Protocol

The Operation of Proficiency Testing Schemes

Organized by: **Center for Laboratory Proficiency Testing (CLPT), Department of Science Service, Ministry of Higher Education, Science, Research and Innovation, Thailand**

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1. Introduction

The DSS provides a proficiency testing service to laboratories operating in the areas of food, chemistry, physics, calibration, and environmental analysis. The objective of the provider is to provide the proficiency testing to the participants with the best quality of all aspects of proficiency testing, including test material quality, characterization, assignment of property values, evaluation of participating laboratories' performance, distribution of artifacts and test material. Its aim is to promote quality for analytical laboratories. The programs enable participants to demonstrate to regulatory bodies and customers, on an international basis, the validity of their results.

CLPT facilitates knowledge sharing and skill development by providing innovative capacity building programs to testing laboratories.

One of the key activities in this regard 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 Laboratories and generate valid results.

2. Technical Term

Proficiency Testing (PT) *is one form of external assessment of laboratories to ensure their ability to perform to the level of competence and quality required and a process that evaluates a laboratory's ability to perform a specific test or measurement accurately and reliably, often compared to other laboratories.*

Proficiency testing provider (PTP) *is organization that offer and manage proficiency testing schemes, which are inter-laboratory comparisons used to evaluate a laboratory's performance against established criteria. These providers ensure the reliability and validity of these schemes by following standards like ISO/IEC 17043. They play a crucial role in maintaining the quality of laboratory testing and measurement.*

Testing/calibration laboratory (Participants) *means a laboratory that provides testing/calibration services or conducts research.*

3. Purpose and scope of proficiency testing

3.1 Provide laboratory proficiency testing programs to domestic and overseas laboratories in the field of food, environment, chemistry, Physics and instrument calibration according to international standards.

3.2 Produce, distribute, and develop reference and control materials for the use in quality control in laboratory and support of traceability of laboratories according to international standards.

3.3 Cooperate technically with both domestic and overseas agencies/ organizations.

3.4 Provide support and collaboration with other agencies/organizations, or perform other duties as assigned.

4. Organization

The DSS proficiency testing schemes are administered by the Center for Laboratory Proficiency Testing (CLPT), Department of Science Service. Scientific advice is provided by an advisory committee. Each activity is the responsibility of the Proficiency Testing Section. This includes the administration of participants' details, data processing and reporting.

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5. Impartiality and Confidentiality

Information concerning the performance of individual laboratories in confidential between the individual laboratory and the program organizer. The participant laboratory and counters codes are notified to the laboratory upon registration. Participants will be identified on Tables of results or of z scores, E_n score and any other public document only in the form of a randomly numeric code, changed every round. The DSS will not disclose the code identity of a participant to a third party, without the written approval of participants

6. Participation Fees and Charges

For most participation is open to all laboratories. Typical rounds include more than seventeen laboratories from Thailand and overseas. The rapid studies are designed based on participants requests where a pre-set assigned value is used and may include only one participant.

Participation fees are charged in Thai bath for the participant laboratory in Thailand and in dollars for participants overseas according to the current proficiency testing price list in fiscal year. (https://www.dss.go.th/ptservices/publication)

Proficiency test samples lost or damaged in transit will be replaced free of charge, if feasible. Proficiency test samples lost or damaged after receipt by the participant laboratory will be replaced at a cost (e.g. additional samples participant laboratory price).

7. Externally provided services

Analytical testing associated with the PT program such as provision of homogeneity and stability testing may be done externally from time to time by a competent provider (accredited to ISO/IEC 17025 or when this is not possible, then a proven track record such as satisfactory performance in PT).

8. Documentation

The main documents associated with the initial phase of a proficiency program are.

8.1 Inviting the participants

A letter dealing with the program and inviting laboratory will be sent to prospective participants, including all accredited and applicant laboratories to advise that the program will be conducted and provides information on the type of sample and tests which will be included, the time schedule and participate fees.

8.2 Instructions to participants

The instruction will be designed for each individual program. To ensure the results from the program can be analyzed properly, participants are asked to adhere carefully to them. It will be attached with the dispatch of samples.

8.3 Results sheets

For most programs a pro-forma result sheet is supplied to enable consistency in the statistical treatment of results.

8.4 Interim report

For testing programs, the interim report will be issued to participants as soon as practicable after the results are received from the participants. Laboratories reporting one or more results that are significantly different from the consensus values are encouraged to commence investigative / corrective action prior to the release of the final report**.**

8.5 Summary report

The summary report will be issue to participants for each scheme. There is the summary statistics as assigned value, standard deviation for proficiency assessment and the laboratory performance by z score or E_n score. This summary sheet should be read in conjunction with the final report.

8.6 Final report

The final report will be produced at the end of the program and includes data on the distribution of results from all participants, together with an indication of each participant, s performance by a confidential code number.

9. PT Sample and preparation

9.1 PT Samples for testing program

The coordinator is responsible for organizing the supply and preparation of the samples. Sample preparation procedures are designed to ensure that the samples used are as homogeneous and stable as possible. The proficiency testing section will ensure that any subcontracted work to prepare and/or analysis test samples are carried out by a competent laboratory. Test materials should generally be typical of the sample types routinely tested in the participating laboratories. Sometimes, suitable matrix samples cannot be found and additives are added to a natural matrix or a complete synthetic sample is prepared.

9.1.1 Packaging and dispatch of sample

The packaging and method of transport of the samples are considered carefully to ensure that they are adequate and able to protect the stability and characteristics of the samples. Samples are packaged and dispatched from the DSS. Ensuring that there are sufficient samples for the participants in program and for the homogeneity check. Certain restrictions on transport such as dangerous goods regulations or customs requirements are complied with

9.1.2 Random sampling

Sampling to test sample homogeneity and stability, including sampling for sending to participants, will be carried out using statistical sampling methods or specific methods specified in the activity to reduce possible bias from sampling.

9.1.3 Homogeneity testing of test material

The homogeneity analysis has demonstrated that there is no systematic variability from the first to the last sample in the production run. The batch is divided in subsamples, which will be sent to the participating laboratories. Prior to distribution the homogeneity of the subsamples is tested by randomly checking one. The results of this homogeneity testing are analyzed statistically and may be included in the final report.

9.1.4 Stability testing of test material

Test materials used in the DSS proficiency testing program have been demonstrated to be stable for the period of each program. The results of this stability testing are analyzed statistically and may be included in the final report.

9.1.5 Storage

Samples after packaging and testing their homogeneity are required to be kept in an appropriate condition before sending to participants. The condition is considered to ensure an adequacy and ability of protection the stability and characteristics of the samples. If the test materials used in the DSS proficiency testing program require chemical preservation, storage temperatures, holding times, etc. which will be addressed in instruction.

9.2 Artifacts for calibration program

The artifacts used in the proficiency testing schemes shall be stable so that they can be expected to adequately hold their calibration for the period of the schemes. If it is not possible, more frequent recalibrations will be necessary.

An important feature of a calibration scheme is that there should be reference values for the requested measurements against which the laboratories' results can be judged. The reference values are provided by a Reference Laboratory which normally is the National Institute of Metrology (Thailand). In some cases, the proficiency testing section may use the service from other laboratories which hold ISO/IEC 17025 for calibration of the artifacts.

10. Distribution of proficiency test items

The PT samples for each participant are randomly sampling and record the sample no. or artifact no. for distribution to participants. For testing, each participant will be provided one postal bag including with samples and related documents. The details of sender and receiver are addressed carful on the postal box. For calibration, each participant will be provided one safety box including with artifact and related documents as well as a testing.

10.1 For testing

The packaged sample and the related documents will be packed in postal box and sent by EMS (Express Mail System) or DHL express. When laboratory get the sample together with the related documents, the laboratory shall check the condition of the sample and fill the received form and send the form back to CLPT.

The left samples will be kept in an optimal temperature such as $(20 \pm 5)\ ^{0}C$, $(4 \pm 2)\ ^{0}C$ and room temperature which depends on each sample.

10.2 For calibration

The laboratory will come to the CLPT to receive the artifact by the specified date, which is packed in safety box and the related documents. The laboratory shall check the condition of the artifact and fill the received form. The serial numbers of artifact circulated to participants are recorded in the form.

11. Receipt of results

Results from participants for proficiency testing programs are required to be sent directly to proficiency testing section's office via post, facsimile, or e-mail. A "due date" for return the result is set for each program, usually allowing participants two to three weeks to test the samples. If any results are outstanding after the due date reminders are issued. However, as late results may not be included in the data analysis, participants are strongly encouraged to submit all results on time.

12. Statistical design

12.1 Establish the assigned value and its standard uncertainty

Five ways of determining the assigned value are described in topic 12.1.1 – 12.1.5. The choice between these methods shall be the responsibility of the advisory group and according to ISO 13528:2015.

12.1.1 Assigned Value and Measurement Uncertainty

The determination of the assigned value shall be the responsibility of the coordinator. The assigned value shall not be disclosed to the participants until they have reported their results to the coordinator. The coordinator shall prepare a report for the advisory group giving details of how the assigned value was obtained, the identities of laboratories involved in its determination,

and (where possible) statements of the traceability and measurement uncertainty of the assigned value.

The assigned value $x_{(pt)}$ 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 ≥ 8 as explained in design. The standard uncertainty of assigned value $u_{(x_{pt})}$ is calculated using the following formula: The assigned value used to calculate z score is based on the consensus value from participants using the robust mean calculated according to robust analysis: Algorithm A in Annex C of ISO 13528:2015 (E)-Statistical methods for use in proficiency testing by interlaboratory comparisons. The assigned value will not be disclosed to participants until interim report is issued.

The standard uncertainty of the assigned value xpt is estimated as

$$u_{(x_{pt})} = 1.25 \times \frac{s*}{\sqrt{p}}$$

Criteria: If

$$u_{(x_{pt})} < 0.3\sigma_{pt}$$

then, the uncertainty of the assigned value is negligible and need not to be included in the interpretation of the results.

The test material may be prepared by mixing constituents in specified proportions, or by adding a specified proportion of a constituent to a base material. In this case the assigned value $x_{(pt)}$ is derived by calculation from the masses used.

The approach is especially valuable when individual samples may be prepared in this way, and it is the proportion of the constituents or of the addition that is to be determined: there is then no need to prepare a bulk quantity and ensure that it is homogeneous. However, when formulation gives samples in which the addition is more loosely bonded than in typical materials, or in a different form, it may be preferable to use another approach.

12.1.2 Certified reference values

When the material used in a proficiency trial is a certified reference material, its certified reference value is used as the assigned value.

12.1.3 Reference values

In this approach, samples of the test material are prepared first, ready for distribution to the participants. A few of the samples are then selected at random and analyzed along with certified reference materials (CRMs), in one laboratory, using a suitable measurement method, and under repeatability

conditions. The assigned value of the test material is then derived from a calibration against the certified reference values.

With a non-destructive test, it may be possible to test every sample, or a portion of every sample. When the proficiency test requires test items rather than test samples, an equivalent procedure is to establish the assigned value by a calibration traceable to a national or international standard.

12.1.4 Consensus values from expert laboratories

As with the "reference values" approach, samples of the test material are prepared first, ready for distribution to the participants. Some of these samples are then selected at random and analyzed by a group of expert laboratories. The assigned value is calculated as the robust average of the results reported by the laboratories.

12.1.5 Consensus value from participants

With this approach, the assigned value X for the test material used in a round of a proficiency testing program is the robust average of the results reported by all the participants in the round.

13. Evaluation of Performance

Criteria for performance evaluation shall be established after considering whether the performance measure involves certain features. These features are the following.

13.1 Expert consensus:

Where the advisory group, or other qualified experts, directly determine whether reported results are fit for the purpose. Expert consensus is the typical way to assess results for qualitative tests.

13.2 Fitness for purpose:

Considering, for example, method performance specifications and participants recognized level of operation.

13.3 Statistical determination for scores:

Where criteria should be appropriate for each score. Common examples of application of scores are:

13.3.1 Testing schemes: for z scores:

The z score for the proficiency test result is calculated as:

$$z = \frac{x_i - x_{pt}}{\sigma_{pt}}$$

When $u(xpt)$ $>0.3\sigma pt$, then the uncertainty can be considered by expanding the denominator of the performance score and calculated as z' score. The z' score for the proficiency test result is calculated as:

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

The conventional interpretation of the z-score is as follows:

- A result that gives | z, z' | ≤ 2.0 indicates "satisfactory" performance and generates no signal.
- A result that gives 2.0 < | z, z' | < 3.0 indicates "questionable" performance and generates a warning signal (W).
- A result that gives | z, z' | ≤ 3.0 indicates "unsatisfactory" performance and generates an action signal (A).

13.3.2 Calibration schemes for E_n score:

The En score for the proficiency test result is calculated as:

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

The conventional interpretation of En score is as follows:

- A result that gives | En | < 1.0 indicates "satisfactory" performance.
- A result that gives | En | ≥ 1.0 indicates "unsatisfactory" performance.

14. Complain and Appeal

If participants disagree with their performance in a proficiency testing scheme organized by Center for Laboratory Proficiency Testing (CLPT), Department of Science Service, they should inform CLPT in writing. The person whose name has been given to CLPT to be the person who receives report or an authorized representative should submit a written request to CLPT to the address below. All appeal must be submitted no later than thirty (30) days following receipt of final report.

All written appeals shall be sent to: Director of Department of Science Service Rama 6 Road, Rachathewi District Rama 6 Road Bangkok 10400, click link to: https://www.dss.go.th/complaint/