



ACCREDITATION COMMISSION FOR CONFORMITY ASSESSMENT BODIES

CAB Accreditation Policy Document

Document Title: Policy on Laboratory Personnel Qualifications

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Revision Number	Revision Date	Paragraph Number	Description of Revision	Revision Author

1.1	Purpose:
1.1.1	To ensure that personnel qualifications including minimum experience in the relevant field of activity for each position of organization's (laboratory/where relevant inspection body) is documented in the quality management system.
1.2	Scope:
1.2.1	This policy is applicable to ACCAB Accreditation Applicant & Accredited testing and calibration laboratories, medical laboratories and inspection bodies.
1.2.2	This policy is applicable to permanent, part time. Contractual, substitute, temporary and visiting persons.
1.3	Definitions:
	NIL
1.4	Details:
1.4.1	The Organization shall ensure that the qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed.
1.4.2	<p>The Organization shall follow the following requirements as minimum to the personnel, evaluating the test results and approving the calibration certificates and test reports:</p> <ol style="list-style-type: none"> 1. Education: must show that the qualification holder has successfully completed a university or equivalent technical or higher education or post-secondary course of at least 3 years duration, or of an equivalent duration part-time at a university or establishment of higher education or another establishment of similar level conforming to the field of activity. National, regional and local regulations should apply with regard to qualifications and training. 2. Experience: not less than 3 years in the relevant field of testing and calibration. 3. Training: where appropriate, that he/she has successfully completed the professional training required in addition to the post-secondary education conforming to the field of activity. 4. Appropriate continual education/ongoing training.
1.4.3	<p>The Organization shall follow the following requirements as minimum to the quality managers:</p> <ol style="list-style-type: none"> 1. Education: must show that the qualification holder has successfully completed a university or equivalent technical or higher education or post-secondary course of at least 3 years duration, or of an equivalent duration part-time at a university or establishment of activity, where appropriate, that he/she has successfully completed the professional training required in addition to the post-secondary education. National, regional and local regulations should apply with regard to qualifications and training. 2. Experience: not less than 1 year in the relevant field of testing and calibration. 3. Training: training in quality management and internal audit.
1.4.4	The Organization shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.
1.4.5	The Organization shall provide training as appropriate for all personnel which includes the quality management system; assigned work processes and procedures; the applicable laboratory

	information system; health and safety, including the prevention or containment of the effects of adverse incidents; ethics and confidentiality of information.
1.4.6	The Organization shall ensure that personnel that are undergoing training are supervised at all times.
1.4.7	The Organization shall make available continuing education programme to personnel who participate in managerial and technical processes and shall ensure that personnel take part in continuing education.
1.4.8	The Organization shall ensure that the effectiveness of the training programme and the continuing education programme is periodically reviewed.
1.4.9	The Organization shall ensure that following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria.
1.4.10	The Organization shall ensure that in addition to the assessment of technical competence, reviews of staff performance considers the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.
1.4.11	The Organization shall ensure that records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel are maintained.
1.4.12	In case of medical laboratories, the standard ISO 15189:2012 clause (4.1.1.4) states laboratory shall be directed by a person or persons having delegated responsibility and the competence to assume responsibility for the services provided. This implies that the standard accepts team management with responsibilities and competence. The standard does not specify whether the laboratory director should be medically qualified or the academic or professional qualifications one must attain for fulfilling the role. ACCAB accreditation scheme shall consider the academic or professional qualifications required of a laboratory director or directors according to local factors such as the setup of the whole medical system, the local education system and opportunities, public expectation and local economy.
1.4.13	As per ISO 15189:2012 Clause 5.7.1 – The laboratory must have procedures to ensure that authorized personnel review the results of examinations before release and evaluate against internal quality control and, as appropriate, available, clinical information and previous examination results. As far as the personnel qualifications are concerned the clause 5.1.2 states that laboratory management shall document personnel qualifications for each position.
1.4.1.4	ACCAB policy is flexible when assessing a medical laboratory’s personnel qualification and demonstrated competency while placing priority on ISO 15189 requirements as ACCAB accreditation scheme is voluntary and its sole purpose is to facilitate medical laboratories developing their quality management systems and assessing their own competencies and continually improve its effectiveness. The standard acknowledges that a country could have its own specific regulations or requirements to some or all its professional personnel and their activities and responsibilities in this domain.
1.5	References:
1.5.1	Details
	Document Number
	NIL