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Proficiency Testing Schemes

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1. INTRODUCTION:

1.1 Purpose 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.

SASO Proficiency Testing provides a wide range of schemes designed to facilitate the improvement of the quality of measurements in many sectors covered. 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.

When performed within the context of a comprehensive quality assurance programme, proficiency testing is an independent means of assuring the quality of test and calibration results, as described in ISO/IEC 17025^[1].

1.2 Quality Standards

International standards of proficiency testing include ISO/IEC 17043^[2] (2023) 'Conformity assessment – General requirements for proficiency testing' and ISO 13528^[3] (2022) 'Statistical methods for use in proficiency testing for interlaboratory comparison'.

PTP-SASO is committed to continual improvement in quality and further information is available on the SASO Proficiency Testing website <u>Proficiency testing programs</u>

1.3 Terms and conditions

- It is the responsibility of the participant to determine if the PT scheme in the plan is relevant to their work. If the PT scheme is not relevant, however, the participant may request a PT scheme.
- The participation fee of proficiency testing programs in Saudi Riyal (SR).
- The participant may incur fees in addition to the base Fees for a Proficiency Test including where:
 - The participant requests additional Proficiency Test Items;
 - Transfer costs.
 - $\circ~$ For participants from outside the KSA, customs charges may have to be paid by the recipient in the destination country.
 - International shipping cost.
- A participant may cancel an order and withdraw from the proficiency testing program at any time, before issuing the report, by notifying PTP-SASO in writing. The refund policy is given below.

1.4 Refund Conditions

The refund a participant is entitled to after cancelling an order is based on the circumstances surrounding the cancellation:

A. PTP Cancels the Proficiency Testing Program:

- If PTP-SASO cancels the proficiency testing program for any reason, participants will receive a full refund of the amount paid.
- Reason for Cancellation: This may include changes to program availability, insufficient participant numbers, or unforeseen logistical issues affecting the program.
- Refund Processing: Refunds will be processed within 30 business days of the notification of program cancellation, and the participant will be notified once the refund has been issued.
 B. Participant Cancels After Payment is Completed:
- If the participant cancels after the payment has been processed and the participant is officially registered in the program, no refund will be issued. This includes situations where the participant has received PT items or other program-related services.
- Payment Completion: A payment is considered "completed" once PTP-SASO confirms the





transaction has been fully processed and payment is reflected in their system, whether by credit card, bank transfer, or other methods.

• No Refunds for Post-Payment Cancellations: Refunds are not applicable for cancellations made after payment has been processed due to the administrative costs and program preparations involved.

2. SCHEME ORGANISATION

2.1 Scheme coordination and responsibilities

The day-to-day operation of each scheme is the responsibility of PTP-SASO. Individual schemes are managed by Proficiency Testing Scheme Coordinators, responsible for customer service. Technical experts are used to provide the full range of relevant knowledge and expertise needed to operate the scheme effectively. Technical experts are selected on the basis of their technical knowledge and experience of the industry to which the scheme is related. Technical experts shall be used on an ad-hoc basis, being contacted when specific issues need to be addressed.

Technical experts will meet on a regular basis to design and review the progress and performance of the scheme, and to provide advice on future operation and development of the scheme.

For schemes the technical experts are responsible for providing expert opinions and interpretations against which the performance of the participants are assessed.

2.2 Joining a PT scheme

The PT plan is announced publicly at the beginning of the year, and these include information about the deadline of registration, the date of issuing the reports, and costs of participation.

In order to join a scheme, the participants should register for an account and place an order via our PT Website. Alternatively, the participant can send request to participate by <u>PTP@saso.gov.sa</u>. If the availability of any information changes during the scheme year, participants are kept fully informed. Most schemes do not have any restrictions on participation, but where these do occur this will be made clear on the PT plan.

Once an order placed on PT Website is received, an order confirmation will be sent to the participant at the deadline of registration, confirming the PT scheme selected and the invoice will be issued. Participants are advised to participate in the scheme(s) that are most appropriate to their ownarea of testing. Where necessary, staff at SASO Proficiency Testing can advise on which scheme(s) are most suitable for participants.

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.
- Dispatch of test materials to participants.
- Participants analyze the test materials and report their results to SASO 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.

Reports are issued as soon as possible after the registration of round closure, although the timescale

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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.

2.4 Costs of participation

Costs for participation are fixed and the current price for each scheme is 1700 SR in accordance with Board decision No 083 on 05/ 11/ 2023. Payment terms are detailed in SASO Proficiency Testing.

2.5 Confidentiality

In order to ensure confidentiality, participants in all schemes are allocated a unique laboratory code number. The participants' codes are randomly selected, and they do not refer to any technical or statistical information and this number enables results to be reported without divulging the identities of participant laboratories. For some 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 PTP-SASO, the affected participants will be notified of this action in writing.

Confidentiality can be waived by the participant for regulatory or recognition purposes. In this case, the proficiency testing results can be provided to the relevant authority by the participants themselves. Unless it is instructed.

2.6 Impartiality

All PT activities are undertaken impartially. PTP-SASO monitors its activities and its relationships to identify threats to its impartiality. If a threat is identified, action is taken to eliminate or minimize so that impartiality is not compromised. This monitoring includes the relationships of its personnel.

3. PROFICIENY TESTING ITEMS

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. 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 instruction for each scheme.

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^[3] (2022). Further details regarding homogeneity testing are included in the scheme design and/or reports.

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 provision of replacement test materials. In these instances, full details will be provided to participants.

3.3 Packaging and transportation

PT items are sent in appropriate packaging and under conditions intended to maintain the integrity of the test materials during transit. Once packages have been delivered, PTP-SASO cannot be held responsible if they are not stored under the recommended conditions.



Participants are asked to check the contents of packages immediately on receipt and to contact PTP-SASO if there are any problems with the condition of the test materials. If packages are received damaged, then it would be very useful if participants could supply photographic evidence to assist our investigations. Otherwise, it would be a confirmation of receiving the PT items in good conditions.

4. **REPORTINC OF RESULTS**

4.1 Timescales

To enable reports to be processed and issued as soon as possible after the closure of the proficiency test round, deadlines for the return of results are specified and must be adhered to. Results received after the reporting deadline cannot be included in the report. The main report is available to all participants subscribing to the round regardless of whether their results were submitted or not.

4.2 Choice of method or procedure

Participants are expected to use a technically appropriate test or measurement procedure of their choice, unless otherwise instructed. Participants are asked to treat the PT item as a routine sample as much as possible. PTP-SASO ensures that the effect of different procedures on evaluation of performance.

4.3 Reporting your results

For the majority of schemes, results are returned through our Proficiency Testing website, full instructions for which are provided. For some schemes (or parts of a scheme) alternative reporting mechanisms are provided, details of which will be emailed to participants prior to test material receipt.

It is recommended that results and calculations are checked thoroughly before reporting. Results should be reported clearly, in the format and units detailed in the scheme Instruction. Participants should to report the measurement uncertainty for each result within the result sheet. The measurement uncertainties may be included in the final report for the purpose of assessment.

4.4 Collusion and falsification of results

The participants shall not communicate with others or with any other parties concerning the proficiency testing scheme.

5. DATA ANALYSIS AND PEFRORMANCE ASSESSMENT

5.1 Objective of statistical design

The objective of the statistical design is to measure the performance of the participants in the conducting the predefined test procedure.

5.2 Determination of the assigned value

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 scheme and test parameter and is detailed in the relevant scheme instruction. For quantitative tests, all assigned values are derived in accordance with ISO 13528. However, in most cases either reference Laboratory, certified reference material (CRM), or a consensus value will be used. The selection of the method will be determined in each PT scheme.

5.3 Feasibility for metrological traceability

Metrological traceability is necessary to ensure the accuracy of the assigned value. Therefore, PTP uses ILAC accredited laboratories in performing the test measurements. However, the feasibility of metrological traceability will be determined in each PT scheme.



5.4 Standard deviation for proficiency assessment (SDPA, σ_{pt})

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. 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. The approach of determining the value of SDPA will be given in the instructions sent to the participants.

5.5 Analysis of results reported by different method

PTP ensures that the same test procedure is used by the participants. However, if different test procedures are used, PTP will ensure that this difference will not affect the evaluation of performance. Nevertheless, the participants shall inform the PTP if their test procedure is different than that instructed.

5.6 Minimum number of participants

When robust algorithms are used in either the valuation of the assigned value and/or standard deviation for proficiency assessment, a minimum number of participants should be reached. If the number of participants has not been approached, other methods for the determination of the assigned value/standard deviation for proficiency assessment should be established, or the PT scheme has to be canceled. The required minimum number of will be determined in each PT scheme.

5.7 Number of samples/replicate measurements

The participants will be instructed to conduct the test measurements to a certain number of samples/replicate measurements.

5.8 Number of significant figures / decimals

The number of significant figures/decimals of reported results are determined so that accurate and precise assessment is approached. The standard test procedure may provide information about the number of figures/decimals required for reporting the results. The required number of figures/decimals will be instructed for the participants before starting the PT scheme.

5.9 Homogeneity assessment

The main aim of the homogeneity assessment is to ensure that the dispersions between the samples have no influence on the evaluation of performance for the participants and conducted using the final form of the proficiency test items. The homogeneity assessment will normally be conducted prior to the distribution of the proficiency test items over the participants.

5.10Stability assessment

The purpose of a stability assessment is to ensure that the stability of the PT items during the transportation and duration of the PT round affects the evaluations of performance for the participating laboratories. All the properties that are used in the PT scheme will be checked or otherwise verified for stability. This can be accomplished with previous experience and technical justification based on knowledge of the matrix (or the artifact) and measurand. The repeatability number may be estimated using the sample power analysis statistical method.

5.11Identify and handling the outlier

When the assigned value and/or standard deviation proficiency assessment is determined as a consensus value from the results reported by the participants. The outlier value(s) will be handled using the robust algorithm in accordance with ISO 13528. Nevertheless, the results reported by the participants may be subjected to outlier tests as a part of performance analysis. In this case the Grubbs



and Cochran's methods will be used in accordance with ISO 5725-2.

5.12Evaluation of performance

For quantitative data, participants are assessed on the difference between their result and the assigned value with this difference being represented by a performance score called a z or z' (z prime):

$$z_i = \frac{(x_i - x_{pt})}{\sigma_{pt}}, \qquad z' - score = \frac{x_i - x_{pt}}{\sqrt{\sigma_{pt}^2 + u^2(x_{pt})}}$$

where;

xi is the result reported by the participant, x_{pt} is the assigned value, σ_{pt} is the standard deviation for proficiency assessment, and $u(x_i)$ and $u(x_{pt})$ are the standard uncertainty values of the participant *i* and the assigned value, respectively. The z score expresses performance in relation to an acceptable variation of the participant result to the assigned value, and can be interpreted as:

$$z = \begin{cases} |z| \le 2.0, & Satisfactory\,result\\ 2.0 < |z| < 3.0, & Questionable\,result\\ |z| \ge 3.0, & Unsatisfactory\,result \end{cases}$$

For qualitative tests, participant results will be compared against the assigned value, based on expert assessment. A result which is the same as the assigned value is considered satisfactory. If they are not identical, then expert judgement is needed to determine if the result is fit for its intended use.

5.13Uncertainty assessment

It is highly recommended for the participants to report their measurements of uncertainty (using a coverage factor k = 2 or as instructed). $\zeta - score$ can be useful when an objective for the PT scheme is to evaluate a participant's ability to have results to be close to the assigned value within their claimed uncertainty, it can be defined as

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

- ζ *score* can be interpreted as *z score*. However, cautions shall be taken not to allow the uncertainty reported by the participant influence the evaluation of performance.
- ζ *score* can be used in conjunction with *z score* to assess the uncertainty reported by the participant.

6. INFORMATION DISTRIBUTED TO PARTICIPANTS

6.1 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, the homogeneity and/ or stability of PT items, subcontracting services and tabular and/or graphical representations of participants' results and performance. Copyright to all reports remains with PTP-SASO.

6.2 Advice and feedback

Communication with participants will be conducted through scheme-related documentation, e-mails or via the PT website. Open meetings may also be organised and all interested parties invited to attend.

We welcome feedback on any aspect of the scheme. Participants can share their comments via email, add note on PT website, or letter. In case of a complaint, we will investigate it thoroughly under our quality system to identify the root cause and determine the appropriate course of action. The results of this investigation and the actions taken will be communicated to the participant. Further details about our complaints process are available upon request.





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ANNEX II - References

[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 interlaboratory comparison'.