DAkkS
Deutsche
Akkreditierungsstelle

Rule for evaluation and determination of accreditation eligibility of new private conformity assessment schemes according to section 4.6.3 of EN ISO/IEC 17011

71 SD 0 016 | Revision: 1.3 | 27.11.2018

Changes compared to the previous version are highlighted in yellow or marked in the margin.

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.

Inhaltsverzeichnis

1 Scope of this rule

1.1 Horizontal scope

(1) This Rule is binding as a horizontal rule for all divisions of DAkkS and applies to all certification bodies (ISO/IEC 17065, ISO/IEC 17021, ISO/IEC 17024) and inspection bodies (ISO/IEC 17020).

(2) This rule is generally not applicable to new procedures/conformity assessment activities developed/introduced by laboratories, reference material producers or proficiency testing providers and applied for inclusion in the scope of accreditation ISO/IEC 17034, 17043, 14065 (17029). Evaluation of"in-house procedures" in the laboratory sector is performed exclusively in accordance with ISO/IEC 17025 within the accreditation procedure for the laboratory.

1.2 Technical scope

(Clause 4.6.3 EN ISO/IEC 17011)

(1) According to clause 4.6.3 EN ISO/IEC 17011 the accreditation body shall have rules and documented procedures to determine the suitability of conformity assessment schemes and standards for accreditation purposes.

(2) This rule concerns the examination and determination of the accreditation eligibility of **private conformity assessment schemes** for inclusion or (after modification) their retention in the DAkkS accreditation programme and, as far as the DAkkS is the responsible home accreditation body or has been designated by EA as a so-called "Home Accreditation Body", also the inclusion and retention as a **European scheme** in the scope of the signatories of the EA-MLA, as far as this has been applied for separately.

(3) This rule does not apply to the **extension of accreditation activities** due to **legal assignment** or due to the publication of new standards providing for conformity assessment (Type A standards). If an applicant is of the opinion that DAkkS should extend its accreditation activities on the basis of a new international, European or national standard, he may apply for this informally. Applications should be sent to:

Deutsche Akkreditierungsstelle GmbH (DAkkS)
Standort Berlin, Spittelmarkt 10 | 10117 Berlin
grundsatz@dakks.de

(4) As far as **ministries or authorities** in the federal and state governments want to draft a **conformity assessment scheme** in order to formulate it as a technical regulation in the sense of Regulation 1025/2012 or Directive 1535/2015 for the **national mandatory application**, DAkkS can support in an advisory capacity by way of administrative assistance. However, the responsibility for the conformity assessment scheme remains with the authority or state institution. Requests for assistance should be addressed to:

Deutsche Akkreditierungsstelle GmbH (DAkkS)
Standort Berlin, Spittelmarkt 10 | 10117 Berlin
grundsatz@dakks.de

(5) The DAkkS strives to be involved in the development of conformity assessment schemes, which are elaborated in the form of legal regulations or standards, in order to exclude contradictions and conflicts with Regulation (EC) No. 765/2008, the AkkStelleG, DIN EN ISO/IEC 17011 and the EA, ILAC, IAF or DAkkS rules.

(6) New conformity assessment schemes established by the legislator, or which are the subject of international and European standards, are in principle included in the DAkkS accreditation program, provided that the legislator has set an implementation deadline. Otherwise, DAkkS determines the date of commencement of the activity at its due discretion, taking into account the time required to build up the competences and procedures as well as the market demand and urgency.

(7) Conformity assessment schemes that have already been evaluated by IAF or ILAC or another European accreditation body according to the rules of EA are in general not re-evaluated by DAkkS. In principle, the DAkkS recognizes the examination already carried out, provided that these do not violate binding legal regulations, which will be examined within the accreditation procedure. The DAkkS decides on their inclusion at its due discretion, taking into account the time required to build up the competences and procedures as well as the market demand and urgency.

(8) This rule does not describe the **negotiation process with so-called scheme owners**, if they make concrete specifications to the accreditation body or the accreditation process (IAF/EA Level 1). Such specifications can be part of a scheme (quality label), but require a separate negotiation process, a **contractual agreement** between DAkkS and the scheme owner as well as the consultation of EA. The necessary negotiations can, however, be additionally requested within the process described below.

2 DAkkS - Policy on the Evaluation of New Conformity Assessment Schemes

(1) The DAkkS is the national accreditation body of the Federal Republic of Germany. According to the Regulation (EC) No. 765/2008 and the Accreditation Bodies Act (AkkStelleG), it acts in the public interest as the sole competent authority for the accreditation and surveillance of conformity assessment bodies in Germany in the area regulated by law and in the area of voluntary conformity assessment (Art. 3 Regulation (EC) No. 765/2008).

(2) The importance of conformity assessment and accreditation has increased significantly in recent years because conformity assessment and accreditation have been established as a horizontal (i.e. sector-independent) basic infrastructure for market access of safe products and services in the European Union and the EEA on the basis of Regulation (EC) No. 765/2008.

(3) In addition, conformity assessment certificates based on accreditation in accordance with Article 44 of the Public Procurement Directive (Directive 2014/24/EU) are the preferred instrument for providing evidence in the EU and the EEA. Public contracting authorities may therefore only demand certificates of conformity and quality seals issued by bodies that have been accredited in accordance with Regulation (EC) No. 765/2008.

(4) As a result, new conformity assessment services in the various sectors and for the respective state of the art increasingly have to be developed by conformity assessment bodies, other independent market participants such as associations and NGOs or issuers of quality labels in order to be able to meet the diverse market requirements.

(5) The flexible system of harmonized conformity assessment schemes with regard to accreditation requirements is an important factor for mutual recognition of internationally recognized test results in highly innovative markets, even if the harmonization of standards for the object of assessment has not yet been completed.

(6) According to ISO/IEC 17011, a system for accreditation of conformity assessment bodies shall ensure consistent performance of conformity assessment to standards and conformity assessment schemes based on international consensus for the benefit of health, safety, environment and welfare, as well as for the support of legislators and end users.

(7) The procedure described below for evaluating the accreditation eligibility of conformity assessment schemes, for use by accredited conformity assessment bodies, clarifies in a binding manner for the applicant in advance of the accreditation procedure of the conformity assessment body that the conformity assessment scheme meets the requirements from a technical and regulatory point of view in order to be included in the accreditation programme of the national accreditation body.

(8) The conformity assessment scheme will only become part of the DAkkS accreditation programme when at least one accredited conformity assessment body, which is supervised by the DAkkS, has adopted the confirmed conformity assessment scheme into its product portfolio by applying for initial or extended accreditation and has been granted accreditation for it.

(9) For the assessment of the accreditation eligibility of private conformity assessment schemes, DAkkS follows the following policy:

- With regard to the decision to include new conformity assessment schemes, DAkkS acts independently and impartially and upholds the principle of equal treatment;
- According to the TBT Agreement of the WTO, DAkkS is obliged to support the instrument of standardisation with regard to the establishment of new conformity assessment schemes. As far as standards or draft standards are available in certain areas, these should be used as a basis for the schemes or taken into account in order not to impair the corresponding harmonization results.
- In the spirit of promoting the free movement of goods in Europe and within the scope of the WTO Agreement, DAkkS welcomes the establishment of internationally oriented conformity assessment schemes.
- The DAkkS promotes the exchange of information and the coordination with the national accreditation bodies in Europe regarding the inclusion of new conformity assessment schemes and adheres to the applicable rules of EA (EA-1/22).
- Conformity assessment schemes of scheme owners who are not conformity assessment bodies themselves usually require evidence that the conformity assessment scheme is provided to the market for accredited conformity assessment bodies on non-discriminatory terms in order to be in line with the requirements of Art. 101 and 106 TFEU (FRAND agreement). However, it is not the task of the DAkkS to assess the admissibility of the applicant under competition law within the scope of this examination. The compatibility of the scheme owner's actions with European competition law is the sole responsibility of the scheme owner.

3 Rules for the accreditation programme (IAF Level 1)

(Clause 7 of EN ISO/IEC 17011 – Accreditation process)

3.1 Procedure for the evaluation of conformity assessment schemes

3.1.1 Necessity of a scheme evaluation

(1) A scheme evaluation is always necessary if an accredited conformity assessment body wants to issue conformity assessment certificates to the market on the basis of the conformity assessment scheme to be reviewed, within the framework of third party attestation (3rd party audit), which are not or not completely regulated in legal requirements, technical regulations or recognized standards, or which deviate from them or go beyond them (especially in the case of quality labels/ conformity marks).

(2) This may be the case in particular in innovative areas, where intensive standardization activities for the object of assessment already exist on a regular basis, but no conformity assessment procedures have been harmonized yet. Typical areas for such conformity assessment schemes are applications in the context of product and service quality, food safety, IT and data security, Industry 4.0 or smart energy systems (smart grit/smart mobility/smart home and always in the area of personnel certification when creating new qualification profiles, etc.).

(3) In addition, international quality label systems have been established in certain sectors, in particular food/environment and sustainability, which have almost completely substituted further international standardisation. These are held by the scheme owner of the quality label (brand).

(4) In these cases, for the purpose of accreditation of the conformity assessment scheme, it must be separately demonstrated that the statement associated with the accredited conformity assessment result does not violate mandatory legal requirements and that the conformity assessment procedure described in the scheme ensures the strict accreditation requirements for **comparability and reproducibility** of the conformity assessment statement.

(5) Any revisions to the scheme must be resubmitted by the scheme owner to DAkkS for review and determination. Depending on the extent and nature of the changes, a new examination is carried out or only the statement that the revision was not substantial and the statement effect on the accreditation eligibility continues to exist.

3.1.2 General evaluation standard

(1) The DAkkS must reject the determination of the accreditation eligibility of the applied conformity assessment scheme if the scheme is in contradiction to legal requirements, in particular the requirements of Regulation (EC) 765/2008, the Accreditation Body Act (AkkStelleG) or relevant international and European standards for conformity assessment and accreditation

and/or not in accordance with the rules of the DAkkS, including the rules of the international accreditation organizations (EA/IAF/ILAC).

(2) The determination of the accreditation eligibility of the conformity assessment scheme must still be refused if the applicant cannot demonstrate to the conviction of the DAkkS that all necessary regulatory and normative minimum requirements for the object of conformity assessment (IAF Level 4 and 5) are checked and evaluated in the conformity assessment scheme according to the respective state of the art and under consideration of the assessment risk.

(3) The same applies if the applicant cannot prove to the satisfaction of DAkkS that the conformity assessment procedures described in the conformity assessment scheme ensure **comparability and reproducibility** of the results.

3.1.3 Eligibility to apply

3.1.3.1 General

(1) In principle, only **accredited conformity assessment bodies** and persons or other legally identifiable organizations that wish to provide a conformity assessment scheme to accredited conformity assessment bodies as **scheme owners** on the conformity assessment market are entitled to a determination of accreditation eligibility.

3.1.3.2 Accredited conformity assessment bodies

(2) For the proof of the eligibility to apply it is sufficient that the applicant bindingly declares to submit an application for accreditation as conformity assessment body for this scheme to the DAkkS after confirmation of the scheme.

(3) If in the course of the procedure an existing accreditation as a conformity assessment body is denied with legally binding effect, the eligibility to apply shall cease retroactively, provided that the assessment notice had not yet become final.

(4) Only accredited conformity assessment bodies based in Germany or bodies from abroad under the conditions of cross-border accreditation according to Art. 7 of Regulation (EC) No. 765/2008 and EA 2/13 (Cross Frontier Accreditation) are eligible to apply.

3.1.3.3 Scheme owner

(1) Only scheme owners based in Germany or, under the conditions of cross-border accreditation in accordance with Art. 7 of Regulation (EC) No. 765/2008 and EA 2/13 (Cross Frontier Accreditation), bodies from the EEA and bodies based in third countries are eligible to apply.

(2) The scheme owner must prove the support of at least two accredited conformity assessment bodies for the application eligibility. This can be done, for example, by submitting declarations of the accredited bodies that they intend to submit an application for extension of accreditation (for inclusion in their portfolio of services) related to the scheme of the scheme owner in the event that the accreditation eligibility is established.

(3) In areas where no bodies have yet been accredited for comparable activities as described in the scheme, it is sufficient for the supporters to declare that, after confirmation of the scheme, they will submit an application for accreditation to DAkkS within 12 months of the scheme's eligibility for accreditation being established.

3.1.4 Sequence of the procedure

3.1.4.1 Application stage (approx. 4 weeks)

(1) The accreditation eligibility evaluation must be requested in writing. The following form must be used:

- **46 FB 001 Antrag**

In addition, the following documents must be submitted:

- **46 FB 002 Proofs according to „List of documents to be submitted“**
- **46 FB 003 Information according to "Combined checklist”**
- **46 FB 004_Sample-Matrix-according to clause 6.5.1-17067**

(2) Applications together with supporting documents shall be sent in writing to:

Deutsche Akkreditierungsstelle GmbH (DAkkS)
Stabsbereich II Programmprüfstelle
Spittelmarkt 10
10117 Berlin

(3) Upon receipt of the complete application documents at the scheme evaluation unit, receipt will be acknowledged and a file number will be assigned that the applicant must use in all future correspondence.

(4) Within 4 weeks of receipt, the scheme evaluation unit will check whether the application is complete and whether the applicant is eligible to apply. The applicant will receive an acknowledgement of receipt if the application and supporting documents are complete and the applicant is eligible to apply.

3.1.4.2 Involvement of supervision (approx. 5 weeks)

(1) After examining the application documents, the scheme evaluation unit decides whether a legally regulated area could be affected by the scheme or whether the relevant supervisory authority should otherwise be informed.

(2) If the supervisory authority is to be involved, a "New Work Item Proposal" (NWIP) is prepared and sent to the responsible supervisory authority after positive completion of the Formal Review Section 3.1.4.1 by the scheme evaluation unit.

(3) The expiry of the period of silence (4 weeks) is awaited before further examination is undertaken in the procedure.

3.1.4.3 Evaluation phase incl. assessment of the validation report (approx. 3-8 months)

(1) After the expiration of the period of silence for the supervision or after clarification of reservations of the supervision, the substantive evaluation of the scheme begins.

(2) First of all, a system review is carried out by the scheme evaluation unit against legal requirements and the accreditation standards at Level 3.

(3) The substantive technical review is performed after the system review by the scheme evaluation unit, depending on the complexity, with the help of competent reviewers. The technical audit includes in particular the review of the suitability of the evaluation activities. In addition to the staff of the scheme evaluation unit, suitable reviewers are internal or external technical assessors and system assessors or technical experts and other technically suitable DAkkS staff.

(4) If an power conferring authority (BeB) is to be involved in the scheme evaluation or the approval of criteria on the basis of statutory regulations, it must be commissioned with the technical review. Any approval of criteria to be granted by the BeB shall be made by separate administrative act by the BeB outside this procedure.

(5) In addition to the procedure file, the BeB receives in particular the DAkkS system review report for further review and evaluation.

(6) A regular processing time of 3 to 8 months should not be exceeded.

(7) The validation report of the applicant is of central importance within the review. The validation report must show that the scheme submitted has been successfully validated by the applicant for suitability, in particular with regard to comparability and reproducibility of the results. The validation report must contain meaningful results and evaluations of the validation procedure at the applicant's site, which enable a knowledgeable third party to comprehend the evaluation result within a reasonable period of time.

(8) The scheme evaluation unit summarizes findings from the system or technical review in a report and sends the findings to the applicant. In the case of incomplete application documents or obviously inadequate schemes, the scheme evaluation unit may conclude the review with a negative decision with a concise statement of reasons without a report. A submission to the scheme committee is not necessary.

3.1.4.4 Elimination of findings (1 month)

(1) In the event of a generally positive evaluation of the scheme, the applicant shall be given a period of up to 1 month at the end of the system audit and at the end of the technical audit to remedy the findings or to comment on the findings and, if necessary, to provide further evidence.

(2) In the case of complex procedures (cf. Section 3.1.4.7), this period may be extended several times upon request.

(3) The scheme evaluation unit summarizes the returns from the applicant, the BeB, obtains feedback from the reviewers, if necessary, to resolve the findings, and, in the event of a positive recommendation by the System and Technical Review, prepares a decision document for the scheme committee and convenes the committee.

(4) In the case of conformity assessment schemes that require approval of criteria/standards (Level 4/5) due to legal regulations, the submission of the decision document to the scheme committee only takes place after approval by the responsible BeB.

(5) If the applicant cannot reach an approval with the responsible BeB even after a reasonable grace period, the application will be decided negatively.

3.1.4.5 Review and decision in the scheme committee (approx. 6 weeks)

(1) In the case of a positive recommendation by the scheme evaluation unit after final review of the elimination of findings, the scheme committee makes a final decision on the accreditation eligibility of the scheme based on the file, the approval of the BeB if applicable, the reports of the reviewers including the review on the applicant's actions to eliminate findings, and on the scheme evaluation unit's decision document.

(2) The decision of each member of the scheme committee shall be briefly justified.

3.1.4.6 Confirmation/rejection of the determination of accreditation eligibility (approx. 4 weeks)

(1) Based on the decision of the scheme committee, the applicant receives a final, written, declaratory notification of the scheme's suitability for accreditation. This is issued by the scheme evaluation unit.

3.1.4.7 Special features of complex/innovative systems (precompetitive)

(1) In the case of the establishment of private conformity assessment schemes by a scheme owner that cover innovative or particularly complex subject areas, a **pilot phase** can be requested as part of the application procedure. The pilot phase serves to involve the DAkkS in the **examination of the draft conformity assessment scheme** at an early stage, so that the DAkkS obtains an in-depth understanding of the risks and technical interrelationships.

(2) During the pilot phase, DAkkS will only act in an reviewing capacity. Advising the applicant is not permitted. A pilot phase can only be carried out with **scheme owners** who are **not conformity assessment bodies**.

(3) Within the scope of reviewing and validation in the pilot phase, DAkkS only uses experts who are not members of the scheme committee, which has to decide on the application after completion of the pilot phase.

(4) The applicant must request the intent to conduct a pilot phase and justify why the project is considered particularly complex or innovative and cannot be successfully implemented without a pilot phase.

(5) The expenses of DAkkS associated with the implementation of the pilot phase are to be paid by the applicant.

3.1.4.8 Special features of procedures with review at EA according to EA 1/22

(1) For the cooperation of DAkkS with the European co-operation for accreditation (EA), the current provisions of rule EA 1/22 apply. For the applicant/scheme owner, the following provisions are relevant in particular:

1. For internationally applicable schemes, a National Accreditation Body (NAB) is designated by EA, at the request of the scheme owner, as the so-called Home AB, which is responsible for the initial evaluation and all modifications of the scheme. It is exclusively this NAB with which the scheme owner cooperates;
2. If these schemes contain requirements for the accreditation body that go beyond DIN EN ISO/IEC 17011, Regulation (EC) No. 765/2008 or binding IAF, ILAC, EA documents, these requirements have to be confirmed by the General Assembly of EA. This may cause a considerable delay in the process of scheme evaluation;

3. The results of the initial assessment are provided to EA by the Home AB. EA shall make the results available to its members for a 30-day comment period. The scheme may not be included by the Home AB until the comment period has closed with no comments, or any resulting negative feedback has been resolved;
4. Questions to the scheme owner are exclusively directed via the Home AB;

(2) The process for review as a European scheme at EA is initiated by DAkkS only if the national procedure has been completed positively in its entirety.

3.1.4.9 Special features when involving power conferring authorities

(1) If authorities other than DAkkS are legally authorized to endorse or approve conformity assessment schemes within their area of responsibility, the respective competent authority shall already be informed of the application.

(2) Following the technical examination, the competent authority is requested to grant its agreement or approval. If no agreement is given, no positive determination can be made by DAkkS. The applicant will receive a negative notification.

3.2 Requirements for assessors in the scheme evaluation process

(1) Legal, formal and system review are performed by employees of the scheme evaluation unit.

(2) The scheme evaluation unit selects suitable reviewers for the technical review at its own discretion. For reviewers in the scheme evaluation procedure, the competence requirements according to ISO/IEC 17011 for technical and system assessors or technical experts for the accreditation procedure shall apply accordingly.

3.3 Requirements for decision-makers in the scheme evaluation procedure

(1) The minimum requirements for members of the Accreditation Committee (AkA) according to § 10 para. 1 no. 3 AkkStelleG apply accordingly.

(2) The scheme evaluation unit shall compose the scheme committee from suitable experts at its due discretion. A decision-maker may be selected as suitable if he or she is appointed to the AkA and could make decisions related to the Level 3 standard to which the scheme applies

3.4 Composition and functioning of the Scheme Committee

(1) The Scheme Committee shall be composed of at least 3 persons. The employee of the scheme evaluation unit convenes the scheme committee and chairs it without the right to vote. As a rule, the following are to be appointed as members: the department head responsible for the scheme area, another department head and the chairman of the HC. If several departments are affected by the scheme, the scheme committee must be expanded to include all necessary departments. If a department cannot yet be determined, department heads with suitable experience background shall be appointed.

(2) The Scheme Committee may decide by electronic circular ballot and may discuss the matter by video conference.

3.5 Database of determined schemes

(1) All schemes whose suitability for accreditation has been positively determined are listed on the DAkkS website with the name of the owner and the version on which the determination was based. For this purpose, the scheme owner grants the DAkkS, free of charge, the necessary rights to make the quality labels publicly available in the database. As far as conformity marks in the sense of ISO/IEC 17030 are used, the publicly accessible source for the criteria of the quality label must also be indicated.

3.6 Costs of the procedure

(1) The entire expenses of the DAkkS associated with the evaluation of the accreditation eligibility of the scheme, including the necessary out-of-pocket expenses, shall be borne by the applicant.

(2) The fees of the DAkkS shall be calculated according to the time spent in accordance with tariff item 1.2 in conjunction with tariff item 7 AkkStelleGebV.

(3) Expenses for external representatives (travel expenses and costs for external reviewers, especially from BeBs) will be reimbursed by the applicant upon presentation of proof in accordance with § 4 AkkStelleGebV.

4 Requirements for conformity assessment schemes (IAF Level 3 and 4)

(EA 1/22 / ISO/IEC 17067 / ISO/IEC 17000 Annex A / ISO/IEC 17030)

4.1 General requirements for conformity assessment schemes

4.1.1 Permissible regulatory subject matter of conformity assessment schemes

(1) A conformity assessment scheme is a technical specification for accredited conformity assessment bodies describing specific requirements, rules, selection, testing and evaluation procedures to be used for conformity assessment by certification or inspection of a product, service, process, system or person in order to make the statement associated with the conformity assessment evidence (e.g. certificate, inspection report, quality label, etc.) in a scientifically traceable, systematic and reliable manner.

(2) The regulations of a conformity assessment scheme always concern requirements on level 4 according to EA-MLA 1/06, which describe the activities of the conformity assessment body. It is permissible to define requirements for the object of conformity (Level 5) in a scheme if national or international standards are missing or insufficient.

(3) Such criteria shall fulfil the requirements of ISO/IEC 17007.

(4) Requirements for the accreditation body are not to be defined in the scheme, but require a contract with the accreditation body (section1.2 (8)).

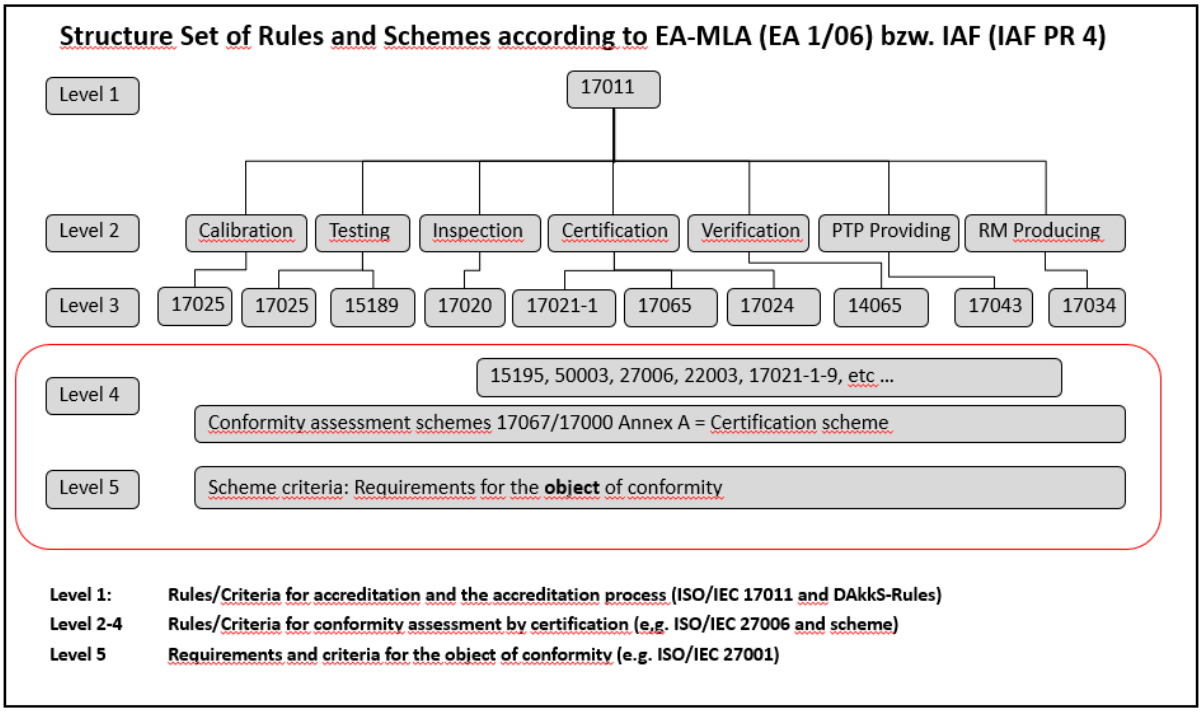


Figure 1: Structure EA 1/06, IAF PR 4

4.1.2 Minimum requirements for a conformity assessment scheme

(1) A conformity assessment scheme shall contain for accreditation eligibility in general and as far as applicable the typical elements according to **DIN EN ISO/IEC 17000:2005 Annex A**.

(2) A complete list of relevant standards for establishing conformity assessment schemes can be found in the "CASCO Toolbox", which is available on the ISO website (www.iso.org).

(3) When using conformity marks, the requirements of ISO/IEC 17030 shall be complied with. This implies that the requirement criteria shall be publicly available and that surveillance measures shall always be specified.

(4) **ISO/IEC 17067** provides valuable guidelines for understanding, developing, using or maintaining certification schemes for products, processes and services. Essential specifications can be taken from the standard with regard to the areas mentioned below:

- Types of schemes (clause 5.3)
- Position of the scheme owner (clause 6.3)
- Scheme development (clause 6.4),
- Content of a scheme (clause 6.5),
- Maintenance and improvement of a scheme (clause 6.6 in conjunction with clause 6.4 ISO/IEC 17030),
- Scheme documentation (clause 6.7).

(5) The typical elements and the internal structure of a conformity assessment scheme are presented in the standard DIN EN ISO/IEC 17067, table 1 and can be applied **prototypically for <u>all</u>** accreditation activities, especially for inspection schemes.

(6) Each conformity assessment scheme must formulate concrete statements on the necessity and, if applicable, the design in the areas of **selection, evaluation, review and attestation and monitoring**, which must be supported by evidence within the evaluation process.

(7) If possible, an assignment to the scheme types of ISO/IEC 17067 should be made. If, from the applicant's point of view, these scheme types are not suitable, it shall be explained which additional requirements exclude an assignment.

(8) The following minimum information is always required for the functional approach to conformity assessment activities in the sense of ISO/IEC 17000:

I. Minimum statements on the "Selection" area

(ISO/IEC 17000 Annex A, A.2.2.)

1. Description and delimitation of the object of conformity assessment. (ISO/IEC 17000 Annex A, A.2.3.)

2. Description of the requirements for the object of conformity assessment (IAF/EA Level 5), e.g. from laws, international standards or technical regulations, as well as the required expertise necessary to evaluate the decision and on its fulfillment, to confirm the object of conformity assessment.

3. These requirements shall generally be international standards or standards or specifications established within the sector or specifications of a group of manufacturers. Factory standards and manufacturer's specifications shall only exceptionally become the subject of third party attestations.

4. The scheme owner's requirements shall be described clearly and unambiguously so that they can be interpreted accurately and consistently, so that entities making use of these requirement documents can extract from their contents a common understanding of their meaning and intent. Requirements shall be expressed in terms of deliverables, together with limits and margins of error where appropriate; requirements shall be expressed in unambiguous terms. Terms should be used that are objective, coherent, sound, and specific.

5. It shall also be described for regulatory criteria to what extent the principles of **ISO/IEC 17007** can be fulfilled for conformity assessment purposes, if necessary by additions in the scheme. This description includes:

   Principle 1: Separation of specified requirements for the object of conformity assessment (IAF/EA Level 5) from specified requirements for conformity assessment activities (IAF/EA Levels 2 to 4), see 4.2 ISO/IEC 17007;

   Principle 2: Neutrality towards parties in the performance of conformity assessment activities, see 4.3;

   Principle 3: Suitability of the criteria for implementing the functional approach to conformity assessment, see 4.4 ISO/IEC 17007);

   Principle 4: Enabling comparability and reproducibility of conformity assessment results, see 4.5 ISO/IEC 17007);

   Principle 5: Evidence of use of good conformity assessment practices, see 4.6 ISO/IEC 17007.

   (ISO/IEC 17000 Annex A, A.2.4.)

6. Presentation of the applicable conformity assessment type and its selection with regard to the object of conformity assessment (e.g. laboratory tests, certification, inspection services, etc.). It shall be demonstrated why the selection of the type of conformity assessment, or a combination, is technically suitable to achieve the regulatory or technical objective of the conformity statement.

   (ISO/IEC 17000 Anhang A, A.2.1.)

7. Description of the necessary planning and preparation activities and planning information collections and any necessary sampling activities or sampling procedures.

8. Information must be provided on how to ensure the integrity and reliability of the information collected for the investigation. In particular, when data are provided by the manufacturer, it shall be specified how the integrity of these data can be ensured by concrete verification or other controls by the CAB.

9. If the scheme includes sampling, information shall be provided on the sampling method to be used in order to obtain consistent and reproducible results. As far as possible, sampling methods based on statistical methods to allow a representative statement or those specified in international standards should always be used.

II. Minimum statements on the area of "determination"

1. Demonstrate the use of one or more determination methods (e.g., testing, auditing, and/or examination) to obtain complete information on the compliance of the object of conformity assessment or its sample with specified requirements.
2. In the case of series products or services, it must be explained how a representative determination is ensured by statistical methods.
3. As a rule, evidence of the use of good conformity assessment practices shall be provided (see 4.6 ISO/IEC 17007).
4. If good procedures are deviated from, this must be described in detail with an explanation of the reasons.

III. Minimum statements on the area of "Review"

Description of the procedure for checking the evidence of conformity obtained during the determination stage to determine whether the specified requirements are met. The respective requirements of the accreditation standards (ISO/IEC 17065/ ISO/IEC 17025/ ISO/IEC 17021/ ISO/IEC 17020/ ISO/IEC 17024 etc.) must be observed.

IV. Minimum statements on the area of "Decision"

Description of the criteria, which are prerequisites for: Granting, maintaining, extending, restricting, suspending, or withdrawing confirmation. The criteria must indicate when non-conformities are critical. If necessary, non-conformity/defect categorization systems must be described.

V. Minimum statements on the area of "Attestation/Approval"

Description of the process of review and attestation, including the review of evidence from the determination stage and subsequent attestation of whether compliance with the specified requirements has been reliably demonstrated as the object of conformity assessment, and (where applicable) any subsequent marking or approval and its control (cf. in particular ISO/IEC 17030).

a. Issue a certificate of conformity or other statement of conformity (attestation)
b. Granting the right to use certificates or other statements of conformity
c. Issuing a certificate of conformity for a batch of products
d. Granting the right to use marks of conformity (approval) on the basis of monitoring or certification of a batch
e. Ensuring the prohibition of use on products when no product testing has been done.

VI. Minimum statements on the area of "Surveillance"

A description of the surveillance process, including the interval and extent of surveillance activities and re-assessments, to ensure that the object of conformity assessment continues to meet the specific requirements. The risk adequacy of the regular surveillance activities shall be addressed and how extraordinary findings will be addressed.

4.1.3 Comparability and reproducibility of results

(1) The applicant must demonstrate to the satisfaction of DAkkS that the conformity assessment procedures described in the conformity assessment scheme ensure **comparability and reproducibility** of the results.

(2) For this purpose, it must be shown in detail and demonstrated by submitting the **validation report** that the requirements for comparability and reproducibility of the results as defined in clause 4.5 of ISO/IEC 17007 can be guaranteed.

(3) The validation of a conformity assessment procedure serves as practical proof that the conformity assessment procedure described in the scheme is demonstrably suitable for the specific intended use. For this purpose, depending on the type of conformity assessment, the following are considered, for example:

- Representativeness
- Robustness
- Measurement uncertainty, if applicable
- Comparability

The more detailed requirements or even permissible simplifications result from the standard-related specifics and the respective context of application.

(4) Specific information on the representativeness of all sampling methods must always be provided. For this purpose, the statistical or other selection procedures and their appropriateness must be explained in detail.

4.1.4 Relevant minimum legal requirements

(1) The accreditation eligibility of a scheme requires that the scheme owner who is not a conformity assessment body (who only wants to use the scheme himself) offers the scheme to all accredited conformity assessment bodies on non-discriminatory terms. For this purpose, the scheme owner must regularly submit a so-called "FRAND self-commitment" (cf. clause 287ff Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements (2011/C 11/01).

(2) Depending on the scope of the scheme, the scheme owner may also be subject to the requirements of Annex 3 to the TBT Agreement of the WTO and the quality label requirements pursuant to Art. 43 of Directive (EU) 2014/24 with regard to the preparation process for the technical criteria and, where applicable, to the requirements for common ICT specifications pursuant to Regulation (EU) 1025/2012 in the case of schemes in the ICT sector. The scheme must contain a statement as to whether these requirements are met or why they are not relevant.

(3) If the scheme is relevant for use by public procurement bodies, the applicant must demonstrate compliance with all requirements of Art. 43 RL (EU) 2014/24.

(4) However, it is not the task of the DAkkS to assess the admissibility under competition law for the applicant within the scope of this evaluation. The compatibility of the actions of the scheme owner with European competition law is solely his responsibility. The application must be accompanied by a declaration of the applicant in which he confirms that he has examined the competition law issues and assessed them positively.

4.1.5 Specifications for the structure of the schemes

(1) The conformity assessment scheme shall be structured in principle to follow the main headings of the underlying conformity assessment standard.

(2) All explanations in the scheme are to be referenced to a specific clause of the reference standard (Level 3) to enable evaluation.

(3) If, in justified cases, the scheme does not follow the structure of the standard, a reference matrix showing the standard references shall be provided.

4.2 Particular requirements

4.2.1 Area: Certification of management systems (ISO/IEC 17021)

(1) The conformity assessment scheme shall include a necessity analysis showing why and to what extent existing international standard requirements for conformity assessment of management systems cannot be used or need to be specified by the scheme.

4.2.2 Area: Certification products/processes/services (ISO/IEC 17065)

(1) The conformity assessment scheme shall include statements on all items in section 6.5 of ISO/IEC 17067.

(2) The object of conformity assessment can be defined or formulated generically, provided that the following condition is met: the object is described by means of generally abstract properties in such a way that it is possible to distinguish it from other evaluation objects and the suitability of the defined evaluation types/methods remains possible in relation to the object of conformity assessment.

(3) According to clause 6.5.1 lit. b) and g) ISO/IEC 17067, a concrete evaluation type/method must be specified for each material requirement for the object of conformity assessment (legal requirement/standard/approved criteria at level 5).

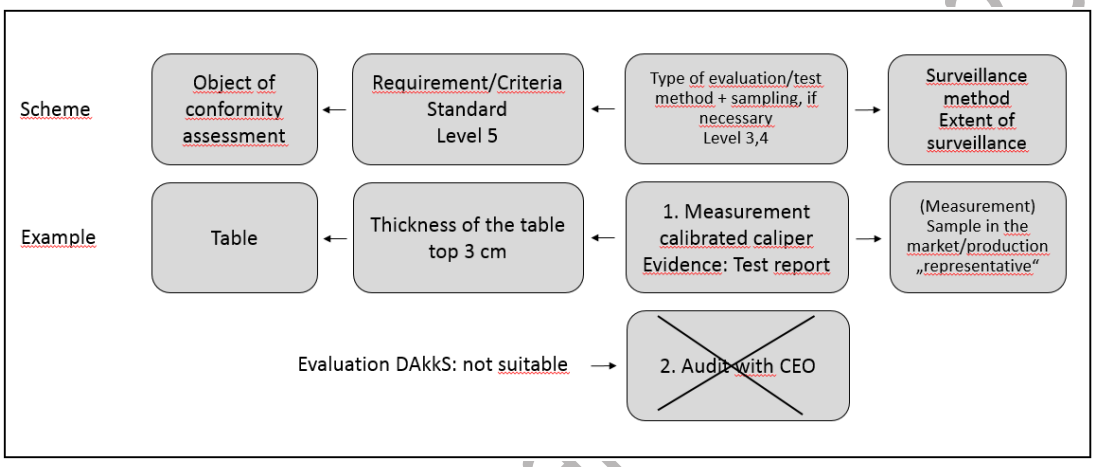


Figure 2: Object and determination acc. to clause 6.5.1 lit. b) and g) ISO/IEC 17067

(4) A sample matrix for mapping requirements and evaluation type/method is available on the DAkkS website (46 FB 004).

(5) If the evaluation methods or procedures are not themselves standardized, they must be described separately.

4.2.3 Area: Certification of Person (ISO/IEC 17024)

(1) The conformity assessment scheme must include an analysis of the legal requirements for the qualification of persons, in particular under national law, in order to distinguish the scheme from the legally regulated area of education and other legal requirements.

4.2.4 Bereich: Inspektion (ISO/IEC 17020)

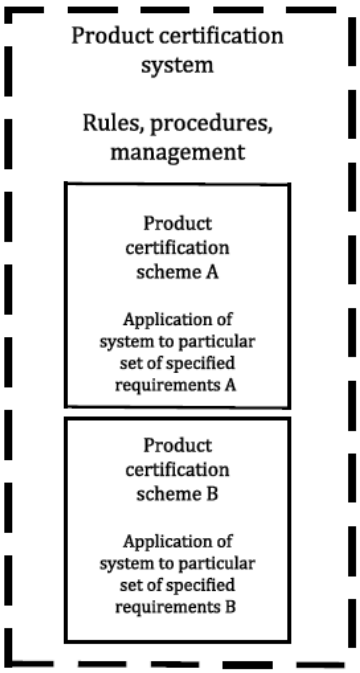
(1) Currently no specification.

5 Other applicable documents

EA-1/22	EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members

6 Glossary

Accreditation activity	An accreditation activity is an area in which the accreditation body issues accreditations. The inclusion of an activity presupposes the existence of competence in the accreditation body and consequently requires a decision as to whether the accreditation body can and wishes to include this activity in its scheme. If an activity is not included, an applicant can turn to another national accreditation body in the EEA (cf. Art. 7 of Regulation (EC) No. 765/2008).
Accreditation scheme	Rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply cf. 3.8. ISO/IEC 17011
Power conferring authority (BeB)	Authorities within the meaning of §1 Para. 2 in conjunction with § 2 para. 3 sentence 2 AkkStellG as well as § 39 BDSG
Conformity assessment scheme (Scheme)	Conformity assessment system related to specified objects of conformity assessment to which the same specified reqiurements, specified rules and procedures apply (ISO/IEC 17000:2005).
Standard	Standard means a technical specification adopted by a recognized standards organization for repeated or continuous application, compliance with which is not mandatory and which falls into one of the following categories: a. "international standard" means a standard adopted by an international standardization organization; b. "European standard": a standard adopted by a European standardization organization; c. "harmonized standard": a European standard adopted on the basis of a mandate from the Commission implementing Union harmonization legislation; d. "national standard" means a standard adopted by a national standardization organization; The term standard also includes European or national standardization documents, as other technical specifications (PAS/ DIN-SPEC).
Product certification system	The following illustrations from DIN EN ISO/IEC 17067 are helpful in understanding and differentiating between the terms conformity assessment system and conformity assessment scheme.

	 a) Unique product certification scheme  a) Product certification system relating to several schemes
Scheme owner (SO)	A scheme owner is a person or other legally identifiable organization according to clause 3.11 ISO/IEC 17065 who, as an issuer of a mark of conformity according to clause 3.3 ISO/IEC 17030 (conformity assessment body) or as an owner of a conformity mark according to clause 3.2 ISO/IEC 17030 and, by legally binding agreement with accredited conformity assessment bodies, agrees and, if necessary, monitors compliance with the criteria of the scheme owner for the award of the certificate, quality seal or similar confirmation.
Scheme holder	Scheme holder is either a scheme owner or a conformity assessment body and expresses that there is legal ownership of the scheme text. The term is used when a distinction between CAB and SO is not relevant.

Examination risk	Describes the risk of a conformity assessment body confirming the object of conformity assessment as conforming, although a non-conformity has existed undetected.
Legal regulations	Legal regulations are formal and substantive laws in the sense of the GG and Art. 288 TFEU as well as international agreements in the rank of a federal law (e.g. TBT-agreements; MRA's).
Technical specification	Technical specification according to the RL 1535/2015 EU is a specification contained in a document prescribing characteristics for a product, such as quality levels, fitness for use, safety or dimensions, including provisions on sales description, terminology, symbols, tests and test methods, packaging, marking and labeling of the product, as well as conformity assessment procedures. The term 'technical specification' also covers the manufacturing methods and processes for the agricultural products referred to in the second subparagraph of Article 38(1) of the Treaty on the Functioning of the European Union (TFEU), for the products intended for human and animal consumption, for the medicinal products referred to in Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (1), and the manufacturing methods and processes for other products, in so far as they affect the characteristics of those products. The term "technical specification" also includes "other requirements" for a product, other than a technical specification, adopted in particular to protect consumers or the environment and relating to the life cycle of the product after it has been placed on the market, such as requirements for use, recycling, reuse or disposal, where such requirements may significantly affect the composition or nature of the product or its marketing.
Technical regulation	Technical regulation according to Directive 1535/2015 EU means a technical specification or other rule or regulation concerning services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as the laws, regulations and administrative provisions of the Member States prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider. Technical de facto regulations are in particular:

	The laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or to other requirements or to rules on services, compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions; ii) voluntary agreements to which the State is a party and which are aimed at ensuring, in the public interest, compliance with technical specifications or other regulations or regulations concerning services, with the exception of public procurement regulations; technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or the use of services by encouraging compliance with such technical specifications or other requirements or rules on services; this does not apply to technical specifications or other requirements or rules on services concerning national social security systems. This concerns the technical regulations established by the authorities designated by the Member States and included in a list drawn up and, where appropriate, updated by the Commission in the framework of the Committee referred to in Article 2.
Concealment period	In administrative and state organizational law, the period of silence is the period of time after which a decision to be voted on by different participants is deemed to have been adopted if no objection is raised by either side.