

## Information sheet on the accreditation procedure

**M 17011**

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14. April 2020

### **Scope:**

This information sheet informs about the general course of an accreditation procedure

### Contents of information sheets

- Information sheets of DAkkS are no Rules.
- Information sheets of DAkkS do not generate new requirements. They may explain existing requirements of laws, standards or rules and in this respect repeat them.
- Information sheets of DAkkS inform applicants, accredited conformity assessment bodies and further interested parties – where applicable or reasonable – about accreditation procedures which are processed according to DIN EN ISO/IEC 17011 and where applicable further requirement documents.
- Information sheets of DAkkS explain – where necessary – contents of DIN EN ISO/IEC 17011 and inform how DAkkS applies this standard. Therefore information sheets support a common understanding of the standard by conformity assessment bodies and the consistent implementation through DAkkS including its assessors and technical experts.
- Information sheets of DAkkS explain – where necessary or reasonable – contents of harmonized standards and further documents that include requirements for conformity assessment bodies, their activities and procedures. Therefore information sheets support a common understanding and a common use of these documents within the accreditation procedure and by accredited conformity assessment bodies.
- Information sheets are generally aligned with the structure of the relevant harmonized standard. Nevertheless it is also possible to publish information sheets to individual sectors or fields to provide an overview for interested readers about accreditations within a particular sector or field.
- Information sheets will be updated when necessary and published with the current issue date.
- Information sheets do not raise a claim to completeness at no time in the sense that all aspects of a law or standard are addressed.

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### I General

The German Accreditation Body (Deutsche Akkreditierungsstelle GmbH (DAkkS)) is the national accreditation body for the Federal Republic of Germany and is entrusted to carry out accreditations and surveillances of conformity assessment bodies (CAB – such as laboratories, certification bodies etc.). Because of its entrustment by the Federal Republic DAkkS acts as a sovereign body within Germany and Europe statutory and acts externally as an administrative authority. It acts in accordance with the provisions of the Administrative Procedure Act (Verwaltungsverfahrensgesetz – VwVfG) and further legal requirements. It finances its activities primarily by charging administrative fees on the basis of a fee regulation.

With this information sheet we want to inform potential applicants and already accredited bodies about basic requirements on accreditation of conformity assessments bodies (CAB) and about the accreditation process.

For the fields mentioned within § 1 section 2 sentence 2 AkkStelleG (Accreditation Body Act) the responsible authorities will be integrated by DAkkS within the accreditation process as specified by the law.

## II Requirements for accreditation

DAkkS is responsible for the accreditation of CABs which have its registered office in Germany. DAkkS grants an accreditation if the CAB fulfills the requirements applicable to them. Significant requirements are stated within the relevant harmonized standards. However, further requirements may also apply - for example from laws, DIN EN ISO/IEC 17011, agreements or specifications from the owners of conformity assessment programmes or from international rules. Which detailed technical requirements the CAB has to fulfil for granting the accreditation is very individual and is depending on the applied scope of accreditation.

The following table shows the current types of conformity assessment bodies (accreditation activities) and the respective normative requirements:

<b>Laboratories</b>	<b>Testing and Calibration Laboratories</b> DIN EN ISO/IEC 17025
	<b>Medical Laboratories</b> DIN EN ISO 15189
<b>Inspection Bodies</b>	DIN EN ISO/IEC 17020
<b>Certification Bodies</b>	<b>for Persons</b> DIN EN ISO/IEC 17024
	<b>for Management Systems</b> DIN EN ISO/IEC 17021-1
	<b>for Products, Processes and Services</b> DIN EN ISO/IEC 17065
<b>Validation- and Verification Bodies</b>	DIN EN ISO 14065
<b>Proficiency Testing Providers</b>	DIN EN ISO/IEC 17043
<b>Reference Material Producers</b>	DIN EN ISO 17034
<b>Biobanks</b>	ISO 20387

**Figure 1:** Types of conformity assessment bodies (accreditation activities) and relevant normative requirements

### III Sequence of the accreditation procedure

#### 1 Application procedure

##### 1.1 Request and technical consultation

The Website of DAkKS contains information according to accreditation procedure and specific requirements for particular accreditation fields. Contact details of the different divisions are also available.

New customers may take advantage once of an initial consultation to the accreditation procedure and its requirements about two hours at one of the locations of DAkKS. Further consultations are subject to the fee regulation and must be paid.

Subject of such technical consultation may be for example:

- Information about content, process and fees of the accreditation procedure
- Clarification of the scope of pursued accreditation
- Information about specific accreditation criteria for the pursued accreditation
- Rights and obligations of the customer and of DAkKS after granting the accreditation

##### 1.2 Application for accreditation

Application documents and relevant forms are available on the Website of DAkKS. The application must contain the intended scope of accreditation completely and must be signed in a legally binding manner by an authorized representative of the CAB. As an alternative to submitting applications in writing, only the alternatives to the written form provided by law may be used:

- Submission by E-Mail to [zab@dakks.de-mail.de](mailto:zab@dakks.de-mail.de) or
- Submission of digital documents with qualified electronic signature to [zab-qeS@dakks.de](mailto:zab-qeS@dakks.de)

Changes to the application within the ongoing procedure are possible. Usually a subsequent change does delay the procedure, especially if the assessment is already planned. It might be necessary to carry out the assessment planning again or further assessments must be scheduled to take the change into account.

All applications within DAkKS will be registered by the Central Application Processing unit (ZAB), formally verified and forwarded to the respective technical division(s) for the technical review. The ZAB also determines the case number. The responsible division acknowledges the receipt of the application and informs about the case manager in charge. The case manager is responsible for the further handling of the accreditation procedure and is the contact person for the CAB for all questions regarding the accreditation procedure.

### 1.3 Submission of necessary documents and information

Following the application the applicant must provide all necessary documents and information for the preparation of the assessment. For each accreditation activity the necessary documents and information are listed, relevant forms are available from the documents-area on the Website of DAkKS. Documents are sent electronically as requested by DAkKS. The planning of the assessment can only be made if all documents and information are available to DAkKS and reviewed according to its general suitability and plausibility. If the review reveals significant deficiencies, corrections are requested.

## 2 Assessment

### 2.1 Preparation of the assessment

DAkKS reviews all submitted documents according to its completeness and plausibility and determines the necessary assessment extent.

This contains inter alia:

- choice and arrangement of the assessment team
- determination of the duration of the on-site assessment
- determination of necessary sampling for the assessment
- determination of type and extent of necessary witness-activities
- if applicable further framework conditions for the assessment

The CAB will be informed about foreseen assessors including the organizations they belong to. The CAB may raise immediatly reasoned objections to the announcement of individual assessors (immediately is judged individually and covers a maximum period of two weeks). Objections after this period are inadmissible. Objections that become known later must also be raised immediately. DAkKS is responsible to decide if raised objections will be considered. If objections are raised against assessors due to a lack of impartiality, DAkKS conducts a review procedure in accordance with § 21 VwVfG (concern about impartiality). Objections must be justified and documented.

Assessors will be assigned by DAkKS, after the assignment they get the relevant documents of the CAB. For the preparation of the assessment DAkKS may request further documents.

With these documents the assessors perform a document review. As a result of this review it might be necessary to cancel or postpone the planned assssment. An assessment only takes place if the document review confirms that there are no non-conformities which might oppose to perform the on-site assessment.

Upon request of the CAB a chargeable preliminary visit made by one assessor may be processed. Key issues of the preliminary visit are:

- the estimation of personell, equipment and spatial conditions for the accreditation
- the estimation of the suitability of the present quality management system
- checking of documents
- coordination of the scope of accreditation
- exchange of information and clarification of outstanding issues regarding the accreditation process

### 2.2 Assessment

Before the assessment the case manager prepares an assessment plan. The assessment plan is sent to the CAB at least one week before the assessment. According to the applied scope of accreditation and according to the availability of the assessors the assessment may be processed temporally coherent or in different parts at different dates. If the CAB also carries out activities outside its own permanent or mobile premises, the assessment shall include additional witnessing beside the assessment of the office regarding theses activities, e. g. at one or more of its clients. These usually take place on additional dates.

Each assessment starts with an opening meeting with the intention to explain the purpose of the assessment, the used criteria and the assessment plan. During the assessment, the processes described in the documentation of the CAB are reviewed in their practical implementation and are evaluated, with regard to the accreditation criteria. The aim of the assessment is to determine the competence of the CAB, to perform the applied conformity assessment activities competent in accordance with all relevant requirements.

The assessment team shall be granted access to all accreditation-relevant premises, records and documents including records of personnel, as far as necessary for performing the assessment and review of the accreditation requirements. Assessors and technical experts of DAkkS are obliged to treat all data to which they have access through their work for DAkkS as confidential.

For their activities, the assessment team shall get the necessary assistance and support as relevant to the assessment. The assessment of the CAB takes place at the administrative office as well as at locations at which the CAB processes conformity assessment activities or other key activities. The CAB shall ensure that assessors have the possibility to perform witness-activities at the premises of customers and subcontractors, if applicable.

The assessment ends with a closing meeting of the assessment team and the representatives of the CAB. During this meeting the assessment team presents the assessment results, records the determined non-conformities and informs about the next steps of the accreditation procedure. The acknowledgement of the non-conformities is confirmed by the signature of a representative of the CAB.

### 2.3 Postprocessing of the assessment

Subsequent to the assessment the CAB performs to each non-conformity a root cause- and extent analysis and determines suitable corrective actions. Root cause- and extent analysis as well as corrective actions must be documented clearly and sent to the responsible case manager and the assessor in due time including all evidences regarding the implementation of the corrective actions. Documents shall be sent preferably in electronic form. The date of receipt at DAkkS is decisive for meeting the deadline. Only after the submission of relevant and suitable documentation the non-conformity can be closed by the assessor.

Deadlines regarding the complete processing of the corrective actions by the CAB are determined within each non-conformity report. For initial accreditations the non-conformities shall be closed within four month at the latest. For surveillances including re-assessments and extensions the deadline is usually two month. If immediate measures are necessary, much shorter deadlines may be determined.

Because of the assessment results a follow-up on-site assesement may be determined by DAkkS. All evidence with regard to the closure of the non-conformities are finally provided to DAkkS. DAkkS reviews the evidence according to its suitability for closing the non-conformities.

Assessment reports will be send to the CAB after receipt and review by DAkkS immediately. After receipt the CAB may comment the reports within two weeks.

## 3 Granting the accreditation

### 3.1 Accreditation decision

The accreditation committee (AkA) is a corporate body of DAkkS and consists of members who may be involved in accreditation decisions. Members of the accreditation committee are competent persons which have been assigned by the Management of DAkkS. For each member it is determined for which technical areas they can be involved for the accreditation decision.

If several technical areas are concerned within the accreditation procedure, several accreditation committees decide independently regarding to their areas.

The AkA will be convened when all corrective actions are implemented by the CAB or if a closure of the non-conformities can no longer be expected in due time. Therefore the documentation including the accreditation recommendation of the assessment team must be available completely. Usually the decision of the accreditation committee takes approximately four weeks.

### 3.2 Accreditation notification, accreditation certificate and annex to the certificate

Accreditation is granted in the form of a notification in accordance with the requirements of the VwVfG. Together with a positive notification the applicant receives the accreditation certificate including the annex with details of the scope of accreditation. If applied for, the authorization to use the accreditation symbol is included in the notification of accreditation. Conditions that might be connected with the positive decision are specified in the notification of accreditation.

When accreditation is granted the conformity assessment body will be published in the database of accredited bodies at the Website of DAkkS. This database is maintained by DAkkS and reflects the current accreditation scope of the bodies accredited by DAkkS.

In the case that the accreditation is not or only partially granted the CAB receives a corresponding notification including the reasons. Appeals according to DIN EN ISO/IEC 17011 against (partially) negative accreditation notifications are treated as objections according to § 79 VwVfG.

Usually accreditations will be granted by DAkkS for an unlimited period of time, unless otherwise regulated by law.

#### 4 Surveillance of granted accreditation

To maintain the accreditation, regular surveillances are required during the accreditation cycle. Determined surveillance intervals are related to requirements of DIN EN ISO/IEC 17011 and defined by DAkkS according to risk criteria. Surveillance measures may be, e. g.:

- On-site assessments at the CAB
- Remote assessments, if on-site assessments are not possible in a justified case
- Document review
- Witnessing

In addition the following principles apply:

- Additional requirements of power-conferring authorities (BeB) or scheme owners (e. g. certification bodies for products) regarding scope and frequency of surveillance activities will be considered if they differ from the above-mentioned surveillande activities.
- In justified cases and for a specific reason the surveillance intervals may be shortened. This may happen e. g. on recommendation of assessors, a decision of the accreditation committee or decision by DAkkS.
- In justified cases extraordinary surveillances are possible.

The preparation, processing and postprocessing of surveillance activities are performed according to the procedure described in section 2. After concluding the process the CAB receives a confirmation of the maintenance of the accreditation by the responsible case manager of DAkkS, unless the surveillance measure lead to a reduction of the accreditation scope. In these cases an accreditation committee will be convened and a corresponding notification will be prepared.

## 5 Modification, Reaccreditation and Reassessment

### 5.1 Change of Accreditation

The most significant change of accreditation is the extension of the scope of accreditation. A change to the scope of accreditation will only be processed on request. Changes may be considered within a planned surveillance or processed independently. For being able to conclude the assessment planning early the application for change within the surveillance process should be received by DAkkS at least 10 weeks before the planned date of the assessment. In the interest of the CAB, unnecessary costs can thus be avoided.

In general the procedure will be processed as described in sections 1 to 3.

The reduction of the scope of accreditation is also a modification for which an application is needed. In this case a decision of the accreditation committee is not necessary.

### 5.2 Reaccreditation

If accreditations have been granted for a limited period on a legal basis, DAkkS will inform the CAB in due time before of the accreditation terminates and offers the reaccreditation. Reaccreditation requires a new application from the CAB. The procedure for reaccreditation corresponds to the procedures described in sections 1 to 3.

### 5.3 Reassessment

For unlimited granted accreditations a reassessment is necessary at the end of the accreditation cycle, as a rule every five years. The reassessment includes the same scope as for the assessment for granting the accreditation and must include all standard requirements. The procedure corresponds to the procedures described in sections 1 to 3.

### 5.4 Cancellation of accreditation

If a CAB wants to cancel its accreditation completely, the case manager of DAkkS shall be informed in written form. The accreditation will be withdrawn, the entry in the database will be deleted and the accreditation procedure will be closed.

### IV Suspension, Withdrawal or reducing the accreditation (Art. 5 paragraph 4 Regulation (EG) No. 765/2008)

Within the DIN EN ISO/IEC 17011 the following terms are defined:

Suspension:	putting temporary restrictions in place for all or part of the scope of accreditation
Withdrawal:	cancelling accreditation for the full scope
Reducing:	cancelling part of the scope of accreditation

If DAkkS determines that a CAB is either no longer competent or has seriously violated its duty, it takes measures to suspend, reduce or withdraw the accreditation concerned.

The determination may result of own findings (within assessments or other measures) or from information provided by third parties. First DAkkS clarifies the circumstances, the CAB must participate in this to the necessary extent.

Prior to a suspension, reducing or withdrawal, DAkkS usually asks the CAB concerned for a hearing to give the opportunity to explain their position. Within DAkkS, the accreditation committee decides about the suspension, reduction or withdrawal.

The loss of competence or a serious violation of duty may result of the following situations:

- Loss of significant accreditation requirements (e. g. personnel, equipment, premises), repeated or serious violation against standard requirements
- Conscious deception of the accreditation body when transmitting wrong or incomplete information which are significant for assessing the CAB
- Non-fulfillment of issued conditions even after granting a grace period

If an accreditation will only be suspended or reduced partially, DAkkS will issue an updated accreditation certificate. The entry on the database of accredited bodies will accordingly be aligned or deleted. Issued certificates including annexes must be send back to DAkkS upon request. Authorities which have granted an approval, appointment or notification according to the accreditation will be informed about the measures taken by DAkkS.

The repeal of the suspension of the accreditation will also be decided by the accreditation committee and will usually be determined after an on-site assessment.

Appeals according to DIN EN ISO/IEC 17011 against the suspension, reduction or withdrawal will be treated as appeals according to § 79 VwVfG.

### V Procedures outside the scope of the EU-Regulation No. 765/2008

The Accreditation of CABs outside the scope of the EU-Regulation 765/2008 is not subject to the requirements of the VwVfG, the Accreditation body Act (AkkStellG), the ordinances issued on its basis and other legal provisions under administrative law. The accreditation of CABs outside the scope of the EU-Regulation 765/2008 is therefore carried out on a non-statutory basis and under consideration of the applicable regulations of the European co-operation for accreditation (EA) and the international accreditation networks ILAC and IAF.

Once the application has been confirmed, the accreditation procedure is processed on the basis of a contract between the CAB and DAkkS.

Procedures and requirements described in this document apply accordingly, unless they have been explicitly excluded by contract.

Accreditations outside the scope of the Regulation No. 765/2008 will be granted for a limited period.