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# PT PROTOCOL- General Information

This PT protocol is a part of Information brochure on PT Scheme(s) including the following and is in public domain <a href="https://www.proficiencytesting.in">www.proficiencytesting.in</a>

- 1.Frequently asked questions 2. Registration form 3.PT calendar(s) 4. Terms & Conditions for participation
- 5. PT protocol 6. NABL Scope

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# **Symbols**

d	Difference between a measurement value for a proficiency test item and an assigned value of a CRM	
g	Number of proficiency test items tested in homogeneity checks	

Number of repeat measurements made per proficiency test items

p Number of participants taking part in round of proficiency test schemes

Sr Estimate of repeatability standard deviation
 SR Estimate of reproducibility standard deviation

ss Estimate of reproducibility standard deviation
ss Estimate of between sample standard deviation

s\* Robust estimate of the participants standard deviation
sw Within-sample or within-CAB standard deviation

 $\sigma_{pt}$  Standard deviation for proficiency assessment (SDPA)

 $\begin{array}{ll} \sigma_r & & \text{Repeatability standard deviation} \\ \sigma_R & & \text{Reproducibility standard deviation} \end{array}$ 

 $u_{hom}$  Standard Uncertainty due to difference between proficiency test items  $u_{stab}$  Standard Uncertainty due to instability during the period of proficiency testing

 $u_{trans}$  Standard Uncertainty due to instability during transport conditions

 $u(x_i)$  Standard Uncertainty of a result from participant i  $u(x_{\rm pt})$  Standard Uncertainty of the assigned value  $u(x_{\rm ref})$  Standard Uncertainty of a reference value

x Measurement Result (generic)

 $x_{char}$  property value obtained from characterization (determination of assigned value)

 $x_i$  Measurement result from participant i

 $x_{pt}$  Assigned value

 $egin{array}{ll} x_{\rm ref} & {\sf Reference} \ {\sf value} \ {\sf for} \ {\sf a} \ {\sf stated} \ {\sf purpose} \ & x^* & {\sf Robust} \ {\sf estimate} \ {\sf of} \ {\sf the} \ {\sf participant} \ {\sf mean} \ & \bar{{\sf x}} & {\sf Arithmetic} \ {\sf average} \ {\sf of} \ {\sf a} \ {\sf set} \ {\sf of} \ {\sf results} \ & {\sf results} \ & {\sf value} \ & {\sf value}$ 

w<sub>t</sub> Between test portion range

z Score used for proficiency assessment (absolute value ±)

z' Modified z-score (commonly pronounced as z-prime) that account for  $u(x_{pt})$  which is not negligible when compared to  $\sigma_{pt}$ . Performance evaluation given in terms of z'-score where participants are less than 12 is only indicative. PT Provider,

however, follows appropriate procedure as applicable for small number of participants.

 $\delta_{\it hom}$  Errors due to difference between proficiency test items

 $\delta_{stab}$  Errors due to instability during the period of proficiency test items  $\delta_{trans}$  Errors due to instability during under transport conditions

X Homogeneity AverageY Stability Average

B

Blunder - Obvious odd values by visual review as well as subjecting the data to any one of the following methods individually or in combination (i) Results that deviate from the X by more than  $\pm 5\sigma_{pt}$  or (ii) Outlier detection test such as Grubbs test (iii) presence of any obvious blunders or erroneous

reporting by experience in case of qualitative schemes

RNS Results not submitted—Participant may not submit results for a parameter(s) for various reasons- It is not in their scope or they have already covered that parameter(s) or participating only for outlier parameters or as per their plan will participate in parameter(s) in next scheme run or during testing is not

confident of the results etc. PT provider in this case does not give score and mark the column as '--'.

RNC Results not considered (Where participants - Report results as zero (except where results can be zero) or non-numerical results e.g. <0.1 or >1, Nil, BDL etc.

or results are qualified by any symbol or given with any remarks etc.; these results are not considered for performance evaluation) – PT provider in this

case do not give score and mark the column as '--'. This is also applicable, in case of sampling schemes if participant does not provide information as desired by PT Provider in line with requirements of case study.

In order to ensure σpt used for performance evaluations is fit for purpose in line with ISO 13528 clause 8.6.2, PT provider can use initial σpt from perception (literature review, expert advice and or from experience) or Horwitz equation for evaluating score for a parameter as mentioned in summary and performance statistics.

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# **Abbreviation**

ACV	Absolute compliant value		
Amd.	Amendment		
APAC	Asia Pacific Accreditation Cooperation		
CAB	Conformity assessment body		
CRM Certified reference material			
	Decimal point. This indicates the number of decimal places to which participants should report		
DP	their measurement results		
e.g.	Stands for exempli gratia and means "for example"		
etc.	Is a Latin expression that is used in English to mean "and other similar things"		
E	ı G		
ELPT	Expert  Environment Laborated DT Coll		
HDPE	Envirocare Labs Pvt. Ltd PT Cell		
	High-density polyethylene		
IEC	International Electrotechnical Commission		
ILAC	International Laboratory Accreditation Cooperation		
ISO	International Organization for Standardization		
MRA	Mutual recognition arrangement		
MU	Measurement uncertainty		
n	No. of key criteria indicators in sampling scheme		
NABL	NABL National Accreditation Board for Testing and Calibration Laboratories		
NMI National metereological Institute			
OPI Overall Performance Index			
PDF	Portable document format, used to display documents in an electronic form independent of the		
PDF	software, hardware or operating system they are viewed on.		
PS	Performance Score		
PT	Proficiency testing		
PT coordinator	Proficiency testing coordinator		
	Proficiency testing item or Sample for analysis of determination of measurands or analytes or		
PT item	case study in case of sampling schemes		
PT protocol	Proficiency testing protocol – general information on PT schemes by PT provider		
PT program	Proficiency testing program or round		
PT provider Proficiency testing provider Proficiency testing provider			
PT scheme Proficiency testing provider  PT scheme Proficiency testing scheme			
SI International System of Units			
w.r.t.	acronym for with respect to		
***************************************	This indicates the units used for the assessment of data. These are the units in which participants		
	should report their results. For some analytes in some schemes participants may have a choice of		
Units	which units to report their results, however, the units stipulated in this scheme description are		
Onits	the default units to which any results reported using allowable alternative results will be		
	converted to.		
	נטוויכונכע נט.		

Any other symbol or abbreviation used is described at the first instance. For more details including terms and definitions refer to ISO/IEC 17043, ISO 13528, ISO/IEC 17025 and ISO/IEC 17011.



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1.0	INTRODUCTION			
	Envirocare Labs Pvt. Ltd. PT Cell herein thereafter referred as ENVIROCARE LABS PT CELL facilitates knowledge sharing and skill development by providing innovative capacity building programs to testing laboratories. One of the key activity in this regards providing PT schemes for ensuring validity of results and monitoring competence of personnel in accordance with clause 7.7 & 6.2 of ISO/IEC 17025 respectively with the objective of promoting confidence in the operation of CABs and generate valid results.			
2.0	DVDDOGE AND GOODE OF DOCKGERYOV TROTTENS			
2.0	PURPOSE AND SCOPE OF PROFICIENCY TESTING  DT is defined as the evaluation of participant performance against two established criteria by many			
	PT is defined as the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.			
	ENVIROCARE LABS PT CELL organizes various types of schemes as defined in ISO/IEC 17043, both quantitative and qualitative (simultaneous) to provide insight into competence of CABs performing the testing by way of comparing it with that of their peer group. A typical feature of schemes is to help CABs in improving their performance. For more details refer to PT calendars. The schemes are conducted in line with ISO/IEC 17043, ISO 13528, NABL-181 and customer requirements.			
3.0	SCHEME ORGANISATION			
	PT schemes are organized by ENVIROCARE LABS PT CELL			
	PT coordinator: Dr. Nilesh Amritkar			
	Address: Envirocare Labs Private Limited PT Cell,			
	A-7, A-8, Enviro House, MIDC Main Road, Wagle Industrial Estate,			
	Thane (West), 400604, India.			
	+91- 9167702413  pt@envirocare.co.in			
4.0	NAME/CODE FOR PT SCHEMES			
	Codes of PT schemes are given in PT calendar			
5.0	SUBCONTRACTED ACTIVITIES			
	ENVIROCARE LABS PT CELL uses a competent subcontractor, in line with ISO/IEC 17043 for testing homogeneity and stability of PT items as applicable for quantitative and qualitative programs. The sampling schemes does not involve subcontracting of any activities.			
6.0	PARTICIPATION IN A PT SCHEME			
	Participation is given to participants (as defined in ISO/IEC 17043) directly or indirectly through customers. Both accredited and non-accredited CABs and individuals are eligible for participation. CABs shall use calibrated equipment's and or certified reference material in line with NABL 142 for testing the parameters including sampling for which participation is made irrespective of status of accreditation.			
	In order to participate in a PT scheme, participants shall fill the registration form and submit to PT provider by email. Submission of registration form may be exempted by PT provider on its sole discretion under any special circumstances as deemed fit by PT provider and registration may be accepted via other means as request on email, work order etc The decision of PT provider is final in this regard.			
	Registration is on first cum first basis. Participants who register late may be shifted to next PT scheme. PT provider may suggest/ request for participation in a specific scheme for meeting the minimum participants requirement or otherwise. PT provider may also restrict participation depending upon the nature of the scheme and issues related to availability of infrastructure support or any other issues specific			



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to the scheme.

Registration for a scheme normally closes on the date of registration mentioned in PT Calendars unless the scheme is extended. However, PT provider can admit participants who fail to register by the given deadline and may allow registration as long as sample preparation has not started or extra samples can be provided from the lot. The decision of PT provider is final in this regard.

Minimum number of participants allowed in a PT scheme are two or more. For commercial reasons and or to meet requirements of standard, quantitative schemes may be run when minimum 8 or 12 (preferable) participants are available. The qualitative scheme can be run with minimum of 3 participants.

Parameters in a PT scheme are decided based on customer requirements and aligned as per regulatory standards or product protocols. The technical feasibility as interferences and related issues including costs and PT item handling issues also play a role in deciding parameters covered in a scheme.

Participants do not necessarily have to analyse/sample all the measurands (analytes/parameters) in a PT scheme. ELPT team can advise on which PT schemes are most suitable for participants and help draw a PT plan in line with NABL 163.

ENVIROCARE LABS PT CELL, however, tries it best to provide PT schemes and incorporate parameters to deliver optimum solutions to CABs in terms of cost without compromising quality.

Participation in PT scheme is given in good faith. ENVIROCARE LABS PT CELL may refuse participation to testing CAB of a competitor PT provider or any other organizations due to issues of conflict of interest, involvement in collusion, engagement in activities deterrent to the interests of PT provider, bringing disrepute to PT provider or any other reason as deemed fit. The decision of PT provider is final in this regard. Further, if it is found that any participant is misusing registration or making any other false claims to meet the requirements of accreditation or regulatory bodies and subsequently drop their registration or do not respond or does not make payments, the PTP has a right to bring the same to the notice of the concerned accreditation or regulatory body and disclose the identity of such participant including taking any other appropriate action as deemed fit.

## 7.0 **FEES**

The fee for taking participation in a PT scheme are provided in PT calendar.

Programs may have to be re-run due to problems in homogeneity and stability or any other technical or unavoidable circumstances, including requisite numbers of participants are not available for a particular scheme by the registration closure date. Fee is refunded except for tax part only when scheme cannot be run for more than 18 months from date of closure of registration. Refund of fee else otherwise is subject to sole discretion of PT provider on such grounds as found to be satisfactory.

## 8.0 USE OF ADVISORS AND ADVISORY GROUP

ENVIROCARE LABS PT CELL uses an advisory committee that have on board a range of stakeholders in line with clause 4.4.1.4 / 4.4.1.5 of ISO/IEC 17043 as per the requirements of the relevant PT schemes such as (I) Personnel from regulatory authorities (II) Personnel from institutions of repute (III) Personnel from CABs (IV) Personnel from subcontractor (V) Independent experts well versed in subject matter and



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or ISO/IEC 17025 and or ISO/IEC 17043 and or ISO 17034 etc. Where relevant to a PT scheme persons association may be declared to registered participants.

#### 9.0 PROFICIENCY TEST ITEMS

PT scheme design discusses selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test or sample in the specific PT scheme as well as description of the range of values or characteristics, or both, to be expected for the PT items. Relevant information is available to participants initially in PT calendars. Registered participants are provided all relevant information subsequently in detail during the operation of the PT scheme.

The determinants in PT items may either be at natural levels, incurred or spiked at a particular formulation level and or manipulated. The range of PT items can usually be varied from round to round in order to be realistic and challenging.

A parameter can be removed/added in a scheme or range of testing may be varied at the time of running; This may be due to operational reasons; new developments; due to nature of product or matrix; homogeneity or stability issues and or reasons beyond control. PT provider may also add additional notaccredited parameters in a scheme in line with NABL-181 / NABL-163. These are clearly identified. Report is issued for such parameters in line with NABL-133. The non-accredited parameters are brought under accreditation in next cycle of reassessment by PT provider or otherwise as deemed fit. Decision of PT provider in this regard is final. Registered participants are informed as applicable.

#### 10.0 **HOMOGENEITY AND STABILITY**

# Quantitative and qualitative schemes-

For homogeneity ten replicates ( $g \ge 10$ ) at random are used for first PT scheme and or during trials. It is done prior to distribution of the PT items to the participants and after the PT items are packed and unique ID numbers are given. The PT items are ensured to be sufficiently stable for the duration of the program by doing stability checks every time over the duration of PT scheme by selecting a minimum of six replicates and testing two replicates at the conclusion of the PT testing scheme and compare these with one replicate tested prior to run. Where required during initial run of the scheme or during trials or otherwise stability checks may additionally involve establishing suitable transport and storage conditions that may involve combination of simulated conditions, expert advice and assessment of historic data as applicable and documented in PT design. Stability check may include comparing PT items retained at the PT provider's premises with PT items subjected to shipping and return. Studies based on exposure to reasonably foreseeable conditions of transport may also be used. However, for parameters where PT items used are sufficiently stable over the desired period, the stability testing may also not be carried out as laid down in design.

The homogeneity and stability are ensured by establishing  $s_s \le 0.3 \, \sigma_{\rm pt}$  for homogeneity and Homogeneity Average (X)- Stability Average (Y)  $\leq 0.3 \, \sigma_{pt}$  for stability. This can also be subsequently revalidated using σ<sub>pt</sub> derived from participants algorithm. The PTP may additionally use Cochran's C Test Cmax< C critical (implying no evidence of analytical outliers).

In line with 4.4.3 of ISO/IEC 17043 there may be cases where it is not feasible for PT items to be subjected to homogeneity and stability testing e.g. sampling schemes or there are schemes where homogeneity



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testing cannot be carried out prior to distribution for practical, technical or logistical reasons. Such cases are documented in PT design and described in the report.

Further, in line with clause 6.1 of ISO 13528 as documented in PT design on case to case basis for subsequent schemes, the number of PT items included in homogeneity check may be reduced to  $g \ge 4$  based on experience under repeatable conditions or on the basis of experience with the behaviour of closely similar PT items in previous rounds of the PT scheme verified as necessary for the current round. Critical measurands in a program may be analysed only instead of all irrespective of replicates used.

The aim is to ensure that homogeneity and stability is fit for purpose and every participant receives comparable proficiency test items.

In case of non-compliance, heterogeneity and or instability of the PT items is considered for evaluating the performance of participants as per procedures. In these circumstances further explanation is given in the report and design is reviewed as applicable as certain PT items may be heterogenous by nature.

# 11.0 POTENTIAL MAJOR SOURCES OF ERRORS INVOLVED IN PT SCHEMES OFFERED

Potential major sources of errors are discussed in PT design for each PT scheme. PT design is improved from time to time on the basis of experience gained in running the PT schemes. The errors may be related to issues with selection of PT items, PT item preparation, homogeneity, stability, packing, environmental factors etc. and vary scheme wise.

Where, prior to dispatch, the homogeneity and or the stability is not acceptable, the PT items are not distributed to participants. If this may cause a delay in the distribution of PT items, participants will be informed. There are chances, that issues with PT items may not be identified until after distribution. If this happens this is considered when assessing participants performance. The outcome will vary depending upon the situation but may involve reporting of evaluation scores for information only, or the provision of replacement PT items. Under such circumstances, relevant details are provided to participants and scheme may be rerun or action taken as per ISO 13528.

# 12.0 PACKAGING AND TRANSPORTATION

PT items are sent in appropriate packaging and under conditions intended to maintain the integrity of the PT item during transit. The packaging guidelines as given in standard methods or on the basis of experience and trials are followed in choosing a suitable packaging.

The PT item supplied is sufficient for the analysis required once, including any re-analysis permitted by the PT scheme design.

On receipt of PT item, participants are asked to fill the PT item receipt acknowledgment form and email scanned copy (pdf format) to PT provider within two days from the receipt of the sample. This is to bring to notice of PT provider that it has received the PT item intact. If PT item is received damaged than PT provider may issue another item subject to its satisfaction of genuineness of the issue after due diligence. Decision of PT provider in this regard is final. No claim is entertained if made beyond the stipulated period. ENVIROCARE LABS PT CELL is also not responsible for any claims once the PT item is opened and used.

Once PT item have been delivered, ENVIROCARE LABS PT CELL cannot be held responsible if it

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subsequently fails to reach the correct personnel or are not stored under the recommended conditions. Delays in the dispatch of PT item may occasionally arise. Dispatch of a PT item may be delayed sometime due to unforeseen circumstances, participants are informed and updated regularly. PT provider cannot be held responsible for the delay in delivery of PT items due to un-foreseen circumstances or to causes beyond their reasonable control, including but not limited to acts of God, war, riot, embargos, and acts of civil or military authorities, pandemic, fire, floods, energy, labour or material. Appropriate decision is taken after discussion with the participants.

For PT schemes as on sampling packaging and transportation of samples is not applicable.

# 13.0 REPORTING OF RESULTS

Results should be reported clearly, in the format titled 'Result submission sheet' and provided to registered participants. The handling and analysis instructions as given along shall be followed by participants.

Once submitted and received by PT provider, results cannot be amended unless allowed by PT provider for the reasons to be documented prior to due date of submission. This is, however, strongly discouraged. PT provider can consider an appeal from participant in this regard if there are valid reasons. Decision of PT provider in this regard is final.

Results cannot be altogether amended after the due date of submission for any reason. PT provider although can seek resubmission of result sheet without any change in result values prior to circulation of draft result sheet to avoid any misinterpretations at its own end e.g., from mentioning of wrong CAB code allotted, changes done in reporting format etc. or where there are issued related to reporting units with due justification.

After the completion of analysis or sampling, the results sheet or records desired as per instructions given only is to be sent back by participants on email provided as a scanned attachment in 'PDF' format within stipulated timeline, unless extended due to fall of holidays or any other circumstances beyond control as documented. The participants are advised to keep record of all calculations, graphs and other raw data to demonstrate that testing is done by them in their CAB. The PTP is not seeking this information along with test reports but may ask for the same if required. The said information may also be verified by regulatory authorities or accreditation bodies during their audits. The said information is also useful in doing root cause analysis. The failure of CAB to provide above information any time as asked by PTP may lead to 'Results Not Considered' / Cancellation of participation and decision of PTP in this regard shall be final.

Results reported in a semi-quantitative manner as "less than" or "more than" a value, or results reported as zero except where it may be appropriate to report a result of zero together with qualitative results, will be collated and listed in the PT round report as Results not Considered' but shall not be included in the statistical analysis including any results that are tagged i.e., any comments are given.

Results may be rounded up or down for the purposes of reporting and may not be identical to your original reported result. The effects of rounding may also mean that occasionally percentage totals do not add up exactly to 100%.

ENVIROCARE LABS PT CELL cannot be held responsible for the misinterpretation of results submitted for a PT scheme, e.g., the use of a comma can be ambiguous and could be interpreted as either a decimal point



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or a thousand separators. The participants are advised to type the results rather writing by hand.

Summary of test results of participants as used by the PT provider are made available in draft result sheet, prior to release of final report. Draft result sheet is submitted only to verify that data read and entered by PT provider is correct and there are no readings or typing errors on PT provider's part. The data values are, however, rounded to the decimal points as per standard practice laid down by IS e.g. if reporting decimal point (DP) asked is 2 and CAB report results as 23.445, then it is recorded 23.45 and if CAB reports as 23.444 then it is recorded as 23.44. No requests for any change in results are accepted except if there are typing and reading errors at PT provider's end. Participants are asked to crosscheck and confirm in two days from the date of sending email and no claims are entertained later.

PT provider does not provide draft result sheet or final report to participants who have not cleared the payment. In such a case, PT provider is not responsible if subsequently it is found that any results provided by participants are entered wrong due to lack of cross checking or otherwise.

The ENVIROCARE LABS PT CELL also cannot be held responsible for 'Results Not Considered' due to above or any other reasons as not following instructions; following methods not allowed in the PT scheme or choosing sampling scenarios that are different to case studies given or submitting information by manipulating formats or submitting partial information in case of schemes as sampling.

The data values are however rounded to the decimal points as per standard practice laid down by IS e.g. if reporting decimal point (DP) asked is 2 and CAB report results as 23.445, then it is recorded 23.45 and if CAB reports as 23.444 then it is recorded as 23.44

For PT schemes as on sampling instead of 'Result submission sheet' information may be asked in other formats as relevant to the PT scheme. In addition, participants are also asked to submit certain information in formats used in their CAB.

#### 14.0 TEST OR SAMPLING METHODS

Participant shall use a specified method in accordance with the design of the PT scheme as given in handling and analysis instructions. The participants should use a different test method only with prior permission in writing e.g., if they want to validate a method; The risk of results not being considered or failure in PT scheme in such a scenario lies totally with participant

Methods based on same principle and methodology in any other standard method, however, can be used. Participants to use latest methods with amendments if any.

For some parameters in an area there may be large variation in test methods followed by CABs due to nonavailability of standard methods or otherwise; in such scenario's PT provider may provide specific instructions for the purpose of uniformity.

#### 15.0 TIMELINE

Timeline is given in PT Calendars. ENVIROCARE LABS PT CELL endeavours to follow timeline and complete schemes in time.

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PT scheme can be run earlier/postponed or two schemes may be merged; This may be due to operational reasons; new developments; due to nature of product or matrix; homogeneity or stability issues and or reasons beyond control. There may be changes in timeline of PT schemes due to holiday(s). Registered participants are informed.

#### 16.0 PREVENTION OF COLLUSION AND FALSIFICATION

Following measures are built into the scheme to try to prevent collusion. However, ultimately the responsibility rests with each participant to behave in a professional manner as collusion, either between participants or between individual participants and the scheme provider, is contrary to professional scientific conduct and serves only to nullify the benefits of proficiency testing to customers, accreditation bodies, and analysts alike. Collusion is, therefore, to be strongly discouraged.

The amount of PT item sent to participants is as required for testing and not too large. For qualitative schemes photographs of important aspects are taken.

The duration of the program is kept so that the time gap between receipt of the sample, date of testing and date of reporting is minimum. The schemes are completed in designated timeline.

The participants are asked to maintain all raw data and audit trail for tests done and is mandatory to be provided to PTP when asked or to assessors when the CABs are audited. This is also required by CABs for root cause analysis. At random raw data is asked.

PTP may take measures as use of blind samples within the program to avoid collusion among the participants such as discussion among participants, testing of PT item in another CAB (better equipped, specialized)

Subcontractors are not allowed to participate in the program in which they have tested samples for homogeneity and stability.

Request from participants for duplicate PT items is accepted only after detailed investigation.

PT provider where associated with testing CAB including associations of staff on contract or advisory or steering committee members a declaration on impartiality and confidentiality is taken. Appropriate measures are taken to ensure that such associations if any do not lead to collusion including that for an activity the concerned person may be kept out of a particular aspect. When a relationship poses unacceptable threat to impartiality, PT services shall not be provided to the related participant. PT provider also has a cooling period policy for the personnel employed w.r.t association with an organization.

The assigned values are not made known to anyone before the report is issued and no results are accepted after the publication of the report. It is ensured that PT items are prepared, handled and distributed by authorized person / agencies. The access to the records of codification and distribution of PT items is controlled and is in custody of authorized person.

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## ANALYSIS OF DATA AND PERFORMANCE ASSESSMENT

## **Quantitative schemes-**

17.0

The statistical analysis of data set is done by identification of blunders by visual review as well as subjecting the data to any one of the following methods individually or in combination (i) Results that deviate from the X by more than  $\pm 5\sigma_{pt}$  or (ii) Outlier detection test such as Grubbs test. The odd value identified are not included for determination of both  $x_{pt}$  and  $\sigma_{pt}$ . When any participant result is excluded then it is excluded only for the purpose of determination of  $x_{pt}$  and  $\sigma_{pt}$  or other evaluation criteria.

After removal of blunders, PT provider further uses robust estimators such as Algorithm-A in line with ISO 13528 for the determination of both assigned value as well as  $\sigma_{pt}$  from the consensus value of participants when  $p \ge 12$  (after removal of outliers) as specified in Note 2 under D.1.2 of Annex D of ISO 13528. When p < 12 (after removal of outliers) PT provider uses other techniques as provided in ISO 13528 and laid down in its procedure as median of the participants' results or robust average from modified Algorithm-A.

When z-score or z-prime score is determined as specified above, PTP ensures that participants identified as blunders are getting z-score or z-primes score  $\geq \pm 3$ .

## Qualitative schemes-

Where assigned value is reported on a categorical (or nominal) scale, the assigned value determined by any of the methods should match exactly with the results obtained from homogeneity assessment. Where assigned value is reported on an ordinal scale, the assigned value determined by any of the methods should not differ by more than the permissible limit (that is used for performance evaluation of participants) with the results obtained from homogeneity assessment.

#### 18.0 ASSIGNED VALUES $(X_{PT})$

## Quantitative schemes-

The assigned value  $x_{\text{pt}}$  is the value selected as being the best estimate of the 'true value' for the parameter under test. A consensus value of participants is taken by PTP as assigned value when PT scheme is planned and run with  $p \ge 8$  as explained in design. The standard uncertainty of assigned value  $u(x_{\text{bt}})$  is calculated using the following formula:

$$u(x_{\rm pt}) = 1.25 \text{ x} - \frac{s^*}{\sqrt{p}}$$

The  $u(x_{pt})$  is compared with the following criteria to ensure compliance:  $u(x_{pt}) \le 0.3 \, \sigma_{pt}$ . In case of noncompliance with the above criteria, performance evaluation is not done using z-score but using z'-score (z-prime) by taking into consideration the standard uncertainty of the assigned value also in the denominator.

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The validity of the assigned value for measurands or characteristics of interest determined in PT items is done by determining the estimate of the reference value of the PT items determined independent of the participants results,  $x_{ref}$  (for example homogeneity average of the concerned measurand determined by an accredited CAB which is not a participant i.e. CAB that has done homogeneity or stability testing). The difference between homogeneity average and consensus average of participants is then calculated. The difference should be less than 2 times  $u_{\text{diff}}$  where  $u_{\text{diff}} = \sqrt{\left[u\left(x_{\text{pt}}\right)^2 + u\left(x_{\text{ref}}\right)^2\right]}$ 

However, where PT scheme is planned and run with p <8, assigned value and its uncertainty is determined (i) by formulation (also called as Known Value Scheme) or by using a CRM as PT item or by characterizing the PT item using a valid CRM in one CAB (also called as Value transfer from a CRM to a closely matched candidate RM); or (iv) by using consensus value from expert CAB (which are not participants in the PT Scheme)

The assigned value is traceable to SI units in line with requirements of ISO/IEC 17025 read along NABL-142 through traceable calibrations and reference materials.

# Qualitative schemes-

When the test results reported on categorical (nominal) scale, mode (most common observation) reported by participants is used as the assigned value or when the test results reported on ordinal scale (i) either mode (most common observation) or (ii) median reported by participants is used as the assigned value.

### 19.0 STANDARD DEVIATION FOR PROFICIENCY ASSESSMENT ( $\Sigma_{PT}$ )

## Quantitative schemes-

Initially expected or target  $\sigma_{\rm pt}$  can be chosen by perception (literature, expert opinion and or experience for previous programs) or predicted from model by Thompson based on Horwitz equation.

Subsequently, the robust standard deviation of the participants results is treated as  $\sigma_{pt}$  and it is determined by using Algorithm A as given in ISO 13528 where  $p \ge 12$  of if p < 12 PT provider uses other techniques as provided in ISO 13528 and laid down in its procedure as median of the participants' results or robust average from modified Algorithm-A.

The proficiency testing provider ensures that the  $\sigma_{pt}$  used for performance evaluations from participants results is fit for purpose. The use of participants results can lead to criteria for performance evaluation that are not appropriate.

Therefore, in line with ISO 13528 clause 8.6.2, PT provider can place a limit on the lowest value of  $\sigma_{pt}$  as well as a limit on the largest that will be used.

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	$\sigma_{pt}$ is not applicable in case of <b>qualitative schemes</b> .
20.0	PERFORMANCE EVALUATION
	Quantitative schemes: Performance evaluation is conducted in terms of z-score which is calculated using the following formula: $\{x_{i}  .  x_{nt}\}$

z-score = ----- $\sigma_{\text{pt}}$ 

It is possible for the z-scores published in this report to differ slightly from the z-score that can be calculated using the formula given above. These differences arise from the necessary rounding of the data prior to its publication in report.

When  $u(x_{pt})$  is not meeting the criteria:  $u(x_{pt}) \le 0.3 \sigma_{pt}$  performance evaluation is done using z'-score (zprime) by taking into consideration the standard uncertainty of the assigned value also in the denominator:

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

If p < 12 PT provider uses other techniques as provided in ISO 13528 and laid down in its procedure.

## The following interpretation is given to results

Result	Interpretation	Coding
$ z/z'$ -score $  \le 2.0$	Satisfactory result	Black
2.01 <  z/z'-score  <2.99	Questionable result (straggler)	Bold Black
$ z/z'$ -score $  \ge 3.0$	Unsatisfactory result	Bold Red
	No score RNS or RNC as explained	Black
Blunder	Obvious odd values as explained	B (Score) Bold Red

Where |z| denotes the absolute value of the z-score. When an outlier is identified the sign of the z-score indicates whether the result is too high (positive z-score) or too low (negative z-score).

## **Qualitative schemes**

The method used for performance evaluation is as under in line with section-11 of ISO 13528:

When the test results reported on **categorical (nominal) scale**, each participant CAB which has reported

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the result should be marked as **satisfactory** (or scored as a success) if it exactly matches the assigned value. Otherwise, the participant CAB should be marked as unsatisfactory, or given an adverse performance score.

When the test results reported on **ordinal scale**, each participant CAB which has reported the result should be marked as satisfactory (or scored as a success) if the difference between the result and assigned value do not deviate by more than half a grade.

Otherwise, the participant CAB should be marked as **unsatisfactory**, or given an **adverse performance** score.

In both the cases specified above, the PT scheme report should clearly indicate the proportion or number of participants who have reported the assigned value correctly or with in permissible limits. In circumstances where number of participants whose results are not in agreement with assigned value are more than 75%, further explanation shall be given in the report.

No score is given for RNS or RNC as explained

#### 21.0 CONFIDENTIALITY

Identity of participants is kept confidential by unique coding. Participants may be given the same code number in different PT scheme by chance. ENVIROCARE LABS PT CELL has a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of this program. If an actual or potential organizational conflict of interest is identified, ENVIROCARE LABS PT CELL will immediately make a full disclosure to the appropriate parties.

The information provided by participants to PT providers is kept confidential:

- o When PT provider is required by law or authorized by contractual arrangements to release confidential information, the consent of participant is taken, unless prohibited by law.
- As per NABL-181 the records of PT scheme participation shall be accessible to NABL. PT provider does the same so that NABL can use the results in line with NABL 163 for the benefit of participants. Results shall also be shared with regulators when asked by them. Results may also be shared with customer for which a PT scheme is provided through a contractual arrangement for its participants.
- o Participants can also be asked to waive of confidentiality within the PT scheme for the purpose of discussion and mutual assistance or as required due to very nature of PT scheme.
- o PT provider shall share data with organizations providing accreditation or recognition e.g., NABL as part of its audit or assessment requirements.
- o PT provider may also use data and experience from operation of PT schemes for the purpose of further developments including, but not be limited to, use for research publications or conferences, however, identity of participants shall be kept confidential.

#### 22.0 POST PROGRAMME SUPPORT, COMMENTS ON PERFORMANCE AND RECOMMENDATIONS

In case of an outlier participant have to do root cause analysis, take corrective action and identify improvements or risks in line with ISO/IEC 17025. Outlier in proficiency testing is not a negative issue, rather the purpose of entire exercise is to help participant monitor and identify the problem areas and in



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turn help improve CABs performance. The root cause and corrective action is to be completed within one month as per NABL 163. A sample root cause cum risk analysis format is provided along with the report.

Participants that want further specific assistance for improving their performance may discuss and same can be undertaken as mutually agreed upon using skype, email, and or telephone. However specific onsite inputs may involve additional cost depending upon the nature of inputs desired. Once corrective action has been taken by a CAB, in order to establish effectiveness of corrective action taken PT provider encourages re-participation in outlier measurands for PT item by offering the PT scheme at a nominal or free of cost. More details are provided while providing the report.

#### 23.0 FEEDBACK, COMPLAINTS AND APPEAL

All due diligence is exercised in conducting the PT scheme yet if a participant has any concern about any aspect of PT scheme, they should contact undersigned within 15 days from the date of release of final report:

# **Quality Manager**

Envirocare Labs Pvt. Ltd. pt@envirocare.co.in 9167702413

Participants are encouraged to provide feedback for improving any aspect of the PT scheme. Feedback form is sent along with the final report. Appeal, a request can be made by a participant for reconsideration of any adverse evaluation. If a complaint is received, an investigation is conducted in accordance with procedure laid down by ENVIROCARE LABS PT CELL and the participant is conveyed of the outcome.

#### PT REPORT 24.0

This report is produced by PT provider in good faith and in accordance with best industry practice. Neither Envirocare Labs Pvt. Ltd. PT Cell (PT provider) nor any individual or any other organization involved accepts any liability whatsoever from application or use of information contained therein or from any inadvertent error in the information in report including without limitation indirect or consequential loss or damage. This statement does not affect your statutory rights.

- Comments or recommendations in PT report does not construe to be any legal or technical advice to participant. PT provider is also not soliciting any action based on it. Any trade name given in this report is information given for the convenience of users and does not constitute as endorsement.
- The parties agree that any matters are governed by Indian law. All disputes are subject to original jurisdiction of Courts Bombay, India.

**USE OF REPORTS:** The report is strictly for use by participant for (i) to monitor its performance and or to improve the CAB's activities (ii) to show to the CAB's customers, regulatory authorities and organizations providing accreditation or recognition as part of audit or assessment requirements. PT report in part or whole shall not be given by participant to anybody for any reason other than as stated above without

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taking the permission of PT coordinator in writing. PT provider can act as per terms and conditions, if misuse of PT report is found.

- If recipient is not the intended individual or organization for the report, it has been sent to you by mistake. Do not circulate the report or its contents further and inform to pt@envirocare.co.in
- PT provider reserves the right to make any modifications or alterations in the report as may be required from time to time without any prior notice. All affected participants are informed when an issue is detected.

## 25.0 OTHER IMPORTANT INFORMATION

Participants are requested to go through all related documents as PT calendar, registration form, **terms and conditions for participation**, NABL scope and handling and analysis instructions and clarify if there are any doubts any time. All these documents are in public domain including website (<a href="www.proficiencytesting.in">www.proficiencytesting.in</a>) All clarifications must be taken in writing on email, conclusions drawn from telephonic discussions are at participants own risk.

PT samples are sent on address given in registration form and all communications are done on emails given in registration form unless otherwise agreed

ENVIROCARE LABS PT CELL is not responsible for any lapses due to incomplete or illegible registration forms / non-payments or delay in receipt of payments or information on account of problems with email / internet / online transactions and similar issues. We acknowledge all emails within 72 hours (3 Days) except for result sheets or sample acknowledgement receipt forms. For Participant Result Sheet PT provider contacts participants after result submission date if results are not received. In case no acknowledgement is received and or no information is received as per timeline provided for the PT scheme please contact on telephone and or email.

Communications are through email only.

It is for a participant to update its contacts with PT provider if there are any changes. We are not responsible for any miscommunication due to change in staff of the CAB or otherwise.

In any other scenario arising out of unexpected issues the decisions are taken in line with ISO/IEC 17043 and ISO 13528 and the PT design is amended for future schemes to address the issue and participants are informed.