Jordanian Accreditation System

نظام الاعتماد الأردني

Accreditation Unit

POLICY OF PROFICIENCY TESTING

Purpose

The Accreditation Unit (AU) has set this document to ensure consistency in applying proficiency testing as a requirement for accreditation of testing and calibration laboratories.

Scope

- This document covers the proficiency testing activities of testing and calibration laboratories.
- This document will help participating laboratories, the Accreditation Unit, regulatory authorities and clients of laboratory services to use proficiency testing as a tool for assessment of technical competence of laboratories within their scope of accreditation.

Authorship

This publication has been written by the Technical Committee, and approved by the Accreditation Director.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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Further information

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1. Introduction

1.1 Proficiency testing as defined by ISO/IEC 17025:2005 is one of the powerful tools to help testing laboratories to demonstrate their competence to the accreditation bodies or any other third party as required by this policy.

Also ISO 15189 requires that medical laboratories seek confirmation for confidence in their results through participation in suitable interlaboratory comparisons

1.2 Proficiency testing enables laboratories to monitor their test overtime and conduct corrective actions as necessary.

1.3 There are particular areas where proficiency testing is just not available as defined by the applicant lab and agreed with the technical assessor and approved by the Technical Accreditation Committee.

1.4 It is important that cost effective aspects are taken into consideration.

1.5 The proficiency testing should be conducted by a proficiency testing provider that is accredited by, or comply with at least one of the following:

- ISO/IEC 17043
- Internationally approved, or
- as agreed between AU and the testing laboratory.

1.6 Proficiency testing should be carefully and competently planned, prepared, carried out, interpreted and documented.

2. Definitions

The following definitions used in the proficiency testing procedures are taken from international references:

- Laboratory proficiency testing

Determination of laboratory testing performance by means of interlaboratory comparisons (ISO/IEC Guide 2).

- Interlaboratory comparisons

Organization, performance and evaluation of measurements or tests on the same or similar test items by two or more laboratories in accordance with pre-determined conditions (ISO/IEC 17043:2010 (3.4))

Note: In some circumstances, one of the laboratories involved in the inter-comparison may be the laboratory which provided the assigned value for the test item.

Inter-laboratory proficiency testing includes, for example:

- Qualitative schemes - For example where laboratories are required to identify a component of a test item.
- Data transformation exercises - For example; where laboratories are furnished with sets of data and are required to manipulate the data to provide further information.
- Single item testing - Where one item is sent to a number of laboratories sequentially and returned to the organizer at intervals.
- One-off exercises - Where laboratories are provided with a test item on a single occasion.
- Continuous schemes - Where laboratories are provided with test items at regular intervals on a continuing basis.
- Sampling - For example; where individuals or organizations are required to take samples for subsequent analysis.

3. Policy

The laboratory **shall have** quality control procedures for monitoring the validity of tests undertaken. The resulting data **shall be recorded** in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. The lab **shall have** a policy in their quality manual for participation in proficiency testing.

The performance of accredited laboratories in proficiency testing is one of many tools that should be assessed to be used in accreditation procedures by accreditation bodies. Proficiency testing techniques (Schemes) vary depending on the nature of the test item, the method in use and the number of laboratories participating.

One of the elements by which accredited laboratories can demonstrate technical competence is by satisfactory participation in PT activities where such activities are available and appropriate . Where relevant, this also holds for accredited inspection bodies. Technical competence can also be demonstrated by successful participation in interlaboratory comparisons that have been organized for

purposes other than PT in its strictest sense. For example: - to evaluate the performance characteristics of a method; - to characterize a reference material; - to compare results of two or more laboratories on their own initiative; - to support statements of the equivalence of measurement of NMIs.
Other arrangements are acceptable only when PT is not applicable or not found.

The following are common types of proficiency testing schemes: **(**ISO/IEC 17043:2010 (Annex A))

1. Sequential participation schemes
2. Simultaneous participation schemes.
3. Split-level designs.
4. Split-sample testing schemes.
5. Partial-process schemes.
6. External quality assessment (EQA) programs.

3.1 Level and Frequency of PT Participations

The minimum PT participation according to a laboratory scope is:

- Evidence of satisfactory participation -related to the scope- prior to gaining accreditation and expansion of scope.

- Further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan.

It shall also be considered that according to ISO/IEC 17025 and ISO 15189 participation in PT shall be planned (5.9.1/5.6.3), therefore, once the “level” and “frequency” of participation is established, laboratories shall develop a participation plan covering, at least, one accreditation cycle (period between full reassessments) and shall be regularly reviewed during assessment in response to changes in (staffing, methodology, Instrument……..)

AU shall receive list of PT participations for approval using following form (qf072-05), and should be regularly reviewed in onsite assessment response to covers accreditation scope.

It is recognised that there are areas of testing and calibration for which suitable PT doesnot exist or is not practical. In such cases, AU and the laboratory shall discuss and agree on suitable alternative means by which performance can be assessed and

monitored. This would need to be considered as part of the planned PT and/or related activities.

Additional proficiency tests may be required, if:

a. Due to changes of personnel, there are doubts regarding the technical competence of the laboratory

b. from an assessment point of view, the external quality measures taken for the test methods/types of tests applied in the scope of accreditation are not sufficient, regarding, e.g.:

- The number of proficiency tests performed in specific cases.
- The application of the test method to another matrix.
- The extension of the scope of accreditation.
- The performance of insufficiently validated and documented in-house methods.
- The use of procedural steps deviating from the test standard.

c. The results of the proficiency tests submitted by the laboratory are unsatisfactory as defined by the acceptability criteria.

- For food and water testing labs

The laboratory shall have yearly PT participations covering all accredited scope. If the time period between PT participations is more than one year then the laboratory shall participate in an inter laboratory comparison every six months with at least three laboratories unless no similar laboratories that provide the same analysis are available, in this case the laboratory shall prove this and justify its results to the assessment team.

- For medical labs

The labs shall implement the instruction from MOH related to this issue:

- Condition & Principle of lab quality control and Improvement for the year (2012).
- Update Licensing system no (92) for the year (2008) for Private medical lab.
- Instruction no(5) for the year (2005) “Instructions of internal quality control basis in the laboratory work”
- Update Licensing system no (35) for the year (2004) for Private medical lab.
- Licensing system for the medical laboratory (Issued under articles (5) and (66) Of the Public Health Law No. (54) For the year 2003.

3.2 Records of Performance in PT

Accredited laboratories shall be required to maintain their own records of performance in all types of proficiency testing, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective or preventive actions. Records shall be kept for five years at least

3.3 Determination of Acceptability Criteria for the Evaluation of PT Results

For providers of PT schemes, the procedures, organization, performance and evaluation are usually defined between the organizer and the laboratories on the basis of respective standards and/or regulations. The procedure for establishing both the assigned value and its uncertainty should be clearly stated in the scheme documentation (protocol) as defined in ISO/IEC 17043:2010

3.4 Assessment of PT Results by AU

Generally the assessment team should use the criteria stated by the organizer of the proficiency testing scheme.

The Accreditation committee takes into consideration on its decision the lab PT Participations results, if the results are unacceptable a corrective action is required and, the relevant corrective action should be assessed and granting o confirmation of accreditation shall be considered upon the appropriateness of these actions and obtaining acceptable proficiency testing results in a follow up scheme or in the next proficiency testing scheme. An onsite assessment may be needed to confirm that corrective actions are effective.

The accredited lab should not have three consecutive unacceptable proficiency testing results for the same test/ calibration method, otherwise; **AU decision will be temporary suspension or even withdrawal of the relevant tests of accreditation.**

Note: AU assists laboratories in identifying and formulating their PT participation needs and plans

5. References

[1] ISO/IEC 17043:2010, " Conformity assessment — General requirements for proficiency testing"

[2] EPTIS, http://www.eptis.bam.de “European Proficiency Testing Information System”,

[3] ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities.

[4] EA-4/18 - guidance on the level and frequency of proficiency testing participation

Annex 1
Guidelines for the Assessment

1. Protocol for performing a bilateral proficiency test

Bilateral Proficiency Test (Sometimes called “Check Sample Test”)

Laboratory receives a test item with accurately determined characteristics, which are to be tested in the frame of an accreditation procedure. The test item is given either by the assessor or provided by a third party (EA-03/04 clause 4.3).

1.1 Upon agreement with AU and, if possible, the laboratory, the assessment may include a bilateral proficiency test, where a number of different scenarios can occur:

a. The assessment team has access to the appropriate test material, and hands it over to the laboratory after proper announcement.
b. The assessment team does not have a sufficiently characterized test material. In this case the assessment team after gaining the approval of AU can subcontract a competent organization to provide the test material to the laboratory cost-effectively.

1.2 In both cases the following procedures should be agreed with the laboratory:

a. Type and number of test materials: the material should be unambiguously and unequivocally characterized concerning its homogeneity and stability, (e.g. a test material taken from interlaboratory comparisons or certified reference materials with undisclosed properties).
b. The test methods to be used, the parameters (which have assigned values) to be determined, and the acceptability criteria to be used for the evaluation by the assessment team.
c. The dates for delivering the test material (e. g. by hand or by mail), for carrying out the tests and for reporting the results to the assessment team.
d. Reporting the results as a test report, using forms from the PT provider if appropriate which conform to standards, where appropriate. Furthermore, it should be guaranteed that the raw data leading to the test results are also

provided to the assessor through AU, in order to detect possible errors in the calculation more easily.

e. The bilateral proficiency test's costs are included in the normal accreditation fees. When not included in the normal accreditation fees, the estimate for the bilateral proficiency test's costs should be made known to the laboratory prior to carrying it out. These costs should be roughly the same as those of comparable commercial PT schemes.

f. The acceptability criteria for the test should be agreed before the commencement of the test.

g. The conditions under which the bilateral proficiency test needs to be repeated as a consequence of insufficient results. A repeat of the bilateral proficiency test carried out under the same conditions with the same or a comparable test item has proved to be a satisfactory procedure.

1.3 The test items used for a bilateral proficiency test should fulfill the following requirements:

a. They should have been produced and characterized by competent laboratories.

b. The assigned values including the uncertainties for the parameters to be determined should exist.

c. These assigned values should only be determined by recognized and competent laboratories, which have carried out, and demonstrated expertise in the respective test method for a long time in the testing field concerned.

d. The laboratory supplying the assigned values has to prove its competence by participation in appropriate interlaboratory comparisons.

2. Assessment of results in inter-laboratory comparisons.

2.1 This type of inter-laboratory comparison can be planned and carried out among the laboratories themselves, or among the laboratories of one organization. The results of such inter-laboratory comparisons are mostly available in a shorter time than commercial ones and are often cheaper.

Furthermore, they have the advantage that they can be applied to the specific problems of laboratories.

2.2 A precondition for the recognition of inter-laboratory comparisons is that the provider of the inter-comparison should clearly state in their programs the assigned values according to ISO/IEC 17043:2010

2.3 For inter-laboratory comparisons, which are organized or carried out by the laboratories themselves, an additional examination of the proper choice of the selected methods should be made by the assessment team. In certain cases, the acceptability criteria used for the evaluation of the inter-comparison and defined by the laboratories should also be checked by the assessment team.

2.4 If the laboratory is able to state the uncertainties of its results on the basis of its own experience with the test method, and if the laboratory uses this knowledge to determine the evaluation criteria for the inter-laboratory comparison, then the assessment team should accept and use these criteria. A precondition is that the laboratory organizing the inter-laboratory comparisons defines the assigned values, which are agreed with the participating laboratories

2.5 Special case:

If the organizer of inter-laboratory comparisons does not provide any criteria for acceptance of results (e.g. inter-laboratory comparisons for validation of procedures and certification of reference substances), then the assessment team, in agreement with the laboratory under evaluation, should define-according to statistical evaluation (mean values of participating laboratories and Z-scores)

Annex 2
Procedure for the Assessment of Laboratories by Accreditation Bodies Using Proficiency Testing (Flowchart)