



Specific Accreditation Criteria

ISO/IEC 17025 Application Document Infrastructure and Asset Integrity - Annex

Testing of air control equipment

XXXXXXXXXXXXXXXXXXXX 20XX

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Testing of air control equipment

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 for accredited facilities conducting testing of air control equipment and controlled environments, e.g. testing of Biological Safety Cabinets, fume cupboards, cleanrooms, HEPA filter installations, etc.

Applicant and accredited facilities must comply with all relevant documents in the NATA Accreditation Criteria 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.

5 Structural requirements

5.4 Accredited facilities may coordinate their activities across a geographically dispersed area, where technicians are individually responsible for their equipment and testing activities.

Accredited facilities must ensure that key testing personnel are made available during NATA assessments. Where NATA is unable to evaluate the effectiveness of technical control solely from an assessment of the base facility, further assessments may be required at these other locations.

6 Resource requirements

6.4 Equipment

6.4.5

Common equipment performance checks

Accredited facilities must ensure that, where standard methods have included equipment calibration & checking intervals, these must be followed. Facilities should refer to the NATA publication *General Accreditation Guidance: 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:

Item of equipment	Calibration interval (years)	Checking interval	Procedures and references
Aerosol generator (fittings)			
Barrier test fitting		Regular checks	Dimensions and profile. Includes flow straighteners.
Laskin nozzles		Regular checks	Dimensions checked to AS 1807 using drill bits that closely match the specified diameter.
Aerosol delivery hose			Verification of minimum internal diameter.
Aerosol photometer			
	1		Linearity. Sample flow rate. Minimum threshold sensitivity. Measurement range.
Anemometer			
Thermal (hot wire)	1		Range and resolution.
		Regular checks	Dust, wear and tear. Misalignment between outer housing and internal components.
Vane	1		Accuracy. Range.
		Regular checks and prior to use	Dust, wear and tear. Integrity of housing (e.g. cracking, deformity).

Item of equipment	Calibration interval (years)	Checking interval	Procedures and references
Photometer probe tip for filter integrity			
Circular tip	Initial		Maximum included angle, $\theta = 21^\circ$. Maximum internal inlet diameter.
Square or rectangular tip			Refer to AS 1807 clause 3.8.2 b).
Flow hoods / Balometers			
	2		Dimensions and flow rate.
KI discus			
Aerosol generator		Initial	
Spinning disc	Initial	Prior to use	Rotational speed.
Air sampler	Initial		Volumetric flow rate of sampling heads.
		Prior to use	Check gap between nozzle and disc using 0.1 mm shim.
Metal cylinder		Initial	Cylinder size.
		Yearly	Determine time elapsed to dispense potassium iodide solution.
Manometer			
Digital	1		
Inclined-tube		Prior to use	Liquid to be replaced as needed.

Item of equipment	Calibration interval (years)	Checking interval	Procedures and references
Magnahelic gauges	1		Typical range of use: 0 to 500 Pa. May be checked against a calibrated digital manometer.
Orifice (limiting)	Initial		Calibrated in-situ using reference flowmeter. Flow or dimensional calibration plus inspection for wear and damage.
		Prior to use	Visual examination to ensure no restricting matter is present.
Orifice plates	Initial		Flow or dimensional calibration plus inspection for wear and damage. Refer to BS 1042-2.2 and ISO 3966.
		6-monthly	Visual check for wear and damage.
Particle counter			
Particle counts in cleanrooms	1 or less		Refer to ISO 21501-4
Pitot tube	Initial		Dimensions. Refer to BS 1042-2.2 and ISO 3966.
		Prior to use	Inspect for damage, blockages etc.
Smoke generator		Prior to use	Smoke to be introduced isokinetically.

Item of equipment	Calibration interval (years)	Checking interval	Procedures and references
Sound level meter	2	Prior to use	Check against reference device both before and after each series of measurements. Testing should be repeated in the event of any significant deviation, e.g. greater than 1 dB.

6.4.11 For test results that reflect an average (mean) of a series of readings, e.g., for air velocity measurements:

- Correction factors must be applied to each reading.
- Averages must be calculated using corrected readings.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 In controlled environments 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 shall be documented. This includes any compliance criteria nominated by the customer or any specific customer requests regarding the conditions for testing which might influence the outcome.

Note: Classification of a cleanroom to AS ISO 14644.1 requires an understanding of the status of the cleanroom facility at the time of test (i.e., 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.

7.8 Reporting of results

7.8.1 General

7.8.1.2 The NATA endorsement covers the reporting of air change rates only where facilities have been specifically accredited to a standard method (or validated in-house method) for such work. Refer to *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation*.

7.8.1.3 Regulations may require the placement of 'compliance stickers' on tested equipment to provide a visible indication of compliance, i.e., within the current period of its validity.

Compliance stickers are simplified test reports, and they must comply with the *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation*. Compliance stickers must not be used to imply that an item, product or installation has been certified.

Where such 'compliance stickers' are used, these must include:

- a title which unambiguously indicates that the sticker represents information extracted from a specific test report;
- identification of the laboratory, e.g., address, accreditation number, location;
- date(s) of performance of the testing;
- a result for each test conducted, which can be in the form of a statement of conformity (e.g., pass or fail) provided that the source of the compliance criteria is stated;
- a reference to the full test report;
- signature of the person authorising the result(s).

Note: 'Compliance stickers' should be printed on chemical-resistant paper to ensure they remain durable and legible when exposed to cleaning chemicals.

7.8.2.1 Where deviations from a test method are specifically permitted, the report must describe the deviation.

Note: The apparatus and test conditions detailed in AS 1807 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 (e.g., if the filter guard cannot be removed). In this case, the standard does permit readings to be taken at air velocities greater than the specified limit. 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.

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.

Statements of overall conformity to AS/NZS 2243.8 or AS 2243.9 cannot be made if accreditation is only held for smoke testing and face velocity tests. Face velocity and smoke test results do not constitute all activities required for an assessment of overall compliance of an item against the requirements of the standards.

Under accreditation to ISO/IEC 17025, results obtained via AS 1807 test methods cannot be used to imply that an air-handling system (e.g., an operating theatre) is compliant to AS 1668.2.

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 1668.2	<i>The use of ventilation and air conditioning in buildings, Part 2: Mechanical ventilation in buildings</i>
AS 1807	<i>Separative Devices — Biological and cytotoxic drug safety cabinets, clean workstations and pharmaceutical isolators — Methods of test</i>
AS/NZS 2243.8	<i>Safety in laboratories, Part 8: Fume cupboards</i>
AS 2243.9	<i>Safety in laboratories, Part 9: Recirculating fume cabinets</i>
BS 1042-2.2	<i>Measurement of fluid flow in closed conduits — Part 2: Velocity area methods — Section 2.2 Method of measurement of velocity at one point of a conduit of circular cross section</i>
ISO 3966	<i>Measurement of fluid flow in closed conduits — Velocity area method using Pitot static tubes</i>
ISO 14644-1	<i>Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration</i>
ISO 14644-3	<i>Cleanrooms and associated controlled environments — Part 3: Test methods</i>
ISO 21501-4	<i>Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces</i>
ISO/IEC 17025	<i>General requirements for the competence of testing and calibration laboratories</i>

NATA publications

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

Further reading

ILAC G8:09 *Guidelines on Decision Rules and Statements of Conformity*

Amendment Table

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

Section or Clause	Amendment
Whole document	Some requirements from the previous edition (July 2018) have been editorially revised and/or moved to a more appropriate clause of ISO/IEC 17025.
5.4	New requirements regarding site access for NATA assessments.
6.4.5	The equipment table has been updated.
7.8.1.2	New text regarding NATA accreditation for reporting air changes.
7.8.6	Clarifications added regarding making statements of conformity under accreditation for ISO/IEC 17025.