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UKAS Policy on Participation in Proficiency Testing

United Kingdom Accreditation Service, 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR
Website www.ukas.com Publications requests Tel: 01784 429000 email: info@ukas.com

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Changes since last edition

Reference added to use of suitable comparison schemes by inspection bodies *(where relevant)*.
Other minor editorial changes.

1. Introduction

1.1 ISO/IEC 17025 requires laboratories to have quality control procedures for monitoring the validity of tests and calibrations undertaken. The monitoring may include participation in interlaboratory comparisons (ILCs) or proficiency testing programmes (PTs), but also by other means, eg, the regular use of reference materials or replicate tests/calibrations using the same or different methods. These methods provide a mechanism for a laboratory to demonstrate its competence to both its customers and the accreditation body.

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 ISO/IEC 17020 also requires that inspection bodies seek confirmation for confidence in their inspections through participation in suitable comparison schemes.

2. Scope

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

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3. Terminology

3.1 *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 comparison. The term *External Quality Assurance*, EQA, that is often used in some sectors (e.g. medical), is considered to be equivalent to Proficiency Testing.

3.2 *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.

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 (IBs).

Technical competence can also be demonstrated by successful participation in interlaboratory comparisons 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 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 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 *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 PTs that are appropriate.

4.5 Laboratories and inspection bodies should define the level and frequency of participation after careful analysis of other QA measures *(especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude)*. The participation should be made dependent on the extent to which other measures have been taken. Other types of QA 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 before accreditation can be granted.

4.7 Where no appropriate PT or ILC is 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 UKAS may specify participation in a particular scheme/exercise where it is deemed necessary to demonstrate technical competence. Where participation in an externally run scheme is a mandatory requirement, this shall be stated in an appropriate UKAS publication *(see UKAS publications list)* or relevant legislation or sector scheme documentation, where relevant.

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/IEC17043 *Conformity Assessment - General Requirements for Proficiency Testing*

5.5 EA-4/18 *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*

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