DAK
DREJTORIA E AKREDITIMIT E KOSOVËS
DIREKCIJA ZA AKREDITACIJU KOSOVA
KOSOVO ACCREDITATION DIRECTORATE

POLICY
ON USE OF PROFICIENCY TESTING AND INTERLABORATORY COMPARISONS

DAK-PO-05

APPROVED BY,
GENERAL DIRECTOR
Irfan LIPOVICA

CONTENTS

1. SCOPE

This document describes the policy of the Kosovo Accreditation Directorate (DAK) regarding proficiency testing schemes and interlaboratory comparisons, and the participation of testing and calibration laboratories and inspection bodies (where relevant) in these schemes.

Proficiency testing may be used in certain types of inspection (where available) when the results of testing activities directly influence and determine the inspection outcome, or when required by law or regulation.

2. REFERENCES

- Law No. 05/L-117 on Accreditation;
- ISO/IEC 17011:2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies;
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories;
- ISO/IEC 17043:2023 Conformity assessment – General requirements for proficiency testing;
- EA-4/18 G:2021 Guidance on the level and frequency of participation in proficiency testing;
- ILAC-P9:01/2024 Policy for participation in proficiency testing activities.

3. RESPONSIBILITIES

This policy is mandatory and applies to all internal and external personnel of DAK involved in accreditation (such as DAK staff, PC, AC, TC, assessors and experts), and to accredited testing/calibration laboratories and inspection bodies, or those seeking accreditation from DAK. Where a product certification body performs product testing during conformity assessment activities, the requirements for testing laboratories apply.

4. VOCABULARY AND ABBREVIATIONS

4.1 Vocabulary

For the purpose of this policy, the terms and definitions given in ISO/IEC 17011:2017 and ISO/IEC 17043:2023 apply.
The term External Quality Assurance (EQA), often used in some medical examination sectors, is considered equivalent to Proficiency Testing (PT).

4.2 Abbreviations

CAB	Conformity Assessment Body
DAK	Kosovo Accreditation Directorate
EA	European co-operation for Accreditation

EPTIS	Proficiency Testing Scheme database
IB	Inspection Body
ILAC	International Laboratory Accreditation Council
ILC	Interlaboratory Comparison
NMI	National Metrology Institute
PT	Proficiency Testing
EQA	External Quality Assurance

5. DESCRIPTION OF THE POLICY

DAK considers participation in interlaboratory comparisons (ILC) and proficiency testing (PT) to be an important tool for demonstrating the technical competence of a laboratory. ISO/IEC 17025 requires laboratories to have quality control procedures to monitor the validity of tests and calibrations undertaken. Monitoring may include participation in interlaboratory comparisons (ILCs) or proficiency testing programmes (PTs), but also other means such as regular use of reference materials or replicate testing/calibration using the same or different methods. These methods provide a mechanism for a laboratory to demonstrate its competence both to its clients and to the accreditation body.

ISO 15189 also requires medical laboratories to seek confirmation of confidence in their results through participation in appropriate interlaboratory comparisons.

Proficiency testing may be used in certain types of inspection, where available, and justified by the inclusion of testing activities that directly influence and determine the inspection outcome, or when required by law or regulation. However, it is recognised that proficiency testing is not a common or expected element in the accreditation of most types of inspection.

5.1 Requirements for Participation in Proficiency Testing (PT) and Interlaboratory Comparisons (ILC)

DAK policy is that all accredited laboratories shall participate in PT/ILCs where such schemes are available and relevant to their scope of accreditation. Where applicable, this also applies to inspection bodies and product certification bodies.

Technical competence may also be demonstrated through successful participation in interlaboratory comparisons (ILC) that have been organised for purposes other than PT in its strictest sense, for example:

- to evaluate the performance characteristics of a method;
- to characterise a reference material;
- to compare results of two or more laboratories on their own initiative;
- to support statements of the equivalence of measurement of the National Metrology Institute – hereinafter NMI.

Accredited testing/medical and calibration laboratories, and inspection bodies, must investigate the availability of schemes and determine their suitability.

ISO/IEC 17025 and ISO/IEC 15189 require laboratories to evaluate suppliers, this includes proficiency testing (PT) providers.
ISO/IEC 17043:2023 contains criteria for the competence of PT scheme providers. This standard is recognised as an acceptable basis for such an evaluation.

DAK recommends the use of an accredited scheme where available.

Laboratories may refer to the EPTIS database for availability of proficiency testing (PT) Schemes. EPTIS is an international database, the website address is www.eptis.bam.de.

Where no appropriate PT or ILC is formally organised, laboratories are required to demonstrate the ongoing validity of their tests by other means (use of reference materials, replicate testing, etc.).

Where proficiency testing (PT) schemes are organised by a non-accredited provider, the participating laboratory shall be able to demonstrate that it has evaluated the provider against the requirements of standard ISO/IEC 17043:2023 and applicable EA and ILAC guidance.

The compatibility of the provider is demonstrated by the preparation of the documented information related to:

- Implementation of quality management system
- Confirmed experience in organization of proficiency testing schemes.
- Information on sample preparation and handling
- Analysis of the testing data and definition of laboratory performance
- Definition of reference values and reference uncertainties from testing and calibration laboratories to demonstrate the traceability of their measurements in accordance to requirements of ISO/IEC 17025:2017, where relevant and achievable.

The above-mentioned information is collected from the participating laboratory and assessed by DAK during the assessments.

Laboratories and, when applicable, inspection bodies accredited by DAK are obliged to participate in PTs organized by EA at DAK's proposal.

Laboratories and inspection bodies shall formulate and document a strategy for the level and frequency of PT participation and a plan for participation in PT during an accreditation cycle. The plan shall be regularly reviewed in response to changes in staffing, methodology, instruments, scope etc. Laboratories/IBs should use the EA Publication EA 4/18 Guidance on the level and frequency of proficiency testing participation for further guidance on how to establish a plan.

Laboratories shall justify their policy and approach for both frequency of participation and any non-participation in readily available PTs that are appropriate.

Laboratories/Inspection Bodies (IBs) and, where relevant, product certification bodies, must determine the level and frequency of participation after a careful analysis of their other quality control measures (particularly those capable of detecting, quantifying, and monitoring the development of biases of a declared magnitude). Participation should depend on the extent to which other measures are in place. Other types of quality assurance include, but are not limited to:

- Regular use of reference materials
- Comparison of analyses using independent techniques
- Participation in method development/validation and/or reference material preparation
- Characterization studies
- Use of internal quality control measures
- Other inter/intra-laboratory comparisons, e.g. analysis of “blind” samples
- Within-laboratory comparisons

DAK requires applicants for initial accreditation or extension of scope to participate in at least one (1) PT/ILC where such schemes are available and relevant to their field of application before accreditation can be granted. For medical examination laboratories, participation is required in at least one (1) PT/ILC/EQA in each technical discipline (e.g. biochemistry, haematology, immunology, genetics, clinical microbiology, etc.) with acceptable results.

DAK requires accredited laboratories/IBs and, where relevant, product certification bodies during an accreditation cycle, to participate in at least one (1) proficiency test at a frequency sufficient to ensure performance in key analyses within their accredited scope. For medical examination, participation is required at least once in each sub-discipline/sub-field of technical activity during an accreditation cycle with acceptable results.

During the accreditation cycle, participation of laboratories/IBs and, where relevant, product certification bodies is particularly important in cases where there are doubts about the technical competence of the laboratory/IB (e.g. staff changes, inadequacy of methods used, unsatisfactory results from previous testing, etc.).

DAK requires accredited laboratories/IBs and, where relevant, product certification bodies, to have a procedure for investigating their results and taking appropriate corrective/preventive actions where necessary. Laboratories/IBs are also required to monitor and review their ongoing participation and performance, and track trends in results as appropriate.

5.2 Use of Participation in Proficiency Testing (PT) and Interlaboratory Comparisons (ILC) in Assessment

Evaluation of results from laboratory participation in schemes is carried out by the DAK assessment team. The lead assessor includes in the final report a brief evaluation of the laboratory’s performance in PT and ILC.

Results of PT participation are taken into account in the proposal for granting accreditation. The following rules apply:

- Successful participation of the laboratory is considered positive in the final proposal for granting accreditation.
- In cases where the laboratory presents a low percentage of unsuccessful results compared to overall results, the assessment team evaluates the corrective actions and their effectiveness. If the laboratory's interpretation and actions were/are appropriate, the proposal for granting accreditation is not affected by the unsuccessful PT results, and the laboratory is required to participate again in a relevant test before the next surveillance visit.

- If the laboratory presents unsuccessful results in the vast majority of proficiency tests, the final proposal may require a limitation of the scope of accreditation until an eventual successful participation in relevant tests**.**
- Results from proficiency testing are not considered the sole criteria for issuing accreditation, but they help to formulate an objective opinion regarding the technical competence of the laboratory.
- The assessment team evaluates the plan drafted by the laboratory in accordance with EA-4/18 G:2021 Guidance on the level and frequency of participation in proficiency testing.

6. ANNEXES

Not applicable

7. RECORDS

Not applicable

8. HISTORY

Date of Edition	Prepared by	Description of Applied Changes
02.12.2015	Ibush Luzha	New document
15.11.2019	Valmira Sejdiu	Full revision in accordance with ISO/IEC 17011:2017 and DAK-PM-01
19.05.2021	Valmira Sejdiu	Revision in accordance with DAK-PM-01
25.02.2026	Valmira Sejdiu	Revision in accordance with DAK-PM-01