ASHRAE DESIGN GUIDE for CLEANROOMS

Fundamentals, Systems and Performance



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ASHRAE DESIGN GUIDE for CLEANROOMS

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Preface

Cleanrooms and associated technologies are commonly used in modern microelectronics, semiconductor, pharmaceutical, biotechnology, nanotechnology, medical device, life science, aerospace, optics, automotive, health care, biosafety laboratory, and food processing industries, virtually covering all the major high-tech sectors where indoor airborne or surface-borne contaminants can adversely affect the manufacturing process or scientific research. Such contaminants include particles, viable microbes, chemical vapors, and unwanted gases. Cleanrooms demand much lower levels of contaminants than commercial spaces, and though noncontamination cannot be completely achieved, cleanrooms *can* be designed, operated, and controlled with ultralow concentrations of these contaminants to meet specific process requirements for indoor air cleanliness.

For the cleanroom design industry worldwide, currently ISO 14644-4 is a condensed standard that covers basic cleanroom design requirements, Institute of Environmental Sciences and Technology's Recommended Practice 12.3 provides cleanroom design considerations, and Chapter 18 of *ASHRAE Handbook—HVAC Applications* provides a brief discussion of cleanroom design elements. Of course, there are also a few reference books on the market drafted from the academic sector. However, there is an urgent need from the global cleanroom design industry for a more practical, comprehensive, and technical book that covers not only the HVAC systems of cleanrooms but also cleanroom theories, fundamentals, performance, control, testing, and industrial applications.

ASHRAE Technical Committee (TC) 9.11 is concerned with HVAC&R systems for cleanrooms and clean spaces, including process, product, and facility air conditioning and related process ventilation for research and development, manufacturing, assembly, test, and clean medical areas. This includes cleanrooms associated with electronic, microelectronic, pharmaceutical, and aerospace facilities as well as operating rooms. In conjunction with ASHRAE's overall goal of supporting the design of energy-efficient HVAC&R systems, TC 9.11 members are committed to raising such awareness in cleanroom design and operation and to developing proactive solutions to support ASHRAE's position.

In 2011, TC 9.11 formed a Design Guide subcommittee, led by Wei Sun as the principal author of the book, who was also the TC 9.11 chair from 2011 to 2014. The subcommittee took lead of a multiyear effort to develop a comprehensive design guide for cleanrooms. The Basic Requirements document was initiated and drafted; it defined the book's structure and style, each chapter's content subheadings and coverage, and the approximate word count for each chapter to have a balanced structure. The intention was to provide a technical reference book to assist cleanroom design engineers, university students in cleanroom study, cleanroom facility managers in various industries, and profes-

sionals in cleanroom control, automation, performance testing, certification, qualification, and commissioning.

After the public announcement to develop the book, more than 50 highly recognized experts agreed or volunteered to participate, including university professors, cleanroom design engineers, researchers, facilities and operation managers, and testing and certification engineers. Over 30 individuals were selected as coauthors, and another 20-plus people served as contributors and reviewers. Since 2012, this book has become a truly multidisciplinary effort that included the top experts not only from the United States but also globally.

This design guide was developed in the technical book category—it is neither an encyclopedia nor a high-level normative standard. It uses easily understood language and simple descriptions to explain complex cleanroom information to readers who may only have basic knowledge about cleanrooms or are new to the industry. It does not use the rigid language and structure of a code, and it is not like conference proceedings that have various structures and are less consistent in style. This book was developed instead to have balanced technical perspectives from many experts with various expertise and experiences and from different market sectors. It was intended to provide mature technologies and techniques with the latest information. Our goal was to make this single-volume guide one of the most-used technical books in cleanroom design today.

This design guide is divided into four parts, each containing multiple chapters: Cleanroom Fundamentals; Cleanroom Design and Environmental Control Systems; Cleanroom Testing, Certification, Commissioning, and Qualification; and Cleanroom Design In Select Industries. It is the work of many authors over many years; the editors have attempted to blend the various writing styles to meet ASHRAE publication guidelines and improve the overall readability of the book. It is the hope of the editors that *ASHRAE Design Guide for Cleanrooms* will be an indispensable resource to designers, builders, owners, and operators of cleanrooms and advance HVAC engineering practices, providing the guidance needed for designers of successful cleanroom projects.

This first edition took countless hours; a great deal of energy from the coauthors, contributors, and reviewers; and especially the diligent efforts from ASHRAE Special Publications staff. Although many highly renowned experts served as coauthors, we eagerly look forward to readers' comments and suggestions to help us improve the content for a future revision.

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Wei Sun, the principal author, initiated the concept to develop a cleanroom technical book and developed the book's structure, chapter contents, style, and coverage. He invited, mobilized, and communicated with more than 30 coauthors and contributors of various backgrounds and expertise to transform their common dream into a reality.

Abbreviations and Acronyms

ACH, ach	air changes per hour
ACR	air changes rate
A/E	architect/engineer
AHJ	authority having jurisdiction
AHU	air-handling unit
AMC	airborne molecular contamination
AMHS	automated material handling system
API	active pharmaceutical ingredient
BAS	building automation system
CFD	computational fluid dynamics
cfm	cubic feet per minute
CGMP	Current Good Manufacturing Practice
CPC	condensation particle counter
CR	contamination rate
Cx	commissioning
DCS	distributed control system
DDC	direct digital control
DPC	discrete particle counter
EMA	European Medicines Agency
EMI	electromagnetic interference
EU	European Union
FDA	U.S. Food and Drug Administration
FFU	fan filter unit
FOUP	front-opening unified pod
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
HEPA	high-efficiency particulate air
HF	hydrofluoric acid
HMI	human-machine interface
IBC	*International Building Code*®
ICC	International Code Council
I/O	input/output
MPPS	most penetrating particle size
µm	micrometre, micron
nm	nanometre

NVR	nonvolatile residue
OEL	occupational exposure limit
OPC	optical particle counter
PAL	personnel air lock
PAPR	positive air-purifying respirator
PFD	process flow diagram
PLC	programmable logic controller
PLC/HMI	programmable logic controller/human machine interface
POU	point of use
PTFE	polytetrafluoroethylene
QA	quality assurance
RFU	recirculation fan unit
SME	subject matter expert
ULPA	ultralow particulate air
UPS	uninterruptible power supply
UPW	ultrapure water
UR	user requirement
URS	user requirements specification
VFD	variable-frequency drive
VOC	volatile organic compound

Part 1

Cleanroom Fundamentals

1

Introduction

1.1 HISTORY OF CLEANROOMS AND CLEANROOM STANDARDS

Clean spaces are used for patient care in hospitals and for the testing and manufacture of products in such industries as microelectronics, pharmaceuticals, biotechnology, aerospace, medical devices, and food and beverages. A cleanroom is an enclosed space that can "provide for the control of airborne particulate contamination to levels appropriate for accomplishing contamination-sensitive activities" (ISO 2015a, p. 4). The contamination may be viable, such as bacteria, microbes, or viruses, or it may be in the form of nonviable particles such as metals, organic or inorganic compounds, pollution, or dust.

Hospitals were the first spaces to attempt to control the air where patients were located. Controlling the ventilation of hospital spaces was seen in first-century Roman military hospitals. Over the centuries, hospitals were large, open halls that were well heated and ventilated. Florence Nightingale made dramatic improvements in the mortality rates of wounded soldiers by insisting on scrupulously clean, well-ventilated hospital rooms (Thompson and Goldin 1975). While bacteria were first discovered in the fifteenth century, it was not until the late nineteenth century that the connection between bacteria and germs was proposed and proven by Pasteur and Koch (Wikipedia 2017). This led to a need for improved clean, ventilated spaces for patients.

In 1861 a report from the American Sanitary Commission recommended that hospitals be specially constructed to provide the needed heating and ventilation for patient wards. The development of formal hospital ventilation standards did not occur until the mid-twentieth century, when the United States passed the *Hospital Survey and Construction Act* (or the *Hill-Burton Act*) in 1946, which called for the construction of hospitals and related health care facilities. In the 1950s, experiments performed by Bourdillon and Colebrook (1946) in the United Kingdom showed that supplying clean air through the ceiling and exhausting at floor level further reduced contamination in a hospital. They concluded that ventilation of the whole room was required to offset "the great variability of the sources of contamination" (Bourdillon and Colebrook 1946). Sufficient under-standing of ventilation and airflow direction resulted in the publication of a comprehensive design guide in 1962 by the United Kingdom Medical Research Council (Blowers et al. 1962).

In industrial applications, reducing contamination can be dated back to the nineteenth century, when watchmakers Aaron Dennison and Edward Howard moved their watch factory from downtown Roxbury in Boston to the suburbs of Waltham because "the city streets in Roxbury were not paved, and the dust thrown up by traffic wreaked havoc on

the small mechanisms" (Holbrook 2009, p. 175). The drive to reduce military component sizes required cleanrooms for high-precision manufacturing in support of this miniaturization (Shadewald 1963).

The watershed in the history of the cleanroom was the invention of the first "laminar flow" or unidirectional concept of ventilation in 1961 by physicist W.J. Whitfield at Sandia Laboratories (Whitfield 1962). Soon thereafter, other Sandia technicians developed the first clean bench. The success of the laminar flow cleanroom and clean bench quickly spread, with Dr. Randy Lovelace, MD, using a cleanroom during operating procedures, and NASA seeking proposals to have cleanrooms used in the space program. By the end of 1962, more than 20 companies had been licensed to construct and build cleanrooms and clean benches for various projects.

1.2 EVOLUTION OF INTERNATIONAL STANDARDS FOR CLEANROOM DESIGN

The first standard written for a clean manufacturing room or cleanroom was published by the U.S. Air Force in March of 1961. Technical Order (TO) 00-25-203 (USAF 1961) was the first standard with wide appeal to science and industry.

By 1963, the lack of a set of cleanroom standards was evident, and in April 1963 Sandia Laboratories, the U.S. General Services Administration (GSA), the U.S. Air Force, the United States Atomic Energy Commission, and other experts from across the United States gathered in Albuquerque, New Mexico, with the mission to create the first federal standard on cleanrooms (Bice 1963; Whitfield 1963; Casberg 1963). A group chaired by J. Gordon King was formed, and together they created the first federal standard, entitled *Cleanroom and Work Station Requirements, Controlled Environments*. It was issued by the GSA and assigned the code FED-STD-209. In 1966 it was released as FED-STD-209A, *Air-borne Particulate Cleanliness Classes in Cleanrooms and Clean Zones* (GSA 1966). U.S. Federal Standard (FS) 209 was revised several times over the years (see Table 1.1. Until it was superseded by the ISO 14644 standards in 2001, FS 209 was the benchmark for cleanroom cleanliness. It defined a cleanroom as an enclosed area with control over the particulate matter in the air as well as control of temperature, humidity, and pressure as required, and it established standard classes of air cleanliness for airborne particulate levels in cleanrooms and clean zones.

Other cleanroom standards have been issued by many countries, including Australia, France, Germany, Holland, Japan, and the United Kingdom (see Table 1.2). With the evolution of the global economy the need for an international standard for cleanrooms became apparent. In 1993 an international group, International Organization for Standardization (ISO) TC 209, was assembled to produce the first international cleanroom standards: ISO 14644, *Cleanrooms and Associated Controlled Environments.*

As of the time of this writing, the ISO 14644 standards (ISO 2016) consist of the following parts:

- *Part 1: Classification of Air Cleanliness by Particle Concentration*
- *Part 2: Monitoring to Provide Evidence of Cleanroom Performance Related to Air Cleanliness by Particle Concentration*
- *Part 3: Test Methods*
- *Part 4: Design, Construction and Start-up*
- *Part 5: Operations*
- *Part 7: Separative Devices (Clean Air Hoods, Gloveboxes, Isolators and Mini-Environments)*

Table 1.1 History of FS 209

FS 209, 1963
FS 209A, December 1966
FS 209B, April 1973; amended May 1976
FS 209C, October 27, 1987
FS 209D, June 15, 1988
FS 209E, September 11, 1992
Canceled, November 29, 2001

Table 1.2 Cleanroom Standards Timeline

1960s	1970s	1980s	1990s	2000s	2010s
U.S. Air Force TO 00-25-203	FS 209B	FS 209C	FS 209E	ISO 14644-3	ISO 14644-1
US-MIL-STD-1246	Australia AS 1386	FS 209D	ISO 14644-1	ISO 14644-4	ISO 14644-2
FS 209	Britain BS 5295		Russia GOST R 50766	ISO 14644-5	ISO 14644-12
FS209A	Japan JIS B 9920			ISO 14644-6	ISO 14644-13
	France AFNOR X44101			ISO 14644-7	ISO 14644-14
	Germany VDI 2083:3			ISO 14644-8	
	Holland VCCN 1			ISO 14644-9	

- *Part 8: Classification of Air Cleanliness by Chemical Concentration (ACC)*
- *Part 9: Classification of Surface Cleanliness by Particle Concentration*
- *Part 10: Classification of Surface Cleanliness by Chemical Concentration*
- *Part 12: Specifications for Monitoring Air Cleanliness by Nanoscale Particle Concentration (Draft International Standard, DIS)*
- *Part 13: Cleaning of Surfaces to Achieve Defined Levels of Cleanliness in Terms of Particle and Chemical Classifications*
- *Part 14: Assessment of Suitability for Use of Equipment by Airborne Particle Concentration*

Additional parts of ISO 14644 are under development.

1.3 CLASSIFICATION OF CLEANROOMS

Cleanrooms are classified according to the number and size of particles permitted per volume of air. Table 1.3 shows the particle concentration values for various classes from various standards. Since the development of the ISO 14644 family of standards (ISO 2016), contamination levels for chemicals and surface contamination have also been developed.

FS 209 was developed using hybrid Systéme International and Inch-Pound units of measure, with particle sizes being metric and concentrations in particles per cubic foot. Starting with the FS 209E revision (GSA 1992), volumetric measures using cubic metres were introduced to be more aligned with standards outside the United States. In the

Table 1.3
Comparison of Various International Cleanroom Classifications
(Naughton 2016)

ISO 14644-1 (ISO 2015a)	FS 209D (GSA 1988)	FS 209E (GSA 1992)	Britain BS 5295 (BSI 1989)	Australia AS 1386 (SA 1989)	France AFNOR X44101 (AFNOR 1989)	Germany VDI 2083? (DIN 1990)	Japan JIS B 9920 (JSA 1989)	*EU Guidelines to GMP* (EC 2010)
ISO Class 1							1	
ISO Class 2					—	0	2	
ISO Class 3	1	M1.5	C	0.035	—	1	3	—
ISO Class 4	10	M2.5	D	0.35	—	2	4	—
ISO Class 5	100	M3.5	E or F	3.5	4 000	3	5	A/B
ISO Class 6	1 000	M4.5	G or H	35	—	4	6	—
ISO Class 7	10 000	M5.5	J	350	400 000	5	7	C
ISO Class 8	100 000	M6.5	K	3500	4 000 000	6		D
ISO Class 9								

FS 209 formula for cleanliness classes, "Class 100" or "Class 1000" referred to the number of particles of size 0.5 µm or larger permitted per cubic foot of air.

Table 1.4 provides a comparison of classifications between ISO 14644-1 and FS 209E. Because 1 m^3 is approximately 35 ft^3, the two standards are mostly equivalent when measuring 0.5 µm particles, although the testing standards differ. Ordinary room air is approximately ISO Class 9, or Class 1,000,000.

1.4 CLEANROOMS REQUIRED BY VARIOUS INDUSTRIES

Today, cleanrooms have grown from Whitfield's laboratory (Whitfield 1962) to a global industry of an estimated 125 million ft^2 (12 million m^2), up 5% from 2013. It is estimated that the cleanroom market will continue to grow at a compound annual growth rate of 5% until at least 2018 (Technavio 2014). Figure 1.1 demonstrates the cleanroom market by application in 2013.

1.5 CLEANROOM AIRFLOW

During Whitfield's work in the early 1960s, the concept of clean air entering from one plane and exiting at the floor was developed. Whitfield had identified the primary problem with earlier cleanrooms: they were not self-cleaning. In other words, the dirt in the room stayed in the room unless taken out by the janitor (Whitfield 1963). Whitfield and his team addressed this problem by having all air within the room leave at the floor to be captured by a prefilter outside the cleanroom. Whitfield described this design in his patent application as using a laminar airflow concept (Whitfield 1963). While the flow streamlines are intended to be parallel, the room air velocity was not technically laminar flow. The 1988 edition of FS 209, FS 209D, corrected this and introduced the terms *unidirectional* and *nonunidirectional* (Naughton 2016).

Since the issue of FS 209D, air pattern configurations in cleanrooms generally fall into two categories: unidirectional airflow and nonunidirectional airflow. Unidirectional airflow is controlled airflow through the entire cross section of a cleanroom or a clean

Table 1.4 Classification of Air Cleanliness by Particle Concentration

ISO Classification (ISO 2015a)	Maximum Concentration Limits (particles/m^3) Equal to and Greater Than the Considered Sizes Shown Below						FS 209 Cleanliness Class (GSA 1992)
	0.1 µm particle	0.2 µm particle	0.3 µm particle	0.5 µm particle	1.0 µm particle	5.0 µm particle	
ISO Class 1	10	Note 3	Note 3	Note 3	Note 3	Note 4	
ISO Class 2	100	24	10	Note 3	Note 3	Note 4	
ISO Class 3	1000	237	102	35	Note 3	Note 4	Class 1
ISO Class 4	10,000	2,370	1,020	352	83	Note 4	Class 10
ISO Class 5	100,000	23,700	10,200	3520	832	Notes 3,4	Class 100
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO Class 7	Note 2	Note 2	Note 2	352,000	83,200	2,930	Class 10,000
ISO Class 8	Note 2	Note 2	Note 2	3,520,000	832,000	29,300	Class 100,000
ISO Class 9	Note 2	Note 2	Note 2	35,200,000	8,320,000	293,000	

Notes:
1. All concentrations in the table are cumulative.
2. Concentration limits are not applicable in this region of the table due to very high particle concentrations.
3. Sampling and statistical limitations for particles in low concentrations make classification inappropriate.
4. Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.
5. Conversion to alternative units of measure is not recommend or allowed for ISO classes.

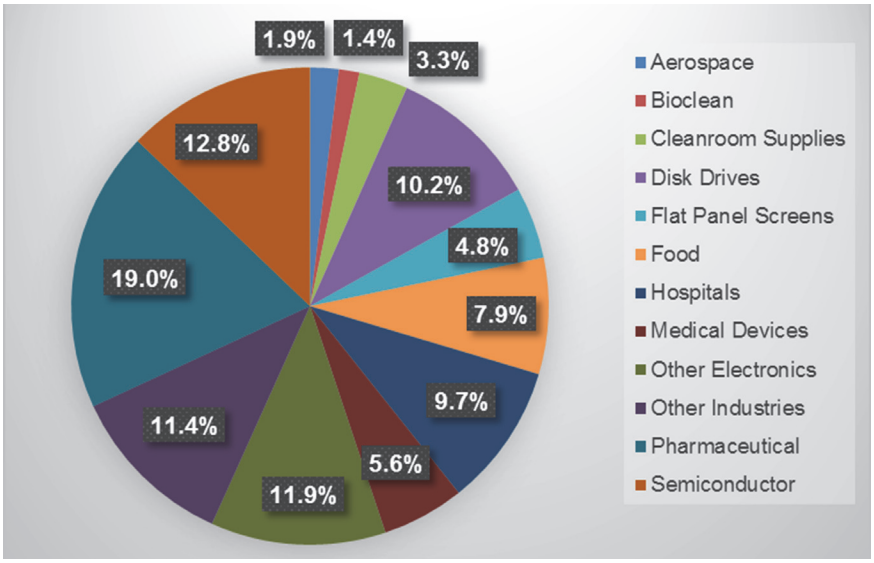


Figure 1.1 Estimated Global Cleanroom Area by Industrial Sector

zone with a steady velocity and airstreams that are considered to be parallel. Ideally, the flow streamlines are uninterrupted, and although personnel and equipment in the airstream do distort the streamlines, a state of constant velocity is approximated. Nonunidirectional air distribution is where the supply air entering the cleanroom or clean zone mixes with the internal air by means of induction.

Some examples of unidirectional and nonunidirectional airflow systems are shown in Figures 1.2 and 1.3. Airflow is typically supplied to the space through supply diffusers containing high-efficiency particulate air (HEPA) filters (Figure 1.2) or through supply diffusers with HEPA filters located in the ductwork or air handler (Figure 1.3). In a mixed-flow (nonunidirectional) room, air is prefiltered in the supply and then HEPA-filtered at the workstations located in the clean space (see the left side of Figure 1.3) (ASHRAE 2015).

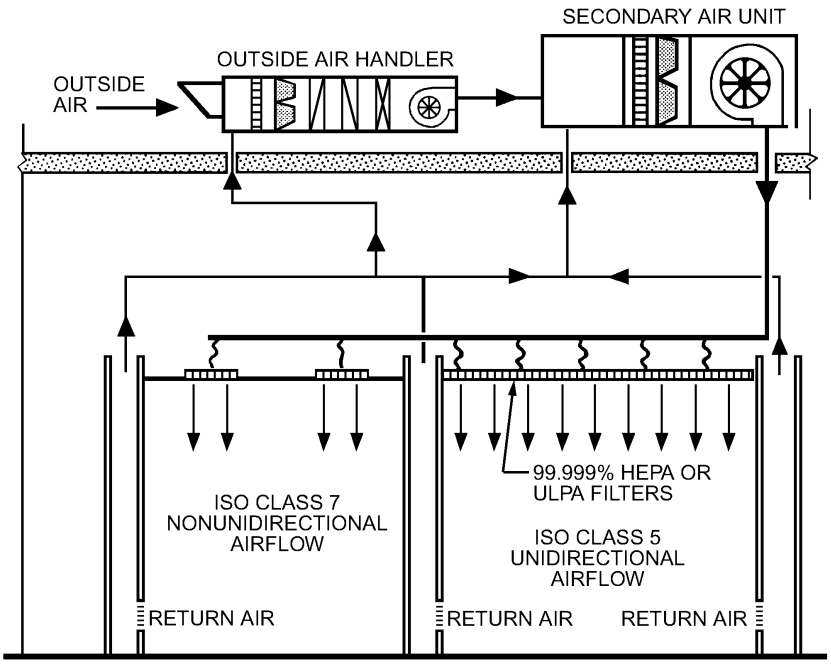


Figure 1.2 ISO Class 7 Nonunidirectional Cleanroom with Ducted HEPA Filter Supply Elements and ISO Class 5 Unidirectional Cleanroom with Ducted HEPA or ULPA Filter Ceiling

(ASHRAE 2015)

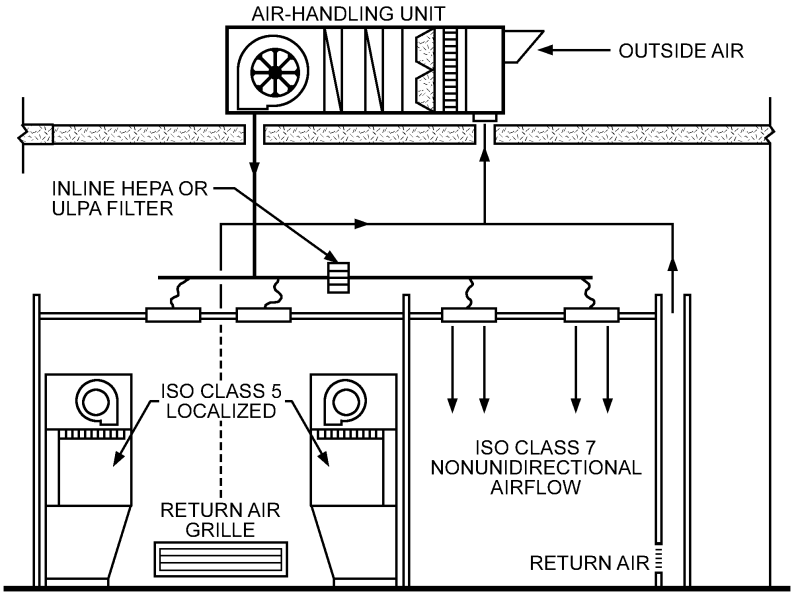


Figure 1.3 ISO 14644-1 Class 7 Nonunidirectional Cleanroom with HEPA Filters Located in Supply Duct and ISO 14644-1 Class 5 Local Workstations

(ASHRAE 2015)

1.5.1 UNIDIRECTIONAL AIRFLOW

In unidirectional airflow, air patterns are optimized and air turbulence is minimized. In a vertical laminar flow (VLF) room, typically air is introduced through ceiling HEPA or ultralow particulate air (ULPA) filters and returned at the base of sidewalls or through a raised-access floor. The air enters from the entire ceiling area, so this configuration produces nominally parallel airflow. In a horizontal flow, air enters from one wall and returns on the opposite wall (ASHRAE 2015).

A downflow cleanroom has a ceiling with HEPA filters, but air flows from only a portion of the ceiling. In a cleanroom with a low class number the greater part of the ceiling requires HEPA filters. For an ISO Class 5 (ISO 2015a) or better room, the entire ceiling

may require HEPA filtration, though more common practice is that only a high percentage of the ceiling need contain filters—enough to provide good uniform velocity. ISO Class 3 to ISO Class 5 cleanrooms may warrant only 90% to 70% filter coverage (Naughton 2003). Ideally, the air return is a grated or perforated floor; however, this type of floor is inappropriate for several types of cleanrooms, including pharmaceutical cleanrooms, which require solid floors and low-level wall returns. In a vertical downflow cleanroom, the entire room is bathed in a uniform shower of downward-flowing ultraclean air. With this design, contamination that is generated in the space is swept down and out through the floor and will not move laterally against the downward flow of air or contribute to contamination buildup in the room. To seal a HEPA or ULPA filter ceiling, care must be taken in design, selection, and installation. Properly sealed HEPA or ULPA filters installed in the ceiling can provide the cleanest air currently available in a workroom environment (ASHRAE 2015).

In a horizontal-flow cleanroom, the supply wall consists entirely of HEPA or ULPA filters supplying air at approximately 90 fpm (0.45 m/s) across the room. The air exits at the opposite side of the room through the return wall and recirculates. As with the vertical downflow room, this design minimizes cross-contamination perpendicular to the airflow and removes contamination generated in the space. However, this design is limited because the downstream air becomes contaminated: the air that leaves the filter wall is the cleanest, and it is contaminated by the process in the room as it flows past the first workstation. Ideally the process activities should be oriented so that the most critical operations are at the cleanest end of the room, progressing with less critical operations, with the least critical operations located at the return air end of the room. Unidirectional airflow systems have a predictable airflow path that airborne particles tend to follow. However, unidirectional airflow only indicates a predictable path for particles to follow if no good filtration practices accompany it. With a good understanding of unidirectional airflow, though, superior cleanroom performance can be achieved. This airflow is designed to remain parallel (or within 18° of parallel) to below the normal work surface height of 30 to 35 in. (760 to 900 mm). The result is a cleanroom with areas of good unidirectional airflow. However, this flow deteriorates when the air encounters obstacles (for example, work benches or process equipment) or if the air must travel excessive distances. The movement of personnel also degrades the flow. Turbulent zones have countercurrents of air with no flow at all (stagnancy), reverse flow, or high velocity. These countercurrents can produce stagnant zones where particles cluster and settle on surfaces or may lift particles from already contaminated surfaces. Once lifted, these particles may deposit on product surfaces (ASHRAE 2015).

1.5.2 NONUNIDIRECTIONAL AIRFLOW

Variations of nonunidirectional airflow are typically based on the locations of supply inlets and outlets and air filters. Satisfactory contamination control results for cleanliness levels of ISO Classes 6 through 8 (ISO 2015a) may be achieved with nonunidirectional airflow. Attainment of desired cleanliness classes with designs similar to those in Figures 1.1 and 1.2 assumes that makeup air is the major source of space contamination and that this contamination is removed in the filter housings of air handlers or ductwork or through supply HEPA filters. When particles generated within the cleanroom are the highest concern, clean workstations should be provided in the clean space (ASHRAE 2015).

1.6 SOURCES OF CONTAMINANTS INSIDE CLEANROOMS

Contamination is a process that causes surfaces to be soiled with contaminating substances. The two broad categories of surface contaminants are particulates and film type.

These contaminants can produce what's known as a "killer defect" in a miniature circuit manufactured in a semiconductor cleanroom. Film contaminants of only 10 nm, for example, can drastically reduce the adhesion of a coating on a wafer or chip. Though particles of 0.5 μm or larger are typically the target, some industries are now targeting even smaller particles (McFadden n.d.).

A partial list of contaminants is found in the following subsection. Any of these can be the source of a defect that may damage a product beyond repair. The objective is preventing these contaminants from entering the cleanroom, and succeeding requires commitment of everyone who enters the cleanroom, including professional cleaning personnel. Whenever personnel enter or clean a cleanroom, strict procedures must be followed. Compromise is not acceptable when cleaning in a cleanroom (McFadden n.d.).

1.6.1 CONTAMINATION SOURCES

Some of the commonly known contaminants that can cause problems in various cleanroom environments are included here. Research has found that many of these contaminants are generated from five basic sources—facilities, people, tools, fluids, and the products being manufactured (McFadden n.d.):

- Facilities
  - Walls, floors, and ceilings
  - Paint and coatings
  - Construction materials (gypsum wallboard, saw dust, etc.)
  - Air-conditioning debris
  - Room air and vapors
  - Spills and leaks
- People
  - Skin flakes, oil, and perspiration
  - Cosmetics and perfumes
  - Spittle
  - Clothing debris (lint, fibers, etc.)
  - Hair
- Tools and supplies
  - Noncleanroom writing materials and supply bags
  - Friction and wear particles
  - Machinery vibration
  - Lubricants and emissions
  - Brooms, mops, and dusters
  - Raw-material bags and containers
- Fluids
  - Particulates floating in air
  - Bacteria, organics, and moisture
  - Floor finishes or coatings
  - Cleaning chemicals
  - Plasticizers (off-gasses)
  - Deionized water
- Products
  - Silicon chips
  - Quartz flakes
  - Cleanroom debris
  - Metal particles

Table 1.5 Number of Particles Produced per Minute During Various Activities *(McFadden n.d.)*

Activity	Particles/min (0.3 μm and larger)
Motionless (standing or seated)	100,000
Walking about 2 mph (3 km/h)	5,000,000
Walking about 3.5 mph (5.5 km/h)	7,000,000
Walking about 5 mph (8 km/h)	10,000,000
Horseplay	100,000,000

1.7 EFFECT OF HUMAN INTERFERENCE

When personnel are present in cleanrooms there are both physical and psychological concerns. Physical behavior such as sneezing, coughing, fast motion, and horseplay can increase contamination. Psychological concerns such as claustrophobia, odors, room temperature and humidity, and workplace attitude are important. People are a major source of contamination in cleanrooms. They produce contamination in several ways (McFadden n.d.):

- Body processes and products, such as hair, skin flakes, perspiration, and oils
- Behavior such as sneezing, coughing, and other types of movement
- Attitudes such as communication between workers and work habits

Table 1.5 shows the number of particles produced per minute during the activities listed.

1.7.1 GENERAL CLEANROOM GUIDELINES

The following are actions that are typically prohibited in cleanrooms of all types (McFadden n.d.):

- Fast motions such as walking fast, running, or horseplay
- Leaning or sitting on work surfaces or equipment
- Writing on cleanroom garments or equipment
- Removing items from beneath cleanroom garments
- Wearing cleanroom garments outside the cleanroom
- Wearing torn or soiled cleanroom garments
- Reentering a cleanroom wearing previously used cleanroom garments

Personnel entering a cleanroom—including operators, supervisors, cleaning personnel, and the like—need to be trained and at all times be aware of and follow the regulations of the cleanroom. According to McFadden (n.d.), general regulations recommended as a minimum for successful cleanroom operation are as follows:

- Personal items such as keys, watches, rings, matches, lighters, and cigarettes should be stored in personal lockers outside the gowning room.
- Valuable personal items such as wallets may be permitted in the cleanroom provided they are never removed from beneath the cleanroom garments.
- Eating, smoking, and gum chewing are not allowed inside the cleanroom.
- Only garments approved for the cleanroom should be worn when entering.
- Cosmetics are not to be worn in the cleanroom. This includes rouge, lipstick, eye shadow, eyebrow pencil, mascara, eye liner, false eye lashes, fingernail pol-

ish, hair spray, mousse, and the heavy use of aerosols, aftershaves, and perfumes.
- Only approved cleanroom paper is allowed in the cleanroom.
- Approved ball point pens are the only writing tool allowed for use.
- Use of paper or fabric towels is prohibited. Use of hand dryers equipped with HEPA filters is suggested.
- Only approved gloves, finger cots (powder-free), pliers, or tweezers should be used to handle products. Fingerprints can be a major source of contamination on some products.
- Gloves or finger cots should not be allowed to touch any item or surface that has not been thoroughly cleaned.
- Solvent contact with bare skin should be avoided. Solvents can remove skin oils and increase skin flaking.
- Approved skin lotions or lanolin-based soaps are sometimes allowed. These can reduce skin flaking.
- Tools, containers, and fixtures used in the cleaning process should be cleaned to the same degree as the cleanroom surfaces. All of these items are sources of contamination.
- No tool should be allowed to rest on the surface of a bench or table; it should be placed on a cleanroom wipe.
- Only cleanroom-approved wipes are allowed to be used. The wipes must be approved for the class of cleanroom being cleaned.
- Equipment, materials and containers introduced into a sterile facility must be subjected to stringent sterilization prior to entrance.
- No one who is physically ill, especially with respiratory or stomach disorders, should enter a sterile room. This is a good practice in any cleanroom environment.

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