
DKD-2

**Accreditation of
Calibration Laboratories -
Criteria and Procedures**

Published by the Accreditation Body of the Deutscher Kalibrierdienst (DKD) at the Physikalisch-Technische Bundesanstalt (PTB).

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Deutscher Kalibrierdienst (DKD)

The DKD comprises calibration laboratories in industrial enterprises, research institutes, technical authorities, inspection and testing institutes. They are accredited and supervised by the Accreditation Body of the DKD at the PTB and calibrate measuring instruments and material measures in the range and scope of accreditation. The DKD calibration certificates issued by these laboratories prove traceability to national standards as required in the ISO 9000 family and ISO/IEC 17025.

Calibrations carried out by DKD laboratories ensure that the user can rely on measurement results and also increase the customers' confidence and competitiveness on the national and international markets and serve as a metrological basis for the inspection of measuring and test equipment within the framework of quality assurance measures.

Calibrations offered by DKD cover electric measurands, length, angles and other geometric quantities, roughness, coordinate and form measurement, time and frequency, force, torque, acceleration, pressure, flowrate, temperature, humidity, medical measurands, acoustic measurands, optical measurands, ionizing radiation and other measurands.

Publications: see Internet

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Foreword

This publication documents the DKD accreditation criteria and details of the accreditation procedure. It is intended to fully inform potential applicants about the requirements to be met and the individual steps of the procedure, and at the same time to serve as a basis for the work of all those involved in the accreditation procedure. For other accreditation bodies at home and abroad – especially the accreditation bodies for test laboratories represented in the Deutscher Akkreditierungsrat (DAR) and foreign accreditation bodies cooperating in the European co-operation for Accreditation (EA) – this publication may serve as information about how the DKD works and thus provide a basis for trustful co-operation.

The DKD accreditation rules apply to the accreditation of calibration laboratories and for alterations to existing accreditations (e.g. with respect to measurands, measurement methods and uncertainties of measurement). They are also to be applied accordingly to the surveillance of accredited calibration laboratories. All specifications are in agreement with the standards DIN EN ISO/IEC 17011 and DIN EN ISO/IEC 17025:2005 and the requirements of the corpus of regulations of the EA.

This version of the publication DKD-2 incorporates the changes in the standards (particularly the new edition of DIN EN ISO/IEC 17025:2005) and includes the publication DKD-7, withdrawn in 2006.

1 Documents applicable

DIN EN ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
DIN EN ISO/IEC 17011	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
DIN EN ISO/IEC 17000	Conformity assessment - Vocabulary and general principles
DKD-3 ^{1,2}	Expression of the uncertainty of measurement in calibration
DKD-5 ¹	Instructions for issuing a DKD calibration certificate

¹ in the valid version

² German translation of the main part of publication EA-4/02; examples of the expression of uncertainties of measurement are given in DKD-3-E1 and DKD-3-E2 (translation of annexes to EA-4/02).

2 Accreditation criteria

The accreditation criteria for calibration laboratories are laid down in a general form in the "DKD Contract" (see Internet: <http://www.dkd.info>) which specifies that a calibration laboratory can be accredited by the DKD if it meets the requirements of the standard DIN EN ISO/IEC 17025:2005³ for calibration laboratories and of supplementary interpretation documents of the DKD, i.e. especially if

- the calibration laboratory operates a quality system in compliance with the standard,
- the necessary technical facilities, including the standards, are available,
- for the standards and standard measuring devices for use in the calibrations the metrological traceability to standards of the PTB or other national standards has been proved and the DKD has agreed to the measurement procedures proposed for the calibration,
- suitable technical measurement conditions are available,
- the necessary expert and reliable personnel is available,
- the holder responsible for the calibration laboratory guarantees that it
 - (a) is in a position and ready to raise the funds necessary for the maintenance and proper operation of the calibration laboratory,
 - (b) is in a position to compensate the damages and liabilities within the scope of the calibration activity.

Unless an amicable agreement is possible, any disputes arising from or in connection with the DKD Contract will be settled finally and bindingly by a court of arbitration in accordance with the Rules of Arbitration of the Deutsche Institution für Schiedsgerichtsbarkeit e.V. (DIS) ousting the jurisdiction of a court of law.

The requirements of the DKD Contract are to be understood as follows:

(1) The calibration laboratory must meet the requirements of DIN EN ISO/IEC 17025 in its valid edition⁴. These cover above all the operation of a quality system and its documentation in a quality manual.

The quality manual or the subordinated documents must contain detailed information about all elements of the quality system.

(2) The requirements to be met by the technical facilities (e.g. measuring set-ups, standards) are dependent on the scope of accreditation (measurands, ranges of measurement, calibration methods) and the uncertainty of measurement aimed at; accordingly, they cannot be defined in a general manner.

³ to be obtained from Beuth Verlag GmbH, Burggrafenstrasse 6, 10787 Berlin.

⁴ If necessary, the Accreditation Body will fix further specific accreditation requirements according to DIN EN ISO/IEC 17025:2005, Annex B.

The uncertainty of measurement must be calculated by the calibration laboratory for each measurand and for each range of measurement on the basis of DKD-3 ("expression of uncertainty"). The uncertainty of measurement specified after the assessment is documented in the annex to the accreditation document. It then is considered to be the best measurement capability, with the consequence that later on a greater but never a smaller uncertainty may in the individual case be stated in the calibration certificate. The laboratory can apply for specifying, within the scope of the accreditation, a higher than the technically possible value of the best measurement capability.

During the assessment of the laboratory it is checked whether the existing facilities are sufficient for carrying out the proposed calibration tasks within the scope of the uncertainty of measurement aimed at. By sound specialist knowledge and additional training of the assessors, their co-operation with other assessors working in the sector in question and by exchange of experience in the DKD Technical Committees it is ensured that the criteria applied are always comparable.

(3) The metrological traceability of the reference standards and of other measuring facilities used in the calibration laboratory to national standards must be proved by calibration certificates. Calibrations can be carried out in the PTB, by another national metrology institute or by an accredited calibration laboratory. If a calibration of the standards and measuring facilities used is not possible or impractical, outside the calibration laboratory, an indirect traceable method (e.g. by comparison measurements) can be used. This is to be documented accordingly.

The calibration laboratory must specify reasonable recalibration periods for the standards and measuring facilities as well as the uncertainties of measurement. Experience as regards the stability of the standards with time and the requirements arising from the uncertainty of measurement are to be taken into account in order to come to specifications which are economically justifiable. It is checked in the assessment whether these specifications are adequate and whether the recalibration periods have been complied with (see section 4).

(4) For some measurands calibration regulations have been agreed (see Internet <http://www.dkd.info>), which have been laid down by the Technical Committees of the DKD and have to be applied in all comparable cases. Basically, the calibration laboratory is free to select a suitable calibration procedure; it is, however, obliged to have the procedure validated should it differ from any calibration guideline or another relevant normative document. It is checked during the assessment whether the procedure and its validation is suitable for the particular calibration task.

(5) As to the laboratory rooms, the statements in (2) above are valid. Here, the calibration laboratory has to prove that the ambient conditions (e.g. temperature, relative humidity, atmospheric pressure) lie within the required limits and that potential external disturbing influences (e.g. mechanical vibrations, electromagnetic radiation) cannot lead to erroneous measurement results.

For calibrations which shall be carried out in subsidiaries, in a mobile facility or in rooms of a third party (e. g. customer), specific arrangements have to be made and documented, observing the respective characteristics.

(6) The expert knowledge of the personnel is to be specifically proved. Special requirements are to be met by the head and by the deputy head of the calibration laboratory (see section 3 of the DKD Contract). The expertise is proved:

- for the post of head of the calibration laboratory: by a person having at least completed training as an engineer and having carried out a comparable activity for at least two years;
- for the post of deputy head of the calibration laboratory: by a person having at least passed the technicians' examination or having undergone an equivalent specialist training and having carried out a comparable activity for at least two years.

The DKD Accreditation Body may in individual cases permit exceptions.

An activity as the head or deputy head of the calibration laboratory is excluded if

- there are facts which justify the assumption that the person proposed does not possess the trustworthiness necessary for acting as the head or deputy head of the calibration laboratory, and in particular does not guarantee impartiality;
- the necessary specialist knowledge has not been proved.

(7) If there are any doubts as to whether the continuing funding of the laboratory and liability in the event of damage or loss are guaranteed, the holder responsible for the calibration laboratory has to clear up these doubts by suitable evidence.

This may be, for example:

- liability insurance
- General terms of business with clause restricting liability
- proof of entry into the commercial register
- proof of sufficient financial independence
- statements regarding financial position (tax assessment notice, job volume).

3 Accreditation procedure

The accreditation procedure consists of the following steps: the application procedure (chapter 3.1), the assessment procedure (chapter 3.2) and the accreditation (chapter 3.3). The accreditation procedure is usually preceded by a phase during which the calibration laboratory can request suitable information material or that contacts are established with responsible officials, among others, of the PTB. This phase may help avoiding potential misunderstandings from the start and thus speed up the actual procedure.

3.1 Application procedure

3.1.1 Application documents

An application for accreditation must be filed in accordance with DIN EN ISO/IEC 17011 on an official application form. It must have been bindingly signed and contain the necessary statements, in particular as regards the proposed scope of calibration. The forms are available on the Internet (<http://www.dkd.info>) and will be forwarded upon request. The documents to be submitted together with the application in accordance with chapter 2 of the DKD Contract are stated in the form.

It has also to be stated in the application if the service is offered

- in a permanent laboratory (continually operated at a fixed location)
- by on-site calibrations (in the customer's premises)
- in a mobile laboratory (fully equipped transport vehicle).

The "Check list – Accreditation/Reassessment" with complete information of the applicant in the first column must be enclosed to the application for accreditation (initial accreditation).

The application is to be submitted in German or English.

The DKD Accreditation Body checks the documents submitted and acknowledges receipt of the application, stating the official responsible and a registration number. The check first covers only the completeness and formal correctness of the statements. Together with the acknowledgement of receipt, the calibration laboratory receives information about the documents lacking or having to be supplemented.

The detailed technical check of the documents will be carried out within the scope of the assessment procedure.

3.1.2 Contracts and fees

Normally, together with the acknowledgement of receipt, the applicant will receive two copies of the DKD Contract and an invoice for a payment on account of the costs to be expected (section 10 of the DKD Contract) to the amount of 1,500 €. The subject-specific processing of the application will be started with when

- all documents requested are on hand,
- a copy of the DKD Contract signed by the body responsible for the calibration laboratory is available to the Accreditation Body, and
- the payment on account has been remitted.

3.1.3 Modification of an existing accreditation

The application form is also to be used for requests for modifications of an existing accreditation. An application is to be filed if the specified conditions of accreditation have changed or if it is intended to expand the measurement capabilities of the accredited calibration laboratory (e.g. to cover further measurands or further ranges of measurement). The DKD Accreditation Body acknowledges the receipt of the application. The specific processing will be started with as soon as all documents are available.

A separate advance payment is not necessary. All costs are invoiced on the basis of the DKD Contract concluded.

Any application of a holder responsible for a laboratory already accredited to accredit another laboratory at another place or with other personnel is considered to be a new application for accreditation. The only difference will be that it is not necessary to conclude another contract, and possibly the advance payment need not be effected.

Applications for confirmation of a new head or deputy head of the calibration laboratory can be filed at any time without a specific form being required but must be accompanied by the documents requested in section 2 (6).

Any application for modification requires that the relevant sections of the quality manual be updated.

3.1.4 Appointment of assessors, confidentiality

The Accreditation Body decides from case to case on the number of assessors necessary and on how they share their tasks. When a team of assessors is assigned, a lead assessor is appointed. The calibration laboratory is informed in writing by the DKD Accreditation Body on all assessors proposed for the evaluation of the application. If the application for accreditation relates to different measurands, further experts can be called in. The laboratory can make objections to the nomination.

DKD assessors have been trained in depth and are officially appointed. Most of them are employees of the relevant PTB departments as well as experts in part from other institutions with the necessary qualifications.

Assessors and all other persons involved in the accreditation procedure are obliged to treat confidentially any information they get to know in connection with the accreditation and surveillance of calibration laboratories. Information of third parties about events in connection with the accreditation may be passed on only with the express consent of those concerned.

3.1.5 Separation of assessment and advice

The standard DIN EN ISO/IEC 17011 requires that the assessors themselves should not offer consultancy services which may affect the objective character of the accreditation or of the decisions. When nominating assessors the DKD Accreditation Body ensures that this requirement is strictly complied with.

3.2 Assessment procedure

The assessment is carried out on the basis of DIN EN ISO/IEC 17011 and the accreditation criteria of the DKD specified in section 2. It can be performed by one or several assessors. The complete assessment of a calibration laboratory in the DKD covers the following five modules:

Module 1 Assessment of the QM documentation according to QM aspects	Module 2 Assessment of the QM documentation according to technical aspects
Module 3 On-site assessment of the implementation of QM aspects	Module 4 On-site assessment of the implementation of QM aspects
	Module 5 Supplementary metrological measures (comparison measurements)

It may be reasonable in the individual case to change the above order of the modules. If an application relates to the modification of an existing accreditation, individual modules may be inapplicable. If the application for accreditation covers different measurands, additional specialist assessors or specialist experts may be called in to assess the technical aspects (see section 3.1.4). The lead assessor ensures the coordination of the activities of the specialist assessors and specialist experts to avoid duplication of work. It is aimed at completing the assessment procedure within three months after receipt of the complete documents.

For the on-site assessment the applicant has to provide the assessors with suitable rooms and equipment for the performance of their work.

3.2.1 Assessment of the QM documentation according to QM aspects (module 1)

The lead assessor checks the documentation made available through the DKD Accreditation Body for compliance with the QM aspects (DIN EN ISO/IEC 17025:2005 chapters 4 and 5). He records his findings of his evaluation in Part B of the “Report on the Assessment of the Calibration Laboratory”.

3.2.2 Assessment of the QM documentation according to technical aspects (module 2)

The assessor checks the documentation made available through the DKD Accreditation Body or the lead assessor for compliance with the technical aspects (DIN EN ISO/IEC 17025:2005 chapter 5), e.g. technical equipment, prevailing ambient conditions, realisation of the calibration procedures and their validation, calculation of uncertainty of measurement and metrologi-

cal traceability. He also records his findings of the assessment in Part B of the “Report on the Assessment of the Calibration Laboratory”.

3.2.3 On-site assessment of the implementation of QM aspects (module 3)

This assessment essentially serves to check whether the actual conditions are in agreement with the statements in the QM documentation. It is carried out together with module 4. Remarks in the check list (Part B) which during the visit turn out not to be founded are to be marked accordingly. The deviations from the requirements found are entered into Part C of the “Report on the Assessment of the Calibration Laboratory” and classified as regards to their relevance for the accreditation.

3.2.4 On-site assessment of the implementation of technical aspects (module 4)

The on-site assessment serves to make sure that the calibration laboratory has the technical competence for the calibration task provided. This concerns especially the assessment of the technical facilities and of the qualification of the personnel. It is to be checked whether the actual conditions are in agreement with the statements in the application documents. The deviations from the requirements found are entered into part C of the Report and classified as regards their relevance for the accreditation.

3.2.5 Concluding discussions

- a) In the concluding discussions, the assessor responsible informs the applicant about all deviations from the accreditation criteria he has ascertained stating their classification.
- b) To rectify the deviations, the calibration laboratory suggests corrective actions which are entered into Part C of the “Report on the Assessment of the Calibration Laboratory”.
- c) The assessor summarises all corrective actions agreed in Part D of the Report and also enters the dates agreed with the applicant for carrying out these actions.

a), b) and c) can be combined in dependence on the situation. Part C must at least contain the findings and planned actions which are not included in Part D. Each page of Parts C and D is to be signed by the assessor and the applicant. The assessor informs the applicant whether he will recommend the Accreditation Body to accredit the laboratory. The applicant is to be provided with at least one copy of Parts A, C and D of the Report for assessment.

3.2.6 Supplementary metrological measures (module 5)

The supplementary metrological assessment is generally carried out in the form of a comparison measurement. Its objective is, among other things, to prove by an example that the calibration laboratory is in a position to perform a calibration according to the best measurement capability applied for. The comparison measurement can be a bilateral comparison with a PTB department or, when possible, a national or international intercomparison. Details are fixed by the assessor and the applying laboratory.

The result of the comparison measurement and the measurement values are to be advised to the laboratory in writing. If corrective action is to be taken, an appropriate period of time for this action is agreed with the laboratory.

3.2.7 Final report

After completion of the assessment procedure, the assessor gives his recommendation regarding the continuation of the accreditation procedure in a final report.

If this recommendation is positive, the assessor submits his final report together with a draft for the annex to the accreditation document according to the specimen, stating the scope of the calibration which can be accredited.

The assessor forwards the final report with annexes and all documents made available by the DKD Accreditation Body as well as the letters he has exchanged in connection with the accreditation to the Accreditation Body for evaluation of the assessment result and final processing. The result of the "supplementary metrological evaluation" can be submitted at a later date.

3.3 Accreditation

On the basis of the final report, the assessment manager of the DKD Accreditation Body gives a concluding evaluation of the assessment documents. If the scope of accreditation includes different measurands and if the assessment documents are available only for a subarea, he may suggest granting the accreditation for the time being only for this subarea and treating the remainder as a modification of the accreditation granted.

The decision on the granting of the accreditation is taken by the Head of DKD. If it is positive, an accreditation certificate is issued. If no accreditation is granted, the applicant is informed in writing about the reasons.

Objections to the decision on the granting of the accreditation are to be addressed by the applying laboratory to the Head of DKD. The laboratory may bring the decision on the objection before the court of arbitration.

The accreditation document contains a registration number according to a system agreed in the Deutscher Akkreditierungsrat (DAR). Documents for modifications of existing accreditations are identified by additions. Factual contents of the accreditation and of its modification are fixed in the annex to the document. Hereunto belong the type of calibration laboratory (permanent laboratory, on-site calibration, mobile laboratory) as well as specifications regarding measurand/calibration item, measurement range, measurement conditions/procedure, best measurement capability and additional remarks.

Accreditations and their modifications are published in the "PTB-Mitteilungen", the official and information bulletin of the PTB. The directory of DKD calibration laboratories which is kept on the Internet (www.dkd.info) is updated accordingly. This is the "official" list of all calibration authorisations granted by the DKD Accreditation Body. It is updated as well with those data which do not result in a formal modification of the accreditation (e. g. new telephone number).

The accreditation is granted without any time limit. It is ensured by appropriate surveillance activities (see section 4 and article 6 of the DKD Contract) that the conditions of accreditation are complied with lastingly.

The obligations of the accredited laboratory arise from the provisions of the DKD Contract (see especially articles 5, 7 to 9). In particular, the calibration laboratory must inform the DKD Accreditation Body about all relevant changes in the personnel and equipment. Requirements as regards the contents and outer appearance of the calibration certificates issued by the calibration laboratories are specified in the publication DKD-5.

If the evaluation of the applying calibration laboratory has led to a negative result, the calibration laboratory may apply for another assessment after having carried out appropriate corrective measures.

For the services provided within the scope of the accreditation, immediately after completion of the procedure, the costs incurred are invoiced in accordance with article 10 of the DKD Contract taking the advance payments already effected into account.

4 Surveillance measures

Standard DIN EN ISO/IEC 17011 requires that it be ensured by suitable surveillance measures that the accreditation criteria are lastingly met. For this purpose, the following rules are valid in the DKD (see also article 6 of the DKD Contract):

- (1) The reference standards of the calibration laboratory must be recalibrated at particular intervals of time (see section 2 (3)). It is checked during the surveillance visits whether the recalibrations are carried out according to schedule.
- (2) The DKD Accreditation Body is entitled and obliged to satisfy itself at regular intervals after having arranged a date that the conditions for the accreditation exist. Suitable supervision measures are surveillance visits to the calibration laboratory from assessors who examine above all whether significant changes have occurred compared with the state upon initial assessment. The assessor can, for example, inform himself about the work of the laboratory by direct observation of a complete calibration including the calculation of the measurement uncertainty. During his visit, the assessor can confine himself to the assessment of selected criteria. Focuses are always the compliance with the recalibration dates for the reference standards and the corrective actions taken to eliminate deficiencies ascertained during previous visits. The surveillance visits to a laboratory are scheduled one year after the accreditation at the latest and after that at least every 18 months. After five years at the latest, a reassessment of the same scope as the initial assessment is carried out.

From time to time the PTB organises national intercomparisons in which all calibration laboratories accredited for the measurand in question must take part if requested to do so. Furthermore, the DKD calibration laboratories are obliged to take part – after having been requested to do so by the DKD Accreditation Body - in international comparison measurements which are carried out within the scope of the co-operation of the European calibration services in the EA with the aim of proving the technical equivalence of the calibration certificates issued by accredited laboratories in Europe and making them transparent.

Furthermore, important tools for lastingly ensuring technical competence are considered to be provided by technical contacts of the DKD calibration laboratories with the relevant technical departments of the PTB, visits of employees of the laboratories to the PTB and co-operation of the heads of the calibration laboratories in the Technical Committees of the DKD and the participation in PTB seminars.

If the above-mentioned surveillance measures provide indications that the conditions of accreditation are no longer met, the DKD Accreditation Body takes without delay suitable measures on behalf of its Head. This is to be done in particular if the measurement results obtained by a calibration laboratory in a comparison measurement do not comply with the specified values within the uncertainty of measurement stated. If the causes for the deviations cannot be recognised and eliminated immediately after having become known, the Head of the DKD Accreditation Body – after having heard the calibration laboratory in question – can decide, among other things, to limit the scope of the accreditation or to suspend or terminate the accreditation (see section 5). The list of DKD laboratories will be modified accordingly.

5 Termination of accreditation

The accreditation can be revoked if at a later date a situation arises or facts occur or become known which would have justified a denial of the accreditation (see article 6 of the DKD Contract). Prior to revocation, the calibration laboratory concerned must be given the opportunity to comment.

The accreditation can be terminated if it turns out within the scope of the surveillance measures that the conditions of accreditation are no longer met (see section 4) and the calibration laboratory does not eliminate the deficiencies in time.

The accreditation can also be terminated if the calibration laboratory violates the provisions of the DKD Contract or the conditions linked with the accreditation.

The accreditation will expire if the calibration laboratory is dissolved or its calibration activity discontinued or if the calibration laboratory declares that it no longer desires an accreditation.