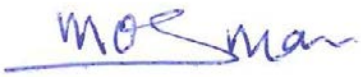
EGAC Policy on Implementation and use of Proficiency Testing
PB12G

Prepared by: Calibration Laboratories Accreditation General Manager
Alaa Ismail

Testing Laboratories Accreditation Manager
Rasha Toni

Reviewed by: EGAC Accreditation Director
Mohamed Osman



Authorized by: EGAC Executive Director
Hany El Desouki

Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
3 / Mar 2017	Medical Department	5/11 & 10/11	- Modifying the specific requirements for Medical laboratories - Stating the policy for participation in PTs programs organized in regional or international levels.

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EGAC Policy on implementation and use of Proficiency Testing

1. SCOPE

This document defines the policy for EGAC's implementation of Proficiency Testing. It applies for the assessment of all accredited laboratories.

2. POLICY

EGAC considers proficiency testing as an important tool in the review of the performance of laboratories. It provides a basis for improving the quality of testing and calibration.

EGAC requires its accredited/applicant laboratories to develop a plan for participation in Proficiency Testing schemes, when available and relevant to their scope. EGAC will review this plan and its implementation by the Laboratory.

The proficiency testing program – when available – should cover at least one Major sub-discipline in each discipline in the scope of accreditation of the accredited laboratory.

The required frequency of participation in the proficiency testing should be relevant to the technical scope as will be assessed by EGAC, however it should not in any case be less than once per 4 years (within the period between two subsequent reassessments) for each major sub discipline of the laboratory's scope of accreditation. Sub-disciplines may need to be more divided requiring more PT schemes; this will be advised by EGAC assessors/ experts. Major disciplines and sub disciplines are published on EGAC's website.

Proficiency testing providers shall be accredited or at least known to be trusted by the EGAC.

EGAC will accept the PT provider's acceptance criteria if available, otherwise it will set one according to the PT results presented to the laboratory.
The laboratories are required to make the results available to be analyzed by EGAC. These results should be adequately documented in the laboratories before they can be considered as part of an accreditation process.

The laboratories are required to demonstrate their ability to take the necessary corrective action and/or preventive actions when appropriate.
Records of proficiency testing results should be analyzed and kept, to establish the competence and stability of the accredited laboratory.

It is EGAC's policy to encourage Laboratories to participate in PT schemes that are being operated in their areas, also encouraging the formation of new proficiency testing schemes where considered necessary and cost effective for the laboratories.

EGAC also organize some proficiency testing schemes in the frame work of cooperation with the regional accreditation bodies (AFRAC, ARAC,APLAC, ……) in the fields of calibration , testing and medical laboratories.
EGAC nominates the required number of required accredited CABs and send the nomination to the region and then receives the samples to be distributed on the selected CABs.

EGAC follow the process for the participated CABs until it completed with its results.

Acceptable types of proficiency testing in accreditation are:

- Bilateral proficiency testing with EGAC or EGAC selected Lab.
- Proficiency testing schemes.
- Interlaboratory comparisons designed primarily for other purposes.

If there are interlaboratory comparisons made originally for other purposes, EGAC still may use their gained results for the assessment of the laboratory's competence to carry out specific test methods, if the acceptability criteria are correctly and adequately defined.

Additional proficiency tests may be required when:

- Changes of personnel operating in the accredited scope, which may affect the technical competence of the laboratory,
- External quality measures taken for the test methods/types of tests applied in the scope of accreditation are not sufficient, regarding, e.g.:
  - Number of proficiency tests performed in specific scopes
  - Extension of the scope of accreditation

  - Insufficiently validated and documented in-house methods
  - Procedural steps deviating from the test standard
- The results of the proficiency tests submitted by the laboratory are unsatisfactory as defined by the acceptability criteria.
- The conclusions drawn and the necessary corrective actions of the laboratory have not been carried out or documented, or are not sufficient
- Assistance in detecting systematic errors in the laboratory is needed and if the laboratory has no other means to provide evidence of its technical competence and quality of measurement

Assessment process

Before or during the assessment, the assessment team would obtain the laboratory's plan for participation in the proficiency testing schemes and a report on the participation of the laboratory in proficiency tests. This report of proficiency tests shall always be part of the documentation of the laboratory's accreditation or surveillance procedure. Such a report should contain:

- Plan for the participation of the laboratory in the PT schemes.
- Success reporting of this plan.
- Dates of proficiency tests already carried out.
- Organizer of PT scheme.
- Test materials, measured quantities, parameters, artifacts, calibration equipment.
- Matrices (where applicable).
- Acceptability criteria.
- Results (satisfactory/questionable/unsatisfactory)
- Corrective actions and follow ups, where required.

If the laboratory submits a greater number of proficiency tests, then the assessment team should limit its assessment to a sufficient number chosen in a representative way. From the survey on proficiency tests and considering the above mentioned main points, proficiency tests that are to be checked on-site are to be selected by the assessment team

The laboratory shall be prepared to justify non-participation in readily available proficiency testing schemes, where one or more appropriate schemes exist.

Document review and preliminary assessment

The quality and extent of the accompanying documentation allow for a correct evaluation of the proficiency testing already carried out.

Assessors shall check the following before starting the assessment:

- The plan for the participation of the laboratory in the PT schemes, along with its justifications.
- The successful execution of this plan, according to the laboratory's success report.
- The results achieved in proficiency tests are adequately documented in the laboratories before they can be considered as part of an accreditation procedure.
- Accredited laboratories are maintaining their own records of performance in all types of proficiency testing, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective or preventive actions.
- The period for keeping the records of proficiency testing results and other documentation is at least 5 years, to establish the competence and stability of the accredited laboratory.
- Accredited laboratories have a written procedure covering participation in proficiency testing, including how the performance in proficiency testing is used to demonstrate the laboratory's competence and procedures followed in the event of unsatisfactory performance.

Technical assessor shall check the conformity of the frequency and regularity of the laboratory's participation in the proficiency testing with regard to EGAC policy.

Determination of acceptability criteria

General rules

Generally the assessment team should use the criteria stated by the organizer of the proficiency testing scheme.

If the organizer of inter-laboratory comparisons does not provide any criteria for acceptance of results (e.g. inter-laboratory comparisons for validation of procedures and/or certification of reference substances), then the assessment team, in agreement with the laboratory under evaluation, should define - according to his technical knowledge - their own acceptance limits or they may

take over the acceptability criteria of the laboratory defined by itself on the basis of their own experience.

Regulatory authorities' criteria

If the laboratory is active in the concerned mandatory area, the assessment team should use the criteria set by the regulatory authority.

If the laboratory is not active in the mandatory area, but is taking part in the proficiency testing scheme for purposes of internal quality assurance, then the assessment team should use the criteria defined for the intended use by the laboratory, after checking the ability of the laboratory to set criteria.

Note: The criteria set by the authority or customer should normally have precedence over the criteria given by the accreditation body

Corrective actions and additional measures

The general conclusions that have been drawn by the laboratory from the participation in proficiency tests concerning their work and, if necessary, where corrective actions have been taken, shall be studied by the assessment team.

If the laboratory did not have satisfactory results then, the explanations and corrective actions shall be checked for sufficiency and suitability. The assessment team shall study these actions to gain information about a laboratory's competence. These actions may include the following internal and/or external quality measures:

- Calibration of measuring devices.
- Use of quality control charts.
- Performance of duplicate/multiple determinations/measurements and appropriate statistical methods.
- Use of standard methods for calibration/ testing.
- **For testing (including medical laboratories):**
  - Regular use of certified reference materials, where appropriate or use of purchasable or in-house calibration and control materials.
  - Introduction of "blind" test materials into the laboratory (e.g. by the Quality Manager).
- **For calibration:**
  - Regular use of cross checks methods, where appropriate and the use of higher level calibrations.

- All kinds of proficiency tests already carried out on the laboratory's own initiative.

In any case, if there are doubts concerning the competence after studying the corrective actions, the technical assessor should find out - in agreement with the laboratory - whether interlaboratory comparisons with other laboratories or the participation in existing interlaboratory comparison schemes or even a bilateral proficiency test should be performed. The extent, selected type, the way of performing and evaluating the proficiency tests shall be explained to the laboratory by the assessment. Other internal as well as external quality measures may be considered, e.g.:

- To repeat the PT.
- To check internal quality assurance measures.
- To ask for detailed report on corrective actions.
- To make an on-site surveillance

If the laboratory did not have satisfactory results after all extra measures taken, then suspension, withdrawal or reduction of scope shall be considered according to EGAC's procedures and regulations.

Special requirements for Medical Laboratories

Due to the special nature of the Medical Laboratories, EGAC emphasizes the following requirements:

- The applicant Medical Laboratory shall participate in PT programs, relevant to its scope of tests, and provided by PT providers which are accredited or trusted by EGAC.
- The applicant Medical Laboratory shall prepare plans for participation in PT schemes, these plans shall be matched with the PT programs provided by the PT providers.
- The applicant Medical Laboratory shall deliver all reports of its current PT scheme cycles, before application, which should prove successful participation, according to the criteria of the PT providers.
- The accredited Medical Laboratory shall deliver all PT reports of its participation in the PT schemes according to its plan to EGAC before each surveillance.

- The Medical Laboratory shall treat the PT samples in the same manner as the patient samples and as mentioned in the PT scheme protocol.
- When the lab participates in "external quality assessment program", the lab has to **assure** that it is "**appropriate** to the examination and **interpretations** of examination results"**,** and supplied by **a PT provider** that is totally **impartial** from the lab activities.
- When the lab is **submitting** for inclusion of **an analyte** in the **scope of accreditation**, the lab shall successfully pass at least one complete PT cycle for this analyte. A successful PT cycle means that the lab **shall** pass at least **80%** of the samples tested **through the whole cycle**.
- The Lab has to **continuously** participate in the PT program it chose/or equivalent one until accredited, not just one cycle.
- **To retain accreditation** for discipline/sub-discipline/analyte, the lab shall maintain the **80%** success through every coming PT cycle. The lab **shall send** the following reports, every 6 months to EGAC:

  - ✓ Reports of all PT results through the past 6 months.
  - ✓ A self assessment report that includes the lab performance through the past six months and the root causes and corrective actions/justifications for **failed** or **unreported** test results.

- **Refusing** to regularly send the above-mentioned reports, **will result in suspension** of the lab scope in this particular discipline/sub-discipline/analyte for **three months followed by withdrawal** of this discipline/sub-discipline/analyte from the accreditation scope.
- The lab shall deeply investigate the root cause for any unsatisfactory results and implement comprehensive corrective action(s). This ***may include but not limited to*** staff retraining and supervision, recalibrations, performing new method verification studies, communication with the PT provider and equipment manufacturer or changing PT provider.
- If the lab fails to achieve **80%** success for a specific discipline/sub-discipline/analyte in a six month period, the lab will be **suspended** in this discipline/sub-discipline/analyte for the next **six months**, during which the lab shall have evidence of **achieving** successful performance.
- If the lab fails to correct its performance for the next **six months**, forthis particular discipline/sub-discipline/analyte, a **reduction of the lab scope** will occur for this particular discipline/sub-discipline/analyte.

3. REFERENCES

ILAC-P9:06 Latest version
ISO/IEC 17043 Latest version
ISO/IEC 17011 Latest version
ISO/IEC 17025 Latest version
ISO 15189 Latest version
IAF/ILAC-A2_02
ISO 5725