Requirements for the application of ISO/IEC 17065 for the accreditation of bodies certifying products, processes, and services

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Scope:

This Rule includes further specifications on specific requirements set out in ISO/IEC 17065 and requirements for and explanations on the accreditation procedure and the description of the scope of accreditation of bodies certifying products, processes, and services. The Rule also provides a framework on how to formulate areas of accreditation with a flexible scope defined within limits. This Rule is intended to ensure the equal treatment of conformity assessment bodies, and a common approach between the assessors and the staff members of the Deutsche Akkreditierungsstelle GmbH (DAkkS).

Further requirements may be specified in subordinate, sectoral rules.

Date of confirmation by the Accreditation Advisory Board (AKB): 25. 11. 2014

Contents

1 Purpose / Scope

This Rule is divided into three parts. Part A includes detailed specifications on specific requirements set out in ISO/IEC 17065. Part B includes requirements for and explanations on the accreditation procedure, and Part C the requirements on how to formulate the scope of accreditation of bodies certifying products, processes, and services. This Rule also provides a framework on how to describe areas of accreditation with a flexible scope defined within limits. This Rule is intended to ensure the equal treatment of conformity assessment bodies, and a common approach between the assessors and the staff members of the Deutsche Akkreditierungsstelle GmbH (DAkkS).

Further requirements may be defined in subordinate sectoral rules.

2 Terms and definitions

Scope of accreditation	Specific conformity assessment activities for which accreditation is sought or has been granted (ISO/IEC 17011:2005-02)
Service	Result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible (ISO/IEC 17065:2013)
Scope of certification	Identification of: – the product(s), process(es) or service(s) for which the certification is granted; – the applicable certification scheme; and – the standard(s) and other normative document(s) including their date of publication, to which it is judged that the product(s), process(es) and service(s) comply. (ISO/IEC 17065:2013)
Product	Result of a process (ISO/IEC 17065:2013) (e. g. food with a protected geographical identification, certain transportation services, specific software, certain household devices or certain construction products)

Product requirement	Requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme (ISO/IEC 17065:2013)
Process	Set of interrelated or interacting activities which transforms inputs into outputs (ISO/IEC 17065:2013) (e. g. certain manufacturing processes)
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled (Clause 3.8.5 of ISO 9000)
Witnessing	Observation of evaluation activities of the certification body on site within a specific certification process with respect to the compliance with the requirements as set out in ISO/IEC 17065
Certification requirement	Specified requirement, including product requirements, that is fulfilled by the client as a condition of establishing or maintaining certification (ISO/IEC 17065:2013)
Certification scheme	Certification system related to specified products, to which the same specified requirements, specific rules, and procedures apply *Note: From ISO/IEC 17067:2013: The rules, procedures and management for implementing product, process, and service certification are stipulated by the certification scheme.* *Note: For a better distinction between the terms certification system and certification scheme – see Clause 6.2 of ISO/IEC 17067:2013* *Note: Specified requirements are certification requirements according to Clause 3.7 of ISO/IEC 17065* (e. g. harmonized product standards under the Construction Products Regulation; GLOBAL G.A.P.; EC-type examination according to the Pressure Equipment Directive; In-house certification schemes in the voluntary (legally non-regulated area))

Certification system	Rules, procedures, and management for carrying out certifications *Note: The term certification system is not used consistently in the standards (ISO/IEC 17065, ISO/IEC 17067)* (e. g. Annex V of the Construction Products Regulation; Machinery Directive, certification systems in the legally non-regulated area, such as IEC-CB)
Certification procedure	Documented procedure of the certification body for carrying out certifications

For distinguishing between the terms certification system and certification scheme, the following Figure taken from ISO/IEC 17067 is useful:

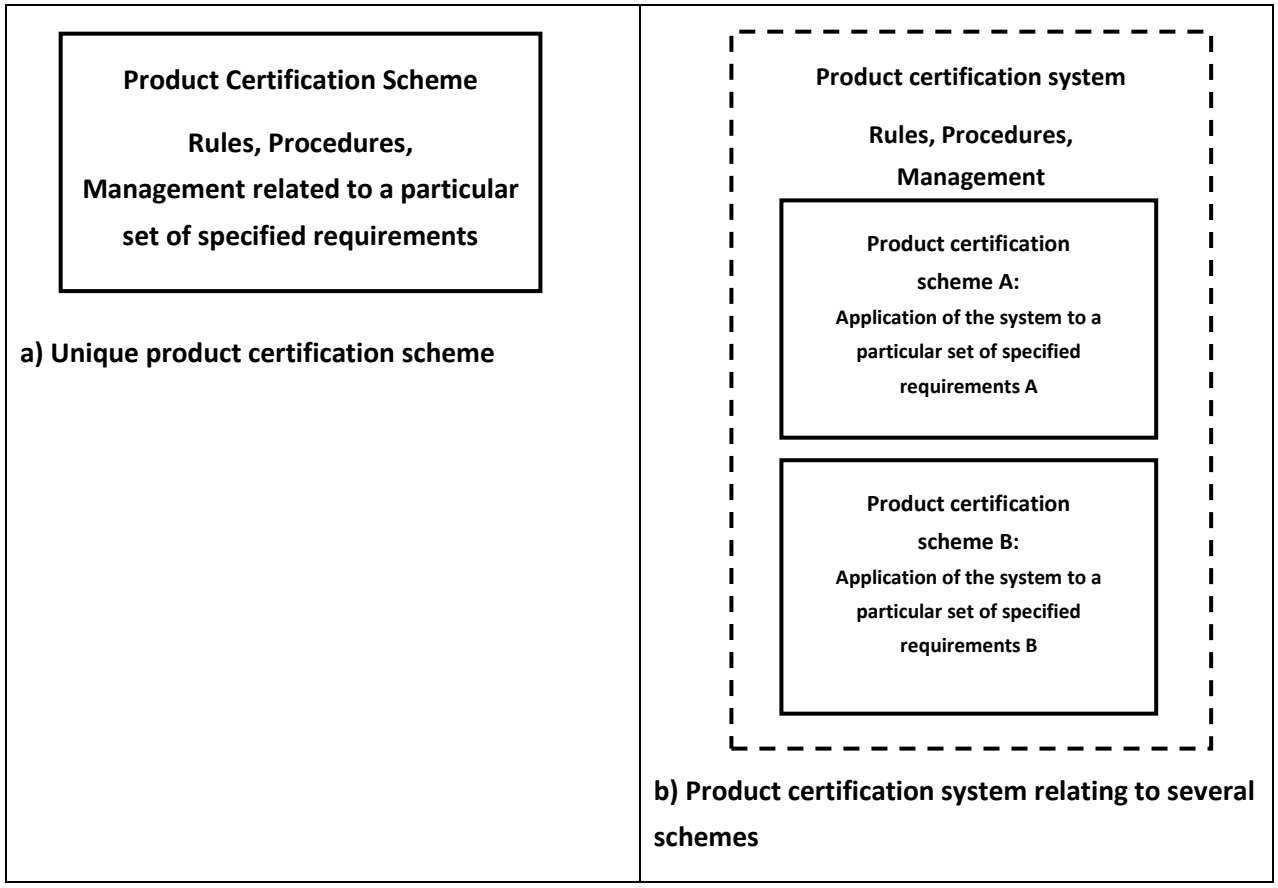

Figure 1: Relationship between product certification system and product certification scheme (from ISO/IEC 17067) [1]

[1] Reprint courtesy of the German Standardization Institute (DIN Deutsches Institut für Normung e. V.). The applicable DIN standard is the version with the latest issue date, which is available at the Beuth Verlag GmbH, Burggrafenstraße 6, 10787 Berlin, Germany.

3 Part A: Detailed specifications on specific requirements set out in ISO/IEC 17065

In the following the relevant items of the standard ISO/IEC 17065 are referenced in the headlines in order to provide a better assignment to the standard. Not all items of the standard are provided with a specification. In the legally regulated area, additional requirements may apply, if applicable.

The term **consultancy**, which is used in different Clauses of the Standard without being limited in its application, includes only the activities described in Clause 3.2 of the Standard. It is, however, to be considered that participation in the activities described under Clause 3.2 may pose a risk to impartiality for similar competing products/processes/services and shall be evaluated by the certification body accordingly.

3.1 Management of impartiality (Clause 4.2 of ISO/IEC 17065)

In accordance with Clauses 4.2.3 and 4.2.4 of the Standard ISO/IEC 17065, the management of impartiality means the identification of risks (certification body, personnel, relating bodies; see also Note 1 of Clause 4.2.3 of ISO/IEC17065) on an ongoing basis and the elimination or minimization of such risks.

A significant part of the evaluation of risks that threaten the impartiality of the body is made by analyzing the related bodies (see Note 1 of Clause 4.2.3 of ISO/IEC 17065). This risk analysis shall be made and documented by the certification body on an ongoing basis and when specific changes occur.

This documentation should include the following:

1. Analysis and identification of the risks
2. Evaluation of the risks
3. Identifying measures to be taken for eliminating or minimizing risks

Furthermore, the documentation shall be kept up-to-date and be made available to the mechanism for safeguarding impartiality.

If the activities of a related body present a potential conflict of interest, the certification body shall demonstrate – according to their established documented procedures – how it eliminates or minimizes such a threat. In addition, in any case information shall be provided as soon as possible to the mechanism for safeguarding impartiality. To prove evidence of impartiality and independence the following indications shall be used, among others:

- Documentation of the legal form (e. g. an excerpt from the Commercial Register);
- Identification of the shareholders including specifying the shares and further relevant data;

- Shareholders Agreement;
- All relevant data of related bodies including description of their activities, any existing contracts/agreements, if applicable.

Relevant requirements for handling of impartiality of the certification body with respect to the **same legal entity** and **entities under the organizational control** of the certification body are set out in Clause 4.2.6 of ISO/IEC 17065. Restrictions on permitted activities for certification bodies and for all units under the same legal entities (among others prohibition on the provision of consultancy services – Clause 4.2.6 d)) shall also apply to all entities under the organizational control of the certification body, even if they belong to other legal entities.

Requirements that apply to **separate legal entities, which are not under the organizational control of the certification body**, are described in Clause 4.2.7 et seq. of ISO/IEC 17065.

This means among other things:

1 It is generally not prohibited that certification bodies use the **trademark of the organizational unit** or group of companies they belong to;

2 **Publication and marketing** shall not give the impression as if the activities relating to certification and consultancy (see Clause 3.2 of ISO/IEC 17065) were connected in any form. Such statements or analyzes should be publicly available (for example on the websites of the certification body).

As regards the permitted activities of persons who are staff members of the entities under the organizational control of the certification body, the same restrictions apply as to the permanently employed staff of the certification body (see Clause 6.1 Human Resources of ISO/IEC 17065).

3.2 Liability and financing (Clause 4.3 of ISO/IEC 17065)

The certification body shall have adequate arrangements to cover liabilities arising from its activities. This can be done, for example, by insurance, adequate financial reserves or by covering the liabilities by the State; evidence shall be submitted in writing. If a certification body safeguards its liability risks through financial reserves, it shall demonstrate to the accreditation body how such reserves are protected against unintended use. The adequacy of such reserves has to be documented by a written risk assessment (business sector, the potential consequences of “errors”, geographical area covered by the certification body, potential contractual penalties, etc.). This assessment shall include any personnel involved in the certification process.

If a coverage of risks of a certification body by means of insurance is required for specific activities (e. g. for a notification or from owners of certification schemes), it is required without exception and cannot be replaced by other measures.

3.3 Structural requirements (Section 5 of ISO/IEC 17065)

Mechanism for safeguarding impartiality (Clause 5.2 of ISO/IEC 17065)

Compared to the preceding version of the standard, ISO/IEC 17065 provides greater flexibility with respect to safeguarding the impartiality of the certification body by means of a structure formed by interested parties. This structure is referred to in the Standard as a "mechanism for safeguarding impartiality". Especially where the mechanism is not a committee of the certification body meeting at regular intervals, the certification body is obliged to explain how it is ensured that it fulfils its tasks in conformance with the Standard.

The mechanism for safeguarding impartiality shall be effective for all certification activities which are object of accreditation.

3.4 Resource requirements (Section 6 of ISO/IEC 17065)

Certification body personnel (Clause 6.1 of ISO/IEC 17065)

With respect to the staff employed in the certification process, it is necessary to distinguish between three categories of persons:

1 Permanent staff of the certification body;

2 Persons working under contract in a different way and acting on the certification body's behalf;

3 Persons who are employees of entities that are under the organizational control of the certification body (Clause 7.6.3 et seq.). From Clause 7.6.5 follows that such persons can both be permanent employees and contractually bound individual persons.

For managerial technical personnel a university degree of scientific or engineering disciplines or an equivalent qualification is required. In addition, several years of professional experience in the certification of products/processes/services or comparable experience have to be demonstrated.

3.5 Process requirements (Section 7 of ISO/IEC 17065)

3.5.1 Certification systems and certification schemes

Certification systems and certification schemes that are applied by the certification body with reference to an accreditation shall be validated. If developed in-house certification schemes are introduced in the scope of accreditation, a validation of the schemes by the certification body shall be demonstrated to the accreditation body prior to conducting the on-site assessment. Similarly, when introducing new normative certification schemes within the scope of legally regulated activities,

proof of a validation of the schemes shall be provided. After appropriate review decision is taken by the DAkkS on the general possibility of including new certification schemes in the accredited scopes.

3.5.2 Evaluation (Clause 7.4.5 of ISO/IEC 17065)

The certification body can recognize results of evaluations (results of testing and inspection, or results from audits) that were completed before the application for certification, under the following conditions:

- Based on appropriate records, the certification body shall demonstrate that all relevant requirements of the applicable standards of the 17000 series as well as of the certification system or the certification scheme were observed during the evaluation process;
- The competence of the bodies included in the evaluation process shall be demonstrated in a suitable manner. This applies in particular, if monitoring the performance of tests in the manufacturer's laboratory is no longer possible.

3.5.3 Review (Clause 7.5 of ISO/IEC 17065)

The requirement for a technically sound review of all requirements related to evaluation has been explicitly underlined by this new Clause of the Standard. This defines how the demand on the decision-making competency is established.

With respect to the use of the term "Review" changes have been made between the previous standard EN 45011 and ISO/IEC 17065 (see Figure 2). According to ISO/IEC 17065, evaluation is followed by the process step „Review". Persons, who have carried out the "Review", may also take the decision on certification (however, they shall not have been involved in the evaluation process).

When defining authorities and responsibilities of the personnel involved in the certification process the changed meaning of "Review" shall be noted. In both standards, the 4-eye principle is consistently required.

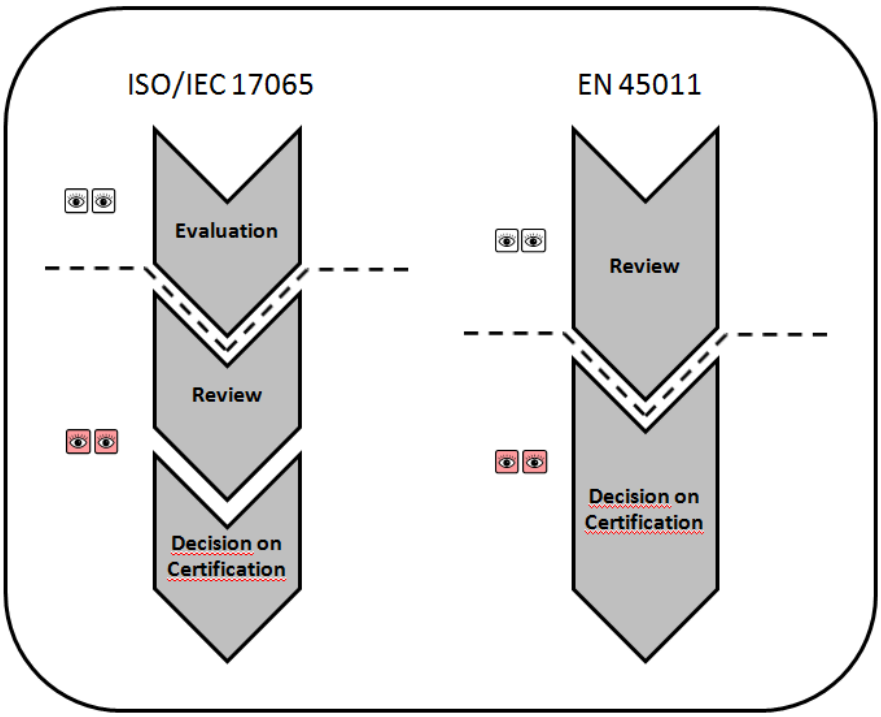

Figure 2: Comparison of the process steps in certification between ISO/IEC 17065 and EN 45011

3.5.4 Certification decision (Clause 7.6 of ISO/IEC 17065)

The decision on certification may only be taken by persons assigned by the certification body and bound by a contract or a formal agreement to:

- the certification body;
- an entity under organizational control of the certification body.

The persons bound to the certification body by contract may either be permanent employees of the certification body or freelancers.

3.6 Termination, reduction, suspension or withdrawal of certification (Clause 7.11 of ISO/IEC 17065)

According to the requirements set out in Clause M.8.3.2.1 of IAF/ILAC-A5, the certification body shall demonstrate that it has taken appropriate action on how to deal with the granted certificates issued for the respective scope in case of suspension or withdrawal of decisions on accreditation or of suspension, withdrawal or reduction of the scope of accreditation or parts of it.

The certification body is committed to inform its clients about this issue and about possible consequences that may arise. This shall be defined and documented in the certification procedure. The assessors of the DAkkS assess the adequacy of the specifications made.

4 Part B: Special provisions for the accreditation procedure

4.1 Requirements for assessment – Witnessing

4.1.1 Assessment of the resources for evaluation (Clause 6.2 of ISO/IEC 17065)

Activities as part of the evaluation carried out under a valid and recognized accreditation (e. g. as a testing laboratory or an inspection body) are generally neither object of the witness audit to be performed nor of the assessment of the certification body.

If the certification body makes use of activities as part of the evaluation which are not covered by valid accreditations, these activities shall comply with the requirements of Clause 6.2 of ISO/IEC 17065. The fulfilment of these requirements shall be assessed and indicated separately in the assessment report.

4.1.2 Witnessing

Witnessing is generally carried out at the place where the activities in the context of the certification process are executed. Depending on the certification scheme, this may take place at the premises of the certification body or at other places where activities take place in the context of the evaluation or, if required by the nature of things, in the form of interviews. The DAkkS reserves the right to determine which personnel or which activities of the certification process shall be subject to witnessing. The extent of the required witnessing as part of the assessment process shall be determined by the DAkkS based on the following principles:

- The initial accreditation of a certification body should be covered by at least one witness ;
- If the activities of the certification body can be initiated only after an accreditation was granted, as stipulated by law or similar provisions, there is the option to determine a witness for the first certification carried out under the accreditation and to establish this as a requirement in the official decision on accreditation.

Moreover, the extent of witnessing shall depend on, among other things:

- the type and number of the certification schemes,
- the risks posed by the products, processes, and services to be certified,
- the number of certificates issued,
- the number of locations where certification activities take place,
- the number of countries where certificates are issued,
- the number of auditors used,
- the staff turnover in the certification body,

- the feedback from any third party, as well as
- special requirements of the scheme owner.

During an accreditation cycle, the certification activities, certification schemes, and product groups shall be covered by adequate witnessing.

The number can be limited if the accreditation body may establish sufficient confidence in the certification body's work.

4.2 Critical location

If the certification body uses contractually bound persons or employees of entities who are under the organizational control of the certification body, then the locations at which these persons are employed are no "**critical locations**", provided that all activities have been carried out under the certification body's control. The decision on whether a location is a "critical location" or not is taken by the certification body. The DAkkS evaluates and reviews this decision based on specifications set out in ISO/IEC 17011 (Clause 7.5.7, 7.5.8), in IAF/ILAC-A5:07/2012 (Clause M.7.5.7.2), and in the DAkkS Rule 71 SD 0 014.

4.3 Liability

Neither the adequacy of the level of liability insurances nor the reserves of the certification body are assessed by the DAkkS assessors, but the adequacy of the risk assessment and the scope of the insurance coverage. It is not task of the accreditation body to confirm the adequate liability coverage and/or the financial stability of the certification body.

5 Part C – Rules for the determination of the scope of accreditation of certification bodies for products, processes, and services

Due to the revisions of underlying standards, the pace of development of the state-of-the-art and of innovation cycles of products, processes, and services accredited, certification bodies affected shall be enabled to provide accredited certification services to the industry (manufacturers, service providers) in due time, taking into consideration all these changes. Taking into account these requirements, in the following arrangements have been specified accordingly for a suitable description of the scope of an accreditation.

5.1 Responsibilities

Based on the recommendations of its sectoral committees and heads of the functional areas, the DAkkS can define specific requirements for the description of the scope of accreditation. If the specifics relating to the extent of an application are not sufficiently covered by the specific skills and competencies available in the sectoral committees, the DAkkS may define the relevant specifications in consultation with other experts and/or assessors. It is the task of the assessors to evaluate the applied scope of accreditation for a specific certification body in cooperation with the DAkkS. In doing so, the specific regulations on a certification scheme defined by the relevant sectoral committees have to be considered.

Requirements for describing the scope of an accreditation, which are used in the legally regulated area for granting an authorization and/or notification, shall be specified in cooperation with the competent power conferring authority (BeB) or the relevant authority, respectively. To this end, specifications regarding the scope as set out in the legislation and, if necessary, supplementary provisions (e. g. guidelines) shall be considered.

The Accreditation Committee shall decide on granting the scope of an accreditation.

5.2 Basic requirements for the description of the scope of accreditation

Basically, the following information shall be included in the description of the scope of accreditation:

1) Scopes of activities of certification bodies for products, processes, and services;

- Certifications according to certification schemes laid down in European and/or national Directives/Regulations/Laws *(legally regulated area)*

- Certifications based on certification schemes fully established in normative requirements *(mainly in the legally non-regulated area)*

- Certifications based on *certification schemes* that are (partially*) not established in normative requirements*
  (In-house certification schemes based on measurable criteria according to the state-of-the-art; legally regulated and non-regulated areas)

2) Applied certification systems with specified status of issue;

3) Applied certification schemes, possibly including subschemes, with specified status of issue;

4) Products or product groups, if applicable.

Depending on the design of the respective scheme, it may be necessary to include specifications on products and/or product groups and/or product requirements in order to clearly define the scope. This becomes necessary in particular if this information is not clearly apparent from the designation of the certification scheme.

The detailed list of product standards that are relevant in the context of accredited certification schemes is generally not covered in the certificate/annex to the certificate.

The list of test standards that will be used to demonstrate compliance with individual product requirements is not covered in the certificate/annex to the certificate.

5.3 Granting degrees of freedom by the description of the scope of accreditation (flexible scope)

The scope of accreditation is granted within the limits resulting from the proven experience and competence of a certification body with respect to the scope of accreditation (see Clause 5.4).

The description of the scope of accreditation can be chosen in such a way that the certification body is granted certain degrees of freedom for those certification schemes which are covered by its accreditation. As part of the degrees of freedom granted, the certification body is allowed to make changes or amendments within the specified limits of the scope of accreditation, without needing to make the DAkkS aware of it in advance. When determining the degrees of freedom, the existing competence and experience have to be considered with regard to the applicable certification requirements or specific product/process/service competence.

The following types of degrees of freedom may be granted:

1) *Degree of freedom with regard to the products – Application of the certification scheme to new products*

Degree of freedom that allows the application of certification schemes to other products covered by the product group, without changing the product requirements. This may include the revision of product standards or be limited to them (e. g. Construction Products Regulation).

2) *Degree of freedom with regard to product requirements – Application of the certification scheme to new product requirements*

Degree of freedom that enables changes with regard to the requirements for the product/product group. This may include normative specifications for product requirements or be limited to them.

A combination of both degrees of freedom is possible.

It is always provided that the certification scheme allows applying the above degrees of freedom and that the scheme owner (legislator, regulator, scheme owner) has not stipulated any other specifications.

When describing the scope of accreditation it is essential that the limits of it are clearly identifiable. The inclusion of a new certification scheme in the scope of accreditation is not possible, regardless of whether it relates to new product groups or new requirements to be placed upon certain product groups. The inclusion of a new certification scheme always presupposes a new assessment[2] by the DAkkS and shall therefore be applied as an extension of the scope of accreditation.

When formulating the scope of accreditation as part of the application, existing specifications of the sectoral committees of the DAkkS relating to the description of the scope of accreditation shall be considered. Requirements from sectoral accreditation rules shall be taken into consideration, where applicable. If no requirements relating to the formulation of the scope of accreditation have been defined by the sectoral committees, the certification body may submit a proposal to the DAkkS on how to describe the desired scope of accreditation in due time prior to the assessment. In the mandatory area, an agreement on the proposal shall be reached between the power conferring authority (BeB) or the relevant authority and the DAkkS.

5.4 Certification systems and certification schemes

If a certification body adds to its certification scheme new products within a defined product group or a product group still to be defined, this will require an in-depth product-related technical knowledge, which includes the testing of the products according to the applicable product/ certification requirements, their use and their manufacturing process. This competence can be acquired through appropriate training, participation in relevant research or development projects, in projects for developing schemes or by means of extensive experience in the respective area of certification activity. This includes, among others, experience gained in production companies as well as through participation in scientific or regulatory committees or through activities involving the provision of an expert opinion or activities in conformity assessment bodies.

[2] The assessment may, if appropriate, include only a document review.

If the certification of a new product or a new product requirement is intended to be added to an existing certification scheme, the accredited status of the scheme can be demonstrated only after verification or validation in relation to these changes.

Documentation shall be provided on the organizational arrangements and responsibilities relating to the development, further development, implementation and validation of certification schemes by the amended, supplemented products/product groups and/or applicable certification/product requirements. This includes the definition of competence criteria through the management and evidence of their compliance. The validation shall be concluded with a confirmation of the changes by the management.

Changes to the certification system shall always be declared to the DAkkS and may be subject to a subsequent assessment.

The certification body shall inform the DAkkS on the extensions/changes in the application of the accredited certification schemes under the relevant scope. To this end, the certification body shall always maintain an up-to-date list of the relevant product standards including updated information on product requirements for all certification schemes covered by the scope of accreditation.

5.5 Special requirements for the assessment

If the applied scope of accreditation includes degrees of freedom (comp. Clause 5.3), the assessment shall then particularly cover the following, in addition to the common requirements:

- the organizational requirements of the certification body relating to the development/validation and the introduction of new products and/or product requirements in the certification scheme;
- the specific procedure of the certification body relating to the development/validation and introduction of new products and/or product requirements in the certification scheme, illustrated by examples;
- the competence of the staff involved and the presence of the relevant product-related, technical expertise as well as knowledge on how to use the same, and knowledge relating to the manufacturing processes of the relevant products (in accordance with Clauses 6.1.2, 6.2, 7.5.1, 7.6.2 of ISO/IEC 17065);
- performance of the tasks of the top management in accordance with Clause 5.1.3 of ISO/IEC 17065;
- measures necessary for the adaptation of the requirements relating to Clauses 7.4 to 7.7 of ISO/IEC 17065 as well as
- corresponding evidence and records.

The assessor's report shall include a clear estimation of the degrees of freedom applicable to the scope and to be granted and of the compliance with the specific requirements. Apart from a statement of reasons, the recommendation shall clearly indicate the certification scheme or certification system for which the degrees of freedom may be granted.

6 Applicable documents

As also cited for the documents referenced in ISO/IEC 17065, the following applies: „For dated references only the cited edition applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2005	Conformity assessment – Vocabulary and general principles
ISO/IEC 17011:2005	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
IAF PL 3:2009	Policies and Procedures for Expansion of the Scope of the IAF MLA
IAF/ILAC-A5:2012	IAF/ILAC MLA/MRA: Application of ISO/IEC 17011:2004
ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems
ISO/IEC 17065:2013	Conformity assessment – Requirements for bodies certifying products, processes and services
ISO/IEC 17067:2013	Conformity assessment – Fundamental of product certification and guidelines for product certification schemes
ISO/IEC Guide 53:2005	Conformity assessment – Guidance on the use of an organization's quality management system in product certification
71 SD 0 014	Accreditation of conformity assessment bodies with several locations
EA 1/22 A-AB:2014	EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members
EA-2/13 M:2012	EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
IAF MD 12:2013	IAF Mandatory Document for Assessment of Certification Activities for Cross Frontier Accreditation