A Review of EN ISO 17141, ISO 14698 and Particle Measuring Systems' Microbial Instrumentation Conformance

Introduction

In August 2020 the normative standard for Europe EN 17141, *Cleanrooms and associated controlled environments – Biocontamination control*, was issued. It essentially replaces the existing European Standards (EN) ISO 14698-1:2003 and (EN) ISO 14698-2:2003 within the European Standards community countries, and is associated with the cleanroom standard ISO 14644-1:2015, *Cleanrooms and associated controlled environments – Part 1 Classification of air cleanliness by particle concentration*. Globally, ISO 14698 –1&2:2003 are still valid and applicable.

There are two sections to the new European standard:

- **Normative**: Those parts that are prescriptive. They should be followed to demonstrate compliance with the standard.
- **Informative**: Those parts that are descriptive. They aid the reader understand the concepts presented in the standard.

The normative chapters describe the establishment of microbiological control, in identifying the risks associated with environments and processes and how to ally a monitoring plan to those identified risks. Those aspects are covered in a separate technical review. The informative chapters offer guidance on how to apply the monitoring plans to meet specific regulated industrial applications. The standard is also very clear that additional regulatory requirements may be made on these industries by local and international regulatory bodies. It is the Informative Annexes E and F that identify the apparatus that can be used to measure within these applications. Guidance is given on selecting the most suitable solution for an application and verifying and/or validating their suitability.

Requirements for Volumetric Air Samplers

Both ISO 14698-1:2003 and EN 17141:2020 have performance criteria for the suitability of volumetric air samplers when used in conjunction with other elements of the standard (media section, incubation and result readings).

TABLE 1 Comparison of standards

ISO 14698-1/2:2003	EN 17141:2020
B.1 Consideration of physical and biological efficiencies	E.5.1 Consideration of physical and biological collection efficiencies. These tests are typically performed by the manufacturer.
	E.5.2 Physical collection efficiency. The requirement of a minimum collection efficiency cut-off size (d50) value smaller than 2 µm is considered appropriate.

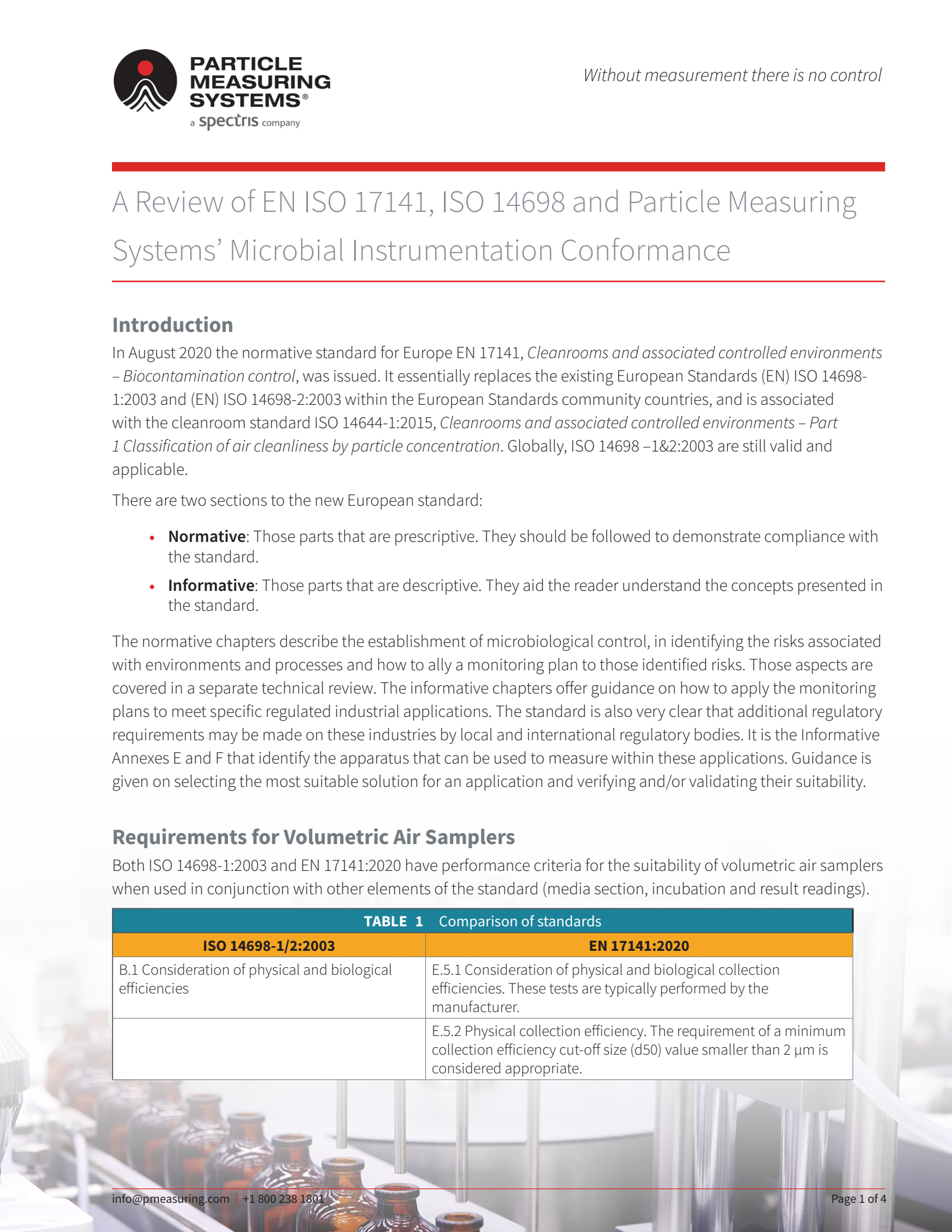


TABLE 1 Comparison of standards	
ISO 14698-1/2:2003	**EN 17141:2020**
	E.5.3 Biological collection efficiency is the ability of a sampler to collect viable particles and include the losses that may arise from physical collection efficiencies and microbe stresses during collection.
B.2 Experimental method – a description of the test chamber and its environmental conditioning	E.6 Experimental methods – a description of the test methods for physical and biological efficiencies is described: chamber environmental conditions and aerosol generation
B.2.2.1 Test Strain required for physical efficiency, and its suitability for survival – or polystyrene spheres	E.6.1.2.1 Test strain example for physical efficiency, which survives testing – or polystyrene spheres
B.2.2.2 Test Strain example for biological efficiency or alternatives based on suitability and predominance in cleanrooms	E.6.1.2.2 Test Strain example for biological efficiency and its suitability and uniformity of dispersal
B.2.4 / B.2.3 Testing – a description of testing methods, enumeration and interpretation of results	E.6 Experimental methods – a description of the testing, enumeration and reporting of results
	E.6.2 Simplified laboratory test method, comparison test using an established, validated, instrument, within a range of microbial concentrations
	E.6.4 Collection efficiency using simplified method E.6.2 = 100% ± 50%
	E.6.5 Because testing may be complex and using a third-party laboratory results retesting of a product type are not expected, where the instrument has been maintained and calibrated according to manufacturer's recommendations.

The two standards harmonize the selection process of a volumetric air sampler. There are two new aspects of the revised EN 17141:

- **E.5.2**: Recommendation of a d50 value for particles smaller than 2 µm
- **E.6.2 – E.6.4**: Simplified laboratory method for allowing new instruments without manufacturer testing to be validated for use by comparing against an established instrument's performance. Allowable tolerance = (100 ±50)%

ISO 14698-2:2003 also offers additional advice on applicability of choosing a sample based on its application to monitoring the environment and the establishment of a monitoring program.

MiniCapt® / BioCapt® – Physical and Biological Efficiency

The sampler heads of the MiniCapt® Mobile Microbial Air Sampler, MiniCapt® Remote Microbial Air Sampler, and BioCapt® Microbial Impactor are all the same design. Parameters and testing of the design have been performed in compliance with ISO 14698-1:2003 and EN 17141:2020. The conformity testing to this standard was performed by CAMR (PHE Biosafety Group) Porton Down, UK, and is reported in the document n° 670/00. Originals of the report are available from the PMS QA department, Boulder (CO), USA.

Physical d50 Efficiency Results

There are three methods for calculation of d50 efficiency that can be correlated to the physical efficiency testing performed using the full efficiency testing results.

1. Estimate the impingement velocity and compare to Mays data set.
2. Calculate impingement d50 direct.
3. The estimation of d50 based on EN 17141, section E.5.2.

$$d_{50} = \sqrt{\frac{40 \times Dh}{U}} \qquad \text{(E.1)}$$

where

40 is the constant factor for air viscosity (°C);
Dh is the equivalent hydraulic diameter of the air inlet nozzle(s) (mm);
U is the impact velocity (m/s).

NOTE For a circular opening, the equivalent hydraulic diameter is the hole diameter. For a rectangular slit, the equivalent hydraulic diameter will be approximately twice the slit width.

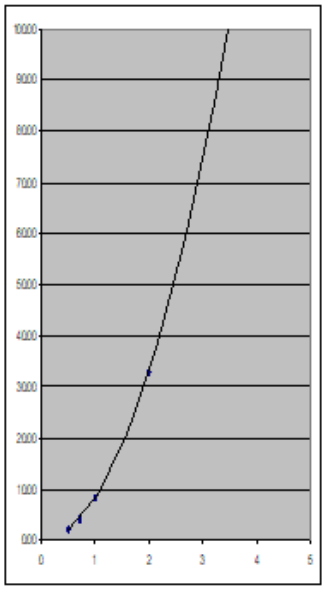
1. Estimate the impingement velocity and compare to Mays data set.

TABLE 2 Mays data set

Instrument	Slit length (mm)	Slit Width (mm)	No. slits	Total swept area (mm²)	Total swept area (m²)	Volume flow rate (LPM)	Volume flowrate (m³/s)	Impinging vel (m/s)
MiniCapt Mobile (25)	20	0.1	20	40	0.00004	25	0.00041667	10.42
MiniCapt Mobile (50)	20	0.1	20	40	0.00004	50	0.00083333	20.83
MiniCapt Mobile (100)	20	0.2	20	80	0.00008	100	0.00166667	20.83

Collection efficiency of particles of different sizes (Moller, reinterpreted from May's results)

2. Calculate impingement d50 direct.



The collection efficiency calculation:

$$E = \frac{\pi \times U \left(p \times d^2 \times C \right)}{2 \times r \left(18 \times \eta \right)}$$

U is the velocity of the air through the nozzle
r is the radius of the curvature of the streamline
2r = maximum diameter of hole
p is the density of microbe-carrying particles
d is the equivalent particle diameter
C is the Cunningham slip factor
η is the viscosity of room air at 20 °C (1.81×10^{-5} Pa x s)

The following theoretical d50 values apply:

TABLE 3 Mays data set

Instrument flowrate	d50 using Mays calculation	d50 using Fluid Dynamics calculation	Average d50 value	d50 using EN 17141 formula
25 LPM	2.2 µm	-	2.2 µm	0.6 µm
50 LPM	1.3 µm	2.4 µm	1.9 µm	0.4 µm
100 LPM	1.3 µm	1.9 µm	1.6 µm	0.6 µm

Summary

There is significant harmonization between the requirements for suitability of instrument sampling parameters between ISO 14698-1:2003 and EN 17141:2020. The MiniCapt and BioCapt family of products, for all flow rates (25, 50 and 100 LPM) meet these standards for high efficiency for physical and biological requirements.

The microbial products from Particle Measuring Systems comply with both these International Standards and suitable, routine maintenance and calibration will keep these instruments within tolerance for many years. Additional validation will not be required.

References

1. EN 17141 (2020): Cleanrooms and associated controlled environments - Biocontamination control
2. ISO 14698-1 (2003): Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
3. CAMR (PHE Biosafety Group) Porton Down, UK, and is reported in the document n° 670/00

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