INTERLABORATORY COMPARISON: THE VIEWS OF LABORATORIES

Context

Participation in interlaboratory comparison and in particular in proficiency testing constitutes an important tool for laboratories to verify the reliability of their results against the assigned values (reference or consensus) and to give confidence by external elements of validation of their competence to clients and accreditation bodies. Participation in interlaboratory comparison may be imposed by authorities or by customers. Subclause 7.7.2 of ISO/IEC 17025:2017 states: *“The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate.”*

The publication in 2010 of two documents ILAC P9 "ILAC Policy for Participation in Proficiency Testing Activities" and EA 4/18 "Guidance on the level and frequency of proficiency testing participation" leads the accreditors to review their policies and focus a part of their assessments on this topic.

The purpose of this document is to provide audited elements to the people, to consider the purpose of interlaboratory comparisons, i.e. one of the tools that help to monitor the validity of results. It allows them, when questions are sometimes too focused on comparisons, to put these questions in a broader context.

Questions

What participation?

If asked: What is your participation plan to interlaboratory comparisons consistent with your accreditation scope?

Think / Rephrase: How the monitoring of the validity of tests and calibrations is planned and reviewed?

This allows to present the laboratory's policy on surveillance, interlaboratory comparisons (and bilateral) being not necessarily the only possible means (see clause 7.7 of ISO/IEC 17025 and 3. (1) of EA 4/18). The laboratory may present the consistency of its surveillance policy, using a risks estimation approach (see
3. (2) of EA 4/18).

If asked: What is the justification by the laboratory of his non-participation in such a comparison?
Think / Rephrase: Is the protocol for this comparison proposed by the organiser of the comparison adapted to the problem of monitoring the results of my lab?

This allows the identification of inappropriate elements of the protocol, e.g. the objectives of the comparison, the scope, the evaluation and assessment method used, the assigned values, especially their metrological traceability and uncertainty.

If asked: Is the selected provider accredited to ISO/IEC 17043 standards?

Think / Rephrase: Is my provider able to provide a valid comparison?

This allows to present the elements used to select a supplier (see Cook Book No. 2, "Criteria for the selection of a proficiency testing scheme").

The participant in a comparison is not obliged to fulfil the requirements of ISO/IEC 17043, because this standard is only applicable to the PT provider (see scope of the ISO/IEC 17043 standard). The participant must comply with the instructions of the organizer.

If asked: Have you done a comparison for such measurement technique, property, instrument or product?
Think / Rephrase: What are the elements available to show my skills?
This allows to highlight groups of skills for methods practiced with common equipment or by common

personnel. (See Para. 4. of Document EA 4/18)

What data processing?
<u>If asked:</u> What are your pre-established criteria for processing the results of comparisons?
Think / Rephrase: What are the recognized methods of treatment? What are the criteria established by the organizer of the comparison?

This allows to specify:

- that the results of proficiency testing can appear in many forms covering a wide range of types of data and underlying statistics distributions. It is necessary that the statistical methods used to analyze the results are tailored to each situation (see B.1 of ISO/IEC 17043).
- that the organizer of proficiency testing must document a plan before starting the proficiency testing program that specifically addresses "the criteria for assessing the performance of the participants" (cf. 4.4.1.3. r) of ISO/IEC 17043). The laboratory can consider this criterion once the program of comparison known.
- that the calculation of performance statistics is described in Annex B.3 of ISO/IEC 17043.
- It is advisable to explicitly mention Annex B of the ISO/IEC 17043 in the management system documentation.

<u>If you are asked:</u> Why you do not take the usual test $E_n \leq 1$ to determine if your lab’s performance is good or bad?
Think / Rephrase: What is the significance of the E_n number, is this statistically relevant, should a z-score be chosen?

$$(E_n)_i = \frac{x_i - x_{pt}}{\sqrt{U^2(x_i) + U^2(x_{pt})}}$$

x_i is the participant's result; x_{pt} is the assigned value;
$U(x_i)$ is the expanded uncertainty of a participant's result;
$U(x_{pt})$ is the expanded uncertainty of the assigned value.

It can be said that:

- $E_n \leq 1$ may mean that the stated uncertainty does not allow to conclude that the deviation from the assigned value is significant;
- $E_n > 1$ may mean that the reported uncertainties are underestimated and do not cover the difference observed.

The interpretation of the performance assessment in a PT based on the evaluation of statistical scores should be done carefully (see C.5.1.2 of ISO/IEC 17043).

The performance evaluation is not necessarily a "proof" of participant’s competence. This depends on the purpose of the comparison (cf. introduction of ISO/IEC 17043) and on the objective of the participant, which may, for example, seek to improve its knowledge of the quality of its results, search trends etc..
What actions:

<u>If asked:</u> What are the provisions regarding corrective actions taken when the results of a comparison call into question the quality of accredited services?
Think / Rephrase: What are the policies and procedures implemented when any aspect of testing and/or calibration work, or the results of this work, do not conform?

This allows to present general procedures for handling non-conforming work and examples of application in

the context of comparisons (see clause 7.10 of ISO/IEC 17025). It is advisable to explicitly specify in the quality system that these procedures apply to comparisons.

Think / Rephrase: What actions have been taken after comparisons.

This allows to introduce the consideration of «outcomes of the assurance of the validity of results» (see 8.9.2. n) of ISO/IEC 17025) during the management reviews and present policies and actions of the laboratory to ensure and improve the validity of its results.

Conclusion

Interlaboratory comparison is a tool for progress. Its use should be defined according to the needs of the laboratory and its customers and the regulatory authorities.

In some areas, the comparison rounds are imposed by regulations.

In other cases, the laboratory shall ask the right questions to clarify its needs and policies in order to select the appropriate comparisons. This allows to have useful thinking elements for discussion with the accreditors.

References

[1] ISO/IEC 17043:2010, “Conformity assessment - General requirements for proficiency testing”
[2] ILAC P9:2014, “ILAC Policy for Participation in Proficiency Testing Activities”
[3] EA 4/18:2010, “Guidance on the level and frequency of proficiency testing participation”
[4] ISO/IEC 17025:2017, “General requirements for the competence of testing and calibration laboratories”
[5] Eurolab Cook Book N°2:2007, “Criteria for the selection of a proficiency testing scheme”