

**National Accreditation  
Agency of Ukraine**

**Approved by**  
NAAU Decree  
Dated 15.07.2015 № 199-Я

## **MANAGEMENT SYSTEM**

### **NAAU Policy on participation in interlaboratory comparisons and proficiency testing**

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## **NAAU Policy on participation in interlaboratory comparison and proficiency testing**

National Accreditation Agency of Ukraine (hereinafter – NAAU) evaluates the fulfilment of requirements of the standard ДСТУ ISO/IEC 17025 for testing, calibration laboratories, as well as requirements of the standard ДСТУ ISO 15189 for medical laboratories and also fulfilment of ДСТУ ISO/IEC 17020 requirements for inspection bodies. These standards require conformity assessment bodies to have a quality management system for testing and/or calibration results, and within this system they have to participate in interlaboratory comparisons (hereinafter – ILC) and proficiency testing (hereinafter – PT) (external quality assessment).

NAAU requires that laboratories before and after granting the accreditation regularly participate in such testing/comparisons (except laboratories in defined fields where assessments of quality of testing through interlaboratory comparisons is not applied). In case when participation in ILC programs is impossible, NAAU assessors or experts can require a laboratory to conduct testing/calibration of a sample that was tested/calibrated by a laboratory before. For achieving this goal, measurement standard materials or reference material can also be used.

*Note: For the purposes of this document, the term proficiency testing (PT) means also external quality assessment programs (medical laboratories) and the other appropriate interlaboratory comparisons (ILC), which results can be used for the evaluation of the competence of the laboratory technical activities and, where relevant, also of the inspection body technical activities.*

ILC and PT are considered as an important tool to demonstrate the competence and upkeep the quality of technical activities of laboratories and inspection bodies (where relevant). For this reason, laboratories and, where relevant, also inspection bodies, which are in the accreditation process or have already been accredited, have to develop the strategy of participation in appropriate PT, which takes into account the risks of activities of conformity assessment bodies and other processes for quality control and quality assurance of technical activities. This strategy is elaborated for one accreditation cycle and has to be reviewed and if it is necessary it should be updated at least once a year. The strategy of participation in PT/ILC is reviewed or considered by NAAU.

Submission of annual plans for participation in ILC and PT in the corresponding calendar year is required by NAAU from accredited laboratories and, where relevant,

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from accredited inspection bodies.

ILC programs shall be prepared by competent coordinators. During conducting of a laboratory assessment, assessors or technical experts shall check participation of a laboratory in ILC for compliance of accreditation scope and obtained results. For assessment of results of participation in particular program, criteria established by coordinators of assessment programs concerning calibration or testing for a certain type of measurement or testing are used.

Before granting the accreditation, calibration laboratories (hereinafter – CL), testing laboratories (hereinafter – TL) have to participate in proficiency testing or an appropriate interlaboratory comparison:

- CL – in each type of measurement (measuring instruments of the highest accuracy class), in each kind of measurement value, draft accreditation scope;
- TL – in each field of a draft scope of its activity that they are applying for accreditation and achieve satisfactory results, if such comparisons are organized, available and appropriate.

Accredited CL, TL has to participate at least one time in assessment programs of quality of conducting calibration, testing within inter-accreditation period. In case of impossibility of comparative calibrations and testing, other methods for control of results are used, for example bilateral comparison of measurement results with other laboratory that has accreditation.

CL and TL shall participate in programs for assessment of calibration and testing quality irrespective of the results of previous comparisons.

In case of negative results of participation in programs for assessment of calibration and testing quality, laboratories shall implement corrective actions and keep this information in accordance with the terms defined by a laboratory.

NAAU requires that accredited TL and CL keep all data regarding their participation in ILC programs and ensure access to it for NAAU assessors and technical experts.

NAAU also accepts the results of participation in other types of comparisons main objectives of which differ from ILC, such as:

- comparisons conducted for assessment of characteristics of methods performance; measurement/testing/calibration;
- determination of characteristics of measurement standard materials;
- comparison of two or more laboratories/inspection bodies by their own initiative, etc.

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In such cases, it is necessary to have clear, predefined criteria or procedures basing on which ILC results will be assessed with the aim to be accepted for ILC objectives. All these organized ILC that will be also used for PT objectives shall meet the appropriate requirements of the standard ISO/IEC 17043.

Before granting accreditation, medical (clinical) laboratories have to participate in external quality assessment (proficiency testing, interlaboratory comparison) in each of the fields of specification of their activities that they are applying for accreditation and achieve satisfactory results, if such comparisons are organized, available and appropriate.

Inspection bodies, where relevant, have to participate in proficiency testing or an appropriate comparison, in one of the fields of specification of activities, that they are applying for accreditation and achieve satisfactory results, if such comparisons are organized, available and appropriate.

When NAAU is assessing the competence of laboratories or, where relevant, also inspection bodies, it takes into account the results of participation in an appropriate PT or ILC that are organized by accredited providers of proficiency testing and also the results of PT/ILC organized by non-accredited providers. In this case it has to be demonstrated that by planning, execution and evaluation of PT/ILC the relevant requirements of ISO/IEC 17043 were fulfilled.

During every on-site assessment NAAU verifies the results of participation of laboratories in proficiency testing or other interlaboratory comparisons in terms of covering the whole scope of accreditation. If an accredited laboratory or inspection body (where relevant) does not participate in PT/ILC for some of identified sub-fields in one accreditation cycle and these PT/ILC were available and appropriate, NAAU can suspend the accreditation for given technical activity from the scope of accreditation. In case of unsatisfactory participation in PT/ILC for all or some parameters/characteristics of the scope of accreditation, NAAU checks whether the laboratory (inspection body, where relevant) analysed the causes of such a situation, took appropriate and effective corrective actions and did activities, which removed the problem. If this was not carried out and there are no relevant reasons for that, NAAU will suspend the validity of accreditation in corresponding scope. Various factors are taken into account, such as other outputs from quality assurance and quality control system, the way of organization and evaluation of PT/ILC, the total results of PT/ILC, the results achieved in the related parameters/characteristics, etc.

NAAU publishes the available PT/MP on its website ([naau.org.ua](http://naau.org.ua)) and, where

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it is possible, available and appropriate, invites and eventually nominates laboratories and inspection bodies (where relevant) to participate in PT organized by EA, ILAC, APLAC and in other PT/ILC organized at national and international level.

The validity of this Policy is not set.

Review of this NAAU Policy should be done if necessary.

The document is developed by:

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