

	List of required documents for the accreditation as a Provider of Proficiency Testing according to DIN EN ISO/IEC 17043	LI-EU_EP_EN	
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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 immediately after request². 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.	<p>Complete documentation of the management system of the PT-provider and of the granted/applied scope of accreditation (quality management manual, procedures, work instructions or other specifications with regard to the applied/accredited PT-programs)</p> <p>The following instructions / documents must be included:</p> <ul style="list-style-type: none"> • Planning • Stability evaluation • Homogeneity evaluation • Choice of the statistical model • Preparation, storage and distribution of the PT items • Determination of reference value (assigned value) and evaluation criteria (standard deviation for proficiency assessment) • Performance evaluation of the participants
2.	List of all quality management (QM) documents (including version and/or date of validity)
3.	Most recent management review with contents required by the standard
4.	<p>For accreditations with a variable scope: A current list of all offered proficiency testing schemes within the scope of accreditation (including the marking of the last implemented proficiency tests)</p>
5.	<p>Evidence of organisational structure, ownership and legal form of the PT-provider (trade register excerpt, list of shareholders, organisation chart(s))</p> <p><i>If the PT-provider 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)</i></p>
6.	Coverage of existing liability risks, e. g. evidence of a liability insurance about the scope of insurance (liability and financial loss) or information on an equivalent solution.

¹ The planning of the assessment for initial accreditation or extension of the PT-provider 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).

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No.	Document
7.	Current information regarding the number of employees ³ for all activities of the PT-provider broken down according to their function ⁴ , working area ⁵ and the contractual binding ⁶ to the PT-provider
8.	Contracts: <ul style="list-style-type: none"> • General Terms and conditions (if available) • Model contracts with clients or reference to applicable QM documents regarding the order processing • Model contracts with external employees • Contracts with sub-contractors
9.	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.
10.	List of the proficiency testing (PT) schemes organized within the last three years <i>(Use the attached Excel file LI-EU_EP_A1_EN)</i>
11.	Copy of at least one original PT-report for each accredited/applied PT-scheme
12.	One model certificate/one model certificate of attendance of a PT scheme for each of the fields applied for, if applicable
13.	Documents related to subcontracting⁷ (if applicable): <ul style="list-style-type: none"> • Documented procedure on subcontracting, including criteria for the involvement of subcontractors in the organization of PTs • List of activities subcontracted structured according to the fields of PT • List of subcontractors with field of activities • Objective evidences of competence of the subcontractors for the tasks performed (e.g. copies of an accreditation certificate with annex, audit reports or similar evidences)
14.	Documents regarding the advisory groups involved (if applicable): <ul style="list-style-type: none"> • Documented procedure for the involvement of advisory groups • List of advisory groups with their fields of activities • Members lists including relevant information of expertise, activities and contractual relationship of the people (e. g. affiliation to companies and organisations)
15.	Spatial plan indicating the areas relevant for organization of PTs
16.	<i>List of equipment used for the production of PT-subjects (without measuring instruments) with house-made registration (including used rental equipment, if applicable).</i> <i>Necessary information: inventory number, location, use, name of equipment/type of equipment/object, producer</i>

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

⁴ e. g. technical employees top management, consultants/experts, etc. according to the job title within the PT-provider.

⁵ e. g. inorganic parameter, organic parameter, according to the organisation of working areas by the PT-provider.

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

⁷ If applicable according to the annex of the application.

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No.	Document
17.	<p>Filled Partial Assessment Report/Checklist DIN EN ISO/IEC 17043</p> <p><i>The template to be filled in is included in the zip-folder. Document will be submitted to DAkKS electronically (Word-document).</i></p> <p><i>The zip folder contains both checklists during the transition period from DIN EN ISO/IEC 17043:2010 to DIN EN ISO/IEC 17043:2023. Please complete the checklist applicable to the assessment.</i></p>
18.	<p>Normative documents within the scope of accreditation</p> <p>Submission of a copy of all certificate-relevant technical standards or standards for the activities of the PT-provider in the accredited area, unless otherwise specified by the DAkKS.</p> <p>All standards, documents equivalent to standards, in-house-methods, etc., which form the basis for the organisation of proficiency tests in the accreditation area and contain requirements for the performance of activities within the scope of accreditation⁸.</p> <p>(The provision is permitted license-free according to § 45 Copyright Act (§45 Urheberrechtsgesetz (UrhG))</p> <p><i>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 PT-provider, only the normative documents concerning changes of the scope shall be submitted.</i></p>

⁸ Publicly freely accessible documents that are subject to the scope of accreditation do not have to be submitted.

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Additional required documents in case of using a non-accredited internal testing/calibration/medical laboratory or of non-accredited testing, calibration or examination procedures used for characterization of PT-items

No.	Document
19.	List of testing -, calibration - and examination procedures applied in the framework of the PTs
20.	List of reference materials used for the procedures mentioned in No. 19
21.	Current list for participation in proficiency testing, like ring tests and interlaboratory comparisons as well as EQAS ⁹ according to DAkkS-rules (only submit the lists, no participants lists of individual proficiency testing)
22.	<p>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).</p> <p>Necessary information: Unique identification, 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) to the metrological traceability, type of measurement traceability (regarding 71 SD 0 005_e).</p> <p><i>Optional specifications: Testing standard, serial number, responsible person for the equipment, and others</i></p>
23.	Spatial plan with indication of the testing, calibration and examination fields including information on using mobile equipment for testing, calibration and examination activities
24.	<p>In the case of testing and calibration procedures: Filled Partial Assessment Report/Checklist DIN EN ISO/IEC 17043 <u>clause 6 and clause 7 filled in</u> The template to be filled in is included in the zip-folder (document shall be provided electronically (word file) to DAkkS)</p> <p>In the case of medical examination procedures: Filled Partial Assessment Report/Checklist DIN EN ISO 15189:2014 (<u>clauses 4.1 and 5</u>) or DIN EN ISO 15189:2023 (clauses 5-7) respectively. The template to be filled in is included in the zip folder (document shall be provided electronically (word file) to DAkkS)</p> <p><i>The zip folder contains both checklists during the transition period from DIN EN ISO 15189:2014 to DIN EN ISO 15189:2023. Please complete the checklist applicable to the assessment.</i></p>

⁹ External Quality Assessment Schemes.