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**The Assessment
And Accreditation of
Opinions and Interpretations
Using ISO/IEC 17025:2005**

PURPOSE

The aim of this document is to promote harmonization between accreditation bodies on how opinions and interpretations should be assessed and how the accreditation of opinions and interpretations may be expressed and communicated to potential customers. The document also provides guidance on the extent to which opinions and interpretations can be used by accredited organisations.

Authorship

The publication has been prepared by a working group formed of members of the laboratory committee with stakeholders.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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1. INTRODUCTION

This document has been produced following extensive discussions and consultations by a joint stakeholder working group set up by the Laboratory Committee. The need for a harmonised approach across Europe, not only in the reporting of opinions and interpretations (O&I), but also for the level of assessment to ensure that O&I cannot be misunderstood by the clients of the CAB offering this accredited service is required.

Note: It is not intended for this document to be applicable to medical laboratories accredited to ISO 15189 although the guidance given may well be useful for any AB that is involved with the assessment of medical laboratories.

ISO/IEC 17025:2005 *General requirements for the competency of testing and calibration laboratories:*

- Clause 5.10.5: *when opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.*
- Note 2 Clause 5.2.1: *The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:*
 - *Relevant knowledge of the technology used for the manufacturing of the items, materials, products etc tested, or the way they are used or intended to be used, and the defects or degradations which may occur during or in service.*
 - *Knowledge of the general requirements expressed in the legislation and standards: and*
 - *An understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.*

ISO/IEC 17011:2004 *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies:*

The standard to which EA MLA signatories are required to operate, states in the introduction that a “cross border” trade facilitating system can work well if accreditation bodies and CAB’s all operate to globally accepted requirements in an equivalent manner and take into account the interests of all parties concerned.

2. GENERAL PRINCIPLES

If accreditation is sought for opinions and interpretations the Accreditation Body has a responsibility to ensure that any request for such assessment is accommodated. This enables laboratories to compete for work across Europe if required whilst being accredited only by their local accreditation body as described in EU regulation 765/2008

All aspects of the arrangements for O&I shall be documented by the laboratory including the boundaries of the offering, the contract review mechanisms, staff, competencies, methods for reporting the O&I and the record keeping.

The accreditation body shall assess any O&I work and report it clearly and distinctively as part of the process for the accreditation of the laboratory. The assessment shall include the performance of O&I in the laboratory and the study of past work. It is important that the customers of the accredited CAB’s are aware of the scope of accreditation provided. The AB

providing the accreditation should ensure that opinions and interpretations are shown on schedules of accreditation, scopes or annexe to certificates of accreditation in the same way as other optional parameters within ISO17025.

3. DEFINITION

Dictionary definitions of opinion and interpretation vary across Europe and to ensure that the phrase is used in a consistent manner the following definition shall be used for the purposes of accreditation:

Opinion and interpretation is the process by which the applicability of a result of a test or calibration may be extended. It is assessed by a technically qualified person / organisation and further inferences are made based on the result produced, using knowledge and professional judgement of the person / organisation in the area of testing / calibration being undertaken. The opinion and interpretation made should be technically sound and supported by definitive evidence.

4. OPINION AND INTERPRETATION – SCOPE OF USE

ISO/IEC 17025 clearly states in Note 1 under sub clause 5.10.5 that *Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065.*

It is necessary to ensure that the scope of use of O&I are 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. They are not to be used for product certification as the only input to that process.

The accredited laboratory that has carried out the test / calibration can therefore give an O&I based on the result that has been produced and add this to the test report. It must be made clear that the O&I given is 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..

Where an accredited laboratory reports a compliance / non-compliance remark along with the test result this is not regarded as being part of O&I. The reporting of compliance / non-compliance with particular requirements is a general reporting activity as detailed in ISO/IEC 17025:2005 (clause 5.10.3.1 (b)).

APPENDIX A includes examples of possibly acceptable and unacceptable scenarios for opinions and interpretations. This is not an exhaustive list but covers a range of scenarios that could be encountered.

NOTE: The examples are guidance and there may well be other factors that need to be considered to ensure that the opinions and interpretations are valid

5. MANAGEMENT SYSTEM

It is the responsibility of individual laboratories to review the areas they are likely to want to make statements of O&I 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.

The management system of the laboratory must clearly detail the policies and procedures related to O&I for which it is accredited. This should include the following:

- 1) Documents reflecting the process that leads to inclusion of O&I in test / calibration reports
- 2) Criteria for competence of personnel authorised to express O&I
- 3) Records of qualifications, experience and training of personnel authorised to express O&I
- 4) Internal audit records to demonstrate that the O&I is being robustly monitored by the organisation.

6. CONTRACT REVIEW

The extent to which O&I are required by the customer should be clearly defined at the contract review stage. The contract review procedure needs to cover the following:

- 1) Confirmation that the client's needs and wishes have been understood with respect to any statements of O&I,
- 2) Whether such statements are appropriate within the laboratory's accredited scope,
- 3) That the client has understood and accepted the implications of such statements,
- 4) That the laboratory has the necessary professional competencies authorised to make such statements,
- 5) That any legal requirements are understood and can be complied with.
- 6) That the O&I given cannot be used for product certification in isolation and are based on the results of the items / products tested.

The laboratory needs to maintain records of contract reviews in line with its general policies on record keeping.

7. PERSONNEL

The qualifications, experience and training of staff that are involved in formation of opinions and interpretations will vary from sector to sector, however there are a few minimum criteria that should be in place.

All staff involved will require a training record with competence criteria set for the area of expertise. If the level is just to state compliance / non-compliance with requirements then as previously stated this would not fall under O&I. A full knowledge of the analytical method, the measurement uncertainty and appropriate standards would suffice and this information would be readily available under the overall laboratory competence that would be required.

If the level of opinion and interpretation is more about the use of the item or result then there will be a need for a more extensive qualification record that would include but not be limited to the following details:

- 1) Experience in particular sector
- 2) Full qualifications record detailing career to date
- 3) Continuing Professional Development records (CPD) to demonstrate how the individual has kept up to date with changes in the particular sector for which opinions and interpretations are given.
- 4) Examples of past work in the required field of expertise.

8. ACCREDITATION BODY REQUIREMENTS

The following guidance is aimed at ensuring a visible and consistent way of assessing and displaying the accreditation of opinions and interpretation across Europe.

The accreditation body is assessing and accrediting the competence of and the process by which CABs are arriving at the opinions and interpretations made. The opinion or interpretation produced is not being accredited. Assessment shall confirm that the management system processes in place and are being effectively implemented.

All Accreditation Bodies need to ensure that they do not allow CABs to use opinions and interpretations 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, of course be one of several inputs to Product Certification.

To aid the customers of CABs that are looking for accredited O&I it would be of benefit for the accreditation to be shown on the schedules of accreditation (if used) or shown on the certificate of accreditation.

If this is not the preferred option of the accreditation body then the extent of O&I across the CAB will need to be clearly understood and the contract review aspects of assessment thoroughly examined to ensure that the process is being well managed.

APPENDIX B shows two ways in which the scope of accreditation can be clearly marked to show tests that are accredited for O&I, there are also further scenarios that may be of use to accreditation bodies

APPENDIX A.

The following scenarios show examples of acceptable and of unacceptable O+I scenarios.

1. A forensic laboratory analyses a garment worn by a victim with a cut through the fabric and a knife found at the scene of the crime. The laboratory reports the findings of the analysis and gives an O&I that the knife found at the scene of the crime could have caused the cut in the jumper:

This is a valid use of opinions and interpretations as the opinion / interpretation given only relates to the items tested.

e.g the cut pattern in the jumper was consistent with the knife blade, there could well be other factors involved, for example the angle of attack etc. and this would be established by somebody with in-depth knowledge of this type of incident using data to make a professional judgment.

2. A sample of soil from an agricultural field has been submitted for analysis. The sampling of the soil was done by an accredited sampling facility that has demonstrated that they can take a representative sample. Analysis is carried out for levels of Nitrogen and microbiological activity in the soil which can be compared with tabulated values which indicate whether the field is fit to grow a certain crop. The laboratory compares the result with the tabulated value and the report shows that it has passed the criteria as listed in the documented table.

This first part of the report is just a statement of conformance with requirements and could be seen as an interpretation of the results produced, this does not need any special training as such and currently this is done by many laboratories without accreditation for opinions and interpretations

The report then also contains a statement from the laboratory that due to the levels of nitrogen and microbiological activity found and the use of other supporting data the field is likely to be able to support growth of the certain crop for another two years before levels are depleted and fertiliser will be required.

This second part of the report is an O&I of the result in the representative sample of that field and as such is a justified use of the opinions and interpretations clause in ISO/IEC 17025. In effect the field has been sampled and so the result is actually for the field and hence an opinion / interpretation made. It will be down to the CAB to justify its approach to this O&I, for example what expertise has been used? What factors have been considered? What is the field used for etc etc. it may be that the evidence to support this O&I is not sufficient and therefore the process used by the CAB not robust enough to be accredited.

3. A metal bolt is analysed by the laboratory for tensile strength and the results reported to the customer. The report also contains an opinion / interpretation from the laboratory that the results demonstrate the process for producing the bolts is well controlled and product certification should be recommended.

The opinion / interpretation included in this report is not valid as it is not solely related to the sample, the reference to product certification cannot be made as the production processes have not been fully assessed. This example demonstrates that it is not possible for a testing laboratory to indicate product certification from the analysis of one sample when they have no knowledge of the production process information

4. A laboratory has tested a door lock which is a right handed version. It wishes to report that the results also apply to a left handed lock.

This would not be acceptable as the result applies in any case only to the sample tested, and would not be valid for any other sample of the lock left or right handed.

Any opinion about the validity of the result for any other sample of a lock would be a product certification exercise to be undertaken by a product certification body using inputs including the test report but also including information about factory conditions.

It would be possible to make an opinion that “had this sample been configured as a left handed version that the same test results would pertain”, if that were the case.

This is quite different from stating that further samples would have the same results and clearly illustrates the difference between the testing of samples and Product Certification

5. A tin of paint has been tested in a laboratory. The customer later in time asks for a further report bearing a different identification mark.

This would not be appropriate as the test results relate to an earlier sample and the testing laboratory has no knowledge of any factory production controls, material input changes or other factors. It should neither issue a further report nor pass an opinion about any other paint production. Such statements and/or risks are to be borne by the manufacturer or by a Product Certification Body

6. A laboratory is asked to report that the paint is also sold under different brands or trade names and that the results also apply to those.

The laboratory should report the identification and labelling of the sample tested. It is for the manufacturer or a Product Certification Body to make assertions about alternative branding and about future production. No opinions about other tins of paint would be valid, unless there were additional inputs concerning factory production controls and other factors. This would then be a product certification exercise. It may be possible to pass the opinion that “had the sample tin been labelled with X rather than Y, this would not have affected the results.

APPENDIX B.

- i) Example of scope that has limited accreditation for O&I

Joe Bloggs Environmental analysis			
007 Bond Street London United Kingdom			
Schedule No. 1234			
The processes by which Opinions and Interpretations are formulated for the effects of chemicals in the environment have been accredited for a number of tests listed in the following scope. The tests that are included in the accreditation have YES entered in O&I column of this scope.			
Material / Matrix	Activity	Method reference	O&I
Soil and sediment	Metals analysis: Fe, Ni, Pb, Sn, As	AB 221 by microwave digestion and ICP-MS	YES
Soil and sediment	Fluoride	AB112 using ISE	
Ground water	pH	AB 190 using meter	YES
Ground water	Conductivity	AB 243 using meter	
Ground water	Pesticides: Isodrin Eldrin	AB 542 using GCMS	
Ground water	Phosphate Nitrate Nitrite	AB 177 using discrete analyser	YES

- ii) Example of scope that has O&I accreditation for all matrix types and tests listed on the scope of accreditation:

Joe Bloggs Environmental analysis		
007 Bond Street London United Kingdom		
Schedule No. 1234		
The processes by which Opinions and Interpretations are formulated for the effects of chemicals in the environment have been accredited for all of tests and matrix combinations listed in the following scope.		
Material / Matrix	Activity	Method reference
Soil and sediment	Metals analysis: Fe, Ni, Pb, Sn, As	AB 221 by microwave digestion and ICP-MS
Soil and sediment	Fluoride	AB112 using ISE
Ground water	pH	AB 190 using meter
Ground water	Conductivity	AB 243 using meter
Ground water	Pesticides: Isodrin Eldrin	AB 542 using GCMS
Ground water	Phosphate Nitrate Nitrite	AB 177 using discrete analyser

iii) The scope / certificate of accreditation have a separate section that details the extent of the opinions and interpretations that will be given under accreditation. This would not necessarily show the individual tests that are covered but would be a more general outline that will give the customers of the CABs an overview. This will also help the NAB to organise the assessment of the CABs as it will be easy to see at a glance what resource is required prior to each assessment.

e.g. The laboratory has an accredited system for give opinions and interpretations based on the accredited results of microbiological tests and forensic tests performed at these facilities by competent personnel.

- iv) The personnel that had been assessed as competent to give opinions and interpretations are detailed on the scope / certificate of accreditation as well as or instead of the general statement. This could be by name or possibly by post within the organisation. If this option is chosen then the assessment of opinions and interpretations would be personnel based. (section 5.2.1 Note 2 of ISO 17025:2005)