areas free of combustible material in transit, such as packaging material. Remove combustible containers or packaging, such as cardboard or plastics, from all equipment and supplies outside the cleanroom. Transfer unpacked equipment and supplies to the cleanroom in noncombustible carts. When unpacking in the cleanroom is unavoidable, empty packaging materials should be immediately disposed of to keep the cleanroom free of ordinary unnecessary combustible material.

2.4.5.2 Use trash containers of metal construction, equipped with self-closing/extinguishing covers (preferably use Approved containers) in cleanrooms, service corridors, computer rooms and areas containing valuable equipment. When corrosion resistance is necessary, 4910-listed plastic-lined metal containers can be used.

2.5 Protection

2.5.1 Provide automatic sprinkler protection in cleanrooms and all other non-storage related occupancies as follows:

a) Provide a wet system hydraulically designed to provide a minimum density of 0.2 gal/min/ft² (8 mm/min) over the hydraulically most remote 3,000 ft² (280 m²) area, plus 250 gal/min (946 l/min) allowance for hose streams for a 60 minute duration of supply. Avoid the use of preaction and dry systems because of increased complexity in the system and delay in water application.

2.5.2 Use Approved quick response, standard coverage, pendant-type sprinkler heads with a temperature rating of 135°-170°F (57°-77°C) for new installations or retrofits during cleanroom renovations. In addition:

- Do not use extended coverage sprinklers because of possible delayed response given the spacing coverage per sprinkler.
- Do not use concealed “sealing” sprinklers. Concealed “sealing” sprinklers use a gasket around the ceiling plate of the sprinkler to seal the small gap formed between the sprinkler ceiling plate and the ceiling tile. These sprinklers are not Approved and are not recommended, since the seal around the ceiling plate of the sprinkler will further delay sprinkler operation. In existing installations where non-Approved concealed “sealing” sprinklers are found, replace these sprinklers with Approved sprinklers.

2.5.3 Design and install the sprinkler system in accordance with Data Sheet 2-0, *Installation Guidelines for Automatic Sprinklers*. Use welded or threaded schedule 40 sprinkler piping inside or above cleanrooms. In new installations, unless required for earthquake protection of piping against breakage, avoid the use of mechanical pipe couplings (plain end or grooved) because improperly installed pipe joints might fail catastrophically, with potential water damage and contamination exposure in the cleanroom.

2.5.4 When needed, use Approved flexible metal hoses to connect sprinkler branch lines to sprinkler heads installed in ceiling grids or inside ducts. Flexible hoses are recommended when frequent changes in the sprinkler system layout are needed to accommodate changes in layout of equipment in the cleanroom, or

to facilitate the removal of sprinkler heads in ducts for inspection. Do not move charged Approved flexible metal hoses; depressurize the sprinkler system whenever sprinkler heads connected to Approved flexible hoses need to be moved.

2.5.5 Provide sprinkler protection beneath raised floor areas when the process equipment above handles ignitable liquids or is of combustible construction.

2.5.6 Provide sprinkler protection in plenum spaces and for attics above the cleanrooms if any one of the following undesirable conditions exist and cannot be feasibly corrected:

- combustible roof or floor system
- HEPA or ULPA filter modules that do not meet the intent of this data sheet.
- combustible plastic fume exhaust ductwork and/or flexible ductwork used to connect HEPA/ULPA filter modules to air-handling fans.

Plenum space and fan attic sprinklers should be hydraulically designed to provide a density of 0.2 gal/min/ft² (8 mm/min) over the hydraulically most remote 3,000 ft² (280 m²) area, plus 250 gal/min (946 l/min) allowance for hose streams for a 60 minute duration of supply. Use standard quick response pendent sprinklers with a temperature rating of 135°-170°F (57°-77°C).

2.5.7 Provide fire extinguishers in accordance with Data Sheet 4-5, *Portable Extinguishers* throughout the cleanroom. Do not use dry chemical extinguishers because of the potential for corrosion and/or contamination. If organometallic compounds, such as trimethylaluminum, diethylzinc and trimethylgallium are used, Class D type fire extinguishers should be provided. Attention should be given to the compatibility of the fire extinguisher agent and the various process chemicals in use.

2.5.8 Earthquake Protection. In FM 50-year through 500-year earthquake zones as shown in Data Sheet 1-2, *Earthquakes*, provide protection to prevent water leakage from automatic sprinkler systems, as well as fires or explosions resulting from strong ground shaking.

2.5.8.1 Provide earthquake protection to automatic sprinkler systems in strict compliance with Data Sheet 2-8, *Earthquake Protection for Water-Based Fire Protection Systems*.

2.5.8.2 Brace raised floors and ceiling grids to resist a seismic design load for a minimum horizontal acceleration (G factor) of 0.5. In active seismic areas, pedestals should be anchored with bolts, and not simply glued down to concrete substrate. This is particularly important if large, heavy tools are on the raised floor.

2.5.8.3 Anchor equipment that uses ignitable liquids or flammable gases to resist a seismic design load for a minimum horizontal acceleration (G factor) of 0.5.

2.5.8.4 Provide ignitable liquid piping and flammable gas systems with devices to safely shut down the systems in the event of strong ground movement that can cause such systems to fail and release material.

2.6 Equipment and Processes

2.6.1 Construction of Equipment

2.6.1.1 Use new process equipment, including mini-environment enclosures and isolators, constructed preferably of noncombustible materials. When, because of process needs, the equipment cannot be built of noncombustible material (such as those handling corrosive, nonflammable, products), use plastic materials that are 4910-listed. This includes all internal support equipment such as process tanks, piping, valves and pumps. Process equipment constructed entirely of noncombustible or FM Approvals Class 4910 materials requires no additional fire protection when ignitable liquids are not handled or stored in it, or when dust explosion protection is not needed per Data Sheet 7-76, *Prevention and Mitigation of Combustible Dust Explosions and Fires*.

2.6.2 Protection of Process Equipment

2.6.2.1 Provide fire protection for processing equipment of combustible construction, or those parts of processing equipment with combustible construction, using an Approved gaseous or fine water mist suppression system specifically evaluated for the hazard. Design and install systems in accordance with applicable FM data sheets and in accordance with Data Sheet 4-0, *Special Protection Systems*.

2.6.2.2 In small cleanrooms, where open-face combustible processing equipment is not protected by local suppression systems, or replaced with noncombustible or 4910 compliant material provide room fire protection using an Approved clean agent (e.g., Inergen, FM200) automatic suppression system. Design the system for activation by an Approved fire detection system. Design and install the cleanroom total flooding suppression systems per applicable FM data sheets. Provide the system with extended discharge to achieve the necessary hold time for deep-seated fires.

2.6.2.3 In rooms protected with total flooding gaseous suppression systems, isolators and mini-environment enclosures of combustible construction or enclosed combustible process equipment or processes using ignitable liquids should still be provided with local fire suppression systems in accordance with applicable FM data sheets.

2.6.2.4 Thoroughly clean all fire protection system storage cylinders and internal piping walls prior to system installation. This is needed to prevent contamination of the process of cleanroom on system discharge.

2.7 Operation and Maintenance

2.7.1 Conduct the various processes or operations in accordance with applicable FM data sheets (e.g., Data Sheet 7-7/17-12, *Semiconductor Fabrication Facilities*, Data Sheet 7-32, *Ignitable Liquid Operations*).

2.7.2 Develop maintenance programs in accordance with Data Sheet 9-0/17-0, *Asset Integrity*, including preventive maintenance of equipment. At least annually, review programs to ensure effectiveness of the entire program as well as keeping the program up-to-date with new developments.

2.7.3 Include the following maintenance items as part of a fire protection systems maintenance program: Actuating devices (such as heat and smoke detectors, and electric thermostats), fire dampers, fire doors, smoke dampers, and sprinklers exposed to corrosive environments should be inspected every six months. Heat and smoke detector systems should be tested every six months by adequately trained personnel. Follow manufacturers' recommendations for maintaining, inspecting, and testing the equipment. The tests should include activation of the fire and smoke control systems and other related equipment by simulating emergency mode conditions.

2.7.4 Inspect filters and ducts frequently, and clean or replace them periodically. Do not patch or plug HEPA and ULPA filters to improve their efficiency. This action can adversely affect their fire resistance.

2.7.5 Flush and clean all piping systems, including piping for fire protection systems, before they are tested or put into service. This applies particularly after repairs, additions or modifications to any systems.

2.7.6 Provide electrical preventive maintenance in accordance with Data Sheets 5-20, *Electrical Testing*; 5-4, *Transformers*; and 5-19, *Switchgear and Circuit Breakers*.

2.8 Contingency Planning

2.8.1 Equipment Contingency Planning

When an equipment breakdown would result in an unplanned outage to site processes and systems considered key to the continuity of cleanroom operations, develop and maintain a documented, viable equipment contingency plan for that equipment per Data Sheet 9-0, *Asset Integrity*. See Appendix C of that data sheet for guidance on the process of developing and maintaining a viable equipment contingency plan. Also refer to sparing, rental, and redundant equipment mitigation strategy guidance in that data sheet.

2.8.2 Sparing

Sparing can be a mitigation strategy to reduce the downtime caused by an equipment breakdown depending on the type, compatibility, availability, fitness for the intended service, and viability of the sparing. For general sparing guidance, see Data Sheet 9-0, *Asset Integrity*.

2.8.2.1 Routine Spares

Routine spares are spares that are considered to be consumables. These spares are expected to be put into service under normal operating conditions over the course of the life of the equipment, but not reduce equipment downtime in the event of a breakdown. This can include sparing recommended by the original equipment manufacturer. See Section 3.4 for guidance on routine spares.

2.9 Training

2.9.1 Train the emergency response team (ERT) to restart the air-handling system in a safe manner. See Data Sheet 10-8, *Operators*, for guidance.

2.9.2 Train all personnel in equipment contingency and emergency procedures, and practice them periodically. Post resulting emergency procedures in cleanrooms where they can be readily seen and consulted in an emergency.

3.0 SUPPORT FOR RECOMMENDATIONS

3.1 General

Cleanroom technology is applied in a variety of fields where contamination control is required for research, manufacturing, assembly or storage of products. Cleanrooms are encountered in such fields as aerospace, bioscience, pharmaceuticals, medicine, computing, and food processing. Each application may have different requirements with respect to air cleanliness; hence different style cleanrooms are commonly found across the industry.

Cleanrooms are defined by ISO 14644-1 as:

"A room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize 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."

Cleanrooms are classified by the cleanliness of the air. The method most easily understood and universally applied is the one suggested in Federal Standard 209 version "D". In this method, the cleanroom is classified according to the number of particles equal to and greater than 0.5 µm present in one cubic foot of air. Hence, a simplified version of Federal Standard 209D is given in Table 2 below.

Table 2. Simplified Federal Standard 209D Classification of Cleanrooms

Federal Standard 209 D Classification	1	10	100	1000	10,000	100,000
No. of particles/ft ³ ≥0.5 µm	1	10	100	1000	10,000	100,000

Federal Standard 209D was superseded by a metric version in 1992 (Federal Standard 209E). However, the classification in version D continues to be used and accepted.

It is likely that the classification in Federal Standard 209D will be superseded instead by the classification used by the new ISO 14644-1 Standard that classifies cleanrooms according to the following equation:

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

Where

C_n = Maximum permitted concentration of airborne particles that are equal to or larger than the considered particle size (particles/m³ of air).

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

D = Particle size in microns (µm)

0.1 = Constant with dimension of µm.

The ISO standard also gives a method by which cleanrooms can be specified in terms of ultra fine particles (smaller than 0.1 µm) and macroparticles (larger than 0.5 µm).

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 cleanroom standard should be. Table 3 gives an indication of the tasks carried out in different classifications of cleanrooms.

Table 3. Sample of Possible Cleanroom Requirements for Different Tasks

Class 1	Sub-micron integrated circuit manufacturing
Class 10	Semiconductor manufacturing with circuits with line width below 0.2 µm
Class 100	Particle-free manufacturing of aseptically produced injectable medicines. Sterilizer unloading, sterile storage area, filling rooms. Implant or transplant surgical operations. Isolation of immunosuppressed patients
Class 1000	Manufacturing of high quality optical equipment. Rooms containing class 100 areas or laminar air flow hoods (LAF hoods) for filling. Assembly and testing of precision gyroscopes. Assembly of miniaturized bearings.
Class 10,000	Assembly of precision hydraulics or pneumatic equipment, servo-control valves, precision timing devices, high grade gearing. Preculture, fermentation, buffer & media preparation rooms.
Class 100,000	General optical work, assembly of electronic components, hydraulic and pneumatic assembly. Prewash rooms, bulk storage areas, equipment assembly areas.

CLEAN AREAS

Clean areas can be divided into four main types:

1. Conventional. These cleanrooms are also known as turbulently-ventilated or non-unidirectional flow. They are distinguished by their method of air-supply, which uses diffusers similar to those found in shops and offices, except that the HEPA filter is installed on the diffuser and there is an increased air supply. The air normally enters from the ceiling and takes a random pattern exiting near the floor. A conventional flow system is shown in Figure 8. These rooms are generally used for classes 10,000 or 100,000.
2. Mixed Flow. This type of cleanroom is conventionally ventilated; however, where the product is exposed to contamination, workstations with hoods or areas with their own unidirectional airflow are used. Figure 9 shows a mixed flow cleanroom.
3. Unidirectional Flow (Vertical or Horizontal). This was previously known as laminar flow. Unidirectional flow cleanrooms are needed to achieve Class 100 or less. In this type of facility, one wall (for horizontal flow) or ceiling (for vertical flow) is made up of a bank of high efficiency particulate air (HEPA) filters and the opposite wall or floor is the exhaust grill. The air is supplied from a bank of HEPA filters and passes in a unidirectional manner through the room. Air velocities are typically 60 to 90 ft/min (0.3 to 0.45 m/s). The air stream makes only a single pass through the cleanroom before being returned to the filters for recirculation. This reduces the likelihood that light particulate matter will be deposited. A vertical unidirectional flow cleanroom is shown in Figure 10.
4. Isolators or Mini-environment. These are used within a cleanroom to give the highest level of protection against contamination. They can have a conventional or unidirectional flow air supply. Isolators or mini-environments are used to provide a small working space of particularly clean environment when this is more economical than providing a complete cleanroom of that standard. Isolators are more common in conventional flow cleanrooms, such as those in the pharmaceutical manufacturing, while mini-environment enclosures are more common in unidirectional flow cleanrooms, such as those in the semiconductor fabrication. For example, the laminar flow workstation shown in Figure 9 provides an assembly area of Class 100 level in a Class 10,000 cleanroom.

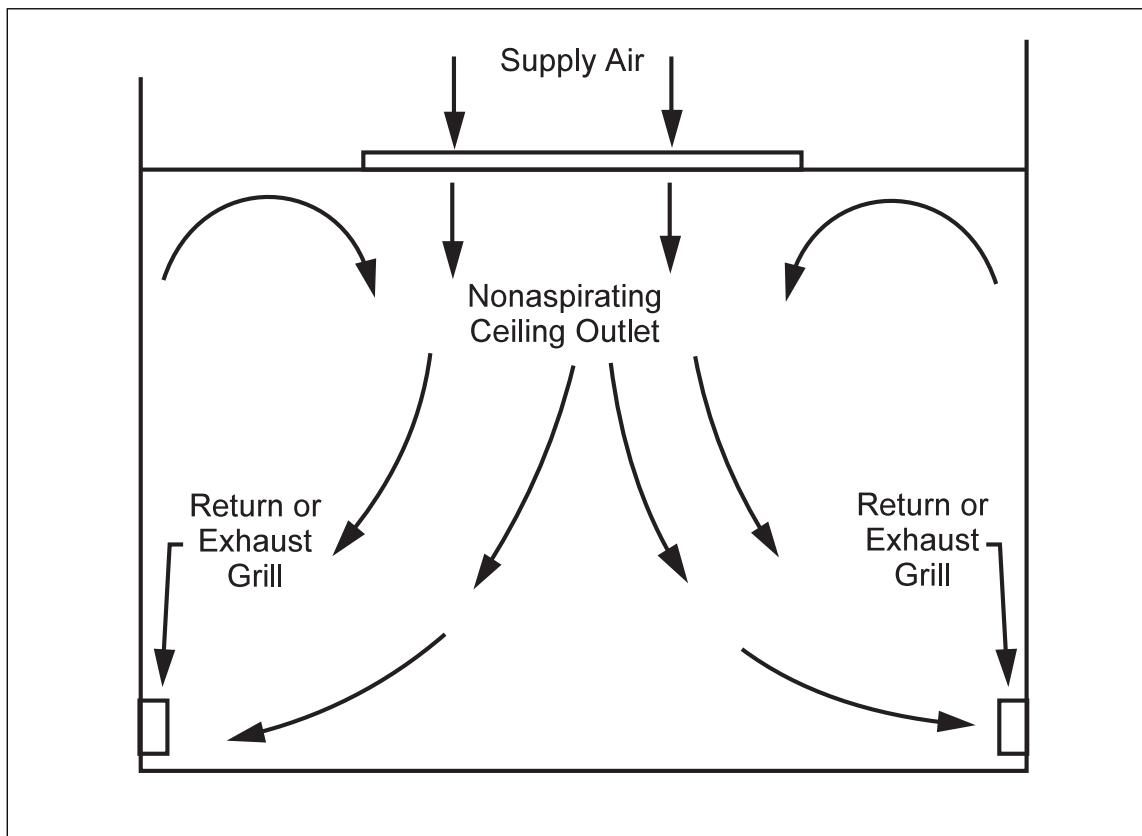


Fig. 8. Conventional flow room.

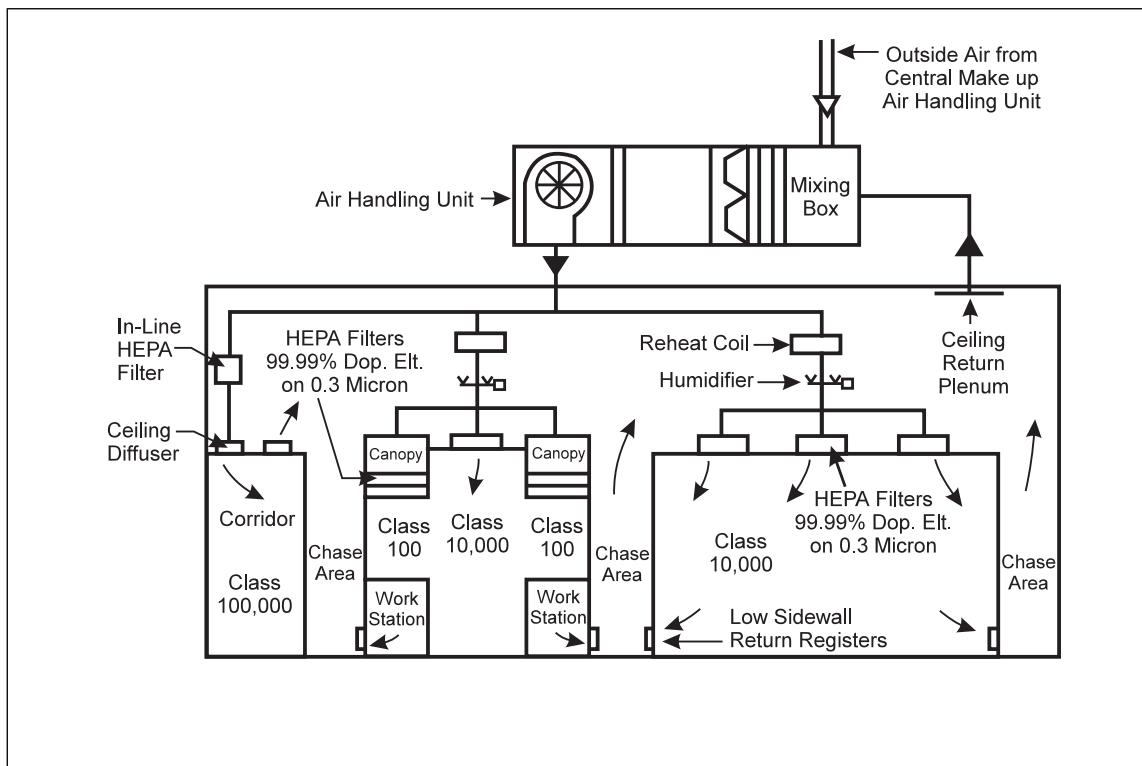


Fig. 9. Combination of conventional-laminar flow cleanroom.

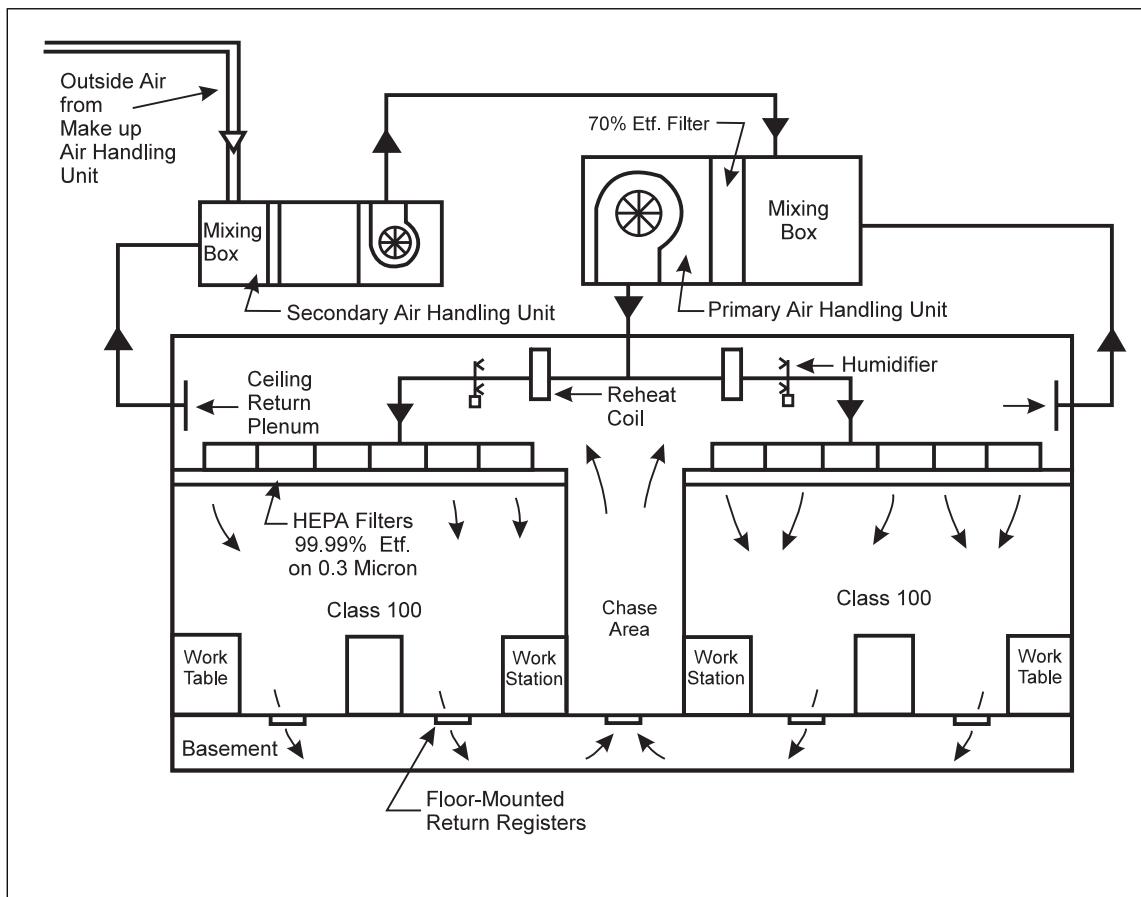


Fig. 10. Laminar flow cleanroom.

HAZARDS

Cleanrooms present loss prevention problems both because of their high value and importance to other processes and because of their operating complexities and delicate nature. Because of the extreme cleanliness required in the work performed within a cleanroom, combustion products from a small fire and other types of contaminants can cause major shutdown time and costly decontamination clean-up. Therefore, the most important recommendation in the cleanroom is for noncombustible construction and equipment followed by a protection system that includes reliable detection, early suppression/extinguishment, and control of contamination in the incipient stages. In addition, minimizing sources of contamination and ignition sources is important.

Fire and Explosion

Fires, explosions, and related hazards in environments surrounding cleanrooms present a serious loss potential because of the stringent control required over air contaminants. Relatively small incidents can contaminate cleanrooms, resulting in substantial losses.

Cleanrooms frequently have a combustible interior finish. The operations in these rooms also may involve the use of flammable and corrosive gases and ignitable liquids. Cleanrooms also may be exposed by other occupancies within a building. They may sometimes take fresh or make-up air from within a plant building, posing possible contamination problems.

Concealed spaces above the ceiling or below the floor are common in these rooms. They are frequently used as service spaces or air handling plenums. Ignitable liquid or flammable gas piping, combustible ductwork, cables, etc., may pass through these spaces. All of these factors contribute to potential losses.

Rapid air movement and high recirculation rates can adversely affect the detection of fires and actuation of automatic sprinklers. Adjacent clean areas that share the same air handling system and have no air locks between also increase the potential for spread of contaminants in case of fire.

Non-Thermal damage from fires involving plastics in construction

The loss potential from smoke damage is very high, even if sprinkler protection is provided. Fire retardant plastic material is often used for fume exhaust ducts. Where combustible ductwork cannot be feasibly replaced it needs to be at least provided with sprinkler protection. A minor fire in these ducts can produce large quantities of smoke that is often corrosive and very damaging to the room equipment and the product.

The increasing use of plastic wall panels in cleanrooms actually increases the fuel available to a fire within the room. Therefore, installation of these panels where occupancies are susceptible to damage from smoke or corrosive fumes should be avoided.

Whether filters are combustible or not, they are soon covered with combustible dust and lint, which can be ignited easily and spread flame and smoke rapidly through the room. Special measures as discussed in Data Sheet 1-45, *Air Conditioning and Ventilating Systems* should be taken to lessen the potential damage caused by fire in the filtering system.

Contamination from Gases, Vapors and Fumes

Contamination also may result from the release of gases, vapors or fumes into the cleanroom atmosphere that may affect the final product. The release of corrosive gases or liquids into a cleanroom may not only affect the product but also corrode the delicate instrumentation in the room. Flammable gases may cause a fire or explosion. Fumes, usually the result of either chemical or thermal decomposition, may produce serious contamination of the product and the processing equipment.

Non-thermal damage caused by environmental controls

Moisture

Water, may be a serious problem for some processes used in cleanrooms.

- High humidity can result in corrosion of instrumentation, and can accelerate the effects of corrosive gases, vapors or fumes.
- Low humidity may increase the fire hazard posed by static electricity.

Temperature

Temperature control is needed to maintain stable conditions for materials and instruments.

Pressure

Typically, differential pressures are maintained between rooms and atmosphere (or adjoining non-cleanrooms) to ensure outward air flow progressively from the cleanest spaces to the least clean, to provide efficient contamination control. Pressure differential progressively outward is not always true for pharmaceutical plants; if a highly toxic material is being used, a "dirty corridor" is provided which is negative to the cleanrooms and the adjacent least clean ordinary area.

CONTROL OF CLEANROOM HAZARDS

Planning means not only designing and supervising the facility for the specific use of product to be handled, but also includes the procedures to be followed in the event of an emergency. The design should include the control of all known or possible hazards to the cleanroom. The recommendations also should include a program of preventive maintenance for the equipment.

Fire Protection

Sprinkler protection is the most reliable protection against fires. However, at some facilities, such as class 1, 10, 100 and 1000 cleanrooms handling radioactive or highly reactive materials, there exists the danger of reactivity with certain materials and contamination by water runoff. In these cases, and if practical, the proper protection is gaseous suppression systems in the room, with the sprinkler system as a back-up. The very high values involved dictate that every effort be made to keep losses to a minimum; this includes fire damage as well as damage from extinguishing efforts. A gaseous system may be expected to successfully extinguish fires in cleanrooms, prior to sprinkler system actuation. However, such systems do not provide a continuous

supply of agent (usually only a single discharge) and, if the fire is not extinguished a major loss can be expected. Consequently, sprinkler protection as a back-up is needed.

Cleanroom Environmental Control

Recent developments have produced monitoring devices that detect and indicate directly the amount of contamination deposited on a given surface. The equipment monitors contamination caused by changes in temperature, humidity, pressure, particulate distribution, radiation, noise and vibration, gases, vapors, fumes, etc.

Appropriate equipment is selected and monitoring routines established to measure air cleanliness levels under normal use conditions, so that conformance to the specified air cleanliness class may be determined.

Smoke Control

Smoke control is an important factor because the cleanroom occupancies are highly susceptible to smoke damage. Recent losses prove smoke damage to be a substantial portion of the total dollar loss.

While air conditioning systems provide a ready means of spreading smoke and contaminant gases throughout cleanrooms, they can be designed to control the smoke movement in a beneficial way. The fume exhaust system can also be used for smoke removal, if adequately designed for this purpose.

Smoke removal is important because smoke generation is proportional to the heat release rate of the fire, which grows exponentially with time. In growing fires, the amount of smoke being generated can rapidly increase. Room pressures also increase as the temperature in the room of origin rises during a fire. The increase in pressure creates buoyancy forces responsible for smoke movement to adjoining areas. A smoke removal system has, then, the dual purpose of removing smoke from the room and restricting smoke movement by lowering room pressures responsible for smoke movement.

If the entire air handling system were shut down upon detection of fire, fire pressures would propagate smoke into neighboring cleanrooms, not only via cracks and such, but also via the ductwork, which now constitutes passive conduits of smoke responding to whatever pressure differentials there are. In addition, with the air handling system shut down, there is no way for the smoke to be evacuated from the cleanroom after an incident. If one simply re-activates the air handling system, letting the smoke dilute by make-up air, smoke and contaminants would spread to other cleanrooms and locations connected with ductwork.

FM Approvals Cleanroom Materials Flammability Test Protocol (Class 4910)

FM Approvals has developed a specification test standard titled FM Approvals Cleanroom Materials Flammability Test Protocol (Class 4910). This standard evaluates the fire hazard of materials used in environments that are highly sensitive to thermal and non-thermal damage, such as the interiors of cleanrooms. All requirements in the standard must be met for materials to be acceptable in cleanrooms.

The protocol uses three small-scale tests and a large-scale validation test if needed. Small-scale tests performed in the FM Approvals Flammability Apparatus are:

Ignition Tests

Fire Propagation Tests

Combustion Tests

This is a performance-based test protocol. Based on results of the three small-scale tests, the following indexes are determined for each material tested:

1. Fire Propagation Index (FPI): this index is determined based on the fire propagation tests conducted and represents the rate at which the surface of the material is involved in fire. Nonpropagating materials have FPI values at or below $6.0 \text{ (m/s}^{1/2}\text{)/(kW/m)}^{1/2}$.
2. Smoke Development Index (SDI): this index is defined as the product of the FPI index and the yield of smoke for a given material. SDI is an indicator of the smoke contamination of the environment expected during fire propagation. Materials expected to limit smoke contamination have SDI of $0.4 \text{ (m/s}^{1/2}\text{)(g/g)(kW/m)}^{2/3}$ or less.

Materials that are FM Approvals Specification Tested to meet the flammability protocol criteria require that high heat fluxes be ignited; once ignited these materials may burn locally in the ignition area, but they will not

propagate a fire beyond the ignition zone. Smoke and corrosive products generated from the combustion of these materials is reduced, minimizing non-thermal damage.

3.2 Routine Spares

The following are common routine spares for cleanroom air-handling systems:

- Fan assemblies, including motors and fans.

4.0 REFERENCES

4.1 FM

Data Sheet 1-0, *Safeguards During Construction, Alteration and Demolition*.

Data Sheet 1-44, *Damage-Limiting Construction*.

Data Sheet 1-45, *Air Conditioning and Ventilating Systems*.

Data Sheet 2-0, *Installation Guidelines for Automatic Sprinklers*.

Data Sheet 2-8, *Earthquake Protection for Water-Based Fire Protection Systems*.

Data Sheet 4-0, *Special Protection Systems*.

Data Sheet 4-5, *Portable Extinguishers*.

Data Sheet 5-20, *Electrical Testing*.

Data Sheet 5-23, *Design and Protection for Emergency and Standby Power Systems*.

Data Sheet 5-48, *Automatic Fire Detectors*.

Data Sheet 6-11, *Thermal and Regenerative Catalytic Oxidizers*.

Data Sheet 7-2, *Waste Solvent Recovery*.

Data Sheet 7-7/17-12, *Semiconductor Fabrication Facilities*.

Data Sheet 7-29, *Ignitable Liquid Storage in Portable Containers*.

Data Sheet 7-32, *Ignitable Liquid Operations*.

Data Sheet 7-50, *Compressed Gases in Portable Cylinders and Bulk Storage*.

Data Sheet 7-73, *Dust Collectors and Collection Systems*.

Data Sheet 7-76, *Prevention and Mitigation of Combustible Dust Explosions and Fires*.

Data Sheet 7-78, *Industrial Exhaust Systems*.

Data Sheet 7-83, *Drainage Systems for Ignitable Liquids*.

Data Sheet 7-95, *Compressors*.

Data Sheet 9-0/17-0, *Asset Integrity*

4.2 NFPA Standards

NFPA 318, *Protection of Cleanrooms*.

NFPA 70, *National Electrical Code*.

4.3 Others

American National Standards Institute ANSI B31.3-1993, *Chemical Plant and Petroleum Refinery Piping*.

International Standard Organization ISO 14644-1, *Cleanroom Classification*.

Federal Standard 209D, *Classification of Cleanrooms*.

APPENDIX A GLOSSARY OF TERMS

Approved: references to “Approved” in this data sheet means the product and services have satisfied the criteria for FM Approval. Refer to the *Approval Guide* for a complete listing of products and services that are FM Approved.

Isolator: term most commonly used in the pharmaceutical and biotechnology industry to refer to contaminant-retaining or contaminant-excluding systems used to separate processes that can either contaminate the surrounding environment or be contaminated by it. This technology relies on actual plastic or metal walls or barriers to isolate the intended process. Isolators are also known as barrier technology. Personnel either enter in half suits or use gauntlets to work at the clean process within the isolator. Most isolators have closed top and bottom.

Mini-environment similar to “isolators”: term most commonly used in the semiconductor industry to refer to contaminant-retaining or contaminant-excluding systems used to separate a variety of processes, or processing equipment, that can either contaminate the surrounding environment or be contaminated by it.

This technology relies on actual plastic or metal walls or barriers to isolate the intended process. Most mini-environments have their own air supply filters on top so that the air cleanliness within the processing environment can be controlled; however, mini-environments open on top or having walls extending to the HEPA filters of the room are also commonly found. Depending on the arrangement of the cleanroom floor, mini-environments can have open or closed floors or bottom.

WIP: Acronym used to refer to work in progress.

APPENDIX B DOCUMENT REVISION HISTORY

The purpose of this appendix is to capture the changes that were made to this document each time it was published. Please note that section numbers refer specifically to those in the version published on the date shown (i.e., the section numbers are not always the same from version to version).

April 2020. Interim revision. Added equipment contingency planning and sparing guidance.

April 2014. Clarification was made to recommendation 2.2.2.5.

April 2012. Terminology related to ignitable liquids has been revised to provide increased clarity and consistency with regard to FM Global's loss prevention recommendations for ignitable liquid hazards.

September 2004. References to FM Global earthquake zones have been modified for consistency with Data Sheet 1-2, *Earthquakes*.

September 2000. This data sheet has been entirely re-written.

September 1999. Editorial revision of the data sheet intended to restructure the document in accordance with new layout.

February 1988. First technical revision of the document including the following major changes:

- Use of FM Approved exhaust ducts for fume removal.
- Recommendation for a pressure-controlled smoke control system within cleanrooms, and allowance for the use of fume exhaust system for smoke removal under certain conditions.
- Restriction on the use of FM Approved panels because of smoke generation during combustion.
- Recommendation for the use of Halon 1301 total flooding systems to reduce damage caused by water and/or smoke.
- Recommendations for vibration and noise control intended as design guidance.

December 1980. Original publication of Data Sheet 1-56, *Cleanrooms*.