EUROPEAN ACCREDITATION

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The Assessment and Accreditation of Opinions and Interpretations using EN 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 customers of a laboratory offering this service under accreditation.

This document is intended to provide guidance on the expression of opinions and interpretations in fields where no sector-specific standards or normative documents are available. In cases where sector-specific standards or normative documents exist, those should be used as the primary reference.

For guidance on opinions and interpretations in forensic science activities see:
ISO 21043-4 Forensic sciences – Part 4: Interpretation and ISO 21043-5 Forensic sciences – Part 5: Reporting.

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

EN ISO/IEC 17025:2017 *General requirements for the competence 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.

EN 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 scope includes opinions and interpretations the National Accreditation Body has a responsibility to ensure that this is assessed in line with EN 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 opinions and interpretations shall be documented by the laboratory including the boundaries of the offering, the contract review mechanisms, staff, competencies, methods for reporting the opinions and interpretation and the record keeping.

The National Accreditation Body (NAB) providing the accreditation of opinions and interpretations shall assess laboratory's competence with respect to any kind of opinion and interpretation that is communicated to the customer as part of an accredited activity. This assessment shall be documented and reported clearly and distinctively as part of the process for the accreditation of the laboratory. The NAB providing the accreditation should show the activities covered by opinions and interpretations on scopes of accreditation, annexes to certificates of accreditation (see Appendix B for examples). Even if the NAB deems opinions and interpretations as something that is assessed routinely it should still be clear in the scope of accreditation issued by the NAB what activities can include opinions and interpretations.

Opinions and interpretations may well be given under accreditation even if the accredited laboratory uses an external supplier to carry out some of the testing in the same technical field; In the case for a laboratory that is accredited for stand-alone sampling, opinions and interpretations may well be given under accreditation even if the accredited laboratory does not carry out the tests and uses an external provider to perform the test. Competence and knowledge of the testing and its impacts would need to be demonstrated by the laboratory.

For accredited opinions and interpretations to be expressed there must be an unbroken chain of accreditation, the laboratory giving the opinions and interpretations will be accredited to EN ISO/IEC 17025:2017 and must make sure that the externally provided service was performed as an accredited activity (was reported by the provider with reference to accreditation). There is no circumstance in which a laboratory can be accredited for opinions and interpretations as a stand alone activity

3. DEFINITION

Dictionary definitions of opinions and interpretations 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:

Opinions and interpretations are the outcome of a process where one or more results of a test or calibration activity are extended beyond the scope of the result or the item under investigation. 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 activity being undertaken. Opinions and Interpretations may not include numerical use of the uncertainty of the measurements, any decision rule or numerical level of risk but understanding and considering uncertainty of results used must be assured as appropriate. They may be based on past experience of the technically qualified person, similarity of results or any other technically sound and supported evidence deemed necessary. For the purpose of EN ISO/IEC 17025:2017 application, opinions and interpretations are considered to be synonyms.

4. OPINIONS AND INTERPRETATIONS – SCOPE OF USE

EN 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 EN ISO/IEC 17020 and EN ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6*.
It is necessary to ensure to what an opinions and interpretations is referred to. The main criterion that applies is as follows:

The opinions and interpretations expressed in (test, calibration or sampling) reports must be based on the results obtained from the tested / calibrated item and must be clearly identified as such.

The accredited laboratory that has either carried out the laboratory activities or has used the accredited results can give opinions and interpretations based on the result that has been produced. (Test, calibration or sampling) reports including opinions and interpretations shall explicitly state that they relate to the specific item under test or calibration.

Statements of conformity are not considered as opinions and interpretations since they are based solely on comparisons against defined limits and applying specific decision rule.

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 opinions and interpretations are valid.

5. MANAGEMENT SYSTEM

It is the responsibility of individual laboratory's to define the areas they are likely to want to offer opinions and interpretations in (test, calibration or sampling) reports or (calibration) certificates, and to act accordingly. This 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 opinions and interpretations if the laboratory includes opinions and interpretations in reports or certificates. This should include the following:

1) Documents reflecting the process that leads to inclusion of opinions and interpretations in (test, calibration or sampling) reports or (calibration) certificates, including documentation related to the basis upon which opinions and interpretations are made
2) Criteria for competence of personnel authorised to express opinions and interpretations,
3) Records of qualifications, experience and training of personnel authorised to express opinions and interpretations,
4) Internal audit records to demonstrate that the opinions and interpretations are being robustly monitored by the organisation
5) Mechanisms to demonstrate that there is consistency among all qualified personnel when assessing the same input results.

6. CONTRACT REVIEW

The extent to which opinions and interpretations are required by the customer should be clearly defined at the contract review stage. The contract review procedure needs to cover and ensure that:

1) the customer's needs, requests and requirements have been understood with respect to any reporting of opinions and interpretations,
2) the customer has understood and accepted the implications of such reporting of opinions and interpretations,
3) the laboratory has the necessary professional competencies authorised to make such opinions and interpretations,
4) any legal requirements within the area for which opinions and interpretations are expressed are understood and can be complied with,
5) opinions and interpretations 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 expression of opinions and interpretations will vary from sector to sector.

All staff involved will require a training record with competence criteria set for the area of expertise.

In order for staff to be deemed competent in issuing opinions and interpretations, a more comprehensive record is required regarding professional experience in the field for which opinions and interpretations are issued. 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. GUIDELINES FOR NATIONAL ACCREDITATION BODIES

The following guidance is aimed at ensuring a transparent and consistent way of assessing the accreditation of opinions and interpretations across Europe. In addition, this guidance also provides further orientation to make accreditation of these activities more visible in the accreditation scopes.

The accreditation body is assessing the competence of and the process by which laboratory's are arriving at the opinions and interpretations made. Assessment shall confirm that the management system processes are in place and are being effectively implemented.

All National Accreditation Bodies need to ensure that they do not allow laboratory's to use opinions and interpretations as a substitute for product certification. The results of a sample test alone, even with an opinion and interpretation, 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 laboratory's that are looking for accredited opinions and interpretations it would be of benefit for the accreditation to be shown on the scopes of accreditation or shown on the certificate of accreditation (if used).
If this is not the preferred option of the accreditation body, then the extent of opinions and interpretations across the laboratory 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 drafted to make clear in which field and for which tests opinions and interpretations are offered under accreditation.
Other scenarios may also be used by accreditation bodies.
It is not a requirement that scopes identify explicitly for which tests opinions and interpretations are offered under accreditation, but it would be useful to customers specifically looking for this.

APPENDIX A

The following scenarios show acceptable, unacceptable and good practice examples of the use of opinions and interpretations, dependant on the competence demonstrated.

Acceptable scenarios:

1. **Environmental Sampling/Testing**
   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 a statement of conformity
   The report then also contains an opinion and interpretation 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 a justified use of the opinions and interpretations clause in EN ISO/IEC 17025:2017. It will be down to the laboratory 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 laboratory not robust enough to be accredited.

2. **Fire Classification / Extended application**
   A laboratory has carried out reaction to fire testing on wooden doors to the requirements of EN 13501 under its EN ISO/IEC 17025:2017 accreditation. The test reports are then used to produce a fire classification report for the specific product.
   The customer has requested that they require the results of the testing to be extended to other types of doors in line with the criteria for extending application of the original fire classification report which based on the product tested.
   As the laboratory has carried out the original testing to the requirements of EN ISO/IEC 17025:2017 they agree to this request and using their knowledge of the testing completed and other aspects they look to follow the details related to extended application for reaction to fire as detailed in CEN TS 15117 - Guidance on direct and extended application, which is referenced in EN 15725:2023 - Extended application on the fire performance of construction products and building elements: Principle of EXAP standards and EXAP reports. They ensure that the appropriate test results are applicable and suitable for extending the application to doors with greater thickness to the one that is tested and supply an accredited extended application report in line with the opinions and interpretations clause of EN ISO/IEC 17025:2017 and the requirements as laid out in the extended application standard.
   This is an acceptable use of opinions and interpretations as the accredited laboratory is carrying out the extended application based on the test results that have been deemed

suitable based on their knowledge of the testing required and in line with CEN TS 15117 that is detailed in EN 15725:2023

3. **Thermometer Calibration:**
   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 thermometer of this type, found to be reading correctly at time of calibration is likely to be stable for many years if handled correctly. They also state that it is suitable for use in damp or dirty environments which might be unfavourable for electronic sensor type thermometers. Such opinion and interpretation 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. Opinions and interpretations are not to be used to give recommendations on calibration intervals (unless this has been agreed with the customer)

4. **Non-Linear Calibration:**
   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 and interpretation 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.

5. **Anti-Doping - Toxicology:**
   Just after a competition at the international level, an athlete was notified by a doping control officer that he was selected for doping control (testing).
   He reported to the doping control station immediately where a urine sample was collected (divided into two bottles: A and B).
   The athlete sealed the bottles and completed the appropriate form. He was asked to provide personal information, a list of substances or methods used, and any comment he may have related to the doping control process.
   The sealed sample was secured and sent to an accredited laboratory. The paperwork that accompanies the sample was anonymized, indicating only the sample bottle number, sport and the athlete's gender.
   The test performed on the urine contained in bottle A showed the presence of a prohibited substance: Clenbuterol.
   The accredited laboratory reported the test and the Testing Authority asked for an Opinion and Interpretation, then the laboratory made the following statement:
   "Laboratory opinion and interpretation: Atypical finding, it is recommended that the results are investigated with regards to the potential consumption by the athlete of contaminated meat"
   This opinion and interpretation seeks to address the fact that, as mentioned in reference document several of these substances may be used as growth promoters for livestock in some countries and therefore may be associated with findings resulting from the consumption of contaminated meat (like Clenbuterol used in China, Guatemala and Mexico, for cattle, lamb, poultry, and swine)

6. **Stand-alone sampling:**
   An organisation that is accredited to EN ISO/IEC 17025 for taking body fluid / tissue samples takes swabs from a person in line with their accredited procedures for paternity sampling. They then send these samples for analysis to an accredited testing laboratory for Short tandem repeat (STR) profiling for relationship testing. The method used on this occasion was automated extraction followed by manual amplification and HDPlex chemistry.

   The results are returned to the sampling laboratory, and they then produce a report that includes opinions and interpretations related to the sample taken and the results of the STR DNA profiling. This is then sent to the customer under accreditation including the opinions and interpretations but detailing that the testing was carried out by an accredited external supplier.

   Although the sampling organisation have not carried out the testing themselves, they have the experience and knowledge of the testing methods used and also demonstrated that they have years of experience in comparison, interpretation and statistical analysis of DNA profiles against compatible DNA Profile Information. The competence and experience of the sampling organisation has been fully assessed by the NAB and therefore they can give accredited opinions and interpretations based on the knowledge of the sampling and testing undertaken.
   Note: The above example is to demonstrate the principle of being able to give opinions and interpretations if some aspects are provided by an external provider.

Unacceptable Scenarios:

1. **Opinions and interpretations given outside of competence**
   A metal bolt is analysed by the laboratory for tensile strength and the results reported to the customer. The report also contains an opinion and 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 and 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.

2. **Results do not only relate to items tested**
   A tin of paint has been tested in a laboratory and the report contains opinions and interpretations related to the paint tested. 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 and interpretation about any other paint production. Such statements and/or risks are to be borne by the manufacturer or by a product certification body.

3. **Rebranding test reports:**
   The laboratory from example 2 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 and interpretations 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.

4. **Non-Standard method:**
   A customer submits for testing a brand-new piece of plastic material being made of a new chemical formulation with the intent to assess if it can be used as external fire enclosure. As the chemical composition is new and no existing international standard for testing of that specific thermoplastic material was already developed, the laboratory decided to apply an international standard for another material where the laboratory has experience, and it thinks it can be similar to the one submitted. After testing, the results were assessed against the same standard and the laboratory issues an Opinion and Interpretation that based on similarity with results obtained for another material, the submitted plastic material made with the new chemical formulation looks to be suitable for usage as fire enclosure.
   This is an unacceptable use of Opinion and Interpretation because the test method applied is a modification of a standard method and it is out of the scope of accreditation until it is properly validated by the testing laboratory and assessed by the NAB. Further, even if the results are perfectly passing the specifications of the applied international standard, it is not possible to issue a Statement of Conformity as the method was used outside of its intended scope and the laboratory can only issue an Opinion based on its experience with another material. On the contrary, if a standard exists for the submitted material, then a clear Pass/Fail statement using the decision rule included in the standard or agreed with the customer may be issued.

Good Practices

1. **Statement of conformity only:**
   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 and interpretation. 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**.**

2. Multiple Certificates:

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 and interpretation 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.

Note: in the above example the laboratory has followed good practice.

APPENDIX B

i) Example of scope that has limited accreditation for opinions and interpretations:

joe bloggs environmental analysis

007 bond street
London
United Kingdom

scope no. 1234

The laboratory is accredited to provide opinions and interpretations on the effects of chemicals in the environment based on results of all of tests and matrix combinations listed in the following scope. The tests that are included in the accreditation have YES entered in opinions and interpretations column of this scope.

material / matrix	activity	method reference	opinions and interpretations
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 opinions and interpretations accreditation for all matrix types and tests listed on the scope of accreditation:

joe bloggs environmental analysis

007 bond street
London
United Kingdom

scope no. 1234

The laboratory is accredited to provide opinions and interpretations on the effects of chemicals in the environment based on results of 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 activities covered by 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 laboratory's an overview. This will also help the NAB to organise the assessment of the laboratory's as it will be easy to see at a glance what resource is required prior to each assessment.

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