EGAC Accreditation Process for Laboratories
PB01L

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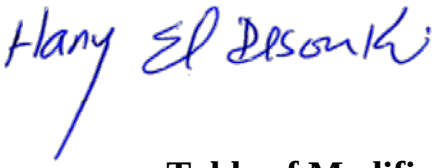

Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
6.1/Aug 2016	Quality Manager	All	No changes, just revision for all publications
6.2/Mar 2017	Quality Manager	8/10	- References adding to the index page. - Adding paragraph about Sampling. - References adding to the end page. - Explaining the period of Surveillance visits

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EGAC Accreditation Process for Laboratories

1. INTRODUCTION

EGAC accreditation is granted to laboratories that have shown that they meet, and continue to meet, the requirements of ISO/IEC 17025 Latest version or ISO 15189 Latest version:, relevant ILAC guidelines and EGAC Regulations.

These documents require laboratories 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 laboratory has been thoroughly assessed by independent technical experts. Buyers and specifiers look for accreditation mark on reports and certificates, so that they can be sure that work has been done to agreed specification.

Laboratories accredited by EGAC are entitled to use the laboratory accreditation mark

Who can seek accreditation?

Any organization that performs measurements, calibrations, objective tests, or examinations providing information for the diagnosis, prevention and treatment of disease of human being may seek accreditation, whether these activities are carried out in a permanent laboratory or on site.

How does ISO 9000 Latest version fit with Laboratory Accreditation?

Laboratory accreditation is specifically designed to determine the laboratory's capability to conduct calibrations and tests in a technically competent and impartial manner and thus be able to issue valid reports and certificates in which the market can have confidence.

To determine this capability, three key elements are assessed:

- The impartiality of the laboratory
- The technical competence of the staff, the suitability of the equipment and environment and validity of individual test methodologies
- The effectiveness of the organization's management system.

It is this third element that is comparable with ISO 9000certification. An effective management system is important, but it is only one of the elements necessary to gain laboratory accreditation.

2. THE ACCREDITATION PROCESS

2.1 Preparing for application

To gain accreditation, a laboratory must be fully conversant, and comply, with the requirements of ISO/IEC 17025or ISO 15189, relevant ILAC guidance and EGAC Regulations.

Application for accreditation is a two-stage process.

2.2 Preliminary application

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

- Application form.
- EGAC scope of accreditation (Testing, Medical & Calibration).
- Current fee structure
- Description of the accreditation scheme (this document)
- EGAC – CAB Agreement.
- List of Publications

A preliminary meeting at the 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:

• The current application charges.
• Laboratory documentation - Articles of Association, or equivalent, for review by EGAC.
• Signed Agreement.

If the applicant has not sent the completed Application Form accompanied with the laboratory Quality Manual within two years, 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 CAB staff members are allowed to attend, participate, and/or communicate with EGAC. By CAB staff members we mean: CAB employees who occupy positions in the CAB organizational structure and its parent organizational structure. These CAB staff employees will participate in the activities that match with their Job Description documented in their management system.

2.3 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 manual and believed that it meets accreditation requirements
- The applicant produced a draft scope of calibrations/ tests for which he wishes to become accredited

The applicant shall complete the Application Form, and send it, together with a copy of the laboratory quality manual and relevant documents to EGAC.
The application will be handled by a dedicated Accreditation Manager, who will study the documentation. The 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 Laboratories to carry out specified calibrations/tests or types of calibration/test, and subsequently to ensure by monitoring that the required standards are maintained. Each applicant laboratory 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 laboratory by assessment in the laboratory and other sites, where appropriate. The purpose of this assessment is to determine whether a laboratory complies with the EGAC requirements for accreditation and the accreditation standard ISO/IEC 17025 or ISO 15189:. In some circumstances specialized publications issued by EGAC or other national, regional or international organizations, for example ILAC, provide guidance of these criteria. These publications are listed in the EGAC Publications List.

On receipt of a completed application form for accreditation, the relevant Accreditation Manager is assigned by the Accreditation Director of EGAC to 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. Accreditation manager shall issue two forms:

The Accreditation Manager shall examine the Quality Manual to check that it addresses all the key elements of a quality system as 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 the Accreditation Manager is satisfied that all the relevant information has been supplied the applicant shall be sent a notification of receipt of application.

Laboratories should discuss the need for a pre-assessment visit with their designated Accreditation Manager. The discussion will also cover the scope-that is, the range of tests or calibrations- of the accreditation it seeks. A pre-assessment visit can be designed to provide an over view of the laboratory's readiness for full assessment.

The 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.

The Accreditation Manager in consultancy with the Accreditation Director shall identify an appropriate Lead Assessor and technical assessors and/or expert according to their area of expertise to allow for a full initial assessment of the applicant for the scope of accreditation. All assessors shall be totally independent of any connection whatsoever with the applicant to be accredited. All assessors 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 assessors. 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 CAB 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 CAB to any of the nominated assessors will be investigated by the relevant accreditation manager. If the accreditation manager is satisfied with the CAB's justification to his objection, he will change this nominated assessors, other wise he shall inform the CAB that his objection is not accepted and EGAC will keep the nominated assessors. Accreditation manager's decision shall be final.

The applicant will be advised of the fees for full assessment and annual surveillance 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. The Accreditation Manager shall give both the Lead Assessor and the Technical Assessor a copy of the CAB quality Manual and relevant procedures for document review according to the relevant accreditation procedure.

All documents given to any assessor shall be recorded. The assessment team shall sign Confidentiality and Impartiality Agreement before starting the assessment.

Before assessment, or accreditation the applicant shall be asked to provide evidence of

successful participation in Proficiency Testing, which involve testing of samples or calibrations of audit artifacts.

Experts are used as assessors to judge the competence of the laboratory to perform the calibrations/tests for which accreditation is sought. Their responsibility is therefore to assess a laboratory's compliance with ISO/IEC 17025 OR ISO 15189 , and EGAC requirements. Their assessment shall be confined to investigating and reporting the findings that result from observation and discussion in the laboratory and through examination of documentation.

All information obtained before, during or after assessment, including the fact that a particular laboratory 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 assessors and the EGAC Council and committees.

EGAC normally uses assessors contracted from external sources to assess laboratories on its behalf. All EGAC assessors, including EGAC staff members acting as assessors, must meet defined criteria in terms of their technical expertise and experience, and must have attended and satisfactorily completed such training as EGAC may specify. EGAC staff may also act as an assessor if qualified as an assessor.

The EGAC staff member will normally visit the laboratory as part of the assessment team. The EGAC Laboratory Accreditation Manager / Lead Assessor, being familiar with EGAC policies, procedures and regulations, will be able to respond during visits to inquiries from the laboratory management on such matters. The Laboratory Accreditation Manager will communicate and assist his/her assessors and the laboratory management with the interpretation of EGAC requirements in appropriate circumstances. The Laboratory Accreditation Manager is also required to monitor the performance of his/her assessors to ensure that the procedures for assessment are maintained between laboratories and between assessors.

EGAC laboratory assessment procedures are applicable to all sizes of laboratory. Assessors shall take into account the size and complexity of the organization when assessing the quality system of a laboratory. The quality system must provide assurance that the laboratory, 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 Lead Assessor can communicate with the 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. The accreditation manager reviews all activities and reports of assessment team during the assessment process.
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 Lab 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.

Applicant's obligations for timings are according to regulation (R05G accreditation process timings and response actions).

This accreditation will be confirmed by annual surveillance visits, with a full re-assessment on the fourth anniversary of accreditation.

In surveillance visits EGAC Sampling procedures applied as follow:

- For Calibration & testing CABs:

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

- For Medical CABs:

  - In general, when a medical laboratory uses backup equipment(s) or examination method(s), the laboratory shall perform comparability of these different examination systems.
  - The laboratory shall provide EGAC with results of comparability.
  - The laboratory has to demonstrate manufacturers' performance claims by conducting verification studies for quantitative as well as qualitative test methods.
  - Results of such verification studies shall be provided to EGAC with the application (F08WI04G_Application for Medical Lab).
  - When the medical laboratory receives samples collected outside its main facility (sample collection sites, lab to lab, and/or, etc.), the laboratory shall communicate its collection instructions to personnel collecting the samples.
  - The lab shall ensure that persons collecting samples are trained enough to do their job.
  - The lab shall identify its sample collection sites in the application form 'F08WI04G_Application for Medical Lab'.

These sample collection sites will be witnessed during EGAC visits (initial assessments, surveillances, re-assessments) according to an established plan.

EGAC will make its plans to have a first surveillance within the first 12 months after granting accreditation, and the following one not exceeding 18 months from the previous surveillance,

The accredited body 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 Advisory Committee (TAC)

TAC is formed for each applicant according to its specific discipline or scope. Each TAC shall consist of at least three members All these members shall be not involved in the assessment process in any way. EGAC has TAC 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 Advisory Committee meeting.

After the TAC members are appointed, they shall sign Confidentiality and Impartiality Agreement before their meeting. TAC members with the relevant Accreditation Manager shall review the CAB assessment file to verify its harmony with the relevant international standard 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 TAC is taken by consensus. The TAC may decide that further actions or information are required. When satisfied, the TAC shall recommend the accreditation of the CAB on the specified scope. This shall be recorded on the TAC Report.

4.3 Conducting the Accreditation Committee (AC) meeting.

EGAC AC is headed by the Executive Director of EGAC. It has 7 members representing the stakeholders. In case that the TAC recommends the accreditation of the conformity assessment body, the AC meeting shall be invited to meet by EGAC Executive Director. The AC shall meet as needed typically every two months.

Meeting papers shall include Summary reports for the assessment activities and the TAC Reports. 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. The 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.

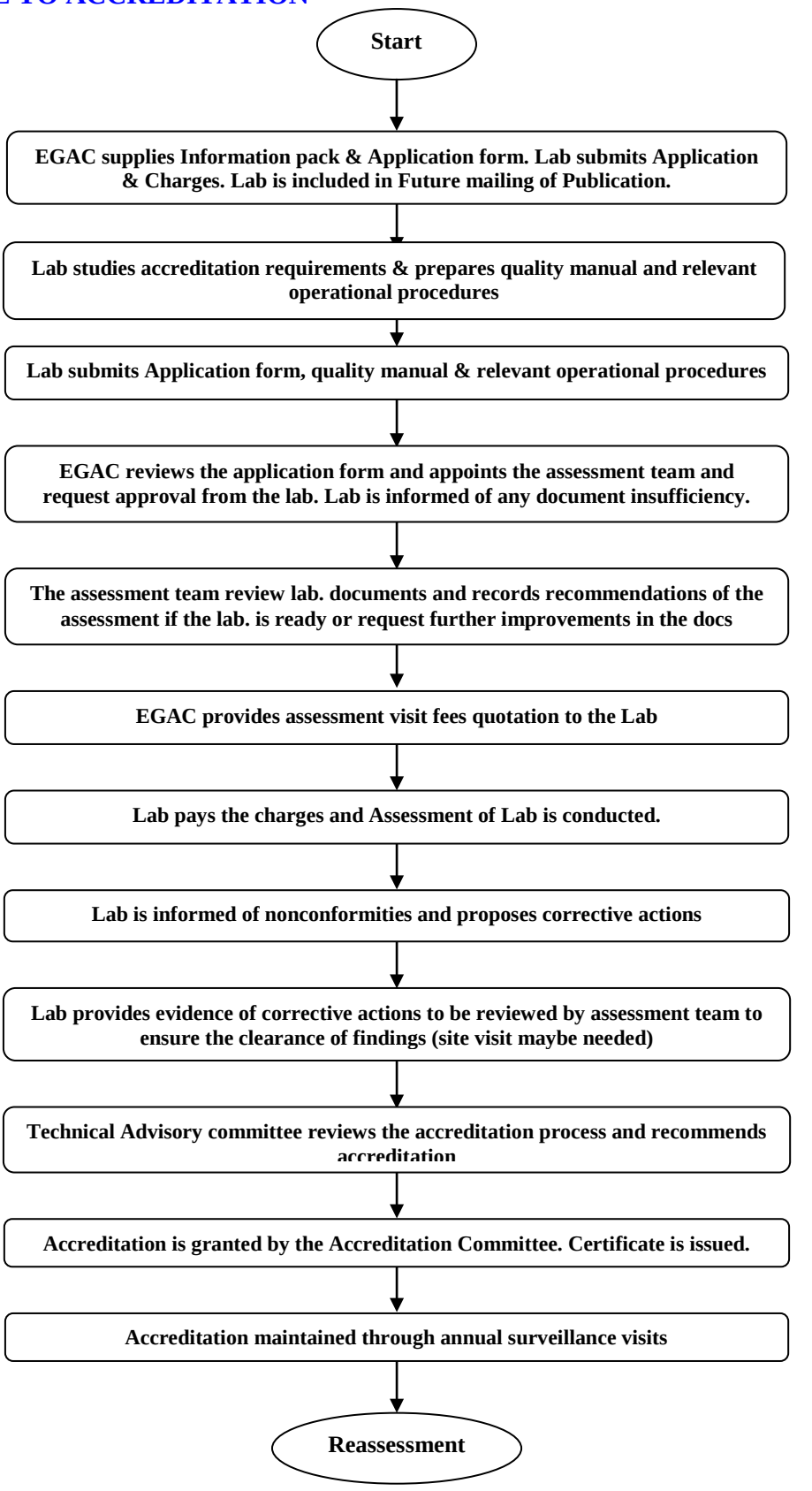
4.4 Decision making and granting accreditation

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 CAB being discussed, will neither participate nor attend the voting process. The AC can decide granting the accreditation to the CAB 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 CAB, EGAC shall inform the CAB 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 body will be asked to fill a feed back report about EGAC's performance during the accreditation process which shall be used for improvement of assessors' performance and/or accreditation process. If the CAB has any complaint it can file this complaint at EGAC or by phone. Also, if the AC did not grant the accreditation to the CAB, the CAB has the right to appeal. If the CAB decides to appeal, it can file an appeal at EGAC. Complaints and Appeals shall be handled by EGAC's Quality Department and according to EGAC's procedure (P16G-Dealing with Complaints and Appeals) which is available on demand. A neutral Appeal Committee shall be appointed to resolve this appeal according to the mentioned procedure.

THE ROUTE TO ACCREDITATION



6. REFERENCIES

- ILAC G26