

GOEIC- PTU
Proficiency Testing Schemes



June 2023

PROTOCOL

PREFACE

This document provides an overview of the GOIEC Proficiency Testing (PT) Rounds with the principles and procedures applicable to the unit of the GOIEC PT. It also explains how laboratory performance is evaluated. The document does not attempt to cover each step in the proficiency testing process. These are discussed in GOIEC internal procedures, which are in compliance with the requirements of the ISO/IEC 17043:2023. The Protocol should be read in conjunction with the GOIEC Proficiency Testing Supplement on Statistical Procedures which describes the statistical procedures for data analysis and performance assessment based on ISO 13528:2022 and the International Harmonized Protocol for the Proficiency Testing of Analytical Chemical Laboratories (IUPAC Technical Report: 2006 IUPAC)

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1.0 INTRODUCTION

GOIEC-PT Unit is a governmental Proficiency Testing unit belongs to GOEIC "General Organization for Export and Import Control" which is a sector of Ministry of Trade.

GOIEC-PT Unit is providing PTs in Food analysis, water analysis, Microbiological testing, Consumer safety, Electrical testing, Chemical testing, Cigarette - E liquid testing, Textile-Leather testing and Environmental testing which aims to contribute in the development and implementation of an analytical quality assurance system.

2.0 PROFICIENCY TESTING

Proficiency Testing is an essential element of the quality assurance of laboratories accredited to ISO/IEC 17025:2017 to establish technical competence of PT participant laboratories.

Proficiency testing provides an independent means of testing and comparing individual performance of participant laboratories against pre-established criteria by interlaboratory comparison of test results. It is way of checking the accuracy of results from laboratories. It involves the distribution of PT materials to participating laboratories for PT participants to analyze measurands at a prescribed period of analysis.

With the increasing demands for independent proof of competence from regulatory bodies and customers, proficiency testing is relevant to all food & industrials testing laboratories for quality and safety purposes.

3.0 QUALITY MANAGEMENT OF PROFICIENCY TESTING SCHEME

3.1 Operation The GOEIC-PTU

Rounds are operated according to the principles defined in the ISO/IEC 17043:2023 standard, "Conformity Assessment – General Requirements for Proficiency Testing". PTU also implements and maintains a quality management system on recognized management standards, ISO/IEC 17043:2023, and the ISO 13528:2022 "Statistical Methods for Use in Proficiency Testing by Interlaboratory Comparison" and IUPAC Technical Report (2006) "The International Harmonized Protocol for Proficiency Testing of Analytical Chemistry Laboratories" for statistical analysis. These requirements are intended to be general for all types of proficiency testing schemes and have been used as a basis for the specific technical requirements of the scheme.

An Advisory Committee is established for GOEIC-PTU Rounds, which is composed of the Technical Working Group Members who are chemists and of Consultants –Chemist/PT Provision Specialist and Statistician. Members of the Advisory Committee are selected on the basis of their qualifications and expertise, and not their affiliations. The Advisory Committee recommends and assists in the decision-

making in the activity of the Scheme and discusses the scientific issues arising from the conduct of PT. During discussion, the GOEIC PTU staff does not disclose any information pertaining to the PT participant, only scientific information is exchanged. Communications with the Advisory Committee are made through telephone or e-mail and minutes are prepared for every Advisory Committee Meeting

3.2 Participation

The GOIEC-PTU Rounds were aimed at providing the participants with the basis to evaluate their laboratory performance in the analysis of Proficiency testing items through an interlaboratory comparison. The PT Rounds were also intended to assist participants in conducting self-help investigative, corrective, and preventive actions to improve their laboratory performance.

The GOIEC-PTU Rounds are made available on the website, www.goiec.gov.eg. Local and foreign PT participant laboratories are invited to participate two weeks before distribution of a homogeneous and stable PT material. A call for participation, containing information of proficiency test item, measurand, PT timetable, and cost of PT participation is sent through e-mail and the PT participant returns a Registration Form with the following information:

- A. laboratory contact person;
- B. address and phone number;
- C. analytes/measurands to be tested.

3.3 Confidentiality

Each participant is provided with a unique laboratory code number, which identifies their results and all data they submitted to the PT provider. This laboratory code is used throughout the period of the Round to ensure their confidentiality. This is achieved by a confidential numeric code system generated by the scheme coordinator. Scheme coordinator has a list of scheme participants in paper form. Against each name the scheme coordinator enters a numeric code. This paper represents the only link between the codes and the participant names. It is kept in a locked cabinet and is not made available to the scheme Manger. The scheme manger therefore communicates to participants when identified by their code number only through the scheme coordinator. Any confidential material from the scheme manger is passed to the scheme coordinator with only the relevant code number.

Information on the performance of a participant laboratory will be confidential to that laboratory. A participant laboratory will not have access to the details of other participants. All information supplied by a participant to the proficiency testing provider shall be treated as confidential.

3.4 Typical Timetable

Organization of GOIEC-PTU Round is done at least once a year. The deadline for responding to invitation, date of PT material distribution, and reporting of results are indicated in the Call for Participation/Invitation to Participate.

For each PT Round, the organizer sets the deadline for the return of results or specifies a closure date, wherein after which, results will not be accepted. This is to ensure that sufficient time is available to complete the test and report the results in time for the set timeframe. Participants are informed by email when any delay arise in the schedule.

A typical GOIEC PT Round list of activities is as follows:

- Preparation of proficiency test item;
- Conduct of homogeneity and stability tests;
- Call for Participation and Registration of participants;
- Dispatch of proficiency test item;
- Analysis of proficiency test item by the participant laboratories and reporting of results to the PT provider – generally, the closing date is one month from the date of dispatch of proficiency test item, but time scale may be reduced in instances of potentially unstable analyte/measurand and/or matrix;
- Collation, screening and verification, and tabulation of results;
- Statistical evaluation of PT results;
- Preparation of the PT report;
- Distribution of the PT Report to PT participants;

3.5 Subcontracting

The GOIEC- PTU does not subcontract proficiency test item preparation while measurements and testing required for homogeneity and stability testing are done by competent laboratory, evaluated based on its accreditation, precision of results, performance in an applicable PT Round and turnaround time.

In necessary instances where additional technical competence and advice in PT operation are needed, the PTU Staff seeks technical assistance from the members of the Advisory Committee (Consultants and members of the Technical Working Group, TWG), particularly on the areas of statistical evaluation of laboratory performance, technical comments on methods used by the participant laboratory, and preparation of the PT Report.

4.0 TEST MATERIAL PREPARATION AND QUALITY CONTROL

4.1 Choice of PT materials

The PT material, which resembles the routine samples tested in laboratories are typically produced by the GOEIC PTU. The PT material with assigned values determined from the PT participants' results will be used as Quality Control Test Material (QCTM) for interested laboratories.

4.2 Test material supply

The proficiency test item is collected/ purchased from a market or is requested from a local manufacturing company. The proficiency test item collected should be from the same batch and/or lot number and date of manufacture.

4.3 Preparation of test materials

The preparation of the proficiency test item is conducted in GOEIC-PTU designated Proficiency Testing Laboratory that is maintained clean and temperature-monitored. Preparation of proficiency test item is specific to the type of matrix used and the relevant measurand. Test materials are usually prepared in bulk and then divided into individual sub-samples.

The proficiency test item is described as follows:

- A. species/brand
- B. scientific name if unprocessed
- C. source of sample
- D. weight per pack.
- E. batch number/ lot number
- F. ingredients/composition

4.4 Measurand

The GOEIC-PTU focused its analytes/measurands of interest to parameters commonly conducted by the private testing laboratories and local government laboratories. The level of the analytes/measurand varies according to the sample matrix.

4.5 Handling and storage of test materials

During preparation and analysis, and prior to distribution, the proficiency test item packets are handled and stored under conditions which minimize contamination, damage, and deterioration, and that the test item integrity is preserved. All proficiency test items are stored in appropriate location (freezer, refrigerator, ambient) until used or dispatched to participant laboratories. After taking the samples for homogeneity testing, the remaining samples for contingency for homogeneity testing, stability testing,

PT participants' testing, and for surplus are stored in a freezer, a refrigerator and/or ambient temperature.

4.6 Packaging and labeling

The packaging is designed to protect the proficiency test item from contamination, damage, and deterioration during storage and distribution. The proficiency test item is packed in a suitable packaging material, i.e. laminated aluminum foil, sealed using a vacuum sealer and/or heat sealer to minimize leakage and absorption of moisture during transport. Each proficiency test item is assigned with a computer-generated random number, and a label indicating the following information:

- 1) Name of PT Provider.
- 2) Name and code number of PT Scheme.
- 3) Measurands.
- 4) Matrix of PT material.
- 5) Sample number.
- 6) Date of preparation (Month YYYY).

4.7 PT material homogeneity

Non-homogeneous proficiency test items will undergo another series of homogenization (i.e., mixing, packaging, sealing) prior to distribution to the PT participants GOIEC-PTU proficiency test items will not be distributed until testing demonstrates that the sample is of sufficient homogeneity. GOIEC-PTU uses the statistical procedure for testing "sufficient homogeneity"

Details of the test material homogeneity testing are retained by the GOIEC-PTU, and may be released on request upon review and approval of the GOIEC-PTU Head as to the purpose of request.

4.8 Transportation

The shipment should be arranged in a way that the time for transport is as short as possible. GOIEC PTU shall specify relevant environmental conditions for the transport of proficiency test items. For artifact, it is intended to re-measure the traveling artifact before and after transport in the reference laboratory to establish a drift rate and to detect transport problems. Particular care should be taken to avoid the shipping case being exposed to extreme temperatureetc.

4.9 Financial aspects

Each participating laboratory covers the costs of the measurement, transportation and eventual customs formalities as well as for any damage that may have occurred within its country (case artefact). The PT participation fee is expected to be received before distribution of PT materials. GOIEC-PTU

reserves the right to withhold distribution of proficiency test item and/or Final PT Reports from participants if payment is not yet settled.

5.0 CONDUCT OF PROFICIENCY TESTING

The proficiency test item is sent to the participant laboratories for analysis in their respective laboratories together with the following documents:

a. Receipt Form

The Receipt Form is provided for the participants to acknowledge receipt of the package containing the proficiency test item and pertinent documents, and indicate the condition of the package and completeness of enclosed documents upon receipt.

b. Instruction to Participants

The Instructions for Participants is carefully designed for each PT Round, and participants are instructed to adhere to them closely. It is the participants' responsibility to read and follow the instructions. The GOIEC- PTU will not be held responsible for any problem arising from failure to comply with the instruction.

c. Method Details Form

The Method Details Form is provided for the participants to supply and clearly state the steps in the analytical procedure used for each measurand. The information in the form is being used to compare similarities and differences in the treatment of the sample among participants, and to evaluate possible causes of error and/or outlying test results. The information is used to support in the interpretation why participants may have obtained a "Warning" or an "Action" signal (e.g. if the method used is not appropriate or has limitations for the analyte/measurand under test). On occasions, the PT provider may require the complete method details used by the participant in the analysis.

d. Results Sheet

The Results Sheet is provided for the participants to write the results of analysis in a prescribed format (e.g. units of measure, number of decimal places). The format is provided in the Results Sheet to ensure consistency of reporting of the results for statistical treatment.

The PT documents are also sent electronically via e-mail to the PT participants' contact person.

5.1 Analysis of Proficiency Test Item

The participants are instructed to perform the analyses using their own routine test method, unless otherwise stated by the PT provider. The proficiency test item should be treated in the same way

samples are routinely tested in their respective laboratories, i.e. no special treatment of the proficiency test item. In the best way possible, participants are expected to use validated/verified standard methods of analysis.

5.2 Reporting of Results

The participants are given a minimum of fifteen (15) days to four (4) weeks after receipt of the proficiency test item to finish the analyses, record the results of analyses on the Results Sheet in the prescribed format, and submit to the GOIEC-PTU on or before the set deadline. Part of the challenge of proficiency testing is the ability to perform calculations and transcribe results correctly.

The PT provider cannot interpret or calculate results for the participants. The participants are also requested to report the estimated measurement uncertainty (MU) for each result as expanded uncertainty, expressed in a prescribed unit, confidence level, and coverage factor.

5.3 Late return of results

The PT provider maintains strict control over the return of results, and all returned results are filed accordingly. Participant results submitted after the due date for submission will not be included in the statistical analysis.

5.4 Collation and verification of results

The PT results, MU, and method details are collated, tabulated, checked for accuracy of entry, and verified before statistical evaluation is performed. Instructions are given to the participants that the reported results are considered final, unless corrected before the set deadline for submission of results. No corrections from participants will be accepted once the statistical evaluation of results started.

5.5 Ethical issues

Participant laboratories shall employ methods used in their routine analyses, and shall not subcontract the analyses to another laboratory. Laboratories shall avoid collusion and falsification of results. Participants should not discuss with each other the results of respective laboratories.

On all occasion, participant laboratories are expected to behave in a professional manner. PT Rounds are intended primarily to help participants test their own methods of analysis, learn from their peers, and ultimately improve their laboratory performance.

Certain measures are built onto the Round to try and prevent collusion, for example, assigned values are not made known to anyone before closure date of the PT Round, and no PT participants' results are accepted once the assigned value has been issued.

APPENDIX A

GLOSSARY OF TERMS

GLOSSARY OF TERMS

For the purpose of this GOEIC PT Protocol, the following definitions apply.

Accuracy

The closeness of agreement between a test result and the accepted reference value

Assigned Value

The value attributed to a particular quantity and accepted, having an uncertainty appropriate for a given purpose. It is the best estimate of the true value of the measurand in the matrix.

Average

The sum of all values divided by the number of values

Certified Reference Material (CRM)

A reference material, one or more of whose property values are certified by a technically valid procedure, accompanied by, or traceable to, a certificate or other documentation issued by a certifying body.

Error

The difference between a reported result and the assigned value.

Interlaboratory Comparisons

The organization, performance and evaluation of tests on the same, or similar items, or materials, by two or more different laboratories in accordance with predetermined conditions.

Internal Quality Control (IQC)

A set of procedures undertaken by the laboratory staff for the continuous monitoring of operations and results in order to judge whether the results are sufficiently reliable. It is a system by which a laboratory is able to monitor the day-to-day consistency of results.

Outlier

A member of a set of values that is inconsistent with the other members of that set.

Precision

The closeness of agreement between independent test results.

Proficiency test item

A sample, product, artefact, piece of equipment or measurement standard sent to one or more participants in a proficiency testing scheme.

Proficiency Testing (PT) Round

A single complete sequence of circulation of proficiency test items to all participants in a proficiency test scheme.

Proficiency testing scheme

Interlaboratory comparisons designed and operated to assess laboratory performance in specified areas of testing, measurement, calibration or inspection.

Reference Material (RM)

A material or substance with one or more properties of which are sufficiently homogeneous and well-established to be used for the calibration of an apparatus, assessment of a measurement method, or for assigning values to other materials.

Robust Statistical Techniques

Techniques to minimize the influence that extreme results can have on estimates of the mean and standard deviation

Standard Deviation

A measure of the dispersion of data about the mean value

Target Standard Deviation

A numerical value that is designated by the organizer of a proficiency testing (PT) Scheme as a realistic goal for measurement quality

Test Method

A defined technical procedure to determine one or more specified characteristics of a material or product

Test Material

The material or sample provided for the purposes of a proficiency testing (PT) scheme.

Testing Laboratory

A laboratory that measures, examines tests, calibrates or otherwise determines the characteristics or performance of materials or products.

Trueness

The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value

True Value

The actual concentration of the measurand under test in the test material

z-score

Standardized measure of performance, calculated using the participant result, assigned value and the standard deviation for proficiency assessment.

z'-score

A common variation to z-score formed by combining the uncertainty of the assigned value with the standard deviation for proficiency assessment before calculating the z score

zeta-score

Standardized measure of performance, calculated using the participant result, assigned value and the combined standard uncertainties for the result and the assigned value.

APPENDIX B

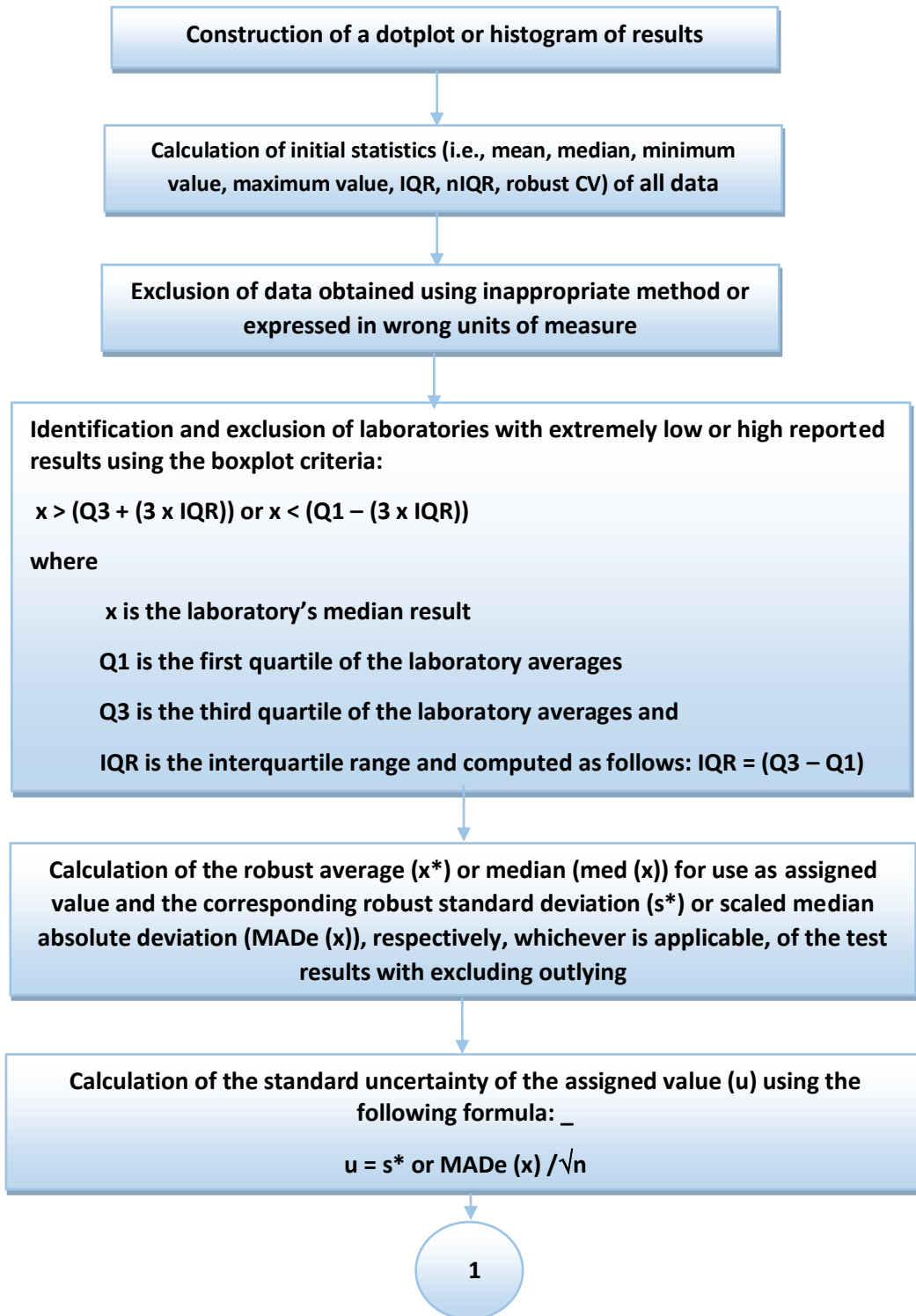
GOIEC - PTU PROFICIENCY TESTING UNIT ON STATISTICAL PROCEDURES

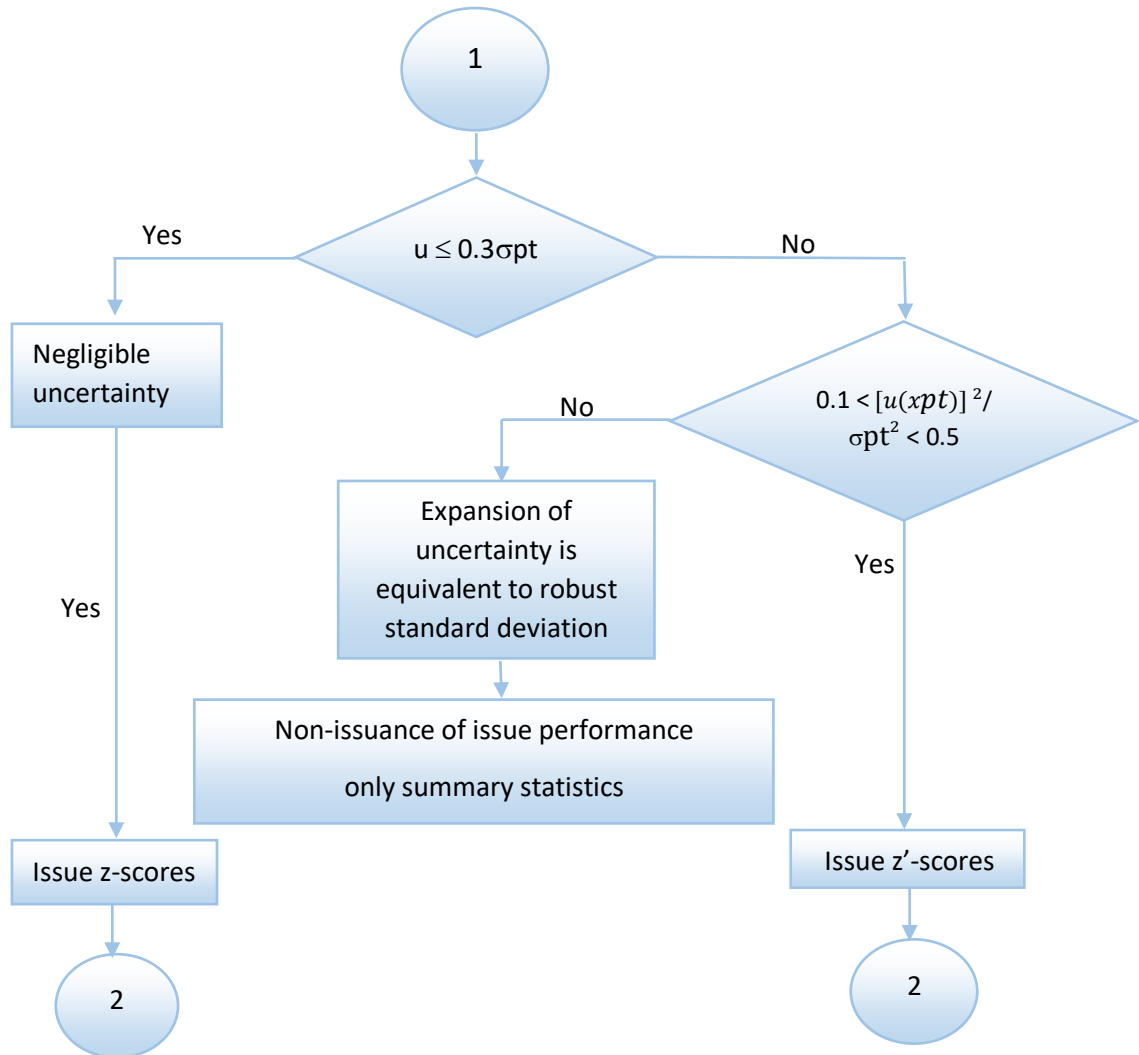
I. EVALUATION OF PROFICIENCY TESTING (PT) RESULTS

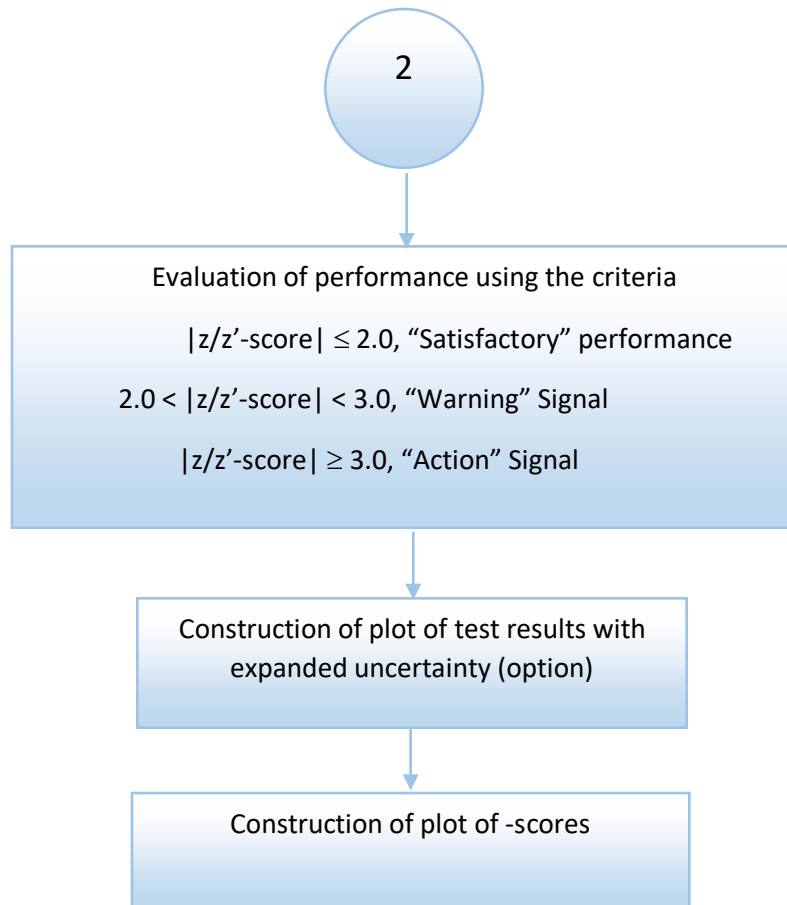
INTRODUCTION

Proficiency test results are assessed by comparison with assigned values derived from the consensus of results (consensus value) from participants, or values determined by a reference laboratory. The consensus values are estimated using robust procedures. Robust procedures are used in the estimation of consensus values because the most commonly used measures of location and dispersion – arithmetic mean and standard deviation are highly influenced by the presence of extreme outliers and their interpretation depends on an implicit assumption that they are a random sample from a normal distribution. Outliers are values that are so far in value from the rest of the data that they may be viewed as coming from a different population, or the result of a measurement error. Employing tests such as Grubbs' test or the boxplot usually identifies suspect outliers. The use of the Grubbs' test presumes that the distribution of the variable is approximately normal. A boxplot, on the other hand, can be used in identifying outliers for both normal and non-normal distributions.

Among the three statistics – mean, median and mode – the mode is least affected by the presence of outliers. However, because the calculation of the mode is more difficult than that of the mean or median, the mode has limit







Establishing the Assigned Value (X_{pt})

Assigned values for quantitative proficiency testing schemes

The assigned value is the “best practicable estimate of the true value of the concentration (or amount) of analyte in the test material.” Methods for establishing assigned value are presented below.

1. Consensus of Participants’ Results (Robust average)

The consensus of participant's results is used as the assigned value when this value is the only practical method available for the proficiency test. GOEIC -PTU will calculate an assigned value by this method only if there is a minimum of six results to ensure a reasonable estimate. The assigned value for the test material used in a proficiency study is the robust average of the results reported by all the participants in the round.

2. Measurement by a Reference Laboratory

An assigned value and uncertainty may be obtained by a suitably qualified measurement laboratory using a method with sufficiently small uncertainty. This is probably the closest approach to obtaining the true value for the test material but it may be very expensive. This approach is used when practical and when resources are available for certain analytes and matrices.

3. Use of a Certified Reference Material

When the material used in a proficiency testing scheme is a certified reference material (CRM) its certified reference value is used as the assigned value. The uncertainty of the assigned value is derived from the information on uncertainty provided on the certificate.

4. Formulation

Formulation is the addition of a known amount or concentration of analyte to a base material which is either free of the analyte or its concentration accurately known. The assigned value is then determined from the proportions of the materials used and the known concentrations added.

This method is advantageous if pure substances are available to spike the test samples, as the added amount can be measured extremely accurately by gravimetric or volumetric methods. Consequently, there is usually no difficulty in establishing the traceability of the assigned value.

Assigned values for qualitative proficiency testing schemes:

Values may be assigned to proficiency test items:

- by expert judgement;
- by use of reference materials as proficiency test items;
- from knowledge of the origin or preparation of the proficiency test item(s);
- using the mode or median of participant results.

Setting the Target Standard Deviation (σ_{pt})

1-From a Predictive Model

Thompson suggested a contemporary model to calculate the reproducibility standard deviation (σ) based on the Horwitz function. This model predicts a standard deviation from a given concentration (c) and requires c to be dimensionless mass ratio, e.g., 1ppm $\equiv 10^{-6}$ or % $\equiv 10^{-2}$.

*For analyte conc. Less than 1.2×10^{-7} (120 ppb)

$$\sigma_{pt} = 0.22 C$$

*For analyte conc. Between 1.2×10^{-7} (120 ppb) and 0.138 (13.8%)

$$\sigma_{pt} = 0.02 C^{0.8495}$$

*For analyte conc greater than 0.138 (13.8%)

$$\sigma_{pt} = 0.01 C^{0.5}$$

2- Normalized IQR

The Normalized IQR is a measure of the spread of the results, and it is calculated by multiplying the interquartile range (IQR) by a factor (0.7413) which relates it to the 'normal' distribution.

3- Collaborative trials / method performance studies

A value from the reproducibility standard deviation of the standardized analytical method

The target standard deviation calculate from the method reproducibility limit by division with 2.8.

$$\sigma_{pt} = \frac{RSDR}{100} \times C$$

Where

RSD_R is the Relative Standard Deviation of reproducibility from collaborative trial, expressed as%.

C is concentration of the assigned value.

Measurement uncertainty :

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

$$u(x_{pt}) \text{ is calculated as: } u(x_{pt}) = s^* / \sqrt{n}$$

where: - s^* is the robust estimate of the participant standard deviation;

- n is the number of participants.

In case of not negligible effects of inhomogeneity and instability, if $0.1 < [u(x_{pt})]^2 / \sigma_{pt}^2 < 0.5$, the standard uncertainty is expanded by the factor 1,25

$$u(x_{pt}) = 1,25 [s^* / \sqrt{n}]$$

In case of median as estimator, the standard deviation is calculated as $s^* = \text{MADe}$ (where MADe is the Median Absolute Deviation).

When the standard uncertainty is too high, the assigned value could be inaccurate.

Therefore:

- In case $[u(x_{pt})]^2 / \sigma_{pt}^2 > 0.5$, the consensus value is not determined and individual laboratory performance scores are not reported. Summary statistics are provided only for information.
- In case $0.1 < [u(x_{pt})]^2 / \sigma_{pt}^2 < 0.5$, the uncertainty is not negligible. The effects of uncertainty are introduced in the calculation of the z-score (that will be calculated as z' -score). The standard uncertainty $u(x_{pt})$ is expanded by factor 1.25 only in case inhomogeneity and instability effects are not negligible.

Performance evaluation

Two types of measurement uncertainty can be taken into account:

1. Measurement uncertainty of the assigned value.
2. Measurement uncertainty of the participant result.

a) "z score" (most commonly used and measurement uncertainty not taken into account);

$$Z = \frac{x_i - X_{pt}}{\sigma_{pt}}$$

where:

x_i = result reported by participant

X_{pt} = assigned value

σ_{pt} = standard deviation for proficiency assessment

b) "z'-score" (standard uncertainty of the assigned value is taken into account);

$$z' = \frac{xi - X_{pt}}{\sqrt{(\sigma_{pt})^2 + [u(x_{pt})]^2}}$$

where:

x_i = result reported by participant

X_{pt} = assigned value

σ_{pt} = standard deviation for proficiency assessment

$u_{x_{pt}}$ = the standard uncertainty of the assigned value X

c) "zeta-score" (standard uncertainty of the assigned value and the participants result is taken into account);

$$\zeta = \frac{xi - X_{pt}}{\sqrt{(u_{xi})^2 + [u(X_{pt})]^2}}$$

where:

u_{x_i} = the participant's own estimate of the standard uncertainty of its result x_i

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

Deciding whether to use either z-scores or z'-scores, GOEIC PTU consider the following aspects:

a) if $u(X_{pt}) \leq 0.3 \sigma_{pt}$, then the standard uncertainty of the assigned value is negligible.

b) when $u(X_{pt}) > 0.3 \sigma_{pt}$ the standard uncertainty of the assigned value is not negligible and it is recommended to use z'-score.

The following judgment is commonly made for z, z' and zeta scores:

- a) $|z| \leq 2.0$ the score indicates “satisfactory” performance and generates no signal.
- b) $2.0 < |z| < 3.0$ the score indicates “questionable” performance and generates a warning signal.
- c) $|z| \geq 3.0$ the score indicates “unsatisfactory” performance and generates an action signal.

Appeals

Each participant can appeal against the evaluation of its performance by email to the following address: PT @goeic.gov.eg.

An investigation will be conducted in accordance with our management system and participant advised of the outcome.

REFERENCES

- [1] ISO/IEC 17043:2023, Conformity assessment – General requirements for proficiency testing.
- [2] ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.
- [3] ISO/IEC 13528:2022, Statistical methods for use in proficiency testing by interlaboratory comparisons
- [4] The International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories. Pure Appl. Chem., 78, 1; 145-196, (2006) .
- [5] ILAC G13:2000 ‘Guide to the Requirements for the Competence of Providers of Proficiency Testing Schemes’.

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