LATAK-D.007-10/07.2021

LATAK Policy for Participation in Proficiency Testing Programmes and Interlaboratory Comparisons

List of Contents

Objective

The State Agency "Latvian National Accreditation Bureau" (hereinafter – LATAK) takes into consideration the results of proficiency testing and interlaboratory comparisons in the testing, calibration and medical laboratories assessment process, assessing the ability of laboratory to competently perform testing and/or calibration and investigation included in the accreditation scope, and to assess the competence of laboratories that wish to complete accreditation for conformity with requirements of standard LVS EN ISO/IEC 17025 or LVS EN ISO 15189. Proficiency tests, if available and justified, can be used by inspection bodies of some separate types (LVS EN ISO/IEC 17020), if such testing activities are included that directly influence and determine the inspection results, or it is determined by regulatory enactments. However, it is recognised that proficiency tests are not a common and expected element in the accreditation process of majority of inspection bodies.

1. Introduction

This document defines the requirements and gives instructions on proficiency testing and interlaboratory comparison activities in the process of accreditation of testing, calibration and medical laboratories and, where essential, inspection bodies.

The standard LVS EN ISO/IEC 17025 specifies the requirements for monitoring of results credibility, incl. a laboratory shall monitor its performance compared to results of other laboratories, where it is available and appropriate. Such monitoring shall be planned and revised, and it shall include, but not be limited to one or both of the activities stated below:

- participation in proficiency testing;
- participation in interlaboratory comparisons, which are not proficiency tests.

The standard LVS EN ISO 15189 defines the requirements for quality assurance of investigation results, incl. for participation in interlaboratory comparison programmes.

The standard LVS EN ISO/IEC 17011 imposes an obligation on accreditation bodies to consider in the decision-making process participation of conformity assessment bodies and their performance in proficiency testing.

In the context of this document "laboratories" refer to all types of laboratories – testing, calibration and medical laboratories.

2. Terminology and definitions

Proficiency testing (PT) is assessment of performance of participants based on predefined criteria by comparison of results of laboratories (according to LVS EN ISO/IEC 17043).

Proficiency testing (PT) schemes is proficiency testing intended for and working in one or several rounds specifically for a particular testing, measuring calibration or inspection area (according to LVS EN ISO/IEC 17043).

Interlaboratory comparison between two or among several laboratories or inspection bodies is organisation, execution and assessment of measuring or testing of

the same or similar objects according to predefined conditions (according to LVS EN ISO/IEC 17043).

CRM
Certified reference material
A reference material characterised by a metrologically valid procedure concerning one or several parameters and a reference material certificate issued for this procedure, where values of the respective parameters, associated uncertainty and a declaration on metrological traceability (ISO/IEC 17034) are indicated.

SIC
Small interlaboratory comparison (EA-4/21 INF).

3. LATAK Policy for Participation in Proficiency Testing Programmes and Interlaboratory Comparisons

3.1. All accredited testing, calibration and medical laboratories and, where applicable, inspection bodies have to participate in proficiency testing or interlaboratory comparisons, where these procedures are available and are related to the accreditation scope. Inspection bodies that perform measurements, shall ensure conformity to requirements of the standard ISO/IEC 17025. Consequently, requirements of this document shall apply also to this type of inspections.

3.2. Laboratories or inspection bodies shall elaborate a plan for participation in proficiency testing or interlaboratory comparisons for the entire accreditation cycle according to the accreditation scope. Laboratories shall determine the level and frequency of participation after careful analysis of other results credibility assurance measures and risk assessment. The following aspects may be considered in the risk assessment:

- volume of performed measurements;
- turnover of the technical personnel;
- experience and knowledge of the technical personnel;
- ensuring of metrological traceability of measurements;
- known stability / instability of methods;
- significance and end use of measurement data, etc.

NOTE 1. Periodicity of participation is usually determined for proficiency testing programmes.

3.3. Laboratories or inspection bodies have to be ready to substantiate their policy and action regarding participation and any non-participation in proficiency testing programmes or interlaboratory comparisons.

There are areas, in which participation in proficiency testing can be complicated due to technical characteristics of measurements, lack of PT schemes, small number of laboratories, innovative technologies and other reasons. In separate cases proficiency testing or interlaboratory comparisons are possible only in certain measuring parts. The most important thing in these cases is to ensure appropriate results credibility control measures.

3.4. Ideally, laboratories have to participate in PT with each parameter to be determined and at each tested object. However, not in all cases it is possible both logistically, and economically. Therefore, laboratories have to determine the areas of technical competence, which include the measuring process, sets of parameters and products, where the result of PT of one of these sets can be directly correlated to other sets of measuring processes, parameters and products.

Various technical competences usually can be identified by a necessity for different qualifications, training, experience and use of various equipment. One group of technical competences may combine, for example, measuring methods, parameters to be determined, equivalent objects to be tested.

3.5. In addition to the assessment of suitability of the level determined by a laboratory, LATAK also carries out assessment of suitability of "frequency" of participation of laboratories in PT, based on the risk level.

The laboratory shall elaborate PT or interlaboratory comparison participation plan, which arises from determining various "levels" and "frequency" of participation, and which covers at least one accreditation cycle (period until full repeated assessment). The suitability of the elaborated plan to the general PT strategy shall be revised at least once a year during the management review.

3.6. The requirement of LATAK regarding participation of laboratory or inspection institution in proficiency testing programmes and interlaboratory comparisons is:

- participation in each testing, calibration and medical examinations area before granting accreditation or scope extension;

- at least one participation in each area during the accreditation period..

In areas of higher risk level, for example, environment and health protection areas, as well as areas with insufficient provision of certified reference materials, more frequent participation in proficiency testing programmes and interlaboratory comparisons is required.

The frequency of participation of laboratory in proficiency testing programmes may be determined by professional organizations and regulatory bodies.

If significant changes to the personnel or the accreditation scope of laboratory or inspection body have occurred, LATAK may request the laboratory or inspection body to submit a certificate on participation in proficiency testing programmes for a shorter period of time.

More detailed information on the level and frequency of participation in PT, as well as examples divided into areas (chemical testing of environmental parameters, microbiological testing, clinical examinations, physical testing, calibration and matrix approach in clinical chemistry) are given in the Directions EA 4/18 of the European Accreditation Cooperation.

3.7. The laboratory or inspection body can choose proficiency testing programmes or their organizers that are most suitable for its operation (accreditation scope), unless specified otherwise.

NOTE 2. Standards LVS EN ISO/IEC 17025 and LVS EN ISO 15189 impose an obligation on the laboratory to assess service providers. The standard LVS EN ISO/IEC 17043 gives recommendations and directions on requirements for suppliers (organizers) of proficiency testing programmes.

Laboratories and inspection bodies shall use accredited suppliers of proficiency testing programmes, if such offers are available.

NOTE 3. Information on PT programmes is available in EPTIS (supported by EC, EA, Eurolab, Eurachem) database https://www.eptis.org/ Information on proficiency testing programmes is also available on the website of LATAK www.latak.gov.lv in the section Database of Proficiency Testing Schemes.

3.8. LATAK assesses participation of laboratories in non-accredited interlaboratory comparisons according to the Document EA-4/21 of the European Accreditation Cooperation. See ANNEX Organisation and Assessment of Results of Small Interlaboratory Comparisons to this document.

3.9. LATAK coordinates and distributes to conformity assessment bodies information on proficiency testing programmes and interlaboratory comparisons, which is received from the European Accreditation Cooperation (EA) or the International Laboratory Accreditation Cooperation (ILAC).

3.10. The laboratory or inspection body shall assess own performance in the respective proficiency testing programme or interlaboratory comparison, and in case of unsatisfactory or questionable results shall carry out corrective measures, documenting them appropriately.

Before the regular assessment procedure, laboratories submit to LATAK a report on participation in proficiency testing programmes or interlaboratory comparisons – Form F.045.

ANNEX

Organisation and Assessment of Results of Small Interlaboratory Comparisons

Small interlaboratory comparisons are organised among a few laboratories (mostly, 2 - 4, max 7, including organizers).

SIC may be organised also among various laboratories of one organization, ensuring that the tested object is not known to any of the participants.

The organizer of SIC shall apply the respective requirements of the standard LVS EN ISO/IEC 17043, if the results and their assessment are used for quality assessment of the results of obtained measurements.

By the number of participants decreasing, it is increasingly more difficult to identify the distribution of results in order to credibly determine deviations or apply a stable (credible) statistical analysis. It is not recommended to obtain the assigned value and standard deviation from results obtained from the results of participants, or it shall be done very carefully and competently.

There are three possible scenarios for correct assessment of SIC results, and application of the respective scenario depends on:

- existence and credibility of externally assigned value,
- quality of the data set,
- experience of participants,
- competence and experience of the organizer of SIC.

Scenario 1: the organizer uses the assigned value, based on the external reference

The assigned value can arise from the respective reference, for example:

- certificate of certified reference material,
- instrument calibration certificate,
- measurements performed by an expert laboratory,
- previous PT results for the same or similar material.

Also a standard deviation may be an externally determined value, which is obtained from the results of previous PT or corresponds to specific testing performance requirements.

In the Scenario 1, the organizer of SIC may use for assessment of performance of participants:

- **z criterion**, where the assigned value and standard deviation is independent from the reported results,
- **En criterion**, if uncertainty is indicated for an assigned value and reported value,
- also **zeta (ζ) criterion** may be used – it includes uncertainty of the results of participants and the assigned value, recommended in combination with z criterion.

Scenario 2: the organizer uses the assigned value, based on the results of participants

If the external reference value is not available, quantitative analysis and performance assessment only on a basis of the results notified by participants is not recommended. However, there can be exceptions, for example:

- Participants are experienced laboratories competent to coordinate their testing accuracy for the specific type of measurements, for example, with interlaboratory comparison results of the same or similar type obtained previously.
- One of the participants operates at a higher metrological level (lower measuring uncertainty), using reference methodology and more progressive equipment. The result of measurements performed by this participant may be used as the assigned value.

Scenario 3: the organizer does not use the assigned value

If the external assigned value is not available or the assigned value cannot be credibly calculated from the data set, the organizer of SIC cannot calculate performance indicators; however, the individual performance of participants can be assessed. The results can be displayed in schematic form and can be discussed among the participants.

The data to be used in the assessment of individual performance:

- reproducibility of the results (variations among the participants);
- repeatability (variations among repeated measurements in one laboratory under the same conditions);
- type of distribution;
- information on the extreme values (deviations or not);
- uncertainty of measurements notified by the participants.

While assessing participation of laboratories in SIC, LATAK takes into consideration, whether:

- the assessed laboratory is the organizer and participant of SIC (assesses the plan and report);
- the assessed laboratory is only a participant of SIC (the laboratory shall be able to give an explanation/evaluation of suitability of the respective SIC).

It is recommended that the organisation of SIC is included in the quality management system of the laboratory.

Documents and protocols concerning the organisation of SIC shall be maintained in accordance with the quality management system.

The organisation of SIC or participation in the process shall be considered cooperation among laboratories, not as a service provided to a customer. Therefore, requirements related to customer service, as well as complaints and appeals, do not apply.

The organisation of SIC shall be included in internal audits and management reviews.

The personnel involved in the organisation of SIC shall be authorised and its competence shall be assessed.

If the organizer participates also as a participant, the personnel that performs measurements, if possible, should not be involved in the organisation process, and also precautionary measures shall be implemented in order to prevent disclosure of the measured parameter.

The organizer of SIC shall elaborate an interlaboratory comparison plan and include in it at least the following details:

- main contact person;
- involved persons or laboratories, if SIC is organised jointly by several laboratories;
- list of participants;
- the unit of measurement or parameter to be determined;
- requirements of SIC test object (production, uniformity, stability);
- information on the use and preparation of SIC test object;
- SIC time schedule;
- information on the used method(-s);
- description of the results comparability assessment methods, and the criteria used for statistical analysis, if such is carried out, and assessment of operation;
- description of the format of participants' and the organizer's reports.

SIC test object

- if prepared by the organizer of SIC – the object shall be assessed, if delivered externally, conformity assessment shall be performed (for example, certificates);
- homogeneity and stability shall be assessed and documented, if it is essential for assessment of results.

Assessment of results

- suitability of the statistical method of assessment of results shall be assessed;
- it shall be ensured that an adequate value is assigned and uncertainty of measurements related to this value is defined and is considered as possibly “confidential”;
- it shall be verified that a standard deviation (SDPA) appropriate for the target needs is determined.

Additional information on the statistical methods used for small data sets is available in ISO 13528:2017 “Statistical methods for use in proficiency testing in interlaboratory comparisons”.

The methods or procedures used by participants shall be documented and, if they differ and it is permissible, this information shall be used in the performance assessment.

Implementation of SIC

Instructions for the participants of SIC shall be documented and be available to them.

Additional conditions for processing, packaging, marking, distribution and storage of SIC test object shall be considered, informing the participants, especially if differences from the routine testing exist.

The organizer of SIC shall prepare a report, including at least the following information:

- date;
- contact person;
- persons or laboratories involved in the organisation of SIC;
- scheme description;
- description of the tested object;
- results of the participants;
- the results comparison assessment methods - the assigned value and the related uncertainty assessment, the standard deviation determination method, range of results, graphic representation;
- comparability of the results and / or performance of the participants;
- comments and recommendations, based on the results of SIC scheme.

If certain parts of information are detailed in SIC plan and have been received by all participants, this information can be skipped in the report.

List of literature

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

2. LVS EN ISO 15189:2013. Medical laboratories. Quality and competence requirements (ISO 15189:2012).

3. LVS EN ISO/IEC 17011 Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies.

4. LVS EN ISO/IEC 17043:2015 Conformity assessment. General requirements for proficiency testing (ISO/IEC 17043:2010).

5. LVS ISO 17034:2017. General requirements for the competence of producers of reference materials (ISO 17034:2016)

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

7. EA-4/18 INF (2010) Guidance on the level and frequency of proficiency testing participation

8. EA-4/21 INF (2019) Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

Register of changes

Version	Content of changes	Date
10.	Structurally changed, putting more accent on PT planning (level and frequency).	14.07.2021
	The section of definitions is supplemented with CRM, SIC, PT programme.	
	Updated information regarding the new version of standard LVS EN ISO/IEC 17025:2017.	
	Supplemented with ANNEX Organisation and Assessment of Results of Small Interlaboratory Comparisons.	