EGAC Guide for Accreditation of Medical Laboratories
PB6M

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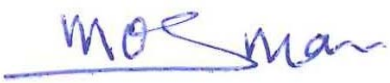

Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
1.1 Jan.2019	EGAC Quality manager	9/11	Modification in consecutive assessment duration
1.2 / May.2019	Medical dept. manager	4, 5 & 9 / 11	- Modification in self assessment form name - Declaring the duration between 2 sequential visits.
Annual Doc. Revision Jan 2021	Quality Manager	All Pages	Annual revision for this document, Conducted by Ahmed Fouli ML Acc. Manager. And no changes needed.

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1. INTRODUCTION

EGAC accreditation is granted to medical laboratories that have shown that they meet, and continue to meet, the requirements of ISO 15189:2012, 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 medical 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 of medical laboratories that performs 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 9001:2015 fit with medical laboratories Accreditation?

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

To determine this capability, three key elements are assessed:

- The impartiality of the medical laboratories
- The technical competence of the staff, the suitability of the equipment and environment and validity of individual test methodologies
- The effectiveness of the medical laboratories management system.

It is this third element that is comparable with ISO 9001 certification. 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, medical laboratories must be fully conversant, and comply, with the requirements of ISO 15189, relevant ILAC guidance and EGAC regulations.

To gain accreditation, a laboratory must be fully conversant, and comply, with the requirements of ISO/IEC 17025:2017, relevant ILAC 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;
- Self-assessment report for medical labs quality system implementation;
- EGAC fee structure;
- EGAC Regulations
- Description of the accreditation scheme (this document);
- Some EGAC publications (as guidance).

2.2 Preliminary application

2.1 Preparation of application

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.
- Self-assessment report for medical labs quality system implementation.
- Lab quality system documents.
- Application fee according to R3G
- lab regulatory documents applicable to the applicant's scope;
- Laboratory 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 lab has not sent the completed application form accompanied with the updated laboratory 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 lab staff members are allowed to attend, participate, and/or communicate with EGAC. By lab staff members we mean: lab employees who occupy positions in lab organizational structure and its parent organizational structure. These lab staff employees will participate in the activities that match with their job description documented in their management system.

2.3 Request for Assessment

The application form 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 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 EGAC medical labs accreditation manager, who will study the documentation. EGAC medical labs 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 medical laboratories to carry out specified tests 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 EGAC requirements for accreditation and the accreditation standard ISO 15189:2012, 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, EGAC medical labs 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 medical labs 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 EGAC medical labs 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 EGAC medical labs accreditation manager. The discussion will also cover the scope-that is, the range of tests 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.

EGAC medical labs 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 shall identify an appropriate team leader, assessor/s and/or technical expert (where appropriate) 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 lab 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 lab to any of the nominated team will be investigated by EGAC medical labs accreditation manager. If the EGAC medical labs accreditation manager is satisfied with the lab's justification to his objection, he will change this nominated assessors, other wise he shall inform the lab that his objection is not accepted and EGAC will keep the nominated assessors. EGAC medical labs accreditation manager's decision shall be final.

The applicant will be advised of the fees for full assessment and annual sequential 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 medical labs accreditation manager shall give both the team leader and the assessors a copy of the lab quality manual and relevant procedures for document review according to the relevant

accreditation procedure.

All documents given to any assessment team personnel 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.

Technical experts are used as assessors to judge the competence of the laboratory to perform the tests for which accreditation is sought. Their responsibility is therefore to assess a laboratory's compliance with ISO 15189:2012, 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 committees.

EGAC staff member will normally visit the laboratory as part of the assessment team. EGAC medical labs accreditation manager and team leader will be able to respond during visits to inquiries from the laboratory management on such matters.

EGAC laboratory assessment procedures are applicable to all sizes of laboratory. Assessment team 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.

The accreditation process shall be according to the flowchart in item 11 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 be cleared.

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 (R5G accreditation process timings and response actions).

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

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 members 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 medical labs accreditation manager shall review the lab assessment file to verify its harmony with the relevant international standard and EGAC requirements.

The lab 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 lab 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. It has 7 members representing the interested parties. In case that the TC recommends the accreditation of the lab, the AC meeting shall be invited to meet by EGAC Executive Director. The AC shall meet as needed at least every one month.

Meeting papers shall include assessment report for the assessment activities and the TC 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.

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 EGAC executive director vote as casting vote. Members involved with the lab being discussed, will neither participate nor attend the voting process. The AC can decide granting the accreditation to the lab 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 lab, EGAC shall inform the lab and ask for its representative to receive the accreditation certificate with the approved scope of accreditation.

EGAC publishes a directory of accredited CBs, which contains details of the accredited scope of each accredited organization. The directory, which is updated regularly, is published on EGAC’s website.

5. FEEDBACK, COMPLAINTS AND APPEALS

After receiving the accreditation certificate the accredited lab will be asked to fill a feedback report about EGAC's performance during the accreditation process which shall be used for improvement of assessment teams' performance and/or accreditation process. If the lab has any complaint it can file this complaint at EGAC or by phone. Also, if the AC did not grant the accreditation to the lab, the lab has the right to appeal. If the lab 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 (PB3G - Guidelines for dealing with complain and appeal) which is available on demand. A neutral appeal committee shall be appointed to resolve this appeal according to the mentioned procedure.

6. Post Accreditation

EGAC publishes a directory of accredited labs, which contains details of the accredited scope of each accredited organization. The directory, which is updated regularly, is published on EGAC’s website.

7. EGAC consecutive assessment visit

EGAC consecutive assessment visit will take place annually to reflect the range of activity of the accredited lab.

It will normally cover a review of the records associated with assessment activity to determine continued conformity of the organization's management system. Witnessed assessments or post-assessment audits will also be programmed.

Following granting of accreditation, labs shall be subject to periodic consecutive assessment visits according to an annual program prepared by the EGAC medical labs 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.

In all cases the duration between two sequential assessment visits shall not exceed than 2 years.

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.

The purpose of sequential assessment visit is to:

- confirm the accredited CB's continued conformity with relevant criteria, and,
- confirm that a CB is operating within its accredited scope and in accordance with EGAC Conditions

Performance, size and complexity of the organization will be key considerations. The anticipated minimum would be annual visits to HQ, one witnessed assessment per year, and each "critical elements" location will be visited at least once during the validity period of the accreditation certificate. One witnessed assessment will be conducted for each scope during the accreditation cycle. A judgment will be made on the level of sampling possible for consecutive assessment cycles according to the sampling procedure.

Any revisions to the documented system will be reviewed during these visits. Where the changes are extensive additional time may need to be scheduled.

8. Re-Assessment and Renewal of Accreditation

Re-assessment visit will take place in four-year intervals. A re-assessment visit will involve a comprehensive re-examination of the CB's quality management system. Assessment activities will be similar in format and in detail to the initial assessment.

The CB must apply for renewal of accreditation at least six months before the expiry of the validity of accreditation. If the CB doesn't apply for renewal of accreditation, three months before the expiry of accreditation it shall be presumed that the CB is no longer interested in accreditation and the accreditation status of the CB shall expire on the validity date mentioned in the certificate. Time frame will be as mentioned in EGAC's regulation (R5G).

At each re-assessment, the accredited CB current schedule of accreditation shall be considered in advance of the visit. Following the re-assessment visit, which will follow the same general procedure as the initial assessment, and the receipt of evidence of clearance of nonconformities, the report and recommendations will be considered, (for a recommendation by the TC and a decision by the EGAC AC), for re-accreditation for a further four year period. A new certificate of accreditation is issued on the renewal; however the certificate number remains the same.

9. Extensions to accredited scope

Accredited organizations may be able to extend the scope of their operation into activities beyond those covered by their accredited scope. Extensions to scope require formal application using the form provided by EGAC, and will be dealt with on a case by case basis.

The application will need to be accompanied by documentary evidence of competence in relation to the relevant industrial and technical activities.

When an accredited CB applies for an extension of its schedule of accreditation, including the addition of new specified staff, it may be combined with the assessment visit of an imminent scheduled visit, or an extra visit is arranged in the normal way. It is helpful in visit planning if the application for extension of scope is submitted to EGAC at least 3.5 months before the next scheduled visit.

If the extension is assessed during a scheduled visit it shall not be allowed to reduce the effectiveness and coverage of the normal consecutive/re-assessment visits.

10. REFERENCIES

- ISO 15189:2012
- ILAC G26

11. THE ROUTE TO ACCREDITATION