



UKAS Guidance on the Application of ISO/IEC 17025 Dealing with Expressions of Opinions and Interpretations

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About the United Kingdom Accreditation Service

The United Kingdom Accreditation Service (UKAS) is recognised by the UK Government as the national body responsible for assessing and accrediting the competence of organisations in the fields of calibration, testing, inspection and certification of systems, products and personnel.

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United Kingdom Accreditation Service
21 – 47 High Street
Feltham
Middlesex TW13 4UN
UK

Tel: +44(0)20 8917 8555
Fax: +44(0)20 8917 8500
website: www.ukas.com

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1 Introduction

- 1.1 ISO/IEC 17025 contains the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate to a quality system, are technically competent and are able to generate technically valid results. It replaces ISO/IEC Guide 25 and EN 45001, and is the standard that UKAS now uses in place of UKAS publication M10 to assess a laboratory's competence for the purposes of accreditation.
- 1.2 The purpose of these guidelines is to set down UKAS policy, process and guidance on assessment and accreditation of laboratories wishing to express opinions and interpretations in test reports or calibration certificates.
- 1.3 This Edition 2 of LAB13 incorporates experience gained during phase 1 of the UKAS development programme to establish UKAS' approach to such assessment and accreditation. Edition 2 will be reviewed on completion of phase 2 of the development programme in September 2002, by which time UKAS expects to have gained further experience through practical assessment.
- 1.4 UKAS welcomes comments on these guidelines, which should be addressed to the UKAS Development Group before the end of August 2002.

2 Policy

- 2.1 Prior to the publication of ISO/IEC17025, laboratories were accredited by UKAS (under M10/EN45001/ISO Guide 25) for providing test results and information necessary for the client to interpret results. Any opinions and interpretations expressed by the laboratory itself were excluded from UKAS accreditation and had to be disclaimed. It is now UKAS policy that laboratory accreditation to ISO/IEC 17025 may include the expression of opinions and interpretation of test/calibration results in reports.
- 2.2 It is the responsibility of individual laboratories to decide whether or not they will make statements of opinion or interpretation in test reports or calibration certificates, whether to seek accreditation to cover this activity, and to act accordingly. This decision shall be clearly stated within the laboratory's quality system documentation.
- 2.3 Expression of opinions and interpretations relating to results is considered to be an inherent part of testing/calibration and UKAS will not accredit expression of opinions and interpretations in reports as a separate activity.

3 Application for accreditation

- 3.1 A laboratory that is already accredited for test/calibration can now apply to UKAS to extend its accredited scope to cover the expression of opinions and interpretations relating to the reported results. The applicant must indicate the accredited test/calibration activities for which the laboratory intends to express opinions and interpretations.

- 3.2 New applicants when applying for accreditation of testing/calibration should state in their application if they wish the accredited scope to include opinions and interpretations and should indicate the test/calibration activities for which they intend to express opinions and interpretations.
- 3.3 It is unlikely that expression of opinions and interpretations of calibration results will be needed for the majority of calibration activities. UKAS will however, accredit the expression of opinions and interpretations in calibration reports where it is demonstrated to be necessary/appropriate.

4 Assessment of applicants

- 4.1 UKAS will assess the processes put in place by the laboratory for the purposes of making statements of opinions or interpretations in order to evaluate the laboratory's competence to do so, but will not accredit or otherwise endorse the statements themselves. Where necessary, UKAS will seek advice from relevant professional bodies as to the appropriate levels of competence to carry out such work.
- 4.2 The laboratory's documented quality system must reflect whether it is expressing opinions and interpretations and if so, for which activities. The process of interpreting test/calibration results for the purpose of expressing opinions and interpretations must be documented. The following documentation must be provided to UKAS for review, at least three months prior to the planned assessment date or within a timescale agreed between UKAS and the laboratory to allow UKAS sufficient time to establish the assessment team and plan the assessment.
- (a) Documentation reflecting the process (procedures & practices) leading to inclusion of opinions and interpretations in reports.
 - (b) Criteria for competence of personnel authorised to express opinions and interpretations.
 - (c) Records of qualifications, experience and training of personnel authorised to express opinions and interpretations.
 - (d) Past (or example) reports including opinions and interpretations.
- 4.3 UKAS will assess the laboratory's competence to express opinions and interpretations by;
- (a) examining the implementation of the procedures and practices
 - (b) examining the adequacy of the competence criteria for personnel
 - (c) examining the adequacy of mechanisms in place to monitor the competence of personnel
 - (d) verifying qualifications, experience, training and knowledge of personnel
 - (e) examining reports where opinions and interpretations have been expressed
 - (f) examining records showing the basis on which opinions and interpretations have been expressed
 - (g) using other appropriate assessment techniques.

5 Accreditation

- 5.1 ISO/IEC 17025 deals specifically with the requirements for the competence of laboratories performing testing and calibration and for the reporting of the results, which may or may not contain opinions and interpretations of the results. Hence UKAS will not accredit organisations to this standard for the activity of expressing opinions or interpretations alone. Correspondingly, the provision of opinions and interpretations should not extend beyond those based on the results of tests or calibrations within the accredited scope of the laboratory.
- 5.2 The UKAS Accreditation Schedule will in future reflect for which test or calibration activities a laboratory has been successfully assessed and accredited to allow it to provide opinions and interpretations.
- 5.3 If the expression of opinions and interpretations not covered by UKAS accreditation is included in reports, then the report must clearly indicate those activities that are not covered by UKAS accreditation by making a suitable disclaimer such as:

The opinions and interpretations indicated are outside the scope of UKAS accreditation

6 Guidance on ISO/IEC 17025

- 6.1 The guidance material contained below is directed specifically at aspects of the standard dealing with opinions and interpretations. It is applicable equally to both test and calibration laboratories; where the terms 'test' or 'test report' are used below, these should also be taken to mean 'calibration' and 'calibration certificate' respectively.

ISO/IEC 17025 Clauses 4.1.1 to 4.1.5

- 6.2 The emphasis of these clauses is very much on the laboratory being able to demonstrate that it maintains impartiality and avoids conflicts of interest through management control, even when it is part of a larger organisation and when personnel are involved in activities relating to that organisation, other than testing or calibration. The links with other parts of the organisation need to be clearly defined when, for example, the laboratory draws on professional input from the related organisation in making statements of opinions and interpretations.
- 6.3 These clauses, in particular ISO/IEC 17025 sub-clauses 4.1.5 (b), (c) and (d), also highlight the need for professional integrity and due diligence in making statements of opinions and interpretations.

ISO/IEC 17025 Clauses 4.2.1 – 4.2.2

- 6.4 The laboratory's policies and procedures for making statements of opinions and interpretations need to be documented within the quality system. These should include limitations to the extent of their use (for example: only in

some technical disciplines but not others; for purposes of clarification only), the circumstances under which they may be given (for example: request of client, compliance with a standard or with legal requirements or objectives, professional opinions based on investigative work or analysis), any specific format for the wording of statements whether set by the laboratory or by external agencies.

ISO/IEC 17025 Clause 4.4.1 – 4.4.5

- 6.5 These clauses relate to the activities which, together, are referred to below as ‘contract review’. A robust contract review process is an essential element in a laboratory’s demonstration of its competence to express opinions and interpretations.
- 6.6 The contract review procedure needs to include confirmation that the client’s needs and wishes have been understood with respect to any statements of opinions and interpretations, whether such statements are appropriate within the laboratory’s accredited scope, that the client has understood and accepted the implications of such statements, that the laboratory has the necessary professional competencies authorised to make such statements, and that any legal requirements are understood and can be complied with. The laboratory needs to maintain records of contract reviews in line with its general policies on record keeping.
- 6.7 The contract review should establish the relative extent to which a statement of opinions and interpretations will be based on test results compared to information drawn from other sources, such as documentary research, precedent or previous experience. Care will need to be exercised in the latter case since it is possible that opinions and interpretations based on such sources, although being within the professional capacity of the laboratory, may fall outside the scope of testing or calibration work covered by their accreditation to ISO/IEC 17025.
- 6.8 Similarly, the contract review should establish the extent to which such statements may incorporate information from tests which are not covered by the laboratory’s scope of accreditation, or on any other externally supplied data, and determine their validity for the purposes of forming opinions and interpretations (see also para 6.21).
- 6.9 The contract review should also establish when the client requires only opinions and interpretations and does not want to receive details of measurement results.
- 6.10 In situations where the laboratory is reporting results of statistical calculations which have been based on an assumption, the contract review must ensure that the client is aware of, and accepts, the basis for the calculations.

ISO/IEC 17025 Clause 4.9.1 – 4.9.2

- 6.11 These clauses also apply when there is doubt about the validity of statements of opinions and interpretations that have been made, or of any sources of information upon which those statements have been based.

ISO/IEC 17025 Clause 4.14.1 – 4.14.2

- 6.12 Where a laboratory undertakes to make statements of opinions and interpretations, management reviews should include appraisal of the basis on which these are made and of the competency requirements of the individuals authorised to make such statements.

ISO/IEC 17025 Clause 5.2.1 – 5.2.5

- 6.13 The laboratory management should be able to demonstrate that the personnel it authorises to give opinions and interpretations are competent to do so within the scope vested in them. Competence criteria should be established specifying qualifications, experience and knowledge required, in line with advice given in Notes 1 and 2 appended to clause 5.2.1 (ISO/IEC 17025). Competence criteria established by professional bodies, trade organisations, etc., may be used for these purposes.
- 6.14 Laboratories need to have procedures for ensuring that personnel authorised to make statements of opinions and interpretations maintain up to date their knowledge and understanding of the relevant technical issue.

ISO/IEC 17025 Clause 5.10.2

- 6.15 Test reports and calibration certificates will normally contain the factual results of the measurements performed unless the laboratory has a valid reason for omitting them. One example of this is where the client has specifically requested the laboratory to pronounce solely on whether or not the item tested is in compliance with a stated specification containing measurable criteria, without giving details. As such, and if based solely on objective evidence, these would not normally be regarded as opinions and interpretations. However, the laboratory needs to record those test results and maintain them for possible future reference for a period of time consistent with its record retention policy.
- 6.16 Normally reports contain results that relate only to the items tested or calibrated. Where opinions and interpretations are given that extrapolate those results beyond the item tested, for example where the item is a sample from a wider set, the laboratory should check that the extent of opinions and interpretations is consistent with that established in contract review (see paras 6.7 & 6.8 above) before issuing the report.

ISO/IEC 17025 Clause 5.10.4

- 6.17 Unless superseded by legal requirements ISO/IEC 17025 sub-clause 5.10.4.4 forbids calibration laboratories from recommending calibration intervals except where this has been agreed with the client. However, the laboratory may wish to draw the client's attention to the likelihood, based on previous records of drift characteristics, that the calibrated instrument may go out of specification on one or more parameters before the expected next calibration is due. In such cases the laboratory needs to take note of para 6.3 above.

ISO/IEC 17025 Clause 5.10.5

- 6.18 Where a laboratory gives opinions and interpretations on an item which has not been tested to its complete specification the report needs to carry a qualifying statement to the effect that “these opinions and interpretations have been derived from the results of a limited set of tests”, or similar wording. The report should state what tests have been performed as the basis for such opinions and interpretations.
- 6.19 Where a laboratory gives opinions and interpretations indicating that an item may meet a specification despite having failed one or more tests, it needs to give a clearly reasoned explanation as to how and why it has arrived at this conclusion. The laboratory should present the detailed test results in order to aid the client in assessing the validity of the opinions and interpretations given.
- 6.20 Where opinions and interpretations are communicated to a client by direct dialogue, this should be done by appropriately authorised personnel, and any written record of the dialogue should include the identity of the personnel involved.

ISO/IEC 17025 Clause 5.10.6

- 6.21 Additional care should be taken where reports contain opinions and interpretations which rely on results obtained from tests performed by subcontractors and/or data provided by the supplier of the test item. The documented records for such reports should clearly identify the source of data used in forming opinions and interpretations, and the steps taken by the laboratory to establish their validity. The requirements of ISO/IEC 17025 clause 4.5 also apply.