

List of required documents for the accreditation as a Certification Body according to DIN EN ISO/IEC 17065

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Required documents shall preferably be submitted electronically, in the way that the numbering can directly be assigned to the relevant documents. For submission the Deutsche Akkreditierungsstelle GmbH (DAkkS) provides a **structured zip-folder** where the required documents should be stored electronically and resend to the DAkkS. In individual cases it may be necessary to submit documents in hard copy.

All documents/evidences must be submitted¹ <u>immediately after request²</u>. By sending the documents the CAB ensures DAkkS the completeness of the submitted documents. If necessary, further documents may be required by DAkkS or the assigned assessor.

Documents must be submitted in German or English language.

No.	Document
1.	Complete documentation of the management system of the certification body and of the granted/applied scope of accreditation (quality management manual, procedures, work instructions or other specifications with regard to the applied/accredited certification schemes)
2.	List of all quality management (QM) documents (including version and/or date of validity)
3.	Most recent management review with contents according to DIN EN ISO/IEC 17065 section 8.5.2 and 8.5.3
4.	Evidence of organisational structure, ownership and legal form of the certification body (trade register excerpt, list of shareholders, organisation chart(s))
	If the certification body is part of an organisation (within the legal entity or within a larger corporate structure) the ownership structure, the integration within the organisation and the relations to other organisational units must be submitted with appropriate information (e. g. with detailed organisational charts and lists of shareholders of all sub-organisations).
5.	Coverage of existing liability risks, e. g. evidence of a liability insurance including information about the scope of insurance (liability and financial loss) or information on an equivalent solution.
6.	Current information regarding the number of employees ³ for all activities of the certification body broken down according to their function ⁴ , (with information about qualification requirements for each function), working area ⁵ and the contractual binding ⁶ to the certification body as well as model contracts for external employees.
7.	List of contractors for external provided services (sub-contractors) and other cooperation partners as far as involved in the conformity assessment activities as well as relevant model contracts
8.	Standard contract with clients including current general terms and conditions and if applicable with existing liability limitation clauses
9.	Regulations for the use of marks according to ISO/IEC 17030 – if applicable
10.	Rules of procedures of all established committees – if applicable

¹ The planning of the assessment for initial accreditation or extension of the certification body takes place immediately after confirmation of the application. The documents are requested with this confirmation and must be submitted immediately. If no documents are submitted, the application will be rejected.

Documents for surveillance and reassessment must be submitted immediately upon request.

² To submit documents incomplete or late can be punished as an administrative offence according to § 12 AkkStellG (Accreditation Body Act).

³ Regardless of the extent of employment, each employee counts.

⁴ e. g. auditors, decision makers, administrative employees, etc.

 $^{^{\}rm 5}\,$ e. g. depending on the certification programme within the scope of accreditation.

⁶ Permanent employees (internal) or further employees bound by contract (external).



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No.	Document
11.	Evidence of obligation of the certification bodies top management regarding the impartiality according to DIN EN ISO/IEC 17065 section 4.2.5
12.	Up to date analysis of risks regarding the impartiality including the analysis of related bodies according to DIN EN ISO/IEC 17065 section 4.2.3 and 4.2.4 and presentation of the mechanism for safeguarding impartiality according to DIN EN ISO/IEC 17065 section 5.2
13.	Directory of certified organisations – broken down to the certification schemes and countries (for cross-border certifications)
14.	List of all countries in which certifications have been issued with information on the number of certificates in each country
15.	List of countries with a permanent office address where certification activities are processed with information to each activity
16.	Regulations of the certification body for the management of foreign permanent locations or of "remote personnel"
17.	Sample-certificates for each accredited/applied certification area/certification scheme
18.	Documentation of certification rules and - procedures, submission of all certification schemes and notices of determination regarding the suitability for accreditation of certification schemes , if applicable
19.	Fee regulation or price list as well as all distribution agreements with third parties and performance-based remunerations of employees and contractual partners
20.	List of all authorised auditors/inspectors with information on assignment extent and location (country)
21.	List of employees who process certification activities as "remote personnel" (employees who do not work at a permanent office-address) with information on function(s) within the certification process
22.	Explanation on used IT-systems and their function and a description of interfaces between those IT-systems as well as to external databases/archive systems including the process of release of those systems
23.	Filled Partial Assessment Report/Checklist DIN EN ISO/IEC 17065
	The template to be filled in is included in the zip-folder. Document will be submitted to DAkkS electronically (Word-document).
24.	Submission of a copy of all certificate-relevant technical standards or standards which are referred in the certification schemes or to accredited activities stated in the certificate, as far as DAkkS does not determine a different regulation ⁷ .
	Each standard (level 4 or 5) which is stated on the certificate must be submitted in copy for examination purposes. The provision is permitted license free according to § 45 Copyright Act §45 Urheberrechtsgesetz (§ 45 UrhG)
	These documents will be send separately from the other listed documents in a separate zip-folder. The identification of the normative documents is part of the respective file name. If the normative documents within the scope of accreditation have already been submitted by the certification body, only the normative documents concerning changes of the scope shall be submitted.

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 $^{^{7}}$ Publicly freely accessible documents that are subject to the accreditation scope do not have to be submitted.



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No.	Document
25.	Clearance certificates ⁸ (only for the area AZAV)
	Excerpt Central Federal Register (Bundeszentralregister) for key-personnel
	Tax authority
	Social insurance agencies
	Employers' liability insurance association

Additional required documents of using a non-accredited <u>internal</u> testing laboratory, or of non-accredited testing-, calibration- or examination procedures processed within the certification procedures.

No.	Document
26.	List of testing-, calibration- and examination methods processed within the certification procedures
27.	List of reference materials used for procedures stated under 26.
28.	Current list on the participation in proficiency tests such as round robin tests and interlaboratory comparisons and EQAS ⁹ according to published rules of DAkkS. (No submission of certificates)
29.	Metrological traceability: List of equipment with in-house registration (including used rental equipment, used working standards as well as equipment/facilities which are not under permanent control of the CAB).
	Necessary information: Inventory-No., location, measurand (of which an evidence of the metrological traceability must be available), name of the equipment/type of equipment/object, producer, calibration-/functional checks interval, identification/name of the evidence(s) regarding metrological traceability, type of measurement traceability (regarding 71 SD 0 005_e).
	Optional specifications: Testing standard, serial number, responsible person for the equipment, and others
30.	Spatial plan with information on testing-, calibration-, examination areas including information about the use of mobile facilities for the testing-, calibration - and examination activities
31.	In cases of testing- and calibration procedures: Checklist/report according to DIN EN ISO/IEC 17025 section 6 and section 7 filled (documents will be submitted to DAkkS electronically (Word-document))
	In cases of medical test methods: Checklist/report according to DIN EN ISO 15189 section 4.1 and section 5 filled (documents will be submitted to DAkkS electronically (Word-document))

⁸ Not older than three month.

⁹ External Quality Assessment Schemes.