EUROPEAN ACCREDITATION

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The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2017

PURPOSE

The aim of this document is to promote harmonization between National Accreditation Bodies (NABs) 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.

Further information
For further information about this publication, contact your national member of EA or the Chairman of the EA Laboratory Committee.

Please check our website for up-to-date information http://www.european-accreditation.org/

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CONTENTS

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 aim is to promote a harmonised approach across Europe, not only in the reporting of opinions and interpretations, but also for the level of assessment to ensure that opinions and interpretations cannot be misunderstood by the clients of the Conformity Assessment Body (CAB) offering this accredited service.

NOTE: It is not intended for this document to be directly applicable to healthcare diagnostic services accredited to ISO 15189 although the guidance given may well be useful for any NAB that is involved with the assessment of medical laboratories.

ISO/IEC 17025:2017 *General requirements for the competency of testing and calibration laboratories:*

- *Clause 6.2.6: The laboratory shall authorise personnel to perform specific laboratory activities, including but not limited to, the following:*
  b) Analysis of results, including statements of conformity or opinions and interpretations

- *Clause 7.8.7 Reporting opinions and interpretations*

  7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

  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 7.8.6.

  7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

  7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

ISO/IEC 17011:2017 *Conformity assessment – 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 system to accredit conformity assessment bodies is intended to provide for a consistent application of conformity assessment to international consensus-based standards and conformity assessment schemes, in order to benefit public health, safety, environment and welfare and support regulators and end users. It can facilitate national and cross-border trade, as pursued by trade authorities and organizations.*

2 GENERAL PRINCIPLES

If the accredited activity includes opinions and interpretations the National Accreditation Body has a responsibility to ensure that this is assessed in line with ISO/IEC 17025:2017 requirements. This enables laboratories to compete for work across Europe, if required whilst being accredited only by their local National Accreditation Body as described in Regulation (EC) No 765/2008.

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

The National Accreditation Body shall assess any opinion and interpretation work that is communicated to the customer as part of an accredited activity and report it clearly and distinctively as part of the process for the accreditation of the laboratory. The NAB providing the accreditation could show the extent of opinion and interpretation on schedules of accreditation, scopes or annexe to certificates of accreditation in the same way as other optional parameters within ISO/IEC 17025:2017 (see Appendix B for examples).

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 outcome of a process by which the applicability of a result of a test or calibration may be extended. it is formulated 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 evidence.

4 OPINION AND INTERPRETATION – SCOPE OF USE

ISO/IEC 17025:2017 clearly states in the Note under sub clause 7.8.7.1 that *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 7.8.6*.
It is necessary to ensure that the scope of use of opinion and interpretation are clearly defined. The main criterion that applies is as follows:

The opinion and interpretation expressed in test / calibration reports must be based on the test results obtained from the tested / calibrated item.

The accredited laboratory that has carried out the test / calibration can therefore give an opinion and interpretation based on the result that has been produced. reports including opinion and interpretation shall explicitly state that they relate to the specific item under test or calibration.

Statements of conformity are not considered as opinion and interpretation since they are based on unambiguous data and clarified by decision rules (ISO/IEC 17025:2017 (clause 7.8.6)).

APPENDIX A includes examples of possibly acceptable and unacceptable scenarios for opinions and interpretations

NOTE: The examples are guidance and there may well be other factors that need to be considered to ensure that the opinion 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 opinion and interpretation in test reports or calibration certificates, and to act accordingly. This policy shall be clearly stated within the laboratory's management system documentation.

As stated above the management system of the laboratory must clearly detail the policies and relevant procedures related to opinion and interpretation if the laboratory includes opinion and interpretation in what it reports to the client. This should include the following:

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

6 CONTRACT REVIEW

The extent to which opinion and interpretation 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 opinion and interpretation,
2) That the client has understood and accepted the implications of such statements,
3) That the laboratory has the necessary professional competencies authorised to make such statements,
4) That any legal requirements are understood and can be complied with,
5) That the opinion and interpretation 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.

For staff to be deemed competent to give opinion and interpretation a more extensive qualification record to confirm the professional status of the individual or organisation should be in place. This 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 NATIONAL 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 the competence of and the process by which CABs are arriving at the opinions and interpretations made. Assessment shall confirm that the management system processes in place and are being effectively implemented.

All National 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 opinion and interpretation 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 opinion and interpretation 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 could be marked to show accredited tests that include opinion and interpretation, there are also further scenarios that may be of use to accreditation bodies. it is not a requirement that scopes identify which tests include opinion and interpretation, but it can be useful to customers that are looking for this before contacting the CAB.

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 opinion and interpretation 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 conformity 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 opinion and interpretation 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 opinion and interpretation, for example what expertise has been used? What factors have been considered? What is the field used for? etc. It may be that the evidence to support this opinion and interpretation 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 and 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 and may wish to issue reports for other product versions not tested.
   A test report applies only to the sample tested so it would be incorrect to issue test reports for any other samples or versions. Certification of a range would be a product certification exercise possibly aided by a test report on a sample containing an opinion about the applicability of the results to other samples or versions.
   Any opinion about the validity of the result for any other sample of a lock would aid a product certification exercise to be undertaken by a product certification body (or the manufacturer making a self-declaration) using inputs including the test report but also including other 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, or wrongly issuing numerous reports with different identifications 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.

7 A laboratory analyses a metal bar that has been produced to a certain specification. there are limits set for the content of the metal bar for chromium and cobalt and the laboratory analyses for these elements. The maximum level of chromium is set at 17% and for cobalt 32%. The laboratory results are 16% for chromium and 34% for cobalt. They have decision rules in place that state if the final result is within $\pm$ 3% of the target value then a pass will be reported. The technician uses this rule and states in the report that both chromium and cobalt have passed according to the decision rules.
   In this example the technician has not had to interpret the results with regards to how they can be used or provide any sort of opinion. They have just looked at the results, used the decision rules and reported as detailed in the laboratories procedures. The customer will be fully aware of the decision rules used as the contract will clearly state them. This is not an opinion and interpretation; it is just a calculated conformity statement necessitating no professional judgement.

8. An expert calibration laboratory wishes to advise a customer about the possible use of a calibrated item. The calibration laboratory has many years' experience in applications for different types of thermometer. It has calibrated the customer's liquid in glass thermometer and advises the customer that a calibrated such thermometer, found to be reading correctly at time of calibration is likely to be stable for many years if handled correctly and that it is suitable for use in damp or dirty conditions which environment might be unfavourable for electronic sensor type thermometers. **Such opinion is often accompanied by advice on use, cleaning and storage. This is a valid use of opinions and interpretations based on the calibration undertaken, the type of equipment and the experience of the laboratory.**

9 A calibration laboratory has been requested and has agreed to make a 3-point calibration on a device known to the calibration laboratory to be notably nonlinear in its performance. **The laboratory undertakes the calibration and supplies the results for the three levels requested. It also provides the opinion that the customer would be well advised to never extrapolate the results beyond the range and to apply extra uncertainty to any use at values in between those calibrated. This is also a valid use.**

10 A calibration laboratory is asked to provide 1000 copies of a calibration certificate for one sample of a measuring equipment it has calibrated. The laboratory establishes from the customer that this is because they are going to supply a copy with every such device leaving their production line. After extensive discussion the calibration laboratory is asked to either remove the serial number from the certificate or to make an opinion on the certificate that all examples of this model are likely to have the same calibration performance. The laboratory declines because they do not have any knowledge of the production consistency of the factory and because to omit the serial number would aid and abet misuse of a calibration certificate as being product certification. **This is a compliant calibration laboratory that has not provided information that could mislead the customers.**

APPENDIX B.

i) Example of scope that has limited accreditation for opinion and interpretation:

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 opinion and interpretation column of this scope.

material / matrix	activity	method reference	opinion and interpretation
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 opinion and interpretation 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 has 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 6.2.6 (b) and 7.8.7.1 of ISO/IEC 17025:2017)