PROFICIENCY TESTING PLAN

Kenya Bureau of Standards
Proficiency Testing Schemes

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PREFACE

This plan outlines how the Kenya Bureau of Standards Proficiency Testing (PT) Schemes will be organized and managed. It details the sample matrices, statistical tools for data analysis and the standard deviation to be used for proficiency testing.

CONTENTS

1. INTRODUCTION

KEBS Testing services provides Proficiency testing in the fields of Biochemistry and Materials Engineering testing.

Different laboratories in KEBS provide Proficiency Testing in various fields on a regular basis depending on needs of the industry.

Provision of the PTs/ ILC is carried out according to the requirements of ISO 17043.

Most of the laboratories participating in KEBS PT/ILC have been accredited by using performance reports obtained from the KEBS PT scheme.

One of the requirements for laboratory accreditation to ISO 17025 is participation in PT/ILC.

Thus KEBS PT scheme has been established with the **main purpose** of supporting the Testing Laboratories infrastructure in Kenya and the region to comply with the requirements of ISO 17025. This support is for all laboratories whether accredited or not.

2. PROFECIENCY TESTING (PT) & OBJECTIVES

As defined by ISO/IEC 17043, PT is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

The objectives of the KEBS PT therefore include but not limited to:

i. Provide support to laboratories to enable them comply with requirements of **ISO/IEC 17025.** In addition to the use of validated methods and internal quality controls, proficiency testing is essential for quality assurance of testing laboratories.
ii. Providing a way of checking the accuracy of tests provided by laboratory. Apart from internal quality checks as part of laboratory's routine procedures, PT as an external quality check enables a laboratory to compare their analytical results with those from other laboratories.
iii. Validation of methods of tests by industry and standard development processes. PT/LC would analyse the comparability and acceptability of results obtained using different methods.
iv. Provision of reference materials for use by the laboratory infrastructure thus saving foreign exchange that would have been used to import the materials.
v. Provision of PT/ILC at departmental level is one of the income generating activity for the department and is well captured in the strategic plan of KEBS for the year 2022 - 2027.

Resources required for PT provision are provided by the Director/HoD – Testing through an annual budget.

3. ORGANIZATION OF SCHEMES

3.1 Administration

Administration of the PT/ILC scheme is done in accordance with the requirements of ISO/IEC 17043 and also IUPAC/ISO/AOAC International Harmonized Protocols for the Proficiency testing of (Chemical) Analytical Laboratories.

KEBS PT/ILC shall be conducted annually as per established schedule and PT Calendar. An evaluation workshop for all participants shall be held once a year for all participants to share experiences. In the workshop, the following will be given priority for discussion:

- Presentation of reports of all the matrices and analytes for discussion
- Obtains feedback from participants on the concluded PT rounds
- Challenges and identification of opportunities for improvement
- Charting way forward for the KEBS PT scheme
- Providing planning for forthcoming PT rounds.

Laboratory Managers shall be the PT coordinators for the PT matrices and analytes that their laboratories offer testing services.

3.2 Confidentiality

All information held by KEBS about participants, including their performance is held confidential and will not be disclosed anyone unless agreed with the participant for particular purpose.

When sending reports, laboratory are given code numbers without identifying the particular laboratory and same code number may be assigned to participant only by chance. The KEBS laboratories participating in PT are treated in the same manner as other participant i.e. they will not have access to details of any other participants.

Specific personnel are assigned specific duties and only the those assigned responsibilities of performance evaluation have the identity of the participating laboratories confidential codes and not any other personnel.

3.3 Scheme timetable

The KEBS PT scheme timetable and schedule of provision for the various matrices and analytes are as covered in the activity schedule and PT calendar which are documented and maintained by the PT coordinators.

The process of conducting PT for each matrix includes;

1. Announcement and registration of participants.
2. Processing of payment to complete registration process
3. Procurement of PT item an associated materials for packaging and distribution
4. Sample preparation
5. Homogeneity studies prior to dispatch
6. Dispatch of the PT samples
7. Stability studies to demonstrate analytes are stable
8. Receipt and processing of results from participants
9. Evaluation of Performance
10. PT report preparation
11. Dispatch of PT Reports to participants
12. Evaluation & Training Workshop
13. Feedback processing from participants
14. Planning for the next year PT round while incorporating customer feedback.

3.3 Scheme Review

The matrices and test parameters are continually reviewed to ensure they meet the needs of current laboratory testing infrastructure, regulatory requirements and participants request.
Annual review of all matrices shall be discussed in the Management review meeting which is held at least once in a year.
The concentration of analytes for the PT is provided in the ranges specified in the respective product standard specification.

4. PARTICIPATION IN PT SCHEMES

There is no minimum number of participants or frequency of participation and participants are free to choose and participate as frequently as they want.

Participation shall be open to all laboratories in both private and government, in and outside Kenya.

The minimum requirement to participate is by registering and paying the applicable fees.

4.1 Enrolment and fees

The fee for participation is reviewed annually and communicated to customer through the announcement documents. The fee review shall be approved by the Board of KEBS/Management before communication to customers.

4.2 Preparation

Sample preparation shall procedure shall be documented for each PT matrix and analyte as necessary. The PT coordinators shall be responsible for establishing and review of the procedures for the matrices they provide.

The analyte and concentration for each PT scheme shall be guided by the product specification or a need in industry. PT coordinator shall be responsible for determining the analyte and concentration with consultation with stakeholders.

Sample preparation shall be done with equipment on site in KEBS or subcontracted. KEBS personnel shall be responsible and supervise sample preparation even when such equipment is offsite.

4.2.1 Homogeneity

Homogeneity analysis is carried out before dispatch. Ten samples are randomly picked and analyzed in duplicates. The results are subjected to statistical analysis (ANOVA – analysis of variance). This shall be done in accordance with requirements of ISO 17043 and IUPAC International Harmonized Protocol for Proficiency Testing.

Homogeneity test shall be carried in Testing department at KEBS. Some tests may be subcontracted if need be. The PT coordinator will document the same in the PT report.

Evaluation of homogeneity is carried out in accordance with ISO/IEC 13528, ISO 5725 and/or IUPAC International Protocol for Proficiency Testing.

4.2.2 Dispatch and receipt of test materials

Samples are dispatched to participants with recommended methods where applicable, though participants are free to use their normal routine methods. A method may be prescribed also based on the objective of the PT/ILC.

4.2.3 Stability test

Stability studies are carried out on a date coinciding with the deadline for submission of results. This is to confirm that the analyte is stable in the entire window period for submission of results. Evaluation of stability is carried out in accordance with ISO/IEC 13528, ISO 5725 and/or IUPAC International Protocol for Proficiency Testing.

Stability test will be carryout at KEBS testing department facilities. Some tests may be subcontracted if need be. The PT coordinator will document the same in the PT report.

5. ANALYSIS

Recommended methods are stated to participants, however, participants are free to use their normal routine methods and no special treatment of the PT sample which is beneficial as an external check on routine work.

6. SUBMISSION OF RESULTS AND METHODS OF TEST

Participants are requested to submit their results in specified units and to state the method used. The deadline and results template shall be documented in the results template for each PT matrix. The respective PT coordinator is responsible for documenting and communication the results template to participants at times stated in the activity schedule and PT calendar.

7. REPORT DISTRIBUTION

Detailed reports indicating participants' performance are distributed to all paid up participants via e-mail. The contents of the report include the following as a minimum:

- Details of the composition of the test material
- Record of all results without disclosing the laboratories identity
- The assigned values and method used to determine assigned values
- The standard deviation for proficiency testing
- Tabular representation of participants performance
- Graphical representation of participants performance
- Summary of performance for each analyte and general performance trends

8. RETAINED TEST PORTIONS

After conclusion of each PT round, retained portions of the PT if available shall be offered for sale to the industry at a fee which may be reviewed by KEBS board from time to time.

9. EVALUATION OF PERFORMANCE

The results are subjected to statistical analysis according the requirements of ISO/IEC 17043, ISO/IEC 13528, ISO 5725 and the IUPAC/ISO/AOAC International Harmonized Protocols for the Proficiency testing of (Chemical) Analytical Laboratories.

The method used to determine the assigned value shall be documented in the performance report. The PT coordinator is responsible for determining the method for use in determining the assigned value and is also responsible for the evaluation of performance.

9.1 Assigned value

The assigned value X, is the best estimate of the 'true' value for purposes of proficiency testing assessment. The assigned value can be established from one of the following:

1. Consensus values from participant results
2. Consensus value from a group of participants results
3. Formulation of the proficiency testing material
4. Consensus values from expert laboratories
5. Results from an expert laboratory
6. Certified reference value

9.2 Standard deviation

The standard deviation for proficiency testing assessment (σ_{pt}) determines the limits of performance for a PT.

The value at which it is set needs to represent the fitness for purpose of the analyte being evaluated.

The standard deviation can also be established based on experience from previous rounds of PT schemes as per requirements of ISO 13528.

Detailed calculations of how the standard deviation is calculated is documented in ISO/IEC 13528. The PT coordinator will also document this in the performance report for reference by the participating laboratories.

9.3 Evaluation

The most commonly used and preferred evaluaton method is based on z-score.
Evaluation is based on 'estimate of laboratory bias' as percent difference.

$$\text{z score} = \frac{x - X}{\sigma}$$

Where:

x= the participants reported result

X = the assigned value

σ = Standard deviation for proficiency assessment

The PT coordinator can however use a different method for evaluation but has to document this in the performance report. The method must also be one of those prescribed in ISO/IEC 13528.

9.4 Performance Evaluation

Performance based on z-score is interpreted as follows:

|z| score = ≤ 2 ---------- Satisfactory

|z| score = < 2 |z| >3 --- Questionable

|z| score = ≥3 ---------- Unsatisfactory

10. APPEALS & COMPLAINTS

In case of any concern regarding any decision made by the KEBS PT, a participant can appeal by writing to the Managing Director KEBS.

The Managing Director will then form a committee to review the appeal and give recommendations. Timelines for investigation will depend on nature of the appeal.

Complaints and appeals shall be handled according the procedure for Complaints, appeals and Non-conformities (TES/OP/08).

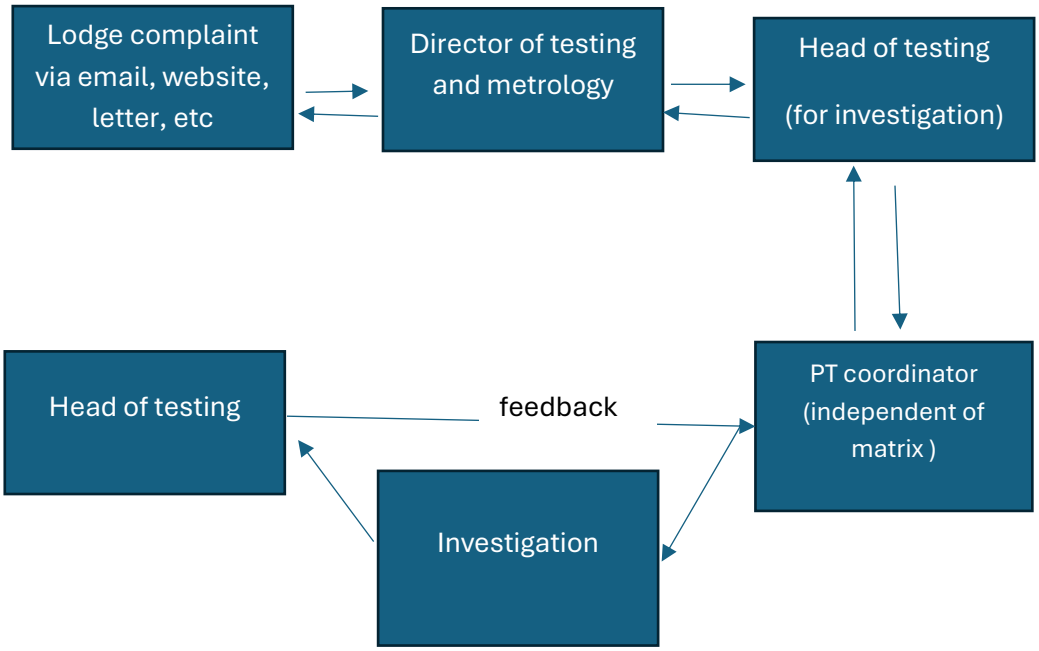
Corrective action shall be taken to improve the PT provision as necessary following the documented procedures for corrective action.

Communication to PT participant or customer on the conclusion of investigation and action taken shall be done by the PT coordinator or Head of Testing and PT.

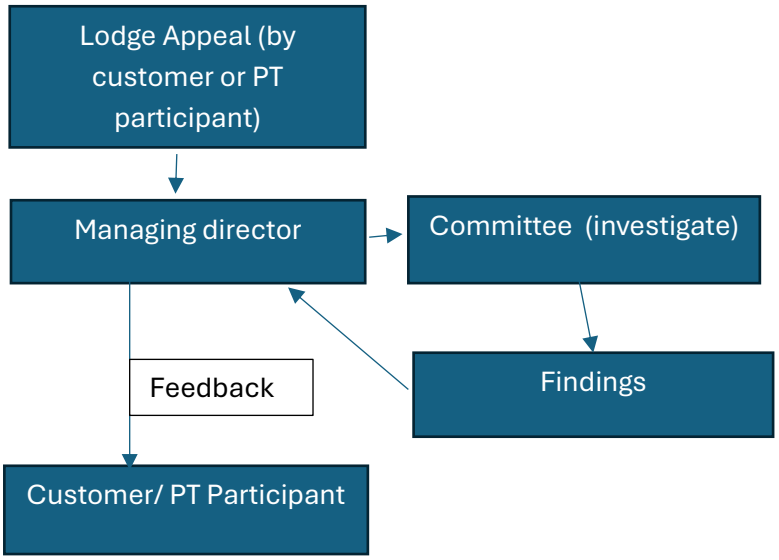
The process for handling complaints and appeals shall be made publicly available through the PT plan or upon request and the flow charts for the process will be available in the KEBS website.

A brief description of the Complaints and Appeals procedure is shown in the flow chart below.

Flow chart for Complaints:



Flow chart for Appeals:



11. REFERENCES

11.1 ISO/IEC 17043

11.2 ISO/IEC 13528

11.3 IUPAC/ISO/AOAC International Harmonized Protocols for the Proficiency testing of (Chemical) Analytical Laboratories

11.4 KEBS Testing department procedures

11.5 ISO/IEC 5725