	List of required documents for the accreditation as a Provider of proficiency Testing Schemes 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 case manager. In individual cases documents must be submitted in hard copy. The case manager will inform you accordingly.


All documents/evidences must be submitted¹ before the assessment in due time². By sending the documents the CAB ensures DAkkS the completeness of the submitted documents. If necessary, further documents may be required by the case manager 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
4.	<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>
5.	Risk analysis and liability estimation for the calculation of an appropriate level of insurance and evidence of a liability insurance or an equivalent solution (especially for financial loss). Information on scopes with a statutory insurance obligation.
6.	List of employees stating their qualification/professional training/responsibilities at all levels of the activity of the PT-provider

¹ To submit documents incomplete or late can be punished as an administrative offence according to § 12 AkkStellG (Accreditation Body Act)

² The assessment for initial accreditation of the PT-provider will be scheduled not before the required documents are submitted completely. In case of surveillance, extension of accreditation or reaccreditation documents shall be submitted at least 6 weeks before the scheduled assessment.

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No.	Document
7.	Standard contract with clients including current terms and conditions and with existing liability limitation clauses, if applicable.
8.	Regulations for the use of marks ³ – if applicable
9.	List of existing contractual regulations with external personnel (e. g. consultants), contractors (sub-contractors) and other cooperation partners as far as involved in the conformity assessment activities as well as samples of relevant contracts.
10.	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.
11.	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>
12.	Copy of at least one original PT-report for each accredited/applied PT-scheme
13.	One certificate/one Certificate of Attendance of a PT scheme for each of the fields applied for, if applicable
14.	Documents related to subcontracting⁴ (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) • All contracts with subcontractors
15.	Documents regarding the advisory groups involved (if applicable) (according to clause 4.4.1.4 f of DIN EN ISO/IEC 17043): <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)
16.	Spatial plan indicating the areas relevant for organization of PTs
17.	Last annual report with information on/data of the PT-provider and performed PT's (Exception: Initial assessment) <i>The template to be filled in is included in the zip-folder. Document will be submitted to DAkkS electronically (Excel-document).</i>
18.	Filled Partial Assessment Report/Checklist DIN EN ISO/IEC 17043 <i>The template to be filled in is included in the zip-folder. Document will be submitted to DAkkS electronically (Word-document).</i>

³ Only relevant in the case where the provider of proficiency tests issues its own marks for use by itself or its customers.

⁴ If applicable according to the annex of the application

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No.	Document
19.	<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 are applied for accreditation or belong to the scope of accreditation and contain requirements for the performance of activities in the context of DIN EN ISO/IEC 17043, as well as other documents which are or shall be listed in the annex to the certificate shall be submitted⁵.</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 contained in 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>

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
20.	List of testing -, calibration - and examination procedures applied in the framework of the PTs
21.	List of RM used for the procedures mentioned in No. 20
22.	Current list for participation in proficiency testing, like ring tests and interlaboratory comparisons as well as EQAS ⁶ according to DAkkS-rules (<i>No submission of certificates</i>)
23.	<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>
24.	Spatial plan with indication of the testing, calibration and examination fields including information on using mobile equipments for testing, calibration and examination activities
25.	<p>In the case of testing and calibration procedures: Partial Assessment Report/Checklist DIN EN ISO/IEC 17043 <u>clause 6 and clause 7 filled in</u> (document shall be provided electronically (word file) to DAkkS)</p> <p>In the case of medical examination procedures: Partial Assessment Report/Checklist DIN EN ISO 15189 <u>clause 4.1 and clause 5 filled in</u> (document shall be provided electronically (word file) to DAkkS)</p>

⁵ Publicly freely accessible documents that are the subject of the accreditation scope do not have to be submitted.

⁶ External Quality Assessment Schemes