

Specific requirements for the accreditation of testing laboratories according to ISO/IEC 17025:2005

General

ILAC has provided a **transition period of two years** for the worldwide introduction of the new standard ISO/IEC 17025:2005 to be valid from the publication and to finalize on 31st May 2007. From this time on no more certificates with reference to the old DIN EN ISO/IEC 17025:2005 will be issued; certificates based on the out-dated standard will be declared invalid and withdrawn.

The aim of the changes and amendments of the new standard DIN EN ISO/IEC 17025:2005 as compared to the edition in 2000 was to adapt the requirements for the management system of a laboratory to the requirements of ISO 9001:2000. Annex A of the standard contains a cross-reference list with cross-references between ISO 9001:2000 and ISO/IEC 17025:2005.

The extent and type of the changes and amendments show that quality manuals don't have to be revised completely - changes and amendments have to be made.

The term "management system" substitutes the term "quality management system" where the whole management system of the laboratory is meant, that is the management system for quality, administrative and technical operations (item 1.4).

DAP accredits testing laboratories based on either ISO/IEC 17025:2005 or the national edition DIN EN ISO/IEC 17025:2005 of the international European standard.

The specific requirements in this document are established according to the recommendation in Annex B, section B.4 of the standard.

1. Scope of application*

Only **independent laboratories** will be accredited. They may be part of a larger organisation (supplier/consumer laboratories or first party/second party laboratories), the organisational and personnel impartiality must be proven (Clause 4.1.4, Note 2). The laboratory management and the personnel are required to be free from any undue commercial, financial or other pressure, from the parent organisation.

Laboratories will be accredited independent of the **number of employees**, if

- The deputies for the laboratory management and quality manager are specified
- Internal audits are assured to be conducted independently.

* The order of numbering-index follows DIN EN ISO/IEC 17025:2000.

2. Standard requirements for quality systems

Also for existing quality systems complying with ISO 9000 series of standards, the quality system must be assessed within the accreditation period.

The compliance of ISO/IEC 17025:2005 with the fundamental requirements of ISO 9001:2000 was confirmed by a joint Communiqué signed to this effect by ISO, ILAC and IAF.

3. Nil

4. Management requirements

4.1 Organisation

4.1.1 The laboratory shall have a sufficient liability insurance, which includes risk against financial losses or an equivalent measure to cover all testing services.

4.1.5 With regards to the policies and procedures for protecting the confidentiality of customers information and proprietary rights, instructions and declarations on confidentiality are not required to be made on an annual or regular basis.

4.1.6 The communication processes within the quality management documentation shall be described containing at least the following details:

- Title (e.g. start meeting, annual appraisal interviews, team leader meetings)
- Participants
- Time interval, occasion
- Type of documentation (e.g. minutes of the meeting, ...)

4.2 Management system

4.2.2 The minimum requirements with respect to the quality policy statement are as follows:

a) “**Good professional practice**” differs from field to field in the laboratories. As a basic principle, it means that **substantial new developments** of test methods have to be introduced into the activities of laboratories, when the **test objective** calls for them. This does not however apply for every new development of testing facilities that only enable tests to be conducted more efficiently or economically.

The laboratory must provide evidence of knowledge of the new development and document the use or otherwise of the implementation instructions.

“Good professional practice” means in every case that for **assuring test results, omitting steps** in order to make testing more economical **is not permitted**.

In any case, the testing **personnel** of the laboratory must have adequate theoretical background knowledge and understanding for tests carried out and extensive experience in working with the test methods.

* The order of numbering-index follows DIN EN ISO/IEC 17025:2000.

b) The **statement of the laboratories standard of service** has to include at least the declaration, that the laboratory conducts either routine tests only or it is able to change, extend, adapt or develop test methods and to validate them. The declaration shall include the statement, that the laboratory is in the position to carry out new developed tests und that it is available for such tasks.

4.3 Document control

The laboratory must define appropriate intervals for keeping all documents including those that are invalid and/or out-of-date. The interval should at least cover the next assessment for reaccreditation.

4.5 Subcontracting of tests

The accreditation **does not cover external competence**.

Subcontracting within accreditation can only be for testing services, whereby the **control of the relevant test methods**, the **suitability** and **qualifications of its personnel** and the **suitability of its testing facilities** in the subcontracted laboratory have been assessed and found to be positive.

4.12 Preventive action

To determine possible **sources of error**, work processes can be examined, which includes:

- Risk analyses
- Trend analyses
- Statistical process control
- Fault tree analyses
- And other Failure Mode Effects and Criticality Analysis (FMECA) methods, which are suitable to the specific fields (see DIN ISO 9004:2000-01, Cl. 8.5.3).

The results of internal audits and management reviews of the quality system may be taken into account.

Procedures that indicate trends like regular, operational, on-going use of quality control charts may be included.

Necessary improvements on the one hand, result from either further scientific or technological developments, and therefore, the participation in appropriate seminars or studying its literature for keeping constantly updated in the specific fields of expertise is essential. On the other hand such improvements are necessary in order to enable testing to be conducted more efficiently and in a safer manner. For this, the know-how and expertise of developments in testing facilities are crucial and the participation in exchange of information with peers is vital.

4.13 Control of records

The laboratory must specify appropriate retention periods for quality and technical records. Minimum retention periods defined by legal requirements or those specified in contractual agreements by customers should be taken into account.

* The order of numbering-index follows DIN EN ISO/IEC 17025:2000.

4.14 Internal audits

Auditors must be independent of the activity that is audited and must demonstrate that they are suitably trained and qualified.

5.4.2 Selection of methods

Attestation that the laboratory can conduct tests according to standard methods must be documented based on verification processes.

5.4.6 Estimation of uncertainty of measurement

References, guidance and aids related to the estimation of measurement of uncertainty can be found additionally in the following documents:

- DAR-4-INF-01 Uncertainty of Results in Testing; Recommendation for Testing Laboratories and Assessors for Determination and Statement of the Uncertainty of Results in Testing
- DAR-4-INF-02 The Expression of Uncertainty in Quantitative Testing
- DAR-4-INF-08 Requirements for Testing Laboratories and Accreditation Bodies in terms of Estimation of Measurement Uncertainty according to ISO/IEC 17025 (5.4.6 / 5.10.3)
- DAR-4-INF-09 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025

5.5 Equipment

5.5.1 Equipment outside of permanent control

The laboratory may also use equipment (stationary or mobile) that it does not own. For that purpose the laboratory shall have the documents as follows at its disposal:

1. A standard operating procedure describing the use of the external equipment
2. A contractual procedure specifying the terms and conditions of use with the owner, user or administrator of the equipment with the following details:
 - Control of access to the external equipment of facility for operational staff and other persons
 - Maintenance and purchase of spare parts
 - Upkeep of serviceability
3. A work instruction for
 - The upkeep of serviceability
 - The maintenance of equipment
 - Putting into operation and calibration of the equipment
 - Control measures when equipment is defective or out of service, in need of repair
 - Cleaning and restoration of serviceability after use

* The order of numbering-index follows DIN EN ISO/IEC 17025:2000.

4. Policies and procedures of continuous training of laboratory's own personnel in this work area relating to the use of equipment
5. Full documentation of all operational processes using equipment outside the permanent control of the laboratory

The documentation of processes and their implementation have to be assessed by the technical assessor.

5.8 Handling of test items

Where samples are delivered to the laboratory in an apparently improper manner, the laboratory shall do the following:

1. Information to the customer on the improper delivery and note on possible false test results
2. Clarification whether the analysis for the sample delivered shall nevertheless be performed (a) or whether the sampling and delivery shall be repeated so that samples taken and packed properly may be analyzed (b)
3. Immediate proper and regular packaging and storing of the test item (e.g. refilling from plastic bags into safety glass envelopes, cooling, light protection etc.)
4. Note on the state of delivery and risk of false results in the records for conducting the test (sample receipt, sample accompanying forms, LIMS etc.).
5. Note in the test report on the improper state of the test item when delivered and limited significance of the test result (so-called „disclaimer“)

5.9 Assuring the quality of test and calibration results

5.9.1 b) Participation in interlaboratory comparison or proficiency testing programmes

The participation in proficiency testing programmes (interlaboratory comparisons with restricted number of participants, bilateral proficiency tests) is binding for laboratories, when required by sector committees or assessors.

A “policy on interlaboratory comparisons” shall be part of the quality management documentation. This policy shall at least state the participation in interlaboratory comparisons (number and scope) and general rules on how to handle the results of these comparisons.

5.10 Reporting the results

5.10.1 General

If test results are reported in a simplified way, either for internal customers or in the case of a written agreement with the customer, the test report must contain at least the following information:

- Test results
- Information that enables cross-reference of test results to be made

* The order of numbering-index follows DIN EN ISO/IEC 17025:2000.

5.10.2 Test reports

Accredited bodies should use the accreditation logo to prove the recognition of their competence to third parties.

If an accredited organisation announces results, which bear no accreditation logo (or have no reference to the accredited status), the assumption that there is conformity with the requirements of ISO/IEC 17025 may not be assigned. Any reference made to the existing accreditation and the statement of the test results shall only be done in an unambiguous manner in order to rule out any misunderstanding.

(DAR-3-EM-05, EA-3/01, DIN EN ISO/IEC 17011:2005, Cl. 8.1.1).

Test reports and the accompanying documents containing a direct reference to the accreditation or not shall comply with all requirements of the ISO/IEC 17025 as regards to the test reports.

There are the following cases to differentiate:

Case a: Test report and/or accompanying documents with direct reference to the accreditation:

- Non-accredited test methods shall clearly be identified as non-accredited.
- Subcontracting (where an accredited testing laboratory subcontracts tests for which it is accredited) shall clearly be identified.
- If a laboratory subcontracts non-accredited test methods to other laboratories, in addition to the binding identification in accordance with item 1, the laboratory is recommended to put a note on the order assignment (if applicable, with reference to the accreditation of the contractor for the specific test).

Case b: Test report and/or accompanying documents with no direct reference to the accreditation:

- Non-accredited test methods do not have to be identified as non-accredited.

5.10.5 Opinions and interpretations

The testing laboratory shall have arrangements to ensure that opinions and interpretations in the test report are identified.

* The order of numbering-index follows DIN EN ISO/IEC 17025:2000.