




Mechanical Testing ISO/IEC 17025 Application Document

Annex G: Controlled environments

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Mechanical Testing Annex G: Controlled environments

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities conducting testing of controlled environments under Mechanical Testing.

Applicant and accredited facilities must also comply with the ISO/IEC 17025 standard and Mechanical Testing field application document and any field annexes, policies and/or technical circulars (refer to *NATA procedures for accreditation*).

The clause numbers in this document follow those of ISO/IEC 17025 but since not all clauses require interpretation the numbering may not be consecutive.

4.13.2.1 Technical Records

The actual anemometer readings must be recorded on worksheets and then the anemometer corrections applied. The same practice must be adopted for all equipment that require corrections to readings.

Correction factors may be applied to averaged anemometer readings only where this has been shown not to affect the final result.

5.5.2 Common equipment performance checks

Facilities are responsible for establishing their own equipment assurance program. This is to ensure that all equipment used satisfies the need to produce consistent and reliable and where appropriate traceable results. In doing so facilities must ensure that where methods writing bodies have included equipment calibration and checking intervals in standard methods that these intervals must be followed if the methods are covered by the accreditation. Facilities should refer to the guidance documents available for equipment (General Equipment Table) for further information on calibrations and checks on equipment.

The following supplementary information pertains to equipment items having specific application to controlled environments testing and may not be directly described within the General Equipment Table.

Item of equipment	Calibration interval (years)	Checking interval (months)	Procedures and references
Aerosol generator			
<u>Fittings</u>			
Barrier test fitting		Regular check	Dimensions checked:
			50±1mm internal diameter at point of discharge. 250±5mm in length Flow straighteners 100±10mm square cut ends

Item of equipment	Calibration interval (years)	Checking interval (months)	Procedures and references
Laskin nozzles		Regular* check	Dimensions checked to AS 1807.0 using drills that closely match diameters listed in standard.
Aerosol delivery hose			Minimum internal diameter =32mm.
Aerosol photometer			
	1		Complete. Flow (28 ±3 L/min). Minimum threshold sensitivity. 10 ⁻³ mg/L. Range 80 to 120 mg/L. Electronic check. Linearity check. Optical system.
Probe tip for filter integrity			
Circular tip	Initial		Maximum included angle, Θ= 21 degrees.
Square or rectangular tip			Refer AS 1807.0 clause 8.
Air flow nozzles	1	Check* throat diameter	
Flow hoods	2		Check dimensions and flow.
KI discus			
Aerosol generator		Initial	Measure rotational speed 28 000 r/min ± 500 r/min
		Before* use	Check gap between nozzle and disc using 0.1 mm shim.
Metal cylinder		Initial*	Measure cylinder size with ruler 60 mm to 65 mm
		12*	Determine time elapsed to dispense 20 ml potassium iodide solution.
Leak detector	1		
Magnahelic gauges	1		
Membrane filters			
Black/dark green		Initial	0.8 µm nominal pore size, 47 mm diameter gridded on approximately 3.1 mm centres.
White		Initial	5.0 µm nominal pore size, 47 mm.

Item of equipment	Calibration interval (years)	Checking interval (months)	Procedures and references
Microscope (controlled environment testing)	*Initial		Numerical aperture >0.65 at 40 x and >0.15 at 90 x
Orifice (limiting)			
	Initial		Calibrated in-situ using reference flowmeter.
		Prior to each test*	Visual examination to ensure no restricting matter is present.
Orifice plates	Initial		BS 1042 BS ISO 3966
		6*	Visual check for wear and damage.
Particle counter			
Particle counts in cleanrooms	1		Sampling flowrates 10 ± 0.5 L/min (0.17 ± 0.01 L/s)
Particle counts on cleanroom garments	1		28 ± 1.5 L/min (0.47 ± 0.02 L/s)
Pitot tube	Initial		Dimensions. BS 1042 BS ISO 3966
		On use*	Inspect for damage, blockages etc.
Smoke generator		On use*	Smoke to be introduced isokinetically.

*Commonly conducted by laboratory staff

5.10.2 Test reports and calibration certificates

When testing of a controlled environment has been completed an extract of the report (usually in the form of a sticker) is placed on the item which has been tested. These stickers must contain:

- a) the name of the testing authority;

- b) identification of the testing authority (e.g. an address, accreditation number or location details);
- c) the report number;
- d) date of the test;
- e) identification of the tests which have been conducted and the results (or pass/ fail notation) of the tests;
- f) the test methods; and
- g) signature of the person conducting the test.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

AS 1807.0	<i>Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test - List of methods and apparatus</i>
BS 1042	<i>Section 2.1 Measurement of fluid flow in closed conduits - Velocity area methods - Method using Pitot static tubes</i>
BS ISO 3966	<i>Measurement of fluid flow in closed conduits. Velocity area method using Pitot static tubes</i>

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Annex title	Retitled as Annex G
Equipment performance checks table	Amended to include only those activities applicable to controlled environments testing
References	Updated