

Frequently Asked Questions on Medical Laboratories Accreditation



FAQ ON MEDICAL LABORATORIES ACCREDITATION

1. What is accreditation?

Accreditation is a formal recognition by an accreditation body that an organization is competent to perform specific processes, activities, or tasks reliably, credibly, and accurately.

2. Why is medical laboratory accreditation important?

Accreditation ensures that medical laboratories provide high-quality, safe care with accurate and timely diagnoses. It promotes trust in laboratory results among patients, healthcare providers, and regulatory authorities.

3. Which international accreditation standards should medical laboratories comply with?

Medical laboratories should seek accreditation from internationally recognized accreditation bodies operating in line with ISO/IEC 17011 and signatories to the International Laboratory Accreditation Cooperation (ILAC), such as KENAS.



4. What services does KENAS provide?

- Medical Laboratories (ISO 15189)
- Point of Care Testing (ISO 15189)
- Diagnostic Imaging (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 for Management Systems (ISO/IEC 17021), Personnel (ISO/IEC 17024), and Products (ISO/IEC 17065).

5. What are the steps in the accreditation process?

1. Training personnel to ISO 15189 standards.
2. Documenting the management system.
3. Participating in external quality assessment (EQA) from accredited proficiency test providers.
4. Calibrating and maintaining equipment.
5. Validating and verifying methods.
6. Establishing measurement uncertainty.
7. Conducting internal audits.
8. Implementing corrective actions.
9. Managing risks and conducting management review meetings.

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6. After how long should I expect feedback from KENAS after submitting an application on e-Citizen?

You should receive feedback within one day, unless you applied on Friday evening.

7. What are the benefits of accreditation to patients?

Accreditation benefits patients by ensuring they receive high-quality, safe care from credentialed medical staff. It reduces risks of misdiagnosis, lowers costs related to retesting and unnecessary diagnoses, and promotes trust in laboratory results.

8. What are the management requirements for ISO 15189 accreditation?

- Impartiality and confidentiality.
- Compliance with legal and regulatory requirements.
- Documenting the management system.
- Risk management and continual improvement.
- Conducting internal audits and management reviews.



9. What are the technical requirements for ISO 15189 accreditation?

- Standard operating procedures (SOP) for all tests.
- Competent personnel.
- Participation in proficiency testing.
- Traceability of measurement (equipment calibration, quality control materials).
- Validation/verification of methods.
- Establishing measurement uncertainty.
- Implementing a laboratory information system.

10. What should laboratories avoid during preparation for accreditation?

- Copying other laboratories' management systems.
- Falsifying data for method verification or measurement uncertainty.
- Participating in EQA from non-accredited providers.
- Hiding nonconformities.

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11. What is the application process for ISO 15189 accreditation?

The application process involves:

1. Applying through e-citizen.
2. Submitting a filled application form and accreditation agreement.
3. Providing required documents (legal entity certificates, management, and technical documents, EQA/PT results).
4. Undergoing a document review and onsite assessment by KENAS.
5. Closing identified non-conformities within three months.
6. Paying annual accreditation fees and undergoing periodic surveillance assessments during the 4-year accreditation cycle.

12. What are the steps the laboratory can take when the accreditation body finds out there is non-conformity in the lab?

1. Root cause analysis
2. Correction
3. Corrective actions
4. Evaluation of the effectiveness of the corrective actions



Kenya Healthcare Federation

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The Health Sector Board of KEPSA