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Alternatives to Proficiency Testing Schemes (PTS)

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Alternatives to Proficiency Testing Schemes (PTS)

Position Paper

1. Introduction

The need of a testing laboratory to participate in an interlaboratory comparison or proficiency testing programme is described in ISO/IEC 17025 clause 7.7.2 as one of the parameters used to assure the quality of its test results.

An interlaboratory comparison in a proficiency testing programme/scheme (PTS) is a well-recognised option to monitor proficiency. If an appropriate PTS is available for a certain type of test carried out by the OMCL then the laboratory by its successful participation can document its competency.

Where applicable, it is important to keep in mind 3R issues as outlined in "3R issues for method validation and maintenance of competence", PA/PH/OMCL (12) 126 in its current version when demonstrating proof of proficiency.

However, for the types of tests carried out by OMCLs it is not always possible to find a suitable PTS scheme in which to participate and so an approach relying on other proficiency indicators (which usually includes enhanced internal and/or other external Quality Control Procedures) can be adopted to show how the laboratory meets the requirement of ISO/IEC 17025 clause 7.7.

The sections below provide examples on how an OMCL can show proof of proficiency to meet the standard without referring to particular methods. It has to be noted that for some non-complex testing methods individual PTSs are of no added value due to the fact that the main operational steps are covered by other individual PTSs (e.g. weighing operations during HPLC) or are related to the qualification of equipment (e.g. friability). For further examples see Annex 1.

2. Quality Control Procedures

An OMCL like any other testing laboratory shall also have Quality Control Procedures according to the ISO Standard in place to prove the proficiency of testing operations. These procedures can be divided up into internal and external procedures as shown below:

Internal Quality Control Procedures *Benchmarking against internally generated data*	*External Quality Control Procedures* *Benchmarking against externally generated data*
• Use of Ph. Eur., other compendial methods or validated methods • Use of qualified equipment • Use of alternative instrumentation that has been calibrated to provide traceable results;	• PTS available and carried out by the laboratory • Collaboration with other OMCLs with exchange of samples and/or reference materials

Internal Quality Control Procedures *Benchmarking against internally generated data*	*External Quality Control Procedures* *Benchmarking against externally generated data*
• Functional check(s) of measuring and testing equipment • Intermediate checks on measuring equipment • Uncertainty of measurement has been assessed • Documentation of staff's competency in place (e.g. by retesting of retained items, or testing "blind" samples; prepared for this purpose by the Head of the Laboratory or Quality Manager etc.) • Use of primary reference material/standards • Use of quality control samples • Internal (assay) controls are included in the method • Replicate test using the same or different methods are performed • Use of quality control charts/quality control sample where appropriate • Successful performance of the system suitability test of the method where appropriate • Check for compliance with pre-defined acceptance criteria of the method (e.g. deviation of replicates, system suitability criteria) • Re-validation carried out if required • Check of out-of-specification results • Check according to internal procedures for management of invalid test results • Review of reported results • Use of feed-back from anomalies and complaints • Comparisons of results of different analysts (intralaboratory comparisons) • Data monitoring and assessment of assay controls and test samples	• Interlaboratory collaborative study • Independent comparison with manufacturer (OCABR) • Independent comparison with another OMCL (e.g. CAP)

It is not envisaged that all the internal quality control measures should be used, but a selection can be used to develop a documented plan that undergoes regular evaluation. This evaluation would allow the selected procedures to be reviewed to determine any trends where practicable by statistical techniques as required by the ISO Standard (7.7.1) or differences year on year and the report serve as proof of proficiency and could be part of the Management Review process.

The difference between internal and external Quality Control Procedures can be defined as:

Internal Quality Control Procedures

These Quality Control Procedures should be embedded within the routine working of the laboratory. It is accepted that some of these processes are covered by other parts of the standard, but they provide additional control measures and information to show that the method is working as expected and the results are within the agreed limits. Data is collected on an on-going basis and reviewed as part of the formal documented plan.

External Quality Control Procedures

These Quality Control Procedures are processes that allow the OMCL's results to be assessed against data generated in other laboratories. The aim is to provide an external, independent benchmark to compare the performance against predefined criteria.

Proficiency testing is an external quality control and covers the overall performance of a laboratory for the specific testing. The ideal is an externally managed PTS so when one is available and appropriate the OMCL should participate (EA 4/18). But when no PTS is available, valid alternatives in terms of interlaboratory comparisons shall be considered for the monitoring of laboratory performance.

<u>Alternatives to PTS</u>

a) Another external quality control system that could be used is an Interlaboratory collaborative study. This is essentially similar to a PTS but here there is the possibility to compare the results against the finally assigned value or to a Common Test Sample analysed by all participants.

b) A further option that could be considered is to set up an exchange of samples and/or reference materials with another OMCL who also regularly tests the product or runs the same method. If this approach was to be taken it is important that a short protocol is written detailing:

- the samples to be tested
- the controls that should be run
- the method to be used
- the validity criteria for the method
- the acceptance criteria to be applied

c) When a PTS is not available or suitable, a comparison against the manufacturers' results is possible, e.g. for OCABR, as data is available from the protocol review that is carried out as part of official batch release testing, these results could be compared against the results generated by the laboratory. It should be noted that for OCABR this comparison is already carried out for the OMCL

annual report and the results of it should be included in the formal assessment. It allows the test area to benchmark their results against another organisation but care needs to be taken as the same methodology may not be followed in both laboratories. However, even in such cases it is still felt to be useful and helps to provide additional assurance on the veracity of the OMCL results, especially when no PTS has been carried out. A risk based approach can be applied on a case by case basis to assess which kind of quality control procedures are in place, based on trends and former experience or other justification.

3. Planning, Monitoring and Review of the implemented Quality Control Procedure

As stated above there are a lot of ways of monitoring and reviewing the quality control data of a testing laboratory. The OMCL should choose the most appropriate one according to its activities. A possible way is given below.

Grouping by 'Families'

To reduce the amount of work required to review large numbers of similar methods, the products and/or methods could be grouped when they are essentially similar. When this approach is taken a clear explanation as to why the grouping is appropriate should be included in the review.

Review of Quality Control Procedures

The review shall assess compliance to the quality control procedures. The outcome should provide a classification of the different elements, based on the level of availability of appropriate procedures and level of compliance to procedures under development or in place.

One example could be to introduce a colour code system as shown below. Other approaches are possible.

- Red – procedure not in place or not being carried out or significant deficiencies identified
- Amber – working towards putting the procedure in place but not yet fully in place or minor issues identified
- Green – procedure in place and fulfils the clause; no issues identified.

Reporting of Review

A report shall be written detailing the outcome of the review and an action plan developed for any issue identified during the review that may not comply with the Laboratories Quality Management System. The report should also include recommendations for management to consider, review and comment.

The review should also identify any product/method that does not yet have formal PTS. This list can then be submitted to the EDQM to be considered for inclusion in future PTS programmes. In addition the laboratory should investigate if other PTS providers are available for future planning.

4. Related documents

EA 4/18: **Guidance on the level and frequency of proficiency testing participation**.

Annex 1

Examples of techniques for which proof of proficiency could be shown by other means than PTS

- Quality assurance by ongoing comparison to pharmacopoeias, manufacturer's specification, scientific literature and/or retained samples (if no reference material is available). This applies to microscopy and macroscopy of herbals (e.g. Ph. Eur. 2.8.2, 2.8.3), TLC (Ph. Eur. 2.2.27, also mainly of herbals), appearance test before and after reconstitution (e.g. in OCABR) and stability of fibrin sealants (Ph. Eur. 0903).

- Quality assurance by equipment qualification: this applies to Ph. Eur. 2.2.3 pH, 2.2.5 Density, 2.2.6 Refractive index, 2.2.7 Optical rotation, 2.2.18 Freezing point, 2.2.24 IR, 2.2.32 Loss on drying, 2.2.60 Melting point, 2.4.14 Sulfated ash, 2.4.16 Total ash, 2.8.4 Swelling index, 2.9.1 and 2.9.2 Disintegration, 2.9.5 Uniformity of mass (including 0478 Subdivision of tablets and 0672 drops), 2.9.7 Friability, 2.9.8 Crushing and 2.9.17 Extractable volume.

- Quality assurance is built into the assay layout (taste panel comprising at least 6 persons): Ph. Eur. 2.8.15 Bitterness value.