KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

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Assessor Guide and Terms of Reference

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1 Background Information

1.1 Purpose

This assessor guide is aimed at enabling KENAS Assessors and Technical experts carry out the assessment activities efficiently and effectively with a view to arriving at the same conclusions and to promote the development and maintenance of good practice in conformity assessment.

1.2 Scope

This Assessor guide covers KENAS assessments activities from preparation, conducting, reporting and follow up of assessments to closure. It is applicable to all assessments carried out by KENAS Assessors and Experts that are deployed to carry out assessment of CABs.

1.3 Role(s) and Responsibility

Role	Responsibility
All KENAS Technical Staff	Process owner
SCBO/SCLO	Reviewer
CMLA/CMIV	Recommender
CEO	Approval
Assessment Personnel	Compliance

2 Terms and Definitions

For the purpose of this manual, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the Kenya Accreditation Service Act 2019.

2.1 Acronyms and Abbreviations

CEO	Chief Executive Officer
CMCI	Chief Manager, Certification and Inspection
ILAC	International Laboratory Accreditation Co-operation
IAF	International Accreditation Forum
CAB	Conformity Assessment Body
CAR	Corrective Action Request

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CMLA	Chief Manager, Laboratories
KENAS	Kenya Accreditation Service
SCBO	Senior Accreditation Officer, Certification
SCLO	Senior Accreditation Officer, Calibration Laboratories
MS	Management System

2.2 Definition of Terms

2.2.1 Accreditation

A third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.2.2 Conformity Assessment Body.

A body that performs conformity assessment services and that can be the object of accreditation.

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3 Criteria

3.1 Constitution of an Assessment Team

3.1.1 An assessment team shall be appointed consisting of at least one KENAS technical staff, who shall be the Assessment Team Leader, and one or more Assessor and or Technical Experts, covering the ranges of specialization found in the CAB.

3.1.2 In the case where the scope is small requiring one person to do the assessment, the Assessor chosen shall evaluate both the management system and technical competence of the CAB and hence shall be an Assessor with the necessary technical competence.

3.1.3 The Assessors/ Experts in the team are chosen for their expertise and familiarity with the area of specialization.

3.2 Role of the Assessor

3.2.1 Examine all technical aspects of the management and operation of the CAB relevant to the scope of accreditation sought by the CAB.

3.2.2 Assess the appropriateness of the methods or procedures employed; the adequacy of qualifications, experience and competence of the staff; the suitability of the accommodation/environment; the adequacy of equipment and the soundness of all aspects of the CAB's practice, and to keep notes of his/her observations and conclusions.

3.2.3 Advice the Team Leader on areas of concern and any deficiencies noted during the course of the assessment in preparation of the assessment report.

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3.3 Role of the Team Leader

3.3.1 A Team Leader shall be responsible for the assessment team, knowledgeable and experienced in conformity assessment techniques and the normative standard under assessment.

3.3.2 The team leader shall;

3.3.2.1 Coordinate assessment activities in liaison with the CAB.

3.3.2.2 Obtain full background information on the CAB to be assessed and provide technical information in the form of detailed briefing notes to the Assessor / Technical Experts.

3.3.2.3 Review the CAB's assessor pack provided by the scheme for completeness with clarification of the scope applied.

3.3.2.4 Inform the CAB through the scheme of the outcome of the document review.

3.3.2.5 Arrange in conjunction with the scheme on the date and time of the assessment visit as the scheme make all necessary logistical arrangements (Assessment Plan).

3.3.2.6 Conduct opening and closing meetings.

3.3.2.7 Throughout the assessment, provide advice as required on KENAS's policies and accreditation practices relating to the work under consideration; assist Assessors in their assessment of the CAB; ensure the thoroughness of the assessment; and ensure a consistent approach to the assessment of similar CABs.

3.3.2.8 Assess the quality management system aspects and, in consultation with the Assessor / Technical Expert;

a) Prepare the assessment report which details the findings of the assessment team, and specifies where any corrective actions need to be taken

b) Present these findings to the CAB and seek to resolve any questions that arise before leaving the CAB.

c) Agree on corrective action plan with the CAB.

d) Submit the final report for review by the scheme for onward transition to the CAB.

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3.4 Role of a Technical Expert

3.4.1 The role of a technical expert is to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed and does not assess independently.

3.4.2 The Technical Expert can perform witnessing and evaluate technical signatories under the responsibility of an assessor.

3.5 Terms of reference (TOR) for KENAS Assessors/ Technical Experts

3.5.1 Adhere to all the rules in respect of impartiality and confidentiality as prescribed in **ACC-FM-28**.

3.5.2 Manage assessments of conformity assessment bodies (CABs).

3.5.3 Undertake preliminary assessment site visits to client CAB site(s) where necessary.

3.5.4 Execute desk assessments and or documentation review as required.

3.5.5 Execute onsite assessments of CABs.

3.5.6 Prepare assessment reports in respect of the assessment activities undertaken.

3.5.7 Exercise due diligence, deploy analytical skills, impartiality, diplomacy, independence, thoroughness, objectivity and responsibility in the course of duty.

3.5.8 Exercise high standards of integrity, ethics and professionalism.

3.5.9 Provide any other information required in respect of the assessment activities undertaken.

3.6 Teamwork

3.6.1 Teamwork amongst the Assessors and Technical Experts is important to the success of any assessment. The Assessor / Technical Experts should have no hesitation in consulting the Team Leader for assistance if they feel that the assessment process is being disrupted or that they are not securing the full co-operation of the CAB's staff.

3.6.2 Similarly, the Team Leaders have a duty to ensure that the assessment process is thorough and complete, and they may need to alert the Technical Experts to aspects of the CAB's operation which need to be probed further.

3.7 Appointment of Assessors / Technical Experts

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3.7.1 KENAS maintains a database of Assessors and Technical Experts who are selected for a particular assessment on the basis of their understanding of the normative standard, on their professional knowledge of, and expertise in, the particular area of technology and for their ability to assess and evaluate a CAB's technical aspects.

3.7.2 Assessors / Technical Experts work for KENAS as individuals, not as representatives of their employers or any other CAB with which they may be affiliated. It is however good for them to inform of the organizations they are affiliated with in order to guard against any conflicts. Remuneration of Assessors / Experts is guided by KENAS policies and circulars.

3.7.3 Assessors / Technical Experts are free to accept or decline the invitation to participate in any particular assessment. They should not hesitate to exercise this right if their participation could be a source of conflict to themselves, to their employers or to the CAB to be assessed.

3.7.4 If an Assessor / Technical Expert, having been appointed by KENAS, subsequently finds that he or she does not fully agree with KENAS requirements during assessment, then such reservations should be raised with KENAS so that conflict during the assessment is avoided. Such feedback from Assessors / Technical Experts is an essential element in the on-going development of accreditation criteria. External Assessors / Technical Experts are free to withdraw from the list by giving notice as stipulated in their contractual obligations with KENAS.

3.8 Types of Assessment

3.8.1 An assessment of a CAB can take one of a number of forms, depending upon the particular circumstances:

a) An initial assessment of a CAB.

b) Subsequent assessment activities of an accredited CAB conducted under a given schedule.

c) An assessment for extension of s c o p e of accreditation upon a CABs request.

d) Unscheduled assessment following changes in a CAB's list of approved technical signatories, significant changes of the CABs system; complaint against the CAB necessitating system review, the existence of a dispute over results, poor performance of the CAB in any relevant proficiency programs, or other factors that reduce the level of confidence in the CAB.

e) Re-assessment for renewal of accreditation – This takes the same approach as an initial assessment

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3.9 Initiation

3.9.1 Once the need for an assessment has been established, an assessment team shall be allocated to the assessment. The Scheme shall;

a) Contact the assessment team to determine their availability for the assessment;

b) Advise the authorized representative of the CAB of the assessment team and their affiliations;

c) Secure the authorized representative's approval of the assessment team;

d) In consultation with the authorized representative and the assessment team make all necessary logistical arrangements for the assessment including transport and accommodation;

e) Where necessary, request relevant information and documentation from the CAB; and

f) Avail the Assessor package to the Assessment team and brief the team.

3.10 Assessment Team Briefing

3.10.1 The briefing done by the scheme will include;

a) The purpose of the assessment and any pertinent information arising from previous visits or assessments;

b) The scope of accreditation held or sought by the CAB and any variations now being requested;

c) The facilities available;

d) Where applicable, typical or relevant operational procedures in use in the CAB;

e) Where applicable, results obtained by the CAB from its participation in any relevant proficiency / inter-comparison programs; and

f) Any other information on the CAB or its operations which would assist the Assessors/ Technical Experts in their task, such as copies of test records and reports, relevant details from the previous assessment, etc.

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3.11 Document Review

3.11.1 This is carried out before going to the site or on the site as the case may be to check the system as documented but before verification of the system as established. The aim of the document review is to determine the conformance of the CABs documentation (quality manual, Policy Documents, mandatory documented procedures, records etc.) with the applicable conformity assessment standard.

3.11.2 Document review is carried out for every requirement of the applicable conformity assessment standard. The findings are recorded directly in the normative standard checklist and the reference to the CABs documentation provided onto the checklist and remarks provided. In addition to this the adequacy and appropriateness of the test / inspection methods or certification procedures are also captured as an added section if required. This report is signed off by the Team Leaders and reviewed by the Scheme.

3.11.3 For initial assessments, the document review repor is submitted to the CAB by the Scheme with a response back on areas for amendment expected back in one month. On satisfactory response from the CAB, the Scheme shall agree with the CAB and the assessment team on the dates of onsite / witnessing assessment.

3.11.4 For initial and re-assessments, the document review outcome is reported with in the assessment report.

3.12 Pre-assessment

3.12.1 A new CAB can request for pre-assessment upon application to check their preparedness for accreditation. If the application for accreditation is accepted KENAS will appoint the Team Leader to undertake the Document review and a pre assessment.

3.12.2 The CAB whose scope of operations may not be clear from the documents review, a pre-assessment may be carried out to confirm the operation of the CAB as well as to clarify any issues that may have emerged during the document review. This pre-assessment visit will help to guide on the proper composition of the assessment team and the number of days required for the assessment. This exercise though desired is not mandatory and hence the CAB concurrence will be sought. The pre-assessment will ordinarily be done by the Team Leader or delegate KENAS Technical Staff well versed with assessment requirements.

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3.12.3 The output from pre-assessment will be as follows;

a) The Client is ready for initial assessment

b) The Client was found to have a system in place but requires additional information and its recommended to initial assessment

c) The Client was found not to have an effective system and recommends a withdrawal

3.12.4 The pre-assessment shall not raise non-conformities but areas of improvement. Due care shall be taken to avoid consultancy. The pre-assessment shall provide a report **ACC-FM-43**.

3.13 Assessment Plan

3.13.1 The Team Leader or his appointee shall prepare the assessment plan agreed upon by the other assessors / technical experts. The plan shall depend on the extent of the scope of assessment.

3.13.2 The Team Leader shall then communicate the final timetable to the CAB at least within five (5) days of the assessment.

3.14 Assessment Techniques

3.14.1 There are various assessment techniques that can be used to perform an assessment. These can be review of documents otherwise known as document review, interviews, onsite witnessing of assessments, review of participation in proficiency testing and inter-laboratory comparisons, remote assessments, validation/measurement audits, assessments etc. Of all these tools, it is prudent for an assessor to be prepared on what to ask and hence check list come in handy.

3.14.2 Checklists are tools and are also known as ‘***’aide memoire’’*** (memory aide). Theoretically, an experienced assessor can carry out an assessment without using a checklist. However, in practice, this results in confusion and a demonstration of lack of professionalism. An assessor need however not to be enslaved by the checklist.

3.14.3 Checklists ensure that critical aspects of the client management system, structures, processes, outcomes and or products are not omitted.

3.15 Checklist preparation

It is the responsibility of the Team Leader to assign each team member responsibility for assessing specific management processes, functions, sites, areas or activities.

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3.16 Assessment documents

3.16.1 Apart from checklists, other assessment documents include: -

a) Assessment procedures, criteria and assessment sampling plans.

b) Records of assessment findings, **ACC-FM-48,** or populated directly on the checklist template in Q pulse

c) Corrective Action request Forms (CAR) forms, **ACC-FM-19,** or populated directly on the Q pulse CAR template.

d) Assessment summary report, **ACC-FM-10.** Extract of report can be obtained from Q-pulse on population of information during the assessment.

e) Attendance registers for opening and closing meetings, **ACC-FM-04**

3.17 Onsite assessment / Remote assessment

3.17.1 While on-site assessment is the physical assessment at the location where accreditation activities are performed, remote assessment is an assessment normally done using electronic means. The mode of approach is the same, however, there may be heavy reliance on documentation provided electronically to inform decisions especially where virtual demonstration may be limiting due to technology.

3.17.2 Remote assessment will be applied in cases where the risk is minimal to KENAS (e.g. locations that are already assessed by other IAF MLA AB's or ILAC MRA AB's).

3.17.3 Onsite or remote assessments take the same approach:

3.17.3.1 Prior to the start of the assessment, it is advisable for the assessment team to meet together to plan the best approach to the assessment and their respective roles. The journey to the CAB often provides an opportunity for such discussions but if the assessment team is not travelling together, it may be advisable for them to spend some time upfront before starting the assessment.

3.17.3.2 The Team Leader will also, at an early stage, put the CAB's staff at ease, reduce any tension and allay any nervousness they may feel. He or she will seek to encourage the concept of the assessment as a team effort, with CAB and assessment team working together to achieve a common improvement goal.

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3.17.3.3 The Team Leader is expected to lead the assessment process and to assist the Assessors in managing the progression of the assessment during the day by guiding them. There may be occasions when members of an assessment team differ in their opinions on the adequacy of some aspect of the CAB or its operations or on the nature of any corrective action required. When such differences occur, they should not be aired in the presence of staff of the CAB being assessed. If the matter cannot be resolved tactfully at the time, the assessment team should temporarily leave the issue unresolved and seek an opportunity (either during the visit or afterwards) to discuss the matter in private and, if possible, achieve consensus.

3.17.3.4 Sections 5 and 6 contain advice to Assesors/ Experts on various aspects of the assessment of a CAB. It is expected that, in keeping with the 'team approach' already mentioned above, any observed non-conformities will be fully discussed with the assessee at the time they were observed to ensure all the related facts or reasons are uncovered for the assessment team.

3.17.3.5 The assessment team shall observe the following;

a) Punctuality;
b) Diplomacy; and
c) Etiquette.

3.17.3.6 The Team Leader chairs the opening meeting in line with the agenda template **ACC-FM-24**.

3.17.3.7 Based on objective evidence, assessment findings should be recorded on form **IAU-FM-04** or directly on the checklist in Q pulse. Where an assessment finding is a non-conformance, this must be discussed with the CAB's representative. Every assessor must take note of answers to the assessment questions. These notes shall be retained for possible use during the closing meeting.

3.17.3.8 The assessment team shall meet as necessary in order to exchange information and evaluate the progress of the assessment.

3.17.3.9 The assessment team under the guidance of the Team Leader shall:

a) Review the assessment findings and any other appropriate information collected during the assessment;

b) Agree on non-conformities if any and complete CAR forms/templates;

c) Reach consensus on the assessment conclusion and summary report; and

d) Review CARs with CAB's management representative (MR).

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3.17.3.10 It is the responsibility of the Team Leader to present the assessment findings at the closing meeting which shall be carried out in line with **ACC-FM-24**

3.18 Reporting the assessment

3.18.1 The Team Leader shall be responsible for the preparation of the assessment report.

3.18.2 The assessment report should provide a complete, accurate, concise and clear record of the assessment and should contain assessment conclusions and recommendations on issues that include:

a) Extent of conformance and maintenance of the management system to the assessment criteria; and

b) Extent of demonstrated competence.

3.18.3 The assessment report should also include, or make reference to the following:

a) The identification of the CAB and functional units or processes assessed;

b) The identification of the assessment team and their roles;

c) The date/s and place/s the on-site assessment activities were conducted;

d) The audit criteria, and if possible, a list of reference documents against which the assessment was conducted;

e) The assessment findings;

f) The agreed assessment objectives scope and plan;

g) The time period covered by the assessment;

h) The identification of the client's key representatives participating in the audit;

i) A summary of the assessment process including any obstacles encountered;

j) A statement of the confidential nature of the contents;

k) A distribution list of the assessment report;

l) Confirmation that the assessment objectives have been accomplished within the assessment scope in accordance with the assessment plan;

m) Any agreed follow up action plans;

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n) Any unresolved diverging opinions between the assessment team and the client;

o) Recommendations for improvement, if specified in the assessment objectives; and

p) Areas not covered, although with the assessment scope.

3.19 Closure of assessment

The assessment shall be closed by confirming corrective actions taken through documentary evidence provided by the CAB except where matters of competence need to be confirmed. In this case an onsite closure or remote review follow-up assessment to confirm action on the CARs raised shall be scheduled one month from the date of the assessment.

3.20 Report approval and distribution

3.20.1 The Team Leader shall write a report within five (5) working days following the date of the assessment.

3.20.2 The report shall be reviewed by KENAS Manager in charge of the scheme for adequacy and sent to the CAB and a copy retained in KENAS file for records purposes.

3.20.3 The report in the KENAS file shall be forwarded to the Chief Manager of the respective schem for further action.

3.21 Subsequent assessment activities

3.21.1 Subsequent assessment activities assessment is undertaken in a similar manner as initial assessment. The assessors shall take the following into account:

a) Check effectiveness of closure of the previous assessment.
b) Examine in detail subsequent internal audits.
c) Examine in detail inputs/outputs of management reviews and improvements thereof.
d) Check on complaints and their findings.
e) Sample other areas of assessment in the case of rotational assessment in order to cover the entire scope prior to reaccreditation.

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3.21.2 The subsequent assessment activities report/summary should disclose and comment on management improvement in relation to the CABs objectives.

3.22 Preparing for the Assessment

3.22.1 KENAS provides its Assessors / Experts with a comprehensive brief about the CAB to be assessed.

3.22.2 Assessors / Experts should contact the Team Leader for the assessment if they require any additional information about the CAB or if they would like the CAB to be prepared to demonstrate any particular work for which accreditation is being sought.

3.23 Planning the Assessment

3.23.1 The Team Leader should give some thought to the sequence in which the assessment is to be carried out and the time to be spent on each aspect of the assessment including opening and closing meetings. This does not have to be rigidly adhered to but it helps both the assessment team and the CAB to schedule their work if a provisional timetable is developed. A good appreciation of the logistical requirements for planning is obtained through the preliminary visit and or discussions with the CAB.

3.23.2 Confirmation of starting time, closing time as well as breaks like lunch and tea, need to be factored into the plan. The breaks should take minimum time in order not to impact the assessment time.

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3.24 Starting the Assessment - The Opening Meeting

3.24.1 The opening meeting serves to introduce both groups to each other and provides an opportunity for the Team Leader to brief the CAB's personnel on the objectives and format of the assessment and to confirm the assessment plan.

3.24.2 At this stage, the assessment team should determine whether the CAB wishes to introduce any last-minute changes to the information supplied and should ensure that all personnel to be assessed for competence are available.

3.24.3 One of the most important functions of this opening meeting is to allay the fears and apprehensions that the CAB's staff may have about the assessment process. The assessment team must make every effort to put the staff at their ease and to ensure that they are fully aware of the assessment objectives and procedures.

3.24.4 This opening meeting takes about 30 minutes to complete. It is appropriate at this stage to seek clarification or additional information relating to the assessment.

3.24.5 The CAB may want to brief the team on their business. The Team Leader can accommodate such briefs so long as they controlled in a manner not to take significant time off the assessment plan.

3.24.6 Once the assessment process in underway the team should attempt to keep to the agreed timetable, for there is a tendency to spend too long on each topic during the early part of the assessment and a consequent need to rush towards the end.

3.25 Assessment Tactics

3.25.1 Throughout the assessment, team members should be aware of the two main objectives of their visit to the CAB: to determine whether the CAB's operations and facilities comply with the accreditation criteria and to establish the extent of demonstrated competence.

3.25.2 The assessment team members can adopt a number of tactics to aid in the achievement of these objectives.

3.26 Project the Right Image

3.26.1 One of the most valuable tactics for the assessor or expert to employ is to project a professional image of him/herself and that of KENAS.

3.26.2 Look the part - a smart tidy appearance creates a favorable impression and boosts self- confidence. Smile and be approachable.

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3.26.3 Remain calm and courteous - do not become flustered, emotional, argumentative, or dogmatic. “Please” and “thank you” are amongst the most powerful words in an assessor’s vocabulary.

3.26.4 Be precise - loosely phrased questions or requests cause confusion and waste time.

3.26.5 Be prepared - an assessor or expert who has prepared for the assessment projects a professional image.

3.27 Conduct of the Assessment

3.27.1 Keep a sense of proportion - every assessment will reveal examples of human error but evidence of fallibility should be of far less interest to the assessment team than evidence of real deficiencies in the CAB’s quality management systems.

3.27.2 Assess the true significance of any non-conformity found and avoid making an issue out of trivial deficiencies, human errors or isolated mistakes. However, be alert for apparently minor problems which are, in reality, symptoms of a major system fault.

3.27.3 Keep in mind that if a non-conformity cannot be expressed in terms of the Assessment Criteria i.e. the normative standard, or Procedures and Conditions of Accreditation, as appropriate), then there is no non-conformity.

3.27.4 If you find no non-conformities after tracing the clients system by a random selection of records and reports, you can reasonably assume that an effective system is in place and is being effectively maintained. If only a few non-conformities are found, then the system may be in a development phase or staff may not be fully familiar with the system. A large number of non-conformities will indicate the absence of an effective system.

3.27.5 Always be fair, flexible and prepared to listen and to reason. Make allowances - consider the circumstances surrounding each non-conformity and do not expect unreasonable levels of diligence or reliability from the CAB’s staff.

3.27.6 Be sensitive - put staff at their ease. Do not be afraid to admit that you also make mistakes occasionally. Be helpful and constructive at all times.

3.27.7 Be factual; verify findings. Beware of producing findings which rely on opinions, whether they be your own or those of the CAB’s staff.

3.27.8 Be determined and decisive. Once you have gathered sufficient information to form the basis of a sound judgement, there is no point in going over the same ground again. Move on.

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3.27.9 Get on with the job - try not to be side-tracked into irrelevant conversations.

3.27.10 Be aware that in some CABs, all staff are prepared and expect to be spoken to during the assessment, while in others non-signatory staff are pleased to be ignored by the assessment team.

3.27.11 Know who's who - be aware at all times of the relationships between staff members. Not only the formal staff structure but also the more important informal structure should be noted.

3.27.12 Bear in mind staff sensitivities and do not criticize staff in front of their subordinates or their seniors.

3.27.13 It is important to discuss problems on the spot - do not just make a note of non-conformity without discussing the matter fully with the auditee. There may be a valid reason for what the CAB is doing.

3.27.14 Be prepared to return - keep returning to an area of the CAB's operations until you are satisfied that compliance with the accreditation criteria exists. Do not be afraid to reassess should you have second thoughts or should another question come to you.

3.27.15 Be aware of the time - as time begins to run short it is better to concentrate on the vital aspects of the CAB's operations.

3.27.16 Avoid too many escorts - it should not be necessary for a large number of staff members to accompany you. A large group slows down the assessment.

3.28 Tactics of the CAB

3.28.1 It is worth remembering at the time an assessment is being carried out that the majority of the CAB's staff would probably prefer the assessment team not to be there. Prior to the assessment, and once it is finished, the CAB will probably acknowledge the positive benefits that can arise from such an exercise.

3.28.2 On the day of the assessment, however, the staff will be tense and nervous in what can be a very stressful situation. Nobody likes having their work subjected to careful and detailed scrutiny. However, people like talking about their work particularly to Technical Experts.

3.28.3 The following tactics are occasionally adopted by CAB staff, sometimes deliberately but often unwittingly, under stress.

3.29 Time Wasting

3.29.1 The waffler - speaks at length but says nothing and never answers the question directly.

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3.29.2 The long lunch break - the CAB may arrange to take the assessment team to lunch. If this is at a restaurant some distance away, over two hours can be wasted. A light working lunch at the CAB premises is preferable.

3.29.3 Interruptions - the CAB's staff may be constantly interrupted during the assessment to take phone calls, etc. In such circumstances, ask politely if such calls can be held until the assessment is finished.

3.29.4 Key staff unavailable - the CAB has plenty of notice of the assessment so there should be no reason (other than sickness) for the absence or lateness of key staff members.

3.30 'CAB's Tour'

3.30.1 Some CABs present the assessment team with their version of the assessment program which may include a lengthy tour of the CAB and other areas of interest. Such tours should be politely declined until the assessment is finished.

3.31 Pre-selected Documents

3.31.1 The assessment team may be presented with sets of test records and reports for inspection. The assessment team should not waste time by looking at these. Instead, they should select more records and reports of their own choice from the CAB's filing system.

3.32 Other Agendas

3.32.1 Sometimes staffs in the CAB seek support from the assessment team to help justify new equipment, personnel or facilities, and may even request supportive inclusions in the final assessment report. This is not a function of the assessment team and any such open or overt requests must be resisted with great diplomacy and care. It is essential to stick to the observed factual matters.

3.33 Information Gathering Techniques

3.33.1 An assessment involves the evaluation of information gathered by the assessment team from a variety of sources including:

a) The CAB's accreditation questionnaire and documentation

b) Observation of the CAB's practices

c) Checking of CAB's facilities and records

d) Review of proficiency program results

e) Questioning of staff.

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3.34 Observation of the CAB's Practices

3.34.1 Observations of activities of the CAB will provide an insight into the level of competence of the staff and the manner in which the CAB functions. In some CABs, the assessment team will witness some or all of the tests, measurements or procedures under consideration. This allows them to evaluate the manipulative skills of staff and to detect faults which cannot be established in the questioning process. Even if a particular procedure is too lengthy to be performed in its entirety during the visit, it should be possible for at least the most critical phases of the procedure to be performed in the presence of the assessment team.

3.34.2 Depending on the circumstances, samples or specimens or items used in such procedures may be conveniently drawn from the normal work throughput of the CAB.

3.34.3 The CAB should continue to function normally throughout the assessment visit. Assessors and experts should recognize that observation of the work going on around the assessment team will often yield just as much information on the real standard of competence and expertise of the CAB personnel as the specially arranged witnessed work.

3.35 Checking of the CAB's Facilities and Records

3.35.1 Thorough examination of facilities and records is essential to the success of any assessment. It is particularly important that the records and reporting systems be very carefully and thoroughly examined. Depending upon the volume and variety of work being undertaken in the CAB, the assessment team should select multiple examples of the different types of work being performed and trace through the process from start to finish and sometimes in the reverse direction. These records should be examined for clarity, completeness and consistency.

3.35.2 The assessment team should be especially alert to any anomalies or discontinuities; anomalies for which there are no explanation may sometimes be a symptom of a much deeper problem in the operation of a CAB.

3.36 Review of Proficiency Programme Results

3.36.1 Wherever possible, details of any participation by the CAB in Proficiency Testing Programs will be included in the briefing documents for consideration during the assessment.

3.36.2 Opportunity should be taken during the course of the assessment to review with the CAB the results obtained in these Proficiency Testing Programs. Aspects which should be covered include:

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a) The acceptability or otherwise of the results obtained in relation to the assigned values or consensus result and the uncertainty of measurement claimed where results are numerical

b) How closely the program instructions were followed

c) How closely the Proficiency Testing Program approximated the normal operations of the CAB

d) Any subsequent investigation undertaken by the CAB to determine the causes of any outlying results

e) Whether appropriate effective corrective and preventative actions were taken following outlying results.

3.37 Questioning of Staff

3.37.1 Effective questioning of the CAB's staff is vital to the success of any assessment. Questioning must not be aggressive, but it must be thorough and, on occasions respectfully persistent if the real facts are to emerge.

3.37.2 In many situations, it may be desirable for the assessment team to try again to put the CAB's staff at ease at the start of any questioning or interview session. The staff of the CAB will know that they are under investigation and will react in a variety of ways; for example, by becoming withdrawn or defensive or, at the other extreme, by responding aggressively.

3.37.3 While these reactions may be due to nothing more than nervousness, they may result in evasive answers which make it more difficult for the assessment team to establish the facts. Judicious use should be made of both open and closed questions. In general terms, open questions, which require a substantial response, are more useful than closed questions which permit yes/no answers.

3.37.4 For example, it is better to ask: "Tell me about the interferences you have encountered in analysis by this method?" and continue this line of questioning rather than simply ask: "Do you correct for the manganese interference?".

3.37.5 Similarly, it is better to say: "Tell me about your experience in calibration of ..." rather than: "The notes state that you have had five years' experience in calibration of…".

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3.37.6 Closed questions have a role in the questioning process, but they tend to evoke a defensive reaction in the recipient and may be interpreted as being critical or aggressive. They are best used to clarify particular points during the discussion.

3.37.7 The art of questioning also involves listening for what is not said as much as what is being said. Assessors should be alert to answers which appear to be superficial or evasive and be prepared to continue the line of questioning if they sense that a response is incomplete.

3.37.8 It is often productive to ask “Can you show me ... please?” The assessment is being undertaken to evaluate the CAB’s technical management system which should be able to cope with all situations. Hypothetical questions of the “what if” variety often help in understanding the CAB’s systems and in determining whether they can cover all reasonable eventualities. However, the hypothetical scenarios should still be realistic in the context of the CAB’s work.

3.37.9 If the CAB’s explanation or response is unclear or unsatisfactory, the questioner should not be afraid to admit that he/she does not understand. Keep questioning, rephrasing the question if necessary, until the answer is clear.

3.37.10 When junior staff is being interviewed, there is sometimes a tendency for the senior staff accompanying the Assessor to answer on the junior’s behalf. This practice must be tactfully discouraged.

3.37.11 When interviewing, the Assessor should never talk down to the staff member. Such an attitude of superiority is unlikely to elicit co-operation. Speak clearly and carefully, phrasing questions using terminology likely to be understood by the staff member in question. Give credit where it is due.

3.37.12 Compliments and the use of “please” and “thank you” are effective in developing communication.

3.37.13 Finally, Assessors should be alert to differences in information presented to them from different sources; for example, conflicting answers from different staff members, or differences between what is said and what is observed. Any such differences should be probed until the true situation is established.

3.38 Six Task Elements

3.38.1 In assessing a CAB’s operations and facilities, each activity or task can be considered in terms of six elements. These so-called task elements are:

a) The person who performs the task;

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b) The items on which the task is performed and any consumables used;

c) The equipment and facilities used in performing the task;

d) The procedure or method used in performing the task;

e) The records and reporting associated with the task; and

f) Quality control / Assurance mechanism.

3.38.2 In evaluating a CAB's operations, Assessors and Experts should keep these six task elements in mind and ask themselves the following questions;

3.39 The Person

3.39.1 Are they appropriately qualified and experienced?

3.39.2 Do they have the necessary skills?

3.39.3 Are they suitably motivated to undertake the task in a conscientious, diligent and reliable manner?

3.39.4 Are they identified in the training records as the ones who are appropriately trained?

3.40 The Items and Consumables

3.40.1 Is the item being worked upon (sample, patient, object, instrument for calibration, etc.) of the correct type, in the correct condition, suitably identified?

3.40.2 Are consumables of suitable quality and certified/guaranteed where required?

3.41 The Equipment

3.41.1 Are test equipment and other facilities (e.g. CAB, accommodation, and environment) appropriate to the task?

3.41.2 Are necessary standards available and current?

3.41.3 Is test equipment suitably calibrated; does it comply with the requirements of the CAB's documented procedures?

3.41.4 Is equipment well maintained and housed? Is it suitably identified?

3.42 The Procedure or Method

3.42.1 Is the method or the procedure appropriate to the task?

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3.42.2 Is it a current procedure?

3.42.3 Are standard specifications available?

3.42.4 Is the method within the CAB's capabilities?

3.42.5 Is the documented method being followed?

3.43 Records and Reporting

3.43.1 Are the records associated with the task available and appropriate for that task?

3.43.2 Do records and reports, etc. comply with the accreditation criteria for such records?

3.43.3 Are all records appropriately stored and retrievable?

3.44 Quality Control

3.44.1 A task element analysis can be applied to all aspects of the CAB's work, from reception of work to the preparation of a report/ certificate. Each task in the chain must be performed correctly if the CAB's report, is to be of a suitable quality i.e. fit for the purpose to which it will be used.

a) Is there a quality control plan?

b) Are calculations and information/data transfers and reports checked?

c) Is some work repeated to establish repeatability?

d) Are known artefacts or materials tested or inspected?

e) Are there appropriate and sufficient work comparisons with other CABs (proficiency testing)?

f) Is there an action requirement when QC results are unacceptable?

g) Are there trend charts or other statistical means of analyzing QC results?

3.45 Criteria for Accreditation

3.45.1 The formal criteria for accreditation include normative standards, subsidiary documents and applicable legal requirements where;

a) Management system requirements to be assessed mainly by the Team Leader

b) Technical requirements to be assessed mainly by the Assessor.

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3.46 Confidentiality

3.46.1 All information provided by an CAB in relation to its accreditation and all information obtained in the course of or in connection with an assessment must be treated in confidence. Even the fact that a particular CAB has applied for accreditation or has been assessed is regarded as being confidential.

3.46.2 Assessors, Technical Experts, Peer Review Team and Board members are required to sign Confidentiality Agreements before any involvement in the assessment or the granting of accreditation (**ACC-FM-28).** The agreement includes an endorsement that there is no conflict of interest between the Assessor or Technical Expert, committee member and the CAB to be assessed. Assessors and Technical Experts are asked not to discuss any matters relating to an assessment with any person other than those directly involved in the assessment.

3.46.3 A technical matter may arise during an assessment upon which an Assessor may wish to undertake some research or seek advice before formulating final recommendations. As far as is possible, such investigations should be undertaken in a manner that will maintain KENAS's principles of confidentiality.

3.46.4 KENAS also requires that all documents associated with accreditation of an CAB be maintained in confidence. This requirement imposes particular obligations on Assessors and Technical Experts. All the notes, documents, templates, etc., obtained from KENAS on the Cab and collected from the Cab as part of the assessment are to be returned to KENAS at the end of the assessment.

3.46.5 KENAS then includes them in its file and will avail them should it be necessary for the Assessor/Expert/ Peer Review Team to refer to them later during clearance of any conditions of the assessment.

3.47 Reporting Assessment outcome

3.47.1 All information provided by a CAB in relation to its accreditation and shall be noted and positives, observations or area of improvement as the case may be indicated. The assessment team shall record findings and a corrective action request generated for non-conformities raised.

3.47.2 A report shall be generated on Q-pulse or on the ACC-FM-19. Findings shall be classified as;

a) A Non conformity is the absence of, or the failure to implement and maintain one or more of the accreditation requirements, or a situation

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which would, on the basis of available objective evidence raise significant doubt as to the activities of the CAB.

b) An area of improvement / observation is used to document items that may help the client improve the quality of their system.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity Assessment-Requirements for accreditation bodies accrediting conformity assessment bodies
2.	ISO 19011	Guidelines for auditing management systems
3.	ILAC G3	Guidelines for training courses for assessor used by accreditation bodies.
4.	IAF MD 20	Generic competences of AB assessors
5.	IAF ID 12	Principles of remote assessments
6.	ACC-FM-28	Declaration of Confidentiality and Impartiality
7.	ACC-FM-48	Audit/Assessment Findings Sheet
8.	ACC-FM-19	Corrective Action Request
9.	ACC-FM-10	Assessment Report
10.	ACC-CD-06	Selection, Engagement and Contracting of Assessment personnel
11.	ACC-PR-07	Management of Assessment, Subsequent assessment activities, Re-assessment and Reporting
12.	ACC-PR-03	Sampling during Assessment and Internal Audits
13.	ACC-FM-24	Opening and closing meeting agenda template.

5 Revision/ Amendment Record

Date	Ver	Revised By	Reason for Revision
10/10/2022	01	RSQ	Newly developed/formatted document

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Date	Ver	Revised By	Reason for Revision
14/06/2023	02	RSQ	• Review of the Clause 2 on Terms and Defifinitions • Removal of reference to accreditation committee to reference Peer Review Team
30/06/2025	03	QRM	• Systematic Review

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