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 submitted[1] before the assessment in due time[2]. 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.	**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
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)* Evidences about structure, ownership and legal structure of the integrated legal entities as well as information about further accreditations of these legal entities must be submitted.
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 as required by ISO 20387
7.	Copy of at least one original report for each material intended for issue under accreditation
8.	Standard contract with clients including current terms and conditions und if applicable with existing liability limitation clauses
9.	Regulations for the use of marks [3] – if applicable

[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 biobank 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.

[3] Only relevant if the biobank issues its own labels for use by itself or its customers.

No.	Document
10.	List of existing contractual regulations with external personnel (e. g. sampler), contractors (sub-contractors) and other cooperation partners as far as involved in the conformity assessment activities as well as samples of relevant contracts
11.	Impartiality declaration of the top management
12.	Analysis of risks regarding the impartiality including the analysis of related bodies and presentation of managing impartiality
13.	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
14.	List of reference materials used, if applicable
15.	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)
16.	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*
17.	**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 subcontractors
18.	Spatial plan with information on work areas including information on using mobile equipment, if applicable
19.	Last annual report with information on/data of the biobank and performed activities within the scope of accreditation *The template to be filled in is included in the zip-folder.* *Document will be submitted to DAkkS electronically (Excel-document).*
20.	Filled Partial Assessment Report/Checklist ISO 20387 as Word file *The template to be filled in is included in the zip-folder.* *Document will be submitted to DAkkS electronically (Word-document).*

No.	Document
21.	Completed applications and checklists, if applicable (Please make sure to send the completed applications in Word format to the responsible case manager.)
	– List of methods applied for accreditation (if there is a change to the application)
22.	**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 ISO 20387, as well as other documents which are or shall be listed in the annex to the certificate shall be submitted[4]. (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 contained in 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.*

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