Title: General Protocol

Naratech Labs Proficiency Testing Services
Jordan-Amman-khalda
Otba Ben Ghazwan Street-Building No 23
Tel No: +962–6–550 6539
E mail: pt-coordinator@naratechlab.com
Web: www.naratechlab.com

Table of contents

1 INTRODUCTION

This document is intended to give guidance on the selection and use Proficiency Testing (PT) schemes for laboratory analysts, senior managers and quality managers in participating laboratories. These guidelines aim to explain how PT scheme data is produced and how such data should be interpreted to give an objective picture of the performance of individual participating laboratories, a laboratory within its peer group and with respect to the PT scheme as a whole.

Laboratories that perform analyses need to know that they obtain realistic results. They also need to prove this to their clients to be trustworthy. They can obtain this knowledge by performing different kinds of controls. Internal controls may be used to see that no unexpected changes have occurred within the laboratory. Since microbiological analytical results are dependent on the analytical method used, it is also important for the laboratory to be able to compare their analytical results with those of other laboratories. One means of this is to participate in interlaboratory comparative tests. These tests, when they are available, are compulsory for laboratories that aspire to become – or already are – accredited for their analyses. This is a requirement according to ISO 17025, where the name Proficiency Testing (PT) is used for these interlaboratory comparisons.

1.1 Purpose, objectives, and scope of proficiency testing

Proficiency Testing (PT) is defined as the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

NLPTS food/water/waste water and cosmetic scheme designed to:

1. Facilitate the improvement of the quality of measurements (microbiological analyses) in food, water, waste water and cosmetic sectors.
2. Participation provides laboratories with a means of assessing the accuracy of their results and comparability to peer laboratories over time, and also provides information on technical issues and methodologies.
3. Monitoring of its performance by comparison with results of other laboratories.
4. Enabling the participant to learn from their participation in PT schemes and to use this information to improve the quality of their measurements.
5. When performed within the context of a comprehensive quality assurance program, proficiency testing is an independent means of assuring the quality of test, as described in ISO/IEC 17025:2017.

1.2 Quality Standards

The International standards that are relevant to proficiency testing include

A. ISO/IEC 17025 (2017) “General requirements for the competence of testing and calibration laboratories”.

B. ISO/IEC 17043 (2023) “Conformity assessment — General requirements for the competence of proficiency testing providers”.

C. ISO 13528 (2022) “Statistical methods for use in proficiency testing by interlaboratory comparison”.

D. NLPTS Quality management system.

E. JAS,EGAC and ILAC Policy .

Accreditation details for specific PT schemes can be found on the Scheme Contract/Registration Form and Scheme Descriptions.

2 SCHEME ORGANISATION

2.1 Scheme coordination and responsibilities

Proficiency testing scheme (PT scheme): Proficiency testing designed and operated in one or more rounds for a specified area of testing. The day-to-day operation of scheme is the responsibility of NLPTS.

Schemes are managed by NLPTS Coordinators, responsible for design plan, customer service, processing of results and technical and reporting functions. Dedicated laboratory staff are responsible for the manufacture, quality checks and storage of the test material. There is also administrative staff responsible for the participant database, contacts regarding invoices and participation, as well as dispatch of test items. The overall responsibility for the quality management system of the program is assigned to the quality manager.

2.2 Advisory group

Technical expertise may be available in-house or may be provided by Advisors (individually Advisors) Advisors are selected on the basis of their technical knowledge and experience of the industry to which the scheme is related. Advisors may be used on an ad-hoc basis, being contacted when specific issues need to be addressed.

The advisory group members can come from different organizations, and represent both these and themselves. Their role is mainly advisory, with opinions on e.g., analytical parameters, frequency, costs, accepted methods and the content of the reports.

2.3 Typical scheme framework

The structure within each scheme round is as follows:

- Participant orders processed and confirmed.
- Procurement, preparation, dispensing and quality control testing of test materials according to published schedule.
- Dispatch of test materials to participants.
- Participants analyses the test materials and report their results to Naratech labs Proficiency Testing as instructed, and within the specified deadline.
- Results analyzed and the performance of laboratories assessed using appropriate statistical techniques.
- Reports written and issued to participants.
- Round reviewed and requirements for subsequent rounds identified.
- Planning for the next round is initiated.

Reports are issued as soon as possible after the round closure, although the timescale between closing dates and issue of the final report will not exceed 14 days.
A flow diagram showing the typical process for a PT round is given in Annex I.

2.4 Subscribing to a PT Scheme

Contract/Registration Form are available for schemes, and these include information about the distribution dates, the format and availability of test materials, and costs of participation.

A Scheme Description is also available for each scheme, which provides technical and statistical information specific to that scheme.

In order to join a scheme, participants should complete the relevant Contract/Registration Form, indicating which test materials they wish to receive during the scheme year, and place form via **website**. If the availability of test materials changes during the scheme year, participants are kept fully informed. Most schemes do not have any restrictions to participation, but where these do occur this will be made clear on the Contract/Registration Form or through other documentation.

Once a completed Contract/Registration Form or an order is received, an Order Confirmation will be **Uploaded to the participant portal**, confirming the test materials selected and distribution dates. Participants can amend an order up to one week prior to the distribution date, subject to test material availability. Any amendments to a participant's order will be confirmed to them in writing.

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

2.5 The available Schemes

2.5.1 Water& waste water scheme

The scheme includes many quantitative and qualitative analytical parameters of bacteria with a focus on indicator organisms, including some that may cause illness. The parameters are illustrated on the scheme description.

2.5.2 Food scheme

The scheme contains many different quantitative and qualitative analytical parameters – bacteria, molds and yeasts – including the analyses of pathogenic bacteria normally searched for in food. The parameters are illustrated on the scheme description.

2.5.3 Cosmetic scheme

The scheme contains many different quantitative and qualitative analytical parameters– bacteria, molds and yeasts – including the analyses of pathogenic bacteria normally searched for in cosmetic products. The parameters are illustrated on the scheme description.

2.6 Frequency of participation

Parties, such as retail groups, regulatory bodies and accreditation bodies may recommend minimum levels of participation.

To conform to the ISO/IEC 17025:2017 accreditation, participation in all rounds is mandatory and non-modifiable.

Details on frequency and participation will be provided on the Contract/Registration Form and Scheme Descriptions.

There are no technical criteria for participant eligibility and it is the responsibility of the potential participant to ensure that the PT is appropriate to their needs.

2.7 Costs of participation

Costs for participation are reviewed annually and the current prices for each scheme are detailed on the scheme Contract/Registration Form. Payment terms are detailed in Naratech labs Proficiency Testing' standard terms and conditions and on invoices. Non-payment or late payment may result in test materials and/or reports being withheld.

2.8 Confidentiality

In order to ensure confidentiality, participants in all schemes are allocated a unique Participant ID. This number enables results to be reported without divulging the identities of participant laboratories.

Under extraordinary circumstances, in the event that a regulatory authority necessitates the direct submission of Proficiency Testing results by NLPTS, affected Participants will be formally notified in writing, unless this authority is deemed a Legal entity and imposes restrictions on the NLPTS to not notify participants. The Participants retain the option to independently furnish Proficiency Testing results to the pertinent party (Regulatory and legal authority).

2.9 Trials and new products

NLPTS 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. It will be made clear to participants when they are participating in a trial.

3 TEST MATERIALS

3.1 Test material preparation

Test materials may come from a number of sources, and are carefully selected to meet the needs of participants. Wherever practical, test materials will be as similar as possible to those samples routinely tested by participating laboratories. However, in some cases, in order to achieve the required degree of homogeneity and stability, test materials may be in the form of simulated samples or concentrated spiking solutions. 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.

The test items consist of **1ml** freeze-dried broth with different microbial mixtures in 10 ml glass vials. The sample for testing (water, cosmetic and food) is obtained after reconstituting the material in a specific volume of suitable diluent.

Testing materials are prepared within the NLPTS laboratory and have been carefully designed and tested to meet the ISO/IEC 17043:2023 requirement.

3.2 Quality Control

A number of factors will be taken into consideration when determining the quality control testing required to be performed on each type of test material. These include, the degree of natural homogeneity, the stability of the test material, and the use of process control during production. Where undertaken, homogeneity assessment is carried out based on a procedure described in ISO 13528 (2022) 'Statistical methods for use in proficiency testing for interlaboratory comparison'

The assessment of homogeneity and stability shall be performed for every PT production Batch.

The assessment of stability shall be performed for every PT round.

A full description of the procedure is included in Annex III. Further details regarding homogeneity testing are included in the final reports.

3.3 Non-conforming products

Where, prior to dispatch, the homogeneity and/or the stability of test materials are not acceptable, the test materials will be withdrawn prior to distribution to participants. Where this may cause a delay in the distribution of test materials, participants will be informed. Occasionally, issues with test materials may not be identified until after distribution. Under these circumstances, this is taken into account when assessing participant results. The outcome will vary depending upon the situation but may involve; reporting of performance scores for information only, or the provision of replacement test materials. In these instances, full details will be provided to participants.

3.4 Hazards

3.4.1. Risk of infection

All microorganisms used in the schemes belong to hazard groups 1 and 2, as classified by the WHO and this mentioned clearly in the safety data sheet.

3.4.2 Environmental danger

The test material itself consists of sucrose and microorganisms, and usually also contains nutrient broth, peptone, potassium phosphate, and magnesium sulphate. The container consists of glass, rubber, aluminum and has a paper label. Since the container with material does not include any specifically classed or in any other way potentially dangerous chemical compound, it may be discarded in the common waste management after the microorganisms have been rendered harmless by killing.

3.5 Packaging and transportation

Before dispatch to the PT participants, the vials are labelled with individual numbers

Test materials are sent in appropriate packaging and under conditions intended to maintain the integrity of the test materials during transit.

The samples (glass vials) are packaged with an outer packaging for shipping (cardboard box). A receiving conformation form is added to the package.

Once packages have been delivered, NLPTS cannot be held responsible if they subsequently fail to reach the correct personnel or are not stored under the recommended conditions.

Participants are asked to check the contents of packages and packages temperature immediately on receipt and to contact NLPTS if there are any problems with the condition of the test materials or accompanying documentation. If packages are received damaged, then it would be very useful

if participants could supply photographic evidence to assist our investigations.
A refund may be issued to the Participant if the investigation shows that NLPTS was at fault. The investigation report issued by NLPTS may be shared with the participants upon request.

3.6 Dispatch and Receipt of Test Materials

All test materials are distributed with receiving confirmation form. The receiving confirmation form provides details on Participants information, PT items Details, type of analysis required, scheme, round, receiving date and received temperature, conditions and time.
It is the responsibility of participants to read these form and sign it, NLPTS cannot be held responsible for any problems arising from failure to comply with these directions.

NLPTS will inform the participants of the dispatch date by email or mobile for confirmation, It is the responsibility of the participant to contact NLPTS if they have not received the test material within agreed timescales (maximum 5 days). Delays to the dispatch of test materials occasionally arise If the dispatch of a test material has to be delayed for any reason, then participants will be notified of this fact by email prior to the advertised dispatch date.

3.7 Preparation of samples

Instructions for sample preparation and analysis are distributed to the participants before the dispatch date. The standard procedure is to reconstitute the vial content in a given volume (e.g. 250 or 1000 ml) of diluent. The suspension should then be carefully mixed in order to obtain the sample ready for analysis.

3.8 Stability of the prepared samples

After reconstitution of the freeze-dried material, the microorganism concentrations cannot be presumed to be stable for more than about an hour, even after cooling. The prepared sample should therefore be used for analysis within one hour.

3.9 Destruction of test material

The microorganisms need to be killed prior to discarding the material. This can be done e.g. by autoclaving at 121 °C, for a sufficient time to ascertain that the entire content has reached that temperature.

4 REPORTING OF RESULTS

4.1 General

The statistical processing in the PT includes the following main steps:

• Visually numerical checking of the result.

• Transformation of analytical results before statistical calculations, in order to obtain a normal distribution within the range of results for the respective analysis. In the Food, cosmetic and water scheme, log10 transformation is made.

• Identification of false and deviating analytical results (Blunders), including statistical determination of mean values and standard deviations for all quantitative parameters.

• Compilation of the participants results in tables, along with summary statistics.

• Visualization of the results for each relevant quantitative analysis in a histogram for the respective samples.

• Visualization of the standardized analytical results (z scores) in tables, including a summary of the number of outliers and false results. Results that – based on the knowledge of the test material – are obviously erroneous (e.g. undoubtedly false), are excluded without any statistical test (blunder removal).

4.2 Timescales

To enable reports to be processed and issued as soon as possible after the closure of the proficiency test round (Maximum 14 days), deadlines for the return of results are specified (Maximum 21 days) and must be adhered to.

Results received after the reporting deadline cannot be included in the report.
The final report is available to all participants subscribing to the round regardless of whether their results were submitted or not.

4.3 Corrections.

As a general rule, after the reporting deadline, the only allowed adjustments are those that are due to technical reasons (e.g., computer errors) or due to ambiguities/errors made by the NLPTS, e.g., due to unclear or incorrect instructions. Corrections are normally accepted only after careful individual considerations.

4.4 Choice of methodology

Participants are expected to use a technically appropriate test or measurement procedure of their choice, unless otherwise instructed. Participants are asked to treat the test material as a routine sample as much as possible and it's the responsibility of participants to read instructions provided via website and follow them exactly prior to conducting the actual analysis of the test material (all methods adopted for the analytical parameters are evaluated in the PT schemes).

When reporting results, participants are asked to mention the best description of their method on **their portals**. Only the most commonly reported methods will be included in the final report, including standard or reference methods.
This information is then used to produce a statistical summary of the most commonly reported methods for each analyte. These method summaries are given in the final reports and enable the relative performance of each method to be compared.

4.5 Reporting your results

Results and calculations must undergo rigorous verification before reporting. It is imperative to report results unequivocally, adhering precisely to the format and units specified in the Scheme Description. The reported results must remain unaltered, without rounding, decimal places, or exponential substitution. When calculations are employed, the laboratory is strictly instructed to disclose only the final calculated result, unless explicitly directed otherwise.

Proficiency testing demands precision in performing calculations and accurately transcribing results. NLPTS staff cannot provide interpretation or perform calculations on behalf of participants. It is crucial to recognize that once results are submitted and received, no amendments or changes can be made post-report issuance. This underscores the non-negotiable nature of result accuracy and adherence to reporting guidelines.

In general, results of zero should not be reported; results should be reported depending upon the detection limit of the method used, for example (<10).
Results of zero and truncated results, such as < or > cannot be included in the data analysis and therefore cannot be allocated a numerical performance score.

4.6 Reporting reminder

The NLPTS will normally as a courtesy remind participants by e-mail a few days before the reporting deadline. However, the final responsibility to report results lies on the individual participant.

4.7 Number of Permitted Results

To mitigate bias, NLPTS restrict the number of results participants can report, thus reducing bias impact.

Each participant is permitted to submit up to 10 results. If all reported results utilize the same testing method, NLPTS will include only the first result in the statistical evaluation. For the remaining results, NLPTS will issue a Z-score for each, calculated based on the assigned value and SDPA, as reported in the final report, but they will not be included in the statistical evaluation. If different testing methods are employed, NLPTS will consider up to three results, provided each is derived from a distinct method.

4.8 Collusion and falsification of results

Certain measures are built into the scheme to try to prevent collusion, for example, assigned values are not made known to anyone before the report is issued and no results are accepted after the publication of the report. Participants will be contacted if there is clear evidence of collusion. However, ultimately the responsibility rests with each participant to behave in a professional manner.

5 DATA ANALYSIS AND PERFORMANCE ASSESSMENT

5.0 Approaches to data analysis

NLPTS organize a scheme for food, water, waste water and cosmetic, which may include qualitative or quantitative measurements or tests.

Different approaches to data analysis may therefore be used, the most common approaches being described below. Further information on the statistical approach for specific schemes is also provided in the Scheme Descriptions and Final Reports.

The advantages of using a performance score are:

- Results can be expressed in a form that is relatively easy to interpret and understand.
- Results can be summarized in graphical or tabular form to describe overall performance.
- A performance score allows participants to directly compare their own result with others.
- If consistent statistical values are applied, a performance score enables participants to. Monitor trends in their own performance, over time.

When reviewing results, participants should take into account the methods used to analyze,the data and to assess performance, and should review their performance in context, taking into account performance of the whole dataset.

5.1 Qualitative schemes

For qualitative tests, participant results will be compared against the intended result, also called the assigned value, based on formulation. A result which is the same as the assigned value is considered satisfactory. This approach is also used for quantitative tests when the target analyte is absent.

5.2 Quantitative schemes

For quantitative data, participants are assessed based on the difference between their result and the assigned value (see 5.4); with this difference being represented by a performance score called a z or z' (z prime) score (see also Annex IV).

5.3 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 is detailed in the relevant scheme description.

For quantitative tests the assigned value will be derived through a consensus value (in accordance with ISO 13528:2022 that will be the only practicable and technically feasible approach to use.

When the assigned value is determined from the consensus value of participant results, robust statistical methods are used for calculation of the consensus value, details of which are given in Annex II. The uncertainty of the assigned value is then estimated as described in Annex IV.

5.4 Calculating z scores

The advantages of expressing participants' results as a standardized score are that

- they are simple and transparent,
- they present participants' results in a readily understood form,
- they permit comparison over time,
- When tabulated and charted, they place individual performance in the overall context of the PT.

All results from the assessed parameters are transformed into standard values (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 result to the assigned value. A z score of 2 represents a result that is 2 x σpt from the assigned value.

Where alternative scoring methods are used, full details will be given in the final 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 (almost two decimal places) in the final report.

5.5 Standard deviation for proficiency assessment (SDPA)

SDPA: Measure of dispersion used in the evaluation of results of proficiency testing,
Based on the available information

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 13528:2022. 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. The value of SDPA is reported in the final report.

5.6 Interpreting results

For qualitative results, laboratories reporting the assigned result will be considered correct, and therefore have satisfactory performance.

For quantitative results in microbiology, a logarithmic transformation (log10) of the analytical results is carried out and all the statistical calculations are performed with transformed data.
And 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 the final report.

For small data sets (generally with less than 8 results) :

- There will be increased uncertainty around the assigned value and the performance scores will be given for indicative purpose only

If the number of results is less than three:

- No assigned value is estimated→ No performance scores will be given

For data sets where the spread of results is large, performance scores will not be provided.

5.7 Trend analysis

A single result simply reflects the performance of the laboratory on the particular day that the test or measurement was carried out and can therefore only give limited information. Frequent participation in PT schemes over time can give greater insight into long-term performance and can help identify where an internal bias may be occurring. One of the best methods of summarizing performance scores over time is graphically, as this gives a clear overview, and is less prone to misinterpretation than numerical methods. Participants are therefore advised to monitor their PT results over time.

6 INFORMATION DISTRIBUTED TO PARTICIPANTS

6.1 **Participant**: Laboratory, organization or individual that receives proficiency test items and submits results for review by the proficiency testing provider.

6.2 Reports

Reports are made available electronically. The contents of reports vary from scheme to scheme but include details of the composition of test materials, the assigned values, and tabular and/or

graphical representations of participants' results and performance. Copyright to all reports remains with NLPTS 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 may be made without obtaining permission.

A final report is published within 14 days after the reporting deadline. The report contains comments and discussions on the results for the different parameters, as well as general discussions on the outcome and performances of the parameters and methods. Special attention is given to deviating results, and to instances where an analytical parameter was difficult or impossible to evaluate in a certain sample and the results are presented in histograms.

6.3 Renewal information

Renewal information will be sent to participants 2-3 months before the start of the new scheme year. The information sent will detail how to renew, including test material availability and changes since the previous scheme year. Relevant documents will be provided in the form of the renewal letter, the Contract/Registration Form, the Scheme Description and Terms and Conditions.

Participants should review the new scheme year information and return their order to NLPTS

Through the Contract/Registration Form (filled documents shall be send by email).

6.4 Advice and feedback

Communication with participants will be carried out through scheme-related documentation, e-mails and open meetings may also be organized and all interested parties invited to attend.

Part of the challenge of participating in a PT scheme is carrying out appropriate investigation and actions in response to an unsatisfactory or questionable result. Additional test materials are usually available after each PT round to enable participants to repeat testing if necessary.

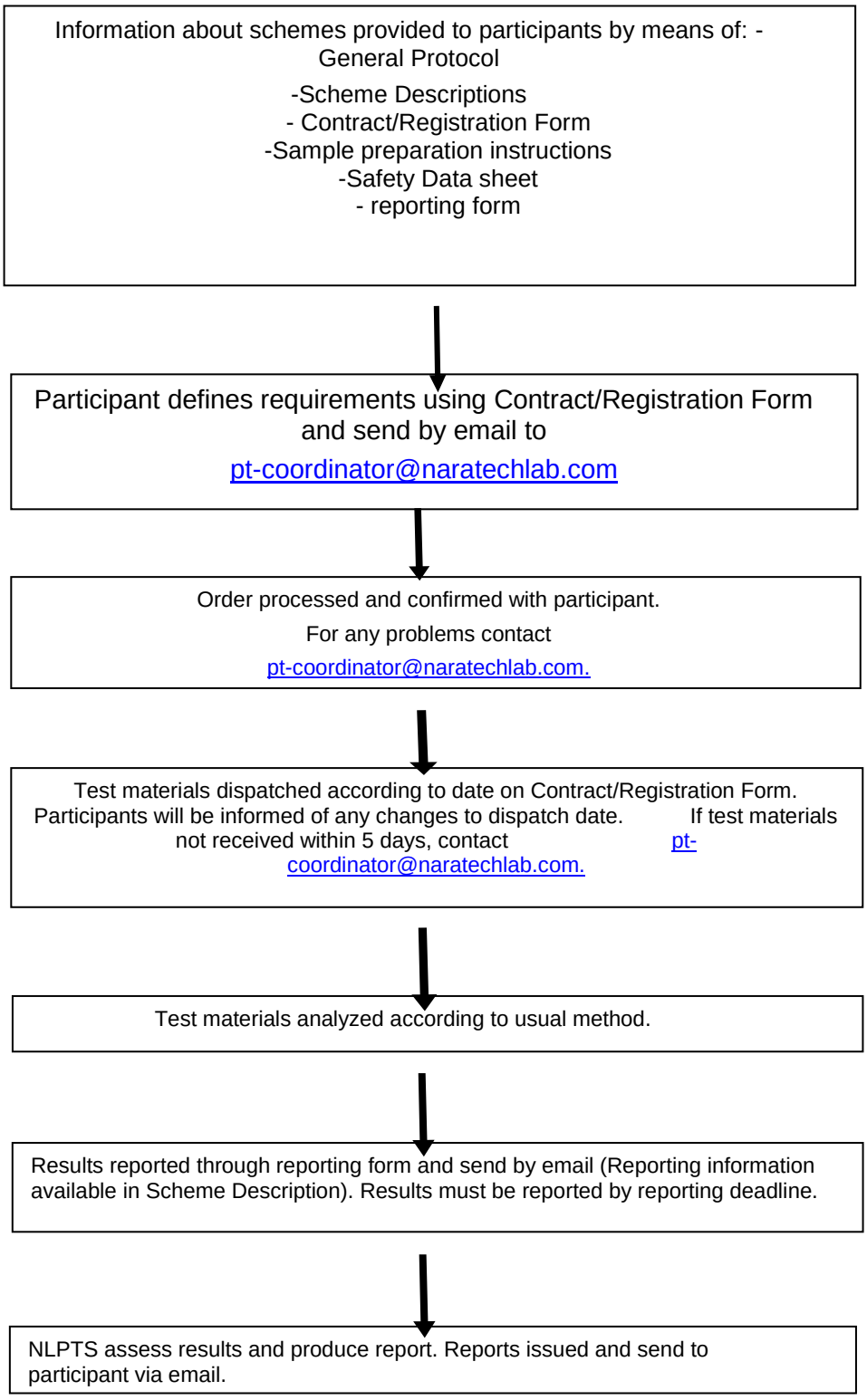
Comments on any aspect of the scheme are welcome either by e-mail or phone.

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. Complaints will receive and handled by Quality manager and technical manager.

6.5 Quality Control samples

Surplus test materials from the batch used for the PT may be available for purchase as quality control (QC) samples or retained for another PT round (property values or characteristics to be determined in the PT scheme will be confirmed prior to distribution). These QC samples may be used for troubleshooting poor performance in the PT, training of new staff, method development or generating QC charts. NLPTS QCs have an associated datasheet which provides the same data of assigned values and performance limits as in the PT. The stability assessment of QC samples is the same as that for the PT.

ANNEX I - Scheme Operation Flowchart



ANNEX II - Procedure for calculating robust statistics

Depending on procedures described in Annex c of ISO13528 :2022 values for the robust mean and standard deviation following Algorithm A, will be calculated.

A brief description of the procedure is described below

Robust mean (median)/ Robust Standard Deviation

The consensus value can be calculated using the robust mean/Robust Standard Deviation of all participant results.

In NLPTS schemes the robust mean used is the median or the robust mean by Algorithm A and the robust standard deviation is the standard deviation by Algorithm A

- Arrange the results of the participants in the increasing order (No of participants not less than 8).
- Calculate Median(x*) of the results of all participants.

(If the data, where there are an odd number of results are arranged in order of magnitude (*x1, x2,…, 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. with normal distribution the mean and median have the same value. The median is more robust, in that it is virtually unaffected by extreme values).

- Calculate absolute difference between each result and median.
- Calculate the median of above data (median of the deviation of all participants from the median).
- Calculate standard deviation(s*) by using formula “1.483 x median of deviation of all participants from the median.
- Calculate δ by using formula “δ = 1.5 x s*” for Iteration.
- Calculate x*– δ using previous value of x* for Iteration.
- Calculate x* + δ using previous value of x* for Iteration.
- Examine the results of each participant. If it is less than x* – δ replace it with x* – δ, if it is more than x* + δ replace it with x* + δ otherwise carry forward same readings.
- Calculate new x* average of the revised participant results.
- Calculate new s* using the formula “1.134 x standard deviation of the revised participant results.
- Repeat previous steps till x* and s* met stopping criterion:

No change in the 3rd significant figures of the robust mean and standard deviation.

- Treat the x* of the last integration as the assigned value.
- Treat the s* of the last integration as the SDPA.

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

Removal of errors, blunders and (outlier ⟶± 5 x SDPA)

Although robust estimators are used in order to minimize the influence of outlying results, extreme results or results that are identifiably invalid (blunders) should not be included in the statistical analysis of the data. For example, these may be results caused by calculation errors or the use of incorrect units.

However, results (outlying results) can be difficult to identify by the Technical manager , the robust mean and standard deviation will be calculated as above, but those results that are out of the range of the assigned value ± 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 scores.

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] (2022). A brief description of the procedure is described below;

a) Choose a property (or properties) to be assessed for homogeneity.
b) Carry out the homogeneity check and the measurement method to use.
c) Prepare and package the proficiency test items for a round of the scheme ensuring there are sufficient 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 the same 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 s_w, and between-sample standard deviation s_s.

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 s_s.

h) Examine the results to look for possible trends in analysis or production order and to compare differences between replicates.
i) Compare the between-sample standard deviation s_s with the standard deviation for proficiency assessment σ_{pt}. The proficiency test items may be considered adequately homogenous if $s_s \leq 0.3\sigma_{pt}$.

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

ANNEX IV - Estimated Standard Uncertainty of the assigned value

Uncertainty: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

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;

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

If $u(x_{pt})$ is ≤ 0.3 x SDPA, then the uncertainty of the assigned value can be considered negligible and need 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
$\underline{x}_{pt}$ = the assigned value
$\underline{x}_i$ = participant result
σ_{pt} = standard deviation for proficiency assessment
$u(x_{pt})$ = standard uncertainty of the assigned value $\underline{x}_{pt}$

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.

This protocol
This protocol will be revised when important modifications or organizational changes are made. Participants will be notified whenever a new edition is available

ANNEX V - 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 the competence of proficiency testing providers.

[3] ISO 13528 (2022) “Statistical methods for use in proficiency testing by interlaboratory comparison”.

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