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UKAS Policy on Participation in Proficiency Testing

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Changes since last edition

Updated to reference ISO/IEC 17025:2017. Reference added to publications EA-4/21, ILAC-G27 & ILAC-P15. Section 1.4 revised (inspection activities). Section 1.5 added (sampling activities). Section 4.5 amended to reference consideration of risk factors. Section 4.6 expanded to refer to the need to demonstrate satisfactory performance in proficiency testing/interlaboratory comparison and/or appropriate corrective actions to address unsatisfactory performance prior to grant of accreditation. Other minor editorial changes.

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1. Introduction

1.1 ISO/IEC 17025 requires 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. This will include either or both of proficiency testing (PT) or other interlaboratory comparisons (ILCs). These methods provide a mechanism for a laboratory to demonstrate its competence to both its customers and the accreditation body.

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.

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

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

1.4 PT or 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 *(ILAC-P9, ILAC-P15)*.

1.5 ISO/IEC 17025:2017 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.

2. Scope

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

3. Terminology

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. The term *External Quality Assessment* (EQA), that is often used in some sectors (e.g. medical), is considered to be equivalent where these EQA activities meet the definition of PT.

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.

Technical competence can also be demonstrated by successful participation 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 NMIs.

4.2 Laboratories and inspection bodies are required to investigate scheme availability and also determine the appropriateness of the scheme.

Note 1: ISO/IEC 17025, ISO/IEC 17020 and ISO 15189 require laboratories and inspection bodies to evaluate suppliers, this includes PT providers. 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 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 Where applicable, laboratories and inspection bodies 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 staffing, methodology, instrumentation, scope etc. Laboratories and inspection bodies should refer to the EA Publication EA-4/18 INF *Guidance on the level and frequency of proficiency testing participation* for further guidance on how to establish a plan.

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.

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. The participation should be dependent on the level of quality assurance activities; historic performance could also be used to justify changes in participation levels. 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 or ILCs 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 scheme provider)* and a procedure for investigating flagged *(or anomalous)* results and carrying out appropriate corrective/preventive actions. Laboratories and inspection bodies are also required to monitor and review their ongoing participation and performance and to monitor trends in results as appropriate.

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 activities may be mandated by a Standard, a Test Specification or by Law. Additionally, UKAS may specify participation in a particular scheme/exercise 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 - Particular 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 INF 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