Jordanian Accreditation System

نظام الاعتماد الأردني

Accreditation Unit

POLICY OF PROFICIENCY TESTING

Purpose

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

Scope

- This document covers the proficiency testing activities of testing and calibration laboratories, and where relevant, inspection bodies.
- This document will help participating laboratories, inspection bodies (where relevant), the Accreditation Unit (JAS-AU), regulatory authorities and customers of laboratory services to use proficiency testing as a tool for assessment of technical competence of laboratories and inspection bodies (where relevant)within their scope of accreditation.

In the context of this document, "laboratories" implies all laboratory types – i.e., testing, calibration and medical laboratories.

Note: Proficiency testing may be used in some types of inspection where available and justified by the inclusion of testing activities that directly affect and determine the inspection result or when required by law or by regulators. It is, however, recognized that proficiency testing is not a usual and expected element in the accreditation of most types of inspections.

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

For further information about this publication, kindly contact JAS-AU.

This document is also available at JAS-AU website where you can check updates directly.

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1. Introduction

1.1 Proficiency testing as defined by ISO/IEC 17025:2017 is one of the powerful tools to help testing and calibration 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

ISO/IEC 17020 provides requirements for the operation of various types of bodies performing inspection.

1.2 Proficiency testing enables laboratories and inspection bodies (where relevant) to monitor their analytical performance 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 laboratory/inspection body (where relevant) and agreed with the technical assessor and approved by the Accreditation Committee.

1.4 The effective cost aspects are taken into consideration.

1.5 The proficiency testing should be conducted by a competent provider that complies with at least one of the following:

- Accredited according to ISO/IEC 17043
- Internationally approved, or
- as agreed between JAS-AU and the testing/calibration laboratory and inspection body (where relevant).

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

1.7 ISO/IEC 17025:2017 specifies sampling as a laboratory activity. This may include work by organizations that undertake sampling as a stand-alone activity where that sampling is intended for subsequent testing or calibration.

Proficiency testing and/or interlaboratory comparison may also apply to that activity.

2. Definitions

- Proficiency Testing (PT)
- Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (SOURCE: ISO/IEC 17043:2010, 3.7)

- Interlaboratory comparisons (ILCs)

Organization, performance and evaluation of measurements or tests on the same or similar 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 intercomparison may be the laboratory which provided the assigned value for the test/calibration item.

3. Policy

3.1 The laboratory and the inspection body (where relevant) shall have a procedure for monitoring the validity of results. Monitoring of the laboratory's performance shall be by comparison with results of different laboratories where available and appropriate. This shall include either or both of participation in proficiency testing (PT) or other interlaboratory comparisons (ILCs).

3.2 Laboratories shall participate in PT/ILCs where such schemes are available and relevant to their scope of accreditation. Where relevant, this also holds for accredited inspection bodies.

3.3 Technical competence can also be demonstrated by successful participation in ILCs 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.

3.4 Laboratories and inspection bodies (where relevant) are required to investigate scheme availability and also determine the appropriateness of the scheme.

Note Laboratories may refer to the EPTIS database for availability of PT schemes. EPTIS is an international database, the website address is **www.eptis.bam.de**.

3.7 Laboratories or inspection bodies (where relevant) preparing for initial accreditation, **changing their accredited location** or wishing to extend their scope of accreditation are required to participate in PT/ILCs where such schemes are available and relevant to their scope of application. Satisfactory performance, and/or appropriate corrective actions to eliminate the cause of unsatisfactory performance, shall be demonstrated before accreditation is granted.

3.5 Laboratories and inspection bodies (where relevant) shall formulate and document a plan for the level and frequency of participation in PT. The plan shall be regularly reviewed in response to changes in personnel, methodology, instrumentation, scope etc.

3.6 The PT participation plan shall cover all the scope of accreditation, at least **once/accreditation cycle given that the period between the PT participations for the same accredited test does not exceed 4years,** except for food and water labs, taking into account analysis of risk factors that could affect the results produced.

Medical labs shall implement the instructions from Ministry of Health related to this issue:

- Condition and 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”

- Licensing system for the medical laboratory (Issued under articles (5) and (66) Of the Public Health Law No. (54) For the year 2003.

3.8 Food and water testing laboratories shall have yearly PT participations covering all scope. If the time period between PT participations is more than one year, then the laboratory shall participate in ILCs 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.

3.9 JAS-AU shall receive a list of PT**/ILC Plan and** participations for approval using the form (qf072-05), the list shall be regularly reviewed in onsite assessment response to cover accreditation scope. Ongoing review of the plan and **participation** shall take into consideration the level of risk factors that may affect the test/calibration results, sensitivity of the test/calibration results, and level of complexity of the test/calibration procedure….etc.

3.10

3.11 Where no appropriate PT is available, In such cases, JAS-AU and the laboratory or where relevant the inspection body shall discuss and agree on suitable alternative means (ILCS , use of reference materials, replicate testing, etc.) to demonstrate the ongoing validity of their results. This would need to be considered as part of the planned PT and/or related activities.

3.11 Where the ILCs is the only available choice to approve the validity of the results, the ILCs shall be organized on regular basis between at least three laboratories unless no similar laboratories that provide the same analysis are available.

3.12 Laboratories and inspection bodies (where relevant) are required to have appropriate acceptance criteria (normally those used by the scheme provider) and a procedure for investigating flagged (or unsatisfactory) results and carrying out appropriate corrective/preventive actions (see annex 2). They are also

required to monitor and review their ongoing participation and performance and to monitor trends in results as appropriate.

3.13 Where is needed ,the corrective/preventive action implemented for the PT / ILCs flagged result will be assessed by JAS-AU, and decision on accreditation shall be considered upon the appropriateness of this action, provided that to obtain an acceptable proficiency testing results in the follow-up scheme or in the next proficiency testing participation. An onsite assessment may be needed to confirm that corrective actions are effective.

3.14 The accredited laboratory or inspection body (where relevant) shall not have three consecutive unacceptable proficiency testing results for the same method, otherwise; **JAS-AU decision will be temporary suspension or even withdrawal of the relevant tests/calibrations/inspection (where relevant) under the scope of accreditation.**

3.15 Additional proficiency testing may be required, if:

a. Due to changes of personnel, there are doubts regarding the technical competence of the laboratory or inspection body (where relevant)
b. from an assessment point of view, the external quality measures taken for the test and calibration methods or inspection methods (where relevant)/types of tests and calibration/inspection (where relevant) applied in the scope of accreditation are not sufficient, regarding, e.g.:

- The number of proficiency testing performed in specific cases.
- The application of the test/calibration 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 or inspection body (where relevant) are unsatisfactory as defined by the acceptability criteria.

3.16 Laboratories and inspection bodies (where relevant) shall maintain their records of PT/ ILCs performance, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective / preventive actions. Records shall be kept for five years at least

Note: JAS-AU assists laboratories and (where relevant) inspection bodies in identifying and formulating their PT participation needs and plans

4. References

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

[2] ISO/IEC 17025:2017, “General requirements for the competence of testing and calibration laboratories”.

[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.

[5] Condition and Principle of Lab Quality Control and Improvement for the year (2012)

[6] Update Licensing System no (92) for the year (2008) for Private Medical lab

[7] Instructions No. (5) For the year (2005) “Instructions of Internal Quality Control Basis in the Laboratory Work

[8] Licensing System for the Medical Laboratory (Issued under articles (5) and (66) of the Public Health Law No. (54) For the year 2003

Annex 1

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