

Accreditation of conformity assessment bodies with several locations

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Scope:

This rule contains mandatory criteria, under which the accreditation of a conformity assessment body (CAB) with several locations is possible. Furthermore key activities are defined that need to be considered compulsory in the accreditation process/in the assessment of the CAB if these activities are performed at a site within the scope of accreditation. This rule is applicable for all kind of CABs, regardless of whether the CAB or its locations, critical locations or subcontractors are located within and/or outside of Germany. With this rule DAkkS implements among other things the requirements of the international rules EA 2/13 and IAF MD 12. DAkkS may define sectoral specifications that differ from the fundamentals set out in this rule.

The following explanations are valid for accreditations that are used by authorities for power conferring in so far as these don't object against additional requirements/contents of legislation or rules set out by the mandatory area (European Commission, Government, Länder).

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1 Purpose / scope

This rule contains mandatory criteria, under which the accreditation of a conformity assessment body (CAB) with several locations is possible. Furthermore key activities are defined that need to be considered compulsory in the accreditation process/in the assessment of the CAB if these activities are performed at a site within the scope of accreditation. This rule is applicable for all kind of CABs, regardless of whether the CAB or its locations, critical locations or subcontractors are located within and/or outside of Germany. With this rule DAkKS implements among other things the requirements of the international rules EA 2/13 and IAF MD 12. DAkKS may define sectoral specifications that differ from the fundamentals set out in this rule.

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2 Terms

<p>Organisation</p>	<p>Following the EA rule EA 2/13 the term “Organisation” is defined for this rule as follows:</p> <p>Legal entity or Group of legal entities, composed of a head office (headquarter, central office, however named) and local sites connected with the head office on the basis of contractual or equivalent legal relationships, operating under the same commercial name and logo.</p>
<p>Head Office</p>	<p>The Head office (headquarter, central office, however named) is the site where the management of the CAB is located.</p> <p><i>Note: Location of the head office may not necessarily be the location of the legal entity of the CAB and the management of the CAB may not necessarily be the top management of the legal entity. It depends highly on the organisational structure of the CAB and its legal entity what has to be defined as the head office of the CAB.</i></p>
<p>Site</p>	<p>A site (branch office, subsidiary – however named) is a physically separated part of the head office/central office of a CAB. Under the technical supervision by the head office individual or various activities within the scope of accreditation are accomplished at the site (e.g. initial contacting of customers of the CAB, information of the customer or the performance of conformity assessment activities).</p> <p><i>Note 1: A site may belong to the same or to another legal entity (e.g. branch offices that operate as separate legal entities).</i></p> <p><i>Note 2: A site can be classified as critical location or non-critical location.</i></p>

Critical location	A critical location is a site of the CAB where key activities according to DIN EN ISO/IEC 17011 or IAF/ILAC A5 are performed. (See in particular section 3.4)
Non-critical location	A non-critical location is a site of the CAB where activities are performed that are not key activities. <i>Note: Normally these activities consist of simple office activities that are executed according to the regulations of the head office of the CAB.</i>
Subcontractor	A subcontractor executes specific conformity assessment tasks on behalf of the CAB. <i>Note: For the purpose of this rule the subcontractor is an independent legal entity; according to this rule a subcontractor is not bound to a specific location – therefore the classification as critical-/non-critical location and resulting consequences shall not apply.</i>

3 Description

3.1 Introduction

DIN EN ISO/IEC 17011 determines in section 7.2.1 that an applicant CAB must provide general information about activities and relations to superior organisations as well as the address of all sites which are included in the requested scope of accreditation. Furthermore DIN EN ISO/IEC 17011 regulates in sections 7.5.7, 7.5.8. and 7.7.2 that all sites in the requested scope of accreditation from where key activities are performed need to be included in the assessment of the CAB.

The Deutsche Akkreditierungsstelle GmbH (DAkkS) may include sites in the accreditation of the CAB regardless of the geographic location and legal entity of the sites.

It is the responsibility of DAkkS to make sure that all activities of the CAB (not only the defined key activities) that are delivered under the scope of accreditation satisfy the respective valid requirements irrespective of where in the world these activities are delivered.

In the following the requirements to the CAB with several sites with regard to the organisation, the management and the management system are explained and key activities for different kinds of CABs are defined.

3.2 General requirements for the accreditation of CABs with several sites

The accreditation of a CAB with several sites is principally possible, provided that the following requirements are demonstrably met:

- The sites listed in the application belong to one organisation (see section 3.2.1);
- The sites listed in the application are under the control of the same management (see section 3.2.2);
- The sites listed in the application are subject to a unique and consistent management system that is demonstrably established and implemented for the entire scope of accreditation (see section 3.2.3).

3.2.1 Requirements to the organisation

The sites listed in the application for accreditation may belong to different legal entities. Based on the name and the used logo the togetherness to the same organisation needs to be distinctly visible. The names of the particular legal entities may be different within certain limits, for example to represent the type of organisation (GmbH, Ltd, s.r.o etc) or adaptation to the respective local markets. The CAB must have documented contractual agreements with all sites (critical- / non-critical Locations). The agreements shall exclude any defective representation and application of services by the sites under accreditation.

The head office of the CAB has the overall responsibility and technical managerial authority over all sites and all conformity assessment activities within the scope of accreditation.

The head office is located in the country of the applying legal entity and is part of it.

3.2.2 Requirements to the management

The sites listed in the application are under the same group of persons respectively the same organisational entity, taking overall responsibility for the accredited activities. Consequently the management has the managerial authority over all employees, who are involved in the conformity assessment process at the respective sites (critical and non-critical Locations), even if the management has no direct disciplinary authority. The CAB maintains the final responsibility for all conformity assessment activities irrespective if these are performed by the head office or by one or more sites.

3.2.3 Requirements to the management system

The sites listed in the application are under the same basic rules and processes, which are reviewed in the accreditation procedure. The CAB has got the full supervision about responsibilities for the implementation and the results of services within the scope of accreditation. Thereto the CAB needs to possess demonstrably the respective technical expertise and also the necessary resources, to warrant the control about the full scope of accreditation.

3.3 Specific determinations

If the scope of the requested accreditation comprises sites which belong to different legal entities - this is especially so if the CAB operates from sites in different countries – the following regulations apply¹.

- The accreditation is issued to the legal entity of head office of the CAB. This entity is „holder of the accreditation“ and is responsible for all conformity assessment activities performed within the scope of accreditation, including the activities which are performed from other sites. The central office must confirm that it carries the full operative, financial and legal responsibility for these activities;
- The local sites may offer services within the scope of accreditation only in the name of the head office, which is the holder of accreditation. Reports for services within the accredited scope must contain the respective name and address of the accredited head office. The reports must not leave the reader in the dark about who holds the accreditation and it must not be suggested that the local site was accredited separately, if this is not the case. The reports may contain the contact details of the local site, but not the logo of it.
- If the scope of accreditation comprises key activities of sites outside of Germany (here especially countries which are signatories to the multilateral agreements) the DAkKS will cooperate comprehensively with the local national accreditation bodies (NAB). As a general rule, assessments of these sites are subcontracted to the respective NAB. A participation in/ performance of an assessment by the NAB may not be principally declined by the accredited CAB.

3.4 Key activities

In the following for each kind of CAB these activities are mentioned that are defined by DAkKS as key activities. The requirements of DIN EN ISO/IEC 17011 and IAF/ILAC A5 are considered.

3.4.1 Key activities for all kinds of CAB

- Policy formulation;
- Process and procedure development and approval;
- Application- and/or contract review;
- Planning conformity assessments (e.g. the creation of a specific audit plan is not meant);

¹ See also: SOGS N595 EN REV6: CERTIF 2009-06 REV6 - CROSS BORDER ACCREDITATION ACTIVITIES (<http://ec.europa.eu/DocsRoom/documents/5745>)

- Review, approval and decision on the results of conformity assessment.

3.4.2 Key activities for laboratories

- Determination of staff powers and responsibilities
- For testing laboratories the performance of tests (DIN EN ISO/IEC 17025)
- For calibration laboratories the performance of calibrations (DIN EN ISO/IEC 17025)
- For medical laboratories the performance of examinations (DIN EN ISO 15189)

3.4.3 Key activities for inspection bodies

- Process of initial selection of inspectors

3.4.4 Certification bodies for products

- Initial assessment of competence and approval of technical personnel and subcontractors;
- Control of the monitoring process of competence of personnel and subcontractors and its outcomes;
- Determination of technical requirements for certification activities in new technical areas or areas of limited sporadic activities;
- Technical review of evaluation activities.

3.4.5 Certification bodies for management systems

- Decision on initial approval of auditing personnel or control of their training;
- Reviewing results of monitoring of auditing personnel;
- Assignment of auditing personnel;
- Control of surveillance or recertification audits.

3.4.6 Certification bodies for persons

- Development and approval of requirements for selection and appointment of examiners;
- Development and approval of policy, processes and procedures for the resolution of appeals and complaints received from applicants, candidates, certified persons and their employers and other parties about the certification process and criteria;
- Final decision on appeals and complaints.

3.5 Implementation in the accreditation procedure

The head office and all sites of the CAB where key activities are performed are subject to the initial assessment as well as to the regular surveillances by DAkKS including reassessments. Key activities that are performed from sites which are not subject to the assessment/surveillance activities by DAkKS are claimed to be delivered outside the granted scope of accreditation. Relevant reports must not include any reference to accreditation.

3.5.1 Provision of information by the CAB

The CAB must inform DAkKS about every site² (worldwide) with regard to the delivery of conformity assessment activities within the scope/applied scope of accreditation, including the kind of legal relationship (legal entity and statements if it is e.g. a branch office or subsidiary) with an indication which activities are performed at the relevant sites.

The CAB must describe to DAkKS in detail the extent of activities at the critical location. The classification of a site as critical or non-critical location is determined by the CAB. DAkKS reviews this classification. Based on the results of the review a correction of the classification may be necessary.

For certification bodies the following current information must be provided on request:

- Countries into which accredited certificates are issued and the number of certificates issued in each country;
- Countries in which the CAB operates from a fixed office location that performs any certification activities;
- Countries in which the CAB has remote personnel³ that perform any certification activities;
- Which fixed office locations are responsible for performing and/or managing key activities or from where remote personnel performing key activities are managed;
- The CAB's arrangements for managing all activities that are performed from a foreign fixed office location or by remote personnel.

Based on annually updated information by the CAB and considering the aspects listed in section 3.6, DAkKS will adjust the planned surveillance activities.

² Every site which performs activities in the requested or in the already granted scope of accreditation, regardless of whether the activities are key activities or not.

³ Internal or external staff that perform certification activities for a CAB and do not work at a fixed office location.

3.5.2 Changes/Extensions with regard to critical locations

Changes/Extension with regard to critical locations have to be applied for. In principle the DAkKS application form has to be used (72 FB 001, see DAkKS Website). This applies equally for new as well as for the deletion/shutdown or relocation of a critical location or for a downgrading into a non-critical location (application for changing of accreditation).

For the inclusion or shutdown of a non-critical location an informal notice is acceptable.

The extension of accreditation for additional critical locations or the extension of the activities performed at an existing critical location, e.g. takeover of further key activities, areas into the scope of accreditation etc. will be effective only after the application, assessment and positive accreditation decision. Afterwards the critical location may get active and perform the delegated activities with reference to the existing accreditation.

In case of a deletion/shutdown of a critical location the CAB must submit a plan, showing the organisational transfer of the responsibilities for the processes and certifications of the critical location to the head office of the CAB or another critical location. A valid list of the certifications that were issued within the responsibility of the site must be included. The correct transfer to the head office of the CAB or to another critical location may be reviewed in the context of a separate assessment.

3.6 Surveillance⁴ of sites

The DAkKS performs the necessary assessment activities to verify, if the CAB complies with the specified requirements of the underlying accreditation standard, the requirements with regard to the scope of accreditation and additional requirements, if applicable, irrespective of where relevant conformity assessment activities are performed.

The following criteria are considered by DAkKS for planning assessment activities:

- The relationship between the CAB and its foreign entities and subsidiaries;
- The CAB's arrangements for managing its foreign conformity assessment activities;
- Whether the CAB holds accreditation from the local AB;
- The number of fixed office locations, undertaking conformity assessment activities, in each country;
- The number of remote personnel, undertaking conformity assessment activities, in each country;

⁴ Additionally the requirements and framework conditions of the rule 71 SD 0 018 apply.

- Where key activities are performed and managed or from where remote personnel performing key activities are managed;
- The range of conformity assessment activities performed, where they are performed and from where remote personnel are managed;
- The effectiveness of the CAB's management controls of its conformity assessment activities;
- The accessibility of the CAB's records;
- The availability of selected CAB personnel (internal and external) for interview;
- The number of certificates/reports issued through a particular fixed office location;
- Schemes for which certification is granted through a particular fixed office location;
- Where a fixed office location manages other fixed office locations or remote personnel;
- The number of different countries covered by remote personnel and how they are managed;
- The risks posed by the activities performed and/or managed and where they are performed and/or managed. (Note: these may be non-key activities);
- Social and cultural aspects of each country;
- The number and type of complaints;
- The effectiveness of the CAB's oversight in controlling its foreign conformity assessment activities, including internal audits it performs on fixed office locations;
- Where there is evidence of malpractice, such as misrepresentation by sales personnel, inappropriate relationships with consultants or ineffective oversight by the CAB.

Each critical location is regularly subject of surveillance according to DIN EN ISO/IEC 17011 by an on-site assessment. DAkkS considers the international rules for collaboration between accreditation bodies (EA 2/13, ILAC G21) as well as specific rules for the surveillance of granted accreditations (e.g. IAF MD 12). For Certification bodies DAkkS requires the submission of relevant Information by the CAB annually.

Normally the surveillance of a non-critical location is not performed through an on-site assessment. The legit inclusion of these sites is part of the surveillance of the CAB. An on-site assessment may be necessary if information concerning:

- Noticeably increase of quantity of the reports/certificates in the region/ in the country;
- Activities of the sites (e.g. activities of the contractual partner which queries the impartiality – consulting services);
- Results of assessments (e.g. deduced from reviews of files in the head office of the CAB);

- Reports about anomalies (e.g. from local/national accreditation bodies) or
- Complaints

give point to that.

The results of the assessment of the CAB's head office are important at this. An observation of a non-critical location may also be performed in the context of a witness audit within the local responsibility of the site.

3.7 Activities of subcontractors

Sites of subcontractors are no sites in the sense of the abovementioned definition in section 2. Nevertheless they performe potentially key activities by order of an accredited CAB. Key activities performed by the subcontractor must meet the requirements of the respective accreditation standards.

If the subcontractor of a CAB performs key activities an assessment / surveillance of these activities may be required, if the DAkkS considers it necessary. In the case that the subcontractor is accredited for the required activity no additional assessment/surveillance is necessary.

Example:

An assessment of a subcontractor may be necessary if in the context of notification the accredited body needs to use a concretely named subcontractor, because this is part of the notification by the authority as it is arranged e.g.in the event of accreditation within EU-Construction Products Regulation. (See also 71 SD 1 018 and 71 SD 1 019).

3.8 Content of the accreditation certificate

After completion of the assessment and the accreditation decision critical locations are outlined in the accreditation certificate / annex of the certificate in the following way:

- 1 Sites (head office and critical locations), are listed with the address on the cover sheet of the accreditation certificate and the annex. If the critical locations cannot be listed on the cover sheet of the accreditation certificate due to lack of space, only the address of the head office is listed and for the critical locations a reference is made to the annex;
- 2 On the cover sheet of the accreditation certificate and the annex only one legal entity, namely the legal entity of the holder of the accreditation is listed. Critical locations are listed only with the address and not with the potentially deviating name of the legal entity;
- 3 Sites, that are classified as non-critical locations are not listed in the accreditation certificate/annex of the accreditation certificate.

In the annex of the certificate it is marked which conformity assessment activities are performed at which sites.

Subcontractors are not listed in the accreditation certificate / annex of the accreditation certificate.

4 Applicable documents

DIN EN ISO/IEC 17011: 2005	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
EA-2/13	EA Cross Frontier Policy for Cooperation between EA Members
EA-2/13 S1	Interpretation of terminology used in clause 5.1 and guidelines to assessment focus
IAF MD 12	Assessment of Certification Activities for Cross Frontier Accreditation
ILAC-G21	ILAC Cross Frontier Accreditation – Principles for Avoiding Duplication
IAF/ILAC A5	IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004
IAF-ML 5	Procedure of IAF Listing of foreign critical locations / premises