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LAB 13

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UKAS Guidance on the Application of ISO/IEC 17025:2017 Dealing with Expressions of Opinions and Interpretations

Contents

Changes since last edition

Updated to reflect the publication of EA-4/23 INF, replacing EA-INF/13. Expansion of Introduction section to clarify the difference between statements of conformity and opinions and interpretations.

Clarification that reports must show that the opinions and interpretations relate only to the items tested / calibrated.

Inclusion of internal audit evidence to be submitted as part of application documentary pack to be provided for review.

1. Introduction

ISO/IEC 17025:2017 contains the requirements that testing and calibration laboratories have to meet if they operate to a quality system, are technically competent and are able to generate technically valid results. Section 7.8.7 of that standard details the requirements on expressing opinions and interpretations which includes the following note: “It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in ISO/IEC 17025: 7.8.6.”

2. Policy

2.1 It is UKAS policy that laboratory accreditation to ISO/IEC 17025:2017 may include the expression of opinions and interpretation of test/calibration results in reports.

2.2 In most cases 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. Some analysis scenarios will have opinions and interpretations as an integral part of the process e.g. they cannot be accredited to ISO/IEC 17025:2017 without opinions and interpretations. As such when these methods are assessed, opinions and interpretations assessment criteria will be included as standard practice. This should be included in the application form (prefix AC) and discussed with your Assessment Manager at the time of application.

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.

2.4 It is necessary to ensure that the scope of use of opinions and interpretations is clearly defined. The main criterion that applies is as follows:

The opinions and interpretations expressed in test / calibration reports must be based on the test results obtained from the tested / calibrated item. Reports including opinion and interpretation shall explicitly state that they relate to the specific item under test or calibration. They are not to be used for product certification as they only input to that process.

3. Application for accreditation

3.1 A laboratory that is already accredited for test/calibration can 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.

3.4 Where an accredited laboratory reports a conformity / nonconformity statement along with the test result this is not regarded as being part of opinions and interpretations. The reporting of conformity / nonconformity with particular requirements is a general reporting activity that is covered in detail in ISO/IEC 17025:2017 (clause 7.8.6).

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.

(e) Internal audit plan and records to demonstrate that the opinion and interpretation process is robustly monitored by the organisation

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) Using other appropriate assessment techniques.

5. Accreditation

5.1 ISO/IEC 17025:2017 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 interpretation 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 As an accreditation body, UKAS has a duty to ensure that opinions and interpretations on test and calibration reports are not implied to be, or used as, a substitute for product certification. The results of a sample test alone, even with an opinion, can never be a viable substitute for factory production

control assessment or in lieu of other features required in a product certification scenario, and so cannot act as product certification in its own right. A test report may be one of several inputs to product certification. EA-4/23 INF contains information with regards to acceptable and non-acceptable scenarios for opinions and interpretations.

5.3 The UKAS accreditation schedule will reflect which test or calibration activities a laboratory has been successfully assessed and accredited to provide opinions and interpretations for. EA-4/23 INF (appendix B) details two ways in which the scope of accreditation can be clearly marked to show tests that are accredited for opinions and interpretations.

As detailed earlier, some testing does inherently contain the need for opinions and interpretations, and this is assessed as part of the testing aspects under ISO/IEC 17025:2017. The schedule of accreditation will need to clearly show what aspects are included, for example if an organisation is involved with fingerprint enhancement and comparison then it will need to be clear on the schedule that the comparison aspects do have opinions and interpretations accreditation, the enhancement activity is separate with no requirement for opinion and interpretation accreditation.

5.4 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 17025:2017

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

6.2 **ISO/IEC 17025:2017 Clause 4.1 Impartiality**

This clause of the standard has some implications that must be considered when assessing opinions and interpretations. There will be risks to consider, e.g. *are there any connections that would benefit from certain opinions related to test results? Are staff, who give opinions on forensic analysis, related to offenders?* The assessment team will need to be assured that all risks have been identified and there are plans in place to prevent these risks from affecting the outcome.

6.3 **ISO/IEC 17025:2017 Clause 4.2 Confidentiality**

This clause of the standard is not specific to opinions and interpretations and is included to ensure the confidentiality of the customers that use the testing service. Any legally enforceable commitments will need to apply across subcontractors if used to give opinions and interpretations. Clause 4.2.2 may well have some implications with forensic cases and this will need to be assessed on a case by case basis.

6.4 **ISO/IEC 17025:2017 Clause 5.1 to 5.6 Structural requirements**

The laboratory's policies and procedures for making statements of opinions and interpretations need to be documented within the quality system to the extent necessary to meet the requirements of the standard and its customers. 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, conformity 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.

The management structure needs to clearly define how the organisation operates and how management, technical operations and support aspects are interlinked; opinions and interpretations could be affected by these links.

6.5 **ISO/IEC 17025:2017 Clause 6.2 Personnel**

Impartiality is emphasised again at the start of this section; competence requirements shall be documented for those activities that influence the results and opinions and interpretations fits into this category. There will be a need for specific procedures and records to demonstrate how competence requirements are determined as well as competence monitoring, authorisation and training. There will need to be specific authorisation records for personnel that give opinions and interpretations

6.6 **ISO/IEC 17025:2017 Clause 6.6 Externally provided products and services**

This only pertains to opinions and interpretations if the service is being supplied by a subcontracted individual. If this is the case, then the resource requirements as detailed in the organisations procedures will need to be applied to the subcontractor. There needs to be clear communication to the external resource as to the service that is required.

6.7 **ISO/IEC 17025:2017 Clause 7.1 Review of requests, tenders and contracts**

This clause relates 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.

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.

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 17025:2017.

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.

Clause 7.1.3 is only related to statements of conformity which are not classed as opinions and interpretations (see EA-4/23 INF).

6.8 **ISO/IEC 17025:2017 Clause 7.5 Technical records**

Opinions and interpretations statements related to the test data in reports must be traceable to the raw data and the personnel involved through the process will be identified in the technical records; this will include the persons that are interrogating the data and making opinions and interpretations.

6.9 **ISO/IEC 17025:2017 7.8 Reporting of results**

EA-4/23 INF goes into some detail with regards to the limitations of opinions and interpretations. The opinions and interpretations expressed in test / calibration reports must be based on the test results obtained from the tested / calibrated item. They are not to be used for product certification as they only input to that process. The accredited laboratory that has carried out the test / calibration can therefore give any opinions and interpretations based on the result that has been produced and add this to the test report. It must be made clear that the opinions and interpretations given are based on the results of the item tested and that the information cannot be used as product certification alone for any product / item that has not been tested.

It must be clear that whatever way of reporting is agreed with the customer, any data that is not reported, but is a product of the testing and opinions and interpretations, must still be available and controlled so that it can be retrieved if needed.

Unless superseded by legal requirements, ISO/IEC 17025:2017 clause 7.8.4.3 forbids calibration laboratories from recommending calibration intervals except where this has been agreed with the customer. However, the laboratory may wish to draw the customer'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 make sure that they are following due diligence and ensuring professional integrity is maintained.

Clause 7.8.7 is specifically targeted at opinions and interpretations reporting. Only the authorised personnel can release the opinions and interpretations statement, and the accredited organisations management system must detail the basis upon which the opinions and interpretations have been made, this is where the technical records control and traceability will need to be well managed.

If the opinions and interpretations is verbal to the customer, again, there will need to be a record of this kept by the CAB to ensure traceability of the information supplied.

6.10 **ISO/IEC 17025:2017 Clauses 7.9 Complaints, 7.10 Nonconforming work**

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. This can be via external means (customer / end user) or through internal quality control / management mechanisms.

6.11 **ISO/IEC 17025:2017 Clause 8.8 Internal audit**

Where a laboratory undertakes to make statements of opinions and interpretations the internal audit system must demonstrate coverage of this process either in the method specific audits or as part of the management system coverage. Competence and basis for opinion and interpretation will need to be included.

6.12 **ISO/IEC 17025:2017 Clause 8.9 Management review**

Although not a specific area as listed in the standard, there would be some evidence in the management review that risk of opinions and interpretations has been considered and is continually reviewed. General competence and resource will also include these aspects. You would expect to see that opinion and interpretation is detailed and discussed at some point in the management review process.