Rule for accreditation of testing laboratories according to DIN EN ISO/IEC 17025:2018

R-17025-PL

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Scope:

This document specifies, where necessary, the general requirements of DIN EN ISO/IEC 17025:2018, and in addition to R-17011 the requirements of DIN EN ISO/IEC 17011:2018 concerning the procedure for accreditation of testing laboratories.

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I Introduction

DIN EN ISO/IEC 17025:2018 (hereinafter simply 17025) sets out requirements for testing laboratories. DAkkS applies 17025 for the accreditation of testing laboratories for the purposes of both international recognition and the fulfilment of its duties as the national accreditation body pursuant to Regulation (EC) No 765/2008. For legal reasons, testing laboratories may have to comply with stricter requirements for the purpose of national application, and this must be taken into account in cases of accreditation.

For administrative practice, this rule sets out the requirements of 17025 in greater detail where necessary, and in addition to rule R-17011 the requirements of DIN EN ISO/IEC 17011:2018 (hereinafter simply 17011). This rule applies only as long as the versions of 17025 and 17011 have the status of a harmonised standard.

With this rule, DAkkS defines no new requirements for testing laboratories going beyond the requirements of 17025/17011. Existing minimum requirements are not restricted or withdrawn. Normative terms or subject matter of 17025/17011 whose interpretation is not unambiguous are specified in greater detail in individual cases as required.

DAkkS assumes a knowledge of the exact requirements of 17025/17011, and the text of the standards is therefore not reproduced. Where applicable and adopted by DAkkS, and independently of this rule, international rules of the organisations *European co-operation for Accreditation* (EA) and *International Laboratory Accreditation Cooperation* (ILAC), which themselves specify the requirements of 17025/17011 in greater detail, apply. Here again, DAkkS does not reiterate their content in this rule. Where appropriate, reference is made to these rules at the relevant points. DAkkS generally provides German translations of the adopted applicable international rules.

In essence, this rule constitutes the accreditation scheme required under 17011 for the accreditation of testing laboratories through the application of 17025 by DAkkS. It includes only aspects that are applicable to all testing laboratories. Specific details for testing laboratories in individual technical sectors/areas can be the subject of lower-level rules.

This rule is based on the structure of 17011 and 17025. Sections of 17011 and 17025 that require no greater detail are omitted.

Further information, in particular explanations of 17025/17011 and their application by DAkkS or information for testing laboratories concerning the accreditation procedure may be available in DAkkS information sheets and on the DAkkS website.

II Specification of requirements for the accreditation procedure

In addition to rule R-17011, this section sets out the requirements of 17011 for the accreditation of testing laboratories in greater detail. The numbering within this section follows the numbering of 17011.

7 Process requirements

7.2 (17011) Application for accreditation

7.2.1

The information provided by the body to be accredited as part of its application must include all locations of the testing laboratory (permanent, mobile, virtual) as well as information as to whether and which testing activities are performed outside the locations of the testing laboratory (on-site activities such as on-site testing, sampling).

To enable DAkkS to determine the body's competence with legal certainty, the application must include extensive evidence regarding property and ownership structures and any relationships to a higher-level entity (group of companies). The submitted organisation charts and descriptions in the QM system, and where applicable also the statement of the formation of dependent units within the legal entity, must be clearly and demonstrably consistent with the actual relationships under commercial and company law.

The statement of the scope to be accredited must meet the requirements of section II 7.8 of this document. Requirements of sectoral rules – if any – must be adhered to.

7.4 (17011) Preparation for assessment

7.4.5

The representative sample size (scope of assessment[1] and depth of assessment[2]) regarding any assessment of a testing laboratory is based on the entire scope of (sought) accreditation.

For initial accreditations and reassessments, the sample to be assessed is determined in a manner that ensures that all test areas[3] within the scope of accreditation, all locations at which key activities

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1 Scopes that will be assessed (selection from the scope applied for/accredited scope and locations as per the current annex to the accreditation certificate, as well as focal points with regard to the normative requirements of 17025).

2 Required samples including witness activities for the defined scope of assessment.

3 Part of the scope applied for accreditation characterised by type of test/test methodology/principle of measurement, matrix/sample/test item/test object and measurand/test parameter/analyte and other parameters where applicable.

are performed and testing activities outside the premises/locations of the testing laboratory are included in the assessment.

Upon request, testing laboratories must provide DAkkS with the required information on planned activities outside the premises of the testing laboratory (on-site activities) prior to the assessment in order to ensure that these activities can be included in the assessment (witnessing).

In addition to those set out in R-17011, the key activities of testing laboratories include the following in particular:

- Preparation, implementation and follow-up of sampling and testing activities;
- Evaluation of the competence and approval of technical personnel and of external service providers providing services related to sampling or testing;
- Any internal[4] calibrations carried out;
- Control of the process of monitoring the competence of personnel and of external service providers providing services related to laboratory activities and their results;
- Approval of test results with and without a decision rule;
- Handling of complaints;
- Validation and verification of test methods;
- Planning and follow-up of internal audits;
- Control of the management system.

7.8 (17011) Accreditation information

7.8.3

For a manufacturer's laboratory acting as an "accredited in-house body" within the scope of Decision (EC) No 768/2008 (Annex II, modules A1, A2, C1 or C2), the accreditation information must state that this body provides its services in this scope exclusively for the organization of which it forms a part.

7.8.4

Provided that there are no sectoral requirements to the contrary, DAkkS offers flexibility of the scope of accreditation upon request. As a prerequisite, the testing laboratory must have demonstrated that it has valid processes in accordance with EA 2/15 in place.

Flexible scopes can only cover areas for which the testing laboratory has the necessary essential competence among personnel and the requisite premises and facilities. Evidence of this must be provided to DAkkS during the assessments carried out before flexible scopes are granted.

[4] Calibrations performed by the testing laboratory or personnel of the same legal entity.

The flexible scopes are shown in the accreditation information (annex to the accreditation certificate). The manner in which flexible scopes are presented is always specified by DAkkS and set out in greater detail where applicable in sectoral specifications.

~~A~~ flexible scope granted for categories B and C (see below) can be withdrawn if the testing laboratory does not make use of a flexible scope granted within an accreditation cycle.

The extent of flexibility is defined in so-called “test areas”. Test areas can include for example groups of analytes or groups of test items within which the testing laboratory can use the flexible scope. Test areas covering more than one type of test/test methodology/principle of measurement are not possible.

Flexibiliy of scopes can be divided into three different categories:

Category A allows under the scope of accreditation the inclusion of different issue dates of standardised or equivalent test methods within a defined test area.

Category B includes category A and allows under the scope of accreditation the inclusion of additional standardised or equivalent test methods within a defined test area. Category B includes – to the extent applicable – new specifications for test items, provided that these can be determined with the method in the test area.

Category C includes categories A and B as well and allows under the scope of accreditation the inclusion of additional modified, enhanced and newly developed test methods (including in-house methods) within a defined test area.

The test areas for a flexible scope of accreditation in accordance with categories B and C are presented in a manner that ensures that the limits of its flexibility are clearly evident.

Within the specified categories and defined test areas, the testing laboratory is permitted to include test methods within the scope of accreditation without obtaining prior notification and consent from DAkkS. A complete and up-to-date list of the test methods implemented or offered within the scope of accreditation must be made available to DAkkS upon request and must be made publicly available by the testing laboratory.

For each test method, this list contains the reference to the test area as specified in the currently published annex to the accreditation certificate, a unique identifier, an issue date and the title of the test method. For in-house methods, the title must always include the test methodology/type of test used, the test item or items and the analytes/measurands/test parameters. For each listed test method, the point in time at which the method was included in the scope of accreditation must be evident within the documentation of the testing laboratory.

The accreditation information concerning flexible scopes issued by DAkkS does not include all test methods listed by the testing laboratory as specified in the above list. For categories B and C, test methods within the designated test areas are listed only as examples.

Unless explicitly stated otherwise, flexible scopes of accreditation are granted on a location-specific basis and marked accordingly in the accreditation information.

7.9 (17011) Accreditation cycle

7.9.3

During assessments, it is necessary to establish on a recurring basis that the testing laboratory continues to possess the competence to perform the specific testing activity, in particular through observations (witnessing) of the testing activity.

If the recurring assessment of the testing activities is not possible due to a lack of orders or customers, DAkkS can allow the testing laboratory to compensate for the lack by taking appropriate measures. In the event of a lack of customers/orders, DAkkS can consider one or more of the listed measures as compensation:

- Successful participation in proficiency testing or, if not available, through qualified laboratory comparisons
- Regular analysis of reference materials/samples
- Completion of a test without an order during an assessment
- Equivalent test methods are used regularly (equivalence with regard to methodology, matrix, analyte)

If there is no satisfactory alternative for compensation, so that ongoing determination of competence by DAkkS is not possible, the accreditation must be reduced for the testing activities affected.

III Specification of requirements of DIN EN ISO/IEC 17025:2018

This section sets out the requirements of 17025 for the accreditation of testing laboratories in greater detail. The numbering within this section follows the numbering of the standard.

6 (17025) Resource requirements

6.2 (17025) Personnel

6.2.1

As proof of adherence to the requirements for accreditation set out in 17011, section 4.2 a), the testing laboratory must submit a contract to DAkkS upon request (e.g. a service, employment or temporary employment contract, where applicable in conjunction with other documents such as a permit for temporary employment or a release of freelancers from their duties by the principal employer). This serves as objective evidence that personnel have made a legally enforceable commitment to act impartially and to comply with the established rules, including those relating to confidentiality, in accordance with the testing laboratory's management system (see also 17025, sections 4.1.1 and 4.2.1).

6.2.2

The requirements of section 6.2.2 of the standard include at least the personnel performing key activities as defined in chapter II. section 7.4.5.

6.4 (17025) Equipment

6.4.2

To demonstrate assurance of all requirements for equipment that are not under the permanent control of the testing laboratory, appropriate written contractual arrangements for the use of, access to and availability of the equipment must be submitted.

All testing activities using equipment of the customer (e.g. manufacturer) can be part of the assessment.

In all cases, the testing laboratory must be able to provide evidence of the suitability, functionality and control, and maintenance and calibration of the equipment. This responsibility cannot be delegated to the owner of the equipment.

The testing laboratory is obliged to perform the tests on its own responsibility with personnel bound by contract, to define and document all management system and technical requirements of 17025 for these tests and to provide evidence of adherence to the requirements.

6.5 (17025) Metrological traceability

6.5.2

The basis for the requirements for demonstrating that appropriate metrological traceability is ensured is the document ILAC-P10:2020. This is supplemented by the following more detailed specifications:

Evidence that a calibration certificate is suitable to demonstrate the metrological traceability of reported results according to ILAC-P10 route 2 (reporting of results by a calibration laboratory whose accredited CMC[5] covers the reported results) is usually in the form of the accreditation symbol of a national accreditation body that is a member of the ILAC MRA for the accreditation activity "Calibration" on the result report. If evidence of traceability according to 3a (provision by a recognised metrology institute or by a designated institute as a CIPM[6] member) is provided outside the CIPM MRA[7], the testing laboratory must demonstrate that the reported results were prepared in compliance with the requirements of the issuing body's management system in accordance with 17025. Route 3b should only be applicable when if routes 1, 2 and 3a are not available. In this case, the CAB must be able to provide evidence of the issuing body's competence in accordance with ILAC-P10. DAkkS decides on a case-by-case basis on the assessment activities required with regard to this evidence, where necessary including an on-site assessment of the issuing body (Appendix A to the document ILAC-P10 provides guidance here).

Result reports from accredited calibration laboratories without reference to the accreditation, although accredited for the relevant CMC, are not recognised as evidence of traceability.

To demonstrate metrological traceability using certified reference materials (CRMs) produced by a non-accredited manufacturer, the testing laboratory must demonstrate that the CRMs were provided by a competent reference material producer and that they are fit for their intended use.

According to 17025 and ILAC-P10, in-house laboratory calibrations are possible. For these calibrations, the requirements of 17025 and ILAC-P10 apply synonymously.

[5] Calibration and Measurement Capabilities

[6] Comité International des Poids et Mesures

[7] Mutual Recognition Agreement

6.6 (17025) Externally provided products and services

6.6.1

Accreditation for laboratory activities provided externally on an ongoing basis is excluded (see section 5.3 of the standard).

For laboratory activities in the accredited scope provided externally by way of exception, only contractors accredited for the respective scope are considered suitable.

6.6.2

The testing laboratory must have a procedure in place to ensure that only suitable externally provided products and services are used where these products and services relate to calibration, sampling and testing, evidence must be provided that the same requirements that apply to the testing laboratory are met.

6.6.3

Where laboratory activities are performed by external providers by way of exception, in accordance with section 5.3 of 17025, section 6.6.1 of 17011 in conjunction with section 4.2 a) the testing laboratory must have contractual arrangements in place to ensure that external providers are committed in a legally enforceable manner to work in accordance with the notified requirements of the testing laboratory. If non-accredited bodies are contracted in justified exceptional cases, the contract must also allow for surveillance of the external provider by DAkkS.

This also applies to external services provided according to ILAC-P10 route 3b in the context of metrological traceability (see section III 6.5.2 above).

7 (17025) Process requirements

7.7 (17025) Ensuring the validity of results

7.7.2

The following provisions are based on the international documents ILAC-P9 and EA-4/18.

As part of its assessments, DAkkS uses, among other things, the results of proficiency testing to verify and assess compliance with the requirements of 17025 in testing laboratories.

On the basis of regulatory requirements, arrangements in sectoral rules or other sources, further requirements for participation in proficiency testing going beyond the requirements set out in this rule may be defined.

In order to obtain or maintain their accreditation, testing laboratories are required to provide evidence of successful participation in proficiency testing and/or interlaboratory comparisons if available and appropriate. If suitable proficiency testing in the above sense is not on offer, interlaboratory

comparisons between two or more test laboratories that are self-organised can be recognised. Where appropriate, comparative tests for the purpose of method validation or certification of reference materials can also be recognised.

DAkkS requires successful participation in at least one proficiency test/comparative test for each technical area of competence[8] in the accreditation cycle.

For this purpose, a general proficiency testing strategy and plan must be described within the quality management documentation. The scope and the frequency of participation in proficiency testing for a specific area of technical competence must be determined by the testing laboratory itself, with due regard to sectoral and other external requirements, risk and representativeness.

Necessity and frequency must be set out in a documented plan. The plan must always cover the current accreditation cycle. It must also be ensured that the plan considers at least the following 3 years in advance. The plan must be reviewed at least once a year and adjusted if necessary.

The testing laboratory must maintain a table summarising all ongoing participation in proficiency testing and interlaboratory comparisons. The table must cover the current year and at least the last three previous years. It must also be ensured that the table contains at least the last participation for each area of technical competence. The results of the proficiency tests shall be evaluated on a parameter-by-parameter basis. Where available, the table must include at least the following information:

- Allocation to the technical area of competence
- Dates on the operation of the proficiency test
- Proficiency testing provider
- Product/matrix
- Parameters determined
- Parameters for which the proficiency test was not passed, where applicableincluding evaluation criteria, e.g. z-score or En-values
- Corrective actions (keywords) for parameters for which the proficiency test was not passed

[8] Area with at least one test method, one property/analyte and one product/matrix that are interrelated (see also EA 4/18).

7.8 Reporting of results

7.8.2 General requirements for reports (testing, calibration or sampling)

7.8.2.1 f)

Results of tests are only usable, informative and fit for purpose if the methods used for them are specified. The unique designation of a method includes at least the short title and the issue status/issue date. This applies irrespective of whether it is a standard, an equivalent method or an in-house method. This information on the test methods used must be included in full in the result reports.

8 (17025) Management system requirements

8.4.2

As evidence of compliance with the requirements for accreditation (see 17011, section 4.2 a)), the testing laboratory must in accordance with section 8.4.1 of 17025 keep all records for at least the duration of the current accreditation cycle and the previous full accreditation cycle.

8.8.2

The audit programme cycle must be representative of all standard requirements and the scope of accreditation covering at least 24 months.

For internal audits within the meaning of sections 8.8.2 a) and 8.1.3, the audit programme must define the planned intervals between internal audits in a manner that ensures that the results of audits are representative of all standard areas and laboratory activities in the entire scope. Records of this must be available for submission as evidence of fulfilment of the requirements within the framework of the initial assessment by DAkkS and ongoing monitoring (see 17011, section 4.2 a)).