

## LATAK-D.048-00/05.2017

### *Requirements for accreditation of proficiency testing providers for conformity to requirements of standard LVS EN ISO/IEC 17043:2015*

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## 1. Introduction

Testing and/or calibration, medical laboratories and, where applicable, inspection bodies are obliged to participate in proficiency testing or laboratory comparison programmes (see: LATAK-D.007 and ILAC P9). Proficiency testing providers can certify their competence by accreditation for conformity to requirements of the standard LVS EN ISO 17043:2015 “Conformity assessment. General requirements for proficiency testing (ISO/IEC 17043:2010)” (hereinafter – LVS EN ISO 17043:2015) (see: ILAC-P13).

Interlaboratory comparison is widely used for various purposes. Interlaboratory comparison is usually performed to:

- ✓ regularly supervise performance of laboratories and assess ability of laboratories to perform specific tests and measurements;
- ✓ timely detect problems in laboratories and initiate improvement measures;
- ✓ determine efficiency and comparability of testing and measuring methods;
- ✓ ensure additional trust among customers of laboratories;
- ✓ identify differences of interlaboratory results;
- ✓ educate participant laboratories, based on the results of interlaboratory comparison;
- ✓ assess measurement uncertainties;
- ✓ assess performance characteristics of method;
- ✓ assignment of value to reference materials and assess their suitability for use;
- ✓ support announcements about conformity of measurements of national metrology bodies, using “key comparison” and supplementary comparison, which is performed by the International Bureau of Weights and Measures (*Bureau International des Poids et Mesures - BIPM*) and ordered by related regional metrology organizations.

Constant trusting in performance of laboratories is significant not only for laboratories and their customers, but also for other interested parties, for example, regulatory bodies, laboratory accreditation bodies and other organizations, which set requirements for laboratories. The standard ISO/IEC 17011 contains a requirement, that accreditation bodies shall take into consideration participation and performance of laboratories in proficiency testing.

## 2. Objective

This document describes the policy of the Latvian National Accreditation Bureau, hereinafter – LATAK, and assessment requirements for accreditation of proficiency testing providers for conformity to requirements of the standard LVS EN ISO/IEC 17043:2015. General accreditation conditions and procedures are described in other LATAK D documents.

## 3. Accreditation criteria

During the process of assessment of proficiency testing providers, LVS EN ISO/IEC 17043:2015 standard, applicable LATAK, EA and ILAC documents, as well as other applicable regulatory enactments are applied in the Latvian National accreditation system. The proficiency testing providing body or sub-contractor shall be accredited in the respective area and/or its competence has to be certified by participation in

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international proficiency testing in the respective area.

## 4. Terminology

### ***Interlaboratory comparison***

Organisation, execution and assessment of measurements or tests of one and the same or similar objects by two or more laboratories in accordance with pre-determined conditions.

### ***Participant***

Laboratory, organization or person, which receives proficiency testing objects or tests them on site and submits the results for verification to the proficiency testing provider.

### ***Proficiency testing***

Assessment of participant's performance in compliance with pre-determined criteria by applying interlaboratory comparison.

The term “proficiency testing” is used in its broadest meaning and it includes, but is not limited to the following elements:

- ✓ quantitative scheme – determination of quantity of one or several measured parameters for proficiency testing object;
- ✓ qualitative scheme – determination or description of one or several characteristics of proficiency testing object;
- ✓ sequential scheme – sequential transfer of one or several proficiency testing objects for testing or measuring and periodical returning to the proficiency testing provider;
- ✓ concurrent scheme – transfer of proficiency testing objects for parallel testing or measuring during a specific period of time;
- ✓ one-time testing – transfer of proficiency testing objects for one-time testing;
- ✓ continuous scheme – transfer of proficiency testing objects for testing in regular intervals;
- ✓ sampling – sample taking for further analysis; and
- ✓ data transformation and interpretation – ensuring of data set or other information and processing of data for interpretation purposes (or for obtaining any other result).

Some bodies, which ensure proficiency testing in medicine, use a term “external quality assessment (*EQA*)” for describing their proficiency testing scheme or broader programme, or for describing both these concepts. The requirements apply only to those *EQA* activities, which correspond to the definition of proficiency testing.

### ***Proficiency testing object***

Sample, product, item, reference material, particular device, measurement standard, data set or any other information used for proficiency testing

### ***Proficiency testing provider***

Organization, which is responsible for all tasks, related to preparation and implementation of proficiency testing scheme

### ***Proficiency testing scheme (programme)***

Proficiency testing, which is prepared and performed in one or more cycles in a specific testing, measurement, calibration or inspection area.

Proficiency testing scheme can include a particular type of test, calibration, inspection or several tests, calibration activities, which are performed on the proficiency testing object.

### ***Proficiency testing cycle***

One fully completed proficiency testing object transfer sequence cycle, assessment and reporting of results to participants

### ***Sub-contractor***

Organization or natural person, to which/whom the proficiency testing provider entrusts performing of activities that are specified in the standard LVS EN ISO/IEC 17043:2015 and which influence the quality of proficiency testing scheme.

### ***Metrological traceability***

Ability to link the measurement result with reference in a documented uninterrupted chain of calibration activities, where each calibration activity makes a contribution to uncertainty of measurements

### ***Uncertainty of measurements***

A parameter, which is not negative and characterizes value distribution of measured parameter, which is attributed to the measured parameter, based on the used information

## **5. LATAK policy for accreditation of proficiency testing providers for conformity to requirements of the standard LVS EN ISO/IEC 17043:2015**

### **5.1. General**

A proficiency testing provider, which applies for accreditation for conformity to LVS EN ISO/IEC 17043:2015, shall prove its technical competence to perform interlaboratory comparison, and special knowledge on the type of proficiency testing objects in the area applied for accreditation. There shall be at least one sample proficiency testing performed in each area before accreditation.

The proficiency testing provider or its sub-contractor shall have sufficient competence to measure the required characteristics.

The proficiency testing provider shall not transfer the following activities to the sub-contractor: 1) planning of proficiency testing scheme; 2) performance assessment; 3) preparation of final report.

### **5.2. Technical requirements**

#### **5.2.1. Personnel**

The leading and technical employees of the proficiency testing provider shall have appropriate education, technical knowledge, authorizations and resources for performance of their duties.

The leading employees shall have a determined and ensured mandatory level of skills and experience. Competence and supervision of permanent or contract agents shall be ensured.

The proficiency testing provider shall authorize special employees for selection of proficiency testing objects, planning of proficiency testing schemes, performing particular sample taking activities, using of special equipment, making of measurements, to determine stability and homogeneity of proficiency testing objects, as well as values assigned to measured parameters and related uncertainty, preparation, processing and transfer of proficiency testing objects, using of data processing system, performance of statistical analysis, assessment of performance of proficiency testing participants, giving of opinions and interpretations, authorization of issuing of testing reports.

The proficiency testing provider shall maintain documentation on competence, education, professional skills, training, abilities, experience and authorizations of permanent technical employees and contract agents.

The proficiency testing provider shall have specified objectives concerning education, training and skills of employees, as well as a policy, procedures and programme for ensuring of training. Efficiency of training activities shall be assessed.

Requirements for personnel are specified in paragraph 4.2 of the standard LVS EN ISO/IEC 17043:2015.

### **5.2.2. Equipment, conditions and environment**

The proficiency testing provider shall ensure conditions appropriate for performance of proficiency testing, including premises and equipment for production, processing, calibration, testing, storage and sending of the proficiency testing object, data processing, communication, recovery of materials and records.

The proficiency testing provider shall ensure, that environmental conditions do not influence negatively the required quality of proficiency testing scheme or activities, especially, if these activities are performed outside permanent premises or by sub-contractors. Technical requirements with regard to the premises and environmental conditions, which can influence proficiency testing, shall be documented. The proficiency testing provider shall ensure, control, supervise and protocol environmental conditions, which can influence quality of proficiency testing objects and activities. Incompatible activities shall be separated and mutual pollution possibility shall be eliminated.

Performance characteristics of methods used for approval of the proficiency testing object's contents, homogeneity and stability, and equipment shall be validated and maintained.

Requirements for equipment, conditions and environment are specified in paragraph 4.3 of the standard LVS EN ISO/IEC 17043:2015.

### **5.2.3. Preparation of proficiency testing scheme**

#### **5.2.3.1. Planning**

The proficiency testing provider shall determine, plan and perform processes in accordance with the specified procedures, in order to ensure quality of proficiency testing scheme. Planning of proficiency testing scheme shall not be entrusted to a sub-contractor. A plan shall be documented, where objectives, tasks and basic structure of proficiency testing scheme shall be determined, and information required in paragraph 4.4.1.3 of the standard LVS EN ISO/IEC 17043:2015 shall be indicated. The plan shall be available for the initial accreditation and by planning new areas, in order to prove, that the standard requirements are fulfilled. Revision of documents shall be carried out, if there are changes to the proficiency testing scheme.

The proficiency testing provider shall have technical knowledge and experience in the testing, calibration, sampling, inspection, as well as statistics area, which can be ensured by establishing a group of advisors, if necessary. Technical expertise shall be applied in areas as determined in paragraph 4.4.1.5 of the standard LVS EN ISO/IEC 17043:2015.

Requirements for planning are specified in paragraph 4.4.1 of the standard LVS EN ISO/IEC 17043:2015.

#### 5.2.3.2. Preparation of proficiency testing objects

The proficiency testing provider shall develop and implement procedures for ensuring of obtaining, collection, preparation, processing, storage and, if necessary, disposal of proficiency testing objects.

Matrices, measured parameters and concentrations of proficiency testing objects shall as far as possible comply with objects or materials used in routine testing or calibration. Proficiency testing schemes, under which preparation and processing of testing object and its submission to the testing provider is stipulated, shall contain directions on preparation, packaging and transportation of the proficiency testing object.

Requirements for preparation of proficiency testing objects are specified in paragraph 4.4.2 of the standard LVS EN ISO/IEC 17043:2015.

#### 5.2.3.3. Homogeneity and stability

Homogeneity and stability criteria shall be developed and substantiated. Homogeneity and stability assessment procedures shall be protocolled and carried out in compliance with corresponding statistical models.

Homogeneity and stability of proficiency testing objects shall be proved in preparation, packaging, storage and transportation conditions.

Homogeneity and stability considerations are described in detail in ISO 13528.

Requirements for homogeneity and stability are specified in paragraph 4.4.3 of the standard LVS EN ISO/IEC 17043:2015.

#### 5.2.3.4. Statistical model

A statistical model shall be developed to achieve the scheme objective, based on characteristics of data (quantitative or qualitative data, including ordinal and categorical data), statistical assumptions, nature of errors and number of expected results. The statistical model and methods of data analysis shall be documented. By developing the statistical analysis, the proficiency testing provider shall assess the requirements specified in paragraph 4.4.4.3 of the standard LVS EN ISO/IEC 17043:2015.

For assessment of correctness of methods and results, the principles specified in standards, for example, LVS ISO 5725, LVS CEN ISO/TS 22117 are applied.

Requirements for statistical model are specified in paragraph 4.4.4 of the standard LVS EN ISO/IEC 17043:2015.

#### 5.2.3.5. Assigned values

The proficiency testing provider shall document the procedure in order to determine the values assigned to measured parameters in the particular proficiency testing scheme. Assigned values in the calibration area shall be metrologically traceable and with uncertainty of measurements. The policy on traceability of measurement results is specified in the document ILAC P10.



Assigned values in proficiency testing schemes in other areas, the metrological traceability and uncertainty of measurements shall be determined taking into consideration specific requirements for participants and interested parties or according to the proficiency testing model. If the assigned value is a harmonised value (see: Annex A and B of LVS EN ISO/IEC 17043), the proficiency testing provider shall document the reason for such choice and assess uncertainty of such assigned value in accordance with the description given in the plan of proficiency testing scheme. A policy for disclosure of assigned values shall be developed.

Requirements for assigned values of measured parameters are specified in paragraph 4.4.5 of the standard LVS EN ISO/IEC 17043:2015.

#### **5.2.4. Selection of method or procedure**

Participants can select a testing, calibration or measurement method, which corresponds to their routine procedures, or the method determined by the proficiency testing provider in accordance with the proficiency testing scheme.

If participants are using self-selected methods, the proficiency testing provider shall have a policy, procedure and knowledge for comparison of results, obtained through using different methods.

Requirements for selection of method or procedure are specified in paragraph 4.5 of the standard LVS EN ISO/IEC 17043:2015.

#### **5.2.5. Implementation of proficiency testing schemes**

Before sending of proficiency testing objects, the proficiency testing provider shall provide participants with information and precisely documented directions, which are indicated in paragraphs 4.6.1.1 and 4.6.1.2 of the standard LVS EN ISO/IEC 17043:2015.

The proficiency testing provider shall ensure, that proficiency testing objects are appropriately identified, separated, stored, assessed, distributed and disposed.

The proficiency testing provider shall supervise packaging and marking processes, determine and, if necessary, supervise and assess the relevant environmental conditions for transportation of proficiency testing objects. Instructions for transportation shall be attached in proficiency testing schemes, under which participants deliver proficiency testing objects to other participants. The testing provider shall ensure, that packaging labels are securely attached, legible and undamaged throughout the entire testing cycle, and shall ensure a possibility for participants to approve delivery of proficiency testing object.

Requirements for implementation of proficiency testing schemes are specified in paragraph 4.6 of the standard LVS EN ISO/IEC 17043:2015.

#### **5.2.6. Data analysis and evaluation of proficiency testing scheme results**

The data processing equipment and software shall be validated according to the relevant procedures. Data backup and system recovery plan shall be ensured. Analysis of results received from participants shall be carried out, and correctness of input, transfer, statistical analysis and reporting of data received from participants shall be verified.

The proficiency testing provider shall develop criteria and procedures, which are applied for processing of possible results that are unsuitable for statistical assessment, and for identification and management of proficiency testing objects, which are distributed and later recognized as invalid for performance assessment.

Valid assessment methods, which correspond to proficiency testing schemes and include assessment justification, shall be used for performance assessment.



Implementation of performance assessment shall not be entrusted to a sub-contractor (paragraph 5.5.2 of LVS EN ISO/IEC 17043:2015).

Requirements for data analysis and analysis of results of proficiency testing scheme are specified in paragraph 4.7 of the standard LVS EN ISO/IEC 17043:2015.

#### **5.2.7. Reports**

Proficiency testing reports shall contain data of all participants, additionally indicating performance of each participant. Preparation of the final report shall not be entrusted to a sub-contractor (paragraph 5.5.2 of LVS EN ISO/IEC 17043:2015). The elements to be included in the report are specified in paragraph 4.8.2 of the standard LVS EN ISO/IEC 17043:2015.

Before reporting of final results, initial results can be reported. If a new or amended report is issued on the proficiency testing scheme, the report shall contain the information specified in paragraph 4.8.5 of the standard LVS EN ISO/IEC 17043:2015. Requirements for reports are specified in paragraph 4.8 of the standard LVS EN ISO/IEC 17043:2015.

#### **5.2.8. Communication with participants**

The proficiency testing provider shall publish precise information on the proficiency testing scheme. The information to be included is specified in paragraph 4.9.1 of the standard LVS EN ISO/IEC 17043:2015.

Documented procedures shall be developed in order to ensure a possibility for participants to challenge the assessment of their performance in the proficiency testing scheme.

Requirements for communication with participants are specified in paragraph 4.9 of the standard LVS EN ISO/IEC 17043:2015.

#### **5.2.9. Confidentiality**

The identity of proficiency testing participants shall be confidential and known only to those persons who are involved in implementation of the proficiency testing scheme, except the instances, when a participant waives the right of confidentiality. Confidential information shall be considered the information, which is provided by participant to the proficiency testing provider. If any of interested parties requests results of proficiency testing directly from the testing provider, participants shall be informed about it before participation. In exceptional cases, if the regulatory body requests results of proficiency testing directly from the testing provider, the involved employees shall be informed about it in writing.

Requirements for confidentiality are specified in paragraph 4.10 of the standard LVS EN ISO/IEC 17043:2015.

### **5. 3. Requirements for management**

#### **5.3.1. Organisation**

The proficiency testing provider or organization to which it belongs, shall be a legally identifiable and responsible structure. An obligation of the proficiency testing provider is to perform proficiency testing in a way that corresponds to requirements of the international standard and needs of participants, regulatory bodies and organizations that perform recognition. If the proficiency testing provider belongs to an organization, which performs other activities, in order to detect possible conflicts of interest, obligations shall be determined for key employees of organization, who are involved in proficiency testing activities or who may influence proficiency testing activities.

If any possible conflicts of interest are detected, relevant procedures shall be applied to ensure impartiality of implementation of activities of proficiency testing provider. Requirements for the proficiency testing provider are specified in paragraph 5.1 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.2. Management system**

The proficiency testing provider shall develop, introduce and maintain a documented management system, which corresponds to the area of activity of the proficiency testing provider and includes the type, range and scope of proficiency testing carried out by the proficiency testing provider. The quality handbook shall determine directions of proficiency testing provider's management system policy in relation to quality. A quality policy declaration, approved by the highest management, shall be issued, which shall contain elements that are specified in paragraph 5.2.3 of the standard LVS EN ISO/IEC 17043:2015.

General objectives shall be set, which shall be revised in the management review. The senior management shall inform the organization about compliance with requirements of customers, laws and regulatory documents. Requirements for management system and senior management are specified in paragraph 5.2 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.3. Management of documents**

The proficiency testing provider shall develop and maintain procedures, which ensure management of all of its management system documents. The management system procedures shall ensure, that documents are identified, approved and revised.

Requirements for management of documents are specified in paragraph 5.3 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.4. Revision of requests, offers and contracts**

The proficiency testing provider shall develop and maintain a policy and procedures for revision of requests, offers and contracts. During revision of contracts, it has to be ensured, that requirements are properly defined, documented and understood, that the proficiency testing provider has abilities and resources for compliance with requirements, and that the proficiency testing scheme is technically suitable. Revision protocols shall be maintained. Participants and customers shall be informed about deviations in the contract or proficiency testing scheme.

Requirements for revision of requests, offers and contracts are specified in paragraph 5.4 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.5. Services of sub-contractors**

If the proficiency testing provider concludes sub-contracts on implementation of works, it shall prove, that experience and technical competence of sub-contractors is sufficient for performance of entrusted tasks and that sub-contractors comply with requirements of relevant paragraphs of this international standard and other appropriate standards, for example, LVS EN ISO/IEC 17025 and LVS EN ISO 15189:2013. The proficiency testing provider or sub-contractor shall be accredited in the respective area and/or shall prove its competence through participation in international proficiency testing in the relevant area.

The proficiency testing provider shall not entrust planning of proficiency testing scheme to sub-contractors (see: paragraph 4.4.1.2 of LVS EN ISO/IEC 17043:2015), performance assessment (see: paragraph 4.7.2.1 of LVS EN ISO/IEC 17043:2015) and approval of the final report (see: paragraph 4.8.1 of LVS EN ISO/IEC 17043:2015).

If the proficiency testing provider entrusts a service to a sub-contractor, participants shall be informed about it in advance and in writing. The proficiency testing provider shall be responsible for works entrusted under a sub-contract.

The proficiency testing provider shall maintain a list, which contains sub-contractors involved in proficiency testing schemes, their area of activity and competence assessment.

Requirements for services of sub-contractors are specified in paragraph 5.5 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.6. Purchasing of services and supplies**

The proficiency testing provider shall develop a policy and procedures for selecting services and supplies, which influence the quality of proficiency testing schemes. Procedures for purchase, receipt and storage of reagents used in the proficiency testing scheme, proficiency testing objects, reference materials and other materials shall be developed. Reviews of procurements shall be carried out, protocols of procurement conformity verifications and a list of approved suppliers shall be maintained.

Requirements for purchasing of services and supplies are specified in paragraph 5.6 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.7. Services for customer, complaints and appeals**

The proficiency testing provider shall cooperate with participants and other customers in order to clarify requests of customers and ensure supervision of performance of the proficiency testing provider, and confidentiality shall be ensured for participants. The proficiency testing provider shall analyse feedback of customers.

Requirements for provision of services to customers are specified in paragraph 5.7 of the standard LVS EN ISO/IEC 17043:2015.

The proficiency testing provider shall have developed a policy and procedure for examination of complaints and appeals received from participants, customers and other involved parties.

Requirements for examination of complaints and appeals are specified in paragraph 5.8 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.8. Management of nonconforming work, improvement, corrective and preventive actions**

The proficiency testing provider shall develop a policy and procedures, which shall be applied in the cases, when any aspect of proficiency testing provider's work does not correspond to self-developed procedures or requirements agreed on with customers. The policy and procedures shall ensure, that obligations and powers in relation to conduct in the case of nonconforming work are specified, activities are formulated, which shall be implemented when detecting nonconforming work, assessment of significance of nonconforming work is performed, an immediate decision on the conduct and execution schedule is made, participants of the proficiency testing scheme and, consequently, other customers are informed, the nonconforming proficiency testing objects or reports are revoked or ignored, and responsibility for giving permission to approve resumption of work is determined.

Requirements for management of nonconforming work are specified in paragraph 5.9 of the standard LVS EN ISO/IEC 17043:2015.

Requirements for improvement are specified in paragraph 5.10 of the standard LVS EN ISO/IEC 17043:2015.

The proficiency testing provider shall develop a policy and procedures, and appoint relevant employees for implementation of corrective actions, if nonconforming work or deviation from the management system policy directions, procedures or technical operations is detected. The procedure of corrective actions shall be started by investigation in order to determine basic causes of the problem. Corrective actions shall be determined and carried out according to significance and risk of the problem, these actions shall be protocolled, results shall be supervised to ensure efficiency of corrective actions, and, if necessary, auditing of respective areas of activity shall be ensured.

Requirements for corrective actions are specified in paragraph 5.11 of the standard LVS EN ISO/IEC 17043:2015.

Areas of technical and management system, where improvements are required, and possible sources of nonconforming work shall be determined. When improvement possibilities are determined or when preventive actions have to be implemented, action plans shall be developed and implemented, and implementation of these plans shall be supervised in order to ensure efficiency of preventive actions.

Requirements for preventive actions are specified in paragraph 5.12 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.9. Management of records**

The proficiency testing provider shall develop and maintain procedures, which shall be applicable to identification, collection, indexing, access, systematization, storage, maintenance and disposal of records. Quality records shall include internal audit reports and management reports, as well as records on corrective and preventive actions.

All records shall be legible and stored in an easy accessible way, protected against damage, deterioration of their condition, or loss. Records shall be stored safely and confidentially. The storage period shall be specified for records.

The proficiency testing provider shall observe procedures to protect and backup electronically stored records and eliminate unauthorized access or making amendments to these records.

The proficiency testing provider shall keep records with all technical data that refer to each testing cycle in a specific period of time, for example, results of homogeneity and stability testing, instructions for participants, initial responses of participants, comparative data for statistical analysis, information for preparation of reports, final reports.

Data input, tests and calculations shall be protocolled at the moment of their occurrence and they shall be identifiable with the specific task and responsible employee.

If mistakes occur in records and amendments are made, actions shall be implemented to indicate the amendment and its date, to avoid loss of initial data, and to identify the person who has made an amendment.

Requirements for management of records are specified in paragraph 5.13 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.14. Internal audit**

The proficiency testing provider shall perform internal audit of own activities periodically and in accordance with pre-determined schedule and procedures. The internal audit programme shall include all elements of management system, including technical procedures, preparation, storage and distribution of proficiency testing objects, as well as reporting on implementation of the proficiency testing scheme.

The quality manager shall plan and organise the audit in compliance with requirements of schedules and management.

The internal audit shall be performed by trained and qualified employees, who, if allowed by available resources, are not related to the activity to be audited. Performance of the internal audit of management system is recommended once in 12 months.

If the facts detected during the audit cause concerns about efficiency of activities, the proficiency testing provider shall timely carry out corrective actions and inform its customers and/or participants about proficiency testing schemes, actions of which may be influenced.

The area of audited activity, facts detected during the audit and relevant corrective actions shall be protocolled. Implementation and efficiency of all performed corrective actions shall be verified and protocolled in the following auditing activities.

Requirements for internal audit are specified in paragraph 5.14 of the standard LVS EN ISO/IEC 17043:2015.

### **5.3.15 Management review**

The top management of the proficiency testing provider shall periodically perform review of proficiency testing provider's management system and proficiency testing activities in accordance with a pre-determined schedule and procedures. Usually, management reviews are performed once every 12 months. During the review, the proficiency testing provider shall observe the policy and procedures suitability, management and supervision reports, reports of recent internal audits, corrective and preventive actions, assessments of external bodies, changes in the amount and type of work, feedback of customers, advisors group or participants, complaints and appeals, suggestions for improvement and other significant factors, for example, resources and training of employees. The facts detected during management reviews and actions arising from these facts shall be protocolled. The management shall ensure performance of these actions within a particular term.

Requirements for management review are specified in paragraph 5.15 of the standard LVS EN ISO/IEC 17043:2015.

## **6. Design of accreditation scope**

In the accreditation scope of the proficiency testing provider, identification and name of the proficiency testing scheme, type of proficiency testing objects, and testing/calibration measured parameters/features and/or characteristics shall be indicated, for example:

- a) in the testing/ medicine area, the testing provider shall indicate in the accreditation scope the name of product/material, matrix (describe comparison object – product, material, matrix), measured parameter (describe characteristics, parameters, what is comparison object), and scheme identification and name (reference to the document, which provides general outline about the accredited scheme) (see: Annex No. 1);
- b) in the calibration area, the proficiency testing provider shall indicate in the accreditation scope the measuring instrument, measured parameter, characteristics (range and, if necessary, conditions, specification), scheme identification and name (reference to the document, which provides general outline about the respective accreditation scheme) (see: Annex No. 1).

According to the document LATAK-D.041, initially, during the first accreditation period, accreditation is based on the “fixed” accreditation scope to ensure that



LATAK assessment is implemented each time before changes in the accreditation scope. During further accreditation periods, based on the institution competence assessed in procedures of previous assessment procedures, implementation of the flexible scope approach is possible. The approach of the European co-operation for Accreditation (hereinafter – EA) on the flexible accreditation scope is specified in EA document EA-2/15.

Guidelines for designing of proficiency testing provider accreditation scope are documented in EA document EA-2/18.

## **7. Documents for submission**

By applying for accreditation, the documents to be submitted for assessment are indicated in the form F.002.00, which is published on the homepage of LATAK.

## **8. Literature**

LVS EN ISO/IEC 17043:2013 Conformity assessment. General requirements for proficiency testing (ISO/IEC 17043:2010)

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

LVS EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

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

LVS CEN ISO/TS 22117:2011 Microbiology of food and animal feeding stuffs. Specific requirements and guidance for proficiency testing by interlaboratory comparison (ISO/TS 22117:2010)

LVS EN ISO/IEC 17011:2004 Conformity assessment - General requirements for accreditation bodies, accrediting conformity assessment bodies

EA-2/18: 2015 Guidelines for Accreditation Bodies on the Contents of the Scopes of Accreditation for Proficiency Testing Providers

EA-2/15 M:2008. EA Requirements for the Accreditation of Flexible Scopes.

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

ILAC P10:01/2013 ILAC Policy on Traceability of Measurement Results

ILAC-P13:10/2010 Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers

LATAK-D.007-08/01.2015 Proficiency testing in the Latvian National accreditation system

LATAK-D.041-02/02.2014 Accreditation in the flexible scope

LVS ISO 5725-1:2006 +TC1 Accuracy (trueness and precision) of measurement methods and results - Part 1: General principles and definitions

Accuracy (trueness and precision) of measurement methods and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method

LVS ISO 5725-4:2006 Accuracy (trueness and precision) of measurement methods and results - Part 4: Basic methods for the determination of the trueness of a standard measurement method

Annex No. 1

Example of accreditation scope

Object/measuring instrument/matrix	Measured parameter/feature (characteristics)	Scheme identification, name
Underground water	pH, EVS, Na, K	PŪ1 Underground water quality
Soil	Cd, Cr, Ni, Cu	SM1 Determination of heavy metals in soil
Dairy products	Fat content, inhibitors	AB1 dairy products testing
Blood serum	K, Na, creatinine	AA2 Blood analysis
Urine	Leukocytes, erythrocytes	UA1 Urine analysis
Weighting instruments	Mass (0.1 - 20 kg)	ABC01 Weighting instruments calibration
Thermometer	Temperature (0-50 °C)	TC1 Temperature calibration