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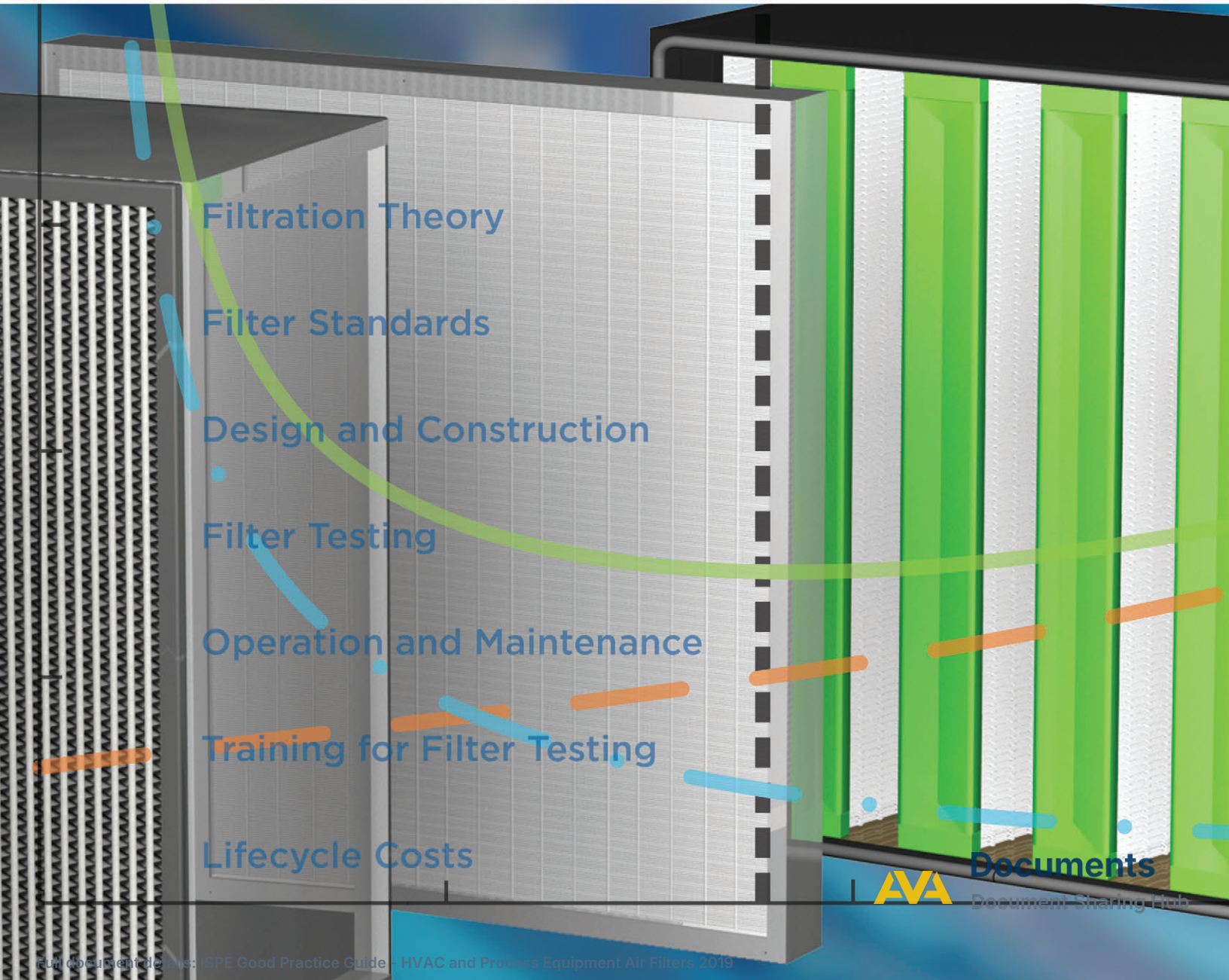
GOOD PRACTICE GUIDE:

HVAC and Process Equipment Air Filters



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HVAC and Process Equipment Air Filters

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Preface

Heating, Ventilation, and Air Conditioning (HVAC) systems can critically affect the ability of a pharmaceutical facility to meeting its objective of providing safe and effective product to the patient. The *ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)*, published September 2009, provides excellent advice regarding the design of HVAC systems in the pharmaceutical industry. Among the key components of any pharmaceutical HVAC system are the types of air filtration incorporated into the system. The *ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)* does address the subject of air filters, their specification, application and testing, and other important considerations. This Guide, the *ISPE Good Practice Guide: HVAC and Process Equipment Air Filters* delves much deeper into the subject of air filters in HVAC and process equipment applications and aims to be the definitive guide to air filters in the pharmaceutical industry, as used for:

- HVAC systems
- Pharmaceutical process equipment
- Laboratory equipment
- Containment systems

This Guide has been written by leading experts in the pharmaceutical industry on the subject of HVAC and air filters. This Guide is intended to be an indispensable reference on the selection, specification, testing, maintenance, and operation of filters in pharmaceutical applications. It is intended to be used to supplement guidance provided in the *ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)* and the HVAC and process equipment sections in the various facility ISPE guides (*ISPE Baseline® Guide: Volume 3 – Sterile Product Manufacturing Facilities, ISPE Baseline® Guide: Volume 2 – Oral Solid Dosage Forms, ISPE Baseline® Guide: Volume 6 – Biopharmaceutical Manufacturing Facilities, ISPE Good Practice Guide: Packaging, Labeling, and Warehousing Facilities,* etc.).

This Guide also explains the principles, objectives, and methods of filter testing during manufacturing and on-site, and includes a suggested approach to evaluate the impact of lifecycle costs in filter selection.

This Guide is written considering the European, US and Japanese requirements (and other countries depending where the authors have relevant experience) on the basis that these regulations provide a reference for other country regulations.

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Chapter Leaders and Writers

The following individuals took lead roles in the preparation of this Guide:

Eugene Bryan	Milholland & Associates	USA
Kimberly Coughlin	Kastango Consulting Group, LLC	USA
Mike Osborne	AAF Flanders	USA
Ron Roberts	Bayer Healthcare	USA
Lisa Warner	Camfil USA	USA

Other Contributors

The Team wish to thank the following individuals for their significant contribution to the document.

Chris Barbieri, PE	CRB	USA
Rahul Bharadwaj	Lydall	USA
Steve Devine	Camfil USA	USA
William Gantz	Bristol-Myers Squibb	USA
Dean Hale	Eli Lilly & Co.	USA
Don Largent	Air Techniques International	USA
Sean O'Reilly	AAF Flanders	USA
David Phillips	Thermo Fisher Scientific	USA
Hasim Solmaz	Lighthouse Worldwide Solutions	Turkey
Andy Stillo	Camfil USA	USA
Don Thornburg	Camfil USA	USA
Shawn Windley	AAF Flanders	USA

Subject Matter Expert Input and Review

Particular thanks for substantial and valuable contributions during review process go to:

Gordon Farquharson	Critical Systems Ltd.	United Kingdom
Harald Flechl	Independent Consultant	Austria
Jose Senatore	AAF Flanders	Brazil
Ulla Thomsen	Novo Nordisk A/S	Denmark

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Company affiliations are as of the final draft of the Guide.

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600 N. Westshore Blvd., Suite 900, Tampa, Florida 33609 USA
Tel: +1-813-960-2105, Fax: +1-813-264-2816

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1 Introduction

1.1 Background

In the pharmaceutical industry, the correct specification and application of air filters in HVAC systems and certain process equipment are critical to maintaining the environment at an appropriate cleanliness.

This Guide is intended to be used as supplement to the *ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)* [1], providing detailed information as to the selection, specification, installation, operation, and maintenance of HVAC and certain process air filters in meeting and maintaining the required environmental cleanliness. This Guide also explains the principles and objectives of filter testing conducted during manufacturing and after installation. Guidance is also provided for air filters in process equipment applications.

1.2 Purpose

This Guide aims to be a valuable reference on the selection, application, specification, testing, and operation and maintenance of filters in the pharmaceutical industry as used for:

- HVAC systems
- Pharmaceutical process equipment
- Laboratory equipment
- Containment systems

The information presented in this Guide is intended to supplement existing ISPE Guidance Documents. The ISPE Baseline® Guide series [2] for pharmaceutical facilities and associated ISPE Good Practice Guides [3] discuss the clean environment required for different types of facilities and processes, and address some of the requirements for air filters. The *ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)* [1] addresses the recommended selection and application of filters from a system perspective for different types of HVAC systems (for sterile products, Oral Solid Dosage (OSD), Active Pharmaceutical Ingredients (API), laboratories, warehouses, etc.). This information is not repeated in this Guide.

Filter technology advancements generally outpace regulatory guidances. This Guide describes current technologies and their application as it relates to the current guidance. The document is written primarily considering the European, US, and Japanese regulatory requirements [4, 5, 6] on the basis that these regulations provide a reference for most other country regulations. Regulations for other countries have been added where the authors of this Guide have relevant experience.

Note: It is recognized that several industry standards and regulatory reference documents listed in this Guide are in the process of being reviewed and revised. As of the Guide publication date, this Guide reflects an understanding of these final documents.

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1.3 Structure of the Guide

The chapters in this Guide are structured to make it easy for the reader to find the relevant content:

- Chapter 2: How filters work
- Chapter 3: Industry standards and references for air filters
- Chapter 4: Filter design and construction
- Chapter 5: Applications of HVAC and process air filters
- Chapter 6: Filter testing
- Chapter 7: Verification (commissioning and qualification) of air filters
- Chapter 8: Operational and maintenance considerations of air filters
- Chapter 9: Training for filter testing
- Chapter 10: Lifecycle costs
- Chapter 11 (Appendix 1): Regulatory and other guidance for air filters
- Chapter 12 (Appendix 2): Example forms

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2 Fundamental Concepts in Air Filtration

2.1 Filtration Theory

2.1.1 Particle Collection

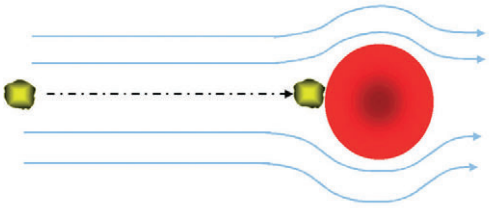
The ability of a filter to collect particles, i.e., the efficiency of a filter, is largely determined by various physical and mechanical phenomena such as diffusional, interception, inertia, and straining effects. These mechanisms of particle collection may not be intuitive since the effects of gravity and momentum become less significant as particle sizes approach micron and sub-micron sizes. Electrostatic effects between particles and fibers can also play a part in particle capture, but caution should be exercised when selecting a filter marketed for this feature. In many cases, the electrostatically charged behavior of the media is only temporary once the filter is put in use, and the added efficiency significantly decreases with time as a result.

In order to discuss and show the different filtration effects on a fundamental level, it is assumed that particles are spherical in shape with a known diameter. It is also assumed that if a particle touches a filter fiber, it will adhere to the fiber mainly due to van der Waals forces. Electrostatic forces also contribute to the adhesion. The adhesive forces are affected by the material, shape, surface roughness, and size of the particle. The following particle capture effects are discussed in the remainder of this section in an order that relates to their significance as the particle sizes of interest decrease.

2.1.2 Inertia Effect

The inertia effect comes into play when larger particles have too great a mass and inertial force to be able to follow the airflow when it curves around a filter fiber. The particles continue instead along their original path and stick to the face side of the fiber. The inertial force increases with increasing air velocity and increasing particle diameter. See Figure 2.1a.

Figure 2.1a: Particle Collection Method – Inertia [7]



2.1.3 Interception Effect

Small, light particles follow the airflow around the filter fiber. If the center of the particle follows a flow path that comes within a distance to the fiber that is equal to or less than its radius, the particle is intercepted and attaches to the fiber. See Figure 2.1b. The interception effect is independent of the air velocity unless the variation is sufficient enough to alter the flow pattern around the fiber. The interception effect increases with increasing particle size, decreasing fiber diameter, and decreasing distance between the fibers. In order to have a good interception effect, a filter medium thus needs to contain a large number of fine fibers, usually with a diameter the same as that of the particles to be collected.

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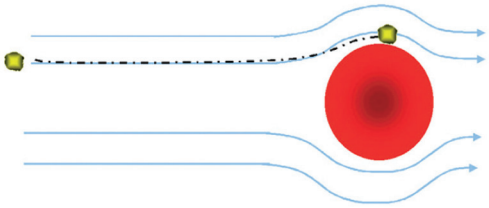
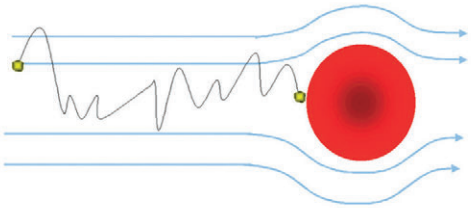
Figure 2.1b: Particle Collection Method – Interception [7]



2.1.4 Diffusion Effect

Particles in the order of 1 µm diameter in size and smaller do not follow typical airflow paths around a filter fiber because they are influenced by the Brownian motion of the air molecules surrounding them. The vibration of air molecules within close proximity of the particles can impact their motion, causing them to take a much longer and more random path through the filter media. This altered path increases their chance of coming into contact with a filter fiber. See Figure 2.1c. The probability of the particles coming into contact with the fibers increases as velocity, particle diameter, and fiber diameter decrease.

Figure 2.1c: Particle Collection Method – Diffusion [7]



2.1.5 Electrostatic Discharge

Electrostatic deposition is a mechanism to be considered in the capture of solid aerosol particles. For example, electrostatic precipitators are used industrially to remove solid particles, where an active high voltage corona discharge is used to charge the target particles. A high voltage with the opposite charge is applied to the collectors so that the particles are attracted to the surface of the collector. This type of active charging system can work as a filtration mechanism. However, more common in the pharmaceutical industry is the use of a passive electrostatic filter, where the fibers in the filter have an applied electrostatic charge. This mechanism can initially increase the separation efficiency. However, the designer needs to be aware there are published independent studies showing this passive electrostatic charge is often reduced or eliminated when the media/filter is exposed to atmospheric aerosol in actual service [9, 10]. Thus, ASHRAE 52.2-2017 [8] Appendix J provides a procedure with a specifiable Minimum Efficiency Reporting Value (MERV) designation, MERV-A, to give the user a more accurate filter efficiency. The Appendix J procedure is based on ASHRAE research [9]. It is also supported by the ASHRAE research work [10] into how filters perform when challenged with atmospheric aerosol. ISO 16890 [11] uses a different procedure, but with a similar result to the ASHRAE 52.2-2017 [8] Appendix J procedure to help the designer specify a filter efficiency value that more accurately reflects the filter performance when the filter is put into actual service.

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2.2 Filtration Efficiency

Capture efficiency, or efficiency of a filter, is typically determined for a specific particle size or particle size range. The efficiency % represents the percentage of particles of the specified size or range that are captured within the filter compared to those entering the filter. The capture of particles occurs by different capture mechanisms as discussed in Section 2.1. It is typically defined by its relationship to filter penetration %, since the penetrating particles are those that are measured, and is defined as follows:

$$\text{Efficiency \%} = 100\% - \text{Penetration \%}$$

Penetration % represents the percentage of particles of the specified size or range that pass through the filter compared to those entering the filter and is defined as follows:

$$\text{Penetration \%} = 100 \times \frac{\text{Particles Penetrating Filter}}{\text{Particles Entering Filter}}$$

As the total efficiency of a high efficiency filter is determined by the sum of different filtration effects, it is natural to assume that the collecting efficiency has a definite minimum value under certain conditions. Both the interception effect and the inertial effect increase with increasing particle size, whereas the diffusion effect decreases with increasing particle size. This should therefore imply that there is a definite particle size which is the hardest to collect in a filter; this particle size is defined as the Most Penetrating Particle Size (MPPS) as shown in Figure 2.2.

Figure 2.2: Efficiency Varies with Particle Size

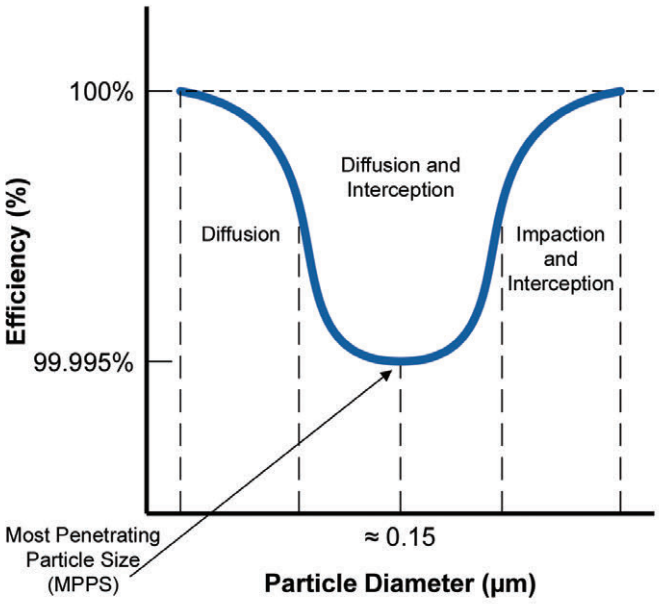

Figure 2.3 shows the collecting efficiency curve of a given filter operating at full airflow and at 50% of that rated flow. The filter collection efficiency has a minimum for particles that are 0.15 µm to 0.25 µm in diameter. At a lower velocity through the filter, the curve shifts to the right, resulting in a slightly larger MPPS. It can also be seen that the minimum collecting efficiency would also rise since a lower velocity through the filter increases the time particles will spend in the filter media. The latter phenomenon is a consequence of the fact that the interception effect is independent of the velocity, whereas the diffusion effect increases with decreasing velocity. Conversely, if the velocity increases, the diffusion effect decreases and the curve will shift left, moving the MPPS towards smaller particles.

Note: By reducing the airflow velocity through the filter media by 50%, the overall efficiency increases 10-fold, i.e., an H-13 filter becomes an H-14 filter.

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Figure 2.3: Effects of Media Air Velocity on Efficiency and MPPS
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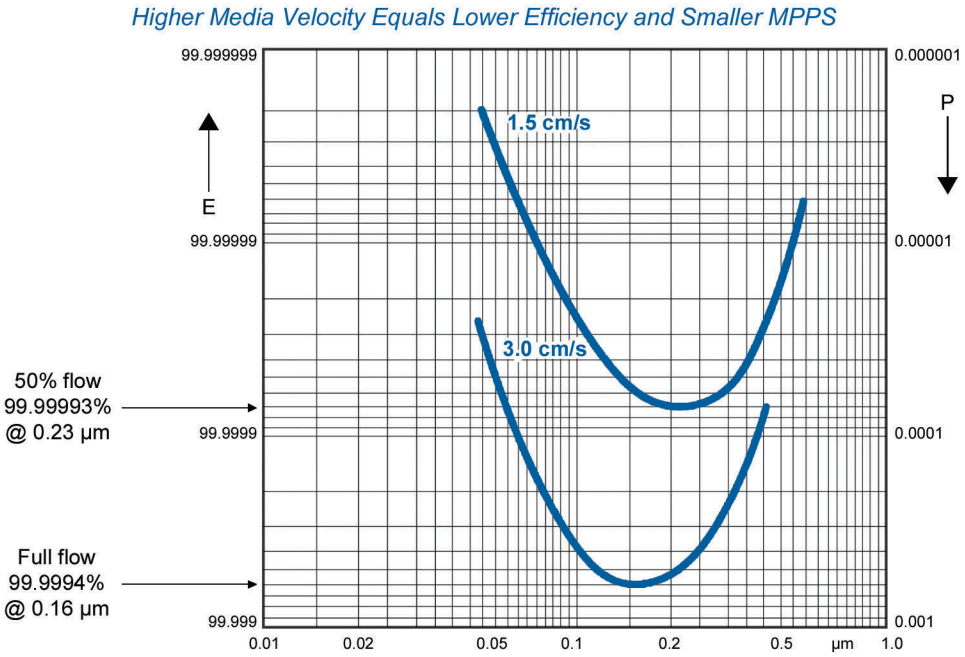

2.3 Air Filtration Characteristics

Air filtration can occur on the surface of filter media as well as within the filter media. These two behaviors are referred to as surface and depth filtration, respectively.

2.3.1 Surface Filtration

Surface filters capture particles on the surface of the medium in the form of a cake; the thickness of the cake increases as filtration proceeds. This buildup layer of particles also aids in the filtration process as this layer provides additional structures for new particles to adhere to. Certain chemical operations involve reuse of the cake as it has value, and recovery of the cake is also required. Surface (or cake) filtration usually occurs due to the straining effect (surface loading) where the diameter of the particles exceeds the pore size of the challenged medium. Although the surface layer can aid in the filtration process, the thickness of the surface layer typically has a significant impact on the pressure drop across a filter. The significance of pressure drop is discussed in Chapter 8. Examples of media for surface filtration include woven meshes, screens, and membranes.

2.3.2 Depth Filtration

As particle sizes decrease, depth filtration becomes more prominent and the effects of inertial impaction, interception, and diffusion begin to play a larger role. HEPA (High Efficiency Particulate Air) filters mainly rely on depth filtration to serve their purpose. Since surface loading can lead to undesired increases in pressure drop across the HEPA media, prefilters are commonly installed. Lower-rated prefilters are designed to remove larger particles and fibers by surface filtration, resulting in lower levels of depth filtration which extends the operational life of the terminal HEPA filter. As in the case of surface filtration, depth filtration can also improve with time as particles are captured and new structures are created within the filter media. Because of this phenomenon, the efficiency of an installed HEPA filter will improve with time.

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2.3.3 Pressure Drop

Pressure drop directly relates to the energy consumption of a filter or filter media. It is the resistance offered by the filter to airflow. Pressure drop is measured in inches of water gauge (in wg) or Pascals (Pa). It is important to note that the filter's resistance or pressure drop is proportional to the airflow volume passing through the filter. When a filter resistance is reported, an airflow volume also needs to be reported. When HEPA or ULPA (Ultra Low Penetration Air) filters are specified with only small reductions in pressure drop, significant energy savings can result from their long-term use. Filter media manufacturers have made great progress in developing low resistance media. Filter manufactures have reduced filter resistance by increasing the total filter media per filter, as accomplished by deeper pack depths and increased number of pleats per inch. Increasing media will increase the filters particulate holding capacity, thus resulting in a longer filter life. See Chapter 10 for additional information.

2.3.4 Slip Flow Condition for Nano-Sized Fibers in Membrane Filters

Nanofibers have a very small diameter and, as a result, only a small fraction of the air molecules paths are redirected by them when compared to larger glass fibers. Since only a small portion of air molecules velocities are impacted by the nanofiber, the air is free to move past the fiber much easier. The movement of the air molecules past the nanofiber without significant interaction is referred to as slip flow.

This slip flow phenomena affects filtration in two important ways. First, because fewer molecules collide with the fiber, there is less air drag on the fiber. This means that the pressure drop through a filter medium of nanofibers will be less than that of a filter medium of microfibers of equal fiber length. The second way that slip flow is important is that it improves the single fiber capture efficiency of small particles on the nanofibers. Because of the slip flow phenomena, the gas flow streamlines pass much closer to the surface of the nanofiber than the microfiber. This means that direct interception of small particles in the gas stream improves because more of these particles pass close enough to collide with the nanofiber than with the microfiber.

2.3.5 Pleated Media

Pleating increases the amount of filtration media that can be inserted into a filter frame; this has a direct impact on the pressure drop, efficiency, and life of a HEPA filter. The additional media and resulting increased surface area provide a higher particle holding capacity as well as added paths for airflow. The additional holding capacity increases the life of the filter and the added paths for airflow decrease the pressure drop across the filter. This explains why a pleated 100 mm filter pack depth can have a lower pressure drop than a 50 mm pack depth, assuming both filters have the same pleat density (pleats per inch). The increased surface area and additional flow paths also decrease a particle's velocity through the filter which improves the overall filtration efficiency. Additional details and information related to the structure and fabrication of pleated media are discussed in Chapter 4.

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3 Filter Standards

3.1 GMP Regulatory Requirements

It is the responsibility of the designer and owner/operator of the facility to know the specific GMP requirements of the authorities having jurisdiction in both the location of the facility and the locations in which the products from the facility may be used. In general, the GMP regulations specify what is required and the filter standards and references provide guidance on how those requirements are best achieved. Therefore, there are relatively few specific requirements regarding filters in most global GMP regulatory documents. However, some GMPs do have specific requirements as to the "how", and some GMP regulations even include reference to applicable filter standards for filter construction, performance, and/or testing.

The requirements within GMP regulatory documents vary country by country. However, most country GMP regulations worldwide generally follow either the US, EU, or Japan GMP regulations [4, 5, 6] and may include additional requirements of their own for filters. Therefore, organizations need to be knowledgeable about the specifics of the GMP regulations as they apply to the specific facility. Among the GMP requirements related to filters that are most commonly addressed in the various worldwide regulatory documents are the following examples:

- Definition of the minimum performance of a HEPA/ULPA filter in terms of both efficiency and integrity (leak) testing
- Required use of prefilters and HEPA/ULPA filters in the appropriate areas – specific applications are addressed in some GMP regulatory documents for both rooms (classified areas) and for some process equipment with HEPA/ULPA filters
- Air velocity (and/or volume) and directional flow (airflow patterns) supplied by HEPA/ULPA filters into clean areas
- Velocity uniformity through the HEPA/ULPA filter
- Required testing of filters – in some cases, the parameters, frequency, and method are specified
- HEPA/ULPA filter repairs
- Documented records of HEPA/ULPA filter testing and maintenance need to be kept
- Use of HEPA/ULPA filters in hazardous or toxic containment applications
- Where recirculation through a HEPA/ULPA filter is allowed or prohibited

As with other pharmaceutical technologies, filter technology advancements generally outpace GMP regulatory documents and filter standards and references. Therefore, some requirements in the current GMP regulatory documents may not represent the most current knowledge about filters. In order to implement methods that may differ from current GMP regulations, it is important to develop a strong documented technical and scientific rationale that is based on science and risk-based assessments. For more information regarding science and risk-based approaches, refer to ICH Q8 [12], Q9 [13], and Q10 [14]. See also the *ISPE Guide Series: Product Quality Lifecycle Implementation (PQLI®) from Concept to Continual Improvement* [15].

Chapter 11 (Appendix 1) contains more detailed information about the various global GMP regulatory documents regarding filter requirements.

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3.2 Relevant Organizations

There are various technical organizations that have developed additional standards and recommended practices beyond GMP regulations which provide more practical guidance to assist the industry in the best methods to meet the requirements stated in various GMP regulations. Where there are relevant country standards that the authors are aware of, the standards have been included below. It should be further noted that although some of these organizations (CETA (Controlled Environment Testing Association) [16], NSF (National Science Foundation) [17], UL (Underwriters Laboratories) [18], NEBB (National Environmental Balancing Bureau) [19], etc.) do not publish filter standards, per se, as do some others (ISO (International Organization for Standardization) [20], CEN (European Committee for Standardization) [21], IEST (Institute of Environmental Sciences and Technology) [22], etc.), they do publish standards and reference documents as to how to test filters in specific applications (cleanrooms, biosafety cabinets, etc.).

3.2.1 ISO (International Organization for Standardization) [20]

The ISO 14644 series of standards [23] are rapidly becoming the standard governing the pharmaceutical industry; it defines cleanroom standards and the specification and associated testing of the rooms and their filters. Furthermore, both US and EU GMP regulations [4, 5] directly reference ISO 14644-1 [24] and ISO 14644-2 [25], thereby making these ISO standards a part of GMP guidance. The ISO standards are meant to serve several industries with different applications for cleanrooms, whereas the GMP guidance is specific to the pharmaceutical industry. Therefore, GMP guidance on the topics of cleanrooms and HEPA filters may contain different, sometimes more stringent, requirements than those stated in ISO 14644 [23].

3.2.2 CEN (European Committee for Standardization) [21]

CEN is described as follows [21]:

> *"CEN, the European Committee for Standardization, is an association that brings together the National Standardization Bodies of 33 European countries.*
>
> *CEN is one of three European Standardization Organizations (together with CENELEC [European Committee for Electrotechnical Standardization] and ETSI [European Telecommunications Standards Institute]) that have been officially recognized by the European Union and by the European Free Trade Association (EFTA) as being responsible for developing and defining voluntary standards at European level.*
>
> *CEN provides a platform for the development of European Standards and other technical documents in relation to various kinds of products, materials, services and processes."*

3.2.3 ASHRAE (American Society of Heating, Refrigerating and Air-Conditioning Engineers) [26]

ASHRAE is an international organization with the goal to advance the arts and sciences of heating, ventilation, air conditioning, and refrigeration to serve humanity and promote a sustainable world [26]. ASHRAE develops many standards for cleanrooms, including requirements for air filtration. Their primary standard for air filters is ASHRAE 52.2-2017, Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size [8].

3.2.4 BSI (British Standards Institution) [27]

BSI is the organization officially chartered as the National Standards Body (NSB) for the UK. BSI is accountable to develop, maintain, and revise consensus standards across a wide variety of industries. International standards (such as ISO 14644-1 [24]) become codified as national standards in the UK when they are adopted as BSI standards.

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3.2.5 ANSI (American National Standards Institute) [28]

ANSI is the organization officially chartered as the NSB for the US. ANSI is accountable to develop, maintain, and revise consensus standards across a wide variety of industries. International standards (such as ISO 14644-1 [24]) become codified as national standards in the US when they are adopted as ANSI standards.

3.2.6 IEST (Institute of Environmental Sciences and Technology) [22]

IEST is the US technical organization that is the ANSI-accredited US TAG (Technical Advisory Group) responsible for developing US cleanroom standards and for providing technical advice from the US to the ISO 14644 [23] governing and working groups. IEST has established a filter rating system for the higher-grade filters. IEST Recommended Practices may be used as references in the design, construction, commissioning and qualification, operational, and maintenance phases of a cleanroom's lifecycle.

3.2.7 NEBB (National Environmental Balancing Bureau) [19]

NEBB is an association of certified firms that perform building systems commissioning, building enclosure testing, cleanroom performance testing, fume hood testing, retro-commissioning, sound and/or vibration measurement, and testing, adjusting and balancing of HVAC systems. In addition to certifying firms, NEBB is a major source of industry information, providing technical and procedural standards, publications, study courses, and newsletters.

3.2.8 CETA (Controlled Environment Testing Association) [16]

CETA is an organization of individuals and companies that test cleanrooms and other controlled environments. CETA is heavily involved in the development of standards related to testing requirements for controlled environments as well as the training and practical execution of standards related to the controlled environment industry. CETA has been very active in developing test methods for USP <797> [29] for compounding pharmacy environments and biosafety cabinets.

3.2.9 NSF (National Science Foundation) [17]

NSF is an independent, accredited organization tasked with developing public health standards and certifications that help to protect food, water, consumer products, and the environment. They are responsible for testing, auditing, and certifying products and systems and for providing education and risk management training. Their primary involvement in clean spaces is to own and maintain the standards for Biosafety Cabinet (BSC) certification and to maintain the accreditation of individuals who can certify BSCs.

3.2.10 UL (Underwriters Laboratories) [18]

UL is the largest global organization for product safety testing and certification. UL standards for air filter product safety are generally accepted as requirements for the specification of air filters in the US and many other countries.

Two of the primary UL standards which apply to filters are the following:

- UL 900 (Standard for Air Filter Units) [30] *"requirements cover tests to determine the amount of smoke generated and the combustibility of air filter units of both washable and throwaway types used for removal of dust and other airborne particles from air circulated mechanically in equipment and systems installed in accordance with the Standards for Installation of Air Conditioning and Ventilating Systems, NFPA 90A (Other Than Residence Type), Installation of Warm Air Heating and Air Conditioning Systems, NFPA 90B (Residence Type), the International Mechanical Code, the International Fire Code, and the Uniform Mechanical Code. These requirements also cover media intended for assembly into air filter units."*

- UL 586 (Standard for Safety for High-Efficiency, Particulate, Air Filters Units) [31] *"requirements cover high-efficiency, particulate, air-filter units intended for the removal of very fine particulate matter (not less than 99.97 percent of 0.3 micron diameter particles) from the air of industrial and laboratory exhaust and ventilating systems."*

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3.2.11 PHSS (Pharmaceutical & Healthcare Sciences Society) [32]

PHSS is dedicated to sharing knowledge, regulatory guidance, and best practices to those within the pharmaceutical, biotechnology, and related healthcare sectors.

3.3 Filter Classifications/Grades/Performance Criteria

3.3.1 ISO 14644 [23]

The following are the various parts of ISO 14644[1] (Cleanrooms and associated controlled environments) [23] and the topics which are addressed (not all of these parts address filters in cleanrooms):

- ISO 14644-1 (Part 1: Classification of air cleanliness by particle concentration) [24] specifies the classes of air cleanliness in terms of the number of particles expressed as a concentration in air volume and specifies the standard method of testing to determine cleanliness class
- ISO 14644-2 (Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration) [25] addresses the need to consider a monitoring strategy in addition to the initial or periodic execution of the classification of the cleanroom or clean zone
- ISO 14644-3 (Part 3: Test methods) [33] specifies test methods for designated classification of airborne particulate cleanliness for characterizing the performance of cleanrooms and clean zones
- ISO 14644-4 (Part 4: Design, construction and start-up) [34] specifies the requirements for the design and construction of cleanroom facilities as classified by ISO 14644
- ISO 14644-5 (Part 5: Operations) [35] specifies the basic requirements for cleanroom operations as classified by ISO 14644
- ISO 14644-7 (Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)) [36] specifies the minimum requirements for the design, testing, and approval of separative devices
- ISO 14644-8 (Part 8: Classification of air cleanliness by air chemical concentration (ACC)) [37] covers the classification of Airborne Molecular Contamination (AMC) in cleanrooms and associated controlled environments
- ISO 14644-9 (Part 9: Classification of surface cleanliness by particle concentration) [38] establishes the classification of cleanliness levels on solid surfaces by particle concentration in cleanrooms and associated controlled environments
- ISO 14644-10 (Part 10: Classification of surface cleanliness by chemical concentration) [39] defines the classification system for cleanliness of surfaces in cleanrooms with regards to the presence of chemical compounds or elements
- ISO 14644-12 (Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration) [40] specifies the guidelines for monitoring of air cleanliness by particles in terms of concentration of airborne nanoscale particles
- ISO 14644-13 (Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications) [41] provides the guidelines for cleaning to a specified degree on cleanroom surfaces, surfaces of equipment in a cleanroom, and surfaces of materials in a cleanroom

[1] Part 6 and Part 11 of ISO 14644 have been withdrawn.

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- ISO 14644-14 (Part 14: Assessment of suitability for use of equipment by airborne particle concentration) [42] specifies the methodology to assess the suitability of equipment (e.g., machinery, measuring equipment, process equipment, components, and tools) for use in cleanrooms and associated controlled environments, with respect to airborne particle cleanliness as specified in ISO 14644-1 [24]

- ISO 14644-15 (Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration) [43] specifies the requirements and guidelines for assessing the chemical airborne cleanliness of equipment and materials which are foreseen to be used in cleanrooms and associated controlled environments which are linked to the ISO standard for cleanliness classes by chemical concentration

- ISO 14644-16 (Part 16: Energy efficiency in cleanrooms and clean air devices) [44] covers how to optimize energy usage and maintain energy efficiency in new and existing cleanrooms, clean zones, and separative devices

- ISO 14644-17 (Part 17: Particle deposition rate applications) is undergoing development at the time of writing and intends to provide guidance on the interpretation and application of the results of the measurement of the particle deposition rate

3.3.2 ISO 16890 [11]

ISO 16890 (Air filters for general ventilation) [11] is a global filtration standard which received unanimous approval in 2016. ISO 16890 replaced EN 779 [45] and is being discussed to replace ASHRAE 52.2-2017 [8] in the US. This international filtration standard consists of the following four parts:

- ISO 16890-1 (Part 1: Technical specifications, requirements and classification system based upon particulate matter efficiency (ePM)) [46]

- ISO 16890-2 (Part 2: Measurement of fractional efficiency and air flow resistance) [47]

- ISO 16890-3 (Part 3: Determination of the gravimetric efficiency and the air flow resistance versus the mass of test dust captured) [48]

- ISO 16890-4 (Part 4: Conditioning method to determine the minimum fractional test efficiency) [49]

Table 3.1 provides an overview of the classifications of filters according to ISO 16890-1 [46].

Table 3.1: Filter Groups (from ISO 16890-1 [46])
©ISO. This material is reproduced from ISO 16890-1:2016 with permission of the American National Standards Institute (ANSI) on behalf of the International Organization for Standardization. The complete standard can be purchased from ANSI at https://webstore.ansi.org. All rights reserved.

The initial arrestance and the three efficiency values ePM_1, $ePM_{2.5}$, and ePM_{10} and the minimum efficiency values $ePM_{1,\,min}$ and $ePM_{2.5,\,min}$ shall be used to classify a filter in one of the four groups given below.				
Group Designation	**Requirement**			**Class Reporting Value**
	$ePM_{1,\,min}$	$ePM_{2.5,\,min}$	ePM_{10}	
ISO Coarse	—	—	< 50%	Initial grav. arrestance
ISO ePM_{10}	—	—	≥ 50%	ePM_{10}
ISO $ePM_{2.5}$	—	≥ 50%	—	$ePM_{2.5}$
ISO ePM_1	≥ 50%	—	—	ePM_1
The filter classes are reported as class reporting value in conjunction with the group designation. For the reporting of the ePM classes, the class reporting values shall be rounded downwards to the nearest multiple of 5% points. Values larger than 95% are reported as "> 95%". Examples of reporting classes are ISO Coarse 60%, ISO ePM_{10} 60%, ISO $ePM_{2.5}$ 80%, ISO ePM_1 85%, or ISO ePM_1 > 95%.				

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In addition, ISO [20] has an international standard for the field testing of air filtration devices: ISO 29462 (Field testing of general ventilation filtration devices and systems for *in situ* removal efficiency by particle size and resistance to airflow) [50]. This document is a useful reference for enabling owners and operators to provide field verification of the air filtration performance of their HVAC filtration devices.

3.3.3 ISO 29463 [51]

ISO 29463 (High efficiency filters and filter media for removing particles from air) [51] is the ISO standard for specifying the requirements for filter classes beyond those of ISO 16890 [11]. The requirements for the various ISO 29463 filter classes and a relative comparison to those of the EN 1822 standard [52] for higher-grade filters are shown in Table 3.2. (See Section 3.3.6.2 and Table 3.7 for the requirements specific to EN 1822.)

Table 3.2: HEPA Filter Classification Comparison – EN 1822 [52] and ISO 29463 [51]
Used with permission from AAF International, https://www.aafintl.com/.

		EN-1822	ISO 29463	Integral Value		Local Value		Leakage Factor
				Efficiency at MPPS	Penetration at MPPS %	Efficiency at MPPS	Penetration at MPPS %	
Group	EPA	E10		≥ 85	≤ 15			
		E11	ISO 15 E	≥ 95	≤ 5			
			ISO 20 E	≥ 99	≤ 1			
		E12	ISO 25 E	≥ 99.5	≤ 0.5			
			ISO 30 E	≥ 99.9	≤ 0.1			
	HEPA	H13	ISO 35 H	≥ 99.95	≤ 0.05	≥ 99.75	≤ 0.25	5
			ISO 40 H	≥ 99.99	≤ 0.01	≥ 99.95	≤ 0.05	5
		H14	ISO 45 H	≥ 99.995	≤ 0.005	≥ 99.975	≤ 0.025	5
			ISO 50 H	≥ 99.999	≤ 0.001	≥ 99.995	≤ 0.005	5
	ULPA	U15	ISO 55 U	≥ 99.9995	≤ 0.0005	≥ 99.9975	≤ 0.0025	5
			ISO 60 U	≥ 99.9999	≤ 0.0001	≥ 99.9995	≤ 0.0005	5
		U16	ISO 65 U	≥ 99.99995	≤ 0.00005	≥ 99.99975	≤ 0.00025	5
			ISO 70 U	≥ 99.99999	≤ 0.00001	≥ 99.9999	≤ 0.0001	10
		U17	ISO 75 U	≥ 99.999995	≤ 0.000005	≥ 99.9999	≤ 0.0001	20

3.3.4 ISO 16170 [53]

ISO 16170 (*In situ* test methods for high efficiency filter systems in industrial facilities) [53] may be either a requirement or a useful reference in some applications. It specifies *in situ* test methods for HEPA filters used to limit releases towards the environment from nuclear facilities or facilities with aerosol toxic or biological releases. It excludes the applications already covered in ISO 14644-3 [33].

3.3.5 ASHRAE [26]

The ASHRAE 52.2-2017 standard [8] rates prefilters and intermediate filters using a MERV (Minimum Efficiency Reporting Value) rating from 1 through 16. The requirements for the various grades of ASHRAE filters are shown in comparison to their equivalent EU grades in Table 3.3.

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Table 3.3: MERV Parameters (from ASHRAE 52.2-2017 [8])
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Minimum Eff. Reporting Value	Composite Average Particle Size Efficiency, % in Size Range, µm			Average Arrestance
	Range E_1	Range E_2	Range E_3	
(MERV)	0.30 – 1.0	1.0 – 3.0	3.0 – 10.0	%
1	N/A	N/A	$E_3 < 20$	$A_{avg} < 65$
2	N/A	N/A	$E_3 < 20$	$65 \leq A_{avg}$
3	N/A	N/A	$E_3 < 20$	$70 \leq A_{avg}$
4	N/A	N/A	$E_3 < 20$	$75 \leq A_{avg}$
5	N/A	N/A	$20 \leq E_3$	N/A
6	N/A	N/A	$35 \leq E_3$	N/A
7	N/A	N/A	$50 \leq E_3$	N/A
8	N/A	$20 \leq E_2$	$70 \leq E_3$	N/A
9	N/A	$35 \leq E_2$	$75 \leq E_3$	N/A
10	N/A	$50 \leq E_2$	$80 \leq E_3$	N/A
11	$20 \leq E_1$	$65 \leq E_2$	$85 \leq E_3$	N/A
12	$35 \leq E_1$	$80 \leq E_2$	$90 \leq E_3$	N/A
13	$50 \leq E_1$	$85 \leq E_2$	$90 \leq E_3$	N/A
14	$75 \leq E_1$	$90 \leq E_2$	$95 \leq E_3$	N/A
15	$85 \leq E_1$	$90 \leq E_2$	$95 \leq E_3$	N/A
16	$95 \leq E_1$	$95 \leq E_2$	$95 \leq E_3$	N/A

3.3.6 EU EN Standards

The EU standards for air filter rating previously consisted of EN 779 [45] and EN 1822 [52]. EN 779 has been superseded by ISO 16890 [11], and EN 1822 in the process of being superseded by ISO 29463 51]. Because ISO 16890 and ISO 29463 are relatively new, many industry documents still reference EN 779 and EN 1822. At the time of this writing, these EU standards are still the governing standards in some countries that have not yet adopted ISO 16890 or ISO 29463.

3.3.6.1 EN 779 [45]

EN 779 [45] addressed the classes of filters usually used for prefiltration and intermediate filtration, up to class F9. Tables 3.4, 3.5, and 3.6 describe the comparison of the classes of the EN 779, ASHRAE 52.2-2017 [8] and ISO 16890 [11] relative to one another.

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Table 3.4: Comparison of Standards

Used with permission from AAF International, https://www.aafintl.com/.

		ASHRAE 52.2: 2012	ISO 16890	EN 779: 2012
Standard	Aerosol	KCl	DEHS/KCl	DEHS
	Aerosol Range	0.3 to 10.0 µm	DEHS: 0.3 to 1.0 µm KCl: 1.0 – 10 µm	0.4 µm
	Particle Sizes for Rating	E1: 0.3 – 1.0 µm E2: 1.0 – 3.0 µm E3: 3.0 – 10.0 µm	PM1: 0.3 – 1.0 µm PM2.5: 0.3 – 2.5 µm PM10: 0.3 – 10 µm	0.4 µm
	Loading Dust	ASHRAE 52.2 Dust	ISO Fine	ASHRAE 52.2 Dust
	Conditioning	Optional: Appendix J (whole filter)	Mandatory: IPA Vapor (whole filter)	Mandatory: IPA Liquid (flat sheet)
	Conditioning Substance	0.03 µm KCl	IPA Vapor	IPA Liquid
	Conditioning Time	Efficiency measured after minimum increments of 6.4×10^7 particles/cm^3 min. Conditioning stops after no further significant drop in efficiency.	25 h	2 min soak
	Classification	MERV 4 – MERV 16	ePM1, ePM2.5, ePM10	G1 – G4, M5 – M6, F7 – F9
	Rating	Worst case	Average of initial and discharged condition	Worst case

Table 3.5: HVAC Filter Designations

Used with permission from AAF International, https://www.aafintl.com/.

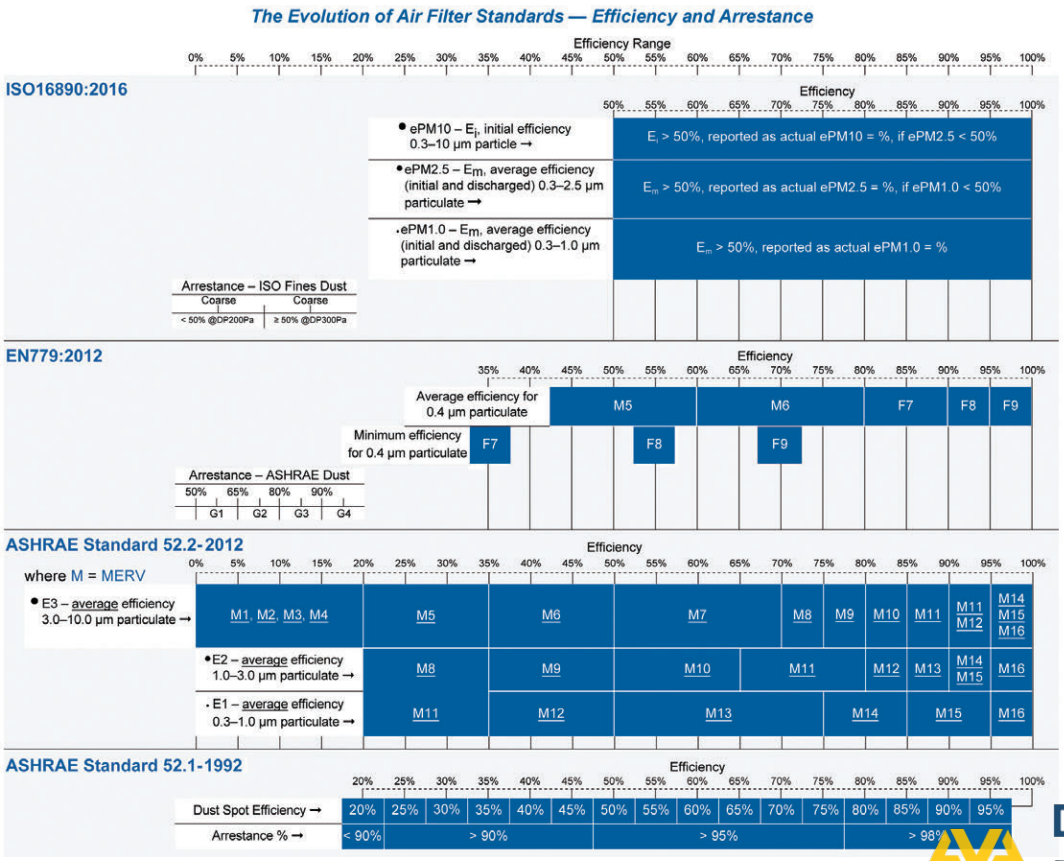

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Table 3.6: Comparison of EN 779 [45] and EN ISO 16890 [11] Rated Filter Classes
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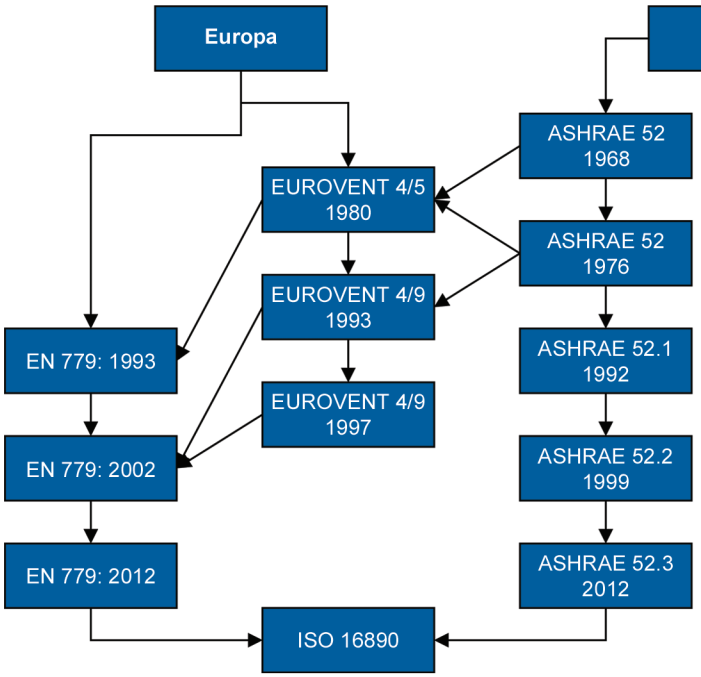
The direct conversion of EN 779 and EN ISO 16890 classes is not possible. To facilitate an indicative comparison, particularly for the purpose of replacing existing filters, the Eurovent Association has developed a table matching both EN 779 and EN ISO 16890 classes tested for the same filters.

The comparison shows the actual overlapping of EN 779 and EN ISO 16890 classes and was developed based on real test data of 91 filters provided by Eurovent Certita Certification.

ASHRAE 52.2	EN 779 2012	EN ISO 16890 – Range of Actual Measured Average Efficiencies		
Filter Class		ePM_1	$ePM_{2.5}$	ePM_{10}
MERV 10	M5	5% – 35%	10% – 45%	40% – 70%
MERV 11	M6	10% – 40%	20% – 50%	60% – 80%
MERV 13	F7	40% – 65%	65% – 75%	80% – 90%
MERV 14	F8	65% – 90%	75% – 95%	90% – 100%
MERV 15	F9	80% – 90%	85% – 95%	90% – 100%

Figure 3.1 summarizes the evolution of filter standards in the US and EU over the years and the harmonization into ISO 16890 [11].

Figure 3.1: History of HVAC Air Filter Standards
Used with permission from AAF International, https://www.aafintl.com/.



- In 1968, ASHRAE published the first unified standard which measured the arrestance, as well as the dust-spot efficiency with article test dust.
- In 1976, ASHRAE 52-76 was published introducing the atmosphere dust-spot efficiency.
  - Dust spot efficiency
  - Arrestance
  - Dust holding capacity
- Initial efficiency as a function of a particle size (MERV: Minimum Efficiency Reporting Value).
- This standard had many improvements over time. Some of the improvements are found in the ANSI/ASHRAE 52.2 standard. The improvement of the 52.2 standard allowed for the 52.1 standard to be retired.

3.3.6.2 EN 1822 [52]

EN 1822 [52] addresses higher levels of filtration including the EPA (Efficiency Particulate Air), HEPA, and ULPA filter classes from E10 to U17. EN 1822 specifies the requirements of the various EPA/HEPA/ULPA filter classes as shown in Table 3.7.

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Table 3.7: EN 1822 [52] Filter Classifications

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Filter Class	Particle Size for Testing	Global Values	
		Collection Efficiency (%)	Penetration (%)
E10	MPPS	≥ 85	≤ 15
E11	MPPS	≥ 95	≤ 5
E12	MPPS	≥ 99.5	≤ 0.5
H13	MPPS	≥ 99.95	≤ 0.05
H14	MPPS	≥ 99.995	≤ 0.005
U15	MPPS	≥ 99.9995	≤ 0.0005
U16	MPPS	≥ 99.99995	≤ 0.00005
U17	MPPS	≥ 99.999995	≤ 0.000005
Efficiency Particulate Air (EPA) filters = E10, E11, E12 High Efficiency Particulate Air (HEPA) filters = H13, H14 Ultra Low Penetration Air (ULPA) filters = U15, U16, U17			

3.3.6.3 BS EN 12469 [54]

BS EN 12469 [54] specifies the basic requirements for Microbiological Safety Cabinets (MSCs/BSCs) with respect to safety and hygiene. It sets the minimum performance criteria for safety cabinets for work with microorganisms and specifies test procedures for MSCs/BSCs with respect to the protection of the worker and environment, product protection, and cross-contamination.

3.3.7 IEST [22]

IEST [22] has established a filter rating system for the higher-grade filters. IEST Recommended Practices (RP), as listed in Table 3.8, may be used as references in the design, construction, commissioning/qualification, operational, and maintenance phases of a cleanroom's lifecycle.

Table 3.8: Listing of IEST Recommended Practices [22]

IEST Recommended Practice (RP)	Title
IEST-RP-CC001	HEPA and ULPA Filters
IEST-RP-CC002	Unidirectional-Flow, Clean-Air Devices
IEST-RP-CC003	Garment System Considerations for Cleanrooms and Other Controlled Environments
IEST-RP-CC004	Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments
IEST-RP-CC005	Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
IEST-RP-CC006	Testing Cleanrooms
IEST-RP-CC007	Testing ULPA Filters
IEST-RP-CC008	High-Efficiency Gas-Phase Adsorber Cells
IEST-RP-CC009	Compendium of Standards, Practices, Methods, and Similar Documents Relating to Contamination Control
IEST-RP-CC011	A Glossary of Terms and Definitions Relating to Contamination Control

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Table 3.8: Listing of IEST Recommended Practices [22] (continued)

IEST Recommended Practice (RP)	Title
IEST-RP-CC012	Considerations in Cleanroom Design
IEST-RP-CC013	Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments
IEST-RP-CC014	Calibration and Characterization of Optical Airborne Particle Counters
IEST-RP-CC016	The Rate of Deposition of Nonvolatile Residue in Cleanrooms
IEST-RP-CC018	Cleanroom Housekeeping: Operating and Monitoring Procedures
IEST-RP-CC019	Qualifications for Organizations Engaged in the Testing and Certification of Cleanrooms and Clean-Air Devices
IEST-RP-CC020	Substrates and Forms for Documentation in Cleanrooms
IEST-RP-CC021	Testing HEPA and ULPA Filter Media
IEST-RP-CC022	Electrostatic Charge in Cleanrooms and Other Controlled Environments
IEST-RP-CC023	Microorganisms in Cleanrooms
IEST-RP-CC024	Measuring and Reporting Vibration in Microelectronics Facilities
IEST-RP-CC025	Evaluation of Swabs Used in Cleanrooms
IEST-RP-CC026	Cleanroom Operations
IEST-RP-CC027	Personnel Practices and Procedures in Cleanrooms and Controlled Environments
IEST-RP-CC028	Minienvironments
IEST-RP-CC029	Contamination Control Considerations for Paint-Spray Applications
IEST-RP-CC031	Method for Characterizing Outgassed Organic Compounds from Cleanroom Materials and Components
IEST-RP-CC032	Flexible Packaging Materials for Use in Cleanrooms and Other Controlled Environments
IEST-RP-CC034	HEPA and ULPA Filter Leak Tests
IEST-RP-CC035	Design Considerations for Airborne Molecular Contamination Filtration Systems in Cleanrooms
IEST-RP-CC036	Testing Fan Filter Units
IEST-RP-CC040	Cleaning of Equipment Surfaces in the Cleanroom and Controlled Environments (under development)
IEST-RP-CC041	Recovery from Disruption to Cleanrooms and Other Controlled Environments (under development)
IEST-RP-CC042	Sizing and Counting of Submicrometer Liquid-Borne Particles Using Optical Discrete-Particle Counters
IEST-RP-CC043	Surface Molecular Contamination (under development)
IEST-RP-CC044	Vacuum Cleaners and Systems for Cleanrooms and Other Controlled Environments
IEST-RP-CC045	Design Considerations for Critical Exhaust Systems (under development)
IEST-RP-CC046	Contamination Control in Controlled Environments
IEST-RP-CC047	Cleanroom Lighting (under development)
IEST-RP-CC048	Guidance of Design, Performance, and Operations for Controlled Environments per USP 797 (under development)
IEST-RP-CC049	Controlled Environments for Regulated Industries

IEST-RP-CC001 [55] specifies the requirements for various HEPA and ULPA filter classes as shown in Table 3.9.

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Table 3.9: Recommended Test and Minimum Rating for Filter Types A Through K (from IEST-RP-CC001 [55])
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Filter Type	Particle Size for Testing (µm)	Global Values
		Collection Efficiency (%)
A	0.3 [a]	≥ 99.97
B	0.3 [a]	≥ 99.97
E	0.3 [a]	≥ 99.97
H	0.1 – 0.2 or 0.2 – 0.3 [b]	≥ 99.97
I	0.1 – 0.2 or 0.2 – 0.3 [b]	≥ 99.97
C	0.3 [a]	≥ 99.99
J	0.1 – 0.2 or 0.2 – 0.3 [b]	≥ 99.99
K	0.1 – 0.2 or 0.2 – 0.3 [b]	≥ 99.995
D	0.3 [a]	≥ 99.999
F	0.1 – 0.2 or 0.2 – 0.3 [b]	≥ 99.9995
G	0.1 – 0.2	≥ 99.9999

High Efficiency Particulate Air (HEPA) filters = A, B, C, E, H, I, J, K
Ultra Low Penetration Air (ULPA) filters = D, F, G
[a] Mass median diameter particles (or with a count median diameter typically smaller than 0.2 µm as noted).
[b] Use the particle size range that yields the lowest efficiency.

Although a comparison between the three major standards to relate exactly the relevant filter classes for higher grade filters is not possible, Table 3.10 provides a practical comparison of the filter classes for the IEST-RP-CC001 [55], EN 1822 [52] and ISO 29463 [51] filter standards.

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Table 3.10: Comparison of Filter Classifications (from IEST-RP-CC001 [55], EN 1822 [52] and ISO 29463 [51])
Used with permission from Norm Goldschmidt, Genesis Engineers, http://www.geieng.com/.

Designation	IEST-RP-CC001 [55] Filter Type	EN 1822 [52] Classification Filter Class	Particle Size for Testing	Global Value	Local Value	ISO 29463 [51] Classification Filter Class (Group)
				Collection Efficiency %	Multiple of Global Efficiency %	
EPA (Efficient Particulate Air Filter)		E10		> 85	-	
		E11	MPPS	≥ 95	-	ISO 15 E
			MPPS	≥ 99	-	ISO 20 E
		E12	MPPS	≥ 99.5	-	ISO 25 E
HEPA (High Efficiency Particulate Air Filter)		MPPS	> 99.9	-	ISO 30 E	
		H13	MPPS	≥ 99.95	5	ISO 35 E
	A		0.3*	≥ 99.97	-	
	B		0.3*	≥ 99.97	-	
	E		0.3*	≥ 99.97	-	
	H		MPPS	≥ 99.97	-	
	I		MPPS	≥ 9.97	5	ISO 40 E
	C		0.3*	≥ 99.99	1	
		H14	MPPS	≥ 99.995	5	ISO 45 E
	K	H14	MPPS	≥ 99.995	1.6	
ULPA (Ultra Low Penetration Air Filter)			MPPS	≥ 99.999	5	ISO 50 E
	D		0.3*	≥ 99.999	5	
	F	U15	MPPS	≥ 99.9995	5	ISO 55 E
			MPPS	≥ 99.9999	5	ISO 60 E
	G	U16	MPPS	≥ 99.99995	5	ISO 65 E
			MPPS	≥ 99.99999	10	ISO 70 E
		U17	MPPS	≥ 99.999995	20	ISO 75 E
Note: The EN 779:2012 differentiates between Medium Filter and Fine Filter. The intent is to have a clear segregation between Medium filter and the Fine Filter with a minimum efficiency. Please refer to the relevant standard for further details and data (i.e. retention, overall and local penetration).						

3.3.8 NSF/ANSI 49 [56]

NSF/ANSI 49 (Biosafety Cabinetry: Design, Construction, Performance, and Field Certification) [56] *"applies to Class II (laminar flow) biosafety cabinetry designed to minimize hazards inherent in work with agents assigned to Biosafety Levels 1, 2, 3, or 4. It also defines the tests that shall be passed by such cabinetry to meet this Standard. This Standard includes basic requirements for the design, construction, and performance of biosafety cabinets (BSCs) that are intended to provide personnel, product, and environmental protection; reliable operation; durability and structural stability; cleanability; limitations on noise level; illumination; vibration; and motor/blower performance."*

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3.3.9 BS 5295 (Withdrawn) [57] and PD 6609 [58]

British Standard BS 5295 [57] was the BSI guidance document for cleanrooms and HEPA filters. BS 5295 was withdrawn when the BSI formally adopted ISO 14644 [23] as the national standard for cleanrooms. After the BSI adopted ISO 14644, much of the content from BS 5295 related to HEPA filters was preserved in another Published Document (PD) from the BSI, BS PD 6609 (Environmental cleanliness in enclosed spaces – Guide to *in situ* high efficiency filter leak testing) [58]. If working in a locale in which PD 6609 may apply, it is important to be aware of the differences between PD 6609 and the test methods in ISO 14644-3 [33].

3.3.10 China GB and GB/T Standards

In China, the national standards are classified as either GB or GB/T. The GB standards are mandatory in China. The GB/T standards are recommended national standards but are not mandatory. The relevant Chinese national standards are the following:

- GB/T 25915 (Cleanrooms and associated controlled environments) [59] consists of six national standards in this series, with requirements similar to the ISO 14644 series [23]
- GB 50457 (Code for design of pharmaceutical industry clean room) [60]
- GB/T 36066 (Cleanrooms and associated controlled environments – Analysis and application of test technology) [61]
- GB/T 16292 (Test method for airborne particle in clean room (zone) of the pharmaceutical industry) [62]
- GB/T 14295 (Air filters) [63]
- GB/T 13554 (High efficiency particulate air filter) [64]

3.3.11 French NF-C Standards

In France, local authorities may expect local projects to meet the requirements of French Standard NF S90-351 (Clean rooms and related controlled environments in medical establishments) [65], which establishes standards for healthcare facilities such as cleanrooms for hospitals and operating blocks.

3.3.12 Japan JIS Standards

The Japanese Industrial Standards Committee (JISC) [66], Japan's national standardization body, plays a central role in developing standards in Japan covering a wide range of products and technologies from robots to pictograms. The JISC creates Japanese Industrial Standards (JIS) and is also responsible for Japan's growing contribution to setting international standards through its work with ISO [20] and the International Electrotechnical Commission (IEC) [67].

The relevant Japanese standards are the following:

- JIS Z 8122 (Contamination Control – Terminology) [68]
- JIS B 9920 (Classification of air cleanliness for cleanrooms) [69]

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4 Filter and Filter Housing Design and Construction

4.1 Filtration Media Structures and Media Manufacturing

4.1.1 Carded Media

The carding process separates and aligns staple fibers using a series of combs to produce a web. The carded web is sent to secondary operations, perhaps to cross-lap the web for transverse directional strength, and then is finished in a bonding process, typically an oven or other thermal method.

4.1.2 Spun Bond Media

Spun bond air filtration media are produced by depositing extruded spun filaments onto a moving belt in a uniform yet random manner, followed by bonding the fibers. The fibers are separated during the web laying process by air jets or electrostatic charges. The collecting surface is usually perforated to prevent the air stream from deflecting and carrying the fibers in an uncontrolled manner. The spun bond media process, since the fabric production is combined with fiber production, is generally more economical than when using staple fiber to make nonwoven fabrics, or instance filtration media made with carded webs.

4.1.3 Melt Blown Media

Melt blown filtration media, produced by melting and extruding polymers directly into a web, can be produced in a wide range of fiber diameters and web basis weights. Melt blown media are recognized for material uniformity, wide range of polymer capability, and ability to consistently meet key performance characteristics. Melt blown webs can be electrostatically charged to increase the attraction of particles.

4.1.4 Wet Laid Media

Wet laid air filtration media are generally produced on a paper machine with short synthetic or glass fibers suspended in a fluid, which are deposited onto a screen or porous surface where the fluid is removed, and the web is formed. The web consolidation bonding can be carried out mechanically, chemically, or thermally.

4.1.5 Air Laid Media

Air laid glass fiber air filter media are made by melting glass pellets and drawing the liquefied glass through a strainer before it is collected at a uniform depth on a belt and dried. Air laid media are characterized as being lofted (i.e., thicker and less dense), resulting in lower resistance to airflow and higher dust holding capacity per unit area. This media is only used in deep-pleated and bag/pocket style air filters.

4.1.6 Nanofiber Media

Nanofiber media offer a high fiber surface area without negatively impacting other performance characteristics, such as basis weight or caliper. Nanofiber coatings are formed with fibers typically ranging from 0.3 µm to 0.5 µm in size but can be increased up to 1 µm. The fiber diameter distribution and layer thickness can easily be varied according to the application requirements. This nanofiber layer, which consists of the nanofiber coatings, has a thickness in the range of 15 µm to 30 µm and is applied directly to the macro filtration substrate. The nanofiber web has a thickness of between 100 µm to 200 µm when supplied as a standalone substrate. The nanofiber web can be applied as a coating to any nonwoven base material, such as glass, cellulose, or synthetic fibers.

Figure 4.1 shows examples of nanofiber media applied to substrates.

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Figure 4.1: Examples of Nanofiber Media Applied to Substrates
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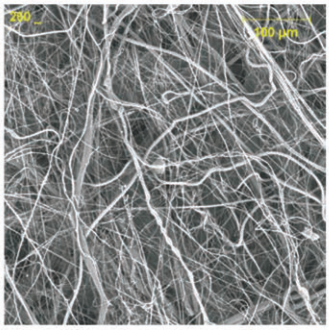
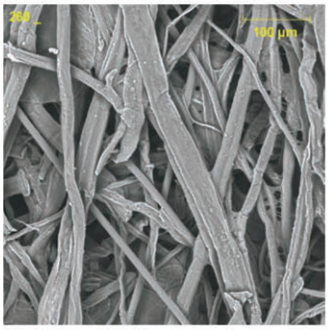
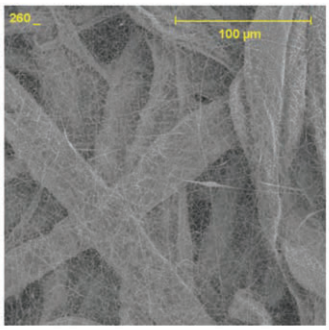


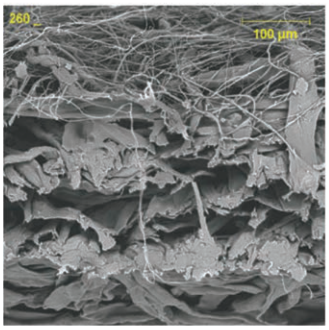
Top view of nanofiber coating, 260X.



Top view of standard cellulose media, 260X.



Top view of electrospun nanofiber coating, 260X.



Side view of nanofiber coating, 260X.

4.1.7 Needle Punched Media

Needle punched media are produced by using barbed needles to mechanically entangle the nonwoven web. Typically needle punching is used on the nonwoven carded webs to produce very strong yet lofty filtration media.

4.1.8 Electrostatically Charged Media

Electrostatically charged media are a high performance electrostatically charged nonwoven media used in air filtration. They have a high efficiency with lower initial resistance and with higher dust loading capacity. They exhibit a unique electrostatic charge that is beneficial for multiple air filtration applications such as HVAC and facemasks.

Electrostatically charged media can be an effective and energy-efficient air filtration media, but caution needs to be taken to evaluate and understand the efficiency of these filters after the electrostatic charge has been dissipated, as required by ASHRAE [26], EN, and ISO [20] standards. The designer needs to be aware of the requirements for rating these filters after the electrostatic charge has been dissipated, as specified in ASHRAE 52.2-2017 Appendix J [8], EN 779 [45] and ISO 16890 [11].

4.1.9 Membrane Media

Membrane media for air filtration are essentially limited to expanded polytetrafluoroethylene (ePTFE). ePTFE membranes are typically used as the fine filtration layer bonded within spun bond support layers to make the air filtration media. The ePTFE membrane is made from the compression of PTFE (polytetrafluoroethylene) powder suspended in oil that is then expanded in both the length and width dimensions, with the depth of the membrane being approximately the same thickness as prior to the expansion. ePTFE media are characterized by having approximately half the pressure resistance of glass fiber media and its mechanical strength. Semiconductor grade ePTFE media are susceptible to flooding by oil-based test aerosols, but pharmaceutical grade ePTFE media are available with the same initial tolerance of oil aerosols as micro-glass media.

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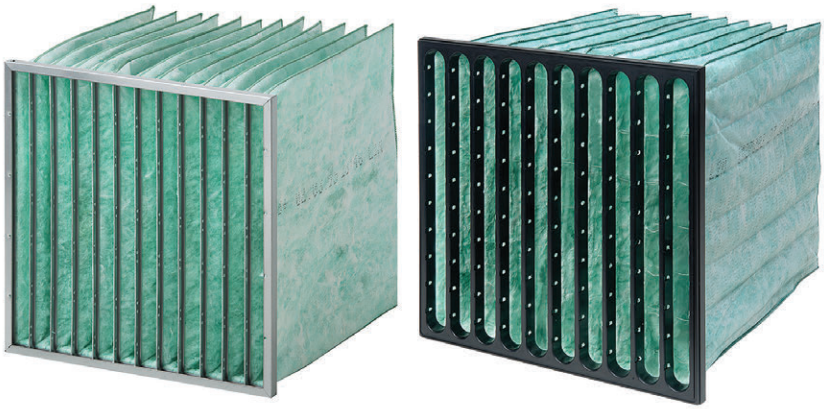
4.2 Filter and Filter Housing Construction

4.2.1 Bag Filter Prefilters

In pharmaceutical applications, bag filters are most often used as prefilters. A typical bag filter has a nominal dimension of 592 mm (2 ft) × 592 mm (2 ft) and consists of 4 to 12 parallel bags. The nominal length and depth of the bag filter varies from 300 mm (12 in) up to 900 mm (36 in). Bag filter media efficiency varies from very low (coarse fibers) to very high (fine fibers). The bag filter material is made of glass or polymer fibers of different sized fibers and different thickness or number of layers, depending on the required filter performance. Figure 4.2 shows an example of bag filters.

Figure 4.2: Example of Bag Filters
Used with permission from Camfil, https://www.camfil.com/en-us.



Because of the large media area, bag filters are expected to have longer service cycle times as compared to disposable pleated prefilters. The maximum length and depth of a bag filter that can be utilized in an air handling unit is dependent upon the design of the air unit.

Note: Bag filters can become a problem in Variable Air Volume (VAV) systems, especially if they deflate or collapse at low airflow rates. Consideration should be taken to understand how the specific bag filters will perform at minimum airflow and in pulsing and surging airflows before using them in a VAV system.

4.2.2 Pleated Prefilters

Pleated filters are most often used as prefilters in pharmaceutical air handling units. A typical pleated filter has a nominal dimension of 592 mm (2 ft) × 592 mm (2 ft) and consists of zig-zag pleated media. The length and depth of the pleated prefilter varies from 50 mm (2 in) up to 200 mm (8 in). Pleated prefilter media efficiency is low (mostly coarse fibers). The pleated prefilter media material is made of mostly polymer and glass fibers of different thickness or number of layers, and sometimes contains natural fibers, like cotton, depending on the required filter performance. Because of the low stiffness of some prefiltration media, wire reinforcement is needed for pleat formation and to provide filter strength. Prefiltration media can also be formed by heat setting pleats. Figure 4.3 shows an example of a pleated prefilter.

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Figure 4.3: Example of a Pleated Prefilter
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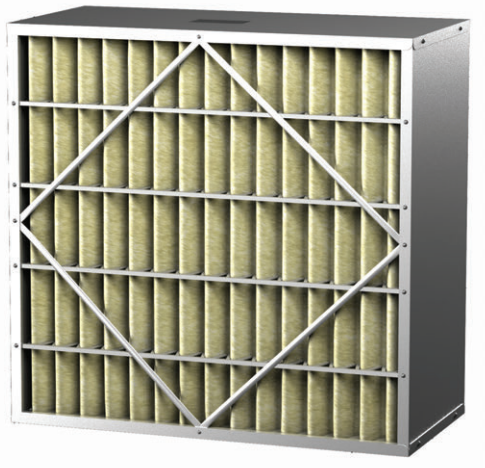
The service cycle of pleated prefilters is dependent upon the quality and amount of filtration media and the pleat design in the filter. Servicing of fully loaded pleated prefilters is easier than servicing fully loaded bag filters whose shape has collapsed with the weight of captured dust.

4.2.3 Rigid Filters

Rigid filters are designed to meet specifications in medium to high efficiency applications. Rigid filters are most often used as either prefilters or secondary filters in pharmaceutical air handling units. They are ideal for VAV systems where changes in airflow rates can have adverse affects on non-rigid (bag type) filters. A typical rigid filter has a nominal dimension of 592 mm (2 ft) × 592 mm (2 ft) and consists of media with controlled spacing through the use of flame retardant, plastic media separators, which are part of the filter framing. The nominal depth of the rigid filter varies from 150 mm (6 in) up to 300 mm (12 in). Rigid filter media efficiency varies from very low (coarse fibers) to very high (fine fibers). The filter media is a high density micro-glass fiber or synthetic fiber. The media is supported by heavy-duty metal backing to aid in maintaining its rigid configuration. Figure 4.4 shows an example of a rigid filter.

Figure 4.4: Example of a Rigid Filter
Used with permission from Camfil, https://www.camfil.com/en-us.



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The service cycle of rigid filters is dependent upon the dust capturing capability and the efficiency of the media in the filter. Servicing of fully loaded rigid filters is relatively easy even if fully loaded. The design (with or without header) and depth of a bag filter that can utilized in an air handling unit is dependent upon the design of the air unit filter frames.

4.2.4 Extended Surface Area (Low Pressure Drop)

Most modern air filters are developed with extended surface areas usually composed of pleated micro-glass, synthetic, or natural fiber media inside a frame. Flat panel (non-extended surface area) filters have to be made increasingly thicker to achieve higher efficiencies or with greater fiber densities, which can restrict the airflow. The larger surface area of extended surface area filters reduces the pressure drop and increases the capacity of the filter to remove particles, up to 50% over a standard flat panel filter. It also extends the lifecycle of the filter. While inexpensive flat panel filters need to be changed monthly in high use seasons to maintain optimal performance and efficiency, pleated extended surface area air filters generally have a minimum of three to twelve months, possibly longer, before recommended replacement.

4.2.5 Box Style Filters

Box style air filters have additional filter surface area and can be a direct replacement for older, less efficient rigid cell or bag filters. Box filters are designed for use in air filtration handler systems using filter banks and/or side access housings. These filters are specifically designed to withstand surging and pulsations due to variable airflow situations. Box filters provide a combination of low pressure drop and high efficiency through the use of aluminum separators or a mini-pleat design. This extended surface area design ensures low resistance to airflow and reduces energy cost. Bypass is often eliminated by the use of urethane sealants between the media and the filter housing.

Box filters come in variety of filter pack configurations—from designs similar to the rigid box, but with more media separated by glue beads (mini-pleat, greater area) or separated by narrow aluminum or plastic separators (separator style, greater area), to V-bank designs with even more media separated by solid glue beads with mini-pleat media packs in multiple *V's* within the same dimensions as the rigid box. Box filters are typically in the middle to high (HEPA) efficiency ranges, made with media that ranges from synthetics, micro-glass, and ePTFE membranes. Some box filters in the V-bank style are available with a combined particle and charcoal absorber, allowing the removal of particles and odors with a single filter cell.

Figures 4.5 through 4.8 show examples of box type filters.

Figure 4.5: Example of a Box Type Filter, Aluminum Separator Style for Air Handling Units – Middle to HEPA Efficiency
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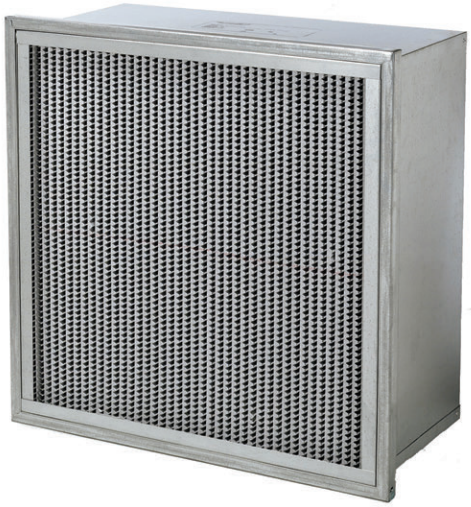

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Figure 4.6: Example of a Box Type Filter, V-Bank Style for Air Handling Units – Middle to High Efficiency
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Figure 4.7: Example of a Box Type Filter, V-Bank Style for Air Handling Units – HEPA Efficiency
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Figure 4.8: Example of a Box Type Filter, Mini-Pleat Style Terminal Cleanroom Filters – HEPA Efficiency
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4.3 HEPA Filters

HEPA panel filters provide fine airborne particulate control to meet the requirements of high technology cleanrooms, clean benches, and clean air devices. HEPA filters utilize micro-glass fiber or ePTFE media with efficiencies from 99.95% at 0.3 µm to 99.9995% at MPPS (Most Penetrating Particle Size). MPPS is typically between 0.1 µm to 0.2 µm for glass media and 0.05 µm to 0.10 µm for membrane media; It will vary with velocity but at normal design for a terminal filter, this range is accurate 80% of the time with a H14 filter at 90 FPM (0.45 m/sec), MPPS is 0.17 µm to 0.18 µm. The MPPS is typically identified in a factory scan test and noted on the HEPA filter label.

The HEPA filter active face area should be determined exclusive of the filter frame. For example, the gasket seal version of a HEPA filter may have an extruded aluminum frame with an industry standard 3/4 in flange, resulting in active face dimensions that are 1 in to 1-1/2 in smaller than the overall face dimensions. An additional subtraction also needs to be made if a center divider is present. Some manufacturers may base their calculations on overall dimensions which may be misleading. When comparing products, it is important to ensure performance data is provided in a consistent format. Figure 4.9 shows an example calculation of performance data.

Figure 4.9: Example of HEPA Filter Performance Data Calculation
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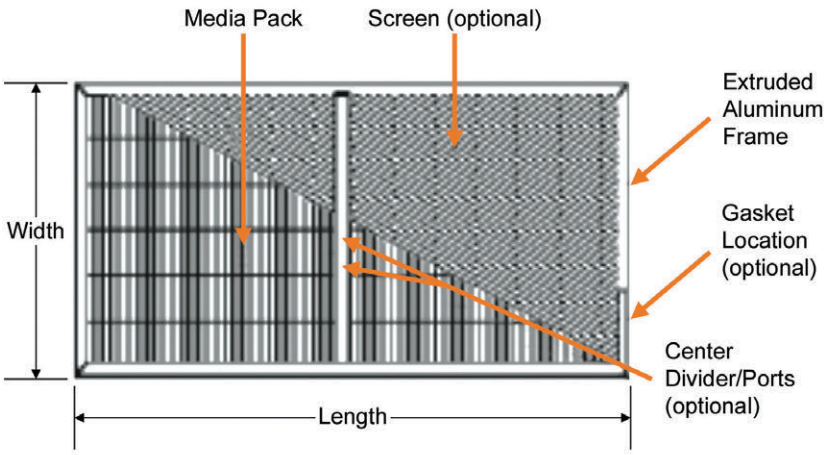

$$Q_{CFM} = V_{FPM} \times A_{ft}^2$$

Where:

Q = volumetric flow rate, CFM (ft^3/min)

V = filter face velocity, FPM (ft/min)

A = active face area, ft^2

A = {24 in − (2 × 0.75 in)} × {48 in − (2 × 0.75 in)} = 1046.25 in^2 or 7.27 ft^2

If V = 100 FPM, then Q = 727 CFM

Various framing materials and configurations are used for mounting HEPA filters into a wide variety of ceiling grid, housings, and equipment configurations, including:

- Center dividers and additional access ports
- Gaskets, profile, and materials

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- Face screens, various finishes, and materials
- Media choices including micro-glass fiber and PTFE

4.3.1 Sealing Techniques

4.3.1.1 Gel Seal

A common sealing technique is a gel seal. The filter frame is designed with an integral gel channel that is filled with a silicone or low outgassing polyurethane-based gel. The gel interfaces with an opposing knife edge integral to the ceiling grid, housing, or equipment. The gel offers a fluid seal integrity that makes it a good choice for filters that are difficult to install or frequently replaced. This technique is most often seen in bottom loading or room side replaceable applications. Figure 4.10 shows an example of a gel seal.

Figure 4.10: Example of Gel Seal
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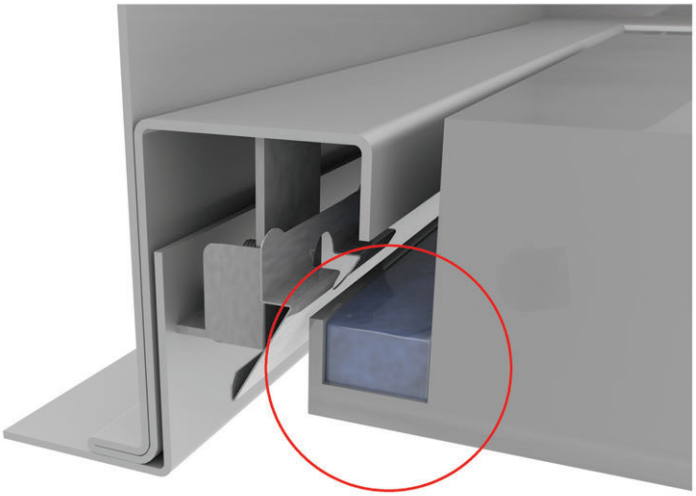

A filter guide within the grid or housing ensures that the HEPA filter fits properly to the gel-sealing knife edge of the housing. The filter should fit into place creating a uniform gel penetration and leak free filter perimeter seal. The filter is then secured into place with filter clamps.

The gel-penetrating knife edge affects a positive seal between the housing and the filter. The corner joints of knife edge junctures should be continuously welded to eliminate leak paths. A controlled depth knife edge design ensures that the filter will not bottom out in the track, eliminating metal to metal contact and the most common location for potential air bypass.

4.3.1.2 Gasket Seal

Another optional sealing technique is a gasket seal. Cleanroom seamless foam gaskets can be applied to either the upstream or downstream flange. The gasket is compressed between an opposing flange mating surface on the ceiling grid, housing, or equipment. Proper compression is important; too much can result in the gasket failing.

4.3.1.3 Knife Edge Seal

HEPA filter panels can also be produced in a frame with an integral knife edge. The knife edge interfaces with a gel channel that is integral to the ceiling grid or equipment. This technique is frequently seen in common plenum applications where the weight of the filter and pressure from airflow are all that is needed to affect a positive seal—no mounting hardware should be required. Figure 4.11 shows an example of a knife edge seal.

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