

ACCREDITATION COMMISSION FOR CONFORMITY ASSESSMENT BODIES

QUALITY MANUAL

References, Terminology & Definitions Used

Authorized By:

Issue No.: 01

Date: 01/09/2010

Doc. No.: ACCAB-QM-4.0

BOD

Revision: 00

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Effective Date: 01/09/2010

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4.1	Purpose:
4.1.1	To define the meanings of terminologies and abbreviations used in this manual.
4.2	Scope:
4.2.1	Applicable to quality management system of ACCAB.
4.2.2	The definitions contained in the following documents along with cross-referred documents are applicable.
4.2.3	Additional information for clarity is acceptable provided it does not conflict with the governing standards.
4.3	Operation:
4.3.1	Accreditation:
4.3.1.1	Third-party attestation related to a conformity assessment body conveying a formal demonstration of its competence to carry out specific assessment tasks.
4.3.2	Accreditation Body:
4.3.2.1	A body responsible for third party attestation related to conformity assessment and calibration facilities conveying a formal demonstration of their competence to carry out tasks against specified criteria, including that of given in the international guides and the standards.
4.3.3	Accreditation Certificate:
4.3.3.1	A formal document or a set of documents, stating that accreditation has been granted for the defined scope.
4.3.4	Accreditation Criteria:
4.3.4.1	The requirements and conditions that have to be met before a laboratory, body, proficiency scheme provider or certification body can be considered for accreditation by ACCAB.
4.3.5	Accreditation Schedule for Calibration Laboratory:
4.3.5.1	A document describing the parameters ranges and best measurement capabilities for which a calibration laboratory is accredited. The document also contains other information including the names of authorized signatories of laboratory certificates.
4.3.6	Accreditation Schedule for Testing Laboratory:
4.3.6.1	A document that defines the scope of accreditation in terms of materials/products tested, types of tests, properties measured and range of measurements. The techniques and test methods for which accreditation applies are identified as well as the names of authorized signatories of test reports.

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4.3.7	Accredited Body:
4.3.7.1	An organization or facility that has been accredited by ACCAB.
4.3.8	Advisory Committee:
4.3.8.1	A voluntary committee consisting of industry / stakeholder's and other individuals representatives with an interest in accreditation, established by the board and whose main object is to provide strategic/technical advice , guidance and inputs to the board of ACCAB.
4.3.9	Appeal:
4.3.9.1	Request by a CAB for re-consideration of any adverse decision made by the ACCAB related to its desired status.
4.3.9.2	Note: Adverse decisions include: <ul style="list-style-type: none"> a. refusal to accept an application; b. refusal to proceed with an assessment; c. changes in accreditation scope; d. corrective action requests; e. decisions to deny, suspend or withdraw accreditation and f. any other action that impedes the attainment of accreditation.
4.3.10	Applicant:
4.3.10.1	The body seeking accreditation from ACCAB.
4.3.11	Accreditation Approval Committee (AAC):
4.3.11.1	A ACCAB committee whose task is to determine whether an applicant meets all relevant ISO/IEC guides, International Standards, OECD principles of GLP and ACCAB requirement documents etc. and as such is eligible for accreditation compliance as appropriate. This committee may be composed of only one person.
4.3.12	Assessment:
4.3.12.1	A process undertaken by ACCAB to assess the competence of a CAB, based on particular standard(s) and /or other normative documents and for a defined scope of accreditation.
4.3.12.2	Note: Assessing the competence of a CAB involves assessing the competence of the entire operations of the CAB, including the competence of the personnel, the validity of the conformity methodology and the validity of the conformity assessment results.
4.3.13	Assessment Cycle:
4.3.13.1	The period between an initial assessment and a re-assessment.
4.3.14	Assessment Reports:

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4.3.14.1	The reports compiled by the lead assessor in conjunction with the assessment team. Parts of this report are presented to the applicant and his/her representatives immediately following completion of the assessment. The full report is submitted to the Accreditation Approvals Committee (AAC) for approval.
4.3.15	Assessor:
4.3.15.1	A person assigned by ACCAB to, alone or as part of an assessment team, perform an assessment of a CAB.
4.3.16	Audit:
4.3.16.1	Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.
4.3.17	Bilateral Arrangement:
4.3.17.1	An arrangement whereby two parties recognize or accept each other's conformity assessment results.
4.3.18	Calibration Laboratory:
4.3.18.1	A body that performs a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or reference material, and corresponding values realized by standards whatever their uncertainty. It ensures that calibration results are traced back to the applicable national/international standards.
4.3.19	Certification Body:
4.3.19.1	An organization that certifies other organizations in respect of the compliance of their management systems, schemes or products with recognized specifications or standards.
4.3.20	Certificate of Competence:
4.3.20.1	A certificate issued to a metrologist who has demonstrated his competence in a specific field of metrology.
4.3.21	Certificate of GLP Compliance:
4.3.21.1	A formal document or set of documents stating that GLP compliance has been demonstrated.
4.3.22	Clearance of Findings Visit:
4.3.22.1	A process undertaken by an ACCAB assessor/s to assess the implementation of corrective actions raised during an assessment. It is during this visit that the Corrective Actions are verified as cleared.
4.3.23	Complaint:

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4.3.23.1	An expression of dissatisfaction other than an appeal, by any person or organization, to ACCAB, relating to the activities of ACCAB or of an accredited CAB, where response is expected.
4.3.24	Complainant:
4.3.24.1	A person / body who has a complaint related to the activities of a CAB or ACCAB.
4.3.25	Compliance Criteria:
4.3.25.1	The requirements and conditions that have to be met before a facility can be considered for compliance status by ACCAB.
4.3.26	Conformity Assessment:
4.3.26.1	The procedure used to determine, directly or indirectly, that the relevant requirement in technical regulations, voluntary standards or any other relevant and validated documentation has been fulfilled.
4.3.27	Conformity Assessment Body:
4.3.27.1	A body that performs conformity assessment services and that can be the object of accreditation.
4.3.28	Consultancy:
4.3.28.1	Participation in any of the activities of a CAB subject to accreditation. Examples: <ul style="list-style-type: none"> a. preparing or producing manuals or procedures for a CAB; b. participation in the operation or management of the system of a CAB; c. giving specific advice or specific training towards the development and implementation of the management system and/or competence of a CAB; d. giving specific advice or specific training for the development and implementation of the operational procedures of a CAB.
4.3.29	Corrective Actions (CA's):
4.3.29.1	The documented action taken by the organization's management to solve each problem noted as a non-conformity by the assessment team.
4.3.30	Dispute:
4.3.30.1	A disagreement with a decision made by ACCAB.
4.3.31	Divisional Head (DH):
4.3.31.1	The person responsible for a particular field of accreditation i.e. specific areas of calibration, testing, inspection, certification, etc.
4.3.32	Expert:

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4.3.32.1	Person assigned by ACCAB to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed.
4.3.33 Extending accreditation:	
4.3.33.1	Process of enlarging the scope of accreditation.
4.3.34 External Accreditation Body:	
4.3.34.1	An accreditation body other than the ACCAB.
4.3.35 External Assessor:	
4.3.35.1	A person employed by an external accreditation body.
4.3.36 Extension Assessment:	
4.3.36.1	Assessment is scheduled if and when required by the organization. An Extension can also include application for approval of personnel.
4.3.37 Franchising:	
4.3.37.1	Franchising is the business practice whereby a franchisor allows a franchisee to use a certain trademark or trading name, and typically supplies support and training in exchange for a recurring royalty fee. The trademark is typically the name under which the business operates. The franchisee is a separate legal entity to that of the franchisor, although this is not necessarily apparent to the customer who assumes that the legal entity is the holder of the trademark or name under which the organization operates. As the franchisee does not own the trademark or name under which they operate, the franchisee is not explicitly identified as the entity that is legally responsible.
4.3.38 GCP(Good Clinical Practice):	
4.3.38.1	International Conference on Harmonization (ICH)'s Good Clinical Practices (GCP) is an ethical and scientific quality standard for designing, conducting and recording trials that involve the participation of human subjects.
4.3.39 GLP (Good Laboratory Practice):	
4.3.39.1	A quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded and reported.
4.3.40 GCP/GLP Inspector:	
4.3.40.1	A person who performs the test facility inspections and study audits on behalf of ACCAB.
4.3.41 Inspection Body:	
4.3.41.1	An organization that performs examination of a product design, product, service, process or plant and

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	determination of their conformity with specific requirements or, on the basis of professional judgment and with regards to applicable requirements.
4.3.42	Interested Parties:
4.4.42.1	Parties with a direct or indirect interest in accreditation.
4.4.42.2	Note: Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests of those who use or rely on accredited conformity assessment services. ACCAB has extended the ISO/IEC 17011:2004 definition to include business, academia, industry and government institutions with an interest in accreditation.
4.4.43	Initial Assessment:
4.4.43.1	An Initial assessment is the first full assessment of the organization. All the disciplines and/or methods indicated on the application form.
4.4.44	Laboratory:
4.4.44.1	Any specialized confined environment used for the performance of scientific work, including laboratories involved in testing work.
4.4.45	Lead Assessor:
4.4.45.1	A competent person registered as a lead assessor with ACCAB, who complies with the relevant ACCAB requirements.
4.4.46	Major Non-Conformance:
4.4.46.1	This category of non-conformance is allocated by the lead assessor against those observations indicating that the technical competence of the organization to continually perform work within the limits of its proposed/approved accreditation schedule/scope has either been or is in imminent danger of being seriously compromised.
4.4.47	Minor Non-Conformance:
4.4.47.1	This category of non-conformance is allocated by the lead assessor against those observations indicating that although the organization has failed to conform to the prescribed accreditation requirements, the failure has no immediate or imminent effect on its competence to perform work within the limits of its proposed/approved accreditation schedule/scope.
4.4.48	Non-Conformance:
4.4.48.1	If the subject of a particular observation is deemed to cast doubt on the organization's ongoing ability to meet ACCAB accreditation criteria, the consultation with the assessment team, shall convert the observation to a non-conformance. Non-conformances are graded as major and minor.
4.4.49	Observation:

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4.4.49.1	This is a comment recorded by a member of the assessment team when noting a situation or action, which may prejudice the organization's ability to meet ACCAB accreditation requirements. A representative of the facility must acknowledge (by signature) that the observation has been accurately recorded.
4.4.50	On-Site Assessment:
4.4.50.1	An assessment performed at a location where specific activities are conducted.
4.4.51	Personnel Records:
4.4.51.1	Records of personnel qualifications, experience etc. which are used to determine eligibility for assessments.
4.4.52	Pre-Assessment:
4.4.52.1	A visit undertaken by the lead assessor to the applicant's organization to determine the applicant's capacity, capability and state of readiness for an initial assessment. This assessment is confined to assessing the quality management system of the organization.
4.4.52.2	Note: In the voluntary domain a pre-assessment is optional, need not cover the entire system in detail and only verbal feedback is given.
4.4.53	Proficiency Testing Scheme:
4.4.53.1	Inter-laboratory comparisons designed and operated to assure laboratory performance in specified areas of testing, measurement and calibration.
4.4.54	Re-Assessment:
4.4.54.1	A procedure performed after the initial assessment and normally after two surveillance assessments for certification bodies and for laboratories, to verify continued compliance with ACCAB accreditation requirements. A re-assessment is scheduled at the end of each assessment cycle.
4.4.54.2	Note 1: A re-assessment can be performed at the end of an assessment cycle.
4.4.54.3	Note 2: A re-assessment can also be performed on an organization in the event of the lifting of a period of suspension.
4.4.55	Regulatory Body:
4.4.55.1	Any governing body that uses accreditation by ACCAB, as the basis for their decision to grant an organization approval to operate within the regulatory domain.
4.4.56	Six-Month Follow-up Assessment:
4.4.56.1	A six-month follow-up assessment is the first assessment of the organization after the initial assessment.

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4.4.57	Specialist Technical Committee (STC):
4.4.57.1	An ACCAB committee of technical experts tasked with providing guidance to ACCAB on technical matters pertaining to accreditation, in their specific field of expertise.
4.4.58	Surveillance Assessment:
4.4.58.1	Set of activities performed at a defined frequency, except reassessment, to monitor the continued fulfillment by accredited CABs of requirements for accreditation. Items are selected from the accreditation schedule in such a manner to ensure that normally after a complete assessment cycle all aspects of the schedule have been covered.
4.4.59	Suspending Accreditation:
4.4.59.1	A process of temporarily making accreditation invalid, in full or for part of the scope of accreditation.
4.4.60	Technical Assessor:
4.4.60.1	A person with appropriate technical competence and recognized training in assessment practice and techniques appointed by ACCAB to an assessment team for the purpose of assessing the technical competence of a facility with respect to their schedule of accreditation.
4.4.61	Technical Expert:
4.4.61.1	A person with appropriate technical competence but who has not undergone or completed ACCAB training in assessment practice and techniques. The Technical Expert is appointed to the assessment team for the purpose of assessing the technical competence of a facility with respect to their schedule of accreditation or for GLP Inspections to assist the Inspectors with the technical component of the inspection activities. A technical expert will normally be accompanied by an ACCAB registered assessor/inspector for the duration of the assessment / inspection. For laboratory accreditation the lead assessor may decide alternatively to monitor the technical expert him/herself and allocate more time (if necessary) to complete the assessment.
4.4.62	Withdrawing Accreditation:
4.4.62.1	A process of canceling the scope of accreditation.
4.4.63	Witnessing:
4.4.63.1	Observation of the CAB carrying out conformity assessment services within its scope of accreditation.