

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

R-17025-K

Revision 1.0 | 10 February 2025

Scope of application:

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 calibration laboratories.

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I Introduction

DIN EN ISO/IEC 17025:2018 (hereinafter simply 17025) sets out requirements for calibration laboratories. DAkkS applies 17025 for the accreditation of calibration 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, calibration 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 calibration 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 Existing minimum requirements are not restricted or withdrawn.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 calibration laboratories through the application of 17025 by DAkkS. It includes only aspects that are applicable to all calibration laboratories. Specific details for calibration 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 calibration 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 calibration laboratories in greater detail. The numbering within this section follows the numbering of 17011.

7 (17011) 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 calibration laboratory (permanent, mobile, virtual) as well as information as to whether and which calibration activities are performed outside the locations of the calibration laboratory (e. g. on-site calibration).

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 assessment¹ and depth of assessment²) regarding any assessment of a calibration 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 calibration areas³ in which calibration and measurement services (CMC) are pro-

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 Sectors of related calibration and measurement services (CMC).

vided within the scope of accreditation, all locations at which key activities are performed and calibration activities outside the premises/locations of the calibration laboratory are included in the assessment.

Upon request, calibration laboratories must provide DAkkS with the required information on planned activities outside the premises of the calibration 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 calibration laboratories include the following in particular:

- Preparation, implementation and follow-up of calibration activities;
- Evaluation of the competence and approval of technical personnel and of external service providers providing services related to calibrations;
- Any internal⁴ 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 results reports;
- Handling of complaints;
- Validation and verification of CMC;
- 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 calibration laboratory must have demonstrated that it has valid processes in accordance with EA 2/15 in place.

⁴ Calibrations performed by the calibration laboratory or personnel from the same legal entity to establish metrological traceability whose associated CMCs are not listed in the accreditation certificate.

Flexible scopes can only cover areas for which the calibration 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.

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 calibration laboratory does not make use of a flexible scope granted within an accreditation cycle.

The accreditation of calibration laboratories refers to CMC, the flexibilisation of accreditation with regard to CMC is carried out in accordance with the basic international harmonisation described in ILAC G18.

In accordance with 17011, CMCs contain information on calibration objects, calibration methods or procedures⁵, measurement ranges, measurement uncertainties and, if applicable, other parameters (e.g. frequency). It is not possible to flexibilise the scope of the accreditation for the entries measurement ranges, measurement uncertainties and other parameters (e.g. frequency). The flexibilisation refers to the information on calibration objects and calibration methods or procedures in accordance with the categories described below.

⁵ For definitions of the terms calibration/measurement method and calibration/measurement procedure, see JCGM 200 (VIM) sections 2.5 and 2.6.

Category A Flexibilisation in relation to the normative calibration procedure

For calibration procedures fully described in standards or equivalent documents, there is the possibility of flexible accreditation of this procedure. A new edition of this standard or equivalent document can be used under the existing flexible accreditation if it does not contain a deviating calibration method and if the other associated entries of the CMC do not change as a result.

Category B Flexibilisation in relation to the calibration object

It is possible to apply for flexible accreditation of the calibration laboratory with regard to a CMC in relation to measurement objects with an unchanged calibration procedure within the CMC. For this purpose, a laboratory can apply for the naming of a device class (e.g. voltage sources) as a calibration object that is calibrated within the scope of the accredited procedure. In this case, the calibration laboratory must be able to provide evidence that it can competently carry out the necessary verifications of the suitability of the calibration object with regard to the calibration procedure used. This category also includes the flexibilisation according to category A.

Category C Flexibilisation with regard to the implementation of calibration methods

Upon request, the calibration laboratory has the option of flexible accreditation of a CMC with regard to the calibration procedure that describes the implementation of the accredited calibration method of the CMC. For this purpose, the calibration laboratory can apply for the naming of a calibration method in the CMC to be accredited. Here, the calibration laboratory must be able to provide evidence that it can competently perform the necessary validations of the calibration methods introduced. This category also includes the flexibilisation according to category A and B.

Within the specified categories and the defined CMC, the calibration laboratory is permitted to organise the contents of the CMC within the scope of accreditation according to the above description without the need for prior information and approval by DAkkS. An up-to-date and complete list of the CMCs performed/offered within the scope of accreditation and their contents will be made available to DAkkS on request and must be made publicly available by the calibration laboratory.

For each listed CMC, it must be traceable within the documentation of the calibration laboratory at what time it was changed within the scope of accreditation.

The accreditation information issued by DAkkS on flexible scopes does not include the current status of the CMC according to the above-mentioned list.

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 calibration laboratory continues to possess the competence to perform the specific calibration activity, in particular through observations-(witnessing) of the calibration activity.

If the recurring assessment of the calibration activities is not possible due to a lack of orders or customers, DAkkS can allow the calibration 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;
- Completion of a calibration without an order during an assessment;
- Calibrations of other CMCs in the assigned calibration range are carried out regularly.

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 calibration activities affected.

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

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

6. (17025) Resource requirements

6.2 (17025) Personnel

As proof of adherence to the requirements for accreditation set out in 17011, section 4.2 a), the calibration 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 calibration 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 calibration laboratory, appropriate written contractual arrangements for the use of, access to and availability of the equipment must be submitted.

All calibration activities using equipment of the customer can be part of the assessment.

In all cases, the calibration 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 calibration laboratory is obliged to perform the calibration on its own responsibility with personnel bound by contract, to define and document all management system and technical requirements of 17025 for these calibrations 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. 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 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 CIPM⁶ member) is provided outside the CIPM MRA⁷, the calibration 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 calibration 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.

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 calibration 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 must be provided that the same requirements that apply to the calibration 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 calibration 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 calibration laboratory. If non-accredited bodies are contracted, 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 **Fehler! Verweisquelle konnte nicht gefunden werden.** 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 calibration 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, calibration 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 laboratories that are self-organised can be recognised.

DAkkS requires successful participation in at least one proficiency test/measurement for each technical area of competence⁸ 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 calibration 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 calibration laboratory must maintain a table summarising all ongoing participation in proficiency testing and laboratory comparisons. The table must cover the current year and (if available) 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 CMC 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
- CMC to which the measure relates;
- Measuring areas for which the proficiency test was not passed - including evaluation criteria, e.g. En values;
- Corrective measures (keywords) for CMCs 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 (17025) Reporting of results

7.8.2.1

In legally regulated areas, the use of the calibration certificate model in accordance with Annex A may be prescribed.

7.8.2.1 f)

The calibration method used must be clearly stated in the results report. The unambiguous designation of a method includes at least the short title and the issue status/issue date. This applies regardless of whether it is a standard, a method equivalent to a standard or an in-house method.

8 (17025) Management system requirements

8.4.2

As evidence of compliance with the requirements for accreditation (see 17011, section 4.2 a)), the calibration 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 surveillances (see 17011, section 4.2 a)).

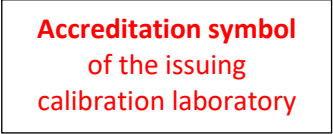
IV Appendix A: Sample calibration certificates - cover sheet

Introduction

The cover sheet of a calibration certificate shown on the following page of this annex serves as a voluntary template for the cover sheet design of calibration certificates for DAkkS-accredited calibration laboratories. It also serves as an “official template for calibration certificates” for areas in which the legislator or another body prescribes the use of such a template, such as the “55th Ordinance Amending Road Traffic Regulations” of June 25, 2021. This template does not include any further recommendations for the content design of calibration certificates other than the cover sheet.



Kalibrierschein / Calibration Certificate



issued by the calibration laboratory
issued by the calibration laboratory

Company name of the calibration laboratory
address

Calibration symbol

000000
D-K- YYYYY-ZZ-NN
jj jj - mm

Object
Object

Manufacturer
Manufacturer

e.g. serial or test equipment no.
Serial number

Customer data
Customer

Order number
Order No.

Number of pages of the calibration certificate
Number of pages of the calibration certificate

Date of calibration
Date of calibration

This calibration certificate may only be distributed in full and unchanged. Extracts or changes require the approval of the issuing calibration laboratory. Calibration certificates are also valid without a signature if the person responsible for approval is named in plain text.

This calibration certificate may not be reproduced other than in full except with the permission of the issuing calibration laboratory. Calibration certificates with the full name of the approval responsible person are valid without signature.

Date of the exhibition
Date of issue

Release of the calibration certificate by
Approval of the calibration certificate by

This calibration certificate documents the metrological traceability to national standards for the representation of units in accordance with the International System of Units (SI).
DAkkS is a signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and the International Laboratory Accreditation-Cooperation (ILAC) for the mutual recognition of calibration certificates.
The user is responsible for observing a reasonable period of time for repeating the calibration.

This calibration certificate documents the metrological traceability to national standards, which realize the units of measurement according to the International System of Units (SI).
The DAkkS is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates.
The user is responsible to have the object recalibrated at appropriate intervals.