Approval and Authorization

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Authored by	**ASSISTANT DIRECTOR TESTING AND CALIBRATION**	Approved	03/08/2015
Checked by	**DEPUTY DIRECTOR TECHNICAL SERVICES**	Approved	03/08/2015
Approved by	**CHIEF EXECUTIVE OFFICER**	Approved	03/08/2015

Periodic Review Approval and Authorization

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1 PURPOSE

Assuring the quality of test and calibration results requires laboratories to have quality control procedures for monitoring the validity of test and calibrations undertaken. The monitoring may include the participation in inter-laboratory comparison or proficiency testing programmes or participation in external Quality Assurance programmes. Where these do not exist, a justification has to be provided on the absence of or reason for non- participation while other means that include regular use of certified reference material or replicate test or calibrations using the same or different methods are employed

Kenya Accreditation Service (KENAS) considers the participation of laboratories in external proficiency testing / inter-laboratory comparisons an important mechanism for monitoring the integrity of test / calibration results. This statement sets out the policy of the Kenya Accreditation Service (KENAS) with respect to participation in proficiency testing / inter-laboratory comparisons by Testing and Calibration Laboratories.

2 SCOPE

This policy applies to the Laboratory accreditation schemes and Inspection schemes where testing results are used as part of the inspection activity.

3 TERMS AND DEFINITIONS

The table below defines new or changed terms that are included in or associated with this process.

Term	Definition
PT	Proficiency Testing
ILC	Inter-laboratory Comparison
Proficiency Testing	The determination of the calibration or testing performance of a laboratory or inspection body against pre-established criteria by means of inter-laboratory comparison.
Inter-Laboratory Comparison	The organization, performance and evaluation of measurements or tests on the same or similar calibration/test items by two or more laboratories or inspection bodies in accordance with

4 ROLE(S) AND RESPONSIBILITY

Role	Responsibility
CEO	• Approval
Technical Staff	• Compliance

5 POLICY

5.1 It is the policy of the Kenya Accreditation Service (KENAS) that all accredited laboratories and those laboratories seeking accreditation participate in proficiency testing / inter-laboratory comparisons and achieve satisfactory outcomes where such schemes are available and are relevant to their scope of accreditation or scope being sort for accreditation. The same also holds for inspection bodies that perform testing activities which inform inspection outcomes.

5.2 Accredited laboratories must participate, as a minimum, in at least one satisfactory PT scheme for each parameter within the laboratory's scope of accreditation, between periods of re-assessment except where regulatory requirements require a higher frequency of PT participation.

5.3 The plan for PT participation needs to be clearly drawn with a clear rationale on the frequency and level of participation and shall be regularly reviewed in response to changes in staffing, methodology, instrumentation and any other changes that could have an impact on the validity of results. Laboratories must be prepared to justify their policy and approach to both frequency of participation and any non-participation in readily available PTs that are appropriate.

5.4 Calibration laboratories shall participate in ILC for items on their schedule of accreditation, including specific instruments or measurement devices where these are separately listed. These items, instruments or measuring devices shall be addressed in the PT activity plan / Protocol.

5.5 The PT / ILC activity plan should cover:

5.5.1 Participants

5.5.2 The PT / ILC Scheme

5.5.3 The proposed measurement artefact or instrument / or proposed test method

5.5.4 The measurement / test parameters

5.5.5 Establishment of the reference values

5.5.6 Acceptance Criteria

5.5.7 Responsibility for issue of the PT/ILC report.

5.6 Accredited laboratories must participate in, at a minimum, one satisfactory inter-laboratory comparison covering the scope and sub-scope of accreditation between periods of re-assessment except where regulatory requirements require a higher frequency of PT participation.

5.7 Laboratories preparing for accreditation are required to participate and achieve satisfactory performance in a proficiency testing or inter-laboratory comparison where such schemes are available and are relevant to their scope of accreditation before a recommendation for accreditation can be considered.

5.8 Where no appropriate proficiency testing or inter-laboratory comparison is available, the laboratories are required to justify the lack of participation and provide for how they demonstrate the validity of their tests and calibrations by other means such as use of certified reference materials, replicate tests or calibrations using the same or different method for verification..

5.9 The KENAS assessment team will review at each surveillance visit the laboratory's performance in proficiency testing / inter-laboratory comparisons and the plans thereof.

5.10 Laboratories are required to have appropriate acceptance criteria and procedures for investigating the cause of problems and for implementing corrective actions when these acceptance criteria are not met. A written record of these activities must be maintained. The laboratory must ensure that it does not claim accreditation for any tests that could be affected by the events that caused "out of specification" proficiency testing / inter-laboratory comparison results until it is satisfied that the investigation into the anomalous result has fully resolved the issue. In the event that the laboratory establishes that test results are compromised, they shall inform KENAS and seek voluntary suspension for the test(s) in question

5.11 If at any time the laboratory's performance in proficiency testing / inter-laboratory comparison in the opinion of KENAS, casts doubt on the integrity of test results. KENAS may suspend the relevant tests from the laboratory's scope of accreditation. The laboratory will be required to provide KENAS with written evidence that the

problem has been identified and satisfactorily rectified (which may include demonstrated satisfactory performance in subsequent proficiency testing / inter-laboratory comparisons) before re-instatement of accreditation can be considered.

5.12 KENAS may specify participation in a particular scheme/exercise where it is deemed necessary to demonstrate technical competence. Where participation in an externally run scheme is a mandatory requirement, this shall be stated in an appropriate KENAS

5.13 Where justification show that participation in externally run PT / ILC programs is not feasible, and or that no formal PT/ILC programs are available, the laboratories shall indicate other inter-laboratory comparison activities in which they intend to participate. These may include activities arranged by themselves (bilateral or multilateral inter-laboratory comparisons etc.) with other laboratories in order to satisfy this requirement.

5.14 The PT/ILC reports shall be clear and comprehensive and include at least the following information:

5.14.1 Participants

5.14.2 Measurement Protocol

5.14.3 Identification of measurement standard /Artefact

5.14.4 Measurement / test results

5.14.5 Reference values and how these were established

5.14.6 Evaluation of measurement/test results

5.14.7 Performance of individual participants

5.14.8 Acceptance criteria

5.14.9 Conclusion

5.15 The KENAS website (www.kenas.go.ke) has a list of proficiency testing providers.

6 REFERENCE AND RELATED DOCUMENTS

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
2.	ILAC P9:11/2010	ILAC Policy for participation in Proficiency Testing Activities
3.	ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
4	ISO/15189: 2012	Medical laboratories – Requirements for quality and competence

7 TRAINING

Awareness sessions are required prior to implementation of this policy

8 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
05/11/2012	01	ADTC	• Initial
01/02/2014	02	ADTC	• Removal of quoted text from 17025 and 15189 standards and alignment of editorial requirements. • Deleted specific areas that require PT since these were limiting and not all exclusive. • Removed reference to EPTIS • Amended KENAS website. • Addition of ILAC P9:11/2010 to the reference • Addition of justification where participation of PT is not feasible • Incorporation of requirements for PT Plan
03/08/2015	03	ADTC	• Amendment of clause 5.4 to capture instruments and details • Inclusion of 5.5 on PT activity plan. • Incorporation of the details required of a PT Plan. • Addition of clauses 5.12 & 5.13