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 is producing. In ISO/IEC 17025:2017 [1] different ways of doing this monitoring is mentioned e.g. use of CRM, intralaboratory comparisons and retesting of retained test items. There are several other possibilities, some mentioned in ISOIEC 17025:2017. It is also stated in the standard that “The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate”. This monitoring shall be planned and reviewed and shall include participation in proficiency testing or/and participation in interlaboratory comparisons other than proficiency testing.

There are also other documents that are dealing with Ensuring the validity of test results two of them for accredited laboratories are ILAC P9 [2] and EA-4/18 [3] which both are focusing on PT/ILC:S and includes requirements (it is possible that these two document may be revised but the main part will probably be the same).

To avoid too much work and also costs it is important for laboratories to handle these requirements in pragmatic way. And the best way to do this is by writing a strategy and a plan for activities to ensure the validity of test results where these issues are handled 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]. It is better if this plan/strategy includes all activities to ensure the validity of results and not be restricted to PT/ILC participation. The strategy/plan should preferably handle the following things:

- The laboratories overall view on validity of test results e.g. how the laboratory looks on the risk associated with laboratories activities,
- How the risks of different tests should be valued and how to minimize them,
- The interaction between the different activities and in general terms state under which circumstances one activity can replace another,
- How different tests may be grouped together in sub-disciplines,
- Where relevant include argument for the different choices made by the laboratory.

The strategy should be decided in the management review.

PLANNING

ISO/IEC 17025, ILAC P9 and EA/4-18 are all mention the need for the plan for PT participation. But it is better to plan all activities to ensure quality 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 which was or will be performed in another year than the present.

In EA-4/18 the term sub-disciplines is defined as: 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 others 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 PT:s. 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 an argument for the participation frequency. In areas where there is low risks the frequency of validity activities may be lower than in areas with high risk associated with the use of the test result. Earlier results of validity activities may be mentioned also as an argument for the participation frequency especially if it is decreased. The risk may be affected by e.g.

- Number of test/calibrations/measurements,
- Turnover of technical staff,
- Experience and knowledge of technical staff,
- Sources of traceability (e.g. availability of reference materials, national standards, etc.),
- Significance and final use of testing/calibration data (e.g. forensic science represents an area requiring a high level of assurance).

In more detail, the plan could include at least the following:

- The activity e.g. participation in PT, comparison with computer calculation etc.,
- Test method e.g. European method for tensile testing of steel (when the activity is planned long in advance) and SS-EN ISO 5178:2011 Destructive tests on welds in metallic materials – Longitudinal tensile test on weld metal in fusion welded joints (ISO 5178:2001) (when the activity is closer),
- The sub-discipline the activity belongs to, e.g. Tensile testing of metals,
- The risk involved with the sub-discipline,
- Date for the activity. The closer the date the more detailed information is needed, e.g. if the activity is planned several years in advance often the year or the quarter is enough,
- Earlier performed activity or other activity performed for the sub-discipline and the result, especially successful participation,
- The result of the activity, when performed.

When an activity to ensure the validity of the test results of the laboratory is performed it shall be documented and the results shall be analysed. A decision if there are needs for immediate actions shall be taken after the analyses. If immediate action is not needed the outcome of several activities can be analysed in a group to try to identify trends etc. The outcome of these activities should be discussed in the management review.

When the accreditation body is visiting for surveillance the laboratory shall motivate the frequency of participation. Arguments in that discussion can be:

- Good performance in earlier activities,
- Low risk in the use of the test result,
- Activities performed on other similar methods,
- Other activities performed e.g. to motivate non-participation in PT:s.

However, it should be recognised that activities to ensure the validity of test results are not performed mainly 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 Examples of plan

Note that the same activities may show up in both plans

Example of plan (short term)

Date	Activity	Method	Sub-discipline	Risks	Earlier Result of the activity or other activity	Result of the activity	Comment
2018-10-10/20	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 analyse)	No earlier results are available		

Example of plan (long term)

Date	Activity	Method	Sub-discipline	Risks	Earlier Result of the activity or other activity	Result of the activity	Comment
2018 Q3	ILC	Not decided	Tensile test of metallic	Medium			