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TPS 47

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UKAS policy on participation in proficiency testing

Contents

Changes since last edition

Minor changes throughout to provide updates and further clarification. Reference added to *ISO 22367 Medical laboratories - Application of risk management to medical laboratories*.

1. Introduction

1.1 Both ISO/IEC 17025:2017 and ISO 15189:2022 have a mandatory requirement for laboratories to have procedures for monitoring the validity of results. It is also clear that laboratories shall monitor their performance by comparison with results of different laboratories where available and appropriate.

Whereas ISO/IEC 17025 requires inclusion of either, or both, of proficiency testing (PT) or other interlaboratory comparisons (ILCs), ISO 15189 is specific in the type of PT as identified by the term 'External Quality Assessment' (EQA) programmes. This is inclusive of point of care testing (POCT) examination methods.

As these methods provide a mechanism for a laboratory to demonstrate its competence to its customers, stakeholders, regulatory authorities, and other organizations that specify requirements for laboratories including the accreditation body, it should be emphasised that participation in ILCs other than PT should only be envisaged when laboratories have demonstrated that PTs are not available, and/or appropriate.

1.2 The monitoring shall include where appropriate participation in PT and/or ILCs, but also by other means, e.g., the regular use of reference materials or replicate tests/calibrations using the same or different methods. The use of external as well as internal quality assurance measures should increase the likelihood of capturing systematic components of uncertainty such as bias from traceability, or problems with laboratory procedures that may not be seen by purely internal activity.

1.3 UKAS considers participation in PT/ILCs an important tool for demonstrating the technical competence of laboratories and inspection bodies.

1.4 Some laboratories that have formed networks (e.g. genomics) where the separate stages of the full sample pathway are conducted over different bodies are still expected to comply with this document (see also UKAS publication *TPS 71 Accreditation of healthcare diagnostic pathways delivered between multiple UKAS customers*).

1.4 PT/ILCs may also 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 *(see also ILAC-P9, ILAC-P15)*.

1.5 ISO/IEC 17025 specifies sampling as a laboratory activity. This may include work by organisations that undertake sampling as a stand-alone activity where that sampling is intended for subsequent testing. PTs and/or ILCs may also apply to that work.

1.6 ISO 22367 *Medical laboratories - Application of risk management to medical laboratories* includes reference to PT and EQA as suitable source of risk information.

2. Scope

2.1 This document relates to applicant and accredited laboratories, including medical laboratories and POCT and, where relevant, inspection bodies.

3. Terminology

Note: ISO/IEC 17043:2023 has been revised to broaden understanding of used terms to include all types of conformity assessment bodies and their activities, respectively.

3.1 *Interlaboratory comparison* (ILC) is the organisation, performance and evaluation of calibration/tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions.

3.2 *Proficiency Testing* (PT) is the determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body against pre-established criteria by means of interlaboratory comparisons.

3.3 The term *External Quality Assessment* (EQA), that is often used in some sectors (e.g., medical), is a specific form of PT. Many EQA schemes provide feedback across the full sample pathway from pre-analytical to post-analytical, are continuous to provide long-term follow-up, and may also provide an element of education. The laboratory is expected to justify its choice in demonstrating its competence across the tasks it performs.

4. Policy

4.1 It is UKAS policy that all accredited laboratories shall participate in PT/ILCs where such schemes are available and relevant to their scope of accreditation. Where applicable, this also holds for accredited inspection bodies.

Where necessary, as judged by e.g. availability and frequency, technical competence can also be demonstrated by successful performance in ILCs that have been organised for purposes other than PT in its strictest sense, for example:

- to evaluate the performance characteristics of a method
- to characterise a reference material
- to compare results of two or more laboratories on their own initiative
- to support statements of the equivalence of measurement of National Metrology Institutes (NMIs)
- To demonstrate acceptance of intended use criteria, e.g. clinical utility

4.2 Laboratories and inspection bodies are required to investigate PT/ILC scheme availability and also determine the appropriateness of the available scheme(s).

Note 1: ISO/IEC 17025, ISO/IEC 17020 and ISO 15189 require laboratories and inspection bodies to evaluate suppliers, this includes PT providers and their schemes. ISO/IEC 17043 contains criteria for the competence of PT scheme providers. This standard is recognised as an acceptable basis for such an evaluation. UKAS accredits PT Providers to ISO/IEC 17043; a list of accredited PT schemes/providers is available on www.ukas.com. UKAS recommends the use of an accredited PT scheme where one is available.

Note 2: Laboratories and inspection bodies may refer to the EPTIS database for availability of PT schemes. EPTIS is an international database, the website address is www.eptis.bam.de.

4.3 Laboratories and inspection bodies shall formulate and document a plan for the selection, level, and frequency of participation in PT. The plan shall be risk-based and regularly reviewed in a timely response to changes in staffing, methodology, instrumentation, scope etc. Laboratories and inspection bodies should be able to demonstrate the effectiveness of PT (see also EA

Publication EA-4/18 G *Guidance on the level and frequency of proficiency testing participation* for further guidance on how to establish a plan, and *ILAC-P9 Policy for Participation in Proficiency Testing Activities*).

4.4 Laboratories and inspection bodies must be prepared to justify their policy and approach to both frequency of participation and any non-participation in readily available PT schemes that are appropriate.

Note: some schemes mandate full participation for all exercises or distributions and choosing to omit from some would not fully assess that measurand/item.

4.5 Laboratories and inspection bodies should define the level and frequency of participation after careful analysis of risk factors that could affect the results produced. This includes, e.g. clinical, operational, regulatory, as well as technical risks where appropriate. The participation should be dependent on the level of quality assurance activities; historic performance could also be used to justify changes in participation levels. Where QA activities include but are not limited to:

- Regular use of reference materials
- Comparison of analysis by independent techniques
- Participation in method development/validation and/or reference material characterisation studies
- Use of internal quality control measures
- Other inter/intra-laboratory comparisons e.g., analysis of blind samples within the laboratory

4.6 Laboratories and inspection bodies preparing for initial accreditation 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, must be demonstrated before accreditation can be granted.

4.7 Where no appropriate PT/ILCs are demonstrably available, or where no distributions/rounds of appropriate PT/ILC are available, laboratories and inspection bodies are required to demonstrate the ongoing validity of their tests by other means *(use of reference materials, replicate testing, etc.)*.

4.8 Laboratories and inspection bodies are required to have appropriate acceptance criteria *(normally those used by the PT scheme provider)* and a procedure for investigating flagged *(or anomalous)* results and carrying out appropriate corrective actions. Laboratories and inspection bodies are also required to monitor and review their ongoing PT/ILC participation and performance, to monitor trends in results and to take actions to address identified risks and improvement opportunities in a timely manner.

4.9 The guidance in EA-4/21 INF should be considered when small ILCs are organised by a participating laboratory.

4.10 In some cases, participation in specified PT/ILC activities may be mandated by a standard, a specification, contract or agreement, or by regulatory requirement, or by UKAS where it is deemed necessary to demonstrate technical competence.

5. References

5.1 ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

5.2 ISO 15189 Medical laboratories - Requirements for quality and competence

5.3 ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

5.4 ISO/IEC 17043 Conformity Assessment - General Requirements for Proficiency Testing

5.5 EA-4/18 G Guidance on the level and frequency of proficiency testing participation

5.6 ILAC-P9 ILAC Policy for Participation in Proficiency Testing Activities

5.7 ISO/IEC 17011 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

5.8 EA-4/21 INF Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

5.9 ILAC-G27 Guidance on measurements performed as part of an inspection process

5.10 ILAC-P15 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies

5.11 ISO 22367 Medical laboratories - Application of risk management to medical laboratories

Note: From 1st January 2026 Global ACI has assumed the former roles of the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).