

Information sheet on the accreditation procedure

M-17011 Annex 1

03 July 2023

Scope:

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

Pursuant to Section 2 in conjunction with Section 3 (9) Federal Act on Gender Equality, Section 4 (3) Federal Act on Gender Equality is not directly applicable to DAkkS. In the interest of good readability, the generic masculine is also used for function descriptions in this document, so far as a concrete designation by natural gender is not possible in any meaningful way and natural gender is either unimportant or male and female persons are meant equally.

DAkkS rules and other technical specifications must be easily readable and must therefore contain no slashes, which excludes the use of the internal / and duplicate designations (concerning admissibility, see Section 115 Manual for Drafting Legislation). Also applicable are the further requirements of DIN 820-2:2012-12 Standardisation – Part 2: Presentation of documents (ISO/IEC Directives – Part 2:2011) for the formulation of technical specifications.



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.

To improve its readability, this information sheet does not strictly follow the structure of the underlying standard DIN EN ISO/IEC 17011.



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I General

Deutsche Akkreditierungsstelle GmbH (DAkkS) is the national accreditation body in Germany. It acts as an authority in accordance with the requirements of relevant Union law, supplemented by the Administrative Procedure Act (VwVfG) and other statutory provisions governing administrative procedures. Union law, in particular Regulation (EC) No 765/2008, takes precedence over national laws and standards, in particular DIN EN ISO/IEC 17011.

With this information sheet, DAkkS informs both potential clients and bodies that have already been accredited about the basic requirements that must be fulfilled for accreditation as a conformity assessment body (CAB) and about the process of accreditation.

II Definitions and abbreviations

1 Terms

Where it is possible and makes sense to do so, DAkkS uses the definitions of Regulation (EC) No 765/2008, followed by the terms defined in the standards for conformity assessment and accreditation in the ISO/IEC 17000 series of standards. A knowledge of the standards governing conformity assessment is essential to any understanding of this information sheet. Where necessary for a proper understanding of this information sheet, terms are defined or explained in the text.

2 Abbreviations

EA	European co-operation for Accreditation
ILAC	International Laboratory Accreditation Cooperation
IAF	International Accreditation Forum
САВ	Conformity assessment body
AC	Accreditation cycle



III Prerequisites for accreditation

1 General

DAkkS is responsible for the accreditation of CABs that have their registered office in Germany. DAkkS grants accreditation if a CAB fulfils the requirements in place for it. The essential requirements are set out in the legal basis of Regulation (EC) No 765/2008 and each of the harmonised standards that flesh out its provisions. Additional requirements arise for example from sectoral legislation, the standard DIN EN ISO/IEC 17011, agreements or specifications from owners of conformity assessment schemes or from international rules of EA, ILAC and IAF. The technical requirements to be met by a CAB for the granting of accreditation are very individual and depend on the scope of accreditation being sought.

The DAkkS website lists the internationally binding rules (<u>LI-015</u>) incorporated by DAkkS into its administrative practice. DAkkS generally provides German translations of the applicable binding rules of EA, ILAC and IAF.

Accreditation activity	Applicable EN standard
Testing laboratories	DIN EN ISO/IEC 17025
Calibration laboratories	DIN EN ISO/IEC 17025
Medical laboratories	DIN EN ISO 15189
Inspection bodies	DIN EN ISO/IEC 17020
Proficiency testing providers	DIN EN ISO/IEC 17043
Producers of reference materials	DIN EN ISO 17034
Certification bodies for management systems	DIN EN ISO/IEC 17021-1
Certification bodies for persons	DIN EN ISO/IEC 17024
Certification bodies for products, processes and services	DIN EN ISO/IEC 17065
Validation and verification bodies	DIN EN ISO/IEC 17029 ¹
Biobanks	DIN EN ISO 20387

The table below shows the types of conformity assessment bodies (accreditation activities) currently in place and the relevant EN standards used as the basis for accreditation in each case:

Table 1: List of accreditation activities with applicable EN standards

¹ The transition from DIN EN ISO 14065 to DIN EN ISO/IEC 17029 is currently taking place. In future, the accreditation of validation and verification bodies will be on the basis of DIN EN ISO/IEC 17029. A transition guideline is published on the DAkkS website.



2 Eligibility to apply

Depending on the accreditation activity, there may be specific requirements in place with regard to the legal entity of the applicant. Natural persons cannot be considered as applicants.

3 Scope of application

An application for accreditation and any accreditation granted on the basis of an application is limited to one accreditation activity (see Table 1) and one CAB. If an applicant seeks accreditation for several accreditation activities, a separate application must be submitted for each accreditation activity. An application for a CAB cannot include more than one organisation/legal entity. In addition, the CAB must have a unified management based in Germany and a unified management system. Provided that the requirements set out above are met, a CAB may comprise multiple locations (both national and international) from which the CAB operates.

The review of new conformity assessment schemes for eligibility for accreditation must be applied for separately. An application for accreditation for these new schemes is possible only after successful verification. DAkkS <u>provides information</u> about conformity assessment schemes for which eligibility for accreditation has been established.

IV Procedure of accreditation processes

1 Preparation for the application

An accreditation procedure requires a great deal of preparation by the applicant/CAB. The CAB must be familiar with the requirements reviewed in the course of the accreditation procedure, and the requirements for the CAB in terms of space, personnel and equipment must be fulfilled for the scope of accreditation being sought. This preparatory work must be completed by the CAB before the application is submitted. It includes among other things compilation of the documents that must be provided by the CAB with the application. The minimum requirements for the documents to be submitted are compiled in a list for each accreditation activity. An overview can be found in the list LI-EU Übersicht_EN. An application cannot be submitted until the relevant documents have been prepared by the CAB.

DAkkS also reserves the right to decide against any submitted application due to a lack of cooperation.

Information on the accreditation procedure is available on the DAkkS website. For enquiries, DAkkS provides options for <u>contacting</u> its various departments, technical and service units.

Before submitting an application, new customers can arrange an initial consultation of up to two hours to discuss the accreditation procedure. All discussions going beyond this consultation are considered as technical discussions and are subject to a fee.



An initial consultation of this kind may for example cover:

- Information about the content, process and costs for the accreditation procedure
- Clarification of the scope of accreditation being sought
- Information about specific requirements for accreditation for the accreditation being sought
- Information concerning documents to be provided immediately after the application has been submitted
- Rights and duties of the customer and DAkkS after granting of accreditation

Technical advice on the accreditation being sought is out of question.

2 Application

An application must be submitted to DAkkS for the following procedures:

- Initial accreditation
- Reaccreditation (for accreditations granted for a limited period due to legal requirements and accreditations in the non-statutory area)
- Amendment of accreditation (extensions/reductions of the scope of accreditation or other changes that affect the certificate, such as changes in legal form, changes of address, etc.)

Further accreditation processes for the surveillance of granted accreditations are initiated by DAkkS and do not require an application to be submitted by the accredited body.

Detailed <u>information on the application</u> and the application forms required are available on the DAkkS website. Questions concerning the application can be sent to DAkkS using a <u>contact form</u>. Applications must be made in writing. The complete application, signed by an authorised representative, can be sent to DAkkS by post or fax.

I. By post

Deutsche Akkreditierungsstelle GmbH Application Service and New Client Support Spittelmarkt 10 10117 Berlin

II. By fax

+49 (0)30 67 05 91-998

As an alternative to the written application, the only alternatives to the written form that may be used are those provided for by law:

- Send by DE-Mail to <u>a-nkb@dakks.de-mail.de</u> or
- Send digital documents with a qualified electronic signature to <u>a-nkb-qe@dakks.de</u>



For processing applications, DAkkS defines a case number for each case of accreditation which is used as a central identification for all further correspondence.

After an initial review of the content of the application, the application is formally confirmed by the relevant technical unit. If more than one technical unit will be involved in the application, a coordinating unit will be appointed for further communication concerning the case. If the outcome of the review of the application is that it cannot be accepted or can only be accepted partially, the applicant will be notified to that effect. With the application confirmation, the contact person responsible for the case is also named. This contact is responsible for further coordination, processing and handling this case of accreditation and is the contact person for the CAB for all questions concerning the specific case. All communication regarding the case is via the designated contact person.

With the exception of additions within the scope already applied for, or of withdrawal or partial withdrawal of the submitted application, amendments to an application are not possible while the case is being processed. In particular, assessments that have already been scheduled cannot be rescheduled or cancelled.

It may be necessary to schedule further assessments to take account of the addition to the application.

3 Preparation for assessment

3.1 Submission of required documents and data

If the necessary documents are not submitted immediately with the application, a deadline for subsequent submission of the complete documentation will be set with the application confirmation. If no documentation has been submitted by the deadline, the application may be rejected due to a lack of cooperation.

The documents are sent to DAkkS electronically in the form specified by DAkkS.

3.2 Advance payment

After estimating the costs likely to be incurred for implementation of the accreditation procedure, DAkkS charges fees in advance. Payment of these fees is a prerequisite for further processing of the case.



3.3 Review of submitted documents

The documents submitted by the CAB (see section 3.1) are subjected to a comprehensive review by DAkkS. The document review relates to the following aspects among others:

- Completeness of submitted documents
- Suitability of the content of the submitted documents for the area for which accreditation is being sought
- For requested extensions, in particular the documents relevant to the area for which an extension is being sought
- For surveillance, in particular with regard to the changes made to the submitted documents

The results of the documentary review are documented in a report containing the deficiencies found in the form of findings. The report is made available to the applicant. If the document review identifies numerous and serious deficiencies in the course of initial accreditation, reaccreditation or extension, DAkkS reserves the right to recommend that the CAB may withdraw the application. If the applicant decides to withdraw the application, the application may be submitted again at a later date. If the applicant decides to continue with the procedure, the assessment will take place on any dates that may have already been set. A delay in the assessment on the basis of the results of the document review at the request of the CAB is not possible.

DAkkS reserves the right to adjust the scheduling and content of the assessment that has already been agreed (see section 3.4) on the basis of the results of the document review.

The CAB will be given the opportunity to provide corrected documents up to 3 weeks before the scheduled on-site assessment².

3.4 Planning of the assessment

DAkkS operates on the general assumption that if an application is submitted, the documents submitted are suitable for the assessment that will follow. DAkkS therefore starts planning the assessment immediately after the application has been confirmed. The assessment dates for the office of the CAB are set by DAkkS and are determined exclusively by the availability of DAkkS staff and assessors. The assessment dates chosen are the earliest possible dates, but with notice of at least 8 weeks to allow the CAB to prepare for them. Provided that capacity planning at DAkkS is not affected, allowance is made for dates requested by the CAB.

The planning of witnessing necessary for the assessment is carried out as far as possible in coordination with the CAB and its customers. At the request of DAkkS, the CAB must provide the necessary appointments for all required witnessing activities within 8 weeks.

² If several assessments are planned, the first assessment date is the decisive date in terms of meeting the deadline.



The CAB is informed about the proposed team of assessors and the organisations to which the assessors belong. Justified objections against members of the assessment team must be raised within 14 days. If nothing is heard within a period of 14 days, the assessment team will be deemed to have been confirmed by the CAB. DAkkS is responsible for the decision as to whether the objections raised should be considered.

The assessors are assigned by DAkkS, whereupon they receive the relevant documents from the CAB. To prepare for the assessment, further documents may be requested by DAkkS. The assessors prepare for the assessment on the basis of the documents provided.

At the request of the CAB, a preliminary visit³, which is subject to a fee, can be made by an assessor to the applicant's premises. The focal points of the preliminary visit are:

- An estimation if the preconditions for the accreditation in terms of personnel, equipment and premises are met
- An estimation about the suitability of the existing quality management system
- Agreement on the scope of accreditation
- Mutual exchange of information and clarification of open questions concerning the continuing accreditation process

Before the assessment, the CAB receives an assessment plan for the upcoming assessment.

3.5 Unscheduled assessments

As part of the surveillance process, bodies that already hold an accreditation may be subjected to an unscheduled assessment without prior notice in accordance with Section 3 of the Act on the Accreditation Body (AkkStelleG). The assessors must be granted access and their instructions must be followed. Objections may be raised retroactively.

4 Assessment

4.1 Assessment techniques

As part of the accreditation procedure, DAkkS can make use of various assessment techniques. DAkkS determines the assessment techniques to be used for assessments. Among the main assessment techniques used by DAkkS are:

On-site assessment

On-site assessment of CAB locations, premises and equipment. The on-site assessment is used for all accreditation processes. Other assessment techniques are generally used in addition to the on-site assessment.

³ Only possible in the initial accreditation procedure



Witnessing

Observation of activities of the CAB within the scope of accreditation.

Witnessing of conformity assessment activities that are carried out at the fixed or mobile premises of the CAB normally takes place during on-site assessments of the permanent premises of the CAB as part of the planned accreditation processes.

Witnessing of conformity assessment activities that are not carried out in or at the fixed or mobile premises of the CAB always takes place at the locations where they are carried out by the CAB, for example at the premises of the customer of the CAB. Because of their physical separation from the CAB's locations, these assessment activities are generally planned separately. The term witness audit is also used to denote the witnessing of CAB activities outside the premises/locations of the CAB.

The type and scope of witnessing activities are determined by DAkkS for the specific case of accreditation / for the specific accreditation process. DAkkS makes allowance for any legal and normative requirements in place, and for requirements from applicable rules or from owners of conformity assessment schemes.

<u>Remote assessment</u>

Assessment of the physical location or virtual location of a conformity assessment body by electronic means.

Whether and to what extent the technique of remote assessments is used is determined by DAkkS with due regard to any risks involved.

Document assessment

Verification of the competence of the CAB on the basis of a review of documents to be submitted specifically with regard to a specific issue.

Whether and to what extent the technique of document review is used is determined by DAkkS.

4.2 Procedure for the assessment

Depending on the scope being sought and the availability of assessors, the assessment can be carried out from start to finish at the same time or broken up into several parts on different dates. Where possible, assessments are always carried out in a team. If the CAB also undertakes activities outside its own (fixed and mobile) premises, for example on-site activities at customers of the CAB, the assessment also includes these activities. Separate appointments may be agreed for this purpose to ensure that these activities are adequately covered by the assessment (witness audits).

The assessment begins with an opening meeting at which matters including its purpose, the underlying criteria and the assessment plan are explained. The goal of the assessment is to determine the competence of the CAB to carry out the conformity assessment activities for which accreditation is being sought in accordance with all relevant requirements.

To achieve this goal, the assessment team requires access to all premises, equipment, documents and records, including personnel records that are necessary to conduct the assessment and verify the



requirements for accreditation. DAkkS assessors and technical experts are obliged to treat all data to which they are given access in the course of their work for DAkkS confidentially.

The assessment team must be provided with the assistance and support necessary for its work. Preparations on the part of the CAB are required to facilitate prompt access to the relevant premises, equipment, documents and records. The CAB must also ensure the availability of people required for the assessment.

If the assessment cannot be completed in full as a result of failure to provide assistance and support or because people or information are unavailable, DAkkS reserves the right to schedule further assessments.

The assessment of the CAB is conducted at the registered office of the CAB and at the locations where the CAB carries out its conformity assessment activities, or in a broader sense, activities in the context of the sought/accredited scope. Locations at which key activities are carried out are given special consideration during determination of the locations to be assessed.

The CAB must ensure that witness audits can be conducted by DAkkS assessors at the premises of customers, and where applicable at the premises of subcontractors of the CAB.

In some cases, it may no longer be appropriate to continue with an assessment, which will then have to be cancelled. Reasons for discontinuing an assessment may include:

- The CAB wishes to terminate the assessment
- The CAB denies access to premises, equipment or documents relevant to the accreditation or refuses to provide information requested by the assessors
- The behaviour of CAB personnel vis-à-vis the assessor is unacceptable

The assessment ends with a closing meeting between the assessment team and the representatives of the CAB, in which the CAB is invited to speak about the results of the assessment as set out in Section 28 of the Administrative Procedure Act (VwVfG). For this purpose, the assessors present the results of the assessment, in particular on the basis of the non-conformity report, and provide information on the progress of the case. The non-conformities are noted by a representative of the CAB.

In exceptional cases, the closing meeting may be postponed if the time does not allow it.

Depending on their nature and importance, non-conformities are classified as critical or non-critical.

For each non-conformity, the assessor determines whether a follow-up assessment of documents is sufficient to evaluate the corrective action envisaged or implemented, or whether a more comprehensive follow-up assessment is required (on-site if necessary). The final decision on how to proceed is taken by DAkkS.

For each non-conformity, a deadline is set for the CAB to deal with the non-conformity.

For critical non-conformities, immediate measures may be required to prevent an immediate reduction or suspension of the accreditation. The goals of such immediate measures are to eliminate and



prevent the consequences of a critical non-conformity in the short term. They do not replace a careful root cause- and extent analysis and the definition and implementation of appropriate corrective actions by the CAB.

The CAB has the ability to raise justified objections to DAkkS in writing in the form of a motion for reconsideration of individual non-conformities. DAkkS is responsible for the decision as to whether the motion for reconsideration is justified. Motions for reconsideration do not have suspensive effect, and in particular do not constitute corrective actions.

5 Follow-up of the assessment

5.1 Assessment reports

Each assessor prepares a report on each assessment conducted. After all reports on an assessment have been received and reviewed by DAkkS, they are sent to the CAB.

5.2 Follow-up of non-conformities

Following the assessment, the CAB carries out a root cause- and extent analysis for each non-conformity and determines the appropriate corrective action. Both the root cause- and extent analysis, which must be transparent and informative, and the corrective action must be clearly documented and sent in good time to the relevant contact person at DAkkS together with evidence of the implementation of the corrective actions, preferably by electronic means. There is no direct consultation between CAB and assessor concerning the corrective action. All communication regarding non-conformities is always through the assigned contact person at DAkkS.

Defined immediate actions must be implemented by the CAB in good time and evidence to that effect must be provided.

The deadlines for complete processing of the corrective actions by the CAB are defined in the individual non-conformity reports. For initial accreditations, the non-conformities must be dealt with by the CAB within a maximum period of four months. For surveillance activities, including reassessments and extensions, the maximum period is two months. With respect to adherence to deadlines, the date of receipt by DAkkS of the documents concerning the corrective actions is decisive.

If critical non-conformities cannot be closed on the basis of the documents submitted, a file recommending a negative decision is submitted to the Accreditation Committee. The applicant is informed of the negative recommendation to the Accreditation Committee and is given the opportunity to comment (hearing on the expected negative decision). If an opinion or motion for reconsideration from the CAB is received, they are also submitted to the Accreditation Committee.



6 Decision on accreditation

6.1 Accreditation Committee

The Accreditation Committee evaluates and decides on an accreditation on the basis of the file submitted to it. The Accreditation Committee is convened when all non-conformities have been closed or after the deadline for resolving non-conformities if it has not proved possible to close non-conformities after the hearing.

Members of the Accreditation Committee are experts in their fields who have been appointed for this purpose by DAkkS. The members of the Accreditation Committee must be in all cases people other than those who conducted the assessment.

If several technical units are involved in a case of accreditation, several Accreditation Committees decide on the areas that concern them independently of each other.

Decisions are made by Accreditation Committees in the cases of initial accreditation, extension/amendment, reduction, reassessment and reaccreditation. In the case of surveillance (with the exception of reassessments) that do not lead to an amendment of the scope of accreditation or where no critical non-conformities that could not be subsequently corrected were identified, a simplified procedure is in place for the decision on maintenance of accreditation.

An Accreditation Committee is also not convened if the scope of accreditation is reduced at the request of the applicant or if the accreditation as a whole is returned.

6.2 Notice of accreditation, accreditation certificate and annex to the certificate

The granting of accreditation in the statutory area is by notice in accordance with the provisions of the Administrative Procedure Act (VwVfG). With a positive notice, the applicant receives an accreditation certificate, or several accreditation certificates depending on the scope, including annexes setting out the scope of accreditation in detail. Permission to use the accreditation symbol is regularly granted with the notice of accreditation.

Where several technical units are involved in one case of accreditation and where the accreditation decision is positive, the CAB receives a partial accreditation certificate for each technical unit concerned, consisting of a cover sheet and the partial certificate annex in each case, as well as an overall accreditation certificate (also consisting of cover sheet and annex). The overall certificate makes reference to all partial accreditation certificates. The scope of the accreditation granted is determined by the partial certificate annexes. Depending on the progress of the case, partial accreditation certificates can be issued subsequent to each other together with the corresponding notices of accreditation.

With the granting of accreditation, the CAB is entered into the database of accredited bodies and its certificate annexes are published on the DAkkS website. This database is maintained by DAkkS and reflects the current scope of accreditation of the bodies accredited by DAkkS.



In the event that the accreditation has not been granted or has been granted only partially, the CAB will receive a notice to that effect setting out the reasons for the decision. Appeals as defined in DIN EN ISO/IEC 17011 against negative or partially negative notices of accreditation are treated as objections within the meaning of Section 79 VwVfG.

DAkkS provides information on suspended or withdrawn accreditations in the database of accredited bodies.

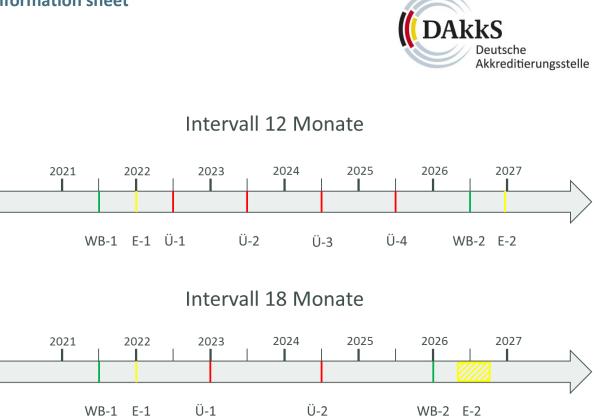
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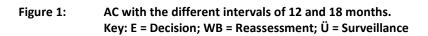
Under DIN EN ISO/IEC 17011, the accreditation cycle (AC) is the period between the decision on initial accreditation and the decision on subsequent reassessment, or the period between decisions on successive reassessments. The interval for an AC under DIN EN ISO/IEC 17011 is a maximum of 5 years. DAkkS has adopted the 5-year period as the maximum permitted period for the AC.

If the decision on accreditation is made at different times as a result of the involvement of several technical units, the AC for the initial assessment and reassessment begins with the first decision in the case.

To maintain the accreditation, regular surveillance measures are required during the accreditation cycle. At present, the regular surveillance intervals⁴ are 12 months for certification bodies and verification bodies and 18 months for all other accreditation activities. Depending on the applicable interval as set out in the standard, the surveillance sequences for the AC are as shown in Figure 2.

⁴ The target date (month) for the following surveillance is determined on the basis of the first assessment activity during the previous surveillance. If surveillance has to be postponed for unforeseen reasons to a later date, the target date (month) is always used as the starting point for scheduling the following surveillance.





For accreditations granted for an unlimited period, the timing of the reassessment is always determined in a manner that ensures that the decision can be made in good time before the end of the current accreditation cycle. If necessary, this may result in a shorter period for the previous surveillance than the specified standard interval (12 or 18 months). For cases of accreditation with an 18month interval, the reassessment is generally planned after the second surveillance in the AC. This ensures that after the reassessment has been conducted, the decision can be made in good time before the current AC comes to an end. There is no provision for a third round of surveillance for an 18months interval.

For accreditations granted for a limited period, the applicant is responsible for submitting an application for reaccreditation in good time. The CAB is responsible for submitting the application early enough to allow the subsequent reassessment to be conducted on time and the decision on the reaccreditation to be made in good time before the end of the current accreditation. Any extension of the validity period for accreditations granted for a limited period is excluded.

If, in cases of accreditations granted for an indefinite period, the accreditation decision after a reassessment is not made in good time before the end of the current accreditation cycle as a result of a failure to cooperate on the part of the CAB, the accreditation must be suspended, withdrawn or reduced. The content of individual surveillance measures is defined in accordance with the requirements of DIN EN ISO/IEC 17011 and is determined by DAkkS on the basis of risk considerations. The content of the assessment, its duration and the techniques to be used are decided by DAkkS.

With regard to surveillance measures, witnessing of conformity assessment activities is among the factors that plays an important role. The scope, number and type of activities to be observed may



vary depending on the accreditation activity, scope and specific operations the CAB. Where applicable, existing international rules or requirements of owners of conformity assessment schemes must be taken into account.

At the discretion of DAkkS, on-site assessments may be supplemented by remote assessments, document assessments or other assessment techniques, with due regard given to rules and framework conditions in place at DAkkS.

In addition, the following principles apply:

- Additional requirements of power-conferring authorities or owners of conformity assessment schemes (for example for certification bodies for products) regarding the scope and frequency of surveillance activities are taken into account
- In justified cases and for specific reasons, surveillance intervals may be shortened, for example on the basis of a recommendation from an assessor, a decision of an Accreditation Committee or the decision of DAkkS
- Extraordinary surveillance is possible in justified cases
- Follow-up assessments may be required as a result of conducted surveillance

The conduct and follow-up of the assessment within the framework of the surveillance measures are in accordance with the procedure described in sections 3, 4 and 5.

8 Amendment

8.1 Amendment of accreditation

The most significant form of amendment of accreditation is the extension of the scope of accreditation. Any amendment of the accredited scope requires an application. This does not affect any flexibility of scope that has been granted.

In general, the procedure is the same as described in sections 2 to 6.

Reduction of the scope of an accreditation is also an amendment requiring an application.

8.2 Abandon an accreditation

If a CAB wishes to entirely abandon its accreditation, DAkkS must be informed in writing. DAkkS provides an application form for this purpose on its website. DAkkS will revoke the accreditation once the CAB has provided evidence that all confirmations of conformity requiring surveillance have been effectively removed from the market.

An entry noting the termination of accreditation is then added to the database of accredited bodies.



V Suspension, withdrawal or reduction of accreditation

Negative accreditation decisions are governed by Article 5 (4) of Regulation (EC) No 765/2008. This is a bound decision. DAkkS chooses between the following measures:

Suspension:	Temporary restriction of accreditation, either entirely or for a part of the scope of accreditation
Withdrawal:	Withdrawal of an accreditation for its entire scope
Restriction:	Withdrawal of a part of the scope of accreditation

If DAkkS ascertains that a CAB is no longer competent or has committed a serious breach of its obligations, it takes measures to suspend, restrict or withdraw the accreditation concerned.

If an accreditation is only partially suspended or restricted, DAkkS issues an updated accreditation certificate. The CAB's entry in the database of accredited bodies is then adjusted accordingly. In the database of accredited bodies, DAkkS publishes the relevant information on accreditations that have been withdrawn or partially or completely suspended.

Issued certificates including their annexes must be returned to DAkkS on request. Authorities that have issued an approval, designation or notification on the basis of the accreditation are informed of the measures taken by DAkkS.

VI Procedures outside the scope of EU Regulation No 765/2008

The accreditation of CABs outside the territorial scope of EU Regulation No 765/2008 is not subject to the provisions of the Administrative Procedure Act (VwVfG) and is carried out on a contractual basis. Applicants are provided with offers of contract for this purpose upon application.

On confirmation of the application, the case of accreditation is handled on the basis of a contract between the CAB and DAkkS.

Unless explicitly excluded by the contract, the procedures and requirements described in this document apply mutatis mutandis.

DAkkS decisions on accreditation (granting, amendment, reduction, suspension, withdrawal) are notified to the CAB in writing.

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

Reaccreditation requires a new application from the CAB.