Document name	Procedure on EA BAS policy for Interlaboratory Comparisons and Proficiency Testing	Version: *5* Revision:1	
Document code	BAS QR 18	Date:	06.01.2019
Approved by	Executive Director of EA BAS: Eng. Irena Borislavova		

PROCEDURE ON EA BAS POLICY FOR INTERLABORATORY COMPARISONS AND PROFICIENCY TESTING

List of amendments:

№	Date	Amendment made on page №	Proposed by		In force from	Signature Quality Manager
			Surname	Signature		
1.	09/08/2004	1-11, procedure code	Pencheva	/s/	12/08/2004	/s/
2.	09/08/2004	BAS Q(F) 21.1, 22.2, 22.3, 22.4 forms code	Pencheva	/s/	12/08/2004	/s/
3.	24/02/2006	3, 4, 5, 7, 8, 11	Ivanichkov	/s/	01/03/2006	/s/
4.	30.11.2008	New version	Ivanichkov	/s/	30.11.2008	/s/
5.	12.11.2012	New version	Ivanichkov Approved by AC on 26.11.2012	/s/	01.01.2013	/s/
6.	30.04.2016	New version	Ivanichkov	/s/	01.05.2016	/s/
7.	15.01.2018	New version	Ivanichkov	/s/	01.02.2018	/s/
8.	06.01.2019	New revision	Ivanichkov	/s/	06.01.2019	/s/

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1. Purpose and scope of application

This document defines the policy of EA "BAS" regarding the participation in ILC/PT of applicants for accreditation and accredited Conformity Assessment Bodies (CABs). The documents also defines the rules for evaluation and use the results of the Interlaboratory Comparisons/Proficiency Testing (ILC/PT) and the measurement audits in accreditation procedures and maintenance of the accreditation of CABs aiming to assure their technical competence . The document refers to the requirements of CABs in ILC/PT and provides guidance to EA "BAS" assessor teams for usage of the results of comparisons and proficiency testing in the assessment process.
This document provides guidance to accredited CABs on appropriate use of ILC / PT for their accredited scope and the provision of evidence for quality assurance and validity of the results of measurements, testing, calibrations and control.

1.1 The main requirements which calibration and testing laboratories shall fulfill, if they wish to demonstrate an introduced quality management system, that they are technically competent and can provide reliable results, are described in the international standards БДС EN ISO/IEC 17025 and БДС EN ISO 15189. Clause 7.7.2 of EN ISO/IEC 17025 requires the laboratories to have procedures for quality control, by means of which to guarantee the validity of results of measurement/testing and calibration. The standard notes that the laboratory can participate in ILC or PT, as this is also recommendation of EN ISO 15189 (Clauses 5.6.3a and 5.6.4) for the medical laboratories.

1.2 Ensuring the quality of the results, provided by inspection bodies, accredited in accordance with БДС EN ISO/IEC 17020 is possible trough participation in ILC/PT for activities to which the technical requirements of БДС EN ISO/IEC 17025 are applicable.

1.3 EA "BAS" encourages and requires the accredited by the agency bodies to participate in proficiency testing or other comparison programs, when available and suitable, as also requires them to undertake corrective/preventive actions when necessary. ILC / PT provide EA BAS with possibility to harmonize accredited activities.

1.4 EA "BAS" may carry out a measurement audit as a part of CABs technical competence assessment process.

2. Terms, definitions and abbreviations

The terms, definitions and abbreviations used in this procedure are according to БДС EN ISO/IEC 17000 and БДС EN ISO/IEC 17043, as follows:

2.1. Terms and definitions

ILC - Interlaboratory Comparison - organization, presentation and evaluation of measurements or testing on the same or similar objects by two or more laboratories in accordance with predetermined conditions (БДС EN ISO / IEC 17043, Clause 3.4.)
PT - Proficiency Testing - evaluating the performance of participants in relation to pre-established criteria by means of interlaboratory comparisons (БДС EN ISO / IEC 17043, Clause. 3.7)
Proficiency Testing Scheme - proficiency testing, which is designed and performed in one or more cycles in a particular field of testing, measurement, calibration or control (БДС EN ISO / IEC 17043, Clause 3.11)
Proficiency Testing Provider - organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme. (БДС EN ISO/IEC 17043, Clause 3.9)

Participant - laboratory, organization or individual, that receives proficiency test items and submits results for review by the proficiency testing provider. (БДС EN ISO/IEC 17043, Clause 3.6)
Measurement audit - calibration/test performed by laboratory with the purpose of proving technical capabilities by comparing results of the calibration/test performed by the laboratory of a technical equipment with known features (measurement device, standard, CRM, etc.), provided for the purposes of the measurement audit.

2.2. Abbreviations

ILC/PT - Interlaboratory Comparison/Proficiency Testing
CAB - Conformity Assessment Body
SI - International System of Units
In the context of this document, the term "laboratory" is applied when referred to testing, calibration and medical laboratories, as well as inspection bodies, for which the requirements of БДС EN ISO/IEC 17025 are applicable.

3. Description of activity

3.1 EA "BAS" Policy

As a National Accreditation Body, EA "BAS" maintains international recognition of the accredited by the agency laboratories and uses successful participation in ILC / PT as a tool for proving their technical competence of activities and scope for which they are accredited.
Technical competence except through participation in PT can be proved by successful participation in interlaboratory comparisons organized for purposes other than those of proficiency testing, such as:

- Evaluation of method features;
- Characterization of reference materials;
- Comparison of results between two or more laboratories on their initiative;
- In order to support the declaration of equivalence of measurements of the National Metrology Institutes, etc.

EA "BAS" considers the successful participation in PT for particularly significant tool for proving the technical competence of laboratories; therefore, the agency defines the following rules in the accreditation of laboratories:

3.1.1 Each accreditation applicant has been successfully participating at least once in PT or measurement audit, prior to granting accreditation by EA "BAS".

3.1.2 All laboratories accredited by EA "BAS" shall participate in PT activities, when such are possible and corresponding to the applied/granted scope of accreditation.

3.1.3 As a minimum, each laboratory shall participate at least once in PT for each of the subfields (see 3.3) of the accredited scope for a period of four years, when PT are possible and corresponding to the scope.

3.1.4 Each accredited laboratory shall develop a plan for ILC/PT, conformed to the subfields of the accreditation scope and the defined minimal criteria for frequency of participation. The plan shall be updated depending on the needs of the laboratory, for instance in the change of personnel, method, technical equipment, etc.

3.1.5 Laboratories shall have criteria for selection of PT provider. EA "BAS" recommends participation in PT, organized by providers accredited against БДС EN ISO/IEC 17043 considering that accreditation provides confidence in their activities.

3.1.6 Laboratories shall have the appropriate criteria for acceptability of results of participation in PT, a documented procedure for analysis of the reasons in the event of unsatisfactory/questionable results of participation, as well as procedure for undertaking corrective/preventive actions in such cases.

3.1.7 When realization of ILC/PT is practically impossible (see 3.2.3), the laboratory must be able to prove its technical competence by other methods, for instance regular use of standards and/or reference material materials, repetition of the testing/calibration by using the same or different method, etc.

3.1.8 Laboratory in procedure for accreditation or maintenance of accreditation may be required to test a sample or to calibrate a device with known features - measurement audit.

3.1.9 When possible, and when the results of measurement audit is an appropriate tool in process of evaluation of the technical competence of the laboratories, EA "BAS" may plan and carry out such audit during the on-site assessments. The results of the measurement audit are an addition to the overall technical assessment performed by the assessment teams of EA "BAS".

3.1.10 Upon request on the part of EA "BAS", the laboratories shall act in support to the EA Multilateral Agreement in the relevant areas of accreditation, to which the agency is a signatory, by participating in PT organized or recommended by EA or ILAC. The financing of participation in these comparisons is undertaken by the laboratory itself.

3.1.11 In the event of specific circumstances /for instance significant changes in the laboratory, raised nonconformities, questionable or doubtful results from testing/calibration, etc./, EA "BAS" may require participation by the laboratory in PT within a short term defined by the Agency.

3.1.12 EA "BAS" publishes in section "ILC and PT" of its webpage information for possible proficiency testing programs and accredited PT organizers, by indicating contacts and additional information, when such is available.

3.2 Guidance for implementation of EA "BAS" Policy

3.2.1 Laboratories should be aware of the purpose and benefits of participation in programs for proficiency testing. They should be able to choose the appropriate PT and to analyze and use the results to improve their activities.
Laboratories shall have developed procedure on planning, participation, analysis and evaluation of results of participation, as well as for appropriate corrective actions. Laboratories shall maintain records of results from these activities, for results of its participation and for analysis of these results. The records must envelop also the undertaken actions on the part of the laboratory in the event of unsatisfactory and disputable results of PT.

3.2.2 Laboratories should carry out feasibility studies and participate in suitable PT offered by competent (accredited) providers of proficiency testing. EA BAS considers as appropriate PT, in accordance with ISO / IEC 17043 and organized by:
• accredited organizers of proficiency testing (as required by ISO / IEC 17043);

- such published in section "ILC and PT" on the website of EA BAS;
- EA, APLAC, ILAC, EURAMET, BIPM and other regional and international organizations;
- organized (co-organized) by the structures of the European Commission;
- national bodies and organizations authorized to perform comparisons (Bulgarian Institute of Metrology, national reference laboratories, etc.).

Note 1: EA BAS required when ILC / PT is used for the accreditation of CABs or for its maintenance participants to provide information about their participation.
Note 2: EA BAS requires national reference laboratories or institutions, defined as those operating in the Republic of Bulgaria, to provide information on relevant ILC / PT and итс participants, in cases where participants are laboratories that are in the process of accreditation or are accredited by EA BAS.

3.2.3 When organization of PT is practically impossible, the laboratory shall determine the fields and subfields from the granted accreditation scope, for which impossibility is claimed. The determination of these fields shall be motivated and justified with evidence, where appropriate, and with examples from the international practice. Upon information sent to EA "BAS" by means of motivated standpoint for particular fields with practical impossibility for organization of PT, the agency requires the Technical Accreditation Committees for laboratories (TAC) for confirmation of this impossibility.

3.2.4. In the event that the laboratory has exhausted the possibilities under item 3.2.2 and has identified impossibility for implementation of the requirements, it must present at EA "BAS" objective and undisputed evidence, which include at least the following:

- Investigations displaying lack of accredited provider in and outside of Bulgaria for the field in which PT is sought;
- lack of PT in the sources indicated by EA "BAS" under item 3.2.2.

The laboratory shall also present information for its planned actions for implementation of the requirements of the present procedure. EA "BAS" considers the presented materials and in communication with the laboratory the Agency conforms the planned actions.

3.2.5. EA BAS requires participants to evaluate their activity for the particular testing (measurement) or calibration included in PT. The results and information obtained by the organizer of PT give confidence to the laboratory's activity if the results are satisfactory or identifying problems and the need for corrective action.

3.2.5.I. EA BAS encourages participants to consider more widely the results of PT and if necessary they can carry out further exchanges of information with the organizer of the PT (within the confidentiality requirements). EA BAS encourages participants IN PT to analyze the received information about the acquisition of possible additional benefit in terms of:

- Identifying problems in measurement (as part of risk management and as a tool for improvement);
- Comparing the methods or procedures and verification of their implementation;
- Comparing the skills of particular staff members;
- Comparing the technical tools and analytical systems;
- Improvement of the activity;
- Personnel training;
- Increasing the confidence of staff and clients;
- Use of objects for testing for internal quality control;
- The uncertainty of measurement.

3.3 Guidance for definition on subfields of accreditation and frequency of participation in PT

In preparing an appropriate plan for participation in PT the laboratories is necessary to analyze the external and internal methods of assurance and quality control. In their procedure and plan for PT, for the laboratories is necessary to split the accreditation scope to representative parts

(subfields), for which to plan PT participation, in the manner to cover the entire scope, if possible. Laboratories can identify these subfields based on:

- Products;
- Characteristics;
- Common methods of measurement (measurement techniques)
- Or a combination thereof for which subgroups are considered to be important and significant (determining) on the scope of accreditation.

It is believed that these subfields are within the same competence (equipment, education, qualification, experience of the personnel, etc.) which shall be proven.
More guidance and examples for determining the subfields are given (can be received) from Guidance EA-4/18 "Guidance on the level and frequency of proficiency testing participation" and Guidance of EURACHEM - Selection, Use and Interpretation of Proficiency Testing (PT) Schemes.

Factors that should also be taken into account (if applicable) for determining the frequency of participation in PT are:

- Volume of activity - the total number of measurements / testing / calibration;
- Changes in personnel, experience and knowledge of the personnel;
- Use and available sources of traceability to SI (use and presence of RM / CRM, availability of national standards, etc.);
- Available information about the stability of the technical equipment and standards;
- Importance and use of results (for the purposes of safety, healthcare, control of working conditions, etc.).
- Opportunities for using the results of PT for the purposes of risk management and training of personnel.
- Recommendations and requirements of regulatory bodies, professional organizations or organizations in different sectors of the economy.

In the event when the traceability is not assured to SI units or reference material / certified reference materials, then the proof of validity (correctness) of the results of measurement / testing very much depends on the results of the participation in PT. Such a situation normally leads to increased frequency of participation in PT.
Successful participation in PT can be used as an argument for extending the period for the next participation and on the contrary - failure of participation should cause shortening of the planned period for subsequent participation or even require extraordinary participation in appropriate or similar PT.
The guidelines for determining the subfields of the granted accreditation scope and guidelines for planning the frequency of participation in PT should be seen as an aid to laboratories. They may also use other appropriate methods and rationale of preparing a plan for participation in PT.

4. Records and information

EA "BAS" stores the records, created by the agency or provided by laboratories in relation to implementation of the present procedure, in the file of the respective laboratory.
When necessary for the purposes of accreditation and meeting the requirements of the standard БДС EN ISO / IEC 17011, EA BAS can request information from the PT providers, as well as from the accredited laboratories or those laboratories - applicants for accreditation for the corresponding PT, following the principles of accreditation.

5. Applicable documents

БДС EN ISO / IEC 17025: 2018	General requirements for the competence of testing and calibration
БДС EN ISO 15189: 2012	Medical Laboratories. Requirements for quality and competence
БДС EN ISO / IEC 17043: 201*0*	Conformity assessment. General requirements for proficiency testing

БДС ISO / IEC 17011: *2017*	Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies
EA-4/18 INF: 2010	Guidance on the level and frequency of proficiency testing participation
EA-INF / 12: 2014	Benefits and importance of the participation in EA highlighted PT schemes
ILAC-P9:06/2014	ILAC Policy for Participation in Proficiency
EURACHEM GUIDE	Selection, Use and Interpretation of Proficiency Testing (PT) Schemes, EURACHEM, 2011, Second edition

- *This document translation has been prepared for the needs of activities related to the accreditation, based on the official document of EA BAS.*
  In case of discrepancies and differences between the Bulgarian document and its translation, the original document in Bulgarian shall be considered as leading.