

DAP-TM-37

Requirements for Certification Schemes and Systems for the Accreditation based on ISO/IEC Guide 65 / DIN EN 45011

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Requirements for Certification programmes (schemes) and systems for the Accreditation based on DIN EN 45011 (ISO/IEC Guide 65)

1. Introduction

In ISO/IEC Guide 67 a certification programme (scheme) is defined as specific requirements, specific rules for conducting conformity assessment for specific products.

This technical note defines the requirements and minimum criteria for the content of certification programmes (schemes) for products and processes or their combination.

The requirements for bodies, which operate certification systems based on the above mentioned programmes, are defined in DIN EN 45011. This document specifies, in particular Clauses 4.1.3 and 6 of DIN EN 45011.

This document is for the application of product certification bodies, who apply for accreditation based on the DAP rules and regulations or for those already accredited. At the same time, it is also meant for bodies, which develop their own certification schemes or programmes, so called the Scheme Owners, who may wish to review if their scheme is suitable for accreditation, and wish to have this recognised as such.

Note

The term “product” used in this document describes products, processes and services or a combination of these.

2. Definitions

The definition of the term certification system and certification programme (or scheme) is derived from ISO/IEC Guide 67:2004, which is based on the definitions 2.7 and 2.8 of EN ISO/IEC 17000:2005

2.1. Certification programme (or scheme)

Certification system related to specific products to which the same specified requirements, rules and procedures apply (on the basis of Definition 2.8 of EN ISO/IEC 17000:2005).

2.2. Certification system

Rules, procedures and management for the carrying out third party conformity assessment (on the basis of Definition 2.7 of EN ISO/IEC 17000:2005)

The certification system of a certification body may constitute the application of a certification programme.

3. Elements of certification programme (or scheme)

3.1 Identification of the object of certification (scope)

The certified products must be clearly identifiable. For this purpose, the following information (where applicable) is required:

- Specification of product(s), including where applicable
 - o planned application or use,
 - o exclusion of products
- Results of processes for customers or interested parties,
- Providers (Producers/manufacturers, suppliers)
- Delivery (Amount, packaging),
- Place(s) of production

3.2 Certified properties

The certification programme (or scheme) constitutes properties of the product, i.e. requirements including possible interpretations to these requirements, which serve as the basis for reviewing or evaluating the object of certification and hence with that, present the certification content. The basis or principles for evaluation can be among others the following:

- Certification standards, produkt specifications, legislative norms and directives,
- Specific criteria, which the certification body has defined for the corresponding certification system (e.g. as opposed to existing legislative requirements)

Certification criteria must fulfil the requirements of ISO/IEC Guide 7 in general, i.e. they must be clear, precise, measurable and verifiable.

Whenever possible, standards and specifications are to be cited with their precise references (e.g. title, date, revision status, or where applicable also part of the standard).

3.3 How assessment of conformity of the product is conducted

The certification programme (or scheme) must describe how (manner or method) conformity assessment of an intended certification is carried out. This covers the first evaluation (including sampling, testing or inspection, evaluation and decision) and, where relevant, the *surveillance* of certified products as well as the procedure of the certification body for dealing with modifications of certified products. These are defined:

- in Clause 6 of ISO/IEC Guides 67:2004 (Elements and types of product certification systems),
- in Clause 4.6.2 of DIN EN 45011:1998; (Procedures for granting, maintaining, withdrawing...)
- in the Clauses 10 (Evaluation) and 13 (Surveillance) of DIN EN 45011:1998

3.4 Requirements for the certification body

Certification programmes comprise requirements for the certification bodies regarding e.g.

- Organisation,
- Method of operation (Modus Operandus),
- Personnel,
- Working equipment and accoutrement or gear
- Documentation (reports, certificates)

4 Requirements for the certification programme

4.1 General

A document, which constitutes exclusively one or more aspects, described in the above clauses 3.1 to 3.4 for example a normative document or interpretation document will not be considered as a programme or a scheme. The evaluation of programmes or schemes will be based on the structure described above.

Certification programmes must be established by personnel, who are demonstrably competent. This competence relates to the technical requirements as well as the method of conformity assessment. It must be proven that the parties concerned such as the producers, consumers or users, authorities, etc. (Clause. **4.1.3** and **6** of DIN EN 45011) were involved in the development process and that a balance of interests is ensured.

Certification programmes or schemes must be publicly accessible.

Before an assessment for accreditation can take place, it must be proven that the certification programme (or scheme) is appropriate (validation). This means that at least, the programme must have undergone a test phase, with its results, it can be shown that the programme is appropriate in practice and that it meets the expectations of the programme or scheme developer (Scheme Owner). The validation must prove that the conformity assessment as described is feasible and that the results are reproducible and reliable.

4.2 Certification based on DIN EN 45011 (ISO/IEC Guide 65)

- The conformity declaration provided by the certification body is related to a clearly identified product (refer to DIN EN 45011, Clause **1.1** and Guidance IAF GD5:2006)
- Requirements, for which their product is identified, must be clearly specified. This can be done, such that reference may be made to other documents e.g. legislative documents, standards or technical specifications. The requirements must enable an objective conformity assessment. (Subjective statements such as “adequate”, “sufficient” or other similar ones must therefore be avoided). Where applicable, limit values and tolerances must be provided (cf. also IAF GD 5 regarding Clause **4.1.3** of DIN EN 45011 or for the certification of services and processes Annex 1 or Annex 2 of IAF GD 5:2006).
- Private commercial programmes (or schemes) must take relevant legislative requirements into consideration.
- If a programme or scheme also includes management system requirements, these must be considered in addition as well (cf. ISO/IEC Guide 53). The fact that such requirements are included into the programme (or scheme), does not mean that declarations or certifications may cover the management system (Clause **12.3** of DIN EN 45011).
- The activities of the certification bodies, carried out for the assessment of conformity, (Clause **4.3** of DIN EN 45011), must prove to be appropriate for the set objective. The method must describe, for example if and how many samples are taken.

- A programme must also describe how (the manner in which) results are interpreted and what conclusions (consequences) can be drawn from these results (Clause **4.6, 10 and 12** of DIN EN 45011). Here it must be made clear and defined, which nonconformities would deter certification or what can lead to a reduction of the scope of certification or to a withdrawal of certification.
- In the certification programme (or scheme), the requirements for the competence of personnel, who are involved in the certification process, must be stated clearly. (Clause **5** of DIN EN 45011)
- The programme or scheme must, where applicable describe, how activities on the surveillance of the continued fulfilment of the certification criteria, are carried out (IAF-GD 5, Clause **13** of EN 45011).
- The certification system must be indicated on the declaration / the certificate (Clause. **12.3** of DIN EN 45011, please also refer to ISO/IEC Guide 67, ISO/IEC Guide 28 and IAF-GD5, G.12.8).
- If the right for using a mark (Certification mark Clause **14** of DIN EN 45011) is granted together with the certification, the general requirements from ISO/IEC 17030 must be applied.

5 Annex 1 Checklist for the review of certification programmes (schemes)

5.1 Application

The following checklist is considered

- for the self-evaluation of certification programmes (schemes) by organisations, which have developed them and that wish to bring them into the market,
- for the self-evaluation of certification systems by certification bodies apply them for the implementation of certification programmes (schemes),
- for the review and evaluation of certification programmes or schemes by DAP.

5.2 Criteria Catalogue

1	General
	<ul style="list-style-type: none"> - Title/Identification of the programme or scheme, where applicable ID-Code - Version, Issue date - Organisation, which administers the programme or scheme (Scheme Owner) - Description of the subject of certification - Requirements, which form the basis of certification - Description of mark (conformity mark) and their rules, where relevant - Identification of the standard, on which accreditation is based (where relevant)
2	Certification activities
	<p>for initial certification, surveillance, recertification, each</p> <ul style="list-style-type: none"> - Description of the required steps for testing/auditing - Description of the required steps for evaluation - Description of the certification decision
3	Requirements for the certification body
	<ul style="list-style-type: none"> - specific requirements for the competence of the personnel engaged in the certification process (detailed for every step in the process) - other requirements (technical or organisational/management in nature)
4	Questions on the certification programme (or scheme)
4.1	Theme / Subject
	<ul style="list-style-type: none"> - What is the object of certification, what is being certified: which product(s) is/are included in the statement of conformity? What aspects of the product are covered?
4.2	Certificate
	<ul style="list-style-type: none"> - What is the actual statement of conformity? - What validity conditions (duration, volume/amount, delivery) apply? - Is the relevant certification system mentioned or is it referred to?
4.3	Mark of conformity
	<ul style="list-style-type: none"> - What importance does the mark have in the market? - How can one track the mark to the certification scheme (traceability to the certification process)?
4.4	Certification requirements
	<ul style="list-style-type: none"> - Which standard or which normative document contains the requirements? - How is it ensured that the requirements, which are transparent and reviewable, formulated? - Are the relevant legislative requirements in the programme or scheme taken into consideration or fully adopted into the scheme?

	<ul style="list-style-type: none"> - Are legislative requirements exclusively adopted into the programme/scheme? What is the value add of the certification programme/scheme for the customers? - Are the clarifications/interpretations for the requirements? Are these published? From whom have these been established?
4.5	Certification procedures / methods
	<ul style="list-style-type: none"> - What procedures/methods/means do you apply for the certification or the surveillance to ensure that the requirements are continuously met by the certificate holder? - Have you described your certification procedures? - How do you prove that they are valid or that they are in practice?
4.6	Conditions
	<ul style="list-style-type: none"> - What specifications and evaluation criteria have you defined for the granting, maintenance, extension and reduction of scope, renewal and suspension or withdrawal of certification? - Is your definition of nonconformities consistent with the accreditation standard (EN 45011) and the IAF-Guidance GD 5:2006? - What rights and obligations have you specified for you as the certification body and for the applicants or certificate holders, and where (what documents)? - What procedures have you established for resolving complaints from the certificate holders?
4.7	Competence of personnel
	<ul style="list-style-type: none"> - What requirements on competence have you specified for the testing personnel/inspectors/auditors/personnel who perform evaluation? - What requirements on competence have you specified for personnel who are involved in the certification decision? - What requirements on competence have you specified for other personnel? - How can you demonstrate that these competence criteria or requirements are appropriate or justifiable?
4.8	Publications
	<ul style="list-style-type: none"> - Which documents are publicly accessible? - How are these published? - How do you make the list of certificate holders (certified products) public? - Does the list contain all the required information?

6 Applicable documents

- DIN EN 45011:1998 General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)
- IAF GD 5:2006 Guidance on the Application of ISO/IEC Guide 65:1996
- ISO/IEC Guide 7:1994 Guidelines for drafting of standards suitable for use for conformity assessment
- ISO/IEC Guide 23:1982 Methods of indicating conformity with standards for third-party certification systems
- IAF PL 3:2004 IAF Policies and Procedures for Industry Specific Programs
- EA-2/11 - EA Policy for Conformity Assessment Schemes, 2006
- ISO/IEC Guide 67:2004 Conformity assessment - Fundamentals of product certification
- ISO/IEC Guide 53:2005 Conformity assessment - Guidance on the use of an organization's quality management system in product certification

This technical note was developed based on the **RvA-T33** document on "evaluation of programmes for conformity assessment", 2007-12, and the French standard **NF X 50-067** "Elaboration on the technical requirements of certification of product or service or a combination of both", 2008-01.