Approval and Authorization

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<td>DEPUTY DIRECTOR TECHNICAL SERVICES</td>
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<td>ASSISTANT DIRECTOR INSPECTION AND VERIFICATION</td>
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Periodic Review Approval and Authorization

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1 OVERVIEW CONTENT

1.1 Purpose

1.1.1 This quality manual describes the KENAS Quality management system as established and maintained by the Kenya Accreditation Service (KENAS). The management system takes into account the KENAS vision and mission.

1.1.2 Vision

To be a global leader in the provision of accreditation services.

1.1.3 Mission

To provide accreditation services that promotes fair trade, health and safety as well as protection of the environment.

1.2 Scope

This quality manual specifies how the quality management system of KENAS is structured in provision of accreditation services to CABs that include certification bodies, inspection bodies, laboratories (testing, calibration, medical/clinical, veterinary) and proficiency test providers.

The manual has been structured in line with ISO/IEC 17011:2004 - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

1.3 Role(s) and Responsibility

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibility</th>
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<tbody>
<tr>
<td>Management Representative</td>
<td>Development and publication of the Quality Manual</td>
</tr>
<tr>
<td>Chief Executive Officer</td>
<td>Approval and provision of funds for implementation of the Quality Management system</td>
</tr>
<tr>
<td>All staff</td>
<td>Compliance</td>
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2 DEFINITIONS

For the purpose of this Quality Manual, the following terms shall apply in addition to those given in ISO/IEC 17000, ISO/IEC 17011, ISO 9000.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>MR</td>
<td>Management Representative</td>
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<tr>
<td>CAB</td>
<td>Conformity Assessment Body</td>
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<tr>
<td>KENAS</td>
<td>Shall mean Kenya Accreditation Service, the national accreditation body established according to the Legal Notice No. 55 of 2009.</td>
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<tr>
<td>KENAS Logo</td>
<td>The logo used by KENAS for the purpose of identifying itself</td>
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<tr>
<td>KENAS Accreditation symbol/mark</td>
<td>The symbol which KENAS has developed and which is issued for use by KENAS accredited CABs, to indicate their accreditation status.</td>
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<tr>
<td>Accreditation certificate</td>
<td>Formal document or a set of documents issued by KENAS, stating that accreditation has been granted to a conformity assessment body for the defined scope or area of application</td>
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<tr>
<td>Complaint</td>
<td>Expression of dissatisfaction, other than appeal, by a person or organization, to KENAS in relation to its activities or of an accredited CAB, including training providers, assessors, auditors and where a response is expected</td>
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</table>
| Appeal                        | Request by a CAB for reconsideration of any adverse decision made by KENAS related to its desired accreditation status or registration. Such adverse decisions may include:-  
  a) Refusal to accept an application,  
  b) Refusal to proceed with an assessment,  
  c) Corrective action requests(CARs),  
  d) Changes in accreditation scope,  
  e) Decisions to deny, suspend or withdraw accreditation, and  
  f) Any other action that impedes the attainment of accreditation. |
| Assessment                    | The process undertaken by KENAS to assess the competence of a CAB, based on particular standard(s) and or other normative documents and for a defined scope of accreditation. The assessment of competence involves assessing the competence of the entire operations of the CAB, including the competence of the personnel, the validity of the conformity assessment methodology and the validity of the conformity assessment results. |
| Unscheduled Assessment        | The process undertaken by KENAS to assess the competence of a CAB, based on particular standard(s) and or other normative documents and for a defined scope of accreditation as a result of complaints and or significant changes in the CABs activities or services. |
| Related Body                  | A separate legal entity that is linked by common ownership or contractual arrangements to KENAS                                                                 |
| Top Management                | The KENAS management that controls and directs the day to day activities of KENAS. It shall comprise of the Managing Director and the Deputy Directors. |
| Proficiency testing           | The process of comparing actual test results from different laboratories employed by KENAS, to complement the onsite peer assessment process and to provide objective data or evidence regarding the performance of individual laboratories seeking accreditation |
3  ABBREVIATIONS

<table>
<thead>
<tr>
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4  REQUIREMENTS

4.1 Legal responsibility

Kenya Accreditation Service, is the sole national accreditation body established vide Legal Notice No. 55 of 2009.

4.2 Structure

4.2.1 KENAS is structured and operationalized in such a way as to ensure its operations safeguard the objectivity, confidentiality and impartiality of its activities hence providing the desirable confidence to its customers: KENAS organizational structure.

4.2.1.1 Top Management
Top Management consists of the Chief Executive Officer (Managing Director), The Deputy Directors in charge of Technical Services, Finance and Administration whose responsibilities are defined in their specific job descriptions.

4.2.1.2 Senior Management
Senior Management consists of the Assistant Directors, legal officer, Internal auditor in addition to top management

4.2.2 KENAS Board
The Board is responsible for formulating matters of policy for the purpose of providing general or specific guidance to KENAS management for performance of its functions. (Legal Notice 55 of 2009)

4.2.3 Accreditation committee
This committee is responsible for decisions on granting, extension and or reduction of scope, suspension and or withdrawal of the accreditation. The accreditation committee is
independent of the team that performs the assessment and has a team charter that governs its operations. (Ref. Legal Notice 55 of 2009, Accreditation Team Charter KENAS-GUD-001)

4.2.4 Standards Tribunal

The Tribunal shall investigate any disputes or appeals raised by any CAB regarding an accreditation decision made by KENAS. (KENAS-TS-OP-009).

4.2.5 Technical committees

Shall deliberate on technical issues regarding the operations of KENAS and make recommendations as appropriate in line with KENAS-GUD-004

4.2.6 Pool of assessors and experts

These shall be responsible for carrying out accreditation assessments for KENAS. The responsibilities of assessors and experts are defined in the contract between KENAS and the Assessor/Expert as defined in KENAS-TS-F-006, while the procedure for selecting, training and appointing of the assessors is defined in KENAS-TS-OP-008.

4.2.7 Documentation structure

KENAS documentation structure consists of Policies, Manuals, Operating procedures, forms and records. Control of these documents and records management is as detailed in KENAS-TS-OP-001.

4.3 Ethics, objectivity and impartiality

4.3.1 All employees, assessors/experts and committee members of KENAS have been made aware of the importance of objectivity and adherence to good code of ethics and governance while discharging their duties. This has been enhanced by ensuring that every employee signs the KENAS-FA-F-023.

4.3.2 KENAS policies and procedures are non-discriminatory. This ensures that its services are available to its customers irrespective of size or membership to any associations.

4.3.3 KENAS has also ensured that all committee members’ assessor/experts involved in the accreditation process act objectively and are bound through the confidentiality declaration KENAS-TS-F-004 as stipulated in Procedure for Management of Confidentiality, Impartiality and Objectivity- KENAS-TS-OP-013.

4.3.4 An accreditation committee has been established to ensure that all the accreditation decisions are made by competent persons different from those who carried out the assessment.

4.3.5 KENAS shall ensure that it does not provide any service that could affect its impartiality
These include;
- conformity assessment services that CABs perform
- Consultancy
- Proficiency Testing

4.3.6 Related bodies

KENAS has identified and analyzed the potential risks associated with its related bodies. This information is captured in the risk register (KENAS-TS-F-018)

4.4 Confidentiality

KENAS has established adequate arrangements at all levels of its operations that will safeguard the confidentiality of the information obtained in the process of its accreditation activities. The various committees and external bodies or individuals acting on behalf of KENAS shall sign the KENAS-TS-F-004. Such confidential information obtained from any CAB cannot be disclosed without the written consent of the CAB, except if disclosure of the information is required by law.

4.5 Liability and Financing

The Board of KENAS shall ensure sufficient budgetary arrangements that will provide adequate financial resources to enable it sustain its operations as well as to cover any liabilities that may arise from its activities. Financial records and statements shall be maintained.

4.6 Accreditation activity

4.6.1 Normative documents

4.6.1.1 KENAS shall carry out its activities as stipulated in Legal Notice No. 55 of 2009 and shall endeavor to carry out its activities in such manner as to fulfill the requirements of ISO/IEC17011:2004.

4.6.1.2 KENAS scope of accreditation is based on the following standards

<table>
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<tr>
<td>4.6.1.2.1</td>
<td>ISO 15189</td>
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<tr>
<td>4.6.1.2.2</td>
<td>ISO/IEC 17020</td>
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<td>4.6.1.2.3</td>
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<td>4.6.1.2.4</td>
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<td>4.6.1.2.5</td>
<td>ISO/IEC 17025</td>
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<td>4.6.1.2.6</td>
<td>ISO/IEC 17043</td>
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<td>4.6.1.2.7</td>
<td>ISO/IEC 17065</td>
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4.6.1.3 KENAS shall develop and use criteria for the above scopes for assessments. Details of the scheme and scope of assessment are indicated in
the directory of accredited CABs and in the schedule of accreditation for the specific CABS.

4.6.1.4 KENAS shall operate an accreditation cycle of three years with periods of surveillance in between as specified in the **accreditation agreement: KENAS-TS-F-015**

4.6.2 Application and Guidance documents

KENAS applies mandatory and guidance documents from ILAC, IAF and AFRAC in its accreditation activities.

4.6.3 KENAS has established a policy to enable it extend its activities and to effectively and efficiently respond to demands of all the interested parties. **(KENAS-POL-020)**

5.0 MANAGEMENT

5.1 KENAS has established a management system and is implementing and maintaining the same in accordance with the requirements of ISO/IEC 17011 It has also put in place appropriate policies and procedures that will continually improve the effectiveness and efficiency of the said management system.

5.2 Management System

5.2.1 KENAS top management has defined and documented the KENAS Quality Policy **KENAS-POL-001** and has ensured that measurable quality objectives that are consistent with its quality policy have been established at all levels of its functions. KENAS has documented policies as required by ISO/IEC 17011

5.2.2 In order to ensure that these policies are understood, implemented and maintained at all levels of the organization, KENAS has put in place appropriate communication channels that include meetings, memos, telephone lines, e-mails, notice boards and web-site. These are also communicated to employees on induction.

5.2.3 These documents have been made available and are accessible to personnel at all user locations in line with the **KENAS-TS-OP-001**

5.2.4 KENAS top management has appointed a Management Representative (MR) with responsibility and authority that includes:-

- Ensuring that procedures in support of the management systems are established,
- Reporting to the rest of the management on the performance of the management system and any need for improvement,
- Ensuring execution of the internal quality audits activities and corrective actions thereafter,
- Reporting the current performance and improvement opportunities related to the results of the Quality Management system during Management review
meetings held annually.

5.3 Document control

In order to effectively control all internal and external documents that relate to accreditation activities, KENAS has developed a procedure for control of documents that defines all the controls needed (KENAS-TS-OP-001).

5.4 Records

KENAS has established a procedure that defines the activities related to identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records (KENAS-TS-OP-001). This procedure also defines the retention period and accessibility of KENAS records that is consistent with KENAS contractual and legal obligations and confidentiality arrangements respectively.

5.5 Nonconformities and corrective actions

In order to effectively manage any non-conformities that arise from its activities, KENAS has established a procedure for management of non-conformities and corrective action (KENAS-TS-OP-003). Where necessary, KENAS shall also take actions to eliminate the causes of non-conformities in order to prevent their recurrence as well as undertaking appropriate corrective actions considering the impact of the problems encountered.

5.6 Preventive Actions

In order to identify opportunities for improvement and to take preventive actions to eliminate the causes of potential nonconformities, KENAS has established a risk management process (KENAS-POL-039). The preventive actions taken shall be commensurate the impact of potential risks.

5.7 Internal Audits

For effective management of internal quality audits, KENAS has established a procedure for internal audits (KENAS-TS-OP-005) to verify that the accreditation activities undertaken by KENAS conform to the requirements of ISO/IEC 17011 and that the management system is implemented and maintained.

5.8 Management Reviews

KENAS has a documented procedure (KENAS-TS-OP-006) for reviewing its management system. This activity is undertaken at planned interval of once every quarter for the purpose of ensuring that the management system is adequate and effective in satisfying the requirements of ISO/IEC 17011 and the stated policies and objectives. The minutes of management review meetings shall be filed for records.

5.9 Complaints

In order to effectively address complaints related to accreditation activities, KENAS has
established a procedure for handling of complaints (KENAS-TS-OP-007).

6.0 HUMAN RESOURCES

6.1 Personnel associated with the accreditation body

6.1.1 KENAS has an adequate number of competent personnel having the education, training, technical knowledge, skills and experience necessary for handling all types, range and volume of accreditation work.

6.1.2 KENAS in collaboration with East African Community partner states is developing an expert pool of assessors, lead assessors and experts for use in accreditation work on contractual basis.

6.1.3 The KENAS top management has defined the duties, responsibilities and authorities for key accreditation personnel (Ref. job descriptions).

6.1.4 All internal and external personnel must sign the confidentiality form committing themselves to comply with KENAS rules and aspects relating to confidentiality, independence from commercial and other interests, and any existing or prior association with CABs to be assessed.

6.2 Personnel involved in the accreditation process

6.2.1 KENAS is maintains a register (KENAS-TS-F-020) of its assessors and experts indicating the qualifications, category, fields/scope of expertise.

6.2.2 In order to effectively undertake the assessment of CABs, KENAS has established a procedure for selection, training and approval of assessors and experts - (KENAS-TS-OP-008).

6.3 Monitoring

To facilitate the monitoring of performance and competence of the personnel involved in the accreditation assessments, KENAS has in its implementation a documented procedure KENAS-TS-OP-008 which covers monitoring and evaluation of the performance and competence of the assessors and experts.

6.4 Personnel records

Records of personnel involved in the accreditation activities are kept in the confidential registry and are kept as per the procedure KENAS-TS-OP-001

7. ACCREDITATION PROCESS
7.1 Accreditation criteria and information

7.1.1 KENAS shall use the criteria developed for each scope and field of accreditation. The criteria documents shall be posted at a central repository and accessible to the public through the KENAS website.

7.1.2 KENAS shall ensure availability of the following to the general public through various means the following:-

7.1.2.1 Detailed information about its assessment and accreditation processes including arrangements and or conditions for granting, maintaining, extending, reducing suspending and withdrawing accreditation.

7.1.2.2 A document or reference documents containing the requirements for accreditation including technical requirements specific to each field of accreditation. *(Application form, procedure for accreditation and criteria documents)*

7.1.2.3 General information about the accreditation fees. *(Fees Structure- Gazette Notice)*

7.1.2.4 Description of the rights and obligations of CABS. *(Application form and accreditation agreement)*

7.1.2.5 Information on the accredited CABs. *(Directory of Accredited CABs)*

7.1.2.6 Information on procedures for logging and handling of complaints and appeals. *(procedure for complaint handling)*

7.1.2.7 Information about the authority under which KENAS operates. *(Legal Notice 55 of 2009)*

7.1.2.8 Information about its related bodies *(Risk Register)*

7.1.2.9 Information about its establishment and source of funds *(Legal Notice)*

7.1.2.10 Information about its activities and limitations *(Quality Manual)*

7.2 Application for Accreditation

KENAS requires that a duly authorized representative of the applicant CAB makes a formal application in the prescribed application form for accreditation. *(KENAS-TS-F-022)*. Information required of the CAB is detailed on the application form. KENAS shall review for adequacy the information provided by the CAB.

7.3 Resource review

KENAS shall review the application presented by the CAB in order to determine its ability to carry out the assessment. The components of review shall include:
7.3.1 Compliance with KENAS policies

7.3.2 Competence and availability of assessors/experts

7.4 Subcontracting the assessment

7.4.1 KENAS shall undertake the assessment on which accreditation is based. However, in order to effectively address situations where KENAS may not be able to carry out the assessment, KENAS has developed a policy under which subcontracting may take place (KENAS-POL-019)

7.5 Preparation for assessment

7.5.1 Preliminary Visit

A preliminary visit is not necessary but is important for proper planning of the assessment. It is recommended that this be arranged if the following suffice:

7.5.1.1 No prior knowledge of the clients operations.

7.5.1.2 The scope applied for is not clear.

7.5.1.3 The location and nature of the CABs establishment is not known.

7.5.2 KENAS shall formally appoint the assessment team consisting of a lead assessor, and where required, a suitable number of assessors and/or experts for each specific scope. The Assistant Director in charge of the scheme to be assessed shall select the assessors and experts from the existing database (KENAS-TS-F-020). A justification for use or assessors /experts who are not on the database shall be provided and approved prior to engagement. In selecting the assessor / expert the following shall be put to consideration:

7.5.2.1 The area of expertise based on the scope for assessment

7.5.2.2 The frequency of use of the assessors and experts on the database in order to ensure balance.

7.5.2.3 The availability of the assessor / expert

7.5.3 In order to ensure impartiality, independence and non-discrimination, members of the assessment team contracted by KENAS to undertake assessment for the purpose of accreditation of CABs, will be required to declare any interests between themselves or their organization and the CAB to be assessed. This shall be done through filling of the KENAS-TS-F-004.

7.5.4 Upon appointing the members of the assessment team, KENAS shall inform the CABs of the names of such members and the organizations they belong to, a week in advance, to enable the CAB make a decision on acceptance or objection. In case a particular CAB raises an objection, this shall be dealt with in accordance with KENAS-POL-018 and KENAS-TS-OP-020
7.5.5 The assessment team shall undertake the assessment as per procedure KENAS-TS-OP-010.

7.5.6 Where the scope of the CAB covers a variety of specific conformity assessment services and or various locations, the assessment team shall use representative sampling to witness a representative number of activities to ensure proper evaluation of the competence of the CAB. This will be done in accordance with KENAS-TS-OP-018.

7.6 Document and record review

7.6.1 The assessment team shall review all relevant documents supplied by the CAB and which form the basis of assessment in order to evaluate its system as documented, for conformity with the relevant standard(s) and other requirements for accreditation. A report shall be availed to the CAB.

7.6.2 Depending on the nonconformities found during document and record review, KENAS may decide not to proceed with the onsite assessment on the basis of non-conformities found. In such cases KENAS shall communicate such decision in writing.

7.7 Onsite assessment

7.7.1 The assessment team shall commence the onsite assessment with an opening meeting. The agenda of the opening and closing meetings will be as outlined in the Assessor guide: KENAS-GUD-003.

7.7.2 The assessment team shall conduct the assessment of the conformity assessment services of the CAB at the premises of the CAB from which one or more key activities are performed and, where relevant perform witnessing at other selected locations where the CAB operates, to gather objective evidence that the applicable scope of the CAB is competent and conforms to the relevant standard(s) and other requirements for accreditation.

7.7.3 The assessment team shall also witness the performance of a representative number of staff of the CAB to provide assurance of the competence of the CAB across the scope of accreditation.

7.8 Analysis of findings and assessment reports.

7.8.1 The assessment team shall gather all the relevant information and objective evidence during the onsite assessment. These will be recorded in KENAS-TS-F-009 if manual, or keyed in directly to Q-pulse. Where non-conformities are raised these shall be filled in the Corrective Action request forms KENAS-TS-010 if manual or directly into Q-pulse whereas the report for assessment shall be provided in accordance to the template KENAS-TS-F-011.

7.8.2 KENAS shall be responsible for the content of the assessment report, including nonconformities, even if the lead assessor is not a permanent staff member.
7.8.3 KENAS shall ensure that the responses of the CAB in terms of resolving any non-conformities raised are reviewed to establish if the actions are sufficient. If the responses are found to be insufficient, KENAS shall request for further information. Additionally, evidence of actions taken shall be requested.

7.8.4 KENAS requires that corrective actions taken for all non-conformities raised are closed prior to presentation of the case file. Effectiveness of closure shall be checked at surveillance or next planned assessment.

7.8.7 The assessment report in the format as provided in KENAS-TS-F-011 shall be reviewed by the Assistant Director in charge of the scheme and forwarded to the Deputy Director Technical Services who shall plan for a peer review before forwarding to the accreditation committee for decision making. This shall be done through KENAS-TS-F-001 or populated directly into Q-pulse.

7.9 Decision making and grant of accreditation

7.9.1 KENAS shall prior to making a decision, be satisfied that the information is adequate to decide that the requirements for accreditation have been fulfilled.

7.9.2 KENAS shall make the decision on whether to grant or extend the accreditation on the basis of an evaluation of all relevant information. Records of such decisions shall be filed in KENAS/00/30.

7.9.3 In cases where KENAS uses the results of assessment already performed by another accreditation body, this shall be done in accordance with KENAS-POL-019.

7.9.4 KENAS shall provide an accreditation certificate to the accredited CAB. The certificate shall contain details as specified in KENAS-TS-OP-019.

7.10 Complaints and Appeals

7.10.1 In order to effectively handle complaints related to the activities of KENAS or an accredited CAB, KENAS has established and implemented complaints management procedure: KENAS-TS-OP-007.

7.10.2 KENAS shall investigate all complaints related to its accreditation services or cause to be investigated those complaints of its accredited CABs that may emanate from its customers to KENAS to a logical conclusion. The resolutions of such complaints will be communicated to the customers formally in writing.

7.10.3 Any disputes and or appeals raised by CAB against any adverse decision made by KENAS related to its desired accreditation status will be resolved in accordance with Management of Disputes and Appeals by CABS: KENAS-TS-OP-009.

7.11 Reassessment and surveillance

7.11.1 Accreditation certificates issued by KENAS are valid for three years. The surveillance
periods are 6 months from initial assessment and thereafter every year until reassessment.

7.11.2 KENAS shall plan and carry out onsite surveillance assessments, to monitor the continued fulfillment of all the accreditation requirements by accredited CABs, in line with the KENAS-TS-OP-010.

7.11.3 The assessment team will carry out reassessments in a similar manner described in clause 7.5 to 7.9 herein. However, experience gained during previous assessments shall be taken into account.

7.11.3 KENAS shall undertake to confirm to the CAB in writing, the continuation of accreditation or any decision regarding renewal, based on the results of surveillance and reassessments.

7.12 Extending accreditation

Whenever a CAB applies for an extension of the scope of accreditation that has already been granted, KENAS shall undertake all the necessary activities required of assessment as indicated in KENAS-TS-OP-010 and KENAS-TS-OP-019. Whereas for KENAS to extend its accreditation services it evokes its policy KENAS-POL-020.

7.13 Suspending, withdrawing or reducing accreditation

7.13.1 In order to effectively address situations that may arise regarding suspension, withdrawal or reduction of accreditation, the KENAS-TS-OP-011 applies.

7.13.2 KENAS shall make decisions regarding suspension and or withdrawal of accreditation when an accredited CAB has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation, alternatively the CAB may decide to voluntarily withdraw from accreditation or ask KENAS to reduce the scope of accreditation.

7.14 Records on CABs

KENAS shall maintain the records on CABs in order to demonstrate that requirements for accreditation including competence have been effectively fulfilled. Such records shall be filed in the individual CAB file, whose maintenance and storage shall be such as to ensure confidentiality of information therein is safeguarded. Such records will include:-

a. Relevant correspondence, assessment records and reports,
b. Records of the accreditation committees’ deliberations and decisions and
c. Copies of the accreditation certificates.
7.15 Proficiency testing and other comparisons for laboratories

In order to ensure sound decisions are made regarding the accreditation of laboratories, KENAS shall consider the participation and performance of laboratories in proficiency testing programs or inter-laboratory comparisons in line with **KENAS-POL-038**.

8. RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB

8.1 Obligations of the CAB

Terms and conditions of accreditation are stipulated in the **accreditation agreement**: **KENAS-TS-F-015**.

8.2 Obligations of KENAS

Obligations of KENAS are covered in the **accreditation agreement** KENAS-TS-F-015.

8.3 Reference to accreditation and use of KENAS symbols

8.3.1 KENAS shall remain the sole proprietary owner of its accreditation symbols considering the legal registration of its logo and symbols/marks under the intellectual property registration Act. An accredited CAB shall therefore use the KENAS accreditation symbol in its reports or certificates issued within the scope of its accreditation in accordance with the **KENAS-TS-F-015: Accreditation agreement and the guidance document on use of marks and reference to accreditation status: KENAS-GUD-032**.

8.3.2 KENAS shall subject the CAB to the necessary provisions of the KENAS Legal Notice Number 55/2009 or take any other action it deems fit, for any violations a CAB may make. Such violations may include incorrect references to accreditation status or misuse of the accreditation symbols in advertisements, catalogues etc. Such action may include request for corrective action, withdrawal of accreditation, publication of the transgression and if necessary, legal action.

9 REFERENCE AND RELATED DOCUMENTS

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<th>Document Identifier</th>
<th>Document Title</th>
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<tbody>
<tr>
<td>1.</td>
<td>ISO 9000</td>
<td>Quality management systems - Fundamentals and vocabulary</td>
</tr>
<tr>
<td>2.</td>
<td>ISO/IEC 17000</td>
<td>Conformity assessment - Vocabulary and general principles</td>
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<tr>
<td>3.</td>
<td>ISO/IEC 17020</td>
<td>General criteria for the operation of various types of bodies performing inspection</td>
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<td>4.</td>
<td>ISO/IEC 17021</td>
<td>Conformity assessment - Requirements for bodies providing audit and certification of management systems</td>
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<td>5.</td>
<td>ISO/IEC 17024</td>
<td>Conformity assessment - Requirements for bodies providing certification of persons</td>
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<td>6.</td>
<td>ISO/IEC 17025</td>
<td>General requirements for the competence of testing and calibration laboratories</td>
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7. ISO/IEC 17043  
Proficiency testing by inter-laboratory comparison - Development and operation of proficiency testing schemes

8. ISO/IEC 17065  
Conformity assessment – Requirements for bodies operating product certification systems

9. ISO 15189  
Medical Laboratories - Particular requirements for the quality and competence

10. ISO 19011  
Guidelines for management systems auditing

11. OIE  
Quality standards and guidelines for veterinary Laboratories, 2nd edition 2008

12. Legal Notice No. 55 of 2009  
Kenya Accreditation Service (KENAS) Legal order

## 10 REVISION HISTORY

<table>
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<tr>
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<tr>
<td>15/06/2012</td>
<td>01</td>
<td>MR</td>
<td>• Format change for entire QMS documentation</td>
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<tr>
<td>15/10/2012</td>
<td>02</td>
<td>MR</td>
<td>• Change of erroneous effective date indicating effective</td>
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| 05/07/2013 | 03  | MR         | • Change from ISO Guide 65 to ISO/IEC 17065  
• Update of KENAS Vision, Mission as reviewed based on the Strategic plan 2012-17  
• Addition of document references to 7.1.2  
• Change of narrative under KENAS symbols on page 3 and VIM on page 18 |
| 05/02/2014 | 04  | MR         | • Addition of KENAS-GUD-032, KENAS-POL-038.  
• Replace major and minor non conformity with non-conformity.  
• Addition of an accreditation cycle of 3 years.. |
| 05/02/2016 | 05  | MR         | • Replaced the Preventive actions procedure with the risk management policy. |