1. Purpose

This document describes the policy of the General Directorate of Accreditation regarding the proficiency testing schemes and interlaboratory comparisons and the participation of calibration, testing, medical laboratories, product certification bodies and inspection bodies (where relevant). Proficiency tests (PT) can be used in some types of product inspection or certification (when it is valid) in cases where the results of the testing activity affect directly and determine the result of the inspection or certification or when it is required by law or regulators.

2. References

This document is based on:

• ISO / IEC 17025:2017 “Conformity assessment - General requirements for the competence of testing and calibration laboratories”
• ISO 15189: 2012 "Medical laboratories - Requirements for quality and competence ".
• ISO / IEC 17020: 2012 “Conformity assessment-Requirement for the function of different types of inspection bodies”
• ISO / IEC 17065: 2012 “Conformity assessment-Requirements for bodies certifying products, processes and services”
• ISO / IEC 17011: 2017 standard
• EA-4/18: 2010 INF "Guide on the level and frequency of participation in proficiency tests ".
• ILAC P9 / 06: 2014 "Policy for participation in proficiency testing activities".
• ISO / IEC 17043: 2010 “Conformity assessment - General requirements for proficiency tests”

This document uses the following definitions according to ISO / IEC 17043: 2010

- Proficiency tests (PT) is the determination of laboratory performance through interlaboratory comparisons
- Interlaboratory comparison (ILC) is the organization, performance and evaluation of tests on the same sample or on a similar sample by two or more laboratories in accordance with the predetermined conditions.

  In this document, the term laboratory also includes medical laboratories, calibration laboratories, certifying products bodies and inspection bodies.

3. Obligations of the testing / calibration laboratory, inspection bodies and / or certifying products.

3.1 Applicants and testing/calibration laboratories, inspection bodies and/or product certification bodies, accredited or under-assessment, must demonstrate their performance through participation in appropriate proficiency schemes or through

interlaboratory comparisons organized by reliable providers according to the criteria defined in point 4 and achieve satisfactory performance.

3.2 Laboratories applying for initial accreditation or extension of accreditation are required to participate in appropriate proficiency tests / interlaboratory comparisons prior to applying for accreditation for matrices or similar groups of matrix. The test / calibration in which the laboratory participated must be included in the field for which accreditation is sought. Satisfactory participation is a condition for making an accreditation decision.

3.3 Accredited laboratories, during the accreditation cycle, must participate at least once in proficiency tests / interlaboratory comparisons valid and appropriate for each accredited testing technique.

3.4 Before surveillance or re-assessment visits and after receiving the final report on participation in the PT, laboratories are obliged to send to DPA information about their participation in the PT schemes. In case the results are not satisfactory, the laboratory should send to DPA also the root cause analysis and corrective actions / actions for improvement proposed and undertaken.

3.5 When appropriate schemes of proficiency tests or interlaboratory comparisons are not available, the laboratory must demonstrate the validity of the test or calibration results through other means such as: repetition of tests, use of reference materials, calibrations using the same or different methods, analysis of white samples, etc.

3.6 Laboratories must develop the plan and frequency level of participation in the PT for the entire 4-year accreditation cycle. The plan should be reviewed and updated when:
- changes in staff or volume of work
-change of laboratory activities, expansion of the field
- changes in equipment, methodology, etc.
-change of environments, different locations, etc.

3.7 The plan shall be based on a detailed and comprehensive risk assessment which shall take into account at least the volume of testing / calibration, the frequency of testing / calibration, the relevance and final use of the test / calibration results in areas where the level of safety of test / calibration results required to be greater, etc. The plan should be prepared taking into account the requirements of regulators or those established by law. The plan should cover all measurement techniques for which the laboratory is accredited all staff performing tests / calibrations shall be included in the plan.

4. Criteria for proficiency testing providers.

4.1 It is DPA policy to accept all proficiency tests / interlaboratory comparisons accredited according to ISO / IEC 17043: 2010 by the signatory accreditation body of mutual recognition agreements (MLA) with EA and ILAC

4.2 In the case where proficiency test schemes are organized by a non-accredited provider, the participating laboratory must have assessed the provider in accordance with the requirements of the standards and guidelines mentioned in point 4.2. The compliance of the provider is demonstrated by the preparation of documented information regarding:
• Implementation of quality management system
• Confirmed experience in organizing proficiency testing schemes.
• Data on sample preparation and handling
• Analysis of test data and determination of laboratory performance
• Determination of reference values and reference uncertainties by testing and calibration laboratories to demonstrate the traceability of their measurements in accordance with the requirements of ISO / IEC 17015: 2017.
Evaluation records of proficiency tests /interlaboratory comparison provider are kept by the participating laboratory and assessed by DPA during assessment and surveillance visits.
4.3 Accredited laboratories and laboratories under assessment are responsible for finding proficiency schemes. To help the laboratories DPA has created a table on its website.

5. Use of results in laboratory assessment

5.1 The DPA assessment team evaluates the performance of the laboratory in proficiency testing / interlaboratory comparison, if these are valid during the initial assessment visit, surveillance visits, extraordinary visits or reassessment visits. Laboratory performance evaluation is reported in the assessment reports.

5.2 Satisfactory results in participation in proficiency testing schemes / interlaboratory comparisons are one of the conditions for a positive decision for initial accreditation or for extension of accreditation. In case the results in PT / ILC are doubtful or unsatisfactory, the laboratory cannot be accredited for that parameter / measured property where it has participated in the proficiency tests / interlaboratory comparison.

5.3 For accredited laboratories, the participation plan in the PT / ILC as required in points 3.7 and 3.8 of this document and the results in participation are assessed during each surveillance visit. Laboratories shall continuously monitor and review their participation and performance in PT / ILC schemes on ongoing basis and actions taken in cases where

results are questionable or unsatisfactory. All records of monitoring, review and actions are kept by the laboratory.

5.4 If at any time, the laboratory's performance in PT / ILC schemes casts doubt on the integrity of the test results, DPA may suspend the relevant test / calibration from the accreditation scope. Cases where the integrity of the results are violated may be:

- In cases where the laboratory presents dubious or unsuccessful results and the assessment team finds that the actions taken by the laboratory are not sufficient or successful.
- In case the laboratory presents unsuccessful results twice in a row in the proficiency test / interlaboratory comparisons schemes for the same parameter / measured property. In the case of medical laboratories, the result means the final result of the external control cycle in which the laboratory has participated.
- Unsuccessful participation by all technical staff of the laboratory.

In such cases the laboratory is required to submit to DPA written evidence that the problem has been identified and satisfactorily rectified (which may require a satisfactory performance in the subsequent PT / ILC scheme) before reinstatement of accreditation can be considered.

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General Director
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