



Kenya  
Accreditation  
Service



# Medical Laboratory Accreditation

**DORIS MUENI MENGO**

**Manager Medical Laboratories Accreditation  
KENAS**

Health Regulations and Quality Standards Committee  
06/08/2024

# Accreditation

- Accreditation (by an Accreditation body) is the formal recognition that an organization is competent to perform specific processes, activities, or tasks, in a reliable, credible and accurate manner.



# Accreditation

- The scope is normally highly specific e.g. clinical chemistry- ALT, calcium, etc.
- Evaluates personnel, skills, and knowledge
- Evaluates the supporting management system for specific activities
- Involves practical tests as appropriate (PT & measurement audits).
- Evaluates equipment used , traceability of measurement etc.





# Who offers international Accreditation

- Medical laboratories should seek accreditation from Internationally recognized Accreditation bodies that operate in line with ISO/IEC 17011
- And who are signatories to the International laboratory accreditation corporation (ILAC) for example KENAS







# Accreditation in Kenya

## KENAS

- **Kenya Accreditation Service (KENAS)** is the sole accreditation body for Kenya established through an Accreditation act of August (8)/2019
- KENAS has existed since 2007





# Accreditation Services offered by KENAS

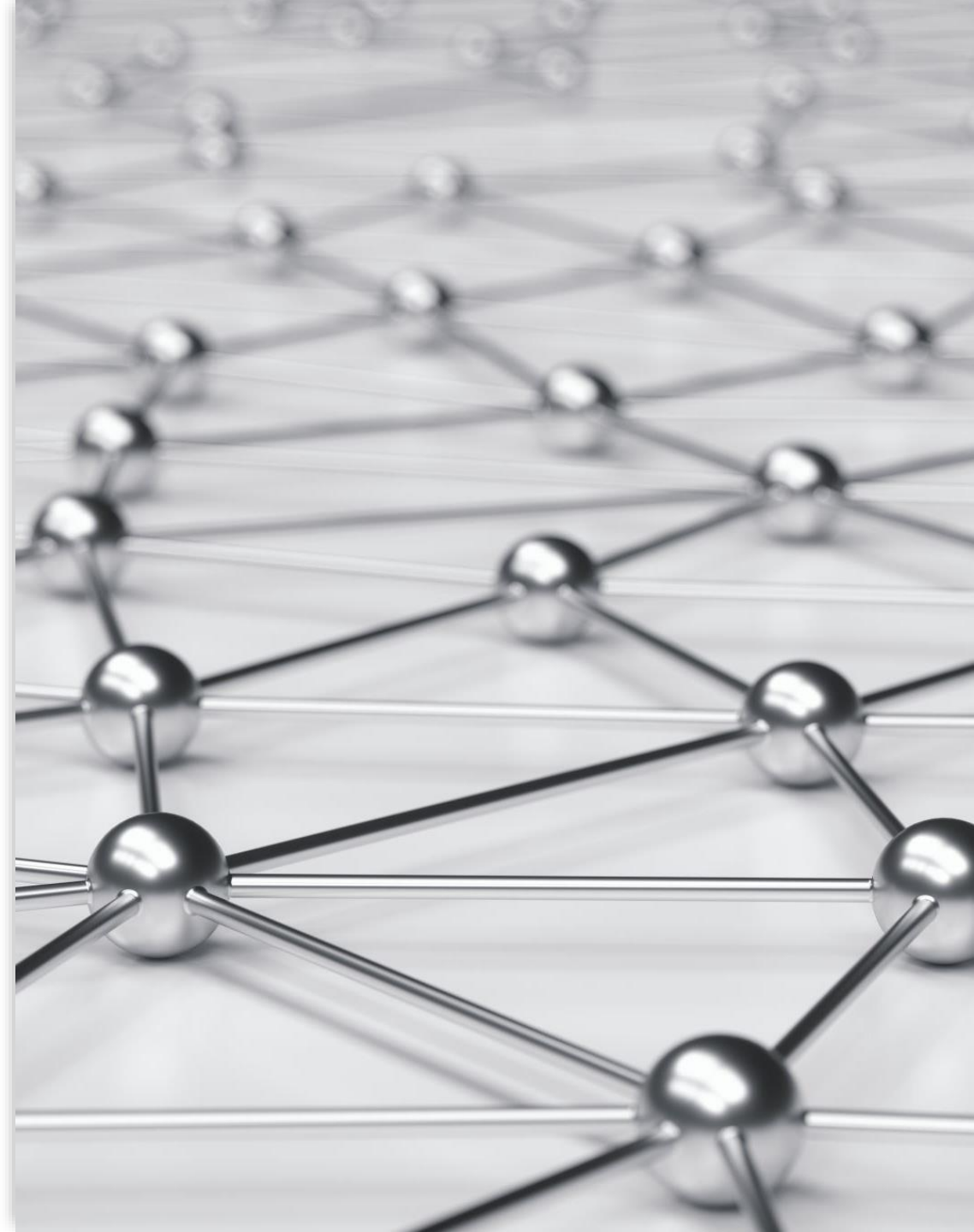
- Medical Laboratories (ISO 15189)
- Point of Care Testing (15189)
- Diagnostic Imaging Accreditation (ISO 15189)
- Biobanking (ISO 20387)
- Test and Calibration Laboratories (ISO/IEC 17025)
- Proficiency Test Providers - (ISO/IEC 17043)
- Inspection Bodies (ISO/IEC 17020)
- Certification Bodies
  - Management Systems Certification Bodies ISO/IEC 17021
  - Personnel Certification Bodies ISO/IEC 17024
  - Product Certification Bodies ISO/IEC 17065





## KENAS Cont'

- It is a Signatory member of:
  - International Laboratory Accreditation Cooperation (ILAC)
  - International Accreditation Forum (IAF)
  - African Accreditation cooperation (AFRAC)
- A members in the East African Accreditation System (EAAB) Community
- KENAS operates in line with the requirements of **ISO/IEC 17011.**





# International Recognition for KENAS



International Accreditation Forum, Inc. (IAF)

Be it known that the  
**KENYA ACCREDITATION SERVICE (KENAS),  
KENYA**

has been accepted as a Member  
of the

*International Accreditation Forum, Inc.*  
*Multilateral Recognition  
Arrangement*

for the following:

Main Scope: Product Certification – ISO/IEC 17065 (28 June 2024)

Main Scope: Certification of Persons – ISO/IEC 17024 (28 June 2024)

The Member on behalf of which this sheet is signed commits itself to comply with the requirements and obligations of Members of the IAF MLA.

Walter Ongeti  
Chief Executive Officer  
Kenya Accreditation Service  
DATE: 09 July 2024

Emanuele Riva  
Chair  
International Accreditation Forum, Inc.  
DATE: 09 July 2024



## ILAC MUTUAL RECOGNITION ARRANGEMENT

### SIGNATORIES

We, the undersigned, endorse the terms of the ILAC Arrangement and undertake, to the best of our ability, fulfillment of its objectives.

**Accreditation Body:** Kenya Accreditation Services (KENAS)

**Economy:** Kenya

**Scope and date:** Calibration ISO/IEC 17025 — 28 October 2017  
Testing ISO/IEC 17025 — 28 October 2017  
Testing ISO 15189 — 28 October 2017  
Inspection ISO/IEC 17020 — 28 October 2017  
Proficiency Testing Providers ISO/IEC 17043 — 16 May 2024

### Authorised Representative:

**Signature:**

Dr. Walter Juma Ongeti

**Chair, ILAC Arrangement Council:**

**Signature:** \_\_\_\_\_

Etty Feller

**Date:** 21/06/24

**Date:** 21 June 2024



Be it known that the  
**Kenya Accreditation Service (KENAS)**

has been accepted as a Member of the  
**African Accreditation Cooperation Mutual Recognition Arrangement**

for

### Scope and Date:

Calibration to ISO/IEC 17025	28 September 2017
Testing to ISO/IEC 17025	28 September 2017
Medical Testing to ISO 15189	28 September 2017
Inspection to ISO/IEC 17020	28 September 2017
Proficiency Testing Providers to ISO/IEC 17043	4 March 2024
Product Certification to ISO/IEC 17065	4 March 2024
Certification of Persons to ISO/IEC 17024	4 March 2024
Management Systems Certification to ISO/IEC 17021-1, ISO/IEC 17021-2 and ISO/IEC 17021-3 in sub-scopes:	
- Quality Management Systems (QMS) to ISO 9001	28 September 2017
- Environmental Management Systems (EMS) to ISO 14001	28 September 2017
Certification to ISO/IEC 17021-1 and ISO/IEC TS 22003 in sub-scope:	
- Food Safety Management Systems (FSMS) to ISO 22000	28 September 2017
Certification to ISO/IEC 17021-1 and ISO/IEC TS 17021-10 in sub-scope:	
- Occupational Health and Safety Management Systems (OH&SMS) to ISO 45001	1 June 2022

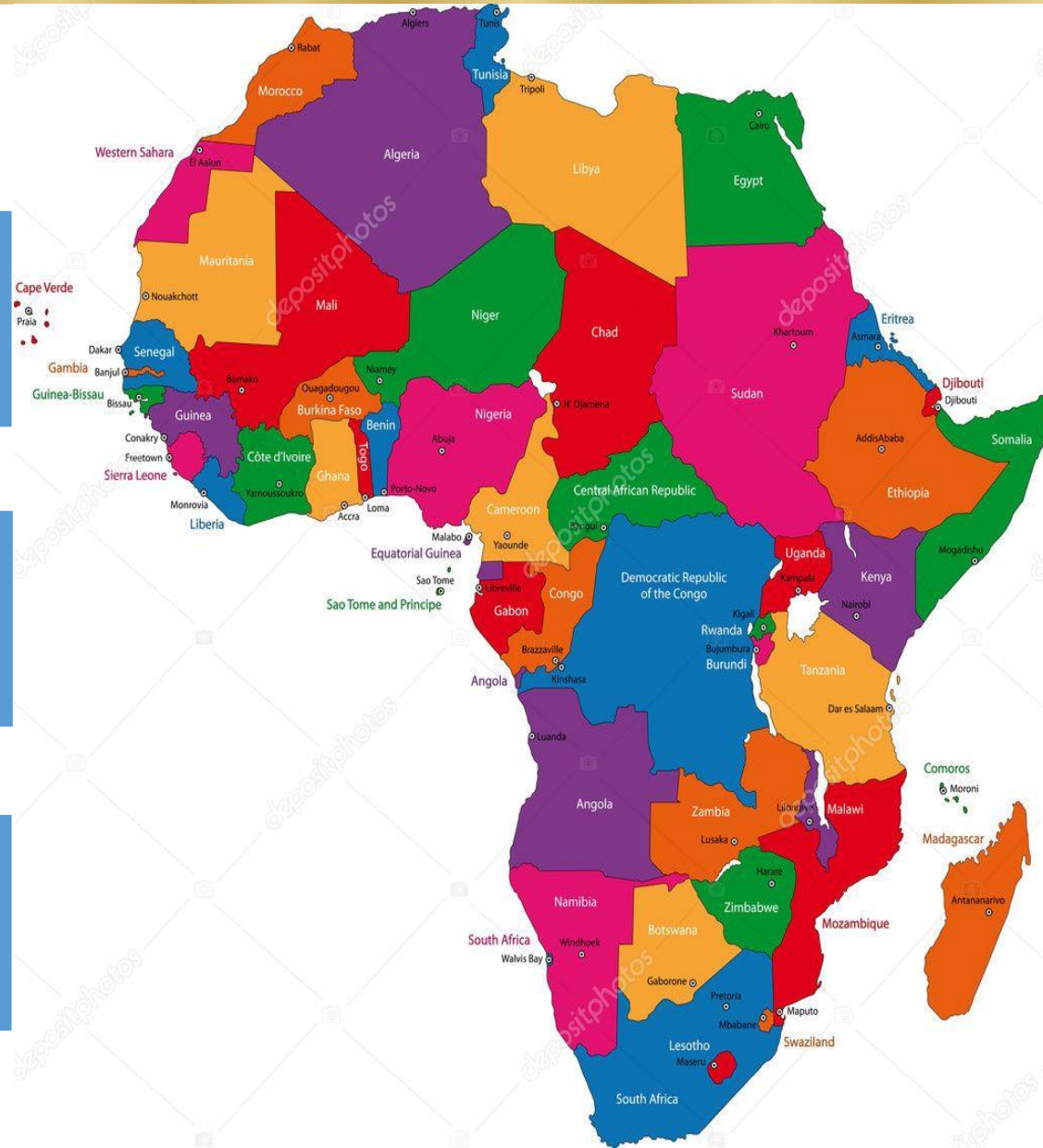
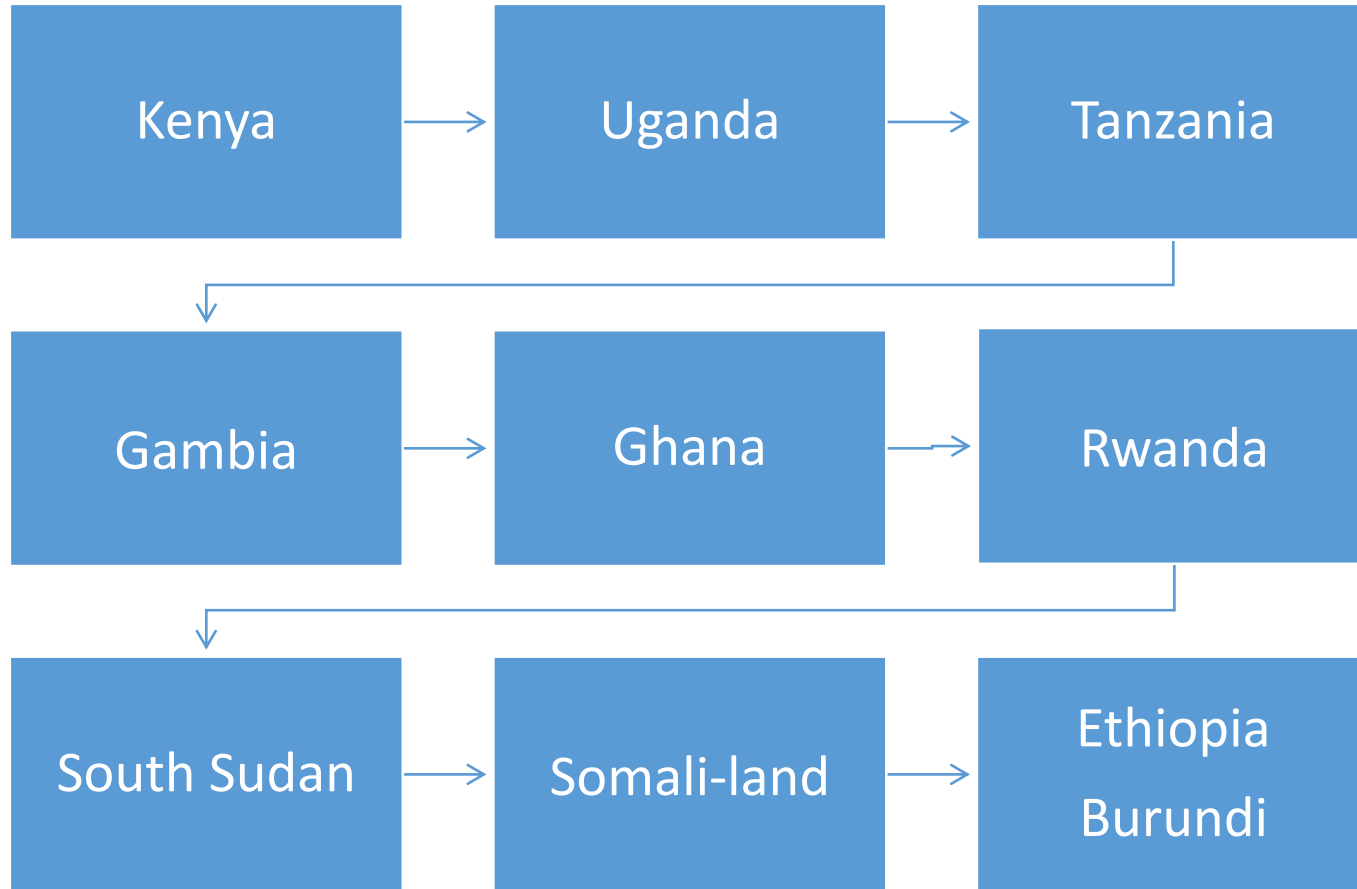
The Member on behalf of which this sheet is signed is committed to complying with the requirements and obligations of the AFRAC MRA Members.

  
Mr Martin Chesire  
KENAS Chief Executive Officer  
Dr Ronald Josias  
AFRAC Chair  
Mrs Susan Munyiri-Ochieng  
AFRAC MRA Council Chair

Signed electronically on 8 March 2024



# KENAS Accreditation- by Countries



# Medical Laboratory Accreditation

- Medical laboratory services are essential in the diagnosis and assessment of the health of patients. The services of medical laboratories encompass:
  1. Arrangements for requisition,
  2. Patient preparation,
  3. Patient identification,
  4. Collection of samples,
  5. Transportation, storage,
  6. Processing and examination of clinical samples, together with subsequent result validation,
  7. Interpretation, reporting and advice.
- Medical laboratory services should therefore meet the needs of all patients, clinical personnel responsible for patient care and any other interested parties.



# Benefits of accreditation to patients



Accreditation benefits all stake holders.

Patients are the biggest beneficiary.



# Benefits of accreditation to patients



- People understandably expect to receive high-quality, safe care when they need it.
- The patients get services by credential medical staff- confidence
- Provides timely diagnosis
- Provides accurate diagnosis = Proper patient Management





## Improved relationships

- Improves patient relationship with the medical laboratory
- Rights of patients are respected and protected
- It reduces risks associated with misdiagnosis
- Reduces lengthy stay in hospitals
- It provides peace of mind to the patient and their families.

## It reduces costs related to:



- Re-testing, or unnecessary costs related to diagnosis. – less patients travel abroad in search of diagnosis e.g. cancer
- Referral systems work much better, therefore no need for additional costs for the patients



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25 YEARS

## Promotes trust

Accreditation promotes trust in laboratories and confidence among authorities, health care providers, and patients that laboratories and the results they produce are accurate and reliable.



# Benefits of Accreditation For Healthcare Regulators

- The need to drive up the quality of care for patients, whilst delivering efficiency and productivity, is a key principle for regulators of healthcare services.
- Accreditation can be used as a tool to support the commissioning or specification of medical laboratory services that are technically competent, safe and reliable, and that continually improve the experience for patients by:
  - providing an independent assurance of quality and safety that supports world-class decisions on how to deliver better care and value for patients;
  - providing a mechanism for measuring quality improvement;
  - supporting consistency in the quality of care; and
  - encouraging innovation





# Benefits of Accreditation For Medical Laboratories

- Accreditation provides proof that a laboratory complies with best practice.
- It also offers authoritative assurance of the technical competence of a laboratory to undertake specified analysis or measurements according to validated methods.



## Accreditation:

- provides an opportunity for external perspectives on the laboratory's practice;
- can prevent the unnecessary duplication of information gathering on performance often required by regulatory bodies;
- encourages the sharing of best practice;
- stimulates innovation;
- reduces risk; and
- provides international recognition.

# Diagnostic Imaging – ISO 15189

Accreditation of ;

1. Mammography,
2. CT scanning,
3. Ultrasound,
4. MR Imaging,
5. Nuclear medicine,
6. Projection/plan film radiography

Inline with the requirements of ISO 15189 and established criteria for diagnostic imaging





# Point of Care Testing Accreditation (ISO 15189:202X)

Point of Care testing (POCT) is testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient.

**POCT** is usually performed outside a medical laboratory and typically performed by non-laboratory personnel and the results are used for clinical decision making.

Other terms commonly used to describe POCT include:

- near patient testing (NPT)
- bedside testing
- extra-laboratory testing
- disseminated / decentralized laboratory testing.



# The Journey to Accreditation

Do's





# Preparation for an ISO 15189 accreditation

- Train personnel to ISO 15189
- Document the Management system
- Participate in EQA from accredited PTP
- Calibrate and Maintain equipment
- Perform Method validation/ verification and
- Determine Measurement Uncertainty
- Conduct Internal audits
- Implementation of Corrective action as applicable
- Identify and manage Risks
- Conduct Management review meeting

INTERNATIONAL  
STANDARD

ISO  
15189

Fourth edition  
2022-12

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**Medical laboratories — Requirements  
for quality and competence**

*Laboratoires de biologie médicale — Exigences concernant la qualité  
et la compétence*



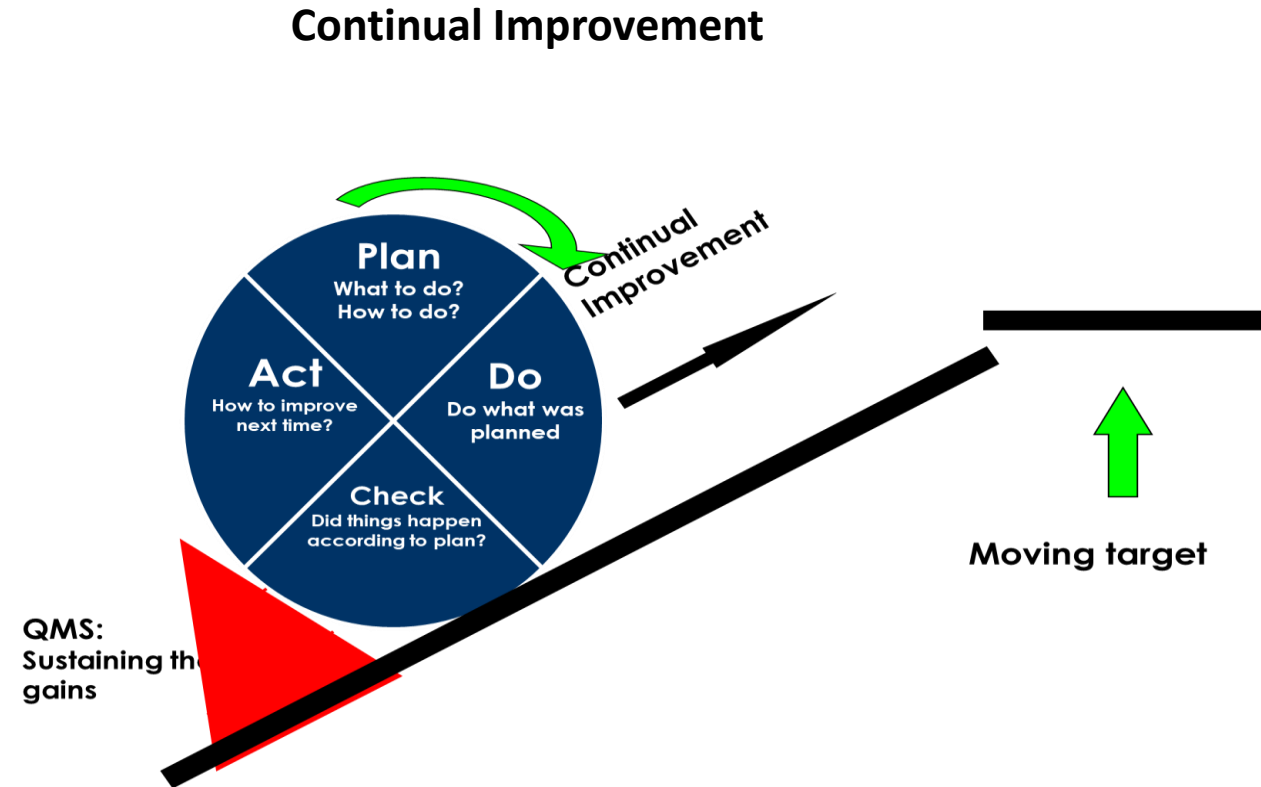
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Reference number  
ISO 15189:2022(E)

© ISO 2022

# Management Requirements

- Impartiality and confidentiality
- Legal entity
  - Regulatory requirements
    - KMPDC
    - KMLLTB
- Laboratory Director
- Structure of the organization
- Quality manager
- Policies and objectives
- Service Agreement
- Externally provided products and services
  - Referral laboratories and consultants
  - Procurement
  - EQA



## Management Requirements- cont'

- Documentation of the management systems
- Risk management , Actions to address risk , opportunities and Improvement
- Nonconformities, corrective actions
- Evaluation
  - Internal audits
  - Quality indicators
- Management reviews



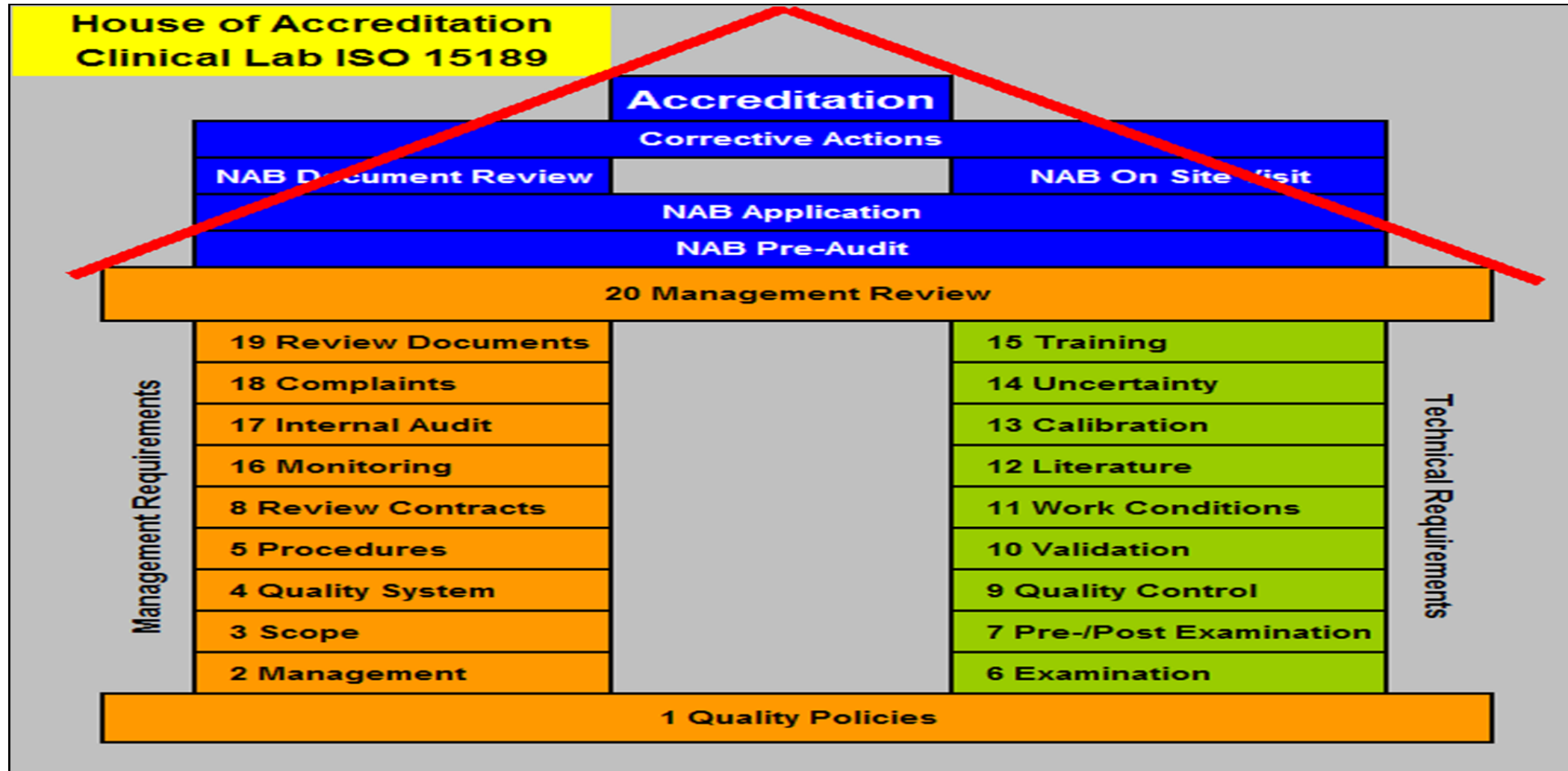


# Technical Requirements

- SOP for all tests applied & other related technical documents
- Competent personnel
- Participate in Proficiency Testing (EQA) results (at least 2 cycles ) for the test applied
- Traceability of measurement (Calibration of equipment / CRMS/ Quality Control Materials)
- Validation/ verification of methods
- Measurement uncertainty establishment
- Laboratory information system



# ISO 15189 Preparedness





**One Login**  
All Government Services

Email address or ID number \*

Enter your email or ID number

Password \*

Password

Show Password

Remember for 30 days

[Forgot Password](#)

Sign In



## Application process

- Apply through e-citizen
- Submit a filled application form
- Filled Accreditation Agreement
- Submit all documents required by ISO 15189:
  - ✓ Legal entity
    - Certificate of incorporation- private organization
    - Act of parliament / Kenya Gazette – government / county
    - Registration as an NGO – Faith based organization
  - ✓ Management documents including Quality Manual
  - ✓ Technical documents
  - ✓ Cross-reference matrix
  - ✓ Results of EQA/PT for at least two cycles



# Assessment process

## 1. Document Review Conducted in KENAS

- Gaps are identified at this stage if any



## Assessment process Cont'

### 2. Onsite Assessment by KENAS

- To ascertain implementation as per ISO 15189:2012 and laboratory's documentation and KENAS guidance documents

### 3. Closure of non-conformities- should be done within three months

### 4. Award for accreditation with periodic surveillance assessments within the 4 years that the accreditation certificate is valid

### 5. Annual accreditation Fees

### 6. Surveillance Assessment – once a year within the accreditation cycle (4 years accreditation cycle).





## Other Do's

- Ensure the system belongs to the laboratory and not the consultant – own your system
- Use right data that belongs to the laboratory
- Implement the requirements of the standard
- Ensure the laboratory complies to legal requirements and all applicable regulatory requirements (country specific)



# Journey to Accreditation



Don'ts





# Don'ts while preparing for accreditation

1

Don't copy other laboratories  
Management systems- organizations are different – this includes documentation

2

Don't cook data for Method verification/  
Measurement uncertainty

3

Don't participate in EQA / PT from non accredited providers

4

Don't hide your sins (nonconformities) - we see everything



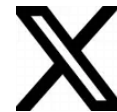
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*Thank You*



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KENAS – Kenya Accreditation Service

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