

General Accreditation Criteria

Equipment assurance, in-house calibration and equipment verification

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Equipment assurance, in-house calibration and equipment verification

Purpose

This policy has been developed to ensure calibrations and equipment verification testing is carried out to the same level of technical competence and is assessed appropriately against all applicable accreditation requirements.

Calibrations performed by a facility in order to establish metrological traceability for its own activities, and which are not part of the facility's Scope of Accreditation, are commonly referred to as in-house calibrations.

For the purpose of this policy, instruments, reference materials, consumables, reagents and analytical systems are included as equipment, as applicable. This policy applies to:

- all NATA applicant and accredited facilities,
- for calibrations and equipment verifications that supports testing within the facility itself; or to a central calibration facility carrying out services for other accredited sections within their own organisation which operate under the same management system.

Those central calibration facilities which do not operate under the same management system as the accredited testing facilities will most likely need to seek accreditation in the relevant calibration service.

Organisations performing calibrations or supplying certified reference materials for external clients must continue to be formally accredited for this activity.

Equipment checks are also part of an equipment assurance program and are performed in order to determine that an item has not deviated significantly from its original value or in between calibrations and verifications. While checks are assessed for competency during a NATA visit, the additional criteria in this policy do not apply to checks in this context.

Guidance on establishing an equipment assurance program is contained in Appendix A.

For NATA's policy on metrological traceability refer to the *General Accreditation Criteria: Metrological Traceability Policy*.

Note: Terms and definitions applicable to metrological traceability may be found in the *General Accreditation Criteria: Metrological Traceability Policy*. A definition of 'check' is stated in the Appendix of this document.

The process for assessment of in-house calibrations and equipment verifications can be found in NATA's *Procedures for Accreditation*.

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Policy on equipment assurance

Equipment shall be shown upon installation and during routine use to be capable of achieving the performance required and shall comply with the necessary specifications to support the tests and examinations concerned.

All test, measurement and maintenance procedures performed on equipment must be appropriately documented, with records maintained and shall be readily available for the lifespan of the equipment plus one NATA assessment cycle.

A report must be produced where results are to be used in another facility, such as in another section or at another site (e.g. a central calibration facility which performs all calibrations within the organisation). When the results are to be used within the same facility, the results must be approved by appropriate facility personnel.

Whenever equipment has been taken out of service due to repairs, maintenance or upgrades, it shall not be returned to service until shown by calibration, verification or testing to meet the acceptance criteria.

In-house Calibrations

Facilities performing in-house calibrations in support of their accredited activities shall be required to demonstrate technical competence of these services, have sufficient evidence of metrological traceability and achieve the required measurement uncertainty associated with the calibration.

As calibrations are performed for internal customers, the results may be reported in a simplified way; however results not reported shall be made readily available.

The facility may elect to treat the measurement uncertainty associated with the inhouse calibration as a compliance decision to a set limit, specification, or Maximum Permissible Error (MPE) based on the needs of the testing. When calibrating to a set limit, specification or MPE, the uncertainty of measurement shall be taken into account in the decision rule as required under clause 7.8.6 of ISO/IEC 17025:2017.

Notes: Further guidance on in-house calibration, measurement uncertainty and using a pre-calculated uncertainty may be found in the accreditation guidance document Inhouse calibrations and measurement uncertainty.

The Maximum Permissible Error is the extreme value of the measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system. The set limit or specification may be considered as a predetermined acceptance criteria based on the requirement of the test method.

In cases where the calibration method follows a recognised published standard for example an OIML, ISO, IEC, ASTM or Australian Standard which specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of the calculated results, the uncertainty of measurement need not be included in the compliance/acceptance decision.

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In-house calibrations will form part of a NATA assessment as defined in the *General Accreditation Criteria: Metrological Traceability Policy*.

Equipment verification, testing and examination

While not all equipment requires calibration and evidence of metrological traceability, some equipment must still be verified in order to determine it is suitable for use. This verification may include compliance to a specification, such as a required precision, required resolution, dimension specification or a required linearity. In these instances, the facility shall be required to demonstrate the technical competence of these tests, measurements and examinations on equipment, whether performed internally or through an external service supplier.

The facility shall ensure reference equipment used in these verifications is appropriately calibrated. The uncertainty of measurement of the verification activity shall be taken into consideration in the compliance/acceptance decision following the criteria for in-house calibrations as stated above.

Facilities accredited for the calibration of this equipment are recognised as being technically competent to perform these verifications, tests and examinations, along with equipment checks.

Further information

If you have any queries in relation to this policy please contact your nominated NATA Client Coordinator. General questions on equipment assurance may be sent to the Sector Manager Calibration, Paul McMullen (paul.mcmullen@nata.com.au).

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.
	The document includes editorial changes with no new interpretative criteria.

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Appendix A

(Informative)

Creating an Equipment Assurance Program

The following may be used as guidance when establishing an equipment assurance program and is acknowledged as being generic and not comprehensive. Recommended calibration and checking intervals for equipment may be found in the *General Accreditation Guidance: General Equipment Table* for equipment used in tests, measurements and inspections and *General Accreditation Guidance: Reference Equipment Table* for equipment used as a reference or working standard to calibrate, test or check general equipment.

Definitions

'Check' is a measurement of at least one point in a range of a measuring instrument or system or material against a known value to confirm that it has not deviated significantly from its original calibrated value. It is also an examination of the condition of an artefact i.e. the reference of known value, to determine that it has not been adversely affected by constant use.

By performing a check on an instrument, a facility is able to determine if the instrument has changed since its last calibration. By performing regular checks, the interval between periodic calibrations may be extended.

Calibration, verification testing and checking intervals

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.

When establishing an equipment assurance program, consideration must be given to the following:

- history of stability;
- frequency of use;
- accuracy required;
- requirement for traceability of measurement;
- ability of staff to perform in-house checks;
- successful participation in proficiency testing programs for the testing for which the equipment is used.

Equipment assurance programs move the emphasis from a high reliance on demonstration of equipment conformance through calibration to:

- having a greater contribution from more frequent checks against reference items or materials;
- cross-verification against similar systems;

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the testing of particular critical features.

Equipment assurance programs should cover:

- commissioning of new equipment (including initial calibration, initial acceptance testing and checks after installation);
- operational checking (checking during use with reference items or materials);
- periodic checking (interim but more extensive checking, possibly including partial calibration or verifications);
- scheduled maintenance by in-house or specialist contractors;
- complete recalibration.

Shorter intervals between calibrations and acceptance testing or checks may be required when the equipment operates under less than ideal conditions. If any suspicion of damage arises, the equipment would be recalibrated, verified or tested to acceptance criteria immediately and thereafter at reduced intervals until it is shown that stability has not been impaired. Furthermore, reduced intervals between calibrations acceptance testing and checks may also be required in particular testing applications or with particular equipment configurations.

An interval may be extended if the facility is able to justify the extension, subject to statutory, contract, specification or test standard requirements.

In order to assist facilities to demonstrate good control of their tests and measurements and to reduce their operating costs, NATA encourages facilities to develop equipment assurance programs.

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