European Federation of National Associations of Measurement, Testing and Analytical Laboratories
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EUROLAB Position Paper

Opinions and Interpretations in Test Reports

Background

ISO/IEC 17025 provides for the provision of opinions and interpretations by a laboratory in its test reports. The respective requirement (clause 5.10.5) reads:

"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 the test report.
Note 1: Opinions and interpretations should not be confused with inspections and product certifications […].
Note 2: Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

- an opinion on the statement of compliance / noncompliance of the results with requirements,
- fulfilment of contractual requirements,
- recommendations on how to use the results,
- guidance to be used for improvements.

During the development of the standard EUROLAB had strongly supported this option. Since then the European accreditation bodies have implemented this clause in different ways. With this position paper, which is based on an inquiry among the EUROLAB members[1] performed in 2011, EUROLAB wants to contribute to a more harmonised approach in Europe, which is fit for the purpose of the laboratory community.

Results of the inquiry

The inquiry revealed that opinions and interpretations (O&I) in test reports are used in all countries. Generally the laboratories thought highly of the importance of this service for their clients. But the use is varying in the different technical sectors. In some areas, e.g. in the forensic sector and in occupational hygiene, the clients do expect O&I from competent laboratories. In other areas, e.g. environmental analysis, at least clear statements on compliance with limit values are expected. But there are also some fields where the provision of O&I is not allowed by legislation. For example the Turkish Ministry of Food and Agriculture does not allow O&I in product test reports for exports and imports. Thus the clear conclusion is that the importance of O&I is differing from sector to sector, but not from country to country.

But the ways how the EA members implement this clause of ISO/IEC 17025 differ. Mainly three approaches can be distinguished: the provision of O&I in test reports

[1] The countries that participated in the inquiry: Austria, Belgium, Croatia, the Czech Republic, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Spain, Sweden, Switzerland and Turkey.

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- is assessed as an integral part of the overall accreditation,
- is treated as a special option which is explicitly mentioned in the accreditation certificate,
- is not allowed as part of accredited test reports.

While the first approach is used in the majority of the countries (9 out of 15), the second one is used in 3 countries. In Italy, Spain and Portugal the national accreditation bodies require that O&I in test reports are explicitly marked as being outside the scope of accreditation.

In virtually all cases the following specific requirements are relevant for the assessment against this clause:

- the competence of the personnel providing O&I,
- the authorisation of this personnel,
- the documentation of the factual basis on which O&I are based,
- the distinction from other conformity assessment activities (e.g. inspection or certification).

Most emphasis is put on the competence of the personnel, in Sweden mainly limited to specially appointed staff.

These requirements are largely considered as legitimate by the laboratories. But concerning the Swedish practice mentioned above it was commented that it would be more appropriate if O&I would be provided by those persons who had performed the test.

Apart from those countries in which the provision of O&I in test reports is not allowed within the scope of accreditation, the laboratories are generally satisfied with the way the respective standard clause is handled by their accreditation bodies. But nevertheless a more harmonised approach is requested. The preference of the laboratory community represented in EUROLAB is the first approach, i.e. the assessment of clause 5.10.5 of ISO/IEC 17025 as an integral part of the overall assessment.

EUROLAB's position

During the development of the standard ISO/IEC 17025 EUROLAB strongly supported the inclusion of the respective clause on O&I. The reasons for this are the need to provide adequate services to the clients who expect more than pure results and the conviction that personnel which is competent to perform measurements and tests is also competent to interpret the results.

In any case, EUROLAB is opposing a position that an additional accreditation against ISO/IEC 17020 is needed to cover the provision of O&I on measurement and test results as laboratory staff, which is assessed against ISO/IEC 17025 to be competent to select the suitable methods, to verify or validate them, to achieve the results and to report on them, could also be assessed to provide O&I.

This does not mean that EUROLAB wants to reduce the differences between different conformity assessment activities. As O&I provided by laboratories in their test reports have to be strictly based on the test results they could never be as far reaching as e.g. certificates issued by product certification bodies which comprise conclusions valid for a whole production series instead of for a single test item.

One can distinguish between different levels of complexity which are connected with the provision of O&I, ranging from comparisons of measurement or test results with limit values

based on well-defined decision rules to opinions on the use or relevance of results concerning the client's needs. While the first one certainly does not require special expertise beyond the competence to perform the respective measurements or tests and to issue the report, the latter might be more difficult and might involve specific knowledge about the test items and their use. Consequently the degree to which the competence of the staff is assessed could be varied, too.

Conclusions

The inquiry clearly reveals that the laboratory community advocates a better harmonisation between the National Accreditation Bodies and an assessment as integral part of the overall assessment.

To achieve this harmonisation and to provide more information for the laboratories the development of an EA guidance document on the provision of O&I would be helpful. Such a document could deal with e.g.

- the differentiation between O&I provided by laboratories based on their results and inspection or product certification activities,
- the way on how to separate O&I in the report from the measurement or test results,
- the documentation of the basis on which the O&I are derived, concerning e.g.
  - the test method performed and the results,
  - the background of the sample in terms of sampling procedure and origin of sample,
  - information given by the client regarding to purpose of sampling/testing etc.,
- the assessments by the accreditation bodies.

We are aware that some EA members have already prepared their own guidance documents on this issue which could be used as a basis for an EA guide. EUROLAB offers its support for the development of such a paper.