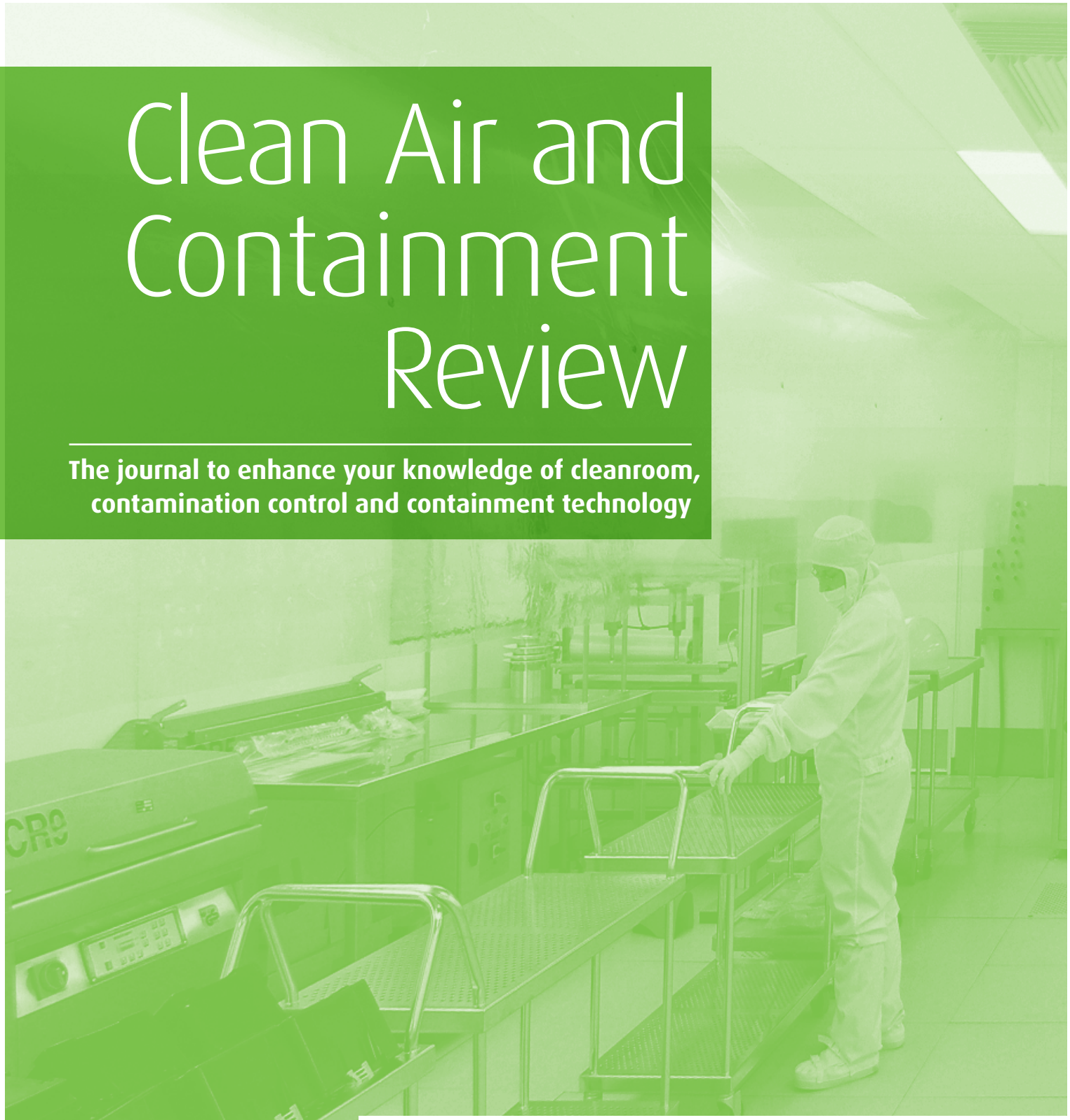
Clean Air and Containment Review

The journal to enhance your knowledge of cleanroom, contamination control and containment technology



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Clean Air and Containment Review is a quarterly journal aimed at users, specifiers, designers, manufacturers, installers and testers of clean air and containment equipment. It publishes articles of topical, technical and historical interest, updates on standards and regulations, news, views and information on relevant events, especially training.

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Editorial

Welcome to CACR 34. This issue starts with an article by Roberta Burrows and John Ensor of IEST. IEST serves as the Secretariat for ISO/TC 209, the ISO Technical Committee responsible for the development of the ISO 14644 and 14698 series of cleanroom standards. It is important that all cleanroom practitioners are aware of what is going on with these standards and of the enormous amount of voluntary work that is involved in their preparation and in their systematic review. The status of all the standards is summarised in a table that follows the article. The annual meeting of ISO TC/209 takes place in the autumn of each year and many of the Working Groups hold their meetings at the same time, so it is convenient to do the update on standards in the April issue that follows.

Three other main features follow. The first, by Bill Peters and Daniel Hillman of NuAire, concerns the question of whether HEPA or ULPA filters should be specified for biosafety (microbiological safety) cabinets. The next, by James Ellis of Hanningford Process Systems, describes three methods of achieving containment in powder milling operations. The third, by Helen Hale of Pharminox Isolation, proposes the ERS (Engineering Requirement Specification) as an additional validation document written specifically for equipment manufacturers and removing unnecessary information that all too often appears in a typical URS (User Requirement Specification).

As a technical publication it is appropriate that we pay tribute to the great Stephen Hawking who died in March. His sayings illustrate his wit, wisdom and sheer intellect. I have therefore chosen a selection of these for Life-lines on page 21. I think of him when I do the Mind Gym in my daily newspaper every morning. Whilst I struggle to hold a few simple numbers in my head as I carry out basic mental arithmetic, he must have held the most complex abstract equations of theoretical physics in his. What a mind! What a man!

I hope you enjoy this issue.

John Neiger

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ISO/TC 209 launches new cleanroom standards and outreach projects

Roberta Burrows, David Ensor

Abstract

US-led outreach task team will foster promotion and education of the expanding body of ISO/TC 209 Standards.

Keywords

ISO, TC 209, 14644, 14698, cleanroom, particle deposition rate, cleanroom consumables

Overview

The October 2017 ISO Technical Committee (TC) 209 meeting held in Sydney Australia centered on creating a coordinated approach for the standards within the committee's work program of *Cleanrooms and associated controlled environments*. The approach is well needed as ISO/TC 209 introduces two projects—a New Work Item Proposal (NWIP) ISO 14644-17 on particle deposition rates and a Preliminary Work Item (PWI) on the assessment of the suitability of consumables in cleanrooms.

Adding to the intensity of ISO/TC 209's workload are not only new projects, but mandatory ISO Systematic Reviews of published standards at five-year points in the standard's lifecycle. When the hallmark cleanroom standard *ISO 14644-1: Classification of air cleanliness* was proposed in 1993, ISO/TC 209 leadership estimated the work would only encompass ten standards. In 2018, the Secretariat anticipates having 20 documents within the ISO work program, with more than half in development or review. The current work program for ISO/TC 209 is shown in Table 1.

As often happens after standards are used in the field, interpretations develop that require subsequent clarification. To that end, the committee is laying groundwork to clarify important terminology used within the ISO 14644 standard series. Through outreach to user communities and harmonization of all projects within the work program, ISO/TC 209 moves proactively to fulfill the ISO mission "…to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity."

Delegates to the 29th meeting of ISO Technical Committee 209, hosted in October 2017 by Standards Australia in Sydney

Outreach task team

To foster a coordinated approach for the promotion and education of the 14644 and 14698 series standards, a new Outreach Task Team will be launched under the leadership of US Head of Delegation Anne Marie Dixon-Heathman. IEST, the ISO/TC 209 Secretariat and US TAG (Technical Advisory Group) Administrator, will lend support to the team, which is anticipated to comprise a global cross-section of ISO/TC 209's 21 voting member nations. The details of the scope and membership of the Outreach Task Team will be developed in the coming year. With the publication of each new ISO/TC 209 Standard, the Outreach Task Team will release complementary information to help advance understanding and usage. The information will be made available to ISO/TC 209 member nations for distribution and potential translation for their user communities. The core of the initial outreach will likely be a white paper from the Convenor of the ISO/TC 209 Working Group responsible for the development of each newly published standard. In the US, information will be distributed through IEST as the US member on behalf of ANSI.

Clarification of "class" and "cleanroom" concepts within 14644 Standards

With advancing technology demanding new requirements, ISO/TC 209 expanded its scope during the past decade to encompass not only the classification and control of air cleanliness, but the control of other attributes and characteristics. The newest remit of ISO/TC 209 takes on "Standardization for cleanrooms and associated controlled environments for controlling cleanliness, as well as other attributes and characteristics, relating to facilities, sustainability, equipment, processes and operations."

Historically, dating back to Federal Standard 209 standards, the focus was on airborne particle cleanliness. A "cleanroom" referred to a room developed primarily to provide a controlled airborne particle environment with known contamination concentrations. Approximately 15 years ago, many cleanroom users began requiring the control of other contaminants in addition to a controlled airborne particle environment.

Chemical contaminants were first elaborated in *ISO 14644-8: Classification of air cleanliness by chemical concentration (ACC)*, which focuses on air cleanliness in terms of airborne concentrations of specific chemical substances where the product or process is deemed to be at risk from air chemical contamination.

Table 1—Projects under the ISO/TC 209 title "Cleanrooms and associated controlled environments"

Document Number	Title of Part	Date for next action	Action
ISO 14644-1:2015 (Ed. 2)	Classification of air cleanliness by particle concentration	-	Standard published
ISO 14644-2:2015 (Ed. 2)	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	-	Standard published
ISO 14644-3:2005 (Ed. 1)	Test methods	-	Standard published; Ed. 2 in progress
ISO/DIS 14644-3	Test methods	6/8/2019 (IS)	Second DIS
ISO 14644-4:2001 (Ed. 1)	Design, construction, and start-up	-	Standard published; Ed. 2 in progress
ISO/PWI 14644-4	Design, construction, and start-up	-	NWIP
ISO 14644-5:2004 (Ed. 1)	Operations	1/15/2018	Systematic Review
ISO 14644-7:2004 (Ed. 1)	Separative devices (Clean air hoods, gloveboxes, isolators and mini-environments)	10/15/2018	Systematic Review
ISO 14644-8:2013 (Ed. 2)	Classification of air cleanliness by chemical concentration (ACC)	1/15/2018	Systematic Review
ISO 14644-9:2012 (Ed. 1)	Classification of surface cleanliness by particle concentration	1/15/2018	Systematic Review
ISO 14644-10:2013 (Ed. 1)	Classification of surface cleanliness by chemical concentration	1/15/2018	Systematic Review
ISO/DIS 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration	12/15/2019 (IS)	FDIS
ISO 14644-13:2017 (Ed. 1)	Cleaning of surfaces to achieve defined levels of cleanlinesss in terms of particle and chemical classifications	-	Standard published
ISO 14644-14:2016 (Ed. 1)	Assessment of suitability for use of equipment by airborne particle concentration	-	Standard published
ISO 14644-15:2017 (Ed. 1)	Assessment of suitability for use of equipment and materials by airborne chemical concentration	-	Standard published
ISO/CD 14644-16	Code of practice for improving energy efficiency in cleanrooms and clean air devices	12/9/2017	DIS
ISO/PWI 14644-17	Specification of requirements for particle deposition monitoring	-	NWIP
ISO 14698-1:2003 (Ed. 1)	Biocontamination control – Part 1: General principles and methods	10/15/2019	Systematic Review
ISO 14698-2:2003 (Ed. 1)	Biocontamination control – Part 2: Evaluation and interpretation of biocontamination data	10/15/2019	Systematic Review
ISO 14698-2:2003/ Cor 1:2004 (Ed. 1)	Part 2 Technical Corrigendum 1	-	

IS = International Standard; FDIS = Final Draft International Standard; DIS = Draft International Standard; NWIP = New Work Item Proposal.

ISO 14644-1 had provided the globally recognized ISO Class numbers 1-9, which represent a designation of the maximum allowable concentration of particles in a unit volume of air. ISO 14644-1 specifically stated in its scope that it could not be used to characterize the chemical, physical, radiological, viable or other nature of airborne particles. During development of ISO 14644-8, the experts adopted the use of a "class" designation indicating the level of air cleanliness by chemical concentration expressed in terms of an ISO-ACC Class *N*. The designation represented the maximum allowable concentration of a given chemical species or a group of chemical species, expressed in grams per cubic meter. Subsequently, *ISO 14644-9: Classification of surface cleanliness by particle concentration* and *ISO 14644-10: Classification of surface cleanliness by chemical concentration* followed a similar path, providing designations of ISO-SCC (surface cleanliness by chemical concentration) and ISO-SPC (surface cleanliness by particle concentration).

However, through feedback from member nations, ISO/TC 209 leadership

soon noted the process of "classification" as used in the 14644-8, -9, and -10 standards could be misinterpreted and used independently of the benchmark for cleanroom classification in ISO 14644-1 and result in construction of a "dirty cleanroom," if applied incorrectly. A Strategic Study Group created from ISO/TC 209 experts reviewed the issue and called for the terminology to be aligned.

In Sydney, ISO/TC 209 agreed that ISO 14644-8, -9 and -10 should be revised to remove the term "classification" and "class" from the text of the standards. The only "ISO Class" reference would be based on the criteria for class designation as spelled out in ISO 14644-1. A suitable replacement term for "class" will be decided in 2018. All three standards will be facing Systematic Review in the first quarter of 2018.

In an effort to clarify another terminology issue, the term "cleanroom" will only be used when ISO 14644-1 is applied, building upon historical precedent. When standards use other cleanliness attributes or characteristics (such as those listed in ISO 14644-8, -9, and -10 for airborne chemicals and chemicals and particles on surfaces), the term "controlled zone" will be used. The rationale for this change is that an important application of these standards will be cleanroom monitoring based on plans establishing critical control points, hence a "controlled zone."

Renewed focus on harmonization with new projects

Due to the expanding number of standards, ISO/TC 209 is stepping up efforts to harmonize all standards within the series to avoid conflicts as new projects are undertaken. To that end, ISO/TC 209 resolved that the new work project on particle deposition rates must align with the work already undertaken in *ISO/DIS 14644-3: Test methods*, as well as ISO 14644-9 as it moves through the Systematic Review process. The preliminary work project on consumables will also require harmonization with *ISO 14644-5: Cleanrooms and associated controlled environments—Operations*, which will also be under Systematic Review and potential revision beginning in 2018.

The year ahead

As outlined in Table 1, ISO/TC 209 leadership anticipates a high level of activity during 2018 by volunteers and by the Secretariat. It is expected that two standards will be published, a new standards project will be undertaken, and a number of Systematic Reviews may lead to new efforts that revise current standards. The 2018 ISO/TC 209 meeting is planned for the Netherlands, held in conjunction with the ICCCS Symposium, and is anticipated to be just as productive as the 2017 Sydney meeting.

Roberta Burrows is the Technical Advisor to IEST, the Secretariat to ISO/TC 209 on behalf of ANSI. She has served on the ISO/TC 209 Secretariat leadership team for twenty years.

David Ensor is Chair of ISO/TC 209. He has also served as Convenor for the US to WG 7 and WG 10.

IEST is the leading global nonprofit contamination control society and Secretariat for ISO Technical Committee 209 (ISO/TC 209), the committee developing the ISO 14644 Standards. IEST has served as the Secretariat for ISO/TC 209 for more than 25 years with an established international leadership role based on more than 45 years of expertise in cleanrooms and controlled environments.

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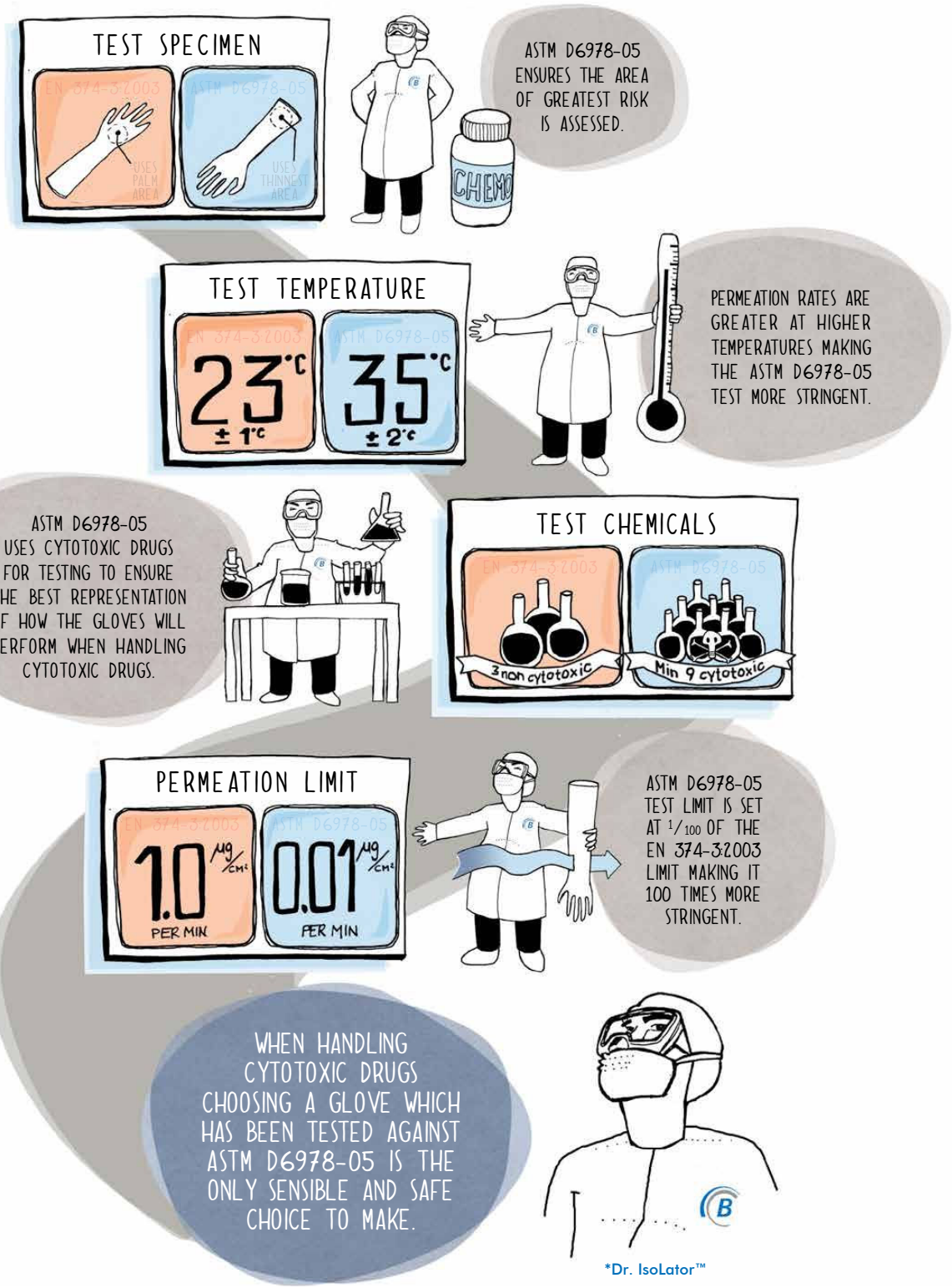

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Standards update summary

John Neiger

The following tables are intended to support and expand on the information in "ISO/TC 209 that launches new cleanroom standards and outreach projects" which starts on page 4.

Table 1 provides information on the status of all the standards in the ISO 14644 and ISO 14698 series of standards, including those that have been withdrawn, those that are current, those that are under review and those that are projected.

Table 2 gives details of two other related standards, one a published ISO standard on HEPA and ULPA filters and the other a European standard under development on microbiological control.

Table 1: ISO 14644 series of standards: Cleanrooms and associated controlled environments

Number	Title	Status
14644-1:2015	Part 1: Classification of air cleanliness by particle concentration	Published. This is the dominant standard. All other standards in the ISO 14464 and 14698 families can only use the term 'cleanroom' when ISO 14644-1 is applied. When other cleanliness attributes are used without being associated with ISO 14644-1, the term the term 'controlled zone' must be used.
14644-2:2015	Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Published. This standard is now a monitoring standard.
14644-3:2005	Part 3: Test methods	Being revised. A second DIS will be ready mid-2018 with the object of publishing the revised standard in June 2019.
14644-4:2001	Part 4: Design, construction and start-up	This standard is undergoing a major revision and is at the NWIP stage. It is intended that a CD is produced after the next meeting of WG4 in June for review by WG4 later in the year.
14644-5:2004	Part 5:Operations	Published. Voting in progress for review[i]
14644-6	Part 6: Vocabulary	Withdrawn in 2014. Definitions now in each individual standard.
14644-7:2004	Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	Published. Confirmed in 2014 following first systematic review. The next review will be in October 2018.
14644-8:2013	Part 8: Classification of air cleanliness by chemical concentration (ACC)	Published. Voting in progress for review.[i] When revised this standard will not be a classification standard and the term 'class' will not be used.
14644-9:2012	Part 9: Classification of surface cleanliness by particle concentration	Published. Voting in progress for review.[i] When revised this standard will not be a classification standard and the term 'class' will not be used.
14644-10:2013	Part 10: Classification of surface cleanliness by chemical concentration	Published. Voting in progress for review.[i] When revised this standard will not be a classification standard and the term 'class' will not be used.
14644-11		Number not used
ISO/DIS 14644-12	Specifications for monitoring air cleanliness by nanoscale particle concentration	DIS approved. FDIS soon. Ultrafine particles have been removed from ISO 14644-1 and are now in this standard.
14644-13:2017	Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications	Published. Covers precision cleaning, not janitorial.
14644-14:2016	Part 14: Assessment of suitability for use of equipment by airborne particle concentration	Published
14644-15:2017	Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration	Published

Number	Title	Status
ISO/CD14644-16	Part 16: Code of practice for improving energy efficiency in cleanrooms and clean air devices	WG13 has submitted a DIS to ISO. This will be issued for voting in late spring 2018.
14644-17	Part 17: Particle Deposition Rate – Measuring, setting limits and monitoring of macroparticles	New work item proposal (NWIP) discussed by WG14 in Stuttgart in March 2018
PWI (Preliminary Work Item)	Part X: Assessment of suitability for use of consumables	WG11 which developed Parts 14 and 15 is looking for international experts to develop this part.
14698-1:	Biocontamination control – Part 1: General principles and methods	Standard was reconfirmed in 2014. The next systematic review will be in October 2019.
14698-2:	Biocontamination control – Part 2: Evaluation and interpretation of biocontamination data	Standard was reconfirmed in 2014. The next systematic review will be in October 2019.

i. The review will determine whether the standard should be a) withdrawn, b) revised or amended, c) confirmed or d) confirmed with correction of errors. Comments are required with a), b) and d).

Table 2: Other related standards

Number	Title	Status
ISO 29463-1:2017	High efficiency filters and filter media for removing particles from air – Part 1: Classification, performance, testing and marking	Published. This standard sits alongside EN1822-1:2009 and IEST-RP-CC001.
CEN prEN 17141	Cleanrooms and associated controlled environments – Microbiological control	CEN TC 243 WG5, having produced this prEN (draft European standard) is in the process of refining it into a further draft for second enquiry by June. The intention is that when approved it will replace ISO 14698 Parts 1 and 2 in Europe.

HEPA versus ULPA: which filter should your biosafety cabinet use?

Bill Peters, Daniel Hillman

Abstract

This article sets out to explain the function and airflows of the most widely used Class II BSC (biosafety cabinet) in both the US and Europe. The two key standards for BSCs are NSF/ANSI 49 for the USA and EN 12469 for Europe. HEPA (High Efficiency Particulate Air) and ULPA (Ultra Low Penetration Air) air filters are described with reference to IEST-RP-CC001 for the USA and EN 1822 for Europe. The article concludes that HEPA filters are perfectly adequate for BSCs whereas ULPA filters have a higher initial cost, a shorter working life and a much higher energy requirement.

Introduction

A biosafety cabinet (BSC) is one of the most important pieces of equipment in virtually every laboratory that handles low-to-moderate risk biological materials. A BSC maintains a safe environment for personnel, and prevents cross-contamination of the work product in industries such as large healthcare providers, testing facilities, or pharmaceutical manufacturers. Among the many important components determining the effectiveness of a BSC, the most critical is the air filter.

HEPA vs. ULPA filters

There are two primary types of air filters used in BSCs: HEPA (High Efficiency Particulate Air), and ULPA, (Ultra-Low Particulate Air). Understanding the similarities and differences between HEPA and ULPA aids in selecting the filter which offers the best combination of performance and capability for the specific needs of an organization.

BSC operation

A BSC is an enclosed, ventilated, laboratory workspace with a blower fan, airflow plenums and grill patterns, a work area with an opening for a technician's hands at the front, a transparent front panel to allow sight of the interior, and a control panel to monitor and adjust system functions.

Standards

There are a variety of standards that define basic performance parameters of a BSC. The most widely used and accepted are NSF/ANSI 49[i] and European Standard EN12469.[ii] These biosafety cabinet standards were created by development organizations with all stake holders participating and continue today to maintain and define minimum standards of how a cabinet should operate. Standards allow lab personnel to compare offerings from competing companies and better plan purchases.

Negative pressure

There are several types of BSC but all share a common operational principle. Blowers force air through the cabinet to create a work area under negative pressure relative to the surrounding environment. This area of negative pressure isolates materials (product protection) inside the cabinet.

A concept from fluid dynamics known as "Bernoulli's principle" can describe the creation of negative pressure due to the movement of air within a BSC. Bernoulli's principle states, in part, that an increase in the speed of a fluid occurs simultaneously with a decrease in pressure. In this case, the air inside a BSC acts as a fluid, the velocity of which is increased by means of a blower. As the velocity of the air increases, the pressure of the moving air decreases creating the negative pressure necessary to operate a BSC.

Bernoulli's principle also describes the creation of lift by an airplane wing. The air flowing over the top of the wing must move a greater distance around the wing in the same amount of time as the air flowing along the bottom moves a shorter distance – see Figure 1. This pressure differential creates lift.

The most widely used type of Class II BSC, the Type A2 – see Figure 2 – uses a blower [A] to circulate air in the cabinet – through the main downflow HEPA or ULPA air filter [F], down through the work space [C], through the front and rear grills in the work surface into the bottom of the cabinet [D]. Additional air [H] is pulled through the front grill from the lab into the bottom of the cabinet [D] underneath the work surface. The combined airstreams are drawn up the back of the cabinet [E] to the top again. At that point, some of the air is recirculated though the downflow filter [F], with the rest of the air [G]

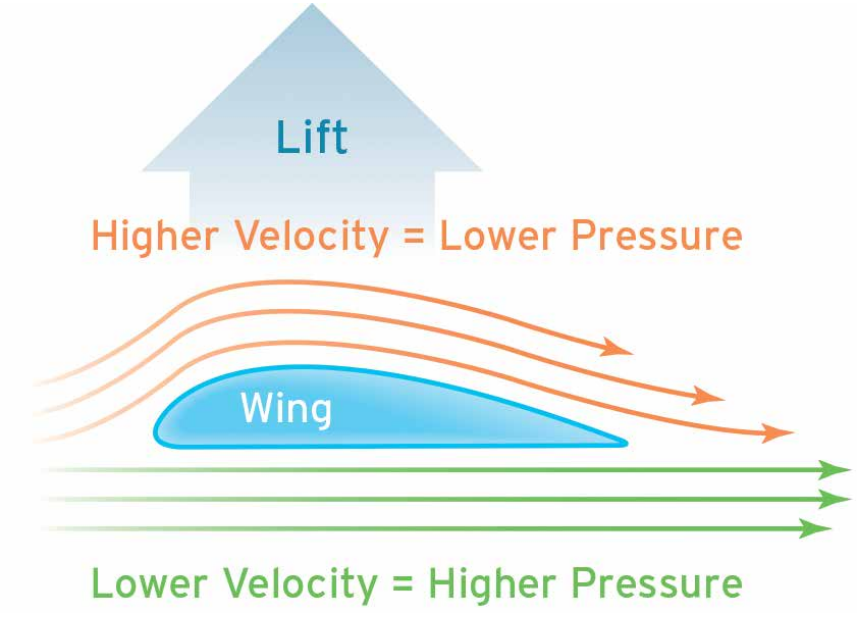


Figure 1: Airflow past an airplane wing

either discharged into the lab through the exhaust filter [B] or through the facility's exhaust system. The discharged portion of air [G] balances the additional air [H].

The velocity of the air creates negative pressure, preventing air from escaping through the user access opening of the workspace. In addition, the cabinet design creates unidirectional airflow, which means air passes smoothly around object in the work area, including the hands of personnel, minimizing turbulence and the chance of cross-contamination between samples. The operation depends on the design and integrity of the cabinet, the power of the blower, and the air filter.

The role of the filter

The filter is integral to the safety and protection of personnel and of the materials in the work space. Without the filter, air passing over the work space could pick up contaminants, cycle them through the cabinet, and deposit them on the work product, creating cross-contamination.

The filter removes airborne particulate from all air delivered into the work space. Some of the particle types that such a filter traps are bacteria, viruses and spores. However, a HEPA or ULPA filter is gas-permeable, so odours, vapours or chemicals such as acetylaminofluorene[1] can remain in filtered air.

Test standards

There are two different types of filters used in BSC designs: HEPA and ULPA. However, there are multiple test standards in use for the two filter types, which can create confusion. The US BSC standard NSF/ANSI 49 applies the Institute of Environment Sciences and Technology's IEST-RP-CC001[iii] filter standards and classifications for both HEPA and ULPA. The EU's EN 12469 BSC standard applies European Standard EN1822-1.[iv] Each has a different approach to measurement. IEST-RP-CC001 uses photometers and particle counters to test the efficiency with which particles of a particular size are removed from the air stream. EN1822-1 uses particle counters or differential mobility analyzers to determine the removal efficiency of the most penetrating particle size (MPPS), which can change with such factors as filter media fibre size or air flow rate.

Which standard a manufacturer uses depends on how the BSC is marketed, whether NSF/ANSI 49, EN 12469, or elsewhere (either standard or other specifications may be used).

HEPA

HEPA filters are widely used in BSCs and also in facilities such as hospitals. HEPA filters remove airborne particulates, allergens, bacteria, and other materials that could cause health problems, or cross-contamination, if allowed to remain airborne.

Standard NSF/ANSI 49 specifies the use of type C or J HEPA filters in a BSC. Under testing method IEST-RP-CC001, a type C HEPA filter must remove particles of 0.3 microns in size with an efficiency of at least 99.99 percent. A type J HEPA filter must remove 99.99 percent of particles from 0.1 to 0.2 microns or from 0.2 to 0.3 microns. HEPA filters are capable of removing particles above and below these size ranges but the efficiency will vary from that of the specified particle sizes. EN standard 12469 specifies the use of H14 filters or better. Under testing method EN1822-1, a filter's efficiency is defined by MPPS (Most Penetrating Particle Size) based on velocity of air flowing through the filter media. The test does not look for a specific size of a particle passing through the filter like IEST but instead defines the filter's efficiency based on the percentage of particles penetrating the filter media. IEST-RP-CC001 and EN1822-1 filter specifications are shown in Table 1.

Both HEPA and ULPA filters use mats of randomly arranged boron silicate fibres – typically of fibreglass – that range in size from 0.5 microns to 2.0 microns – see Figure 3. Unlike a sieve or screen, the filter does not prevent the passage

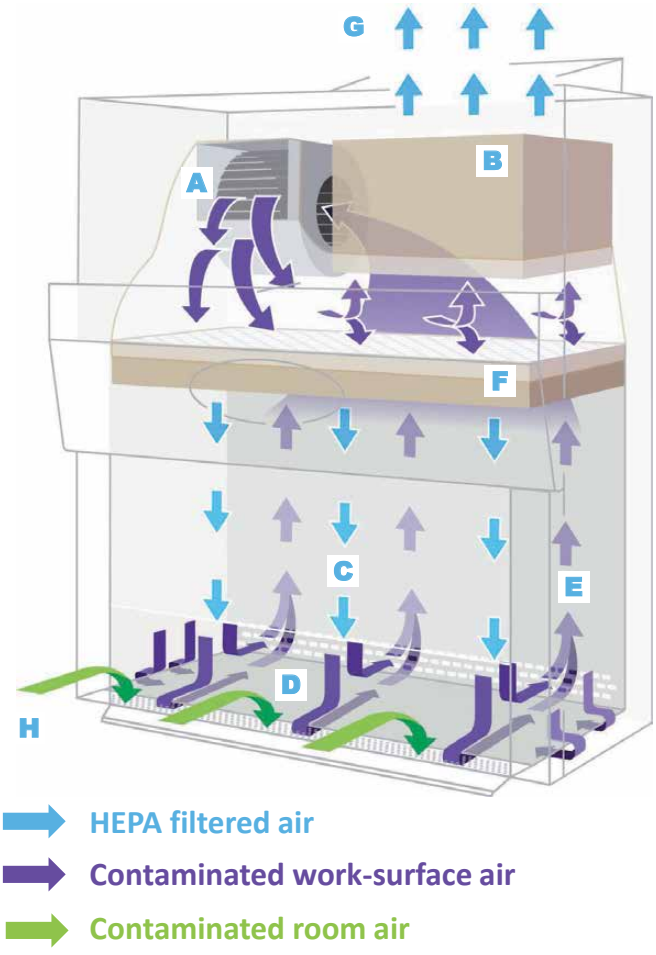


Figure 2: Class II Type A2 BSC airflows and filters

1. A chemical that is used as a tool in the study of the formation of cancer cells

of particles by only offering openings smaller than the size of particles being filtered. If that were the strategy, the holes might quickly fill, requiring more frequent filter replacement.

Instead, the filter relies on several physical mechanisms, as well as electrostatic attraction, that cause the particles to become stuck on the fibers inside the filter.

Because the air passages through the filter are not blocked, a filter can have a long life span. In a BSC, a HEPA filter life span would typically run between five and 15 years, creating a long mean time between replacements thus reducing costs.

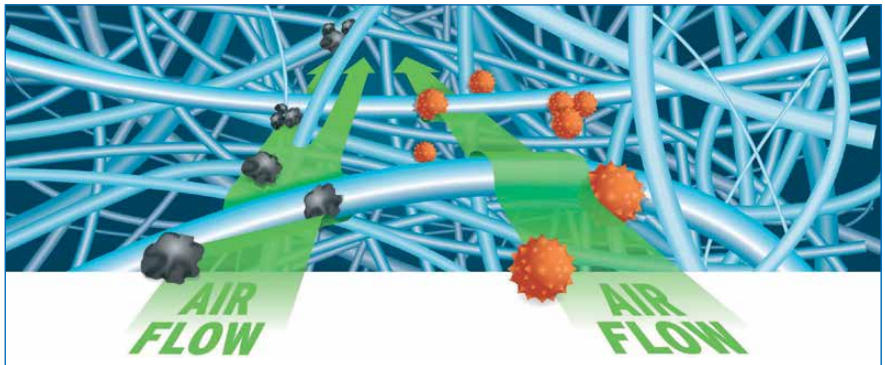
In addition, HEPA filters offer minimum pressure drop and maximum airflow in operation. Air moves easily through them and relatively little power is needed to overcome restrictions.

ULPA

ULPA refers to an air filter using fabrication technology similar to that of a HEPA filter, but with different performance standards. Like HEPA standards, ULPA standards vary in their definitions. Standard NSF/ANSI 49 specifies the use of Type F and K ULPA filters. Under testing method IEST-RP-CC001, a type F ULPA filter and must remove 99.999 percent of contaminants either between 0.1 microns and 0.2 microns or between 0.2 microns and 0.3 microns. A type K ULPA filter must remove 99.995 percent of particles from 0.1 to 0.2 microns or from 0.2 to 0.3 microns. As with HEPA filters, a ULPA filter can remove particles both larger and smaller than the test size. The specification sets a minimum efficiency, which means ULPA filters remove more material from the air than HEPA filters. Under EN1822-1, to be classified as a ULPA filter, the necessary efficiency is 99.9995 percent at MPPS.

The increased filtering does come at a price. ULPA filters are typically 35 percent more expensive than HEPA filters. HEPA filters average a 10-year lifespan while ULPA filters typically last between 5 and 8 years. ULPA filters also, on average, allow 20 percent to 50 percent less air through than HEPA filters. To move the same volume of air through a ULPA filter of the same dimensions will take significantly more pressure than would be necessary with a HEPA filter. A filter with a larger depth will have a larger area of filter media, thus requiring less pressure for the same volume of air, but that would increase the height of the BSC.

Readers should note that HEPA and ULPA filters are also specified in ISO 29463-1:2017[v] but this does not alter the thrust of this article.



Airborne particulates such as dust or mold spores are prevented from passing through a HEPA filter by collision with filter media fibers, as well as electrostatic attraction, causing the particles to be trapped inside the filter

Figure 3: Filtration mechanisms

Table 1: HEPA and ULPA filter standards

	BSC Standard	Testing Method	Filter Type	Efficiency
HEPA FILTERS	NSF/ANSI 49	IEST-RP-CC001	HEPA Type C	99.99% @ 0.3 micron
	NSF/ANSI 49	IEST-RP-CC001	HEPA Type J	99.99% @ 0.1-0.2 or 0.2-0.3 micron
	EN12469	EN 1822-1	HEPA H14	99.995% @ MPPS
	BSC Standard	**Testing Method**	**Filter Type**	**Efficiency**
ULPA FILTERS	NSF/ANSI 49	IEST-RP-CC001	HEPA Type F	99.999% @ 0.1-0.2 or 0.2-0.3 micron
	NSF/ANSI 49	IEST-RP-CC001	HEPA Type K	99.995% @ 0.1-0.2 or 0.2-0.3 micron
	EN12469	EN 1822-1	HEPA U15	99.9995% @ MPPS

Choosing between HEPA and ULPA

The distinction between HEPA and ULPA style filters can be unclear given the range of testing methods per BSC standard. For example, a filter that is 99.995 efficient at a most penetrating particle size might be classified as a HEPA H14 under testing method EN1822-1 (EN12469). However, that same filter could also be classified as a Type K ULPA filter if tested using method IEST-RP-C001 (NSF/ASNI 49). In light of this, the most reliable method for choosing a filter type involves the consideration of the intended purpose of the filter. The following four factors are important considerations when choosing a filter.

Filter standard

A BSC is designed to work with filters which meet a defined standard, typically IEST-RP-CC001 or EN1822-1. Choose a filter that meets the appropriate standard for the BSC.

Level of filtering

The primary purpose of a HEPA or ULPA filter is personnel safety and protection of the work product. A ULPA filter will remove particles with greater efficiency than a HEPA filter of the same dimensions. However, the degree of filtration necessary depends on the type of work being conducted in the BSC. For most biomedical applications, HEPA offers more than adequate filter efficiency to protect personnel and prevent work cross-contamination.

An ULPA filter will function in a BSC, but the level of filtration efficiency is typically far higher than necessary,

providing limited, if any, benefit over the use of a HEPA filter.

Price

ULPA filters are more expensive than a HEPA filter of the same dimensions. Additionally, ULPA filters have a shorter service life than HEPA filters, increasing maintenance costs due to more frequent replacement.

BSC configuration

The difference in amount of air that can pass through a ULPA versus a HEPA filter has significant implications. The operation of a BSC depends on engineering, manufacturing, and operations that permit the level of air flow necessary to maintain the proper amount of negative pressure in the cabinet.

A ULPA filter slows the air flow by 20 percent to 50 percent compared to a HEPA filter. To maintain the same air flow and resulting protective measures of the cabinet, either the filter media area must be enlarged by increasing the depth of the filter, or the power of the blower increased.

Both of these options increase the initial cost of the BSC. Both also increase operating expenses through the shorter life of the ULPA filters and in the case of more powerful blowers, through much higher energy costs.

Conclusion

The choice of whether to install HEPA or ULPA filters in a BSC has short and long-term implications for lab management. HEPA filters meet or exceed the filtration needs for biological work in a BSC. ULPA filters provide no distinct advantage for scientific research and are more commonly employed in the semi-conductor industry. Filter costs with HEPA filters will be lower as will the configuration price of the BSC. Less power is required to run a blower when a HEPA filter is in use, lowering energy costs. In theory, since HEPA filters allow more air to pass through the filter media than ULPA filters, a HEPA filter will take longer to reach maximum load resulting in a longer life. Filter replacement costs and blower maintenance expenses will also be lower, leading to a more economical installation.

i. NSF/ANSI 49-2016: Biosafety Cabinetry: Design, Construction, Performance and Field Certification, ANSI American National Standards Institute

ii. EN 12469: 2000: Biotechnology - Performance criteria for microbiological safety cabinets, CEN European Committee for Standardization

iii. IEST-RP-CC001: HEPA and ULPA Filters, IEST Institute of Environmental Sciences and Technology

iv. EN1822-1:2009: High efficiency air filters (EPA, HEPA and ULPA) - Part 1: Classification, performance testing, marking, CEN European Committee for Standardization

v. ISO 29463-1:2017: High efficiency filters and filter media for removing particles from air – Part 1: Classification, performance, testing and marking, ISO International Standards Organisation

Bill Peters is Vice President of Engineering at NuAire

Daniel Hillman is Biosafety Product Engineer

NuAire manufactures ergonomically designed and engineered scientific laboratory equipment providing personnel, product and/or environmental protection in critical research environments. NuAire's extensive line of laboratory equipment includes: Biosafety Cabinets, Animal Research Products, CO_2 Incubator, Laminar Airflow Products, Polypropylene Fumes Hoods & Casework, and Centrifuges.

Achieving contained (dust-free) milling

James Ellis

Abstract

Implementing a closed system for handling material with strict OEL/OEB requirements is becoming a growing challenge for pharmaceutical manufacturers. This article outlines the challenges and offers real-world solutions for achieving genuine contained milling.

While there are numerous methods to achieve containment, this article will primarily focus on:

- container-to-container milling,
- in-line vacuum transfer,
- milling inside an isolator.

Introduction

The increasing use of high-potency APIs has led to a need for total process containment (including dust-free milling). Ingredients are often hazardous and can be dangerous to both the environment and personnel if mishandled – this is a particular concern during milling, a process often associated with dust generation.

To protect both the operator and the process environment, it is important to consider how to overcome this problem, preferably without restricting throughput.

Glossary of initialisms

OEL:	Occupational Exposure Limit
OEB:	Occupational Exposure Bands
API:	Active Pharmaceutical Ingredient
IBC:	Intermediate bulk container
ATEX:	Explosive atmosphere

Container-to-container milling

This solution uses the principle of gravity to feed product through the mill. By positioning a container or IBC above the mill, and another container below the mill, product is released from the top container through a split butterfly valve, milled, and then passes directly through a split butterfly valve into the bottom container, as shown in Figure 1. This process configuration is best achieved by utilising a hoist to position the top IBC and allows for easy and repeatable handling. This keeps the product contained without affecting throughput.

Containment:
with dust-tight transfer between the bins, the powder flows down using gravity. This keeps the process in-line and protects the operator from exposure to the product. To allow for the displacement of air during the transfer process the lower container must be fitted with a vent-filter.

Throughput:
the in-line nature of the process is optimal and compact, and while this system will not compete with the speed of transfer achieved using vacuum, the ease of bin changeover (either feeding drum or receiving drum) can offer capacity advantages over existing process methods.

This creates a totally contained, in-line solution for dust-free milling. Not only does this contain the product during the milling phase, but this is also a simple and effective method for transferring product from bin-to-bin and cone milling the product during transfer, thus avoiding double-handling.

Figure 1: Conical mill with high containment split valves installed on inlet / outlet (photo Hanningfield Process Systems)

In-line vacuum transfer

Integrating vacuum transfer with milling offers a variety of benefits. Not only does this method keep the powder fully contained, it also increases throughput, keeps the product cool and enables faster transfer to the downstream process.

Containment:
the dust-tight transfer method ensures the powder is contained within the system. This protects the operator from exposure to the product, while minimising waste by preventing spillage.

Increased throughput:
rather than relying on gravity, in-line vacuum transfer actually pulls the product through the mill. This can dramatically increase the feed rate of the mill and help to boost throughput.

Keeps the product cool:
as the air used to transfer the product passes through the machine housing, this will help to keep the internal components of the mill and product itself cool. Reduced processing temperature helps to prevent caking and unwanted changes to the material characteristics.

Faster transfer to downstream process:
by using the system to manipulate the transfer process, the product can be easily transferred to a downstream process. This helps to transform dual-stage processes into a single process, by eliminating unnecessary storage and transportation. For example, the product can be transferred from the drum through the mill and directly into the receiving IBC.

Feeding and discharging from a cone mill using vacuum is a particularly effective method for achieving dust-free milling. Using an in-line vacuum transfer system (such as the Hanningfield Uni-Vac) offers a variety of benefits, enabling the material to be automatically fed into the inlet chute and automatically drawn from the outlet of the mill (to a downstream process). This ensures that from pick-up to discharge, the system is fast and fully contained.

Alternatively, instead of vacuum transfer through the mill, the vacuum hopper can be situated on top of the mill to discharge directly into the inlet.

Isolator milling

Another method for containing powder during milling is the use of an isolator or 'glove-box' to ensure all excess material remains contained. This ensures the fine dust particles are not exposed to either the atmosphere or operator during processing.

Cone mill integration within the isolator is performed by means of a through-the-wall fixing flange. This

Figure 2: Isolator milling – the milling head is contained within the isolator, with the motor and controls mounted externally (photo Hanningfield Process Systems)

fixing flange and particular configuration of the cone mill allow for a physical division of the cone mill head from the technical area that is left outside the isolator. Thanks to this special configuration, all cone mill cleaning operations are performed within the isolator by means of gloves or half-suit, reducing any risk of exposure for the operator and avoiding any transport to the cleaning room.

Containment:
an isolator is one of the most widely recognised and widely adopted means of containment. Indeed, the purpose of the isolator is to prevent exposure, with typical operator exposure levels of < 0.1 µg/m^3.

Throughput:
at first thought, the isolator may represent an obstacle to increased throughput. However, by minimising the need for operator suiting or cumbersome containment, the purpose-built nature of the isolator provides a safe and ergonomic method for milling.

Another benefit of isolator milling is for achieving a zoned area such as ATEX. The isolator itself can be designed to create an ATEX environment for milling, ensuring the entire process environment (including motors and controls) do not need to be changed to comply with the necessary requirements.

Conclusions

In a modern process, containing dust is extremely important. This can be easily achieved during the cone milling stage, simply by employing one of the methods listed above. Each solution will be more or less suited to any particular application.

James Ellis, BSc (Hons), is a Director at Hanningfield Process Systems. James is the son of company founder Colin Ellis and been around the family business since a young age. He joined the company full-time in 2009 following graduation from the University of East Anglia. James is experienced in providing contained powder handling and processing solutions to customers who work with highly potent powders in the pharmaceutical and related industries.

Equipment Requirement Specification – a way to clarity?

Helen Hale

Abstract

The User Requirement Document (URS) for equipment is often used as a 'catch-all', often full of irrelevant information for an equipment manufacturer. This paper introduces the idea of an Equipment Requirements Specification (ERS). Whilst the URS has been used for many years, it has often caused confusion, replication of ideas and standards, leaving the manufacturer to wade through, what is often a large and complex protocol, in the hope of identifying the specifications and data they need. It could be argued that the URS is an internal document therefore. There is another document that could be used for the external / manufacturer use, and that is an Equipment Requirements Specification protocol. Whilst this may contain much of the information in the URS, it is more honed to the equipment requirements and not the processing that will be carried out in the isolator, thereby reducing the initial developmental timescale.

Introduction

When is a URS (User Requirement Specification) not a URS? The answer is when it is an ERS (Equipment Requirement Specification). Yes, yet another acronym, but potentially a useful one. How many times have we heard: *"Well, that wasn't what the URS requested"* or *"That wasn't what we meant"*. Isn't it perhaps time to take a step back, and actually look at what a URS is intended to do.

URS

By definition, the URS lays out what the user wants. It is not necessarily aimed at the person building equipment and can often include a lot of information on the process to be carried out using the equipment. This is no bad thing, but extra complication can lead to confusion, which will at best force changes during the equipment build, and in some cases, lead to delivery of unusable equipment. We also see a lot of duplication, especially if there is more than one piece of similar, but not identical equipment, or where there are specific additions to batches of equipment with the same overall design parameters. These problems lead to delays and rejection of equipment due to non-compliance with the URS or, indeed, significant deviation from what the client thought they had ordered.

Tim Coles has previously explained how easy it is to generate confusion when writing a URS, and guided the reader to a practical way of avoiding this pitfall.[i] However, even though all of the advice is most certainly relevant, we are still seeing complicated, confusing, and repetitious URS documents and experiencing difficulties as a result.

Brainstorming

Clearly, the URS is a good and conventional starting point, but in some instances, it looks more like a brainstorming document developed by a committee consisting of interested parties. Sometimes this can just be the validation team, but other times it can be made up of a team ranging from senior management right through to the operators. However, a brainstorming exercise[ii] resulting in a brainstorming document (BSD) does not help to describe the equipment, apart from ensuring all thoughts are gathered in one place. We have to take care here because once finalized, the URS is the point from which a series of other protocols flow. So, one could suggest that some form of brainstorming document, might come before the URS. You would have thought so, but it seems that some URS protocols just grow like topsy and, very quickly, become not only unworkable, but also unvalidatable.[iii]

So, for the brainstorming exercise, imagine a group of like-minded people from the relevant groups needing new equipment, gathered together in a room with an appointed leader, a white board and a marker. Mind maps, exploding diagrams, thoughts, desires and dates, all up there for everyone to see. This is a good place to gather information, but this should not be repeated verbatim in the URS. Surely, a cost benefit exercise needs to be carried out, together with an analysis of what is actually required, against what is desired. Both the level of investment and any regulatory restrictions need to be considered, but there is nothing wrong with moving things from "this is what we've always done", to "doing it this way actually helps us to move our business forward". We will always see people who would rather keep everything nice and cosy, and not rock the boat. However, this doesn't necessarily move things forward, and, more likely, causes stagnation in the business and, indeed, could cause the business to fall behind trends and future regulatory requirements. The brainstorming exercise should be carefully documented and the resulting BSD will be used as a springboard to the next phase.

So, what can be done at the BSD stage to help to create a more effective URS. Perhaps, it is just to ask the question: If I do this, how does this benefit the product, process, operator, safety – not necessarily in that order. So, all of a sudden, we have gone from a general BSD to a more focused approach without much additional intervention. The BSD is really the wish list, but the question remains as to how to turn this into a URS.

Sadly, many times the brainstorming is carried out by finance managers and senior managers. Whilst this is a good starting point, it doesn't necessarily find out what is really needed by the very people operating the equipment. Simple ergonomics can easily be overlooked. An understanding of the processes being carried out will be known intimately by the operators, but will the finance manager or senior manager know? Probably not. Decision by committee is not ideal either, the BSD points become fuzzy and explanations of requirements repeated but using different words.

So, if the BSD is the starting point, the next stage is to move to a coherent URS. Describing processes within a

URS is not really helpful, but it could form part of an introductory section, if required. We have seen URS protocols festooned with process diagrams which have only succeeded in confusing the equipment manufacturer who, in some instances, produce proposals that are exactly the opposite of the requirements. This is an interesting conundrum that we have seen more than once, and which causes consternation and generates a lack of respect over time. Assuming that we have the URS in a format that is sensible, logical, and workable from the user requirement perspective, what about the manufacturer having to wade through such a wide-ranging document. This is where the ERS takes over.

ERS

The Equipment Requirement Specification (ERS) reduces the guesswork and potential misinterpretations that the URS may throw up for the equipment manufacturer. It is exactly what it states, a specification explaining the precise nature of the equipment required. The measurements, design features, and quality requirements, should all go into this document. There should not be any process diagrams, although a site layout is always useful for the manufacturer to understand the accessibility for equipment delivery. Care is needed in writing this document; it is easy to fall back into the URS mentality and start describing in minute details the governing standards and guidelines. In the introduction there should be subsections listing, first the standards (e.g. EN / ISO standards) which apply to the equipment, and secondly the supporting documents (e.g. Drawings, Diagrams, Material Certificates and Manuals) which will be required. It is important not to restrict these lists. There should be a statement ahead of each list beginning 'including but not limited to'. This ensures that the minimum that should be supplied is in the list, but there could be additional important material that will be captured in the 'not limited to' statement.

Using a pharmaceutical isolator as an example, Table 1 shows how a URS and an ERS may differ.

Where the URS gives general specification such as 'suitable materials and finish for the process should be used', the ERS will give more specific specification, for example: All stainless steel should be of 316L to 240 grit finish. Any corners should be bull-nosed with a 20mm radius.

Any supporting certificates would be covered by mention in the introductory section of the ERS. There is no need to repeat that requirement at this point. Thereby, the ERS will concentrate on the isolator build requirement, leaving out slavish replication of the standards against which it will be tested, as listed in the relevant introduction section of the ERS. The type of equipment required is totally dependent upon the use for which it is intended, and this will have been clearly and succinctly explained, in the introduction of the ERS. For example: "the isolator is to be used for sterility testing and will be sanitized using MCHP (micro condensed hydrogen peroxide)".

It will be the ERS that will enable the isolator manufacturer to put forward their proposal and, as the ERS is more specific than the URS, it will stand a much better chance of reflecting the client's requirements. The general URS could be used as background information but, as this is more general and may contain some of the internal testing requirement to be used during SAT/IQ/OQ/PQ, the use of an introductory paragraph or two in the ERS would satisfy this, and not cause confusion.

The Way Forward

So, as you can see, by producing a more specific document in the form of an ERS, there is a much better chance of the equipment manufacturer to get it right first time around. This, in turn, should help to reduce the overall timescale as there should be fewer iterations, fewer alterations and fewer delays caused by misinterpretation. If the manufacturer proposes alterations because the ERS specifies elements that are not practical, or are better addressed by the

Table 1: URS and ERS – examples of how they may differ

Typical URS Examples	ERS Comments
The isolator will be located in production rooms with a maximum height of 3500 mm…	This would form part of the introductory section outlining access for a) delivery and b) final position. Wording could be: Delivery access dimensions / limitations: Maximum access height: 4000 mm Maximum access width: 3000 mm Access restrictions: 3 corners to lab Laboratory height: 3500mm Laboratory access width: 3000mm
It must be possible to test the integrity of all HEPA filters, both the filter media and the associated filter seals, using an appropriate smoke challenge according to ISO 14644-3 (20-80 µg/l), and in accordance with the filter manufacturer's instructions. Appropriate test ports are to be provided.	This is part of the URS. It would be expected that any HEPA filter could be tested in situ. However, the only part of this wording would need to be repeated would be: • DOP test ports should be provided to introduce challenge DOP smoke, to verify the challenge immediately upstream of the filter, and to measure the penetration downstream of the filter.
The isolator shall fulfil the following requirements: • Air sampling: <2 cfu/m³ • Settle plates: <50 cfu/4 hours – Diameter 90 mm	Microbiological expectations cannot form part of the ERS for an isolator because they are more the result of the operator's actions than the design of the isolator. They should be tested at PQ.

manufacturer's standard design, then these can be addressed at the Functional Design Specification (FDS) stage.

In essence, to summarise:

1. Brainstorming – The BSD captures the thoughts and desires of all interested parties, from the operators to the senior management; from the business managers through to the Qualified Persons
2. User Requirement Specification – the URS hones the BSD further, but is a combination of the process, usage and equipment, including the regulatory requirements
3. Equipment Requirement Specification – the ERS provides a distilled and succinct explanation of the equipment which can be more easily interpreted by the equipment manufacturer.

One could almost argue that we are advocating the funnel analysis approach,[iv] which is true to a point. The objective of the ERS is to reduce duplication, unnecessary complication and concentrate on the specifics required for equipment manufacturing. By producing a separate document to the URS, the ERS therefore becomes the external document that is distributed to prospective isolator manufacturers. Another advantage is that it does not compromise any market sensitive products and processes that may be referred to in the URS.

i. Coles, T. (2014). Isolators and the User Requirement Specification (URS): How to avoid making your solicitors rich and your company poor. Clean Air and Containment Review, Issue 19, 4-6.

ii. Lamm, H., & Trommsdorff, G. (1973). Group versus individual performance on tasks requiring ideational proficiency (brainstorming): A review. European Journal of Social Psychology, Volume 3, Issue 4, 361-388.

iii. Coles, T., & Hale, H. (2018). Taming the Tyrannosaurus of validation. Clean Air and Containment Review, Issue 33, 4-7.

iv. Wheelwright. K. B. and Clark, S. (1992). Revolutionizing Product Development. New York: Free Press.

Dr Helen Hale has been Managing Director of Pharminox Isolation since 2015. Helen holds an MBA from the University of Leicester and a DBA in Management from Bradford University. She has spent most of her career in the financial services industry, as qualified financial advisor, consultant, and, finally, head of a several departments. Following a change in personal circumstances, Helen joined Pharminox Isolation in 2012 as Business Manager and found the shift into the pharmaceutical industry refreshing, although she has discovered that the complexities of compliance and validation in both industry sectors are similarly over-complicated, and could almost be complementary in many ways.

Cherwell publishes in-depth guide to prepared culture media

Cherwell Laboratories has published an eBook titled, "*The Pharmaceutical and Cleanroom Industry's Pocket Guide to Prepared Culture Media*". Available to download from Cherwell's website, the new guide is intended for anyone using or buying microbiological media within the pharmaceutical and cleanroom industry.

This comprehensive guide covers all the best practice information needed in order to produce; purchase; store and use prepared media effectively. The key topics covered in the guide will help readers to ensure their culture media is of a consistently high quality. This will deliver accurate, reproducible, and ultimately repeatable microbial tests.

Topics within the prepared media eBook include: an overview of its various applications; best practice guidelines for handling and storing; the logistics of in-house manufacture; the argument for pre-prepared media versus in-house manufacturing; and guidelines on how to choose a prepared media supplier.

The new microbiological culture media guide can be downloaded at: http://resources.cherwell-labs.co.uk/download-guide-to-prepared-media

The Pharmaceutical & Cleanroom Industry's Pocket Guide to Prepared Culture Media published by Cherwell Laboratories

Cleanroom Guangzhou Exhibition 2018 launches global campaign, and notches up early successes

The first wave of global marketing campaign of 2018 China (Guangzhou) International Cleanroom Technology & Equipment Exhibition (Cleanroom Guangzhou Exhibition 2018) has been rolled out, effectively and successfully! The event will take place between August 16 and 18 2018.

Guangdong Association of Cleanroom Technology (GACT) as the Organizer of Cleanroom Guangzhou Exhibition together with Guangdong Grandeur International Exhibition Group has been extending the global presence of Cleanroom Guangzhou Exhibition. In October 2017, President Xiaobiao Yu and Professor Huoju Xu with other members of GACT had a field trip to Cleanzone in Germany so as to enhance communication and business contact between China and Germany. They actually ran out of show brochures to exhibitors and visitors who showed great interest.

The exhibition has been highly recommended by numerous professional associations from abroad. For instance, Korea Air Cleaning Association (KACA) and Japan Air Cleaning Association (JACA) contributed a lot to the overseas promotion of Cleanroom Guangzhou Exhibition.

When it comes to regular and loyal exhibitors, Cleanroom Guangzhou Exhibition 2018 is gathering momentum and more than 100 stands have already been sold with a high expectation of more as we get further into 2018

Cleanroom Guangzhou Exhibition 2018 promises to bring you an unrivalled exhibition experience.

To pre-register for free entry, please visit www.clcte.com/index.php?lang=en

CRC strengthens HVAC expertise with new appointment

Clean Room Construction, a leading UK cleanroom design and build specialist, has boosted its engineering expertise with the appointment of Rob Tilbury as Projects Engineer.

Previously, Rob was the Site Services Manager at Dantherm Ltd. He has worked in the HVAC industry for more than 30 years in various roles, including production, contracts, estimating, sales and managing installations.

Managing Director Steve Lawton said: "Rob's appointment enables us to further strengthen our existing in-house engineering capability. He has a solid track record in the HVAC industry but also wider project management experience and an ambition to bring added value to our team and to the service we offer to the science and technology sectors. CRC remains absolutely committed to investing in our team to ensure we can continue to offer unparalleled expertise and an unrivalled service."

Rob added: "I am very excited about working for the UK's leading cleanroom design and build specialist and hope that my broad experience across a diverse portfolio of clients will further enhance CRC's existing service offering."

For more information on CRC see www.crc-ltd.co.uk

BPS Crowthorne offers VPHP fumigation of equipment and facilities

Many of BPS Crowthorne service customers perform their own fumigation prior to the servicing of their equipment and facilities. However, by encapsulating the expertise of its sister company Crowthorne Hi-Tec Services (CHTS), BPS Crowthorne can perform this fumigation with its equipment bio-decontamination service (EBDS), thus ensuring a full and successful service with minimal disruption and downtime. Not only does the EBDS service save the customer time, it also saves the capital outlay of buying the necessary equipment.

H_2O_2 (hydrogen peroxide) is an oxidising agent which, when it comes into contact with micro-organisms, oxidises their cells or spores, thus deactivating them. It is however, a surface decontaminant so may not penetrate dirt and detritus; heavily soiled surfaces should be thoroughly cleaned prior to decontamination. This system is operated at ambient room temperature and relative humidity, without the need to significantly reduce humidity, which was traditionally required for fumigation bio-decontamination.

There is now a large body of published scientific research demonstrating that hydrogen peroxide vapour technology is able to inactivate bacteria, viruses and fungi, as well as reduce healthcare associated infections (HAIs), giving you assurance of a 6-log spore reduction.

Not only is VPHP/ VHP an effective decontaminator, it is significantly less hazardous to health than traditional fumigation methods.

The EBDS service is provided by BPS Crowthorne in Ireland and CHTS in the UK. Contact: +353 (0)1824 3670 (Ireland) or +44 (0)1252 372333 (UK)

Life-lines

Quotations of Stephen Hawking

Someone told me that each equation that I included in the book would halve the sales.

We only have to look at ourselves to see how intelligent life might develop into something we wouldn't want to meet.

Intelligence is the ability to adapt to change.

People won't have time for you if you are always angry or complaining.

However difficult life may seem, there is always something you can do and succeed at.

Life would be tragic if it weren't funny.

Work gives you meaning and purpose and life is empty without it.

We are just an advanced breed of monkeys on a minor planet of a very average star. But we can understand the Universe. That makes us something special.

Look up at the stars and not down at your feet. Try to make sense of what you see, and wonder about what makes the universe exist. Be curious.

If aliens visit us, the outcome would be much as when Columbus landed in America, which didn't turn out well for the native Americans.

We are in danger of destroying ourselves by our greed and stupidity. We cannot remain looking inwards at ourselves on a small and increasingly polluted and overcrowded planet.

Contec launches a new Compact Bucket System

Contec has developed a new compact bucket system for cleaning and disinfecting in critical environments. The system is designed for use a with a variety of cleanroom flat mops and Contec's VertiKlean MAX range.

Contec's Compact Bucket System is available with either 2 or 3 buckets and a choice of a standard or a utility handle. The utility handle allows buckets to be positioned on the handle providing additional storage for extra supplies such as: clean mop heads, solution spray bottles, wipes, and other items as needed.

The cart frame has a mop head removal tool positioned on the front for easy, hands-free removal of a VertiKlean MAX or VertiKlean MAX Sealed Edge mop head. Two mop holders with handle clasps on either side of the cart allow for convenient mop storage during transport and storage.

For more information about Contec's Compact Bucket System, go to www.contecinc.com

Events

Dates	Event	Organiser
2018		
April 17–19	Interphex, New York	PDA
April 24–25	Making Pharmaceuticals Exhibition and Conference, Coventry, UK	Step Exhibitions Ltd
April 30–May 3	ESTECH 2018, Orlando, Florida	IEST
May 16–17	Cleanroom Technology Conference 2018	HPCI media
May 22–23	49th R3Nordic Symposium and Exhibition, Naantali Spa, Finland	R3Nordic
June 11–15	ACHEMA, Frankfurt am Main, Germany	DECHEMA
August 16–18	Cleanroom Guangzhou 2018, Guangzhou (Canton), China	Guangzhou Grandeur International Exhibition Group
September 23–26	ISCC 2018, Hague, the Netherlands	VCCN
October 23–24	Cleanzone 2018	Messe Frankfurt
November 12–15	IEST Fall Conference, Schaumberg, Illinois	IEST

Training courses

IEST (Institute of Environmental Sciences and Technology) www.iest.org		
2018	**Event**	**Location**
April 30	Stop Contamination in Your Operations with Reusable and Disposable Garments	ESTECH 2018, Orlando, Florida
May 1	The Unseen Contaminant: Taking Charge of Electrostatic Contamination	ESTECH 2018, Orlando, Florida
May 2	Contamination Busters: Get the Dirt Out of the Cleanroom	ESTECH 2018, Orlando, Florida
May 3	Cleanrooms Won't Fix a Contaminated Product	ESTECH 2018, Orlando, Florida
June 19	Understanding the Cornerstone Cleanroom Standards: ISO 14644-1 and 14644-2	Schaumburg, Illinois
June 20	Application of ISO 14644-3	Schaumburg, Illinois
June 21	Universal Cleanroom Operations Guidelines with ISO 14644-5	Schaumburg, Illinois
July 18	Designing a USP-797 and USP-800 Compliant Compounding Pharmacy	Schaumburg, Illinois

ICS (Irish Cleanroom Society) www.cleanrooms-ireland.ie		
2018	**Event**	**Location**
April 16	GMP Cleanroom Cleaning (Basic)	Dublin, Ireland
May 22-24	CTCB-I Testing and Certification (2/3 day course)	Dublin, Ireland

Note:
CTCB-I Certification: Cleanroom Testing and Certification Board International Certification, see CTCB-1 website: www.ctcb-i.net/index.php

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16 – 17 MAY 2018
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Join us at the **2018 Cleanroom Technology Conference** to keep up to date with the latest regulations / standards and learn about innovative products and services that can enhance your cleanroom operations.

The 2017 Cleanroom Technology Conference gathered over 350 industry professionals from 17 countries and 36 exhibitors. Following on from this sell out event, the 2018 edition looks to repeat that success and establish itself as the leading multi-sector platform for professionals working in cleanroom and controlled environments.

Why attend:

- Recent revisions and proposed standards affecting cleanroom practices
- Obtain practical guidance on planning and specifying your new cleanroom
- Enhance your cleaning regimes and implementation
- Trends in cleanroom operation and design

Attending profiles:

- Senior Pharmacist Aseptic Services
- Microbiologist
- Validation Engineer
- Purchasing manager
- Senior Energy Specialist
- Head of QA

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> **I FELT IT WAS A GREAT SUCCESS. THERE WERE SOME VALUABLE AND INTERESTING POINTS RAISED FROM BOTH THE SPEAKERS AND ATTENDING DELEGATES.**
> *Laboratory technician, Rolls Royce*

CLEANROOM TECHNOLOGY AWARDS

Cleanroom Technology is pleased to announce the first edition of the **Cleanroom Technology Awards**.

The Awards will recognise and reward achievements internationally and for those exhibiting at the 2018 Cleanroom Conference.

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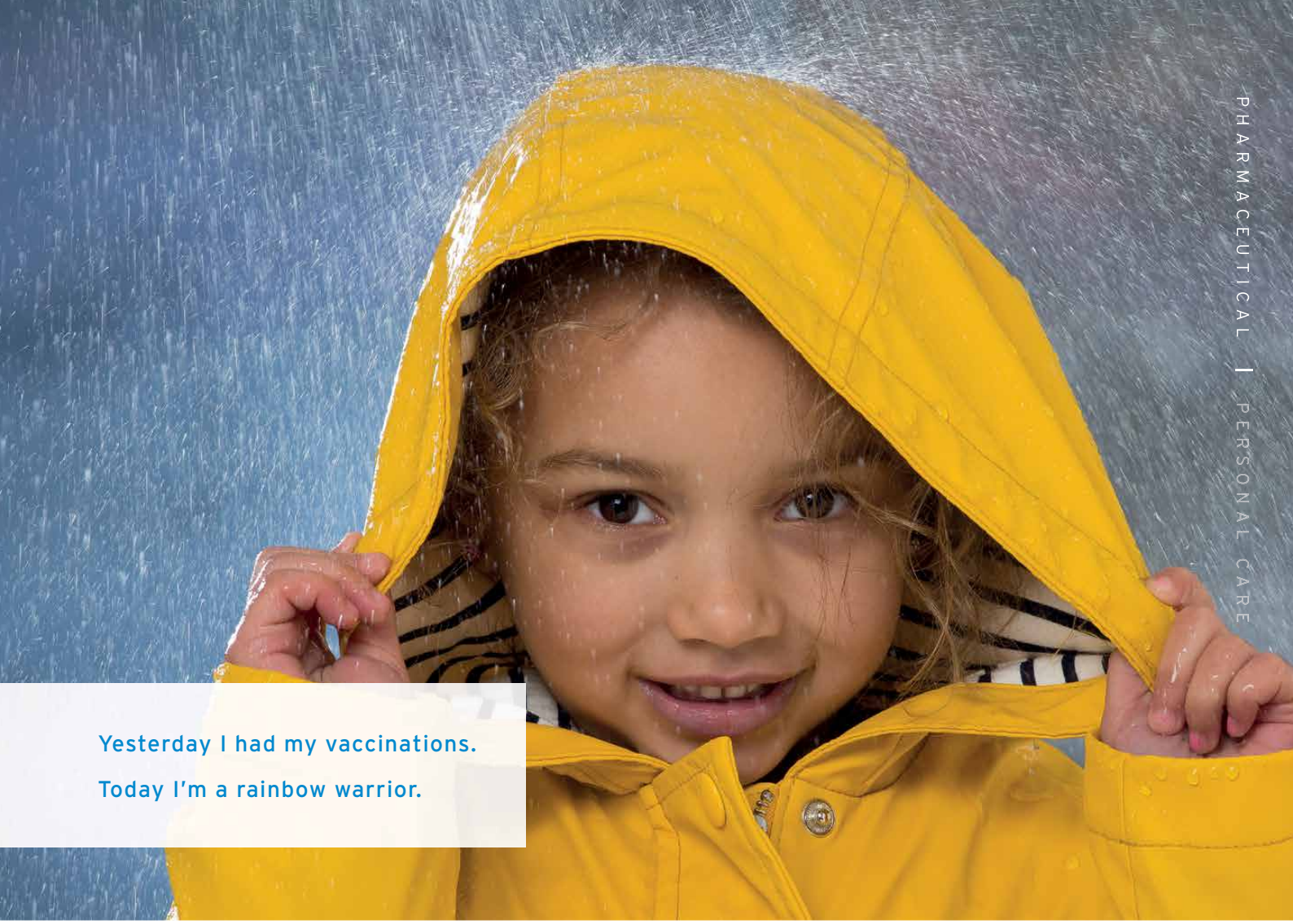

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