TANZANIA BUREAU OF STANDARDS

PROFICIENCY TESTING SCHEME
GENERAL PROTOCOL

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DOCUMENT No. TBS/DTM/PT/PRT-00	Title: General Scheme Protocol	Page 2 of 22
Doc type: Procedure	Prepared by PT Coordinators and QM Signed by PT Coordinators:	Approved by QM Sign:
Controlled/Uncontrolled	CONTROLLED	Effective Date: 2025-09-01

CHANGE HISTORY:

Revision	Publication date	Summary of changes
Rev. 00	2025-09-01	Original version

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1 INTRODUCTION

1.1 General information on proficiency testing

Proficiency Testing (PT) means evaluation of participant performance against pre- established criteria by means of interlaboratory comparisons

TBS Proficiency Testing has a wide range of matrices provided; these matrices are designed to facilitate the improvementof the quality of measurements in those specific areas that are covered. The laboratories that participate in our scheme will be able to assess the accuracy of their results and comparability to peer laboratories over time, and also access information on testing technical issues and methodologies.

The TBS Proficiency test is prepared within the context of ISO 17043 that assures the quality of the programme and thus it is an independent means of assuring the quality of test as described in ISO/IEC 17025

2 SCHEME ORGANISATION

2.1 Scheme coordination and responsibilities

All the Proficiency testing operation for each scheme is the responsibility of TBS Proficiency Quality Manager as a provider while the specific matrices are managed by PT Coordinators. We use subcontractors in testing and distribution of PT item. Also, consultants are used to provide the full range of relevant knowledge and expertise on PT activities when necessary.

2.2 Management Committee

Our PT scheme is operated jointly within TBS as mother organization certified to ISO 9001 and constituted with the PT Coordinators and QM who meets at least once per year to discuss all the business and operational issues regarding the PTP activities. Written record of the meeting in the form of minutes, will be kept as records by PTP Secretariat (QM).

2.3 Scheme framework

TBS provides on-going PT scheme, where PT items are distributed on a regular basis every year but we also provide be spoke PT schemes fulfilling clients purpose, where the PT items are distributed at the time and request of a commissioning client.

For ease of planning TBS has programmed its schemes in annual bases, from July to June following government financial year. The programme of proficiency tests is compiled by PT Coordinators. The new PT round shall be announced between May and June each calendar year

The structure within each scheme round is as follows:

- Announcements of the PT scheme to all participants.
- Participants application forms received and processed
- Invoices are created and sent to participants for payments.
- Procurement and preparation of PT sample (including the homogeneity and stability study)
- Dispatch of PT items to participants.
- Reporting of results by participants within the specified deadline.
- Results analysis and performance evaluation for each participant
- Reports written and issued to participants.
- Workshop round review if any.
- Commencement of next round.

Reports are issued as soon as possible after the round closure, although the timescale between closing dates and issue of the final report will vary from scheme to scheme. A flow diagram showing the typical process for a PT round is given in Annex I.

3 PT SCHEME PARTICIPATION

Application Forms are available upon announcements for each PT scheme, where all the information on the scheme description, dispatch dates and costs

of participation are well captured.

In order to join a scheme, participants should complete the relevant Application Form, indicatingwhich test materials/ matrices they wish to receive during the scheme year.

All the information on the matrix, analytes, sample size, ranges and units are described in the scheme description while the available matrices and the start dates will be shown in the provision plan. Clients should be aware that the sample size is an approximate value and may vary very slightly.

Once a client completes an Application Form the completed form shall be sent to the PT coordinator's email; The clients can do any amendments on the application form before the application deadline by sending a replacement application form through the same mail.

Participants are advised to participate in the PT scheme(s) that are most appropriate to their own area of testing. Where necessary, staff at TBS Proficiency Testing can advise on which PT scheme(s) are most suitable for participants request or consultations.

3.1 Frequency of participation

In our scheme we have no limitation on the frequency of participation nor having minimum level of participation and thus clients are free and open to participate in one or more schemes choosing analytes of their interest to fulfill their purpose. Third parties, such as retail groups, regulatory bodies and accreditation bodies may recommend minimum levels of participation. Details on frequency and participation will be provided on the scheme provision plan, Application Forms and Scheme Descriptions.

3.2 Costs of participation

Costs for participation for each scheme are detailed on the scheme Application Form. Fees given on the application forms are the basic PT participation fee

in TZS and additional fees may apply for courier, bank transfer charges and additional samples. The fees can also be available in USD upon request. TBS reserves the right to withhold test materials and/orPT reports from participants if payment is delayed.

All the participation fees are quoted in the proforma invoice with all the detailed banking information needed for payments. Non-payment or late payment may result in test materials and/or reports not being distributed.

3.3 Confidentiality

In order to ensure confidentiality, all registered participants in all schemes are allocated with a unique laboratory reference number which enables results to be reported without divulging the identities of participant laboratories. For some PT schemes, participants may agree to have their identity made known to others, but this will only be done with the knowledge and full permission of the participant. In situations, when a regulatory authority requires proficiency testing results to be directly provided to the authority by TBS Proficiency Testing, the affected participants will be notified of this action in writing.

3.4 Trials and new products

TBS Proficiency Testing is continually striving to improve current schemes and to introduce new schemes/test materials/test parameters where appropriate. Before formally including in a scheme, new products may be introduced initially on a trial basis which might be free or partially paid on the first provision for depending on the need. Participants will be notified if the scheme is a trial or new scheme through the provision plan and application forms.

4 PT ITEM

4.1 PT Item preparation

PT Item may come from a number of sources; the analyte might be at natural levels /incurred or spiked at a particular formulation level. The PT item is

carefully selected to meet the needs of participants and wherever practical they will be as similar as possible to those samples routinely tested by participating laboratories. The range of test materials will usually be varied from round to round in order to be realistic and challenging. Details of individual test materials are available in the Scheme Description for each scheme.

4.2 Homogeneity and Stability Test

A number of factors will be taken into consideration so as to determine the quality control of the test material. The PT items will only be distributed when the testing demonstrates that the individual samples are of sufficient homogeneity. The degree of natural homogeneity and the stability of the test material are used in the process control during production.

Homogeneity assessment will be done by 'Statistical methods according to ISO 13528. A full description of the procedure is included in Annex III. Further details regarding homogeneity testing are included in the Scheme Descriptions and/or reports.

Proficiency test materials shall be sufficiently stable for the duration of the test. This includes the time between their preparation and the start of the test, as well as during transportation of test materials and for the period of time set for participants to analyze them.

4.3 Packaging and transportation

PT items are sent in appropriate packaging as described in the scheme description and under conditions intended to maintain the integrity of the test materials during transit.

Once packages have been delivered, TBS Proficiency Testing cannot be held responsible if theysubsequently fail to reach the correct personnel or are not stored under the recommended conditions.

Participants are asked to check the contents of packages immediately on receipt from the courier and to contact TBS Proficiency Testing if there are any

problems with the condition of the test materials or accompanying documentation.

5 METHODOLOGY AND REPORTING OF RESULTS

5.1 Methodology

Participants are free and encouraged to use technically appropriate test or measurement procedure of their choice according to their routine analysis. Participants are asked to treat the PT items as a routine sample as much as possible so as to check the quality control of their process.

Participants are required to declare their method on the results templates, Only the most commonly reported methods will be included in the list such as standard or reference methods. Participants are asked to select the method which most closely describes their own method in use. If none of the methods listed are suitable, then 'Other' can be selected and a brief description of the method

5.2 Reporting of results

Participants are requested to submit their results and methods through the results templates which will be sent through their emails. On the availability of the PT Web portal each participant will confidentially be provided with a unique User ID and Password required to accessall the pages including the reporting templates. Occasionally scheme description may specify the number of significant figures that results are to be reported per analyte where this is critical to differentiating analytical data.

For results to be processed and issued a report after the closure of the proficiency test round, the deadlines for the return of results specified shall be observed. For certain test parameters there may be a date(s) specified by which examination of the test material is recommended to have been commenced and/or completed. Results received after the reporting deadline cannot be included in the report. The main report is available to all participants

subscribing to the PT round and their results were submitted.

Where at any circumstances that prevented timely results submission, participantsshould contact PT Scheme coordinators to discuss acceptance of late results. In general, approximated, non-numerical and zero results should not be reported as they cannot be statistically evaluated.

5.3 Collusion and falsification of results

Collusion, either between participants or between individual participants and the scheme coordinator, is contrary to professional scientific conduct. It serves only to nullify the benefits of proficiency testing to customers and analysts.

Collusion is, therefore, to be strongly discouraged because it defeats the objective of taking part in proficiency testing if participants are not returning genuine results. Some measures are taken into consideration to prevent collusion for-instance assigned values are not made known to anyone before the report is issued and no results are accepted after the publication of the reports.

In case there is clear evidence of results collusion participants involved will be contacted and their results will be excluded in the evaluation. However, ultimately the responsibility rests with each participant to behave in a professional manner.

6 DATA ANALYSIS AND PERFORMANCE ASSESSMENT

6.1 Qualitative and Quantitative tests.

TBS Proficiency Testing organizes a wide range of schemes, which may include **qualitative** and **quantitative**. Different approaches to data analysis may therefore be used, the most common approaches being shortly described below while further information on the statistical approach for specific schemes is also provided in the Scheme Descriptions and Scheme Reports.

In **qualitative tests**, participant results will be compared against the intended result, also called the assigned value, based on formulation or expert assessment. A result which is the same as the assigned value is considered satisfactory. This approach is also used for quantitative tests when the targeted

analyte is absent.

For **quantitative tests**, participants are assessed on the difference between their result and the assigned value with this difference being represented by a performance score

6.2 Setting assigned values

The assigned value is the value selected as being the best estimate of the 'true value' for the parameter under test. The method used to determine the assigned value may vary depending upon the particular scheme and test parameter, and is detailed in the relevant scheme description,along with details of the traceability in each case.

For quantitative tests, all assigned values are derived in accordance with ISO 13528. Where it is appropriate, practicable and technically feasible the assigned value will be derived through formulation (or occasionally through the use of a certified reference material) to provide metrological traceability; the associated uncertainty of the value can therefore be estimated. However, in most cases it will not be possible to use formulation or certified reference materials to set the assigned value and a consensus value will be the only be practicable and technically feasible approach to use. When the assigned value is determined from the consensus value of participant results, or from expert laboratories, robust statistical methods are used for calculation.

6.3 Calculating z scores

$$z - score = \frac{X_i - X_{pt}}{\sigma_{pt}}$$

where; X_i = the result reported by the participant

X_{pt} = the assigned value

σ_{pt} = standard deviation for proficiency assessment

The z score expresses performance in relation to an acceptable variation of the

participant resultto the assigned value. A z score of 2 represents a result that is 2 x σ_{pt} from the assigned value.

Where alternative scoring methods are used, full details will be given in the Scheme Descriptionand/or report.

The returned results are rounded to the required number of decimal places specified in the Scheme Descriptions. The statistical calculations are performed on unrounded data and displayed as rounded to the required number of decimal places in the report.

6.4 Standard deviation for proficiency assessment (SDPA)

The method used to determine the SDPA may vary depending upon the particular scheme and test parameter. All SDPAs are derived in accordance with ISO 13528. When the SDPA is determined from the dispersion of participant results, robust statistical methods are used for the standard deviation, details of which are given in Annex II. A fixed, fit for purpose SDPA value is preferable as this enables performance scores to be compared from round to round to demonstrate general trends. This fixed value may be absolute or expressed as a percentage of the assigned value.

The value of SDPA is reported in the Scheme Description and/or report.

6.5 Results Interpretation

For qualitative results, laboratories reporting the assigned result or range of results will be considered correct, and therefore have satisfactory performance. For quantitative examinations, the following interpretation is given to z score results.

$\|z\| \leq 2.00$	Satisfactory result
$2.00 < \|z\| < 3.00$	Questionable result
$\|z\| \geq 3.00$	Unsatisfactory result

Where other performance techniques are used these are described in

Scheme Description and/or report.

7 INFORMATION TO PARTICIPANTS

7.1 Reports

Reports are made available electronically. The contents of reports vary from scheme to scheme but include details of the composition of PT item, the assigned values, and tabular and/or graphical representations of participants' results and performance. Copyright to all reportsremains with TBS Proficiency Testing but permission is granted to participants to make copies for their own internal use, for example for quality control and regulatory purposes. No other copies maybe made without obtaining permission.

In case of any changes in the process that the final report needs to be amended then the replacement report will be issued to the participants to nullify the first report.

7.2 Advice and feedback

Communication with participants will be carried out through scheme-related documentation e-mails or phone contacts. In some cases, open meetings may also be organized when the need arises and all interested parties invited to attend.

Comments on any aspect of the scheme are welcome either by e-mail or phone. In the event of complaints, these will be fully investigated according to our quality system, to determine the underlying cause and to decide upon a course of action. This course of action together with the results of any investigations carried out will be communicated, as appropriate, to the participant.

7.3 Appeals

TBS undertakes to correct any mistakes attributable to errors on its part promptly and sympathetically. If a participant has any concerns about any aspect of the PT they should contact scheme coordinator by email in the first

instance. An investigation will be conducted in accordance with our management system and the participant will be advised of the outcome. Any report to be re-issued as a consequence of an appeal will be limited to a two-year retrospective at the time of receiving the appeal.

ANNEX I - Scheme Operation Flowchart

Information about schemes provided to participants by means of:
The website www.tbs.go.tz
General Protocol
PT Scheme Fliers
Application forms
Scheme Descriptions

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Participant defines requirements on Scheme Application Form and sends through the email; pt@tbs.go.tz.

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Application form received, proforma invoice prepared and sent to participant. For any problems contact scheme coordinator through e-mail: pt@tbs.go.tz

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Test materials dispatched observing the set deadline. Participants will be informed of any changes to dispatch date.

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Test materials analyzed according to usual method. Test material preparation instructions sent to participants through emails and also dispatched with the sample as an attachments

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Participants will send the results through emails. Reporting information is available in Scheme Description. Results must be reported by reporting deadline.

↓

Scheme coordinator assesses results and produces report. Reports issued and sent to participants through emails.

ANNEX II - Robust statistics Robust mean (median)

The consensus value can be calculated using the robust mean of all participant results. In tbs PT schemes the robust mean used is the median. If the data, where there are an odd number of results are arranged in order of magnitude $(x1, x2, \ldots\ldots, xn)$ the median is the central member of the series, i.e. there are equal numbers of observations smaller and greater than the median. Where there is an even number of results, the median is the average of the middle pair of numbers within the series. For a normal distribution the mean and median have the same value. The median is more robust, in that it is virtually unaffected by extreme values.

Robust Standard Deviation

In TBS PT schemes the normalized Median of Absolute Deviations (MADE) from the sample median is used as a robust standard deviation.

$MAD = median(|xi - X|\ i = 1,2, \ldots\ldots n)$ where n = number of results

For example:

Data (g)	5.6	5.4	5.5	5.4	5.6	5.3	5.2
Sample	5.2	5.3	5.4	5.5	5.6	5.6	5.6

Sample median = 5.4

$\|xi - X\|$	0·2	0·1	0·0	0·0	0·1	0·2	0·2
Ordered Difference	0·0	0·0	0·1	0·1	0·2	0·2	0·2

Therefore $MAD = 0.1$

MAD is then scaled by a factor of 1.483 to make it equivalent to a normal deviation (MADE).Hence $MADE = 1.483\ x\ MAD = 0.1483$

If MADE is equal to zero SMAD should be calculated:

$$SMAD = mean\{|xi - X|i = 1,2, \ldots\ldots n)\ x\ 1.2531$$

The Robust Standard Deviation may be used as the Standard Deviation for Proficiency Assessment (SDPA) for calculation of z-scores. Other statistical methods for the calculation of robust estimators are available.

Removal of errors and blunders

Although robust estimators are used in order to minimize the influence of outlying results, extremeresults or results that are identifiably invalid should not be included in the statistical analysis ofthe data. For example, these may be results caused by calculation errors or the use of incorrect units. However, such results can be difficult to identify by the PT organizer. For this reason, the robust mean and standard deviation will be calculated as above, but those results that are out ofthe range of the assigned value $\pm 5\ x\ SDPA$ will be excluded and the robust mean and standard deviation will then be recalculated. These recalculated values will be used for the statistical analysis. All results, including excluded results, will be given performance score

ANNEX III - General procedure and assessment criteria for a homogeneity check

Test materials are assessed for homogeneity using procedures described in Annex B of ISO 13528[4](2015). A brief description of the procedure is described below;

a) Choose a property (or properties) to be assessed for homogeneity.
b) Choose a laboratory to carry out the homogeneity check and the measurement method to use. The method should have a sufficiently small repeatability standard deviation (*sr*) so that any significant inhomogeneity can be detected. If possible, *sr* should be less than $0.5\,x\,\sigma pt$ (the standard deviation for proficiency assessment).
c) Prepare and package the proficiency test items for a round of the scheme ensuring there aresufficient items for the participants and the homogeneity check.
d) Select a number *g* of the proficiency test items in their final packaged form using a suitable random selection process, where $g \geq 10$. This number may be reduced if suitable data are available from previous homogeneity checks on similar proficiency test items prepared by thesame procedures.
e) Prepare $m \geq 2$ test portions from each proficiency test item using techniques appropriate to the proficiency test item to minimize between-test-portion differences.
f) Taking the $g\,x\,m$ test portions in a random order, obtain a measurement result on each, completing the whole series of measurements under repeatability conditions.
g) Calculate the general average *x,* within-sample standard deviation *sw,* and between-samplestandard deviation *ss.*

NOTE When it is not possible to conduct replicate measurements, for example with destructive Tests, then the standard deviation of the results can be used as ss.

h) Examine the results to look for possible trends in analysis or production order and to comparedifferences between replicates.

i) Compare the between-sample standard deviation ss with the standard deviation for proficiency assessment σpt. The proficiency test items may be considered adequately homogenous if $ss \leq 0.3\sigma pt$.

NOTE When the above criterion is met then the between-sample standard deviation contributes less than 10% of the variance for evaluation of performance.

j) Calculate the allowable sampling variance $\sigma^2_{allow} = (0.3 \times$

k) Calculate $c = F_1\sigma^2 allow + F_2 s^2 w,$

m	20	19	18	17	16	15	14	13
F1	1.59	1.60	1.62	1.64	1.67	1.69	1.72	1.75
F2	0.57	0.59	0.62	0.64	0.68	0.71	0.75	0.80

m	12	11	10	9	8	7	6	5
F1	1.79	1.83	1.88	1.94	2.01	2.10	2.21	2.37
F2	0.86	0.93	1.01	1.11	1.25	1.43	1.69	2.10

If $ss > \sqrt{c},$ then there is evidence that the batch of proficiency test items is not sufficiently homogenous.

ANNEX IV - Estimated Standard Uncertainty of the assigned value

The assigned value (x_{pt}) has a standard uncertainty $(u(x_{pt}))$ that depends upon the method used to derive the assigned value. When the assigned value is determined by the consensus of participants' results, the estimated standard uncertainty of the assigned value can be calculated by;

$$u(x_{pt}) = \frac{1.25 \; x \; Robust \; standard \; deviation}{\sqrt{n}} \qquad \text{where } n = number \; of \; results$$

When the assigned value is determined by formulation, the standard uncertainty is estimated by thecombination of uncertainties of all sources of error, such as gravimetric and volumetric measurements.

If u(xpt) is ≤ 0.3 x SDPA, then the uncertainty of the assigned value can be considered negligible andneed not be considered in the interpretation of results.

If $u(x_{pt}) \; is \; > \; 0.3 \; x \; SDPA$, then the uncertainty of the assigned value is not negligible in relation to the SDPA and so z' (z prime) scores, which include the uncertainty of the assigned value in their calculation, will be reported in place of z scores.

z' scores are calculated as follows:

$$z = \frac{x_i - x_{pt}}{\sqrt{{\sigma_{pt}}^2 + u(x_{pt})^2}}$$

Where x_{pt} = the assigned value

x_i = participant result

σ_{pt} = standard deviation for proficiency assessment

$u(x_{pt})$ = standard uncertainty of the assigned value x_{pt}

Expanded $SDPA = \sqrt{{\sigma_{pt}}^2 + u(x_{pt})^2}$

The magnitude of z' scores should be interpreted in the same way as z scores.

ANNEX V - Scheme description

ANNEX VI - References and Sources of Information

[1] ISO/IEC 17025 (2017) 'General requirements for the competence of testing and calibration laboratories'.

[2] ISO/IEC 17043 (2023) 'Conformity assessment – General requirements for proficiency testing'.

[3] ISO 13528 (2022) 'Statistical methods for use in proficiency testing by interlaboratorycomparison'.

[4] M Thompson, S L R Ellison, R Wood, 'International Harmonised Protocol for the ProficiencyTesting of Analytical Chemistry Laboratories', Pure Appl. Chem., 2006, 78, 145-196.

[5] B. Brookman and I. Mann (eds.) Eurachem Guide: Selection, Use and Interpretation of ProficiencyTesting (PT) Schemes (3rd ed. 2021). Available from www.eurachem.org.

[6] LGC Proficiency testing, General Protocol Proficiency testing schemes (Issue 14, November 2021). Available from www.lgcstandards.com.

[7] Fera 2023 (Version 8, January 2023), Protocol for proficiency testing schemes. available from www.fapas.com