Jordanian Accreditation System

نظام الاعتماد الأردني

Accreditation Unit

POLICY OF PROFICIENCY TESTING AND/OR INTERLABORATORY COMPARISONS OTHER THAN PROFICIENCY TESTING

Purpose

The Accreditation Unit (JAS-AU) has set this document to ensure consistency in applying Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing as a requirement for accreditation for all Conformity Assessment Bodies (CABs) that perform testing or calibration activities – i.e. testing, sampling, calibration and medical laboratories, inspection bodies, biobanks, PT providers and reference material producers.

Scope

This document is intended to assist participating CABs, the Accreditation Unit (JAS-AU), to use Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing as a tool for assessment of technical competence of CABs 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

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

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

Contents

1. Introduction

- The revision of JAS -P02 was prepared to align with the latest updated versions of ISO/IEC 17025, ISO 15189, ISO/IEC 17011. specific clauses are included on proficiency testing (PT) and/or interlaboratory comparisons (ILC) other than PT (clauses 7.7.2 and 7.3.7.3 respectively). Within ISO/IEC 17011:2017 the review of performance in PT and ILCs is considered as an assessment technique**.**
- ISO/IEC 17025:2017, clause 7.7.2, requires that the laboratory monitors its performance by comparison with results of other laboratories, through participation in PT and/or ILCs other than PT, where available and appropriate.
- ISO 15189:2022, clause 7.3.7.3, requires laboratory to participate in an External Quality Assessment (EQA) program appropriate to the examination and interpretation of examination results, including (Point of care testing) POCT examination methods. When an EQA program is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance, including ILCs other than PT.
- ISO/IEC 17020:2012 does not mention any specific requirements for PT and/or ILCs other than PT, however, the requirements for ISO/IEC 17025:2017 are to be considered for testing or calibration activities. Further information on the need for ensuring the validity of results in the field of inspection can be found in ILAC G27:2019[6];
- ISO 20387:2018, clause 7.8.2.9, requires that approaches to provide objective evidence to demonstrate the comparability of biological material quality (the processing or testing output) are used, where such approaches are available and appropriate. Such approaches include EQA schemes, PT schemes and/or ILCs other than PT.
- For ISO/IEC 17043:2023, no specific requirements for PT and/or ILCs other than PT are mentioned in the standard, however, the requirements for ISO/IEC 17025:2017 and ISO 15189:2022 are to be met when considering testing or calibration activities.
- An applicant or accredited CAB is therefore required to plan and monitor its participation in PT and/or ILCs other than PT. Based on ISO/IEC 17025:2017, clause 8.5 and ISO 15189:2022, clauses 8.5 and 7.3.7.3, the planning is to take into account the risks and

opportunities of the laboratory activity. This includes an evaluation of the level and frequency of participation in PT and/or ILCs other than PT.

2. Terminology

Interlaboratory comparison (ILC): design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (ISO/IEC 17043:2023, 3.4).

Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2023, 3.7).

Note: Further information regarding the design of various proficiency testing schemes is provided in Annex A (Informative) of ISO/IEC 17043:2023.

External quality assessment (EQA): evaluation of participant performance against preestablished criteria by means of interlaboratory comparisons (ISO 15189:2022, 3.10)

Appropriateness: A PT and/or ILC other than PT can be regarded as technically appropriate, if the scope of activity being provided is similar to the current practice of the accredited CAB. In the case of specific test or measurement techniques, for which no regular PT and/or ILCs other than PT is available, it may be adequate to choose a PT and/or ILCs other than PT, which is similar to the scope, or which covers an important partial aspect of the activity

Availability: A PT is considered available, if:

a) it is offered by a competent PT provider, and the required documents are provided in the national language of the participating body or a language understood by the CAB;

b) if it does not require development by the PT provider and the results can be provided within a short time in regard to the CAB needs formalized in its PT participation plan.

3. Policy

1. Participation is applicable not only to laboratories, but also to CABs accredited to other standards performing testing and/or calibration activities as part of their accredited conformity assessment activities.

2. The CAB shall have a procedure for monitoring the validity of results. Monitoring their performance shall be by comparison with results of different CABs where available and appropriate. This shall include participation in PT and/or ILCs other than PT.
3. The applicant and accredited CABs shall develop a participation plan in PT and/or ILCs other than PT (PT participation plan). The plan shall be regularly reviewed Taking into consideration the outcome of the CAB's risk assessment. participation in PT and/or ILCs other than PT is considered, by ISO/IEC 17025:2017 as mandatory when available, appropriate and deemed necessary. For ISO 15189:2022, participation in PT is considered mandatory when available, appropriate and deemed necessary.
4. There are particular areas where proficiency testing is just not available as defined by the applicant / Accredited CAB in this case shall take approval by JAS-AU.
5. Participation through PT and/or ILCs other than PT to demonstrate the validity of results can be done through:
    - A PT provider, accredited to ISO/IEC 17043:2023 by an AB signatory of the ILAC MRA for PT providers.
    - A PT provider, accredited to ISO/IEC 17043:2023 by an applicant AB or an AB non-signatory of the ILAC MRA for PT providers.
    - Participation in an ILC, which is organized for other purposes than determining a CAB's competence (ISO/IEC 17043:2023).
    - Organization of, or participation in, ILCs organized, in accordance with the relevant requirements of ISO/IEC 17043:2023, to determine the performance of accredited CABs by comparison with the results of other laboratories.
6. CABs preparing for initial accreditation or wishing to extend their scope of accreditation are required to participate in PT and/or ILCs other than PT. Satisfactory performance shall be demonstrated before accreditation is granted/ extended. The PT report shall be valid

two years before conducting the assessment visit, for ILC report shall be valid one year before conducting the assessment visit.

7. JAS-AU shall assess the PT participation plan to ensure that there is a representative and satisfactory participation in PT and/or ILCs other than PT activities regarding an applicant scope before granting accreditation.
8. The performance obtained in the PT for one and/or combination within a defined area can be directly correlated to the other combinations of test or measurement techniques, characteristics and products contained within the same area of technical competence. so, JAS-AU defines the minimum tests or measurement techniques, characteristic and product which are related to the same area of technical competence to demonstrate the validity of their results.
9. The PT and/or ILCs other than PT participation plan shall cover the scope of accreditation, at least once/accreditation cycle given that the period between the PT and/or ILCs other than PT participations for the same accredited test does not exceed 4years,

   CABs shall have one successful participation for applied scope for accreditation before granting accreditation and another one during the accreditation cycle)
10. 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.
11. CABs shall provide JAS-AU with the list PT and/or ILCs other than PT using JAS-AU PT forms related to its sector, the list shall be regularly reviewed and updated by the assessment team during onsite assessment to cover accreditation scope.
12. Ongoing review of the plan and participation shall take into consideration the level of risk factors that may affect the activities results, sensitivity results, and level of complexity of the activities procedure…. etc.
13. The PT participation plan shall foresee representative participation in PT and/or ILCs other than PT activities regarding any accreditation scope.

14. Where satisfactory performance is not achieved, JAS-AU shall assess the evidence of the implementation of prompt and appropriate corrective actions.
15. Participation in ILCs other than PT should only be considered when PTs are not available, and/or appropriate, the ILCs shall be:
    - Organized on regular basis (As determined by JAS-AU).
    - Shall be between at least two or more laboratories in accordance with predetermined conditions and acceptance criteria unless no similar laboratories that provide the same analysis are available.
    - Define the appropriate acceptance criteria
16. Where ILC isn't practical or available, the CABs shall indicate suitable alternative means by which performance will be assessed and monitored. These may include activities such as intra-laboratory comparisons, the use of reference materials or other comparisons and where deemed necessary and applicable JAS-AU shall perform measurement audit as means to ensure the validity of the result.
17. CABs shall consider these alternative arrangements as part of the laboratory's planned activities. It is the responsibility of CABs to provide the details of the plan and its justification to obtain approval from JAS-AU.
18. The accredited CABs shall not have three consecutive unacceptable proficiency testing results within the representative scope of accreditation, otherwise; JAS-AU decision will be temporary suspension or even withdrawal of the relevant activities under the scope of accreditation.
19. Additional proficiency testing may be required:
    - Due to changes of personnel, there are doubts regarding the technical competence of the CABs
    - In some scopes according to JAS-AU risk assessment and decisions.
    - Any requirements for frequency and type of PT participation from other sources, e.g. legislation, regulator, customers, etc.
20. Medical labs shall implement the instructions from Ministry of Health related to participation in external quality assessment programs:

- Condition and Principle of lab quality control and Improvement for the year (2012).

21. CABs shall maintain their records of PT/ ILCs performance, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective / preventive actions.
22. The CABs shall have appropriate evidence of the competence of the PT provider or the organization providing ILCs other than PT.

4. References

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

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

[3] ILAC-P9:06/2024