

EGAC Accreditation Process for Proficiency Testing Providers PB9PT

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1. INTRODUCTION

EGAC accreditation is granted to PT providers that have shown that they meet, and continue to meet, the requirements of ISO/IEC 17043:2010, relevant ILAC requirements, relevant EA requirements and EGAC requirements.

These documents require PT providers to demonstrate their technical competence as well as their ability to run a supporting quality system.

Benefits of accreditation

EGAC accreditation is visible proof that your PT provider has been thoroughly assessed by independent technical experts. Buyers and specifiers look for accreditation mark on PT reports and PT certificates, so that they can be sure that work has been done to agreed specification.

PT providers accredited by EGAC are entitled to use the PT provider's accreditation mark

Who can seek accreditation?

Any organization that provides proficiency testing or inter-laboratory comparison may seek accreditation, whether these activities are carried out by it or subcontracted activities.

2. Accreditation Process

2.1 Preparing for application

2.1 Preparation of application

To gain accreditation, a PT provider must be fully conversant, and comply, with the requirements of ISO/IEC 17043:2010, relevant EA guidance and EGAC regulations.

Applicants will be supplied with an information package containing the following:

- EGAC application form (soft and hard);
- EGAC CAB agreement form;
- Assessment checklist report (self-assessment) for PT providers quality system implementation;
- EGAC fee structure;
- EGAC regulations
- Description of the accreditation scheme (this document);
- Some EGAC publications (as guidance).

Processing of application shall be conducted exactly in accordance with EGAC publications PB1G_Handling of application.

Applicant lab shall submit the following:

- Fully completed EGAC application form (soft and hard)
- Two copies of EGAC CAB agreement to be signed and submitted with the application form.
- Assessment checklist report (self-assessment) for PT provider's quality system implementation.
- PT provider's quality system documents.
- Application fee according to R3G
- PT providers regulatory documents applicable to the applicant's scope;
- PT provider's documentation - Articles of Association, or equivalent, for review by EGAC.

A preliminary meeting at EGAC office is recommended for the purposes of clarifying initial questions. Afterwards, the application form is to be completed and signed by a duly authorized applicant representative, and submitted to EGAC together with:

If the applicant PT provider has not sent the completed application form accompanied with the updated PT provider quality system, the application will be considered to be lapsed.

If the applicant wishes to be assessed at some later date, it shall have to re-apply to EGAC for accreditation, and pay a further application charges.

In All stages of the accreditation process, only applicant PT provider staff members are allowed to attend, participate, and/or communicate with EGAC. By PT provider staff members we mean: PT provider employees who occupy positions in PT provider organizational structure and its parent organizational structure. These PT provider staff employees will participate in the activities that match with their job description documented in their management system.

2.2 Request for Assessment

The second stage of application is the submission of the application form. This should be done when:

- The applicant is satisfied with his quality management system
- The applicant has produced the quality management system and believed that it meets accreditation requirements
- The applicant produced a draft scope of PT activities for which he wishes to become accredited

The applicant shall complete the application form, and send it, together with a copy of the management system to EGAC.

The application will be handled by EGAC PT providers accreditation manager, who will study the documentation. EGAC PT providers accreditation manager will contact the applicant to discuss the arrangements for the assessment process.

3. THE ASSESSMENT PROCESS (IN BRIEF)

The main function of EGAC is to assess and accredit the competence of PT providers to carry out specified/types of PT programs, and subsequently to ensure by monitoring that the relevant requirements are maintained. Each applicant PT provider provides basic information on its activities, equipment and staff in the application form, and its quality documentation, but it is essential to check the competence of the PT provider by assessment in the PT provider and other sites, where appropriate. The purpose of this assessment is to determine whether a PT provider complies with the EGAC requirements for accreditation and the accreditation standard ISO/IEC 17043:2010. In some circumstances specialized publications issued by EGAC or other national, regional or international organizations, for example ILAC & EA provide guidance of these criteria.

On receipt of a completed application form for accreditation, EGAC PT providers accreditation manager will deal with the application. He shall check that all documents indicated on the application form have been received with the application form. In addition, it shall be verified that all sections of the application form have been completed in full.

EGAC PT providers accreditation manager shall examine the PT provider quality management system to check that it addresses all the key elements specified in the relevant standards. He also shall check if the application fee has accompanied the form and shall ensure that all necessary information is completed.

Should any additional information or documentation be required, this will be requested from the applicant. When EGAC PT providers accreditation manager is satisfied that all the relevant information has been supplied the applicant shall be sent a notification of receipt of application.

PT providers should discuss the need for a pre-assessment visit with EGAC PT providers accreditation manager. The discussion will also cover the scope of the accreditation it seeks. A pre-assessment visit can be designed to provide an over view of the PT provider's readiness for full assessment.

EGAC PT providers accreditation manager shall administer the entire application process. The information received shall be used for the preparation of the on-site assessment and shall be treated with appropriate confidentiality.

EGAC PT providers accreditation manager in consultancy shall identify an appropriate team leader and assessors and/or technical expert according to their area of expertise to allow for a full initial assessment of the applicant for the scope of accreditation. All assessment team shall be totally independent of any connection whatsoever with the applicant to be accredited. All assessment team appointed for a specific assessment shall comply with the requirements of EGAC.

EGAC shall notify the applicant in writing of the names and affiliations of the nominated assessment team. The notification shall seek the approval of the applicant to the nominated team. Objection to any nominated team members shall be in writing, include a detailed justification from the applicant to his objection, and shall be lodged with EGAC within seven working days of receipt of the nominations. Failure by the applicant to object to any of the nominated team members shall be considered as acceptance of the team as a whole.

Objections from the applicant to any of the nominated team will be investigated by technical. If the accreditation manager is satisfied with the applicant's justification to his objection, he will change this nominated team, otherwise he shall inform the applicant that his objection is not accepted and EGAC will keep the nominated team. technical's decision shall be final.

The applicant will be advised of the fees for full assessment and consecutive assessment visits before the visits take place, and it will be asked to confirm acceptance of these fees.

All team members shall be informed of the proposed assessment. EGAC PT providers accreditation manager shall give both the team leader and the assessor a copy of the PT provider quality management systems for document review according to the relevant accreditation procedure after signing confidentiality and impartiality agreement, All documents given to any assessor shall be recorded.

The assessment team shall sign confidentiality and impartiality agreement before starting the assessment.

Experts are used as assessors to judge the competence of the PT provider to perform the proficiency testing programs for which accreditation is sought. Their responsibility is therefore to assess a PT provider's compliance with ISO/IEC 17043:2010, relevant ILAC requirements, relevant EA requirements and EGAC requirements. Their assessment shall be confined to investigating and reporting the findings that result from observation and discussion in the PT provider and through examination of documentation.

All information obtained before, during or after assessment, including the fact that a particular PT provider has applied for accreditation, or that an application for accreditation has been deferred or rejected, shall be treated as strictly confidential by EGAC staff, the external assessment team and the EGAC accreditation & technical committees.

EGAC staff member may normally visit the PT providers as part of the assessment team. EGAC PT providers accreditation manager/team leader, being familiar with EGAC policies, procedures and regulations, will be able to respond during visits to inquiries from the PT provider management on such matters. EGAC PT providers accreditation manager will communicate and assist his/her team leader and the PT provider management with the interpretation of EGAC requirements in appropriate circumstances.

EGAC PT provider assessment procedures are applicable to all sizes of PT providers. Assessment team shall take into account the size and complexity of the organization when assessing the quality management system of a PT provider. The quality management system must provide assurance that the PT provider, whatever its size or complexity, or the location where work is carried out, meets EGAC requirements.

All costs associated with the initial assessment must be paid prior to the assessment date. Failure to receive payment shall stop the application process and the applicant shall be notified by telephone and in writing. The application process shall be re-started only after receipt of the full amount.

EGAC assessment team through the team leader can communicate with EGAC PT providers accreditation manager for administrative and technical assistance at any point before and during the assessment process. The team shall also use all the resources of EGAC including documents, standards and guidance papers. EGAC PT providers accreditation manager reviews all activities and reports of assessment team during the assessment process.

The nature of the initial assessment will be dependent upon the schedule of accreditation and the complexity of the supporting quality system that is being operated. However, the following elements will be covered:

- a) Assessment of provider headquarter/facilities;
- b) Assessment of satellites, branches, temporary sites;
- c) Assessment of site activities.

The accreditation process shall be according to the flowchart in item 6 below. Any non-conformity with accreditation requirements found will be notified to the applicant in writing at the end of the assessment visit, and it will be asked to state how it will clear them. An assessment report shall be sent to the PT provider after the assessment visit containing all the non conformities and the assessment team's recommendation. All non-conformities shall be cleared to the satisfaction of the assessment team before the accreditation process can continue. The applicant shall be granted accreditation according to the process in item 4 below.

EGAC assessment team will seek to establish through objective evidence and by using various techniques that:

- a) The quality system supports competence against their schedule of accreditation, it is appropriate to the organization's needs, organizational arrangements and methods of operations, including away sites operations and number of staff members;
- b) All of the requirements of the relevant standard have been appropriately addressed;
- c) The organization has implemented all the requirements of the quality system
- d) The operational, administrative and technical procedures used to support the quality manual are complete, technically valid and appropriate.

EGAC assessors/technical experts will be looking to see that as a minimum:

- I. The provider personnel member has proven competent at the time that the work was performed;

- II. The provider personnel member's competence is consistent with the records of authorization, educational and professional qualifications;
- III. The provider personnel member has been supplied with all necessary documented methods and procedures;
- IV. The procedures are up-to-date;
- V. The provider personnel member implements the procedures in full and correctly, i.e. no short cuts, no personalized application where it is not permissible to do so;
- VI. All records and raw data are signed/initialed, stamped and traceable as applicable;
- VII. Facilities and equipment are fit and adequately maintained for accreditation purposes.
- VIII. Accommodation adequate for the operation of the PT scheme;
- IX. Environmental conditions are such that they did not compromise the PT scheme;
- X. Records available for the monitoring of the environmental conditions.

Vertically all fields and types of operations will be subject to assessment and technical review. The team will assess the technical competence of the provider personnel/statistician in each field or type of operation covered by the schedule. This will be done through:

- The examination of the records outlined above;
- Discussions with staff, supervisors and managers;
- Assessment of the performance of the staff whilst performing work. The performance of staff is assessed in the provider headquarter and at other sites where relevant operations may be performed;
- Witnessing the implementation of the procedures of preparation of PT items, if applicable, or assessment of the procedures followed by the PT provider to assess the technical competence of the provider of the PT samples
- Assessment of the nature of the samples and how sampling/tests/calibrations relevant to the schemes are performed;
- Monitoring the application of homogeneity and stability testing procedure;
- Tracing of the basic statistical data, including the number of samples (n), mean value, and standard deviation for each analyte/property, and, if possible, summary data for each different method used for each analyte/property;
- Validation of any software used for data analysis
- Check how provider evaluate the performance of participants;
- Assessment of schemes final reports issued by the provider.
- Assessment of the method(s) of publication (e.g. printed report, electronic report, web-based).

EGAC assessment team, if applicable, pays particular attention to subcontracting. It concerns the way in which the organizer of PT schemes assesses the supplier.

Periodically an assessment takes place of the applied statistics.

Sampling/Testing/Calibration activities relevant to the scheme is carried out in accordance with ISO/IEC 17025:2017/ISO 15189:2012, EGAC assessors must witness those activities according to the same principles.

Accreditation of sampling/testing/calibration activities relevant to the scheme to demonstrate the competence of such activities.

Also ISO 17034:2016 can be used to demonstrate the competence of producers of reference materials that provide proficiency test items.

Applicant's obligations for timings are according to regulation (R5G accreditation process timings and response actions).

Following granting of accreditation, PT providers is subject to periodic assessment according to an annual program prepared by EGAC PT provider's accreditation manager. EGAC will make its program to have a first assessment visit within the last 6 months at the 1st year of accreditation, and a second assessment visit within last 6 months at the 2nd year of accreditation, and a third assessment visit within last 6 months at the 3rd year of accreditation, and then the reassessment preparations will start after 7 months from the second assessment (11 months before the expiry date of the accreditation certificate). If the 1st, 2nd and 3rd assessment showed that the lab needs more frequent visits then EGAC would decide on more 4th un-planned assessment visit.

EGAC informs the accredited provider at least (3.5) months before the date of assessment for conducting the assessment visit and the provider confirms its readiness within two weeks. The purpose of assessment visit is to determine whether or not a provider is continuing to comply with the requirement of the standard ISO/IEC 17043:2010 and any other requirements specified by EGAC.

At the introductory meeting, the team leader establishes whether all significant changes in the provider status or operation have been notified to EGAC.

If it is found during the assessment visit that there have been significant changes, e.g. of staff, equipment or the range of available, these matters are recorded by the team leader. Assessor/s checks that the changes are not such as to diminish the provider's capabilities as described in the schedule of accreditation, and that they have already been fully notified to EGAC.

Normally, during a single assessment visit, assessment team will not be expected to check the whole of the schemes for which a provider is accredited. However, assessors should examine the complete types of schemes for which the provider is accredited during the course of not more than three consecutive assessment visits. Equally not all the quality system needs to be covered at each assessment visit. The assessment team will take into account the outcomes of the previous audits to be covered.

- **Sampling of assessment for PT providers**

- For Initial and Re-Assessment:**

- No sampling is applied. The PT provider and all other locations (if any) will be assessed as part of the initial/re-assessment. All scopes applied for, will be subject to an office assessment and technical review.

- For Consecutive Assessment [4 years]**

- Normally, during a single assessment visit, assessors will not be expected to check the whole of the PT activities work for which a PT provider is accredited. However, all the accreditation activities covering all areas of competence and a good representative sample of all PT provider authorized personnel shall be assessed during the validity period of the accreditation certificate. Equally not all the quality system needs to be covered at each assessment visit. The assessment team will take into account the outcomes of the previous audits to be covered. The team leader will normally look at the management review(s), internal audit(s) and compliant records at each assessment visit.

- A full re-assessment on the fourth anniversary of accreditation.

- The PT provider may apply for extension of the scope of accreditation at any time, but the cost will be minimized if extensions are assessed as part of the normal annual visits.

4. THE PROCESS FOR GRANTING ACCREDITATION

4.1 Appointing the members of the Technical Committee (TC)

TC is formed for each applicant according to its specific discipline or scope. Each TC shall consist of at least two or more according to the CPT provider related scope members with EGAC PT provider's accreditation manager. All these members shall be not involved in the assessment process in any way. EGAC has TC members covering the main disciplines and sectors within which it operates, who are drawn from experts in the field as appropriate.

4.2 Conducting the Technical Committee meeting.

After the TC members are appointed, they shall sign confidentiality and impartiality agreement before their meeting. TC members with EGAC PT providers accreditation manager shall review the PT provider's assessment file to verify its harmony with the ISO/IEC 17043:2010 and EGAC requirements. The assessment file shall include the proposed scope of accreditation assessed, the assessment report, the resolution of all nonconformities and the recommendation of the assessment team.

The decision of the TC is taken by consensus. The TC may decide that further actions or information are required. When satisfied, the TC shall recommend the accreditation of the PT provider on the specified scope. This shall be recorded on the TC report.

4.3 Conducting the Accreditation Committee (AC) meeting.

EGAC AC is headed by EGAC executive director of EGAC. It has 7 members representing the stakeholders. In case that the TC recommends the accreditation of PT provider, the AC meeting shall be invited to meet by EGAC executive director. The AC shall meet as needed typically every one month.

Meeting papers shall include summary reports for the assessment activities, assessment report and the TC report. The AC may invite to the attendance of its meeting whoever it sees fit for help with experience in the field of accreditation activities without having a vote to be counted in the proceedings.

When setting up a meeting, the AC members shall be required to sign a confidentiality and impartiality agreement. EGAC accreditation director shall attend the meeting to provide any required information about accreditation subjects and to be responsible for the administrative work of the meeting.

4.4 Decision making and granting accreditation

The AC meeting shall be considered legal if more than 50 % of its members attend. Resolutions shall be based on the majority of votes of the attending members, with the executive director vote as casting vote. Members involved with the PT provider being discussed, will neither participate nor attend the voting process.

The AC can decide granting the accreditation to the PT provider directly or require further actions to be taken or information to be provided. This shall be recorded on the AC minutes of meeting. In case that the AC decides granting the accreditation to the PT provider, EGAC shall inform the PT provider and ask for its representative to receive the accreditation certificate with the approved scope of accreditation.

5. Feedback, complaints and appeals

After receiving the accreditation certificate the accredited PT provider will be asked to fill a feedback report about EGAC's performance during the accreditation process which shall be



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used for improvement of assessors' performance and/or accreditation process. If the PT provider has any complaint it can file this complaint at EGAC or by phone.

Also, if the AC did not grant the accreditation to the PT provider, the PT provider has the right to appeal. If the PT provider decides to appeal, it can file an appeal at EGAC and pay the required fees according to EGAC fee structure (R3G - EGAC Accreditation fee structure).

Complaints and appeals shall be handled by EGAC's quality manager and according to EGAC's publication (PB3G - Guidelines for dealing with complain and appeal) which is available on EGAC website. A neutral appeal committee shall be appointed to resolve this appeal according to the mentioned procedure.

6. THE ROUTE TO ACCREDITATION

