

Rule for accreditation of certification bodies for products, processes and services according to DIN EN ISO/IEC 17065:2013

R-17065

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Scope:

This document specifies, where necessary, the general requirements of DIN EN ISO/IEC 17065:2013 including Corrigendum 1 to DIN EN ISO/IEC 17065 of October 2020, and in addition to R-17011 the requirements of DIN EN ISO/IEC 17011:2018 concerning the procedure for accreditation of certification bodies for products, processes and services.

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I Introduction

DIN EN ISO/IEC 17065:2013 including Corrigendum 1 of October 2020 (hereinafter simply 17065) sets out requirements for certification bodies for products, processes and services (hereinafter simply CBs). DAkkS applies 17065 for the accreditation of CBs for the purposes of both international recognition and the fulfilment of its duties as the national accreditation body pursuant to Regulation (EC) No 765/2008. For legal reasons, CBs may have to comply with stricter requirements for the purpose of national application, and this must be taken into account in cases of accreditation.

For administrative practice, this rule sets out the requirements of 17065 in greater detail where necessary, and in addition to rule R-17011 the requirements of DIN EN ISO/IEC 17011:2018 (hereinafter simply 17011). This rule applies only as long as the versions of 17065 and 17011 have the status of a harmonised standard.

With this rule, DAkkS defines no new requirements for CBs going beyond the requirements of 17065/17011. Existing minimum requirements are not restricted or withdrawn. Normative terms or subject matter of 17065/17011 whose interpretation is not unambiguous are specified in greater detail in individual cases as required.

DAkkS assumes a knowledge of the exact requirements of 17065/17011, and the text of the standards is therefore not reproduced. Where applicable and adopted by DAkkS, and independently of this rule, international rules of the organisations *European co-operation for Accreditation (EA)* and *International Accreditation Forum (IAF)*, which themselves specify the requirements of 17065/17011 in greater detail, apply. Here again, DAkkS does not reiterate their content in this rule. Where appropriate, reference is made to these rules at the relevant points. DAkkS generally provides German translations of the adopted applicable international rules.

In essence, this rule constitutes the accreditation scheme required under 17011 for the accreditation of CBs through the application of 17065 by DAkkS. It includes only aspects that are applicable to all CBs (Level 3). Specific details for CBs in individual technical sectors/areas can be the subject of lower-level rules.

This rule is based on the structure of 17011 and 17065. Sections of 17011 and 17065 that require no greater detail are omitted.

Further information, in particular explanations of 17065/17011 and their application by DAkkS or information for CBs concerning the accreditation procedure may be available in DAkkS information sheets and on the DAkkS website.

II Specification of requirements for the accreditation procedure

This section sets out the requirements of 17011 for the accreditation of certification bodies certifying products, processes and services in greater detail. The numbering within this section follows the numbering of 17011.

7 (17011) Process requirements

7.2 (17011) Application for accreditation

7.2.1

The information provided by the body to be accredited as part of its application must include all locations of the CB (permanent, mobile, virtual). This also includes information as to whether and which evaluation activities (such as testing in accordance with DIN EN ISO/IEC 17025) are performed within the body's own legal entity and as to whether and which evaluation activities are performed outside the locations of the CB (e.g. inspections, audits, on-site testing, sampling).

To enable DAkkS to determine the body's competence with legal certainty, the application must include extensive evidence regarding property and ownership structures and any relationships to a higher-level entity (e.g. group of companies). The submitted organisation charts and descriptions in the QM system, and where applicable also the statement of the formation of dependent units within the legal entity, must be clearly and demonstrably consistent with the actual relationships under commercial and company law.

The statement of the scope to be accredited must meet the requirements of section II 7.8 of this document. Sectoral rules, if any, must be adhered to.

An application for discontinuation or restriction of the scope of accreditation requires the submission of a plan by the CB that all statements of conformity with surveillance obligations or those concerning the restriction of scope will be effectively removed from the market by the CB by the date of discontinuation. Evidence that the certificates have been withdrawn from the market must be provided no later than the date on which the reduced scope takes effect.

7.4 (17011) Preparation for assessment

7.4.5

The representative sample size (scope of assessment¹/ depth of assessment²) regarding any assessment of CBs is based on the certification schemes accredited or for which accreditation is being sought. A certification scheme represents a specific statement of conformity. If several similar statements of conformity are processed with modular methods and systems, this constitutes a certification system within the meaning of DIN EN ISO/IEC 17067.

When determining the sample for initial accreditations and reaccreditations by DAkkS, it is necessary to ensure that all of the certification schemes offered and locations at which certification activities take place (7.2.1) are assessed. Prior to the assessment, CBs must provide DAkkS with the information on planned on-site activities needed to enable the planning of witnessing activities.

In addition to those set out in R-17011, the key activities of CBs include the following:

- Collection of data from the client, assessment of the application and of client data, and preparation of tenders;
- Planning of the evaluation and its approval on the basis of the information provided by the client;
- Evaluation of competence and approval of technical personnel and subcontractors;
- Assessment of the acceptance of third party conformity assessment results in terms within the meaning of section 7.4.5, 17065;
- Control of the process of monitoring the competence of personnel and of subcontractors and their results;
- Determination of the technical requirements for certification activities in new technical areas or in areas with limited activities;
- Performance of evaluation activities;
- Technical assessment of evaluation activities;
- Implementation of the decision on certification;
- Processing of appeals;
- Planning, conduct and follow-up of internal audits;
- Control of the management system.

¹ Scopes that will be assessed (selection of conformity assessment activities from the accredited scope and locations as per the current certificate annex, as well as focal points with regard to the normative requirements of the applicable level 3 standard).

² Required samples on a representative or ad hoc basis including witnessing activities for the defined scope of assessment.

7.4.7

As a rule, DAkkS will only grant accreditation after successful completion of an office assessment and at least one successful witnessing activity in each certification scheme for which accreditation is being sought.

DAkkS does however recognise that with regard to the conduct of witnessing activities, there are specific conditions that make the assessment/observation of a real evaluation (e.g. audits, inspections, reviews) impossible prior to obtaining accreditation.

If the permission required for certification within the scheme being sought is subject to approval by private scheme owners or competent authorities, or if the order for certification depends on the prior granting of accreditation, so that there is no possibility of conducting a witnessing activity before the granting of accreditation, limited accreditation may be granted under the condition that activity will be carried out.

In such cases, the witnessing activity must be undertaken as part of the first certification procedure where practically possible. If no witnessing activity can be offered within the period specified as a condition, competence is not demonstrated and the accreditation for the scope concerned will be withdrawn (reservation of revocation under Section 49 (2) no. 1, 2nd alternative Administrative Procedures Act (VwVfG)).

7.8 (17011) Accreditation information

7.8.1

DAkkS reserves the right to specify and communicate the accreditation information (decision and certificate) for CBs in digital form, and also to make it available by publishing it in the database of accredited bodies.

7.8.3

To ensure the uniformity and comparability of public accreditation information, DAkkS reserves the right to introduce further presentations for specific scopes of CBs that go beyond the minimum information required by the standard.

7.8.4

17011 allows for the possibility of setting out flexible scopes. Provided that there are no sectoral requirements to the contrary (originating for example in standards, legal or regulatory requirements or specifications of the scheme owner), DAkkS offers flexibility of the scope of accreditation upon request.

To obtain it, the CB must provide evidence that it has stable processes in place for the design and validation of new certification schemes or their adaptation by virtue of changing requirements for the

object of the assessment, as well as a trustworthy process for approval of the extension and publication of the flexible scope of accreditation. To be granted flexibility under category C (see below), the CB must have provided evidence of these capabilities over at least one accreditation cycle.

In all other respects, DAkkS applies EA rule 2/15.

Once granted, flexibility of scope can be revoked if the CB has not made use of it for a period of more than 24 months (reservation of revocation under Section 49 (2) no. 1, 2nd alternative Administrative Procedures Act (VwVfG)).

The flexible scopes can be divided into three different categories.

Category A includes the extension or adjustment of standardised or equivalent requirements for the object of the assessment (in particular the revision of product standards or testing standards) within certification schemes that have already been accredited, provided that no new evaluation method is required and critical limits, accuracies or measurement uncertainties have not been made more stringent by the change.

Category B includes category A and the addition of new products, processes or services – application of the certification scheme to new objects of assessment – provided that the internal validation undertaken by CBs has provided evidence that the evaluation methods within the accredited certification scheme ensure a reliable statement of conformity by virtue of the similarity of the new subjects to the subjects previously covered by the scheme. If validation shows that a new evaluation method is required or that critical limits, accuracies or measurement uncertainties have become more stringent as a result of the change of standard, the flexible scope has been exceeded.

Category C includes categories A and B and allows the addition of new certification schemes within an accredited certification system. Category C also includes the addition of new evaluation methods or changed critical limits, accuracies or measurement uncertainties, provided that the internal validation undertaken by CBs has provided evidence that the new evaluation methods, critical limits, accuracies or measurement uncertainties ensure a reliable statement of conformity by virtue of the similarity with the existing competences and equipment within the CB and already assessed in the case of accreditation, and that no new personnel competences or equipment are required. If validation shows that personnel competences or equipment not yet assessed by DAkkS are required, the flexible scope has been exceeded.

7.9 (17011) Accreditation cycle

7.9.3

During assessments, the CB must provide recurring evidence, including in witnessing activities, that it possesses the competence to provide the specific certification activity.

If the recurring assessment in form of witnessing activities is not possible over an accreditation cycle due to a lack of applications or clients, the CB cannot compensate for this with other measures.

In this case, a continued confirmation of competence by DAkkS is not possible. The scope of accreditation will be restricted accordingly.

III Specification of requirements of DIN EN ISO/IEC 17065:2013

This section sets out the requirements of 17065 for the accreditation of certification bodies certifying products, processes and services in greater detail. The numbering within this section follows the numbering of DIN EN ISO/IEC 17065:2013.

4 (17065) General requirements

4.1 (17065) Legal and contractual matters

4.1.2 Certification agreement

4.1.2.1

Inadmissibility of conformity disclaimers as part of a certification agreement

As a conformity assessment body, it is inadmissible to disregard identifiable risks of an object of certification in the decision on certification and to supplement the conformity assessment confirmation and/or certification agreement with a disclaimer excluding specific functions or risks of the object of certification that may have an impact on the fundamental safety requirements.

It is also inadmissible as an accredited conformity assessment body on the market to offer confirmations of conformity for requirement documents (in particular standards/norms/schemes) which are no longer in line with the state of the art or are in conflict with the efforts at harmonisation made in EN standards (see also section 4.6).

Suspension, reduction or withdrawal of accreditation

In accordance with requirements 4.3.1 c) and e) of 17011, the CB must provide evidence that it has made appropriate contractual arrangements to preclude any further use of the certificates concerned in the event of the suspension, reduction or withdrawal of accreditation, provided that the statement of conformity includes ongoing surveillance. The CB is obliged to contractually agree obligations regarding information and action to this effect.

With respect to its client, the CB must undertake to fulfil the obligations set out in IAF MD:2 in analogous application even in the event of termination of contract, provided that the statement of conformity includes ongoing surveillance.

4.2 (17065) Management of impartiality

4.2.6 d)

As an independent third party (see section 3.12, 4.2.2, 17065; section 4.5, 7.6, DIN EN ISO/IEC 17000:2020), the CB is not permitted to offer consultancy in the business segment of the CAB.

4.3 (17065) Liability and financing

4.3.1

Evidence of the adequacy of reserves or insurance cover must be provided in the form of a written documented assessment of risk (area of activity, potential consequences of incorrect certification, geographic sphere of activity, expected amount of damage, possible contractual penalties, etc.). This assessment must include all personnel involved in the certification process.

If insurance for specific activities is required by law to cover risks of a CB, this cannot be replaced by reserves.

For CBs that are verifiably subject to state liability in Germany under the rules of official liability pursuant to Section 839 BGB (German Civil Code) in conjunction with Article 34 GG (German Basic Law) or Section 1 of the Law Governing State Liability of the German Democratic Republic, the liability of the state or other bodies under public-law, which is always considered adequate, takes the place of insurance cover or reserves.

For CBs based outside Germany, recognition of state liability claims is reviewed on a case-by-case basis.

4.6 (17065) Publicly available information

4.6. (c)

The description of the rights and duties of applicants and clients with regard to requirements, restrictions or limitations on the use of the name and certification mark of the CB and the manner in which reference to the certification is made be effectively referenced in the certification agreement in accordance with section 4.1.2. This must include the obligation to discontinue any reference to the certification, including before the end of the certificate term where applicable, or to undergo early recertification if the norm, standard or other requirement document at level 4 and 5 on which the certification is based is no longer in line with the state of the art. Insofar as objectively justifiable within the framework of the risk assessment, reasonable transition periods (maximum 3 years) may be used for norm or standard conversions. The CB must specify that it reserves a special contractual right of termination in this case.

6 (17065) Resource requirements

6.2 (17065) Resources for evaluation

6.2.1 Internal resources

The requirements from relevant international standards addressed in section 6.2, 17065 include all harmonised standards existing at level 3.

The DAkkS rules issued for these level 3 standards, including sectoral annexes if any, must also be followed by the CB within the framework of 17065 insofar as they relate to the relevant evaluation type as defined in the certification scheme. In particular for the evaluation type “audit” within the scheme as per 17065, the additional requirements to 17021-1 including the competence requirements for auditors apply.

7 (17065) Process requirements

7.4 (17065) Evaluation

7.4.5

The CB may only accept results of conformity assessment activities (test, inspection or audit results, etc.) completed prior to the application for certification under the following conditions:

- The certification scheme provides for such inclusion of pre-existing results of other conformity assessments;
- The CB can provide evidence on the basis of appropriate records that all relevant requirements of the relevant applicable standards in the 17000 series have been met;
- Records can be used to establish the compatibility of the selection function on which the result was based with the evaluation activity to be replaced;
- There must be technical equivalence in the narrower sense, requiring for example that the measurement uncertainty for the result to be adopted is within the permissible range in the body adopting it or that other requirements of the scheme are comparable.

8 (17065) Management system requirements

8.4.1

As evidence of compliance with the requirements for accreditation (see section 4.2 point (a) of DIN EN ISO/IEC 17011), the CB must keep all mandatory records for at least the duration of the current accreditation cycle and the previous full accreditation cycle.