

LAB 46

Edition 3 November 2018 - **Draft for consultation**

UKAS Policy for Participation in Measurement Audits and Interlaboratory Comparisons

Draft for consultation

Contents

1.	Introduction	2
2.	UKAS Policy	3
3.	UKAS Measurement Audit Activity	3
4.	Purpose of Measurement Audits	4
5.	Analysis of UKAS Measurement Audit Results	4
6.	Costs for Provision of Measurement Audits	5
7.	Confidentiality	5
	Appendix - References	5

Changes since last edition

Minor changes have been made following the publication of ISO/IEC 17025:2017 and to reflect changes to EA policy.

1. Introduction

- 1.1 The general requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate to a management system, are technically competent and are able to generate technically valid results are contained within ISO/IEC 17025:2017^[A1]. This international standard forms the basis for international laboratory accreditation and in cases of differences in interpretation remains the authoritative document at all times.
- 1.2 Section 7.7 of ISO/IEC 17025:2017 requires that laboratories shall plan and undertake quality assurance procedures for monitoring the validity of tests and calibrations undertaken. This shall include participation in interlaboratory comparison or proficiency testing programmes.
- 1.3 UKAS may provide audit measurement artefacts as part of the technical assessment process. This applies particularly to calibration laboratories but may also include testing laboratories that conduct internal calibrations.
- 1.4 This document provides UKAS policy and further details regarding participation in such activities.

2. UKAS Policy

- 2.1 UKAS recognises the benefits of measurement comparisons as an assessment tool in the laboratory accreditation process. Where it is possible and where the results can be expected to provide clear evidence of technical competence, audit measurements will form part of the assessment for all calibration laboratories. Testing laboratories that conduct a significant amount of internal calibrations may also be included. Audit measurements are complementary to other information gathered directly by UKAS assessors, and the results will be used in the context of detailed knowledge of the laboratory being assessed and the technical processes involved.
- 2.2 Interlaboratory comparisons and other measures are also required by ISO/IEC 17025:2017 clause 7.7 which details a list of possible activities. Conformity with ISO/IEC 17025:2017 normally requires both internal and external activities to ensure the validity of results.
- 2.3 ILAC document P9 ^[A2] (*currently under revision to reflect the requirements of ISO/IEC 17025:2017*) specifies ILAC policy requirements on laboratories and accreditation bodies in relation to proficiency testing activities.

3. UKAS Measurement Audit Activity

- 3.1 The laboratory is required to plan and execute interlaboratory comparisons and proficiency testing. UKAS will assess the plan for each laboratory ensuring sufficient audit measurements or alternative provision at each stage of the accreditation cycle. UKAS will review the coverage at the contract review process for reassessment, or, additionally, if there has been any significant change in the scope of the laboratory. The plan will normally ensure that at least one activity in each major sub-discipline of accredited scope will take place between the four-yearly reassessments. Robust pass/fail criteria should be predetermined by the laboratory, such as those detailed in section 5. Evidence of review of the results and the associated conclusions will be assessed during UKAS visits.
- 3.2 Before accreditation is granted for any measurement, there shall be at least one representative audit measurement or equivalent activity, where suitable devices or schemes are available. If no such audits or ILCs are available, the laboratory shall be required to instigate additional quality assurance activities or to arrange their own inter-comparisons with another laboratory. Details of suggested activities may be found in ISO/IEC 17025:2017 clause 7.7.1.
- 3.3 If a laboratory already has in place arrangements for ILCs that are at least equivalent to those that could be supplied by UKAS then such arrangements may be an acceptable substitute. Decisions regarding the acceptance of these arrangements shall be technically based and UKAS audit measurement devices deployed when alternative arrangements are not acceptable.
- 3.4 Decisions on appropriate audits and activity levels will also be technically based. Confidence in all distinct measurement techniques covered by the accreditation shall be ensured. Generic measurement techniques, selecting representative calibrations in each accredited parameter, should be used as much as possible.

4. Purpose of Measurement Audits

- 4.1 The UKAS Measurement Audit service is a valuable tool that supports the technical assessment of calibration laboratories. Its purposes are:
- a) To provide confirmation that the *Calibration and Measurement Capability (CMC)* can be supported by “real” measurements. This gives both UKAS and the participating laboratories confidence in calibration results;
 - b) To enable UKAS to assess the way in which results are reported to customers.
- 4.2 UKAS usually requires applicant calibration laboratories to participate in measurement audit or equivalent activity as part of the initial assessment process. UKAS also has an ongoing programme of measurement audits for accredited laboratories that corresponds with the four-year assessment cycle. This may also apply to testing laboratories that conduct internal calibrations in support of their testing activities.

5. Analysis of UKAS Measurement Audit Results

- 5.1 UKAS compares laboratories’ results with “reference values” that are obtained from the National Physical Laboratory or from other credible sources. The comparison takes into account the difference between laboratories’ results and the reference values, as well as the uncertainties associated with both. The Normalised Error Ratio (E_N ratio) is usually employed for this analysis.

5.2
$$E_N \text{ ratio} = \frac{LV - RV}{\sqrt{U_{LV}^2 + U_{RV}^2}}, \text{ where}$$

LV is the value reported by the laboratory, with expanded uncertainty U_{LV} .

RV is the reference value, with expanded uncertainty U_{RV} .

- 5.3 The E_N ratio should be within the range ± 1 . If the analysis reveals that it lies outside this range, UKAS will request investigation of the results and that any necessary corrective and preventive actions are undertaken. The assessment team will assess the activities of the laboratory in resolving any issues.
- 5.4 Sometimes unexpected changes in the audit device can give rise to this situation. This is identified by examining trends in results reported by laboratories. UKAS will inform participants if it is found that this has occurred, and changes to reference values to reflect, for example, reference value drift, may be indicated. A delay may occur if further reference values need to be sourced.
- 5.5 Occasionally systematic issues arising across a number of laboratories are observed, indicating possible issues regarding methods or specific items of calibration equipment in laboratories. This is fed back into the assessment process, thereby improving measurement results for all concerned.

6. Costs for Provision of Measurement Audits

- 6.1 The provision of measurement audits is a chargeable service and UKAS will provide a quotation at the time the audit is arranged. The prices take into account:
- Purchase cost and depreciation of the artefacts;
 - Costs of maintaining traceability of measurement and maintenance/repair of the equipment;
 - Costs associated with production of measurement instructions and analysis of the results;
 - Costs of storage, inspection, packaging and transport.
- 6.2 UKAS will provide an invoice for the quoted amount upon completion of the audit. If the outcome of the audit requires significant further work on the part of the assessment team, UKAS may raise a further invoice to cover the effort involved. UKAS will inform participants in advance if this situation occurs.
- 6.3 It should be noted that the provision of measurement audits is not a commercial service. It is only available to applicant and accredited laboratories as a support tool that relates to the technical assessment of these organisations.

7. Confidentiality

- 7.1 As with all assessment activities, UKAS does not divulge a particular laboratory's results to any other party. If necessary, UKAS may discuss them with relevant contracted Technical Assessors, however they are bound by the same rules of confidentiality.

Appendix - References

- A1 ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*
- A2 ILAC P9 *ILAC Policy for Participation in Proficiency Testing Activities* (under revision)
- A3 ISO/IEC 17011:2017, *General requirements for accreditation bodies accrediting conformity assessment bodies*