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PROCEDURE

ABOUT THE POLICY OF EA BAS REGARDING PARTICIPATION OF CABs IN INTERLABORATORY COMPARISONS AND PROFICIENCY TESTING

List of amendments

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			Last name	Signature		
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List of amendments

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1.	25.04.2016	Version 4	Update in connection with the withdrawal of Guide EA 2/10, Guide ILAC G 22 and the entry into force of Guide ILAC P-9:2014	01.05.2016
2.	15.01.2018	Version 5	Update regarding opportunities for improvement identified during an internal audit conducted in December 2017	01.02.2018
3.	01.01.2025	Version 6	Update in connection with the new versions of BDS EN ISO/IEC 17025:2018, BDS EN ISO/IEC 17011:2017, BDS EN ISO/IEC 17043:2023 and entry into force of ILAC Guide P-9:01/2024	01.01.2025

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1. Purpose and scope of application

This document sets out the policy and requirements of EA BAS for participation of applicants for accreditation and accredited Conformity Assessment Bodies (CABs) in Proficiency Tests (PT) and/or InterLaboratory Comparisons (ILC) other than PT. The document sets out the rules for assessing and using ILC/PT results in the accreditation process and maintaining the accreditation of CABs in order to demonstrate the technical competence and validity of the results to accreditation body and stakeholders.

This document provides guidelines to accredited CABs for the appropriate use of ILC/PT for their accredited scope and for evidence to ensure the validity of the results of measurements, tests, calibrations, inspection and sampling.

This document refers to the requirements for participation of the CABs in the ILC/PT and provides guidelines to the EA BAS assessment teams for using the results in the assessment process.

1.1 The basic requirements that laboratories should meet, to demonstrate a functioning management system, technical competence and that they provide valid results, are described in the standards BDS EN ISO/IEC 17025 and BDS EN ISO 15189.

Clause 7.7.1 of EN ISO/IEC 17025 requires laboratories to have a procedure for monitoring the validity of measurement/test and calibration results. The standard states that the validity of test and calibration results can be ensured by various approaches, including participation in interlaboratory comparisons and/or proficiency testing (ILC/PT), as is the requirement of BDS EN ISO 15189 (clause 7.3.7.3) for medical laboratories.

1.2 Ensuring the validity of the results provided by the inspection bodies accredited in accordance with BDS EN ISO/IEC 17020 is possible through participation in ILC/PT, formeasurement activities, which are required to meet the relevant technical requirements of BDS EN ISO/IEC 17025 (see ILAC-G27:07/2019, cl.3.6.2 and 3.7.2 and EA-4/21 INF:2018, cl.1.).

Note: For the purposes of this procedure, the term "measurement" is applicable to activities defined by terms such as testing, calibration, analysis, examination, determination, inspection, investigation and other similar terms used to describe the nature of the work of the CAB. The term "laboratory" may be applied to any organization performing "measurements". Activities that may be subject of ILC/PT may also include sampling activities.

1.3 EA BAS encourages and requires accredited CABs to participate in Proficiency Testing (PT) or Interlaboratory Comparison (ILC), other than PT, when available and appropriate.

Participation in Interlaboratory Comparisons (ILCs) other than Proficiency Testing (PTs) may only be considered acceptable, if corresponding proficiency testing (PTs) are not available or appropriate.

The EA BAS considers the participation of the CAB in the ILC/PT as an integral part of assessment and monitoring of validity of the results. The ILC/PT provide to EA BAS opportunity to harmonize the accredited activities.

2. Terms, definitions and abbreviations

The terms, definitions and abbreviations used in this procedure are in accordance with BDS EN ISO/IEC 17000 and BDS EN ISO/IEC 17043, as follows:

2.1. Terms and definitions

Interlaboratory Comparison (ILC)

design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (**BDS EN ISO/IEC 17043, item 3.4**)

Proficiency Testing (PT)

evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (**BDS EN ISO/IEC 17043, item 3.7**)

Proficiency Testing scheme (Proficiency Testing Scheme/PT Scheme)

proficiency testing (3.7) designed and operated in one or more proficiency testing rounds (3.10) for a specified area of measurement, testing, calibration, examination, sampling or inspection (**BDS EN ISO/IEC 17043, item 3.11**)

Proficiency Testing Provider (Proficiency Testing Provider)

organization which takes responsibility for all activities in the development and operation of a proficiency testing scheme (**BDS EN ISO/IEC 17043, item 3.9**)

Participant

person or organization that undertakes activities related to proficiency testing (3.7) and submits their results for performance evaluation by the proficiency testing provider (3.9) (**BDS EN ISO/IEC 17043, item 3.6**)

Measurement audit

calibration/testing performed by the laboratory, which aims to demonstrate its technical competence by comparing the results of the test/calibration performed by it with known characteristics of a technical device/test object provided for the purposes of the measurement audit (measuring device, standard, CPM or object/sample)

External quality assessment (External quality assessment (EQA)):

External quality assessment (EQA): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (BDS EN ISO 15189:2023, 3.10).

Note: According to BDS EN ISO 15189:2023, the term proficiency testing (PT) is equivalent to external quality assessment (External quality assessment (EQA)).

Interlaboratory Comparisons (ILC) other than Proficiency Testing (PT) are considered to be comparisons that do not have as their primary objective the assessment of the competence of the laboratory to ensure the validity of the measurement or test results and the metrological traceability of the assigned value. They may aim at assessing the characteristics of a measurement or test method, characterising reference materials, demonstrating the measurement and calibration capabilities (CMC) of National Metrological Institutes – NMIs, (key comparisons), etc. Such may include the tests (by other laboratories) of samples from internal laboratory quality control described in BDS EN ISO 15189:2023 (item 7.3.7.3f)). They can further contribute to the independent demonstration of competence.

In such cases, compliance with the additional requirements of EA-4/21 INF:2018 "Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation" is required. The fulfillment of these requirements is subject to additional assessment by the EA BAS in the accreditation process.

Level of participation (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. (see IILAC-P9:01/2024, Annex C).

Frequency of 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 (see IILAC-P9:01/2024, Annex C).

The level of assurance of the validity of the results is defined (without limitation) by: regular use of (certified) reference materials, comparison of results obtained from different methods, participation in interlaboratory comparisons for method development, validation and characterization of reference materials, etc.

The level of internal quality control (internal quality control (IQC)) may include intra-laboratory comparisons, e.g. blind testing, metrological traceability chain assessment, etc.

Area of technical expertise is the area of expertise of the laboratory, defined by a measurement process (general measurement techniques) and/or related product and characteristic (e.g. ICP-MS method for the quantitative determination of heavy metals in soils).

2.2. Abbreviations

ILC/PT (Interlaboratory Comparison/Proficiency Testing)
interlaboratory comparison/proficiency testing;

EQA (External quality assessment (EQA))
external quality assessment

Conformity Assessment Body (CAB Conformity Assessment Body)
conformity assessment body;

SI (International System of Units)
International System of Units

3. Description of the activity

3.1 Policy of the EA BAS

The EA BAS, as a National Accreditation Body, maintains international recognition of the Conformity Assessment Bodies accredited by it, defined in cl.1, and uses successful participation in the ILC/PT as a tool for proving their technical competence for the activities within the scope of accreditation.

The EA BAS requires these CABs to demonstrate the validity of their results through participation at the required level of participation and with the required frequency of participation, in ILC/PT when available and appropriate.

The policy of EA BAS for participation in ILC/PT is implemented, in accordance with ILAC-P9:01/2024, cl. 5, as follows:

- Participation in ILC/PT is considered mandatory for laboratories accredited according to the requirements of BDS EN ISO/IEC 17025:2018 and BDS EN ISO 15189:2023, when ILC/PT are available and appropriate and are recognized as applicable, taking into account the results of the risk assessment for the specified laboratory;
- Participation in ILC/PT is applicable to all other accredited CABs when they carry out testing and/or calibration activities as part of their conformity assessment activities;
- Each accredited laboratory (or other accredited CAB or candidate for accreditation) must develop a plan (program) for participation in ILC/PT, consistent with the areas of the accreditation scope and the results of the risk assessment. In this plan, the CAB must document the level of participation and the frequency of participation in ILC/PT, in accordance with its clearly formulated policy. The plan should be updated depending on the needs and changes in the CAB. This is subject to assessment by the EA BAS, and in case of unsatisfactory results, evidence of adequate corrective actions is required (see EA-4/18 G:2021 and ILAC-P9:01/2024, Annex C).

- Where conducting ILC/PT is practically impossible, the CAB or the accreditation applicant must demonstrate its coverage through other alternative approaches. In such cases, the CAB must provide evidence that the alternative approaches applied ensure the validity of the results.

3.1.1 Successful participation in a PT gives an opportunity for an extension of the period for the next participation and vice versa, unsuccessful participation should cause a shortening of the planned period for the next participation or even require additional participation in an appropriate or similar PT.

3.1.2 The EA BAS considers successful participation in the PT as a significant tool for proving the technical competence of laboratories, therefore it defines the following rules for accreditation of laboratories:

3.1.2.1 The EA BAS requires that each candidate for accreditation in the testing area must have successful participation in a minimum one PT before granting accreditation by EA BAS. Each candidate for accreditation in the calibration area must have successful participation in a minimum of one PT for each (physical) quantity before granting accreditation by EA BAS.

3.1.2.2 The EA BAS requires, as a minimum, each CAB to participate in at least one PT for each area of technical competence within the accredited scope for a period of four years.

3.1.2.3 EA BAS requires CABs to have criteria for the selection and evaluation of PT providers, including for cases where ILCs other than PTs are used. EA BAS requires participation in PTs organized by proficiency testing providers, accredited according to requirements of BDS EN ISO/IEC 17043, considering that accreditation provides confidence in their activities. CABs must assess the available ILC/PT schemes and whether they are appropriate for their activities in the frame of the accredited scope (see ISO/IEC 17025, ISO/IEC 17020 and ISO 15189, cl.6 "Products and services supplied by external providers").

3.1.2.4 EA BAS requires CABs to have appropriate:

- criteria for analyzing the results of their participation in ILC/PT,
- a documented procedure for dealing with unsatisfactory and questionable participation results,
- corrective actions in case of unsatisfactory and questionable participation results.

3.1.2.5 At the request of EA BAS, CABs shall support Multilateral agreements - EA MLA and ILAC MRA in the relevant areas of accreditation to which the Agency is a signatory, by participating in PTs organised or recommended by the EA or ILAC. The CAB's participation in these comparisons shall be financed by the CAB itself.

3.1.2.6 EA BAS may require from laboratories additional participation in PT within a short period determined by BAS, in case of specific circumstances (e.g. significant changes in the CABs, identified non-conformities, controversial or questionable test/calibration results, etc.)

3.1.2.7 EA BAS considers as appropriate proficiency testing (PT) those complying with the requirements of ISO/IEC 17043 and are organized by:

- Accredited Proficiency Testing Providers (against the requirements of ISO/IEC 17043). They need to be accredited by National Accreditation Bodies that are signatory of a Multilateral agreement of EA or ILAC in the field of PTP (see ILAC-P9:01/2024, Annex A and B).
- EA, APLAC, ILAC, EURAMET, BIPM and other regional and international organizations;
- organized (co-organized) by structures of the European Commission;

- national authorities and organizations, authorized to organize comparisons (Bulgarian Institute of Metrology, National Reference Laboratories, etc.).
- such as those published in the "ILC and PT" section on the website of EA BAS;
- such as those published in the EPTIS database (<https://www.eptis.org>). EPTIS is an international database, available on internet address www.eptis.bam.de.

EA BAS publishes in the "ILC and PT" section of its website information on available PT programs and accredited Proficiency Testing Providers, indicating contact details and additional information, when available.

3.1.2.8. EA BAS requires that in cases when ILC/PT are used for supporting accreditation of the CAB or in the process of maintenance of accreditation, the participants to provide information about their participation and information about the providers of the ILC/PT.

The EA BAS requires National Reference Laboratories or institutions designated to operate in Republic of Bulgaria to provide information about the relevant ILC/PT for its participants, in cases where the participants are laboratories, or in the process of accreditation or accredited by the EA BAS.

Where there is insufficient information about the provider of ILC/PT, EA BAS may request from the CAB additional evidence for the provider's competence, which may include, but is not limited to, the following (corresponding with meaning of the specified closes of BDS EN ISO/IEC 17043):

- records for the validity of the results, including the use of CM and CRM and/or reference standards (7.2.2.4);
- procedures for evaluation of uncertainty (7.6);
- documents for metrological traceability of the results (6.5);
- documents for ensuring quality of results (7.7);
- documents on competence of the personnel (6.2);
- records of technical instruments having contribution to the results (6.4);
- documents and records for premises and surrounding conditions (6.3);
- results of management system audits (6.6 and 8.8).

For such cases, an appropriate assessment of the level of risk by the CAB is assumed.

3.2 Guidelines to the the CABs for the implementation of the EA BAS policy

3.2.1 CABs can improve their performance by: analyzing and use of the participation results from proficiency testing programs.

3.2.2 CABs should have a **documented policy** for participation in appropriate proficiency testing offered by competent (accredited) Proficiency Testing Providers. EA BAS considers appropriate Proficiency Testing (PT) to be those that comply with the requirements of ISO/IEC 17043 and the EA BAS policy set out in this document.

3.2.3 CABs shall have a **documented procedure** for planning, participation, analysis and evaluation of the results of participation, as well as (where necessary) for appropriate corrective action and improvement.

The CAB should determine the level and frequency of its participation in the ILC/PT (as external quality control) depending on the accepted level of ensurance of the validity of the results, the level of internal quality control and evaluation of level of risk (see point 2 and ILAC-P9:01/2024, Annex C).

3.2.4 CABs must have an **appropriate plan (program)** for participation in the RT based on an analysis of the level of assurance of the validity of the results, the level of internal quality control and an evaluation of level of risk (see 3.2.5 and ILAC-P9:01/2024, Annex C).

For the purpose of the procedure and planning of PT participation, CABs needed to divide the scope of accreditation into representative parts (fields) for which is planned the PT participation, on that way the entire scope to be covered, if possible.

Laboratories may identify these fields based on products/characteristics/quantities/general measurement techniques, or a combination of them, which groups to be considered as significant for the scope of accreditation.

Further guidance and examples for defining the fields can be supported by Guidance EA-4/18 "Guidance on the level and frequency of proficiency testing participation" and Guidance on EURACHEM – "Selection, Use and Interpretation of Proficiency Testing (PT) Schemes".

The guidance on defining the scope of accreditation and guidance on planning PT participation should be considered as helpful for the laboratories. CABs may also use other appropriate alternative methods (appropriately argued and documented) when preparing a plan for participation in RT.

3.2.5 The level of risk is most often determined considering the following factors, which should be taken into account (if applicable) (see ILAC-P9:01/2024, Annex C, A (2)):

- Volume of activities - the total number of measurements/tests/calibrations, examinations or inspections performed;
- Turnover of the personnel, qualifications, experience and knowledge of personnel;
- Used and available sources of metrological traceability (use and availability of CM/CRM, availability and access to national standards, etc.), calibration quantities and intervals;
- Knowledge for stability/instability of the test or measurement techniques used, scope of validation and/or verification, stability of the analyte and matrices used and the impact of storage and transport;
- Significance and final use of testing/calibration/sampling data (for forensic, safety, health, care of working conditions, or other areas requiring a high level of assurance).
- Level of risk posed by hazardous PT items used and the containment precautions required.
- Recommendations or requirements of regulatory authorities, professional organizations or organizations in different sectors of the economy, when when statements of conformity are required and changes in related specifications are made.
- When the activities are part of risk management, 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 and use to assess members of staff or to improve the qualifications of the staff.
- Type of specific ILC/PT or ILC accepted as alternative.
- other goals previously set by the participant.

If traceability to SI units or Certified Reference Materials is not ensured, proving the validity (accuracy) of measurement/test results depends heavily on the results of participation in the PT. Such a situation normally requires an increasing the frequency of participation in PT.

CABs shall maintain records of risk evaluation activities, the results of their participation and the analysis of the results. The records shall also include the actions taken by the laboratory in the event of unsatisfactory or questionable PT results.

3.2.6 In cases where the possibilities are exhausted, two or more laboratories may organize interlaboratory comparisons in accordance to the additional requirements of EA-4/21 INF:2018

“Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation”.

4. Records and Information

The EA BAS stores records, created by the Agency or provided by the laboratories, regarding the implementation of this procedure, collecting in the file of the laboratory.

When necessary, for the purposes of accreditation process and against the requirements of BDS EN ISO/IEC 17011, the EA BAS may request information from the Proficiency Testing Providers, as well as from the accredited CABs or this applying for accreditation for the concrete PT, keeping the principles of accreditation.

5. Applicable documents:

BDS EN ISO/IEC 17025:2018	General requirements for the competence of testing and calibration laboratories
BDS EN ISO 15189:2023	Medical laboratories - Requirements for quality and competence
BDS EN ISO/IEC 17043:2023	Conformity assessment - General requirements for the competence of proficiency testing providers
BDS ISO/IEC 17011:2018	Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
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
ILAC-P9:01/2024	ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing
ILAC-G27:07/2019	Guidance on measurements performed as part of an inspection process
EURACHEM GUIDE	Selection, Use and Interpretation of Proficiency Testing (PT) Schemes, EURACHEM, 2021, Third 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.