Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Infrastructure and Asset Integrity - Annex

Testing of air control equipment

July 2018

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Testing of air control equipment

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 for both applicant and accredited facilities conducting testing of air control equipment.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Infrastructure and Asset Integrity (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.

6 Resource requirements

6.2 Equipment

6.4.5

Common equipment performance checks

Facilities must ensure that where methods writing bodies have included equipment calibration and checking intervals in standard methods that these intervals must be followed. Facilities should refer to NATA's *General Accreditation Guidance*: *General Equipment - Calibration and Checks, 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 NATA's *General Equipment - Calibration and Checks, General Equipment Table*.

Item of equipment	Calibration interval (years)	Checking interval (months)	Procedures and references
Aerosol generator (fittings)			
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.
Laskin nozzles		Regular* check	Dimensions checked to AS 1807.0 using drills that closely match diameters listed in standard.

Item of equipment	Calibration interval (years)	Checking interval (months)	Procedures and references
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.

Item of equipment	Calibration interval (years)	Checking interval (months)	Procedures and references
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.
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)

Item of equipment	Calibration interval (years)	Checking interval (months)	Procedures and references
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.
Sound level meter	Initial	On use*	Check against reference device both before and after each series of measurements. Testing should be repeated in the event of any significant deviation, i.e. greater than 1dB.

Note: ***** Commonly conducted by laboratory staff.

6.4.11 Calibration correction factors must be applied to any equipment reading where the correction could affect the final result. A single correction factor may only be applied over a measurement range where the correction factor remains the same across the range.

Where the average of a series of readings is taken (such as for air velocity), the applicable correction factors may be applied to the averaged reading only where this has been shown not to affect the final result. Where 'self-averaging' anemometers are used, the function must be disabled in order to obtain the maximum and minimum air velocity (some such equipment items have a 'fast response' setting which is acceptable).

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 In controlled environment testing, engagement with the customer at the test site commonly forms an important part of the contract review process and relevant information obtained through this engagement is to be documented. This would include any compliance criteria nominated by the customer (if not known prior to arrival at site) or any specific customer requests in regard to the conditions for testing which might influence the outcome.

Note: Classification of a cleanroom to ISO 14644.1 requires an understanding of the status of the cleanroom facility at the time of test (that is, whether 'at rest' or 'in operation').

The setting up of a cleanroom to the nominated state, in accordance with the site operating procedures, is entirely a matter for the client and the decision of a testing service provider to be involved in cleanroom classification in this circumstance warrants careful consideration, and may require suitable caveats to any reported results.

7.1.8 Facilities are encouraged to seek from the customer a written acceptance of the finalised test arrangements, including any nominated compliance criteria, noting any refusal on the part of the customer to provide such agreement.

7.6 Evaluation of measurement uncertainty

7.6.3 While contributions arising from the uncertainties associated with measuring equipment are to be taken into account, some sources of variability are inherent to the item being tested and are not amenable to uncertainty estimation. Such sources (for example, local variability in air velocity measurement due to turbulence or imperceptible changes in vane anemometer orientation with respect to the airstream) can be regarded as integral to the published testing methodology.

7.8 Reporting of results

7.8.6 Reporting statements of conformity

No statement of conformity can be made which is based, in full or in part, upon tests or evaluations which are not covered by the scope of accreditation (e.g. statements of conformity to AS 2243.8 and AS 2243.9 cannot be made if accreditation is only held for smoke and face velocity testing).

Where deviations from a method are permitted within the standard, it is still possible to make a statement of conformity, provided that the test report provides details of the deviation.

Note: The apparatus and test conditions detailed in AS 1807.6 for determining the integrity of HEPA filter installations ensure that testing is carried out under isokinetic conditions but it may be difficult to meet the 0.6 m/s specified maximum air velocity for a variety of reasons. In this case, the standard does permit readings to be taken at air velocities greater than 0.6 m/s. However, it is not possible to correlate the numerical results obtained using this deviation with results where the nominal air velocity has not been exceeded.

Government regulations may require the placement of ‘compliance stickers’ on controlled environment equipment, in order to provide a visible indication of equipment compliance (i.e. within the current period of its validity)

Where such ‘stickers’ are used, these must contain:

- a title which unambiguously indicates that the sticker represents information extracted from a specific test report
- the name of the testing authority;
- identification of the testing authority (e.g. an address, accreditation number or location details);

- the report number;
- date of the test;
- a result for each test conducted, which can be in the form of a pass/ fail notation provided that the source of the compliance criteria is stated;
- signature of the person authorising the result.

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	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test - List of methods and apparatus
AS 1807.6	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test - Determination of integrity of terminally mounted HEPA filter installations
AS 2243.8	Safety in laboratories - Fume cupboards
AS 2243.9	Safety in laboratories – Recirculating fume cabinets
ISO 14644.1	Cleanrooms and associated controlled environments - Classification and air cleanliness
BS 1042	Section 2.1 Measurement of fluid flow in closed conduits - Velocity area methods - Method using Pitot static tubes
BS ISO 3966	Measurement of fluid flow in closed conduits. Velocity area method using Pitot static tubes
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories

NATA publications

NATA Accreditation Criteria (NAC) package for Infrastructure and Asset Integrity

General Accreditation Guidance:	General Equipment - Calibration and Checks, General Equipment Table

Amendment Table

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

Section or Clause	Amendment
Whole document	Clauses have been aligned with ISO/IEC 17025:2017. Any criteria included in the previous issue that are now covered by ISO/IEC 17025:2017 have been removed. No new interpretative criteria or recommendations have been included other than editorial changes. Addition of Security Classification Label