SLOVENSKA AKREDITACIJA

OA05

PARTICIPATION IN INTERLABORATORY COMPARISONS

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1 TERMS AND DEFINITIONS

Definitions are taken from document EA-4/18.

Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (SIST EN ISO/IEC 17043, definition 3.7).

Proficiency testing (PT) scheme: proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection (SIST EN ISO/IEC 17043, definition 3.11).

Interlaboratory comparison (ILC): organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (SIST EN ISO/IEC 17043, definition 3.4).

Measurement process: The process of measuring the characteristic, including any pretreatment required to present the sample, as received by the laboratory, to the measuring device.

Characteristic: The parameter being measured.

Area of technical competence: Field of expertise defined by a minimum of one measurement process, characteristic and test item/material, which are related. Example: amount of arsenic in soil by ICP-MS.

Level of participation: The number of specific activities that an organisation identifies within its scope of accreditation, and therefore the number of specific proficiency tests that should be considered for participation.

Frequency of participation: The number of proficiency tests per unit of time, in which a laboratory participates for an activity as specified in their scope of accreditation.

Scope of accreditation: specific conformity assessment activities for which accreditation is sought or has been granted (SIST EN ISO/IEC 17011, 3.6).

Small interlaboratory comparison (small ILC): An interlaboratory comparison organized by, and among seven or less laboratories (EA-4/21).

2 GENERAL

The requirements for participation in proficiency testing (PT), or in other types of interlaboratory comparisons (ILCs), are laid down in SIST EN ISO/IEC 17025 for testing laboratories and in SIST EN ISO 15189 for medical laboratories, respectively, and they also apply to other types of CABs, when they perform tests, calibration, sampling or examinations within the scope of their accredited activity.

Proficiency testing is one of the most important tools that the laboratory uses to monitor and control the quality of performing the accredited activities and the validity of the results. The results from PTs/ ILCs allow the identification of potential problems in the performance of the accredited activity, and are particularly important for the verification of laboratory's work when introducing changes or implementing new activities.

Participation in PTs/ILCs helps the laboratory to prove its competence, among other also to the accreditation body. The results from PTs and ILCs and their treatment are an important segment of assessment in accreditation procedures.

3 REQUIREMENTS

Participation in appropriate PTs, when available, or in other types of ILCs, is one of the conditions for obtaining and maintaining accreditation. Documented and satisfactory participation of the laboratory prior to the grant of accreditation is required, as well as its further, regular and continuous participation to an appropriate extent (level of participation), considering the scope of accredited activity, and the appropriate frequency.

In this context, the laboratory must have its policy stated, its plans made, and its procedures for processing the results and implementing the necessary actions in place.

It is important for the laboratory to choose appropriate PTs/ILCs that meet its needs, and to make sure about the suitability of the organizer, the implementation and the evaluation of the results.

Participation in PTs whose organizers are demonstrably competent, i.e., who meet the requirements of SIST EN ISO/IEC 17043, has priority. Also in the case of participating in other types of ILCs, their suitability needs to be evaluated against equivalent requirements. Some guidelines on ILCs with a small number of participants (small ILCs) are given in EA-4/21.

The laboratory shall plan its participation in the ILCs that are appropriate for its accredited activities (capabilities). Its primary consideration shall be the scope of accreditation. In the plan, the laboratory shall define the level and frequency of participation, based on the specifics of areas, factors and levels of risk, depending on the frequency of performing individual accredited activity, on general availability of ILC for individual activity, on considering other relevant mechanisms for ensuring the validity of the results used by the laboratory, and on any other relevant impacts.

Requirements for frequency of participation cannot be defined universally, as each laboratory has to formulate them separately. There are many areas which require rather frequent participation, whereas in other cases, participation to the appropriate or desired extent is difficult to provide due to the lack of organized PT schemes, to small number of laboratories, or to the technical nature of the activities. At the same time it is important that the frequency of participation in PTs or ILCs is aligned with the extent of using other mechanisms for ensuring the validity of testing or calibration, which are therefore particularly important for activities for which participation in PTs or ILCs is difficult to provide.

In order to achieve the purpose of participation as a means of ensuring the validity of results, the laboratory shall introduce procedures for reviewing the results, monitoring the trends, deriving findings, and taking and reviewing corrective or preventive actions. All these activities shall be properly documented.

4 LEVEL AND FREQUENCY OF PARTICIPATION (text taken from Chapters 3 and 4 of EA-4/18)

4.1 General aspects of planning

To ensure the validity of the results, the laboratory must define the level and frequency of its participation in the PT:

1) after careful analysis of its other quality assurance (QA) measures to ensure the validity of the results (especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude). The level and frequency of participation should be made dependent on the extent to which other measures have been taken into account. QA measures can include, but are not limited to:
   - regular use of certified reference materials and/or reference materials,
   - comparison of analysis by independent techniques,
   - participation in ILCs for method development/validation and/or reference material characterisation studies,
   - use of internal quality control (IQC) measures,
   - other inter/intra – laboratory comparisons e.g. analysis on blind samples within the laboratory,
   - robustness of the metrological traceability chain. (Are instruments calibrated under the same conditions as routinely used versus assumptions on e.g. influence factors or secondary parameters).

   Note: Other approaches to ensuring the validity of the results can be found in SIST EN ISO/IEC 17025 (7.7.1) and SIST EN ISO 15189 (5.6).
2) based on the level of risk presented by the laboratory, the sector in which it operates or the methodology it is using. This can be determined, for example, by considering:
   - number of measurements undertaken,
   - frequency of tests at a different concentration level,
   - turnover of technical staff,
   - experience and knowledge of technical staff,
   - source of metrological traceability (information and availability of reference materials, national measurement standards, etc.),
   - known stability/instability of the methodology,
   - complexity and robustness of the methodology,
   - significance and final use of measurement data (e.g. forensic science represents an area requiring a high level of assurance),
   - whether the results are used to determine conformity with specifications,
   - risks and opportunities associated with the laboratory activities, in particular those that will prevent, or reduce, undesired impacts and potential failures in the laboratory activities and achieve improvement,
   - extent of validation and/or verification.
3) based on any requirements for frequency and type of PT participation from other sources, e.g. legislation, customers, etc.

4.1 Planning approach

The first step for a laboratory when planning participation in PT is to consider their scope of accreditation.

Ideally, a laboratory would participate in a specific PT for every measurement process it uses and for every characteristic measured in every type of test item/material. However, it is acknowledged that this is unlikely to be feasible, both logistically and economically. Therefore, laboratory has to identify areas of technical competence comprising sets of measurement processes, characteristics and test items/materials on which the outcome of a PT for one of these sets can be directly correlated to the other sets of measurement processes, characteristics and test items/materials contained within their accreditation scope.

An area of technical competence, as mentioned above, may contain more than one measurement process, characteristic or product as long as the equivalence between the combined measurement processes, characteristics or type of test items/materials can be justified. Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge or experience.

When determining an area of technical competence, it may be helpful to consider a stepwise approach working up from measurement process through characteristics to type of test items/materials. This is because it is more likely that there will be several types of test items/materials and/or characteristics associated with one measurement process within a given area of technical competence than vice versa:

(i) With reference to the **measurement process**: It is possible but not common to include different measurement processes in the same area of technical competence.
(ii) With reference to the **characteristic** to be measured or identified: It may be possible to include more than one characteristic in the same area of technical competence.
(iii) With reference to **type of test items/materials** to be measured: It may be possible to include different test items/materials in the same area of technical competence provided that the items included are of equivalent nature.

Once the laboratory has defined its areas of technical competence the level of participation can be deemed to have been defined. Laboratory defines the frequency of participation in different technical areas taking into consideration the extent and nature of other mechanisms for ensuring the validity of the results.

Once the “level” and “frequency” of participation have been established, this will be included in the laboratory’s overall strategy for ensuring the validity of the results.

It is recommended that the PT participation plan, resulting from the establishment of the various “levels” and “frequencies” of participation, covers, at least, one accreditation cycle (period between full reassessments), and is reviewed with the overall PT strategy by the laboratory for its suitability, usually on an annual basis during the formal management review. If unsatisfactory results are obtained from the PT participation, this may also influence the ongoing strategy.

Case studies from EA-4/18 Chapter 6 could be helpful in providing additional information regarding the determination of areas of technical competence; however, each laboratory must adapt this determination to the specific circumstances of its operation.

5 ASSESSMENT

The suitability of the level and frequency of participation and the adequacy of PT/ILC planned by the laboratory in participation plan shall be assessed by the assessment team during the assessment procedure. Both the actual possibilities and situation in the relevant area should be taken into account.

The plan, the results, the analysis, as well as any possible actions deriving from the result of participation in PTs/ILCs, shall – in accordance with the accreditation procedure – constitute an obligatory part of review during each assessment. Before each assessment, the laboratory shall send together with documentation for assessment also the report on the control of the validity of testing and calibration results provided through its participation in PTs/ILCs. For the activities from the scope of accreditation for which the laboratory did not participate in PTs/ILCs in the given period, it shall indicate, in the same report, the planned date of participation, or, when it does not participate in PT/ILC for this activity, state other mechanisms for ensuring the validity of the results.

Utmost attention should be paid when assessing a laboratory to check its control of the results of participation in PTs/ILCs, the cause analyses and the implementation of corrective actions in the case of derogations or unsatisfactory participation.

A single inadequate result of participation in PT/ILC is not necessarily an obstacle to maintaining accreditation, provided that appropriate corrective actions have been implemented that effectively address the derogation /non-compliance, and that other results for the same accredited activity are for the most part adequate.

When the reason for a considerable derogation or recurrent derogations in the same or similar activities cannot be established, these should be considered as nonconformities for which the assessor team should require immediate action by the laboratory. Should the laboratory not take the appropriate corrective actions within an acceptable period of time, this could provide a reason for suspension or withdrawal (reduction) of the scope of accreditation.

6 CHANGES WITH REGARD TO PREVIOUS REVISION

As the content of this document has been fully revised, the changes are not marked.

The text of Chapters 1 and 4 is taken from EA-4/18. In Chapter 3, the requirements are slightly rearranged with the aim of presenting more clearly the laboratory's policy regarding its responsibility of formulating the plan of participation in PTs/ILCs at appropriate level and frequency with respect to the scope of accreditation, and reference to the guidelines given in EA-4/21 on participation in ILCs with a small number of participants has been added. The complete chapter on ILCs in support of MLAs (EA highlighted PTs) has been deleted. The chapter with references has been updated.

7 TRANSITORY PROVISIONS

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8 CONTROL OF THE DOCUMENT

A valid document shall be located in i4 (SA Information System). A clean copy shall be published on the SA website, and shall be available on printed format at the SA Head Office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies of the document shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4 or on the SA website.

9 REFERENCES

SIST EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017).

SIST EN ISO 15189:2013, Medical laboratories - Requirements for quality and competence (ISO 15189:2012).

SIST EN ISO/IEC 17011:2018, Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2017).

ILAC P9:06/2014, ILAC Policy for Participation in Proficiency Testing Activities.

SIST EN ISO/IEC 17043:2010, Conformity assessment - General requirements for proficiency testing (ISO/CASCO 17043:2010).

ISO 13528:2015, Statistical methods for use in proficiency testing by interlaboratory comparison.

EA-4/18 G:2021, Guidance on the level and frequency of proficiency testing participation.

EA-4/21 INF:2018, Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation.