White Paper

Revision of Standard ISO/IEC 17025:2005

Eurolab's Position

November 2014

1. Background

Background

1. Overview

Eurolab considers that Standard ISO/IEC 17025 is a powerful tool for calibration and testing laboratories to improve their competence and quality of work.

Standard 17025 is a standard which can be used as a standalone standard for conformity assessment and is intended to be used by laboratories to demonstrate their competence.

This Standard is also used by other agents throughout the conformity assessment global infrastructure such as accreditation bodies, regulators, etc., and that's why a common understanding on the requirements of the Standard is considered vital as it enables laboratories to provide competent, high quality services to their customers at the required quality level fixed by customers or by authorities.

It has been some time since EN 45001:1989 and ISO Guide 25:1990 were used as the Standards for laboratories. Standard ISO/IEC 17025:1998 evolved in to ISO/IEC 17025:2005 but the fundamental principles and requirements remain and they should not change, due to the impact this would have on laboratories and the market.

As ISO/IEC 17025 is regarded as a Standard that remains current and applicable to testing and calibration laboratories operating in all industry sectors, Eurolab sees no need to revise it. During the systematic review launched in 2010 a decision was taken not to review the Standard until 2015 and Eurolab objects to the early revision of the Standard, given that the next systematic review was to be launched in 2015.

This early revision of the standard (NWIP) is based on ILAC and SABS request and the rationale for the early revision of the Standard is not regarded by Eurolab to be robust.

As the revision of ISO/IEC 17025 will go ahead, Eurolab proposes that minimal changes are made to the Standard, on the basis that it remains applicable to all industry sectors. We are cognisant that some minor changes would be beneficial in terms of bringing the Standard more up to date. The standard should be kept flexible in terms of being customized by laboratories being free to best combine the different tools offered by the standard in order to provide the quality level requested by customers or authorities.

We respectfully request that you take on board the comments made by Eurolab in this White Paper in terms of the proposed changes and the extent of the revisions to be made to the Standard.

Background

2. Strategy

Eurolab is present at several forums such as EA, ILAC and CASCO where discussion on this item is open.

To clearly state Eurolab's view on the revision of the standard, an enquiry was undertaken in April 2014 among its active members during a 50 days period.

Results have been collected, presented and discussed inside the Technical Committee for Quality Assurance in Testing and Calibration (TCQA). The timetable is scheduled below.

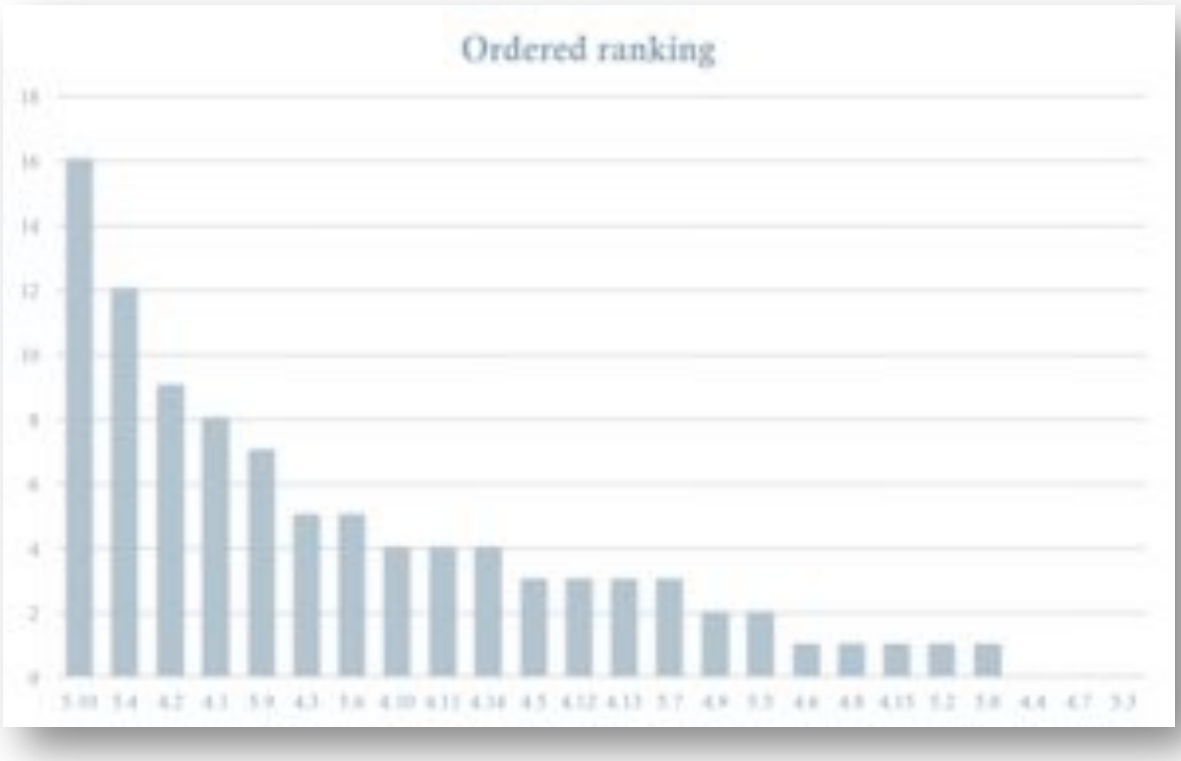
1. Stating Strategy (March 2014)	2. Sending enquiry (April 2014)	3. Compiling results (August 2014)	4. Presenting results (October 2014)

2. Statistics

Statistics

1. Overall results

57% of the Active Members responded to the survey. If the results are ordered per frequency of the comments, we have the following graphic:



As it can be seen, that the Top 5 most commented clauses were:

1. Clause 5.10 "Reporting Results"
2. Clause 5.4 "Test and calibration methods and method validation"
3. Clause 4.2 "Management System"
4. Clause 4.1 "Organization"
5. Clause 5.9 "Assuring the quality of tests and calibration reports"

2. Partial results

If we divide the standard in to two parts, Management and Technical, the following frequency charts are generated.

Management Part:

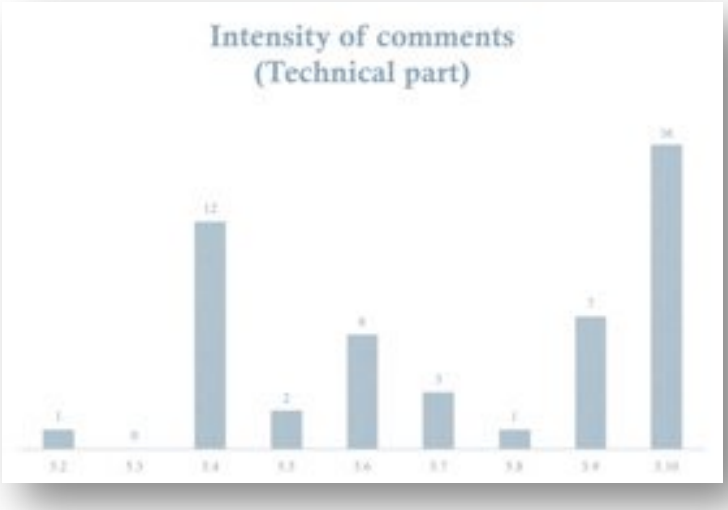
Most commented clauses were:

1. Clause 4.2 "Management system"
2. Clause 4.1 "Organization"
3. Clause 4.3 "Document Control"

Technical Part:

Most commented clauses were:

1. Clause 5.10 "Reporting"
2. Clause 5.4 **"**Test and calibration methods, and method validation**"**
3. Clause 5.9 "Assuring the quality of tests and calibration results"
4. Clause 5.6 "Measurement traceability"



3. Comments

Comments

1 Management part

4.1 "Organization"

Considering the Common Structure adopted by CASCO, included in the CASCO toolbox (former ISO/PAS mainly), The Laboratory community understand that the Standard needs to be harmonised, however special awareness has to be taken when addressing ISO/PAS 17002:2004 requirements –in Clause 4.1 "Organization" in the Standard– as they have been approached differently in different Standards from the ISO/IEC 17000 series.

4.2 "Management System"

There is a general feeling that in order to have a harmonised body of standards available to users, this Standard should be aligned with other Standards such as ISO 9001:2015.

Nevertheless, care should be taken with new concepts included in Draft Standard ISO 9001:2015, pertaining to HLS, as "interested parties", "context of the organization" or the notion of "risk"; these may be carefully considered when talking about laboratories, and the possible impact of such concepts in the revision of ISO/IEC 17025 should not even be considered until ISO 9001 is published and new concepts clarified.

Regarding the applicability of ISO/PAS 17005:2008, laboratories should experience these requirements as a tool to reduce paperwork and duplicity when ISO 9001 is already in place (the experience in other fields as inspection has not been as good as it was supposed to be either for Accreditation Bodies and Conformity Assessment Bodies).

4.3 "Documents control", 4.13 "Control of records" and 5.4.7 "Control of data"

When talking about document and record control –Clauses 4.3 and 4.13 of the standard– the laboratory community would like to include as an improvement, the use of new electronic systems that are nowadays thoroughly accepted, well established and widely implemented.

Regarding control of records, there is an existing link with Clause 5.4.7 "Control of data". This link should be considered when revising the Standard.

In relation to clause 5.4.7, a clarification should be made on the Note, as the use of customized or ad-hoc software is increasing the case, and from the laboratories' experience there is no common understanding throughout the community of conformity assessment on the criteria or activities needed to validate this type of software.

4.5 "Subcontracting"

Considering wide ambiguity how this clause has been understood by different assessors, laboratories feel that some clarification is necessary here.

Sometimes, a competent subcontractor complying with ISO/IEC 17025 has been interpreted as an accredited subcontractor, which is not the same.

We feel that even when accreditation is one of the best and easiest ways to prove competence, it is not the only way, and clarification should be made in this sense to avoid misinterpretations.

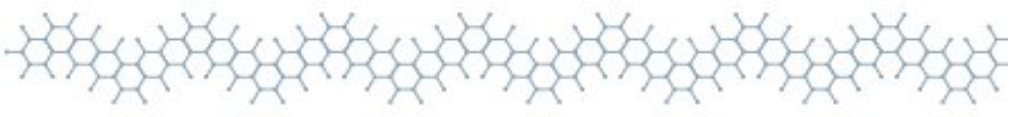
4.8 "Complaints", 4.9 "Control of nonconforming testing and/or calibration work", 4.10 "Improvement", 4.11 "Corrective Action", 4.12 "Preventive Action"

These clauses are considered an interlinked group of requirements, and this link should be made obvious in the Standard.

Also it could be mentioned that all these clauses can be handled with use of new electronic ways already existing in laboratories.

4.14 "Internal Audits" and 4.15 "Management Reviews"

In the experience of laboratories, a clarification in the Notes should be made. Sometimes, the Notes suggesting a period of one year (or 12 months) have actually been considered as requirements, so to avoid misunderstandings, we feel that an open period of time should be mentioned with the laboratories being able



to justify the frequency that they regard to be appropriate for their operations, while complying with ISO/IEC 17025.

Specifically for internal audits, the information obtained from different sources such as previous internal and/or external audits, Interlaboratory comparisons, etc., could be used by the laboratory as a substance for a decision on the appropriate period of time to complete the cycle of internal audits.

2 Technical part

5.2 "Personnel"

Qualification of personnel is an on-going and lengthy process with several assumptions identified in the Standard to be met. Time invested in training is crucial,

5.4 "Test and calibration methods, and method validation"

Care should be taken when revising this clause, as any change would imply extra costs for laboratories.

"Uncertainty"

This issue should not be made stricter than it is now and considering that this is a very important issue for laboratories, perhaps this could deserve a separate clause.

Experience shows us that it is not always necessary to take into account the uncertainty in the evaluation of tests results, so no obligation should be stated in the standard.

Even though there are a lot of guidance documents on how to estimate uncertainty, the standard requirements on it are few and not clear. Some clarification could be included on how to estimate or substitute uncertainty in a realistic way, especially when statistical methods are not applicable, and perhaps include potential rules on it (e.g. using the reproducibility or comparability approach).

Concerns regarding different needs and possibilities for the determination of uncertainty in different laboratories operating in different sectors should be taken into account, e.g. are significant differences between chemical analysis, mechanical testing and legal metrology identified and considered.

"Selection/Validation"

The difference among standardized, non-standardized and "in-house" methods should be made clearer, suggesting or including examples on potential validation activities related to each one, or

verification activities based on internal objective evidence or the performance of the method. Perhaps this could be considered by the inclusion of a “note”.

Eurolab also feels that standardized methods should not be prioritized in relation to non-standardized or "in-house" methods as a customer decides here. Different needs between different sectors should be acceptable within the revised Standard.

5.5 "Equipment"

As an improvement in the Standard, it is proposed to include:

- Suggestion for examples on software validation activities
- Suggestion for permanent suitability of resources and reagents criteria. Validation through an IQ/OQ/PQ (Installation Qualification, Operational Qualification, Performance Qualification) document

5.6 "Measurement traceability"

We feel that testing and calibration laboratories could have different requirements regarding traceability, and this should be made clear in this clause.

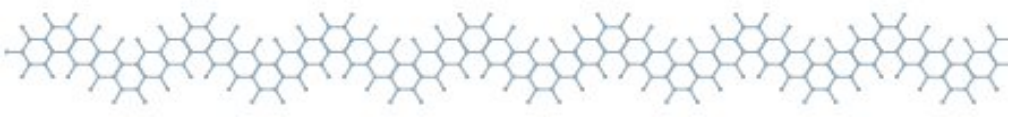
There is a policy by ILAC (ILAC P-10:01/2013) stating requirements to de imposed by Accreditation Bodies on laboratories. There may be some temptations to include this in the revision of this clause. Eurolab feels that this document is strengthening the requirements of the standard and going beyond which is not adequate.

5.7 "Sampling" and 5.8 "Handling of test and calibration items"

Clarification should be made in the definition of these activities. It is not clear what the requirements are with respect to the identification of the sample, production of samples, including workshops for the production of samples.

As the concept is not clear, there is a lack of harmonisation among European Accreditation Bodies.

Comments



5.9 "Assuring the quality of tests and calibration results"

There is a common understanding that PT's or ILC's are powerful tools for laboratories when demonstrating their ability to perform a test properly, consistently and competently, but there are other measures also that can be used effectively.

It should be made clear in the Standard that laboratories have to consider different factors (availability, adequacy, etc., of such schemes) when designing their Quality Assurance Program, taking in to account different activities, frequencies and other such criteria.

Also the Standard could include several control levels and hierarchy on quality assurance measures –minimum requirements on frequency, and different activities– for laboratories to assess data obtained from the quality assurance system.

It would be useful to suggest also the need for a laboratory to have a procedure describing the activities to be carried on when a result do not fulfil quality criteria or to include this topic in the procedure used for Control of nonconforming testing and/or calibration work.

5.10 Reporting

This is the major concern for Laboratories, considering the results of the survey, and based on years of experience in applying the Standard we feel that some clarification should be made on:

"Opinions & Interpretations"

The concept/concepts are not clear. Therefore, the interpretation made by AB's is not harmonised (from countries that do not accredit this activity to countries that consider this activity as a normal part of the Standard when assessing). Definition, boundaries, the way to report it and examples could be included during the revision.

"Uncertainty"

It is not clear when Uncertainty has to be reported; therefore, assessments are not homogeneous throughout Europe, other than in relation to calibration laboratories where this is clear. During

revision, a clarification should be made on this concept, and the clarification shall include the needs of the end user of the results.

"Reports"

There would be an improvement in the Standard if electronic and simplified reports requirements could be broadened out.