Information sheet on the review of determination of eligibility for accreditation of new conformity assessment schemes in accordance with section 4.6.3 of DIN EN ISO/IEC 17011

M-17011 Annex 2

29. August 2023

Scope:

This information sheet provides information about the procedure in place at DAkkS for the review of determination of the eligibility for accreditation of new private conformity assessment schemes. It is aimed at owners of conformity assessment schemes who provide for accreditation of the conformity assessment bodies operating for the conformity assessment activities specified in their schemes. It is also aimed at conformity assessment bodies that wish to include the incorporation of an existing conformity assessment scheme within the scope of their accreditation.

This information sheet applies to all conformity assessment schemes with a scope relating to the standards DIN EN ISO/IEC 17065, DIN EN ISO/IEC 17021, DIN EN ISO/IEC 17024, DIN EN ISO/IEC 17029 and DIN EN ISO/IEC 17020.

This information sheet does not apply to new procedures/conformity assessment activities for which inclusion in the scope of an accreditation is being sought by laboratories, reference material producers, proficiency testing providers or biobanks.

This information sheet serves to implement the requirement of DIN EN ISO/IEC 17011 that an accreditation body must have arrangements and documented procedures in place to determine the suitability of conformity assessment schemes for accreditation purposes.

On the content of information sheets

- DAkkS information sheets are not rules.
- DAkkS information sheets do not generate new requirements. They may nonetheless explain, and in this respect repeat, existing requirements from laws, standards or rules.
- Where necessary or useful, DAkkS information sheets provide applicants, accredited conformity assessment bodies and other parties interested in accreditation with information about the accreditation procedure to be carried out on the basis of DIN EN ISO/IEC 17011, and of other requirement documents where applicable.
- Where necessary, DAkkS information sheets explain the content of DIN EN ISO/IEC 17011 and provide information about the way in which DAkkS applies this standard. Information sheets therefore facilitate a uniform understanding of the standard on the part of the conformity assessment bodies and uniform application by DAkkS, including its assessors and technical experts.
- Where necessary or useful, DAkkS information sheets explain the content of harmonised standards and, where applicable, other documents containing requirements for conformity assessment bodies, their activities and procedures, and they therefore facilitate a uniform understanding and uniform application of these documents in the accreditation procedure and by accredited conformity assessment bodies.
- As a rule, information sheets are based on the structure of the relevant harmonised standards. It is however also possible to publish information sheets on individual sectors or areas in order to provide interested readers with an overview of accreditation in a specific sector or area.
- Information sheets are updated as required and published on the DAkkS website in the latest version.
- Information sheets make no claim at any time to be complete in the sense that all points in a law or standard are addressed.

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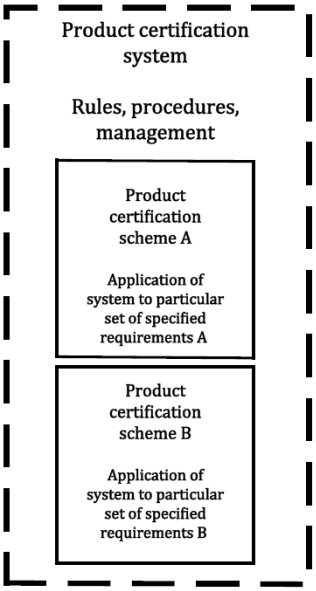
1 Terms/glossary

Accreditation activity	An accreditation activity is an area in which the accreditation body issues accreditations. The inclusion of an activity presupposes the availability of competence at the accreditation body and therefore requires a decision as to whether the accreditation body can and wishes to include the activity in its scheme. If an activity is not included, an applicant has recourse to another national accreditation body in the EEA (see Article 7 of Regulation (EC) No 765/2008).
Accreditation scheme	Rules and procedures relating to the accreditation of conformity assessment bodies to which the same requirements apply (see section 3.8 of DIN EN ISO/IEC 17011).
Power-conferring authority (PCA)	Authorities within the meaning of Section 1 (2) in conjunction with Section 2 (3) sentence 2 of the Act on the Accreditation Body (AkkStelleG) and Section 39 of the Federal Data Protection Act (BDSG).
Conformity assessment scheme (scheme)	Set of rules and procedures that describes the object of conformity assessment, identifies the specified requirements and provides the methodology for performing conformity assessment (see section 4.9 of DIN EN ISO/IEC 17000).
Standard	Standard means a technical specification accepted by a recognised standards organization for repeated or continuous application, compliance with which is not compulsory and which falls into one of the following categories: a. “International standard”: A standard accepted by an international standards organization b. “European standard”: A standard accepted by a European standards organization c. “Harmonised standard”: A European standard accepted on the basis of a mandate from the Commission for the implementation of Union harmonisation legislation d. “National standard”: A standard accepted by a national standards organization The term standard also includes documents of European or national standardisation as other technical specifications (PAS/ DIN-SPEC).

Product certification system	To understand and distinguish the terms “conformity assessment system” and “conformity assessment scheme”, the following illustrations from DIN EN ISO/IEC 17067 may be of assistance.
	 a) unique product certification scheme  b) product certification system relating to several schemes
Scheme owner	A scheme owner is a person or other legally identifiable organisation as defined in section 3.11 of DIN EN ISO/IEC 17065 that, as the issuer of a mark of conformity as defined in section 3.3 of DIN EN ISO/IEC 17030 (conformity assessment body) or as the owner of a mark of conformity as defined in section 3.2 of DIN EN ISO/IEC 17030, is the originator of criteria for the award of a certificate, seal of quality or similar attestation and, by legally binding agreement with accredited conformity assessment bodies, agrees and where necessary monitors compliance with the criteria of the scheme owner for the award of the certificate, seal of quality or similar attestation.

Scheme proprietor	The scheme proprietor is either a scheme owner or a conformity assessment body. The term is an expression of legal ownership of the scheme text and is used when a distinction between CAB and scheme owner is not relevant.
Validation risk	Describes the risk of a conformity assessment body confirming that the object of conformity assessment is in conformity although a nonconformity has gone undetected.
Legislative instruments	Legislative instruments are formal and substantive laws within the meaning of the German Basic Law (GG) and Article 288 TFEU and of international agreements with the rank of a federal law (e.g. TBT Agreement; MRAs).
Technical specification	Technical specification pursuant to Directive 1535/2015 EU means a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures. The term 'technical specification' also covers production methods and processes used in respect of agricultural products, as referred to in the second subparagraph of Article 38(1) of the Treaty on the Functioning of the European Union (TFEU), products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (1), as well as production methods and processes relating to other products, where these have an effect on their characteristics. The term 'technical specification'' also covers ''other requirements'' for a product, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing.
Technical regulation	Technical regulation pursuant to Directive 1535/2015 EU means technical specifications and other requirements or rules on 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 laws, regulations or administrative provisions of 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. De facto technical regulations include: 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 a public authority is a contracting party and which provide, in the general interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications. Technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services linked to national social security systems are not included. This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list drawn up and updated, where appropriate, by the Commission, in the framework of the Committee referred to in Article 2.
Period of silence	In administrative and public organisation law, the period of silence is the period of time after which a decision to be agreed by various participants is deemed to have been resolved if no objection is raised by any party.

2 Scope of the information sheet

2.1 Horizontal scope

(1) This information sheet is a horizontal regulation that is binding for all departments of DAkkS and applies to all certification bodies (DIN EN ISO/IEC 17065, DIN EN ISO/IEC 17021, DIN EN ISO/IEC 17024, DIN EN ISO/IEC 17029, DIN EN ISO 14065) and inspection bodies (DIN EN ISO/IEC 17020).

(2) This information sheet does not apply to new procedures/conformity assessment activities developed/introduced by laboratories, reference material producers or proficiency testing providers, to procedures in biobanks and to applications for inclusion in the scope of an accreditation. A scheme review for “in-house methods” in the laboratory area is undertaken exclusively in accordance with DIN EN ISO/IEC 17025 within the case of accreditation for the laboratory.

2.2 Material scope (section 4.6.3 of EN DIN EN ISO/IEC 17011)

(1) Pursuant to section 4.6.3 of EN DIN EN ISO/IEC 17011, the accreditation body must have arrangements and documented procedures in place to determine the suitability of conformity assessment schemes and standards for accreditation purposes.

(2 This information sheet applies to the review and determination of the eligibility for accreditation of private conformity assessment schemes for inclusion or (after amendment) retention in the portfolio of DAkkS accreditation Where DAkkS is the competent home accreditation body or has been designated by EA as a home accreditation body, it also applies to inclusion and retention as a European scheme within the scope of the signatories of the EA MLA, provided this has been applied for separately.

(3) This information sheet is not applicable to the extension of accreditation activities on the basis of legal assignment or on the basis of publication of new standards providing for conformity assessments (type A standards). Applicants who believe that DAkkS should expand its accreditation activities on the basis of a new international, European or national standard can make an informal application to that effect. Applications should be sent to:

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

(4) Where ministries or authorities at the federal and state level wish to draw up a conformity assessment scheme in order to formulate it as a technical regulation within the meaning of Regulation 1025/2012 or Directive 1535/2015 for binding national application, DAkkS can provide advisory support by way of mutual administrative assistance. However, the conformity assessment scheme remains the responsibility of the authority or government institution. Applications for support should be sent to:

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

(5) DAkkS endeavours to take part in the development phase of conformity assessment schemes that are being developed in the form of legal regulations or standards, in order to exclude contradictions and conflicts with Regulation (EC) No 765/2008, the Act on the Accreditation Body (AkkStelleG), DIN EN ISO/IEC 17011 and the EA, ILAC, IAF and DAkkS rules.

(6) New conformity assessment schemes that have been established by a legislative body or are the subject of international and European standards are generally included in the portfolio of DAkkS accreditation schemes, provided that the legislature has set a date for implementation. Otherwise, DAkkS determines the date for inclusion of the activity according to its best judgement, with due consideration given to the time required to develop competences and procedures and to market demand and urgency.

(7) This leaflet does not describe the negotiation process with so-called scheme owners where the owners set out specific requirements for the accreditation body or the accreditation process (IAF/EA Level 1). While arrangements of this kind can in principle be part of a scheme (seal of quality), they require a separate negotiation process, a contractual agreement between DAkkS and the scheme owner and other EA processes. However, an application for the negotiations required to achieve this can also be made as part of the process described below.

3 DAkkS policy on the review of new conformity assessment schemes

(1) DAkkS is the national accreditation body of the Federal Republic of Germany. Under the provisions of Regulation (EC) No 765/2008 and the Act on the Accreditation Body (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 conformity assessment on a voluntary basis (Article 3 Regulation (EC) No 765/2008).

(2) The relevance of conformity assessment and accreditation has greatly increased in recent years because conformity assessment and accreditation have been established as a horizontal (i.e. independent of sector) 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, evidence of conformity assessment based on accreditation pursuant to Article 44 of the public procurement directive (Directive 2014/24/EU) is the preferred instrument for

providing evidence in public procurement law in the EU and the EEA. Public contracting authorities may therefore only demand evidence of conformity and seals of quality issued by bodies that have been accredited in accordance with Regulation (EC) No 765/2008.

(4) This means that there is a growing need for development of new conformity assessment services in the various sectors and for the best available technology in each case by conformity assessment bodies, other independent market participants such as associations and NGOs, or issuers of seals of quality, to ensure that the many requirements of the market are met.

(5) The flexible system of harmonised conformity assessment schemes with regard to accreditation requirements is an important factor for the mutual recognition of internationally recognised assessment results in highly innovative markets, even if the harmonisation of standards for the object of assessment is not yet complete.

(6) Under the provisions of DIN EN ISO/IEC 17011, a system for the accreditation of conformity assessment bodies should ensure consistent performance of conformity assessment in accordance with standards and conformity assessment schemes that are based on international consensus for the benefit of public health, safety, the environment and public welfare, as well as to assist legislatures and end users.

(7) The procedure described below for reviewing the eligibility for accreditation of conformity assessment schemes, for use by accredited conformity assessment bodies, provides an authoritative explanation for the applicant in advance of the conformity assessment body's case of accreditation that from a technical and regulatory perspective, the conformity assessment scheme meets the requirements for inclusion in the portfolio of DAkkS accreditation .

(8) The conformity assessment scheme only becomes part of the portfolio of DAkkS accreditation when at least one accredited conformity assessment body that is monitored by DAkkS has included the confirmed conformity assessment scheme in its product portfolio by applying for initial or extended accreditation and has been granted accreditation for it.

(9) For the evaluation of the eligibility for accreditation of private conformity assessment schemes, the DAkkS policy is a follows:

- With regard to the decision on inclusion of new conformity assessment schemes, DAkkS acts independently and impartially and upholds the principle of equal treatment
- Under the terms of the WTO's TBT Agreement, DAkkS is obliged to support the instrument of standardisation with regard to the establishment of new conformity assessment schemes. Where standards or draft standards are in place in particular areas, they should generally be used as a basis for the schemes or taken into account to ensure that the corresponding harmonisation results are not compromised
- With a view to promoting the free movement of goods in Europe and within the scope of the WTO agreement, DAkkS welcomes the establishment of conformity assessment schemes with an international focus

- With regard to the inclusion of new conformity assessment schemes, DAkkS promotes the exchange of information and coordination with the national accreditation bodies in Europe and adheres to the applicable rules of EA (EA-1/22) in this respect
- Conformity assessment schemes of scheme owners who are not themselves conformity assessment bodies generally require evidence that the conformity assessment scheme is made available to the market for accredited conformity assessment bodies on non-discriminatory terms to ensure compliance with the requirements of Article 101 and Article 106 TFEU (FRAND agreement). However, DAkkS is not responsible for assessing admissibility under competition law for the applicant as part of this evaluation. The compatibility of the scheme owner's actions with European competition law is the sole responsibility of the owner.

4 Principles governing the portfolio of DAkkS accreditations (level 1)

4.1 Procedure for the review of conformity assessment schemes

4.1.1 Necessity for a scheme review

(1) A scheme review is always necessary if, on the basis of the conformity assessment scheme to be reviewed and in the context of third-party assessments, an accredited conformity assessment body intends to issue evidence of conformity assessment to the market that is not governed or not fully governed by regulatory requirements, technical regulations or recognised standards or that differs from or goes beyond them (particularly in the case of seals of quality/marks of conformity).

(2) Any revisions to the scheme must be submitted again by the scheme owner to DAkkS for review and determination. Depending on the scope and nature of the changes, a new review may be undertaken or it may be determined that the revision was not substantial, so that the initial determination of eligibility for accreditation remains effective.

4.1.2 General review benchmark

(1) DAkkS must reject the determination of eligibility for accreditation of the conformity assessment scheme for which accreditation is being sought if the scheme is in conflict with legal requirements. This applies in particular if the scheme is in conflict with the requirements of Regulation (EC) No 765/2008, the Act on the Accreditation Body (AkkStelleG) or relevant international and European standards governing conformity assessment and accreditation and/or if there is a lack of compliance with DAkkS rules, including the rules of the international accreditation organisations (EA/IAF/ILAC).

(2) The determination of eligibility for accreditation of the conformity assessment scheme must continue to be withheld if the applicant cannot provide sufficient evidence to satisfy DAkkS that in the conformity assessment scheme all necessary regulatory and normative minimum

requirements for the object of assessment (level 4 and 5) are validated and evaluated using the best available technology in each case and taking into account the validation risk.

(3) The same applies if the applicant cannot provide sufficient evidence to satisfy DAkkS that the procedures for conformity assessment described in the conformity assessment scheme ensure comparability and reproducibility of results.

4.1.3 Eligibility to apply

4.1.3.1 General

(1) Entitlement to determination of eligibility for accreditation is limited in principle to accredited conformity assessment bodies (see 4.1.3.2) and legal entities or other legally identifiable organisations wishing to provide conformity assessment bodies with a conformity assessment scheme as a scheme owner (see 4.1.3.3) on the market for conformity assessment.

4.1.3.2 Accredited conformity assessment bodies

(1) To demonstrate eligibility to apply, it is sufficient for the applicant to make a binding declaration that once a scheme has been confirmed, an application will be submitted to DAkkS for accreditation as a conformity assessment body for this scheme.

(2) If an existing accreditation as a conformity assessment body is legally refused during the course of the procedure, eligibility to apply ceases with retroactive effect if the notice of assessment had not yet become final.

(3) Eligibility to apply is limited to accredited conformity assessment bodies established in Germany or, under the conditions for cross-border accreditation set out in Article 7 of Regulation (EC) No 765/2008 and EA 2/13 (cross frontier accreditation), also bodies from abroad.

4.1.3.3 Scheme owners

(1) Eligibility to apply is limited to scheme owners established in Germany or, under the conditions for cross-border accreditation set out in Article 7 of Regulation (EC) No 765/2008 and EA 2/13 (cross frontier accreditation), also bodies from the EEA and bodies established in third countries.

(2) To be eligible to apply, the scheme owner must provide evidence of support from at least two conformity assessment bodies. This can be done for example by submitting statements from the accredited bodies that in the event of determination of eligibility for accreditation, they intend to submit an application for extension of accreditation (for inclusion in their scope) related to the owner's scheme.

(3) In areas where no bodies have yet been accredited for activities comparable to those described in the scheme, it is sufficient for the supporting bodies to state that once the scheme has been confirmed, they will submit an application for accreditation to DAkkS within 12

months after issue of the notice of assessment regarding the eligibility of the scheme for accreditation.

4.1.4 Conduct of the procedure

4.1.4.1 Application phase

(1) A formal application for the review of eligibility for accreditation must be submitted in writing. The following form (available on the DAkkS website) must be used:

Application for the Verification of Accreditation Suitability of Conformity Assessment Schemes, identifier: FO-KBP_Antrag_EN

The following additional documents (available on the DAkkS website) must also be submitted:

- **List of required documents for the determination of the accreditation suitability of a conformity assessment scheme,** identifier: LI-EU_KBP_EN
- **Checklist for new conformity assessment schemes,** identifier: FO-KBP_Checkliste_EN
- **Sample-Matrix for the illustration as well as evaluation types and -methods according to ISO/IEC 17067 clause lit. b) and g),** identifier: FO-KBP_Muster-Matrix-zu-Tz-6.5.1_17067_EN

(2) The application (FO-KBP_Antrag_EN) must be sent in writing to:

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

(3) Once the complete application documents have been received by the scheme evaluation office, receipt is confirmed and a reference number is assigned. The applicant must use this number in all future correspondence.

(4) The additional documents required, as set out in the first paragraph of section 4.1.4.1, must always be submitted electronically via the platform provided by DAkkS.

(5) DAkkS reviews the application to ensure that it is complete and that the applicant is eligible to apply. If the application and supporting documents are complete and the applicant is eligible to apply, the applicant will be sent a confirmation of completeness.

4.1.4.2 Involvement of supervisory bodies

(1) After reviewing the application documents, DAkkS makes a decision as to whether an area regulated by law could be affected by the scheme or whether the competent supervisory authority must otherwise be informed.

4.1.4.3 Review phase including evaluation of the validation report

(1) Once any applicable period of silence for the supervisory authority has come to an end or after clarification of any possible reservations on the part of the supervisory authority, the substantive review of the scheme begins.

(2) In the first instance, DAkkS conducts a system review against regulatory requirements and the accreditation standards at level 3. The result is a system report listing any nonconformities with the above laws and standards.

(3) Following the system review, DAkkS conducts a substantive technical review, using competent assessors depending on the level of complexity. The technical review includes in particular an assessment of the suitability of the evaluation activities. In addition to DAkkS employees, suitable assessors include internal or external technical and system assessors or technical experts and other technically suitable DAkkS staff. In exceptional cases, the separate technical review may be omitted and conducted by the system assessor.

(4) If regulatory provisions require the involvement of a power-conferring authority in the scheme review or approval of criteria, it is assigned with the technical assessment. Any approval of criteria required from the power-conferring authority is granted as part of a separate administrative act by the power-conferring authority outside this procedure.

(5) For the technical review, the power-conferring authority receives, in addition to the case file, the DAkkS report on the system review for further examination and evaluation.

(6) The document **Sample-Matrix for the illustration as well as evaluation types and -methods according to ISO/IEC 17067 clause lit. b) and g)** plays a key role in the scheme review. The applicant must use this matrix to set out in detail which specific evaluation types/methods have been defined in the certification scheme for each material requirement for the object of assessment (regulatory requirement; standard, approved criteria at level 5).

(7) The **applicant's validation report plays an equally important role in the review**. The validation report must show that the scheme submitted has been successfully validated for suitability by the applicant, in particular with regard to comparability and reproducibility of results. The validation report must contain informative results and assessments of the applicant's validation process that enable a competent third party to understand the results of the assessments within a reasonable period of time.

(8) In the event that application documents are incomplete or schemes are clearly inadequate, DAkkS may conclude the review without a report, with a brief explanation and a negative decision. Submission to the scheme committee is not necessary.

4.1.4.4 Elimination of nonconformities

(1) In the event of a scheme evaluation that is positive in principle, the applicant will be given a reasonable period of time at the end of the system review and at the end of the technical review to eliminate the identified nonconformities or to comment on the nonconformities, and

to provide further evidence where applicable. This period may be extended in exceptional cases.

(2) The scheme evaluation office compiles a summary of the responses of the applicant and of the power-conferring authority where applicable, obtains assessments from the assessors concerning the elimination of nonconformities where applicable, and in the case of a positive recommendation by the system and technical assessors, prepares a decision paper for the scheme committee and convenes the committee.

(3) For conformity assessment schemes that require approval of the criteria/standards (level 4/5) as a result of regulatory provisions, the decision paper is not submitted to the scheme committee until approval is obtained from the competent power-conferring authority.

(4) If the applicant is still unable to obtain approval from the competent power-conferring authority after a reasonable grace period, the application will be rejected.

4.1.4.5 Evaluation and decision by the scheme committee

(1) In the event of a positive recommendation by the scheme evaluation office after final evaluation of the evaluation of nonconformities, the scheme committee makes the final decision regarding the eligibility of the scheme for accreditation on the basis of the file, the approval of the power-conferring authority where applicable, the reports of the assessors including their assessment of the measures taken by the applicant to eliminate nonconformities and the decision paper prepared by the scheme evaluation office.

4.1.4.6 Confirmation/rejection of the determination of eligibility for accreditation

(1) On the basis of the decision of the scheme committee, the applicant receives a notice of assessment regarding the eligibility for accreditation of the scheme.

4.1.4.7 Special features of complex/innovative systems (pre-competitive)

(1) In the event of the establishment by a scheme proprietor of private conformity assessment schemes covering innovative or particularly complex subject areas, a **pilot phase** may be included as part of the application process. This is necessary in particular if there is otherwise a lack of data with regard to validation of the scheme in question.

(2) The purpose of the pilot phase is to include DAkkS in the **review of the draft conformity assessment scheme** at an early stage with a view to ensuring that DAkkS obtains an in-depth understanding of the risks and technical aspects involved.

(3) DAkkS is limited to review during the pilot phase, and is not permitted to advise the applicant. A pilot phase is only possible with **scheme owners** who are **not conformity assessment bodies**.

(4) A pilot phase essentially involves witnessing practical evaluation activities accompanied by appropriate experts (such as auditors, inspectors, laboratory staff).

(5) For the purposes of review and validation during the pilot phase, DAkkS only uses experts who are not members of the scheme committee.

(6) Applicant intending to conduct a pilot phase must apply to do so.

(7) The expenses associated with implementation of the pilot phase incurred by DAkkS are borne by the applicant.

4.1.4.8 Special features of cases involving EA evaluation as per EA 1/22

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

- For internationally applicable schemes, auf Antrag des Programmeigners EA designates a national accreditation body (NAB) as a so-called home ABfor each scheme, which is responsible for the initial evaluation and all changes to the scheme. This NAB is the only body with which the scheme owner cooperates.
- 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 or EA documents, these requirements must be confirmed by the EA General Assembly. This can cause a considerable delay in the process of the review of the scheme.
- The results of the first evaluation are made available to EA by the home AB. EA makes the results available to its members for a 30-day comment period. The scheme may not be accepted by the home AB until the comment period has ended without comments, or until the resulting negative feedback has been resolved.
- Any questions to the scheme owner are raised exclusively via the home AB.

(2) The process for review as a European scheme at EA will be initiated by DAkkS only if the DAkkS system and technical reviews have been completed in full with a positive outcome.

4.1.4.9 Special features of involvement of power-conferring authorities

(1) If authorities other than DAkkS have the legal power to authorise or approve conformity assessment schemes within their area of responsibility, the relevant competent authority will be informed already of the application.

(2) Following the specialist review, the competent authority will be asked for its agreement or approval. If its agreement is not forthcoming, DAkkS cannot make a positive determination. The applicant will then receive a negative decision.

4.2 Activities of the scheme committee

(1) The scheme committee makes the final decision on eligibility for accreditation on the basis of the available review reports. The committee is always made up of at least two persons who

were not previously involved in the review of the scheme in question. The scheme evaluation office convenes the scheme committee.

4.3 Database of confirmed schemes

(1) All schemes whose eligibility for accreditation has been positively determined are listed on the DAkkS website, stating the scheme owner and the version on which the determination was based. For this purpose, the scheme owner grants DAkkS the necessary rights, free of charge, to make the representation of labels in the database publicly available. Where marks of conformity within the meaning of DIN EN ISO/IEC 17030 are used, the publicly available source for the label criteria is also indicated.

4.4 Costs of the procedure

(1) All costs incurred by DAkkS associated with the review of the eligibility for accreditation of schemes, including necessary expenses, are borne by the applicant.

(2) DAkkS fees are charged according to time required in accordance with tariff item 1.2 in conjunction with tariff item 7 of the ordinance on fees for accreditation bodies (AkkStelleGebV).

(3) DAkkS reserves the right to make implementation of the procedure dependent on an advance payment up to the amount of the expected fees (see Section 15 (1) BGebG, the act on fees and expenses for federal services).

(4) Expenses for external representatives (travel expenses and costs for external assessors, in particular from power-conferring authorities), will be reimbursed upon proof from the applicant in accordance with Section 4 AkkStelleGebV (ordinance on fees for accreditation bodies).

5 Requirements for conformity assessment schemes (level 3 and 4)

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

5.1 General requirements for conformity assessment schemes

5.1.1 Permissible subject matter of conformity assessment schemes

(1) A conformity assessment scheme is a technical specification for accredited conformity assessment bodies describing specific requirements and rules and setting out selection, testing and assessment procedures. Conformity assessment of a product, service, process, system or person must make the statement associated with the evidence of the conformity assessment (e.g. certificate, inspection report/certificate, seal of quality, etc.) in a scientifically traceable, systematic and reliable manner.

(2) The arrangements set out in a conformity assessment scheme always concern requirements at level 4 as per EA-1/06, which describe the activities of the conformity assessment body. A scheme may also define requirements for the object of assessment (level 5) if national or international standards are not available or inadequate.

(3) Such criteria must meet the requirements of DIN EN ISO/IEC 17007.

(4) Requirements for the accreditation body are permissible only if permitted in EA 1/22 (see section 2.2 (7)).

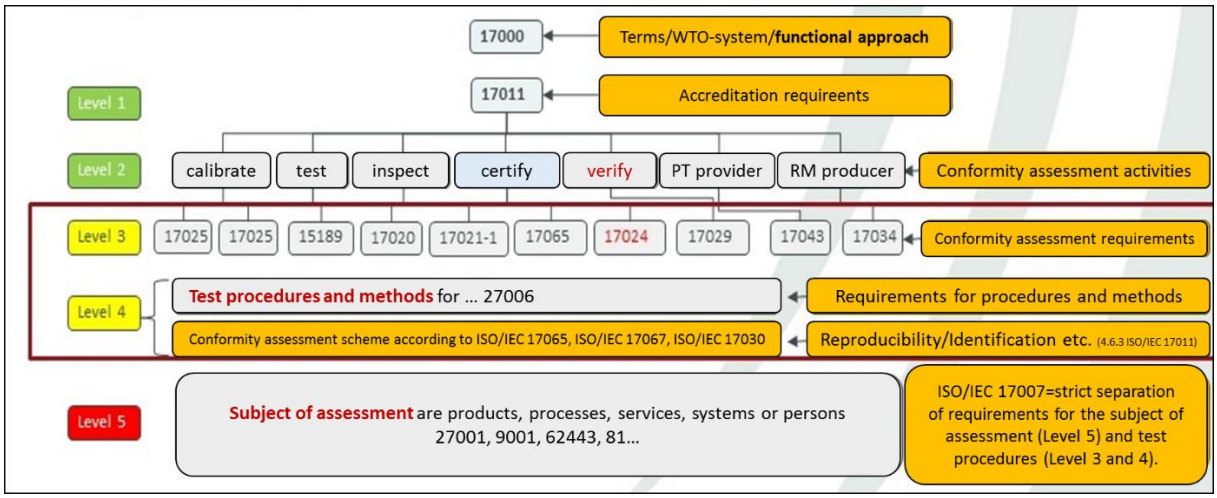


Figure 1: Level structure as per EA 1/06

5.1.2 Minimum requirements for a conformity assessment scheme

(1) To be eligible for accreditation, a conformity assessment scheme must, as a rule and where applicable, contain the typical elements set out in DIN EN ISO/IEC 17000 Annex A.

(2) With regard to the use of marks of conformity, the requirements of DIN EN ISO/IEC 17030 must be adhered to. This means that requirement criteria must be publicly available and that surveillance measures must always be defined.

(3) Where conformity assessment schemes are a procedural description of the proprietor of certification marks that are associated with a statement of conformity and/or the awarding of marks of conformity, labels and the testing and supervision of certification marks within the meaning of Section 106a MarkenG (German Trade Mark Act) or Article 83 (1) of the EU trade mark regulation, the proprietor of the certification mark must provide information on how the characteristics covered by the certification are to be tested and how use of the mark is to be supervised (see Section 106d MarkenG). It follows from Section 106d (2) number 1 MarkG that this conformity assessment must be carried out by or on behalf of the proprietor of the certification mark and that it is necessary to ensure that the proprietor of the certification mark or conformity assessment bodies commissioned by the proprietor do not themselves carry out any activity involving the supply of goods or services of the kind certified. From this it follows that only conformity assessment activities by a second-party conformity assessment activity as per section 4.4 of DIN EN ISO/IEC 17000 or a third-party conformity assessment activity as per section 4.5 of DIN EN ISO/IEC 17000 are permitted. Industry self-declaration systems that function like umbrella brands (such as the “RAL label” in Germany) do not meet these requirements and therefore cannot be the object of the scheme review.

DIN EN ISO/IEC 17067 is indispensable in terms of understanding, developing, using or maintaining certification schemes for products, processes and services.

(4) Every conformity assessment scheme must formulate concrete statements on necessity, and where applicable information required in the areas of selection, determination, assessment and attestation/approval, and where applicable also surveillance, which must be supported by evidence in the context of the review procedure.

(5) Certification schemes in accordance with DIN EN ISO/IEC 17065 should be assigned to the scheme types set out in DIN EN ISO/IEC 17067 where possible. If these scheme types are not suitable from the applicant’s point of view, an explanation of the additional requirements that preclude such assignment is required.

(6) It is essential to follow the functional approach. The schematic structure of the functional approach is as follows:

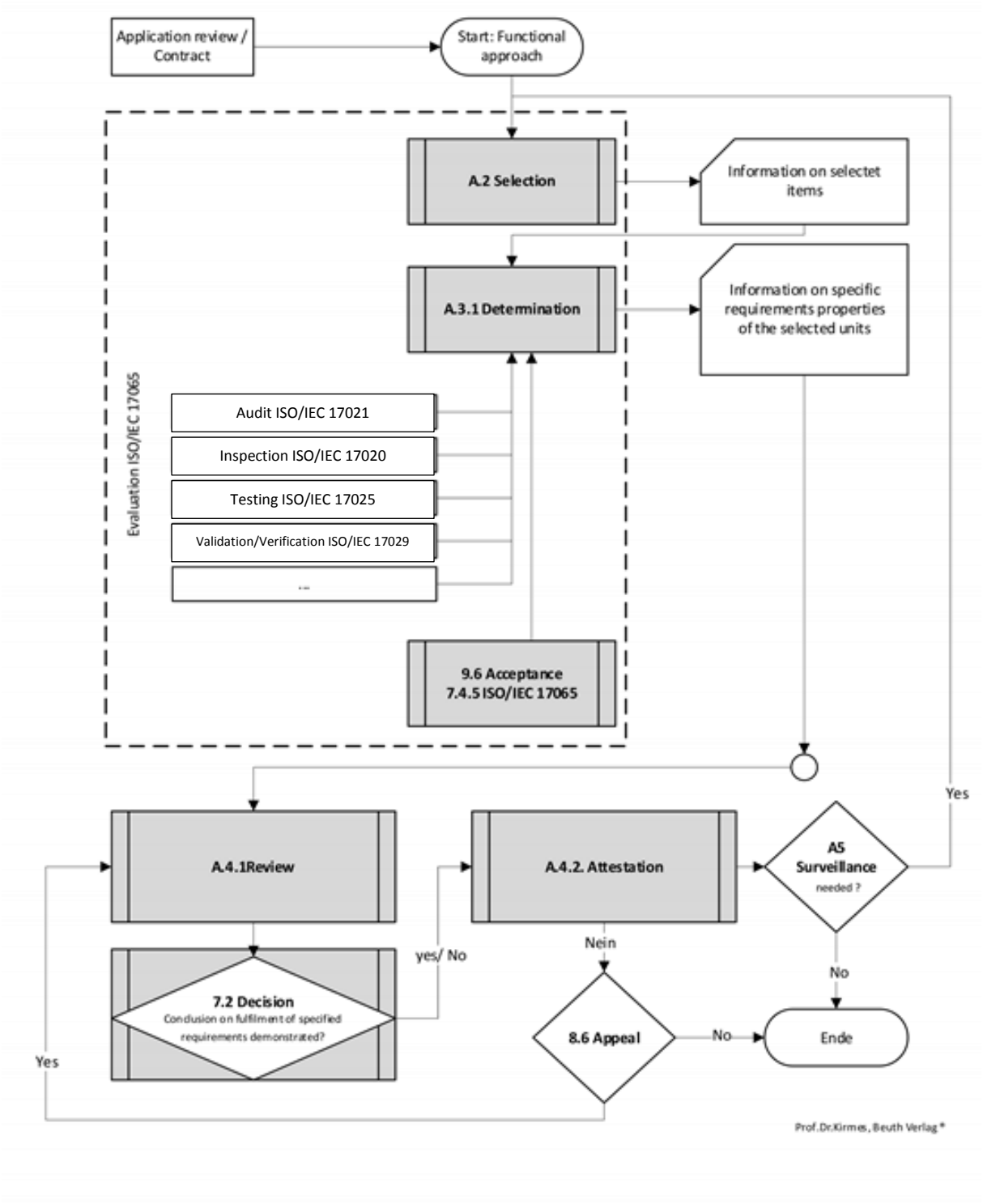


Figure 2: Schematic representation of the functional approach

(1) The following minimum information concerning the functional approach to conformity assessment activities as defined in DIN EN ISO/IEC 17000 is always required:

I. Minimum information required in the area of "selection"

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

1. Description and delimitation of the object of assessment.

(DIN EN ISO/IEC 17000 Annex A, A.2.3.)

2. Description of the requirements for the object of assessment (IAF/EA Level 5), for example from legislation, international standards or technical regulations, as well as the expertise required to evaluate the decision and confirm the object of assessment based on its fulfilment.
3. As a rule, these requirements should be from international standards, standards or specifications established within the sector or specifications of a group of manufacturers. Factory standards and manufacturer's specifications can be the object of first and second-party attestations only in exceptional cases. They cannot be the object of third-party attestations.
4. The scheme owner's requirements must be described clearly and unambiguously so that they can be interpreted accurately and consistently, allowing bodies making use of these requirement documents to derive a uniform understanding of the meaning and intent of their content.
5. Requirements for the object of assessment must be set out in the form of concrete and unambiguous criteria, together with critical limits and margins of error where relevant.
6. For regulatory criteria, the extent to which the principles of DIN EN ISO/IEC 17007 can be fulfilled for the purposes of conformity assessment, if necessary by additions to the scheme, must also be presented. (DIN EN ISO/IEC 17000 Annex A, A.2.4.)
7. Descriptions of the applicable conformity assessment type and its selection with regard to the object of the conformity assessment (e.g. laboratory tests, certification, inspection services, etc.). A description of why the selection of the conformity assessment type or of a combination is suitable in technical terms to achieve the regulatory or technical objective of the statement of conformity.
   (DIN EN ISO/IEC 17000 Annex A, A.2.1.)
8. Description of the planning and preparation activities required as well as planning information collections and any necessary sampling activities or sampling procedures.
9. Information must be provided on ensuring the integrity and reliability of information collection for the determination. For the provision of data from the manufacturer in particular, an explanation is required of how the integrity of the data can be ensured through specific verification or other controls by the CAB.
10. If the scheme also includes sampling, information must be provided on the method of sampling to be used to obtain consistent and reproducible results. Wherever possible,

sampling methods based on statistical methods should be used to enable a representative statement, or methods defined in international standards. Non-statistical methods are allowed only if no mathematically reliable population is available.

II. Minimum information required in the area of "determination"

1. Description of the use of one or more methods of determination (e.g. testing, auditing and/or investigation) to obtain full information on the fulfilment of specified requirements for the object of conformity assessment or its sample.
2. For series products or services, an explanation of how statistical methods are used to ensure representative determination is required.
3. As a rule, evidence of the use of proven conformity assessment procedures must be provided (see section 4.6 of DIN EN ISO/IEC 17007).
4. If best practices are not followed, the reasons for not doing so must be explained in detail.
5. As set out in points b) and g) of section 6.5.1 of DIN EN ISO/IEC 17067, a specific evaluation type/method must be defined (level 4) for each material requirement for the object of assessment (regulatory requirement/standard/approved criteria at level 5).
   The sample matrix for the illustration of requirements and evaluation type/method, which is available on the DAkkS website, should be used for this purpose (see 4.1.4.1 Application phase).

III. Minimum information required in the area of "assessment"

Obligatory description of the procedure used to review the evidence of conformity obtained during the determination stage to establish whether the specified requirements are met. The respective requirements of the accreditation standards must be observed (DIN EN ISO/IEC 17065, DIN EN ISO/IEC 17021-1, DIN EN ISO/IEC 17029, DIN EN ISO/IEC 17024 etc.).

IV. Minimum information required in the area of "decision"

Description of the criteria used as prerequisites for: Granting, maintaining, extending, reducing, suspending or withdrawing of attestation. The criteria must make it clear when nonconformities are critical. Where applicable, categorisation systems for nonconformities/deficiencies must be presented.

V. Minimum information required in the area of "attestation/approval"

Description of the process of evaluation and attestation, including an evaluation of evidence from the determination stage and any subsequent attestation as to whether the fulfilment of specified requirements has been reliably presented as the object of conformity assessment, and where applicable any subsequent marking or approval and its control (see in particular DIN EN ISO/IEC 17030).

1. Issue of a certificate of conformity or other statement of conformity (attestation)
2. Granting of the right to the use of certificates or other statements of conformity
3. Issue of a certificate of conformity for a batch of products
4. Granting of the right to the use of marks of conformity (approval) on the basis of monitoring or certification of a batch
5. Assurance of the prohibition on the use of products if no product testing has been carried out (particularly for management systems)

VI. Minimum information required in the area of "surveillance"

Description of the procedure for surveillance if applicable due to the scheme type (see section 5.3 of DIN EN ISO/IEC 17067), including the interval and scope of surveillance activities and reassessments, to ensure that the object of conformity assessment continues to meet the specific requirements. The risk adequacy of the ordinary surveillance measures must be addressed and an explanation of the response to extraordinary results is required.

5.1.3 Comparability and reproducibility of results

(1) The applicant must provide sufficient evidence to satisfy DAkkS that the procedures for conformity assessment described in the conformity assessment scheme ensure **comparability and reproducibility** of results.

(2) Evidence of this must be provided in the form of a detailed description and submission of the **validation report**, showing that the requirements for comparability and reproducibility of results within the meaning of section 4.5 of DIN EN ISO/IEC 17007 can be ensured.

(3) Validation of a conformity assessment procedure is used to provide practical evidence that the conformity assessment procedure described in the scheme is demonstrably suitable for its specific intended use. Depending on the type of conformity assessment, the characteristics examined include for example:

- Representativeness
- Robustness
- Measurement uncertainty where applicable
- Comparability

More detailed requirements or permissible simplifications follow from the specific features of the relevant standard and the context of use in each case.

(4) Specific information on the representativeness of all sampling procedures is always required. The statistical or other selection procedures and their appropriateness must be explained in detail.

5.1.4 Relevant minimum requirements

(1) The eligibility of a scheme for accreditation requires that the scheme owner who is not themselves conformity assessment body (wishing only to use the scheme themselves) offers the scheme to all accredited conformity assessment bodies on non-discriminatory terms. The scheme owner must regularly submit so-called “FRAND commitments” (see section 287 et seqq. of Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (2011/C 11/01).

(2) With regard to the process for establishing technical criteria, the scheme owner may, depending on the scope of the scheme, also be subject to the requirements of Annex 3 to the WTO’s TBT Agreement and to the label requirements set out in Article 43 of Directive (EU) 2014/24, and where schemes in the field of ICT are concerned, to the requirements for common ICT specifications pursuant to Regulation (EU) 1025/2012. The scheme must contain a statement as to whether these requirements are met or why they may not be relevant.

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

(4) However, DAkkS is not responsible for assessing admissibility under competition law for the applicant as part of this review. The compatibility of the scheme owner’s actions with European competition law is the sole responsibility of the owner. The application must be accompanied by a declaration by the applicant confirming that these competition law issues have been examined with a positive outcome.

(5) With regard to the definition of criteria for the object of assessment and with regard to the requirements of the evaluation, the conformity assessment scheme must not fall below the level of best available technology or state-of-the-art science and technology, as defined by standards. Where there are European harmonised standards in place, conformity assessment schemes must be in conformity with them.

5.1.5 Requirement for the structure of schemes

(1) Conformity assessment schemes must be structured to follow the main headings of the conformity assessment standard on which the scheme is based.

(2) To enable a review, all information in a scheme must be with reference to specific sections of the reference standard (level 3).

(3) If a scheme does not follow the structure of the standard in justified cases, a reference matrix with the standard references must be submitted.

5.2 Specific requirements

5.2.1 Field: Certified management systems (DIN EN ISO/IEC 17021-1)

(1) The conformity assessment scheme must include an analysis of necessity, showing why and to what extent existing international requirements of standards cannot be applied to the conformity assessment of management systems, or are to be set out in greater detail by the scheme.

(2) In the context of DIN EN ISO/IEC 17021-1, this may include audit activities only.

(3) The conformity assessment scheme must specify the audit time and the phase (stage 1 or 2) in which conformity is to be determined, and the objective evidence or other audit techniques on which it is based. This evidence must be provided for each defined requirement for the object of assessment (the sample matrix available on the DAkkS website should be used for this purpose).

5.2.2 Field: Certification of products/processes/services (DIN EN ISO/IEC 17065)

(1) The conformity assessment scheme must include information relating to all items set out in section 6.5 of DIN EN ISO/IEC 17067.

(2) The object of assessment may be defined or formulated generically, provided that the following condition is met: the object is described using general and abstract characteristics that allow it to be distinguished from other objects of assessment and ensure that suitability of the defined evaluation types/methods in relation to the object of assessment remains possible.

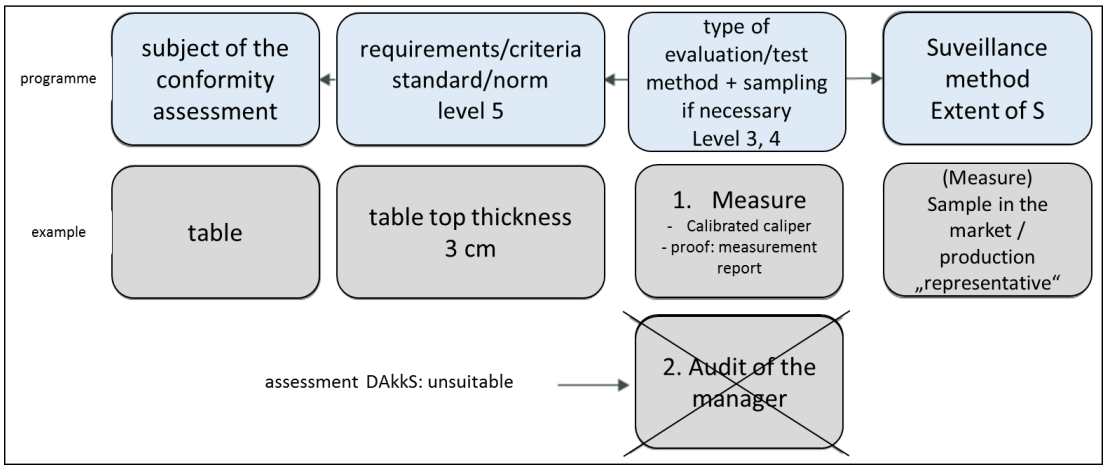


Figure 3: Object and definition as per points b) and g) of section 6.5.1 of DIN EN ISO/IEC 17067

(3) A sample matrix for the illustration of requirements and evaluation type/method is available on the DAkkS website.

(4) If the evaluation methods or procedures are not themselves standardised, they must be described separately in detail. Where standards are available, they must be submitted with the application documents.

5.2.3 Field: Certification of persons (DIN EN ISO/IEC 17024)

(1) The conformity assessment scheme must include an analysis of the delimitation of the scheme from the area of training and education regulated by law and other legal requirements governing personnel qualifications, in particular under German state law.

(2) A sample matrix for the illustration of requirements and evaluation type/method is available on the DAkkS website.

(3) In the event that no surveillance is specified, there must be an indication that the knowledge identified during the review does not require renewal. In all cases, recertification is required.

5.2.4 Field: Inspection (DIN EN ISO/IEC 17020)

(1) A sample matrix for the illustration of requirements and evaluation type/method is available on the DAkkS website.

(2) With regard to DIN EN ISO/IEC 17020, the applicable test methods (SOP) must be submitted as evidence for all testing and sampling activities in accordance with DIN EN ISO/IEC 17025 or ISO 15189.

(3) For each criterion set out in the matrix, a determination regarding the qualifications of the professional expert is required.

6 Other applicable documents

EA-1/22	EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members
FO-KBP_Antrag_EN	Application for the Verification of Accreditation Suitability of Conformity Assessment Schemes
FO-KBP_Antrag_Änderung	Amendment to the Application for the Verification of Accreditation Suitability of Conformity Assessment Schemes
FO-KBP_Checkliste_EN	Checklist for new conformity assessment schemes
FO-KBP_Muster-Matrix-zu-Tz-6.5.1_17067_EN	Sample-Matrix for the illustration as well as evaluation types and -methods according to ISO/IEC 17067 clause lit. b) and g)