

Acknowledgement

The development and publication of this Guide to Medical Laboratory Accreditation was made possible by the support of A Global Public Healthcare Foundation (AGHFP), Presidents Emergency Plan for AIDs Relief (PEPFAR) and Centers for Disease Control and Prevention (CDC) as part of their contribution to support medical laboratory accreditation in the country. KENAS wishes to record its appreciation for this support.

The following persons made enormous and unreserved contribution during the development of the guide. You provided valuable insights at the workshops and through one on one engagement, which informed successful completion of this guide. Special thanks go to:

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The guide will promote understanding of what is required for accreditation of medical laboratories and ease the roadmap towards accreditation.

Foreword

One of the most significant barriers to achieving universal access to treatment and prevention of diseases, meeting health-related MDGs, and implementing the IHRs is the lack of adequate laboratory infrastructure and systems in Sub-Saharan Africa. It is a fact that laboratories form the backbone of health systems around the world, providing doctors and other health care workers with test results that help in diagnosis of diseases such as Malaria, TB, Ebola, etc. When Medical Laboratories function properly, clinicians get correct diagnosis hence giving guidance for appropriate and effective treatment.

In order to overcome and arrest these bottlenecks, Kenya Accreditation Service (KENAS) established a Medical Laboratory Accreditation (MLA) scheme in 2009 to enable laboratories to develop and document their ability to deliver credible results, results that can be relied upon to get correct diagnosis and hence treatment and also help detect, identify, and promptly report all diseases of public health significance that may be present in clinical specimens.

This document candidly spells out the KENAS MLA scheme, benefits of the scheme, vision statement, mission, governance, organizational structure, operating principles and steps to medical laboratory accreditation processes such as application, fees structure, assessments, accreditation granting and decision making, Use of KENAS Accreditation Logos, Marks and Symbols, Re-assessment, Surveillance, Extension of accreditation, Suspension, Withdrawal and Reduction of Accreditation Scope among others.



Chairperson
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Preface

Accreditation is used worldwide for the recognition of Conformity Assessment Bodies (CAB) to perform specific tasks and demonstrate competency in the production of reliable results. KENAS is established under the State Corporation Act, vide Legal Notice No.55 of 2009 as the Sole National Accreditation Body in Kenya. KENAS is mandated by the Government of Kenya to offer accreditation services to Medical, Pharmaceutical, Veterinary, Testing and Calibration Laboratories, Proficiency Test Providers, Inspection Bodies and Certification Bodies.

Once accredited, a medical laboratory is recognized as competent to perform particular tests and analysis by using suitable quality assurance techniques as well as use of calibrated equipment and validated methods of analysis. Accreditation underscores that a laboratory meets requirements of the **International Standard ISO 15189- Medical Laboratories** and demonstrates a commitment to total reliability in producing dependable and impartial results.

Medical laboratory accreditation focuses on a patient's needs and the clinical personnel responsible. The processes are designed to deliver desired value to the customer and to minimize wastage hence reduce costs. Laboratory accreditation promotes workforce retention as it instills a sense of professional pride. External evaluation, assures customers that service meets acceptable quality and safety standards services.

KENAS MLAS is open to all medical laboratories irrespective of size, complexity or nature and whether private, public or faith based.



Managing Director
Mr. Sammy Milgo

List of Abbreviations

CAB	Conformity Assessment Body
CAR Form	Corrective Action Request Form
EQA	External Quality Assessment
IHR	International Health Regulations
ILAC	International Laboratory Accreditation Cooperation
IQC	Internal Quality Control
ISO	International Organization for Standardization
KENAS	Kenya Accreditation Service
KENAS MLA	KENAS Medical Laboratory Accreditation
KENAS MLAS	KENAS Medical Laboratory Accreditation Scheme
MOH	Ministry of Health
PHLN	Public Health Laboratory Network
PT	Proficiency Testing
TB	Tuberculosis
WHO	World Health Organization
WHO-AFRO	World Health Organization Regional Office for Africa
SLIPTA	Strengthening Laboratory Improvement Process Towards Accreditation
MDG	Millennium Development Goals
MLTC	Medical Laboratory Technical Committee

Terms and definitions

Assessment: A process undertaken by an accreditation body to evaluate the competence of a CAB based on a particular standard and or other normative does and defined scope of accreditation.

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

Assessor: person assigned by an accreditation body that perform, alone or as part of an Assessment team, an assessment of a CAB laboratory.

CAB: A body that performs Conformity Assessment Services and can be the subject of accreditation.

Case Officer: Accreditation body personnel who provides advice on the policies, procedures and regulations of the accreditation body and may act as a lead assessor, technical assessor or technical expert, if he/she has the relevant assessor qualifications.

Lead Assessor: Assessor who is given overall responsibility for specified assessment activities.

Note 1 – A lead assessor may also conduct the assessment of the management system or act as a technical assessor during the same assessment.

Medical laboratories: Laboratories engaged in, for instance chemical, hematological, microscopic, transfusion medicine, microbiological, immunological, toxicological, molecular genetic or other laboratory examinations of specimens derived from human beings for the purpose of clinical diagnosis, post-treatment follow-up, health condition assessment, and other related medical laboratory services.

Proficiency testing/ PT/EQA: A program in which multiple specimens are periodically sent to members of a group of laboratories for analysis and/or

identification; in which each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and others.

Internal audit: Periodical audits performed to ensure that a quality system is fully implemented by the laboratory and practiced by personnel at all levels.

Quality manual: Document indicating that the laboratory has established and maintains a quality management system.

Quality policy: Senior management's requirements outlining the laboratory's commitment with regard to quality of services.

Quality management system: Description of organizational structure, duties and responsibilities, operational procedures, processes, and resources to be utilized in order to ensure successful quality management

Technical Assessor: an assessor who conducts the assessment of the technical competence of the laboratory specific area(s) of the desired scope of accreditation.

Note 2 – An assessor or technical assessor may also conduct assessment of the management system, if deemed competent to do so.

Traceability: Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international reference standards, through an unbroken chain of comparisons, all having stated uncertainties.

Note:

- a) The concept is often expressed by the adjective "traceable";
- b) The unbroken chain of comparisons, all having stated uncertainties.

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1.0 Background and Rationale for Setting up the KENAS MLAS

Under the auspices of KENAS, the MLAS was established in 2007 to provide accessible Medical Laboratory Accreditation Service in Kenya with the vision to promote quality in health care services. KENAS promotes competence and creates awareness on the importance of accreditation and factors necessary to facilitate it. KENAS MLAS is based on Government regulations, regional and international directives, market and customer needs and requirements for health and safety.

One of the most significant barriers to achieving universal access to treatment and prevention of diseases, meeting health-related MDGs, and implementing the IHRs is the lack of adequate laboratory infrastructure and systems in Sub-Saharan Africa. It is a fact that laboratories form the backbone of health systems around the world, providing doctors and other health care workers with test results that help in diagnosis of diseases such as Malaria, TB, Ebola, etc. When Medical Laboratories function properly, clinicians get correct diagnosis hence giving guidance for appropriate and effective treatment.

This document is aimed at providing requisite information to all laboratory stakeholders on processes and requirements from application to granting of accreditation.

1.1 Advantages of the KENAS MLAS

An accreditation certificate issued by KENAS is recognition that the laboratory has implemented a reliable quality management system and has appropriate technical competence to give out trustworthy and reliable test results.

Accreditation ensures:

- Quality improvement in internal operations;
- Credibility of results of conformity assessment activities;
- Improved market image which means a more competitive position;
- Accessibility of attracting third-party work.

The KENAS MLAS recognizes that Competence, Quality and Reliability of medical laboratories are vital to the provision of quality patient care.

The cornerstones of the KENAS MLAS are: its Affordability, Sustainability, Effectiveness, Quality and Competence.

1.2 KENAS MLAS Commitment Ensures that;

- Laboratories seeking accreditation build a sustainable quality management system that guarantees the highest quality of laboratory test results;
- Laboratories seeking accreditation meet applicable regulatory requirements and relevant national/international standards; evaluate and continually improve the effectiveness of the services provided.

2.0 Vision, Mission and Motto for KENAS MLAS

2.1 Vision

To be a global leader in the provision of internationally recognized medical laboratory accreditation services.

2.2 Mission

To provide accreditation services that promotes quality health care services to all.

2.3 Motto

Competence in conformity assessment.

3.0 Governance

KENAS Board is the overall governing body who advise the Minister responsible for industrialization on accreditation issues and oversees the financial and administrative functions at KENAS.

The Accreditation committee which is independent of KENAS functions makes decisions with respect to granting, suspension or withdrawal of accreditation in an objective and impartial way and determines use of accreditation marks / symbols and certificates.

The Managing Director who is also the Chief Executive officer in KENAS oversees the day to day operations at KENAS.

Technical functions are overseen by the Deputy Director in charge of Technical Services and the Assistant Director in charge of Health and Safety.

The Medical Laboratory Technical Committee (MLTC) is made up of individuals who are recognized as experts in the Medical laboratory fields, and volunteer to contribute to the success of the KENAS MLAS. The MLTC reviews the KENAS MLAS scopes, processes, procedures, criteria / checklists for conformity on a regular basis and advice the KENAS MLAS Secretariat.

KENAS has defined and documented policies and objectives of its activities. A channel for effective communication, including complaint management and appeals has been put in place. Policies are communicated to and at all levels of the organisation and effort made to ensure they are understood and implemented.

4.0 Steps to Medical Laboratory Accreditation

4.1 Application for KENAS Medical Laboratory Accreditation (MLA)

A laboratory interested in the KENAS MLA should first seek to become familiar with the requirements of ISO 15189: Medical Laboratory-Particular Requirements for Quality and Competence, KENAS ISO 15189 checklist, criteria for Conformity (ies) to which the laboratory is seeking accreditation and regulations. These documents can be downloaded from the KENAS website www.kenyaaccreditation.org except for the ISO 15189 standard which can be purchased from the National Standards body (Kenya Bureau of Standards) and the regulations which would be specific to the laboratory based on its establishment.

When ready, the laboratory will make a formal application requesting for accreditation from KENAS. This is done by filling an application form for accreditation of Conformity Assessment Bodies (CAB) KENAS-TS-F-022 which can be downloaded from the KENAS website. The laboratory will provide as a minimum the following information:-

- A description of the testing services that the lab undertakes and for which the lab seeks accreditation;
- A copy (on paper or electronic form) of the quality manual, relevant associated documents such as procedures, test methods, standard

operating procedures and information on participation in proficiency testing.

4.2 Fees

KENAS fee structure is as follows and is in line with KENAS application form KENAS-TS-F-022

<u>Activity</u>	<u>KES.</u>
• Application fee	40,000.00
• Documentation Review	95,000.00
• Pre-assessment (1 day)	50,000.00
• Initial assessment	250,000.00
• Additional assessor per day	60,000.00
• Surveillance assessment plus Annual Accreditation Fees (AAF)	192,000.00 +VAT

- Application fee is paid initially when a lab hands back the application form to KENAS;
- Documentation review fee is paid when the lab hands in its quality manual, procedures and other documentations for the scope of accreditation the lab is applying for;
- For new facilities, a pre-assessment may be required to enable assessor to draw up an appropriate assessment plan;
- Extension of scope of accreditation – Charges applied at the same rate as initial assessment;
- The costs indicated are based on one assessor unit for two days where an assessor unit consists of a lead assessor and a technical assessor / expert;
- In the cases of complex or wide systems, an additional assessor may be engaged at the cost of an additional assessor per day as indicated above;
- The fees indicated above are purely accreditation fees and hence do not include travel and subsistence allowance for laboratories operating away from Nairobi and its environs. In such cases the travel and subsistence allowance will be borne by the laboratory in case an assessor cannot be identified within the region of the laboratory operation;

- The fees indicated do not include government taxes which have to be paid;
- The annual accreditation fee is paid once a year for every year in accreditation. For labs under suspension, annual accreditation fee will continue to be paid. But labs on withdrawal status regardless of whether voluntary or forced will be charged at pro-rata basis considering the time of withdrawal;
- These fees may be reviewed from time to time as need arises.

The validity period of accreditation cycle is three (3) years with initial surveillance after 6 months of granting accreditation and there after once a year for the cycle of accreditation.

4.3 Assessment Team

Accreditation assessment team consists of at least a Lead Assessor and a technical assessor/ expert. Additional assessors may be added depending on the size and complexity of the laboratory. An assessment team is comprised of individuals who have the necessary technical knowledge to cover the desired scope of accreditation, knowledge in applying ISO 15189 and good communications and interpersonal skills to competently perform an assessment.

All assessors are trained on requirements of ISO 15189 and KENAS assessment/ accreditation requirements.

4.4 Desk Assessment

Upon receipt of the completed application, KENAS MLAS secretariat will conduct a desk assessment of the documents submitted by the laboratory, reviewing for adequacy of the system as documented based on the ISO 15189 requirements and its competence as regard suitable assessors and technical experts. Report of document review shall determine whether KENAS can proceed with an on-site assessment.

4.5 Pre-Assessment

A pre-assessment may be required to give an overview of the facility and general preparedness of the laboratory for accreditation. An assessment

team consisting at minimum of a lead assessor and technical assessor/expert will be formally appointed and informed to the laboratory for acceptance or rejection in cases of conflicts.

4.6 Assessment Planning

The lead assessor will draw an assessment plan detailing areas to be assessed and people to be interviewed. This plan is sent to the lab and copied to all team members at least two weeks prior to the site visit to accommodate changes.

4.7 On-site Assessment

The assessment team shall examine all aspects of the implementation of the quality management system and documentation in the organization to verify that it meets the requirements of the standards and demonstrates competence.

The assessors shall record all details of observations and findings and this shall be acknowledged by the assessee by appending a signature.

The assessment team shall summarize all their findings during the assessors review meeting and making reference to relevant clauses of the standard, quality manuals and other support documentation as well as relevant regulations. Non-conformities noted shall be detailed in a Corrective Action Request (CAR) form and the lead assessor shall ensure that the organization fully and clearly understands each of them. The non-conformities shall be categorized and discussed with the laboratory's management representative.

The lead assessor shall compile the assessment report and indicate areas that require corrective action.

A written report of the outcome of the assessment is submitted by the lead assessor to KENAS MLAS secretariat within one week of the assessment. The report contains comments on the competency and conformity of the laboratories and identified non conformities, and observations.

Non conformities are defined as major or minor.

- **Major-** Non fulfillment of a requirement of the standard or a systematic phenomenon occurring across departments whose

- investigations reveal impact or potential to impact quality of results;
- **Minor-** non-conformity discovered once and no evidence that quality of results have been affected.

All non-conformities are to be addressed by the Laboratory.

Laboratory management should use the grading in the report to prioritize corrective actions.

4.8 Close Out Assessment

The lead assessor shall conduct an onsite close out assessment for the laboratory one month after the onsite assessment to establish if the CAB has come up with effective corrective and preventive measures of the nonconformities that had been identified during the onsite assessment.

5.0 Decision Making and Granting Accreditation

The decision on whether to grant/ extend accreditation or not, shall be made by the Accreditation Committee after reviewing documents submitted by the assessors through KENAS MLAS secretariat.

An accredited laboratory is issued with an accreditation certificate which contains the KENAS logo, mark/symbol for accreditation, laboratory identity (name), unique certificate identification number, and period of accreditation. The certificate is accompanied by a schedule of accreditation which stipulates the scope of accreditation that the laboratory has been accredited to.

5.1 Use of KENAS Accreditation Logos, Marks and Symbols

Accredited laboratories will use marks and symbols as per accreditation agreement signed with KENAS. The above symbols are required to have or be accompanied by clear indication on which activity it is related to. A laboratory is allowed to use these symbols on its reports or certificates within the scope of its accreditation.

Measures have been taken to ensure that accredited laboratory fully conform to requirements for accreditation when making claims on the

media or advertising. The laboratory can only make claims concerning the premises included in the accreditation. The lab is required to take due care that no report or certificate is used in a misleading manner or any statement which KENAS may regard as misleading. Upon suspension or withdrawal, the laboratory is required to discontinue the use of all advertising material that contain any reference to accreditation status and not to allow the fact of its accreditation to imply that a test, analysis, method, process, system or person is approved by KENAS.

Incorrect references to accreditation status or misleading use of accreditation symbols found in the advertisements, catalogues etc. will result to legal actions being taken.

5.2 Re-assessment, Surveillance and Extension

The Accreditation cycle is 3 years after which a laboratory shall apply for re-accreditation. During the cycle, at least three surveillance visits are done.

KENAS has established a procedure on how periodic surveillance activities shall be carried out and at sufficient intervals to monitor the continued fulfillment by the laboratory of the requirements for accreditation. The interval between on-site assessments and reassessment/surveillance assessment depends on the proven stability of the services of the laboratory. A design indicating a plan for reassessment and surveillance of each accredited laboratory is done to assure that representative samples of the scope of accreditation are assessed including all aspects of the requirements in the standard and criteria.

If during surveillance or re-assessment non conformities are identified, then the laboratory is given a timeline for implementation of corrective actions. Continuation of accreditation will be confirmed by KENAS after considering results of the visits.

Extraordinary assessments may be done as a result of complaints or changes which are significant in the status or operation of the laboratory. Should the need to carry out an extraordinary assessment be found, the lab is advised accordingly.

A laboratory may apply to extend the scope of accreditation already granted. All assessment activities shall be undertaken to determine whether or not the extension may be granted.

6.0. Suspension, Withdrawal and Reduction of Accreditation Scope

Suspension, withdrawal or reduction of scope will be as per KENAS procedures.

6.1 Suspension of Accreditation

- KENAS shall suspend the accreditation of the CAB for non-payment of fees, critical non-conformance with the requirements or misuse of accreditation marks and symbols;
- The CAB shall only be suspended on approval by the Accreditation Committee based on reports of assessments and investigations or facts that justify the suspension;
- The Managing Director shall inform the Laboratory in writing regarding the suspension and detail the reasons. The letter shall also stipulate the maximum period of the suspension and the corrective action(s) required to be undertaken by the Laboratory;
- The Laboratory shall continue to pay the accreditation fees in full during the suspension period, The Laboratory facilities that are under suspension have their directory entries as accredited facilities removed from the KENAS website and only re-instated once they fulfil the requirement;
- A CAB facility that is under suspension for non-conformance with the requirements shall:-
 - ❖ Undergo on-site assessment prior to reinstatement;
 - ❖ Be re-instated only when positive recommendation by the assessment team is given and approved by the Accreditation Committee;
 - ❖ Meet all the associated costs.

6.2 Withdrawal of Accreditation

The Accreditation Committee shall withdraw accreditation of CAB's on the

grounds of:-

- Bankrupt;
- Voluntary or involuntary liquidation;
- Failure to make specified payment;
- Failure to adhere to the conditions and terms for accreditation;
- The reasons for suspension are not addressed within the specified period.

The laboratory shall remove all the publicity materials and advertisement(s) on accreditation. For the laboratory to be reinstated, it shall make a new application and meet all the associated costs.

6.3 Reduction of Scope of Accreditation

The Accreditation committee shall reduce the scope of accreditation when:-

- There is no evidence to guarantee that the scope shall be covered as per specified requirements;
- There is no demonstrated competence.

The Managing Director shall inform the laboratory in writing on the reduction of scope of accreditation following the accreditation committee's decision.

The laboratory shall ensure that all claims made on accreditation are within the scope that is granted. Any work done by an accredited laboratory falling outside the scope of the accreditation shall include a statement to the effect that the work carried out does not fall within the accredited scope.

7.0 Appeals

KENAS has established a procedure to address appeals and deals with disputes arising from accreditation of laboratories. These appeals are received by KENAS management and or the standards tribunal and are handled accordingly.

8.0 Proficiency Testing (PT) and Inter-Laboratory Comparison (ILC) Schemes

KENAS uses laboratory participation in proficiency testing and or inter-comparisons schemes reports in its accreditation decision making process. KENAS maintains a list of accreditation PT service providers.

Proficiency testing and inter-laboratory comparison schemes which the laboratory seeks to participate in shall be run according to the requirements of ISO/IEC 17043.

9.0 Support for WHO-AFRO Stepwise Laboratory Improvement Process Towards Accreditation:

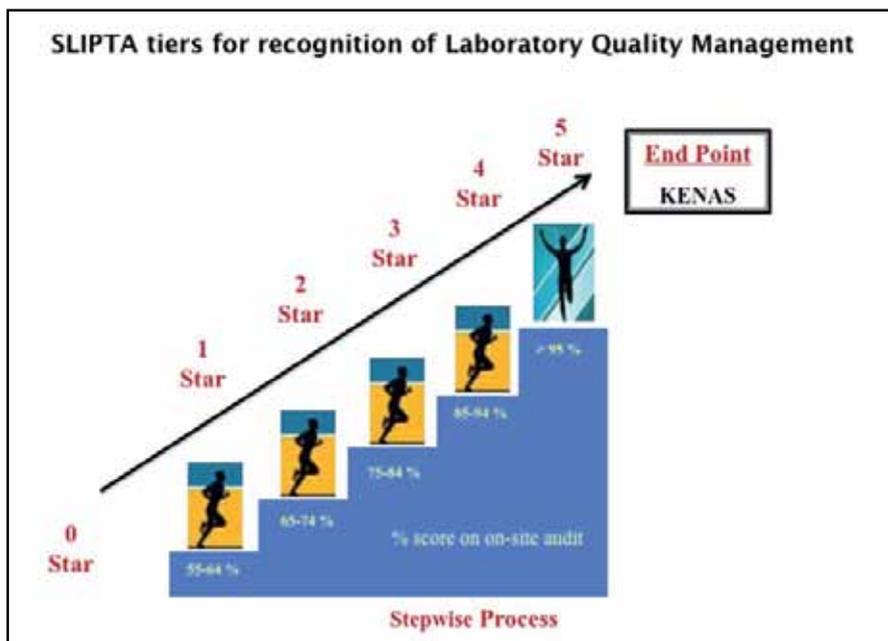
KENAS supports WHO-AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) by conducting assessment for these laboratories.

Laboratories working through the program will progressively develop compliance towards the SLIPTA checklist and ultimately be able to apply for accreditation from KENAS

The Stepwise Laboratory Improvement Process towards Accreditation is a comprehensive approach to strengthen national health laboratory services (and or private laboratories) in a stepwise manner by providing graduated levels of performance recognition towards long term fulfillment of the ISO 15189 standard. Kenya has officially adopted this process which is in line with the overall objective to support laboratories achieve accreditation.

Laboratories will be assessed by KENAS against the SLIPTA Checklist for Baseline, Midterm and End term assessments for which a star rating will be issued. KENAS will report the assessment results as per the checklist, but give areas of improvement as per ISO 15189.

KENAS will accept assessment applications from individual laboratories undergoing this process whether private or public. Ministry of Health can also submit applications for laboratories they have prioritized for accreditation. The below diagram shows the link between the SLIPTA tiers and the KENAS MLA



10.0 Impartiality, Conflict of Interest and Confidentiality.

KENASMLAS is organized and operated in a way that safeguards the objectivity and impartiality of its activities. There is a balanced representation in its structures and operations. Policies on non-discrimination in administration are observed. Firewalls have been put in place to ensure there is no undue influence (financial, commercial or otherwise) in the process of accreditation. Decisions are made after careful consideration of objective evidence. Conflicts of interest are identified regularly and managed at critical points.

By virtue of its activities, KENAS MLAS has access to confidential information about a laboratory that is undergoing accreditation or that is accredited and this is kept confidential at all times. Personnel including accreditation committee members keep confidential all information obtained or created during the performance of KENAS MLAS activities, except as required by law. Where the law requires disclosure of information without consent or after a CAB gives written consent, no confidential information should be disclosed by any personnel at any level in the structure. Only the management of a

laboratory can give confidential information pertaining to their laboratory.

11.0 Responsibility and Obligation of the Medical Laboratory

The principal function of accreditation is for laboratories to deliver quality, efficient laboratory services and reliable test results. Accreditation assessment ensures that laboratories meet explicit quality management criteria and recognizes the laboratory's technical competence

Laboratories are required to provide objective evidence, management commitment, and communication within and outside the laboratory, client satisfaction, and continual improvement through effective IQC/EQA/PT reporting practices.

Laboratories can only claim accreditation with respect to the scope for which they have been granted accreditation by KENAS.

Significant changes in their statutes or operations in respect to legal, commercial, ownership and organizational or other such matters that may affect the ability of the laboratory to fulfill its accreditation requirements are required to be communicated within thirty days to KENAS.

12.0 Responsibility and Obligations of KENAS MLAS.

- Information about the current accreditation status of medical laboratories granted accreditation will be made publicly available on the KENAS website as well as the Kenya gazette;
- Notice on changes to accreditation requirement shall be given on time and expressed views of interested parties taken into account with regard to the precise form and effective date of changes before effecting the changes;
- Information about all international arrangement shall be available to interested parties;
- Information shall be available on suitable ways of obtaining traceability of measurements and participating in proficiency testing and or interlaboratory comparison;
- Changes in accreditation fees shall be communicated to the laboratories.

