



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	1 of 20

Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Name	Job Title / Role	Signature	Date
Authored by	DEPUTY DIRECTOR TECHNICAL SERVICES	<i>Approved</i>	20/09/2018
Checked by	ASSISTANT DIRECTOR INSPECTION AND VERIFICATION	<i>Approved</i>	20/09/2018
Approved by	CHIEF EXECUTIVE OFFICER	<i>Approved</i>	20/09/2018

Periodic Review Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Required by: (09/2021)

Name	Job Title / Role	Signature	Date
Checked by			
Approved by			

Required by: (09/2024)

Name	Job Title / Role	Signature	Date
Checked by			
Approved by			



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	2 of 20

1 OVERVIEW CONTENT

1.1 Purpose

1.1.1 This quality manual describes the Quality management system as established and maintained by the Kenya Accreditation Service (KENAS). The Quality management system takes into account the KENAS strategic direction as provided for in the organizations strategic plan.

1.1.2 Vision

To be the accreditation body of choice beyond borders.

1.1.3 Mission

To provide confidence to users of accredited conformity assessment activities, that promotes fair trade, health, safety and environmental protection.

1.2 Scope

This quality manual specifies how the quality management system of KENAS is structured in provision of accreditation services to Conformity Assessment Bodies (CABs) that include but are not limited to certification bodies (Management systems, Product, Persons), inspection bodies, laboratories (testing, calibration, medical/clinical, veterinary) and proficiency test providers, validation and verification bodies.

The manual has been structured in line with **ISO/IEC 17011:2017- Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.**

1.3 Role(s) and Responsibility

Role	Responsibility
Management Representative	Development and publication of the Quality Manual
Chief Executive Officer	Approval and provision of funds for implementation of the Quality Management system
All staff	Compliance

2 TERMS & 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 and ISO 9000.



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	3 of 20

Term	Definition
CAB	Conformity Assessment Body that performs conformity assessment activities that can be an object of accreditation
KENAS	Kenya Accreditation Service, the national accreditation body established according to the Legal Notice No. 55 of 2009.
KENAS Logo	The logo used by KENAS for the purpose of identifying itself
KENAS Accreditation symbol/mark	The symbol/mark issued by KENAS to accredited CABs, to indicate their accreditation status.
Accreditation certificate	Formal document or a set of documents issued by KENAS, stating that accreditation has been granted to a conformity assessment body with the defined scope.
Complaint	Expression of dissatisfaction, other than appeal, by a person or organization, to KENAS in relation to its activities or of an accredited CAB, where a response is expected
Appeal	Request by a CAB for reconsideration of any adverse decision made by KENAS related to its desired accreditation status. Such adverse decisions may include:- a) Refusal to accept an application, b) Refusal to proceed with an assessment, c) Changes in accreditation scope, d) Decisions to deny, suspend or withdraw accreditation, and e) Any other action that impedes the attainment of accreditation.
Assessment	The process undertaken by KENAS to determine the competence of a CAB, based on standard(s) and/or other normative documents and for a defined scope of accreditation.
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.
Assessment technique	Methods used by KENAS to perform as assessment which include but are not limited to: Onsite assessment, remote assessment, witnessing, document review, file review, measurement audits, review of PT/ILC, validation audits, unannounced visits, interviewing.
Reassessment	Assessment performed to renew the accreditation.
Top Management	The KENAS management that controls and directs the day to day activities of KENAS. This comprises of the Chief Executive Officer and the Deputy Directors.
Proficiency testing (PT) / Inter-laboratory comparison (ILC)	The process of comparing actual test results from different laboratories employed by KENAS, to complement the onsite assessment process and to provide objective data or evidence regarding the performance of individual laboratories seeking accreditation



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	4 of 20

Outsourcing	The process where KENAS enters into agreements with other accreditation bodies which carry out assessments on its behalf for the purpose of accreditation but where KENAS still retains the decision making on accreditation.
Contracting	The process of making a written or oral agreement regarding provision of conformity assessment services between suppliers of such services i.e. assessors and experts and KENAS.
Q-Pulse	Electronic Quality Management system in use at KENAS

3 ABBREVIATIONS

Term	Definition
CAB	Conformity Assessment Body
KENAS	Kenya Accreditation Service

4 REQUIREMENTS

4.1 Legal responsibility

Kenya Accreditation Service, is the sole National Accreditation Body established vide Legal Notice No. 55 of 2009 under the State Corporations Act Cap 446 laws of Kenya.

4.2 Accreditation Agreement

In the provision of Accreditation KENAS requires all CAB's applying for accreditation and those that desire to be re-assessed for renewal of their accreditation to sign a pre-cast **Accreditation Agreement** found in the template **KENAS-TS-F-015**.

4.3 Use of Accreditation symbols /marks and other claims of Accreditation

4.3.1 KENAS shall encourage an accredited CAB to use KENAS accreditation symbol/marks or combined KENAS/ILAC, KENAS/IAF mark(s) 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**.

4.3.2 KENAS shall remain the sole proprietary owner of its accreditation symbols/marks through registration of symbols/marks under the intellectual property registration Act.

4.3.3 KENAS shall monitor use of its mark(s) and the combined KENAS/ILAC, KENAS/IAF mark(s) during assessment to confirm compliance to the Accreditation agreement. KENAS shall in addition to the provisions of the agreement, subject the CAB to the



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	5 of 20

necessary provisions of the KENAS Legal Notice Number 55/2009 by taking any other action it deems fit, for any violations a CAB may make.

4.4 Impartiality Requirements

4.4.1 KENAS shall ensure that its accreditation services are offered in an impartial manner.

4.4.2 KENAS is organized and structured in a manner that there is no influence of external parties on its accreditation activities and also does not allow commercial, financial or other pressures to compromise impartiality.

4.4.3 KENAS top management has committed to impartiality through a documented **Quality Policy KENAS-POL-001** which contains a statement on Impartiality, objectivity, transparency and avoidance of conflict of interest.

4.4.4 All employees of KENAS have been made aware of the importance of being impartial, 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**. 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 the **Procedure for Management of Confidentiality, Impartiality and Objectivity- KENAS-TS-OP-013**.

4.4.5 KENAS has in place a **Risk Management Policy KENAS-POL-039** which provides an opportunity for involvement of interested parties for safeguarding impartiality. KENAS also ensures that there is balanced representation of interested parties at the Board as provided for the **Board Charter KENAS-GUD-007** and Technical Committees as provided for in the **Operational Guidelines for Technical Committees KENAS-GUD-004**.

4.4.6 KENAS utilizes its risk management process as provided for in the **Risk Management Policy KENAS-POL-039** to identify, analyze, evaluate, mitigate and monitor all risks that may impact the organization.

4.4.7 Where risks are identified, these are documented onto the **KENAS risk register KENAS-TS-F-018**.

4.4.8 A review of the risks is done by the risk management committee where any medium to high risks are escalated to the Board of Directors through top management..

4.4.9 Where an unacceptable risk to impartiality is identified, which cannot be mitigated to an acceptable level, KENAS shall not provide accreditation.

4.4.10 KENAS policies and procedures are non-discriminatory. This ensures that its services are available to its clients irrespective of size or membership to any associations. However KENAS has a right refuse to offer service to CAB because of proven evidence of fraudulent behavior, falsification of information or deliberate violation of accreditation requirements.

4.4.11 KENAS does not perform conformity assessment activities that are subject to accreditation, nor does it provide consultancy with respect to specific advice or training towards development and



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	6 of 20

implementation of management system, operational procedures and/ or competence of a conformity assessment body. However KENAS provides generic training in normative standards and related areas. As provided in **KENAS-POL-042: Training on Conformity Assessment Standards and Associated Activities**.

4.4.12 KENAS is not linked to any body offering consultancy or undertaking conformity assessment activities that are subject to accreditation. Except for relationships that exist from State Corporations that carry out Conformity Assessments activities resident in the same Ministry that KENAS reports to. These relationship risks have been analyzed and captured in the **KENAS risk register KENAS-TS-F-018**.

4.4.13 KENAS accreditation activities are not presented as linked to consultancy or other services that pose unacceptable risk to impartiality.

4.5 Financing and Liability

4.5.1 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 where the sources of income are well defined as Appropriation in Aid, Revenue (arising from accreditation and Training services) and other sources deemed appropriate like including grants from support partners.

4.5.1 KENAS has made arrangements for insurance to cover liabilities associated with its accreditation services including professional indemnity

4.6 Establishing Accreditation Schemes

4.6.1 KENAS has adopted accreditation schemes in line with international standards. The KENAS scope of accreditation is based on the following standards:

- 4.6.1.1 Medical Testing : ISO 15189
- 4.6.1.2 Inspection and Verification: ISO/IEC 17020
- 4.6.1.3 Management Systems Certification: ISO/IEC 17021-1
- 4.6.1.4 Certification of Persons: ISO/IEC 17024
- 4.6.1.5 Testing Laboratories: ISO/IEC 17025
- 4.6.1.6 Calibration Laboratories/Centers: ISO/IEC 17025
- 4.6.1.7 Proficiency Testing Service Providers: ISO/IEC 17043
- 4.6.1.8 Certification of Product: ISO/IEC 17065
- 4.6.1.9 Point of Care Testing : ISO 15189 & ISO 22870



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	7 of 20

- 4.6.2 KENAS applies mandatory and guidance documents from ILAC, IAF and AFRAC in its accreditation activities. Additionally, KENAS develops and uses various criteria documents for harmonization of assessments of the schemes indicated above. The criteria are developed by Technical Committees established in line with **KENAS-GUD-004 Operational Guidelines for KENAS Technical Committees**.
- 4.6.3 The suitability of KENAS services and the conformity assessment schemes it offers for accreditation is determined through periodic review at management meetings, quarterly performance contracting updates and management review meetings. KENAS has also established a strategic plan which provides a long term focus of the services it offers.
- 4.6.4 KENAS has in its policy **KENAS-POL-020 Extension and Discontinuation of KENAS Accreditation Services** provides for how the organization identifies and engages in new development of new schemes.
- 4.6.5 The same policy **KENAS-POL-020 Extension and Discontinuation of KENAS Accreditation Services** provides for how KENAS would handle discontinuation of existing schemes.

5. Structural Requirements

- 5.1 KENAS is structured and managed in such a way as to ensure its activities and operations safeguard impartiality thereby providing the desirable confidence to its clients and the public.
- 5.2 The structure showing reporting relationships and lines of authority is as provided in **KENAS-ORG-01** whereas the responsibilities are as provided in the job descriptions for the various roles.
- 5.3 KENAS being a State Corporation is a Body Corporate and with perpetual succession and a common seal, hence is not part of a larger entity.
- 5.4 KENAS being a State Corporation is headed by a Board of Directors from both public and private sector who consult and advise the Minister on accreditation matters. The Board is also responsible for formulating matters of policy for the purpose of providing general or specific guidance to KENAS management for performance of its functions (**Ref. Legal Notice 55 of 2009, KENAS-GUD-007: Board Charter**)
- 5.5 The accreditation decisions are made by the 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 charter that governs its operations. (**Ref. Legal Notice 55 of 2009, Accreditation Committee Charter KENAS-GUD-001**). The decisions are not subject to approval by any other organization person.
- 5.6 The duties, responsibilities and authorities of all personnel engaged by KENAS on permanent or contractual basis are resident in the job descriptions or letters of appointment. Copies of these are kept in file. KENAS has the following internal organs.



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	8 of 20

5.6.1 Top Management

Top Management consisting of the Chief Executive Officer (Managing Director), The Deputy Directors in charge of Technical Services, Finance and Administration. They are responsible for formulating policies and supervising the implementation of the policies, processes and procedures, managing finances of the organization and provision of resources to enable development and adoption of activities for the schemes, assessments, performance management and safeguarding impartiality. Top management delegates implementation roles to the Management team and committees.

5.6.2 Management

Management consists of the Assistant Directors, legal officer, internal auditor, and heads of sections/units in addition to top management. They operationalize the policies and track fulfillment of performance requirements.

5.6.3 Staff

They execute tasks assigned to them towards realization of the KENAS objectives.

5.6.4 Committees

There are a number of committees established to meet strategic deliverables, performance contracting requirements as well as requirements of ISO/IEC 17011. These committees have their terms of reference defined either in a charter of the letter appointing members onto the committees.

5.6.5 Assessors and experts

These, part of who are KENAS staffs are 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**, and the assessor guide **KENAS-GUD-003** while the procedure for selecting, training and appointing of the assessors is defined in **KENAS-TS-OP-008**

6.0 RESOURCE REQUIREMENTS

6.1 Competence of Personnel

6.1.1 KENAS has an adequate number of competent personnel having the education, training, technical knowledge, skills and experience necessary for handling the accreditation schemes and the geographical locations in which KENAS provides its accreditation services.

6.1.2 Determination of Competence Criteria

6.1.2.1 KENAS staff is engaged on the basis of qualification, technical knowledge and experience. These areas stated in the job descriptions or roles specification. The staff undergoes an induction which brings these up to speed with the KENAS requirements and the technical persons are taken through the normative standards to which KENAS accreditation system is based. In addition the



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	9 of 20

technical staffs are taken through assessor training. The requirements and qualification of assessors and engagement of experts are provided in **KENAS-TS-OP-008 Procedure for selection, training and approval of assessors and experts**

- 6.1.2.2** KENAS personnel who perform application review, document review or review assessment reports prior to progressing the same to the accreditation committee for decision making are trained and qualified to assessor level and hence have the knowledge of assessment principles and techniques and management system requirement. The accreditation committee members are brought up to speed on the requirements of the normative standards requirement.
- 6.1.2.3** KENAS personnel who perform application review, document review or review assessment reports and the accreditation committee who make decisions on accreditation are evaluated on their understanding of KENAS policies and procedures, accreditation scheme requirements and the associated guidance documents.
- 6.1.2.4** KENAS personnel who perform application review, document review or review assessment reports and the accreditation committee who make decisions on accreditation have been brought up to speed with the **KENAS Risk management Policy KENAS-POL-039** as applied to internal processes. It is also expected that the same would apply when reviewing and making decisions with respect to the conformity assessment scheme under review. The staff and committees provide inputs based on their reviews that are included and monitored on the **KENAS risk register KENAS-TS-F-018**.
- 6.1.2.5** The KENAS application form **KENAS-TS-F-022** requires CABs to disclose the regulatory requirements that apply to their conformity assessment activities. KENAS personnel who perform application review, document review or review assessment reports prior to progressing for decision making review this information to inform fulfillment of the stated regulatory requirements.
- 6.1.2.6** KENAS assessment teams are selected on the basis of qualification, filed/scope of expertise and skills required for effective assessments. This information is maintained in a register.
- 6.1.2.7** KENAS staff, assessors and experts engaged in any process of accreditation are all required to have note and report writing skills.
- 6.1.2.8** The Accreditation Committee is made up of persons who have been trained on the scheme requirements that KENAS accredits and hence can evaluate assessment outcomes including recommendations made by the assessment team.

- 6.1.3** To facilitate the monitoring of performance and competence of the personnel involved in the accreditation process, KENAS has in its implementation a documented procedure **KENAS-TS-OP-008** which covers monitoring and evaluation of the performance and



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	10 of 20

competence of the assessors and experts. The evaluation of accreditation committee is as provided for in the evaluation tool for committees of state corporations and augmented by specific KENAS requirements.

6.2 Personnel involved in the accreditation process

- 6.2.1 KENAS has access to sufficient number of competent personnel to manage and support its accreditation activities and planned extensions. These are listed on the database **KENAS-TS-F-020**.
- 6.2.2 The external assessment personnel are contracted. All members of the assessment team sign off confidentiality and impartiality declarations **KENAS-TS-F-004** prior to commencement of any assessment activity assigned as stipulated in the Procedure for Management of Confidentiality, Impartiality and Objectivity- **KENAS-TS-OP-013**.
- 6.2.3 The assessment team is provided with an assessment containing documents and information as ticked on the checklist **KENAS-TS-F-036**

6.3 Personnel records

KENAS maintain records including qualifications, training, results of monitoring, experience, professional affiliations for personnel managing and performing accreditation activities. Records are kept in the confidential registry and are stored and maintained as per the procedure **KENAS-TS-OP-001**

6.4 Outsourcing

KENAS shall normally undertake accreditation activities except where this is not feasible. Outsourcing of accreditation activities except for decision making shall be done in accordance to the **KENAS Outsourcing Policy KENAS-POL-019**

7. PROCESS REQUIREMENTS

7.1 Accreditation requirements

Accreditation requirements for CABs are as set out in the relevant international standards and other normative documents. Additional criteria may be utilized for harmonized assessments. Any additional criteria applied is provided on the KENAS website www.kenas.go.ke.

7.2 Application for Accreditation

- 7.2.1 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**. This form requires that an **Accreditation Agreement (KENAS-TS-F-015)** is duly filled and



KENYA ACCREDITATION SERVICE

Document Title: **QUALITY MANUAL**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	11 of 20

submitted to KENAS. Information required of the CAB is detailed on the application form. KENAS shall review for adequacy the information provided by the CAB.

7.2.2 Once the form is filled and the requirements on the application fulfilled, the CAB shall endorse and forward it to KENAS for review.

7.2.3 KENAS reviews the provided information for completeness. If the application is suitable, an acknowledgement shall be written to the client and an assessment team shall be allocated to commence with document review. If the application is not suitable the gaps will be communicated to the CAB through the acknowledgement letter.

7.2.4 At any point in the application or initial assessment , if there is evidence of fraudulent behavior, if the CAB intentionally provides false information or conceals information, KENAS shall reject the application or terminate the assessment process. This is provided for in the **Accreditation Agreement: KENAS-TS-F-015**

7.2.5 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:

7.2.5.1 No prior knowledge of the clients operations.

7.2.5.2 The scope applied for is not clear.

7.2.5.3 The location and nature of the CAB's establishment is not known.

7.2.5.4 A request is made by the CAB to check its readiness for accreditation.

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 and procedures as provided in the application form.

7.3.2 Availability of a competent assessment team to conduct the assessment in a timely manner. The Accreditation Committee charter has room to co-opt person(s) with requisite competence where desired.

7.3.3 Where an assessment cannot be conducted in a timely manner or outsourcing is desired, this shall be communicated to the client accordingly.

7.4 Preparation for assessment

7.4.1 KENAS shall formally appoint the assessment team consisting of a team leader, and where required, a suitable number of assessors and/or experts for the scope to be assessed. The Assessment team shall be selected from the existing database (**KENAS-TS-**



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	12 of 20

F-020). A justification for use of assessors / experts who are not on the database shall be provided and approved prior to engagement. In selecting the assessment team the following shall be put to consideration:

7.4.1.1 The team shall have appropriate knowledge of the specific scope of accreditation.

7.4.1.2 The team shall have an understanding of assessment requirements to enable make a reliable assessment of the competence of the CAB to operate within the scope of accreditation.

7.4.2 Upon appointing the assessment team, KENAS shall inform the CABs of the names of such members and the organizations they belong to preferably a week or more in advance, to enable the CAB lodge an objection to the appointment of any particular team member with supporting justification. In case a particular CAB raises an objection, this shall be dealt with in accordance with **KENAS-POL-018 and KENAS-TS-OP-020**

7.4.3 KENAS shall clearly define the assignment given to the assessment team in the letter of engagement and shall require that the team adheres to **KENAS-GUD-003**

7.4.4 The assessment team shall undertake the assessment as per procedure **KENAS-TS-OP-010**.

7.4.5 Where the scope of the CAB covers a variety of specific conformity assessment activities 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**.

7.4.6 In selecting the activities to be assessed, KENAS shall consider the risk associated with the activities, locations and personnel covered by the scope of accreditation.

7.4.7 The Assessment team shall develop an assessment plan to cover the activities to be assessed, the locations at which the activities will be assessed, the personnel to be assessed where applicable. Various assessment techniques are utilized including witnessing.

7.4.8 KENAS shall confirm with the CAB the date(s) and the plan of assessment.

7.4.9 KENAS shall ensure that the assessment team is provided with the appropriate requirement documents, previous assessment records where applicable, relevant documents and records of the CAB. **An assessment pack checklist KENAS-TS-F-036** shall be duly filled in this regard to ensure that all the relevant information is provided.

7.5 Review of Documented Information

7.5.1 The assessment team shall review all relevant documented information supplied by the CAB in order to evaluate the CAB's system as documented, for conformity with the relevant standard(s) and other requirements for accreditation. A report shall be availed to the CAB for all initial assessments, however for re-assessments; the review of documented information supplied by the CAB shall be indicated in the final report.



KENYA ACCREDITATION SERVICE

Document Title: **QUALITY MANUAL**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	13 of 20

7.5.2 KENAS can decide not to proceed with the assessment on the basis of non-conformities found during the review of documented information. In such cases KENAS shall communicate such decision in writing to the CAB.

7.6 Assessment

- 7.6.1** KENAS conducts its assessments in line with **KENAS-TS-OP-010** which provides for the assessment techniques used and what is considered in arriving at assessment durations. The procedure provides for reporting of the assessments to the CAB.
- 7.6.2** The assessment team shall commence the onsite assessment with an opening meeting irrespective of whether the assessment is conducted on site or remotely. The agenda of the opening is as outlined in the Opening/Closing Meeting template **KENAS-TS-F-043**
- 7.6.3** The assessment team shall conduct the assessment of the CAB based on the assessment plan
- 7.6.4** The assessment team shall analyze all the relevant information and objective evidence gathered during the assessment as recorded in **KENAS-TS-F-009** if manual, or keyed in directly to Q-pulse to determine the competence of the CAB.
- 7.6.5** The assessment team shall discuss the findings and reach a conclusion, however where the team cannot reach a conclusion on a finding, the team shall refer back to the Deputy Director Technical Services for clarification
- 7.6.6** KENAS assessment procedure provides for closing meeting at the end of the assessment as provided in the template **KENAS-TS-F-043**. A written report shall be provided to the CAB in accordance to **KENAS-TS-F-011** or as electronically generated from Q-pulse. In case the report as written differs with the outcome of assessment as informed to the client at the closing meeting, KENAS shall provide an explanation to the CAB in writing.
- 7.6.7** KENAS shall be responsible for the content of the assessment report.
- 7.6.8** When non-conformities are raised these shall be filled in the Corrective Action request forms **KENAS-TS-F-010** if manual or directly into Q-pulse .The CAB shall be expected to provide its corrective action plan by identifying the root-cause, taking immediate correction and a corrective action to resolve the non-conformity and prevent the same from recurring. This shall be agreed upon within 5 days of completion of the assessment and closed within one (1) month but not later than three (3) months of the assessment.
- 7.6.9** 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 and appropriate. If the responses are found to be insufficient, KENAS shall request for further information. Additionally, evidence of actions taken may be requested or a follow-up assessment may be carried out to verify implementation of the corrective actions. KENAS requires that corrective actions taken for all non-conformities raised are closed prior to presentation of the case file for decision making. Effectiveness of closure shall be checked at the subsequent assessment activity.



KENYA ACCREDITATION SERVICE

Document Title: **QUALITY MANUAL**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	14 of 20

7.7 Accreditation Decision Making

- 7.7.1 KENAS makes its accreditation decisions in line with **KENAS-TS-OP-019** and **KENAS-TS-OP-011**.
- 7.7.2 Each accreditation decision on granting, maintaining, extending, reducing, suspending and withdrawing accreditation is done by the accreditation committee which constitutes persons different from those who carried out the assessment. Where reduction, suspension or withdrawal is requested by the CAB, KENAS implements the request upon notification to the accreditation committee.
- 7.7.3 The information provided to the accreditation committee for review is as captured in **KENAS-TS-OP-019**.
- 7.7.4 The Accreditation Committee shall prior to making a decision be satisfied that the information is adequate to decide that the requirements for accreditation have been fulfilled.
- 7.7.5 The accreditation committee charter provides for the frequency of meetings where decisions are made. This is provided in **KENAS-GUD-001**. One decisions are made, the CAB is notified within one week.
- 7.7.6 Where KENAS uses results of an assessment performed by another AB, it shall confirm that the AB is an ILAC MRA or IAF MLA signatory as required in the KENAS outsourcing policy **KENAS-POL-019**.

7.8 Accreditation Information

- 7.8.1 KENAS provides an accreditation certificate which is accompanied by an accreditation schedule containing the detailed scope of accreditation of the CAB upon granting accreditation and upon re-assessment. The schedule is amended upon extending or reducing accreditation.
- 7.8.2 KENAS accreditation holds for four (4) years and hence the certificate issued is valid for four (4) years from the accreditation decision date.
- 7.8.3 The scope of accreditation contains the details provided in the application form **KENAS-TS-F-022** with support from procedure **KENAS-TS-OP-016**.
- 7.8.4 KENAS applies a fixed scope approach to accreditation.

7.9 Accreditation Cycle

- 7.9.1 KENAS Accreditation cycle is four (4) years from the date of decision for granting the initial accreditation and subsequently four (4) years on expiry upon successful decision after re-assessment.



KENYA ACCREDITATION SERVICE

Document Title: **QUALITY MANUAL**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	15 of 20

7.9.2 Once an accreditation decision is made, the scheme draws up an accreditation program with assessment activities executed in line with **KENAS-TS-OP-010**.

7.9.3 The assessment program as drawn ensures that the requirements of the international standards, other normative documents and the scope of accreditation are assessed taking into consideration the risk associated with the assessment activity. An accredited CAB shall be assessed on the sixth month from the date of accreditation and thereafter every one year if the outcome at six months is satisfactory. If the outcome for a CAB that is on a one year review program is not satisfactory, the assessment activity may be tightened further to six months.

7.9.4 A re-assessment shall be carried out six (6) months before expiry of the accreditation taking into consideration the information gathered from assessments performed over the accreditation cycle.

7.9.5 KENAS may conduct extraordinary assessment as a result of complaints, changes or other matters that may affect the ability of the CAB to fulfill requirements of accreditation

7.10 Extending Accreditation

KENAS handles extensions to accreditation scope in line with **KENAS-TS-OP-011**.

7.11 Suspending, withdrawing or reducing accreditation

7.11.1 KENAS handles suspensions, withdrawals and reduction of accreditation in line with **KENAS-TS-OP-011**.

7.11.2 KENAS shall withdraw accreditation where there is evidence of fraudulent behavior or where the CAB intentionally provides false information or conceals information. This is covered in the accreditation agreement **KENAS-TS-F-015** that CAB's sign.

7.11.3 The criteria for lifting a suspension of accreditation is covered under **KENAS-TS-OP-011**

7.12 Complaints

7.12.1 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**.

7.12.2 KENAS shall investigate all validated 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. This procedure shall therefore be posted on the website.

7.12.3 Upon receipt of a complaint, KENAS shall confirm whether the complaint relates to accreditation activities and if confirmed handled accordingly.



KENYA ACCREDITATION SERVICE

Document Title: **QUALITY MANUAL**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	16 of 20

- 7.12.4 KENAS shall acknowledge receipt of any complaint and where validated, provide the complainant with updates where the investigation process takes longer than stipulated in the procedure.
- 7.12.5 The decision to be communicated to the complainant shall be made by the KENAS CEO once investigation and or review is done by person (s) not involved in the activities in question.
- 7.12.6 KENAS shall communicate to the complainant in the outcome of the investigation and close the complaint
- 7.12.7 KENAS clients who raise complaints shall not be discriminated upon

7.13 Appeals

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**.

7.14 Records on CABs

- 7.14.1 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.
- 7.14.2 **KENAS-TS-OP-001** provides for retention of such records

8. Information Requirements

8.1 Confidential Information

- 8.1.1 Confidentiality arrangements are captured in the Accreditation Agreement that is signed by KENAS and the CAB. Except where information is required to be publicly available or when agreed between KENAS and CAB, all the other information obtained during accreditation shall be considered proprietary information hence regarded as confidential.
- 8.1.2 Where KENAS is required by law or authorized by contractual requirements to release confidential information, the CAB shall unless prohibited by law be notified.
- 8.1.3 Information obtained about a CAB from other sources other than the CAB e.g. complainants, regulators, shall be confidential between KENAS and the CAB The provider (source) of the information shall be confidential to KENAS and shall not be shared with the CAB unless agreed by the source.



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	17 of 20

8.1.4 Personnel, including committee members, contractors or individuals working on behalf of KENAS shall commit to confidentiality and keep confidential all information obtained or created during the performance of KENAS activities except as required by the law.

8.2 Publicly available Information

8.2.1 The following information shall be made available on the website

- 8.2.1.1 Legal notice 55 of 2009
- 8.2.1.2 KENAS-TS-F-015 that provides for the KENAS rights and obligations
- 8.2.1.3 Audited Accounts showing sources of funds and any financial support
- 8.2.1.4. Information on training or other support / programs KENAS engages in.
- 8.2.1.5. Information regarding international recognition arrangements
- 8.2.1.6 Accreditation Schemes
- 8.2.1.7 KENAS Quality Manual, relevant policies, procedures and Guidance documents.
- 8.2.1.8 KENS-TS-F-015 that provides for rights and obligations of the CAB
- 8.2.1.9 Procedure on lodging of Complaints and appeals
- 8.2.1.10 Information on use of accreditation marks and combined marks
- 8.2.1.11 Accreditation certificate and schedule of accreditation of a CAB unless there are security reasons
- 8.2.1.12 Due notice for changes are provided in the accreditation agreement

9.0 Management System Requirements

- 9.1.1 KENAS has established a management system and is implementing and maintaining the same in accordance with the requirements of ISO/IEC 17011
- 9.1.2 KENAS has also put in place appropriate policies, procedures and objectives that will continually improve the effectiveness and efficiency of the said management system. The top management commitment is as provided in the KENAS Quality Policy.
- 9.1.3 The responsibilities and levels of authority are as provided in job description and or letter of engagement



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	18 of 20

9.1.4 KENAS operates its management system under option A

9.2 Management System

9.2.1 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 Management system constitutes this manual, policies and procedures and records that inform output of the accreditation services. All these are established in line with the requirements of ISO/IEC 17011

9.2.2 KENAS reviews its management system to inform effectiveness and continual improvements

9.3 Document control

In order to effectively control all internal and external documents that relate to accreditation activities, KENAS has developed a procedure **KENAS-TS-OP-001**.

9.4 Records control

KENAS has established a procedure that defines the activities related to identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records in **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.

9.5 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.

9.6 Improvement

In order to identify opportunities for improvement and to take preventive actions to eliminate risks identified, KENAS has established a **risk management process (KENAS-POL-039)**.

9.7 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.

9.8 Management Reviews



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	19 of 20

KENAS has a documented procedure (**KENAS-TS-OP-006**) for reviewing its management system. This activity is undertaken at planned intervals as specified in the procedure 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.

9 REFERENCE AND RELATED DOCUMENTS

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity assessment – Requirements for bodies accrediting conformity assessment bodies
2.	ISO/IEC 17000	Conformity assessment - Vocabulary and general principles
3.	ISO/IEC 17020	General criteria for the operation of various types of bodies performing inspection
4.	ISO/IEC 17021	Conformity assessment - Requirements for bodies providing audit and certification of management systems
5.	ISO/IEC 17024	Conformity assessment - Requirements for bodies providing certification of persons
6.	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
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
12.	Legal Notice No. 55 of 2009	Kenya Accreditation Service (KENAS) Legal order
13.	AFRAC M001	Policies and Procedures for a Mutual Recognition Arrangement among ABs
14.	AFRAC M002	AFRAC MRA

10 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
15/06/2012	01	MR	<ul style="list-style-type: none"> Format change for entire QMS documentation



KENYA ACCREDITATION SERVICE

Document Title: QUALITY MANUAL

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-QM-MAN-001	07	20/09/2018	20/10/2018	MAN	20 of 20

15/10/2012	02	MR	<ul style="list-style-type: none">Change of erroneous effective date indicating effective
05/07/2013	03	MR	<ul style="list-style-type: none">Change from ISO Guide 65 to ISO/IEC 17065Update of KENAS Vision, Mission as reviewed based on the Strategic plan 2012-17Addition of document references to 7.1.2Change of narrative under KENAS symbols on page 3 and VIM on page 18
05/02/2014	04	MR	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Replaced the Preventive actions procedure with the risk management policy.
10/02/2017	06	MR	<ul style="list-style-type: none">Removed the statement on quarterly management review meetings referred to in clause 5.8 and retained reference to the procedure for further details.Amended clause 6.3 to accommodate all personnel involved in accreditation and addition of evaluation of the accreditation committee.
20/09/2018	07	DDTS	<ul style="list-style-type: none">Alignment to ISO/IEC 17011:2017 requirementsRemoved definition of related bodyAddition of AFRAC MRA references,