ISO/IEC 17025:2017 - GAC additional requirements

Contents

Field Application Document: FAD-1.0

Introduction

This document provides interpretative criteria and recommendations for the application of ISO/IEC 17025 in all fields of testing and calibration for both applicant and accredited laboratories.
Applicant and accredited laboratories must also comply with relevant field ISO/IEC17025 application documents and any annexes, GAC policies and/or technical Notes.

ISO/IEC 17025:2017 standard requires the laboratory to plan and implement actions to address risks and opportunities
Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects.
The laboratory is responsible for deciding which risks and opportunities need to be addressed.

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. General requirements

4.1 Impartiality

Principles for inspiring confidence and threats to impartiality are described in the accreditation standards. It is the responsibility of the testing and calibration laboratories to prove that they have analyzed threats and taken corrective actions when appropriate to safeguard their impartiality.
When analyzing threats and risk on impartiality it remains the responsibility of the laboratory to choose the most suitable tool according to its context.
The standard does not require the laboratories to prove that it has identified every circumstance that may pose a risk to its impartiality, but there is an underlying expectation that the major/most likely risks are indeed identified. Failure to do so shall be considered as a non-compliance.

5. Structural requirements

5.3 The laboratory is required to specify its range of the laboratory activities (both accredited and non-accredited) that is covered and conforming to the requirements of the standard 17025 within its management system, the accreditation assessment shall account the accredited parameters regardless of whether laboratory claims accreditation or not.
Only activities where the CAB can prove its competence to perform are included in the scope, which excludes externally provided activities on an ongoing basis.

6. Resource requirements

6.2 Personnel

6.2.5 Personnel records maintained by the facility must be available for review during the assessment. This would include evidence of qualifications, recognition by professional or regulatory bodies (e.g. licensing and registration), and any other authorizations as defined in the relevant ISO/IEC 17025 field application documents.

6.5 Metrological Traceability

6.5.2 The results of all tests, measurements and calibrations that have a significant effect on the reported result and associated uncertainty of measurement must be traceable. GAC Technical note 2 - Metrological Traceability of measurements should be applied.

In-house calibrations

A facility performing its own calibrations will also be subject to technical assessment of these calibrations. The assessment team will determine if the in- house calibrations are fit for the purpose for which they are being used and that a reasonable estimate of the associated measurement uncertainty has been made. Fees will be charged where significant additional assessment effort is required (i.e. time or additional assessors). Specialist calibration assessors will only be used when either the calibration is outside the area of expertise of the technical assessor(s) who would normally conduct the assessment, or if it would be more time or cost effective.
Note: Refer to GAC Technical note 2 - Metrological traceability of Measurement results.

Testing

Reference standards and equipment shall be calibrated over the range and to the appropriate level of accuracy specified in relevant methods.

Accreditation cannot be given for extremes of the test or measurement range based on extrapolation beyond the minimum and maximum calibration points.

A facility performing its own calibrations may also be subject to proficiency testing and technical assessment for these activities to ensure that all the relevant requirements of ISO/IEC 17025 are met (e.g. adequately documented procedures, procedures to estimate the uncertainty of measurement and complete records of calibration data).

Note: Refer to GAC Technical note 2 - Metrological traceability of Measurement results.

Reference standards/ Materials: Refer to GAC Technical note 2 - Metrological traceability of Measurement results.

6.6 Externally provided products and services

6.6.2 Re-evaluation of the vendors shall account those who are critical in nature that are affecting the integrity of the results or management system for example PT providers, Calibration and testing services provider.
A competent vendor is for example, but not limited to, an accredited GAC facility or a facility accredited by a signatory to a Mutual Recognition Arrangement.

6.6.2 When appropriate**,** the accreditation status of vendors should be regularly reviewed to ensure currency.

Note: Information on accreditation status and scope of accreditation may be found at GAC's website or by contacting one of GAC's offices.

7. Process requirements

7.2 Selection, verification and validation of methods

7.2.1.3 A standard method is defined as a method written by a body that has authority to write standards. Standard methods must be followed without variation for it to be referenced as a standard method on the scope of accreditation, where standard methods are used, the current version must be used unless a legal or regulatory requirement requires the use of a superseded or withdrawn version (in such cases, the year of issue will be denoted on the scope of accreditation – see note below).
Facilities accredited to standard methods must maintain records of all interpretive decisions which they may make as a response to ambiguities in the methods or specifications contained in standards.

Informative note for labs: GAC normally includes as applicable the edition/version/year of a method/standard on the scope of accreditation as if required by the applicable requirement standard, scheme or regulation, it is also assumed that when it is not it is latest standard, in some cases GAC may chose not to include this information e.g., where it is known that the method/standard will be frequently revised such as those ASTM standards.

Note: In some circumstances GAC may impose additional requirements on standard methods. This action is only taken where testing in accordance with the stated requirements of a standard is likely to cause an inappropriate interpretation of the results appearing in a report and thereby bring GAC into disrepute. Such a requirement would only remain in place until the standard was appropriately amended. Where a standard does not adequately define the methods or contains ambiguities which would make it impossible to consistently apply the requirements, GAC may refuse accreditation.

7.3 Sampling

Sampling may be conducted by the facility, by another section in the organization or by a separate organization. Routine sampling falls within the scope of ISO/IEC 17025, so that where ISO/IEC 17025 uses the word 'laboratory' it is also referring to bodies conducting sampling. The phrase 'testing and/or calibration' includes sampling activities. Bodies responsible for sampling are encouraged to seek accreditation with GAC for this activity. Depending upon the structure of the organization, the assessment of sampling activities may be included as an element of the facility's assessment or may demand a different assessment team. In assessing an organization's sampling activities, all the management and technical requirements of ISO/IEC 17025, as relevant to sampling, will be assessed.

In some cases, appropriate sampling activities demand the development of job- specific sampling plans and/or the use of professional judgement. Sampling may also be performed as part of a wider inspection activity. Accreditation for these activities is possible under GAC's Inspection Accreditation Program. Interested bodies are encouraged to contact GAC to discuss accreditation of these sampling activities.

Where a sampling body samples material that are to be tested by another facility, the sampling body should include in its report the information of ISO/IEC 17025, Clause 7.8.5.

The following conditions must be met to gain accreditation for sampling.

- Documented sampling procedures must be maintained. These may be national or international standards. If in-house methods are used, their validity for the intended purpose must be demonstrated.
- The sampling procedure must be cited on the test report whenever the facility wishes to extend the test results from a sample to an entire batch.

7.5 Technical records

a) The records system must include a copy of each report or certificate that contains work covered by the scope of accreditation, or must allow one to be reproduced, including details such as the endorsement (if applicable) and identification of the person who authorised the report.

b) In general, the records system must include the following:
   - The sample identification;
   - The test or calibration document identification;
   - Date of test or calibration;
   - The identity of the method;
   - The identity of the equipment;
   - Original observations and calculations;
   - The identity of the person performing the test or calibration;
   - An indication that calculations and manual data transfers have been checked;
   - Any other information specified in the method, other contractual documents or relevant statutory regulations.

c) Rounding of results shall only be performed at the final stage of reporting, unless otherwise required by the method. Rounding should be made to the level of precision specified in the reporting requirements of the method.

d) As far as practicable, all records must be indelible, and data or observations recorded in such a manner that prevents amendment or loss of the original. alterations to data must also include the date the change was made.

7.6 Evaluation of measurement uncertainty

The requirements for stating calibration and measurement capability (CMC) in laboratories scope of accreditation can be found in the ILAC P 14 – ILAC policy for uncertainty in calibration and GAC Technical note 01 – uncertainty of measurement.

7.7 Ensuring the validity of results

7.7.2 Each applicant or accredited facility is required to participate in appropriate PT activities.
Facilities are encouraged to participate in as broad a range of PT activities as practicable, but at least once every two cycles (different frequencies may be stated in the various field/program policies) for each major area of test, measurement or related activity covered by the scope of accreditation, where such programs are available.

Where formal PT programs are not available for any activities or do not provide sufficient coverage, laboratories must investigate other means of assuring the quality and performance of the activities for which they seek or hold accreditation.
Note: See GAC *Technical note 4 – policy on Proficiency testing for further information.*

7.8 Reporting of results

Note: See GAC *Technical note 6 - Policy on the Use of the GAC logo GAC endorsement and references*

7.8.1 Electronic transmission and remote issue of results

Test reports may be electronically issued (including from a site other than the accredited facility) provided that the reports have been appropriately authorized for release. The adequacy of such arrangements will be reviewed at assessment.
The facility must be able to demonstrate appropriate controls over the electronic generation, access, storage and back-up of results and reports and program controls such as password protection. If the report is to be accessed from a web site by the customer there must be appropriate controls in place to ensure the report can only be accessed and downloaded in a protected format.
Any information normally included in a hardcopy report must be included on the electronically transmitted version and appear in any hardcopy printed by the recipient. Flexible pagination to accommodate formatting changes when printed by the recipient may also be required.
It must be ensured that any handwritten comments included on issued reports are also included in the copy of the reports retained by the facility.

7.8.2 Common Requirements for reports (test, calibration and sampling)

Reports on results from tests or calibrations covered by the scope of accreditation must include the name in which accreditation is held and the accreditation number.

In instances where results of tests or calibrations not covered by the scope of accreditation are included in reports covering accredited activities, the notation 'GAC accreditation does not cover the performance of this service' or disclaimer shall be applied in line with GAC TN-6.

Preliminary reports (however named) may be issued when components of a test or suite of tests have not yet been completed. However, those results which are reported must be checked and authorized and the status of the report evident (i.e. preliminary).
Where an accredited facility issues a preliminary report prior to the final report, the final report shall contain a reference to the preliminary report.

No report, whether preliminary or final, shall include results not authorized for release.

7.8.2.2 Reports issued on activities covered by the scope of accreditation must be authorized by personnel approved by the facility.

7.8.3 Specific Requirements for test reports

Compliance statements shall reference those sections or clauses of the specification to which the compliance statement relates.

When statements of compliance are made, the uncertainty of measurement shall be taken into account.
A compliance statement may be made if:

- The measurement results fall within the specification limits by an amount at least equivalent to the uncertainty of measurement; or
- The measurement results fall within the specification limits and the uncertainty of measurement is within the maximum permissible uncertainty prescribed in the specification; or
- The test specification defines the compliance decision rule to be used and the measurement results meet the specified criteria; or
- The customer and facility have agreed to a compliance decision rule.
- When this applies, it should be detailed in the report and reference to the compliance statement made.

Testing laboratories may not make compliance statements in the situations described in the fourth point above, if the testing is for the purposes of regulatory compliance.

Calibration labels

Calibrations labels that include the “GAC accredited” symbol shall also include an identification of the facility and must be traceable to the appropriate endorsed report.

7.9 Complaints

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question, individual(s) involved in the original laboratory activities in question can not be the investigator themselves.

8. Management System requirements

8.2 Management system documentation

Quality documentation must include or reference the scope of accreditation and the policy on the use of the GAC logo

8.4 Control of records

All records must include the identity of the person making the record.
It is recognized that a number of staff may be involved in test processes or other laboratory procedures. It is the facility’s responsibility to identify the critical steps(s) in the procedure and ensure that the identities of the staff concerned are recorded.
Unless otherwise prescribed by legislation or contractual obligation, retention times shall not be less than 4 years or, in the case of equipment records, the maximum recalibration interval of equipment (whichever is the longer period).

8.8 Internal audits

The internal audit schedule must cover annually both the management and technical requirements including witnessing of sample of the accredited scope or applied scope of accreditation.
GAC requires that the conformity assessment bodies shall apply the clause 6.2.2 to determine the competence requirements for its internal auditors, the laboratory shall ensure that its internal auditors are independent, impartial and are clearly identified in the management system e.g. list of internal auditors.

8.9 Management reviews
The effectiveness of the management system shall be reviewed by management at least once per year.

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.

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- GAC Technical note 1 - Uncertainty of measurement
- GAC Technical note 2 - Traceability of measurements,
- GAC Technical note 4 – policy on Proficiency testing,
- GAC Technical note 6 - Policy on the Use of the GAC logo GAC endorsement and references.

https://ilac.org/publications-and-resources/

- ILAC P 9 – ILAC Policy on PT Participation
- ILAC P 10 – ILAC Policy on traceability of measurement results
- ILAC P 14 – ILAC policy for measurement uncertainty in calibration