# Proficiency Testing Policy

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## Contents

## 1. Purpose

This policy sets out the requirements for, and gives guidance to CABs on the use and assessment of PT and/or ILCs in the accreditation process for all CABs accredited by EAS for their consistence applicability of this policy.

## 2. Scopes

This policy sets out the requirements for, and gives policy to CABs, on the use of proficiency testing and/or ILC activities in the accreditation process of performing testing or calibration activities – i.e., testing, calibration and medical laboratories; inspection bodies; bio-banks and reference material producers.

## 3. References

The following documents are referenced:

- ISO/IEC 17011:2017 Conformity assessment - requirements for accreditation bodies accrediting conformity assessment bodies
- ILAC-P9 ILAC Policy for Participation in Proficiency Testing Activities
- ISO/IEC 17025:2017 General Requirements for the competency of Testing and Calibration laboratories
- ISO 15189:2012 Medical laboratories requirements for quality and competency
- ISO/IEC 17020:2012 take reference from ILAC P9

## 4. Introduction

According to ISO/IEC 17025 a laboratory (testing and calibration), medical Laboratory, Certified reference material producers, inspection, certification body for products when the scheme of product certification supported by testing shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring includes the participation in inter laboratory comparisons or proficiency testing programs, preferably offered by accredited PT providers.

By using one or more of the possibilities as listed below, a laboratory has a final proof that its compliance with the standards to generate results within the given uncertainties and can provide evidence of its competence to its clients, interested parties and the accreditation body.

ILAC P9 requires testing, calibration and medical laboratories; inspection bodies; bio-banks and reference material producers to participate in PT schemes. Accreditation bodies should take into account during assessment and decision- making the lab's frequency of and coverage by PTs and its performance.

## 5. Terminology (ISO/IEC 17043)

5.1 Proficiency testing (PT) is the evaluation of participant performance against pre-established criteria by means of inter laboratory comparisons (ISO/IEC 17043:2010, 3.7)

5.2 Inter laboratory comparison (ILC) is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions (ISO/IEC 17043:2010, 3.4)

## 6. PTs and other methods for proof of competence

EAS prefers as the best and most recognized mean for demonstration of competence a successful participation in a PT offered by an accredited PT provider (ISO/IEC 17043) where PT is available and appropriate. However, in the case where there is no PT provider available as per of the definition then, EAS will consider the list below as proof of competence preferably as per to their order

1. use of PT from a non-accredited PT provider
2. Inter laboratory comparisons (ILC) according to pre-determined conditions and methods,
3. comparison of results between labs on mutual agreement
4. participation in the determination of properties of a (potential reference) material where the mean value determined will be considered as property
5. participation in the determination of performance characteristic of a method where the mean value determined will be considered as property
6. sending samples to other accredited labs for test/calibration on own costs and initiative
7. using CRM or reliable reference materials, even validated in-house reference materials
8. Verification of the procedure

Notes:

Determination of repeatability and reproducibility are part of a verification procedure. Repeated tests or calibrations using the same or different methods, use of already tested retain samples or Control charts are methods for quality control.

Method 1: EAS will check whether the major requirements of ISO/IEC 17043 are fulfilled and thus the PT is trustworthy.

Method 2: The ILC report - to be made available to assessment team – shall include at least:

- Number of participants
- Measurement protocol
- Identification of measurement standard/artifact
- Measurement results
- Reference values and how they were determined
- Evaluation of results and indication of performance of individual participants
- Minimum acceptance criteria and conclusion.
- In case the ILC is repeated, another member of staff should conduct the ILC than the one of the first round (equal competence of staff) The same requirements for the report hold for methods 3, 4 and 5.

## 7. Policy

A positive outcome of a PT is a very good mean to ensure competence. Therefore, EAS encourages labs and certification/inspection bodies if supported by a laboratory to participate in PTs as often as reasonable. EAS clearly prefers participation in PTs offered by an accredited PT provider. Beside of this basic policy, EAS follows the PT regime as set out in ILAC P9.

When applying for accreditation, EAS will require a successful participation in a PT at least for one relevant parameter in the scope the lab is applying for (it is advised to the lab before applying for accreditation to identify with EAS staff the relevant parameters).

Further, EAS requires from a CAB a plan for the whole accreditation cycle in advance for which parameters and methods, how often and by which means it will participate in a PT with justifications for the methods chosen if the PT is from non- accredited PT provider and when using directly inter laboratory comparison.

All parameters of the scope shall be covered within the accreditation cycle if their determination

requires different methods or instruments (if a number of parameters could be grouped in the way it could have been done for flexible scope, PT for one parameter is considered as enough).

Note 1: for medical testing PT participation frequency is depending on the regulatory requirement, if there is no regulatory enforcing requirement on the participation of PT, then the medical laboratory shall participate in PT for all parameters every year.

The plan shall consider the availability of PTs offered by preferably accredited PT-providers, the parameters with significantly different test/calibration methods and the risks for human beings or environment resulting from false results (a test rarely done but with high risk will need more consideration for PT than a test frequently done but with low risk results).
Mainly in the food and health sector regulators require participation in PTs according to a regulatory schedule or method. Fulfilling these requirements has priority over any other regime for participation in the voluntary field.

## 8. Obligations of EAS

Before any activity for accreditation can be undertaken the CAB has to submit the PT-plan to EAS with proof of at least one positive participation in at least one relevant parameter of the scope (see above) with justification if PTs in line with ISO/IEC 17043 have not been used. EAS's assessors will analyze the plan whether it is appropriate for the applied scope and sufficient to give proof of competence.

It is recognized that in many fields of testing no PTs in line with ISO/IEC 17043 are offered or available in the country. In this case the assessors will discuss and preferably agree with the CAB in which way and frequency the requirement for PT can be fulfilled. If the CAB uses one of the alternatives listed above the team should verify very carefully the reasons given for their validity so that the use of alternative methods cannot put into question EAS's PT policy.

The results of PTs shall be analyzed by EAS's assessors in detail (especially when options 3, 4 and 5 under clause 6 are used) whether the PTs have been passed, evaluated correctly and whether the CAB has drawn consequences out of the results.
Reaccreditation is only possible if the lab has participated successfully in PTs for all relevant

parameters in the accreditation cycle.

In case of bad performance (z-score ≥3) EAS will require a root cause analysis for the reasons. It may also impose repeated participation in a new PT for the same parameters in a short time period. If the root cause analysis is not satisfying or the new PT results are still not satisfying, EAS will reduce or withdraw accreditation for these parameters, see P07.0.

EAS will assist CABs in finding appropriate PT- Providers by links on the EAS website.

In addition to the use and analysis of the methods as listed above, EAS may use the possibility of dropping one-off samples at the lab if the scope of the lab is considered as not sufficiently covered.

## 9. Obligations of the CAB

- The CAB will develop and advance continuously its plan for PT participation in all major fields or for all major methods. For medical labs, all testing parameters in all matrices shall be covered by PTs minimum once in a year.
- The CAB shall carefully analyze the PT-results and will draw consequences out of them as to maintain or improve the reliability or reduce uncertainty of its results.
- The CAB shall have a policy how to react on bad performance (root cause analysis) and how to improve.
- PT shall not be subcontracted (delegated to a referential lab) in parts or fully.
- The CAB shall notify EAS in the case of PT result with z≥3.

If no PT is available by an accredited PT provider, the CAB will analyze the PT scheme it wants to use whether the essential procedural and technical elements of ISO/IEC 17043 are kept.

If the CAB uses alternatives as listed above due to absence of accredited PTs it has to justify their use and give evidence of their absence.

The CAB will continue to explore the availability of PT schemes operated by accredited PT providers. Participation in PT does not substitute other means for quality control or improvement.

PT and/or ILC can be regarded as economically appropriate if the entire cost of the PT has no considerable influence on the price of the test, calibration or sampling.

| Revision No. | Date approved | Revision History |
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| 1 | 2021/05/11 | Under Clause 9 added PT and/or ILC can be regarded as economically appropriate if the entire cost of the PT has no considerable influence on the price of the test, calibration or sampling.<br>Note 1: for medical testing PT participation frequency is depending on the regulatory requirement, if there is no regulatory enforcing requirement on the participation of PT, then the medical laboratory shall participate in PT for all parameters every year , under page 5 of 8 |
| 1.1 | 2022-05-09 | The document is revised due to the name ENAO change to EAS and new logo developed. |
| 1.2 | 2023-02-07 | • Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager).<br>• Former director general was resigned and replaced by Mrs. Meseret Tessema. |