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 submitted[1] immediately after request[2]. 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 biobank and of the granted/applied scope of accreditation (quality management manual, procedures, work instructions, SOPs or other specifications with regard to the applied/accredited scope, including sampling, sample preparation, preservation and process control)
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 20387 section 8.9.2 and 8.9.3
4.	Evidence of organisational structure, ownership and legal form of the biobank (trade register excerpt, list of shareholders, organisation chart(s)) *If the biobank 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 biobank broken down according to their function[4] working area[5] and the contractual binding[6] to the biobank as well as model contracts for external employees. List of employees stating their qualification/professional training/responsibilities at all levels as required by DIN EN ISO 20387
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.	Sample of a report for each material intended for issue under accreditation
9.	Current general terms and conditions and, if available, model contracts for the order processing with clients as well as general descriptions of the order processing (if appropriate, reference to applicable QM documents)

[1] The planning of the assessment for initial accreditation or extension of the biobank 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. technical employees, managing employees, etc. according the job title within the biobank.

[5] Depending on the organisation of the work areas of the biobank.

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

No.	Document
10.	Evidence of the obligation of the top management of impartiality according to DIN EN ISO 20387 section 4.2.2
11.	Analysis of risks regarding the impartiality including the analysis of related bodies and presentation of managing impartiality according to DIN EN ISO 20387 section 4.2.4 and 4.2.5
12.	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
13.	List of reference materials used, if applicable
14.	Current list for participation in proficiency tests, such as ring and comparison tests according to the published rules of the DAkkS (No submission of certificates)
15.	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*
16.	**Documents relating to subcontracting (if applicable):** • Documented procedure for subcontracting, including criteria for the involvement of subcontractors for all activities subcontracted by the biobank • List of sub-contractors including subcontracted activities, if applicable broken down by materials held by the biobank • 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 sub-contractors
17.	Spatial plan with information on work areas including information on using mobile equipment, if applicable
18.	Filled Partial Assessment Report/Checklist DIN EN ISO 20387 as Word file *The template to be filled in is included in the zip-folder.* *The document will be submitted to DAkkS electronically (Word-document).*

No.	Document
19.	**Normative documents within the scope of accreditation** Submission of a copy of all certificate-relevant technical standards or standards for the activities of the biobank in the accredited area, as far as DAkkS does not determine a different regulation. 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 20387, as well as other documents which are or shall be listed in the annex to the certificate shall be submitted[7]. (The provision is permitted license-free according to § 45 Copyright Act (§45 Urheberrechtsgesetz (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 biobank, only the normative documents concerning changes of the scope shall be submitted.*

[7] Publicly freely accessible documents that are subject to the accreditation scope do not have to be submitted.