PLANNING OF ACTIVITIES TO ENSURE THE VALIDITY OF TEST RESULTS

INTRODUCTION

A laboratory shall have a procedure for monitoring the validity of the results it produces. In ISO/IEC 17025:2017 [1] different ways of carrying out this monitoring are mentioned, such as the use of CRM, intralaboratory comparisons and retesting of retained test items. There are several other possibilities, some of them are mentioned in ISOIEC 17025:2017. The standard also states: *“The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate”*. Such monitoring shall be planned and reviewed and include participation in proficiency testing and/or participation in interlaboratory comparisons other than proficiency testing.

There are also other documents that deal with ensuring the validity of test results, two of them for accredited laboratories are ILAC P9 [2] and EA-4/18 [3] which both focus on PT/ILCs and include requirements (it is possible that these two documents will be revised, but the main part will probably remain unchanged).

In order to avoid unnecessary work, but also to save costs, it is important for laboratories to implement these requirements pragmatically. It is best to create a strategy and a plan for activities to ensure the validity of test results that address these issues in a “smart” way.

STRATEGY

The laboratory shall plan its activities to ensure the validity of its test results. There are requirements from accreditation for the participation in PTs [2, 3]. However, it is better that this plan/strategy encompasses all activities to ensure the validity of the results and is not limited to PT/ILC participation. The strategy/plan should preferably address the following issues:

- The laboratory’s overall view on the validity of the test results, e.g. how the laboratory handles the risk associated with the laboratory’s activities,
- How the risks of different tests should be assessed and how to minimize them,
- The interaction between the different activities and determine in general under which circumstances one activity can replace another,
- How different tests can be grouped into sub-disciplines,
- Where relevant, justification for the different decisions of the laboratory.

The strategy should be decided in the management review.

PLANNING

ISO/IEC 17025, ILAC P9 and EA/4-18 all mention the need for planning the participation in proficiency tests (PT). But it is better to plan all activities to ensure the validity in one document. The plan may have both a long perspective (one accreditation cycle) and a short perspective (one year). One reason is the possibility to point to activities that were or will be performed in a year other than the current one.

In EA-4/18 INF:2010, the term “sub-discipline” is defined as follows:

“An area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related. “

Laboratories are required to identify ”*groups of sets of measurement techniques, properties and products on which the outcome of a PT for one of these sets can be directly correlated to the other sets of measurement techniques, properties and products contained within the group. These groups of sets of measurement techniques, properties and products are termed a sub-discipline.”*

An activity to validate one test method is valid for the whole sub-discipline, this is not only valid for PTs. Examples of sub-disciplines are tensile testing of metallic materials or fire testing construction elements in furnaces.

The risks associated with different tests may be mentioned in the plan as justification for the participation frequency. In areas of low risks, the frequency of activities in terms of validity may be lower than in areas where the use of the test results involves high risk. Previous results of validity activities may also serve as a justification for the frequency of participation, especially if the risk has decreased. The risk may be affected, for example, by:

- the number of tests/calibrations/measurements,
- the turnover of technical staff,
- experience and knowledge of technical staff,
- the sources of traceability (e.g., availability of reference materials, national standards, etc.),
- the significance and final use of the test/calibration data (e.g., forensic science is an area requiring a high level of assurance).

Specifically, the plan could include at least the following:

- the activity, such as participation in proficiency tests (PT), comparison with computer calculation etc.,
- the test method, such as European method for tensile testing of steel (if the activity is planned well in advance) and EN ISO 5178:2011 Destructive tests on welds in metallic materials – Longitudinal tensile test on weld metal in fusion welded joints (ISO 5178:2001) (if the activity is lined up next),
- the sub-discipline to which the activity belongs, e.g. Tensile testing of metals,
- the risk associated with the sub-discipline,
- the date of activity. The closer the date is, the more detailed information is needed, e.g. if the activity is planned several years in advance, often the year or the quarter are sufficient,
- previous activities or other activities performed in the context of the sub-discipline and the result, in particular successful participation,
- the result of the activity, after it has been performed.

When an activity is performed to ensure the validity of the laboratory’s test results, it shall be documented, and the results shall be analysed. A decision on whether urgent measures are required will be taken after the analyses. If no immediate action is needed, the results of several activities can be analysed in a group to identify trends etc. The result of these activities shall be discussed in the management review.

When the accreditation body carries out an on-site surveillance visit the laboratory shall justify the frequency of participation. Arguments in this discussion can be:

- good performance in previous activities,
- low risk when using the test results,
- activities performed on using other similar methods,
- other activities performed, justifying non-participation in proficiency tests.

In any case, it should be recognised, however, that the activities to ensure the validity of the test results are carried out primarily not for the accreditation body, but for the customers of the laboratory and the laboratory itself.

References

[1] ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
[2] ILAC P9:06/2014 – ILAC Policy for Participation in Proficiency Testing Activities
[3] EA-4/18 INF:2010 Guidance on the level and frequency of proficiency testing participation

Annex 1: Exemplary plan

Note that the same activities may appear in both plans

Example of a plan (short term)

Date	Activity	Method	Sub-discipline	Risks	Previous result of this activity or other activities	Result of the activity	Comment
2018-10-10/20	Proficiency Test (PT)	SS-EN ISO 5178:2011 Destructive tests on welds in metallic materials – Longitudinal tensile test on weld metal in fusion welded joints	Tensile test of metals	Medium risks (see risk analysis)	No previous results available		

Example of a plan (long term)

Date	Activity	Method	Sub-discipline	Risks	Previous result of this activity or other activities	Result of the activity	Comment
2018 Q3	Interlaboratory Comparison (ILC)	Not yet decided	Tensile test of metallic	Medium risk (see risk analysis)			