# REGULATIONS TO BE MET BY CONFORMITY ASSESSMENT BODIES

# R01G

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# Table of Modification

| Mod. No./Date | Proposed by | Page No. | Modification in brief (old/new, added, cancelled ) |
|---|---|---|---|
| 5.1 / Mar 2013 | Quality Manager | 5/9 | Withdrawing the CABs accreditation certificate leads to withdrawn CAB customer certificate |
| 5.2 / Aug 2016 | Quality Manager | All | No changes, just revision for all regulation |
| 5.3 / Mar 2017 | Quality Manager | 4/10 & 8/10 | - Adding explanation to include all the activities for certification<br>- Giving a reference to ISO/IEC 17065 instead of ISO Guide 65 |
| 5.4 / Mar 2018 | Quality Manager | 4/10 | Explain the period of surveillance visits |
| 5.5 / May 2018 | Quality Manager | 10, 11/13 | Adding Conditions to be met by Proficiency Testing Providers |
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# INDEX

## 1. GENERAL

1.1 The Egyptian Accreditation Council (EGAC) operates under the terms of the Presidential Decree number 248/2006. EGAC is the sole Egyptian national body for the assessment and accreditation of all conformity assessment bodies undertaking certification, inspection, testing and calibration

## 1.2 DEFINITIONS

1.2.1 The term “certification” is deemed to cover product conformity certification, certification of quality management systems, certification of environmental management systems, certification of personnel, certification of food safety management system and occupational health and safety management system specification involved in quality verification.".

1.2.2 The term “inspection” is deemed to cover examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements.

1.2.3 The term “laboratory” is deemed to cover both calibration and testing (including medical) laboratories.

1.2.4 The terms “applicant bodies” and “accredited bodies” are deemed to cover certification bodies, inspection bodies and laboratories.

1.3 These regulations apply to the accreditation of certification bodies against ISO/IEC 17021-1, ISO/IEC 17021-2& ISO/IEC 17021-3 Latest version for certification of management systems, against ISO/IEC 17065 Latest version for product conformity certification, and against ISO/IEC 17024 Latest version for personnel certification. These standards shall be followed along with any other relevant criteria of competence specified by EGAC.

1.4 These regulations apply to the accreditation of laboratories against ISO/IEC 17025 Latest version or ISO 15189 Latest version and any other relevant criteria of competence specified by EGAC.

1.5 These regulations apply to the accreditation of inspection bodies against ISO/IEC 17020 Latest version and any other relevant criteria of competence specified by EGAC.

1.6 The granting, maintenance, extension and renewal of accreditation will be afforded only to a body which:

(a) Is legally identifiable

(b) Demonstrates compliance with these Regulations and the relevant standards and the guidelines thereto;

(c) Pays such fees as are due to EGAC;

(d) Gives such undertakings as EGAC may require.

1.7 All applicant bodies for accreditation will undergo initial assessment as required by EGAC to enable EGAC assessors to determine the competence of the certification body, inspection body or laboratory and its compliance with the criteria for which accreditation is sought. In the event that accreditation is awarded, an Accreditation Certificate and a Schedule defining the scope of accreditation will be issued to the accredited body.

1.8 EGAC will indicate how continuing compliance with these Regulations and the relevant criteria will be monitored.

The frequency with which the Accredited Body is normally subject to surveillance and reassessment will be prescribed by EGAC. EGAC will make its plans to have a first surveillance within the first 12 months after the initial visit , and a second one within 18 months from the first surveillance, If the Lab status from initial accreditation , 1$^{st}$ and 2$^{nd}$ surveillance showed that the Lab/C.B/I.B needs more frequent visits then related

department EGAC manager in consultation with the Accreditation Director would decide on more surveillance visits , then the reassessment every 4 years.

1.9 Over and above this, EGAC reserves the right to carry out additional or unscheduled surveillance visits or reassessments at intervals other than those prescribed. EGAC reserves the right to witness assessment visits made by applicant or accredited certification bodies.

1.10 EGAC will specify the procedures by which application for accreditation should be made, the conditions for granting, maintaining, extending and renewal of accreditation, and the conditions under which accreditation may be refused, suspended, reduced, terminated or reinstated.

1.11 EGAC may suspend or terminate accreditation, reduce the scope of an accreditation, impose a moratorium on extensions to scope (in the case of certification bodies) or require reassessment, if:

(a) There is any change in any aspect of the accredited body's status or operation that affects the Accredited Body's compliance with these Regulations and the relevant criteria or affects the Accredited Body's capability or scope of activity; or

(b) The Accredited Body fails to comply with the requirements of these Regulations and/or the relevant criteria specified by EGAC.

1.12 EGAC may, at its discretion, terminate accreditation:

(a) If, the Accredited Body being owned by an individual, such individual is declared bankrupt or enters into a composition with his creditors; or

(b) If the Accredited Body, being a Company, enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purposes of reconstruction), or has a Receiver of its business appointed; or

(c) If the management of the Accredited Body fails in any respect to comply with the law of the land; or

(d) Where, in the reasonable view of EGAC, the Accredited Body has made unreasonable or irresponsible use of subcontracting.

1.13 All information gained by EGAC and its representatives in the granting, maintenance and renewal of accreditation will be treated as confidential between the Accredited Body and EGAC. Such information will be handled within EGAC on a strict 'need to know' basis and will not, subject to the law of the land, be divu1ged without the express written instructions of the Accredited Body's management.

## 2. PRESCRIPTION OF RELEVANT ACCREDITATION CRITERIA

2.1 EGAC shall have the right to specify the relevant accreditation criteria against which an applicant body shall be assessed.

2.2 The criteria set out in the relevant standard will normally be taken as the basis for assessing the competence of the Laboratory, certification body or the inspection body but additional or alternative criteria may be prescribed at the discretion of EGAC.

## 3. DOCUMENT HAS TO BE SUBMITTED BY THE CONFORMITY ASSESSMENT BODIES

A conformity assessment body shall submit the following doc. at its assessment or re assessment case to EGAC relevant department:

3.1 Accreditation for inspection according to ISO 17020

1. Fully filed Application indicating the different premises, branches, key areas,..if any. (hard copy)

2. Agreement (2 (hard copies), signed and stamped.

On a CD contains:

1. Commercial Registration/Legal Entity
2. Updated Quality manual with updated organization chart indicating if the Inspection Body is included in a
3. Within parent Organization.
4. Management procedures and arrangements that address ISO 17020 (last version) management requirements.
5. Technical procedures and arrangements that address ISO 17020 (last version) technical requirements.
6. Scope of accreditation Schedule of Accreditation for inspection
7. Work Instructions /SOPs
8. List of Authorized inspectors.
9. Last management review meeting minuets.
10. Last internal audit.
11. Supporting inspection methods/standards/regulations....
12. List of used instruments/equipment with appropriate calibration certificates

3.2 Accreditation for Certification according to ISO 17021

1. Fulfilled application for accreditation (hard copy)
2. Fulfilled Agreement Form signed and stamped ( Two hard copies )

On a CD contains:

1. Legal entity documents of the CAB (company)
2. The latest version of the CAB documents ( company's distinguished documents) :
3. Quality Manual
4. Administrative procedures and technical procedures
5. List of accredited auditors
6. A list of the countries and activities in which the company operates and wishes to use accreditation Logo of EGAC.

3.3 Accreditation for (Test & Cal. )Labs, according to ISO 17025

a. Fulfilled application for accreditation (hard copy)
b. Fulfilled Agreement Form ( Two hard copies ) signed and stamped

On a CD contains:

1. Legal entity documents of the CAB (company)
2. The latest version of the CAB Technical documents
3. The latest version of the CAB administrative documents
4. Quality Manual
5. (Cal. / Test ) procedure Uncertainty calculation
6. A CAB CMC for each scope
7. Uncertainty calculation for each scope.
8. An updated proficiency testing (PT) report for each scope with satisfactory result with a scope covering plan
9. A list of used equipments standard with a copy of last "non-expired" calibration certificate for each one.
10. Calibration plan
11. A list of involved employees for each scope

3.4 Accreditation for Medical Labs, according to ISO 15189

1. Fulfilled application for accreditation (hard copy)
2. Fulfilled agreement Form (Two hard copies), signed and stamped.
3. Quality manual
4. Information on Safety (manual)
5. Sample collection information (manual)
6. Management procedures and arrangements that address ISO 15189 (last version) management requirements of clause 4.
7. Technical procedures and arrangements that address ISO 15189 (last version) technical requirements of clause 5.
8. Scope of accreditation {F14P15G_Schedule of Accreditation for Medical Lab. DOC.
9. SOPs in scope of accreditation.
10. Results (Records) of:
    a. At least one complete successful proficiency testing cycle.
    b. Verification/validation of test methods (quantitative as well as qualitative methods)
    c. Measurement uncertainty for quantitative methods, as well as semi-quantitative methods that include a cut-off value
11. Plan for continuing participation in proficiency testing.
12. Calibration plan
13. Authorization list for different working shifts
14. Last management review meeting minuets
15. Outcome of last internal audit
16. Supporting reference documents/guidelines
17. List of sample collection sites/facilities (if any) {F05P11G_Plan of Sample Collection Sites for ML.docx.

## 4. CONDITIONS TO BE MET BY CONFORMITY ASSESSMENT BODIES:

### 4.1 The Accredited Body shall:

(a) At all times comply with these Regulations, with the relevant criteria, and with the conditions prescribed by EGAC for use of any EGAC symbols or reference to EGAC accreditation;

(b) Claim that it is accredited only in respect of those activities which are defined in the schedule of accreditation and which are carried out in accordance with these Regulations and the relevant criteria prescribed by EGAC;

(c) Pay promptly all fees due to EGAC, in accordance with the current schedule of charges;

(d) Not use its accreditation in such a manner as to bring EGAC into disrepute, and shall not make any statement relevant to its accreditation which EGAC may reasonably consider to be misleading;

(e) Upon suspension or termination of its accreditation (however determined) forthwith discontinue its use of accreditation and all advertising matter which contains any reference thereto;

(f) Upon termination of its accreditation by EGAC return the certificate of accreditation

(g) Make it clear in all contracts with its clients that its accreditation or any of its reports or certificates in no way constitute or imply product or service approval by EGAC;

(h) Ensure that no certificate or report or part thereof shall be used by a client, or be authorized for use by a client, for promotional or publicity purposes, if EGAC considers such use to be misleading; calibration certificates, test certificates or test reports issued by

a laboratory or certificates and reports issued by an inspection body or certificates issued by certification body shall not be reproduced except in full without the written approval of both EGAC and the Accredited Body

(i) Endeavour to ensure that any properly authenticated complaints from third parties are promptly investigated and resolved in accordance with the Accredited Body's documented policies and procedures for handling complaints.

**4.2 Conditions to be met by Certification Bodies**

4.2.1 The Certification Body shall offer to all its clients a quality of service consistent with these Regulations and the standard to which it has been accredited. A certification body shall not offer to clients non-accredited certification within its accredited scope.

4.2.2 The Certification Body shall offer EGAC and its representatives such reasonable access and co-operation as necessary, to enable EGAC to monitor compliance with the Regulations and the relevant criteria. This co-operation shall include:

(a) permitting scrutiny by EGAC and its representatives of certificates and other records relevant to accredited activities;

(b) permitting scrutiny by EGAC and its representatives of the results of the Certification Body's own internal quality system audits

(c) assisting EGAC and its representatives in the investigation and resolution of any properly authenticated complaints made by third parties about the Certification Bodies accredited activities.

4.2.3 Holders of accredited certificates awarded by Certification Bodies must give EGAC assessors and experts access to their premises in order to conduct assessment activity. Accredited Certification Bodies are expected to make the necessary arrangements with their clients.

4.2.4 The Certification Body may use in documents, brochures or advertising media, without variation, the phrases "an accredited Certification Body listed under registration number" and "listed in the EGAC Directory of Certification Bodies under registration number. The certification body shall, upon withdrawal of accreditation by EGAC, immediately discontinue issue of accredited certificates, take steps to ensure the prompt withdrawal of all such documents, brochures and advertising material, and take such action with existing clients as EGAC may determine.

4.2.5 In case of withdrawal of EGAC accreditation of a certification body CB, then all valid certification certificates issued under the withdrawn EGAC accreditation scope has to be withdrawn too. The certification body is required to provide its customers with information on the withdrawal of its accreditation and on its consequences including withdrawing their certification. EGAC requires the CB to submit a report on all withdrawn certificates. EGAC will post on its side the new status of the CB. EGAC reserves the right to take sanctions in case that the CB fails to abide by this requirement, including publication of transgression and legal actions

**4.3 Conditions to be met by Inspection Bodies**

4.3.1 The Inspection body and its personnel shall be free from any commercial, financial or other pressures which might influence their technical judgment.

4.3.2 The Inspection Body sha11 not allow persons or organizations external to the Inspection Body to influence the results of inspections performed by the Inspection Body.

4.3.3 The Inspection Body shall not engage in any activity that may endanger the trust in its

independence of judgment and integrity in relation to its inspection activities.

4.3.4 The remuneration of the personnel engaged in inspection activities shall not depend on the number of inspections carried out nor on the results of such inspections.

4.3.5 The Inspection Body shall afford EGAC and its representatives such reasonable accommodation and co-operation as necessary, to enable EGAC to monitor compliance with these Regulations and the relevant criteria of competence. This co-operation shall include:

(a) Affording EGAC and its representatives access to relevant areas for the witnessing of inspection

(b) Permitting scrutiny by EGAC and its representatives of inspection certificates and reports and other records relevant to accredited activities

(c) Permitting scrutiny by EGAC and its representatives of the results of the Inspection Body's own internal quality system audits

(d) Assisting EGAC and its representatives in the investigation and resolution of any properly authenticated complaint made by third parties about the Inspection Body's accredited inspection activities

**4.4 Conditions to be met by Calibration and Testing Laboratories**

4.4.1 The Laboratory and its personnel shall be free from any commercial, financial and other pressures which might influence their technical judgment.

4.4.2 The Laboratory shall not allow persons or organizations external to the Laboratory to influence the results of calibrations or tests performed by the Laboratory.

4.4.3 The Laboratory shall not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its calibration or testing activities.

4.4.4 The Laboratory shall afford the Client or his representative reasonable cooperation to enable him to monitor the performance of the Laboratory in relation to his contract. This cooperation shall include:

(a) Undertaking any reasonable check calibrations or tests to enable the Client to verify the calibration or testing capability of the Laboratory

(b) Affording the Client or his representative access (subject to the confidentiality of work for other clients) to relevant areas of the Laboratory, for the witnessing of calibrations or tests performed for the Client.

(c) Preparation, packaging and dispatch of calibration items, test pieces, samples or other items needed by the Client for verification purposes.

4.4.5 The Laboratory shall afford EGAC and its representatives such reasonable accommodation and co-operation as necessary, to enable EGAC to monitor compliance with these Regulations and the relevant criteria of competence. This co-operation shall include:

(a) Affording EGAC and its representatives access to relevant areas of the Laboratory, for the witnessing of calibrations or tests:

(b) Undertaking any reasonable check calibrations or tests to enable EGAC to verify the calibration or testing capability of the Laboratory

(c) Preparation, packaging and dispatch of calibration items, test pieces, samples or other items needed by EGAC for verification purposes

(d) Permitting scrutiny by EGAC and its representatives of calibration certificates, test reports, and other records relevant to accredited activities;

(e) Permitting scrutiny by EGAC and its representatives of the results of the Laboratory's own internal quality system audits, measurement audits or proficiency tests;

(f) Assisting EGAC and its representatives in the investigation and resolution of any properly authenticated complaints made by third parties about the Laboratory's accredited calibration or testing activities.

**4.5 Conditions to be met by Proficiency Testing Providers**

4.5.1 The Providers and its personnel shall be free from any commercial, financial and other pressures which might influence their technical judgment.

4.5.2 The Providers shall not allow persons or organizations external to the Providers to influence the results of tests performed by the participated Laboratories.

4.5.3 The Providers shall not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its calibration or testing activities.

4.5.4 The Providers shall afford the Client or his representative reasonable cooperation to enable him to monitor the performance of the Laboratory in relation to his contract. This cooperation shall include:

(a) Undertaking any reasonable check statistical to enable the Client to verify the testing capability of the its Laboratory

(b) Affording the Client or his representative access (subject to the confidentiality of work for other clients) to relevant areas of the testing.

4.5.5 The Provider shall afford EGAC and its representatives such reasonable accommodation and co-operation as necessary, to enable EGAC to monitor compliance with these Regulations and the relevant criteria of competence. This co-operation shall include:

(a) Affording EGAC and its representatives access to relevant areas of the Provider, for the witnessing of proficiency testing .

(b) Undertaking any reasonable check proficiency test to enable EGAC to verify the process capability of the Provider

(c) Permitting scrutiny by EGAC and its representatives of proficiency test reports, and other records relevant to accredited activities;

(d) Permitting scrutiny by EGAC and its representatives of the results of the Provider's own internal quality system audits.

(e) Assisting EGAC and its representatives in the investigation and resolution of any properly authenticated complaints made by third parties about the Provider's accreditation activities.

**4.6 Conditions to be met by Medical Laboratories**

4.6.1 It is expected that the laboratory provides the necessary pre-examination, examination and post-examination aspects that are essential to provide an effective and efficient laboratory service to their clients.

4.6.2 Laboratory should, when relevant, comply with international standard ISO 15190 Latest version which specifies requirements for safe practices in the medical laboratory.

## 5. SIGNIFICANCE OF ACCREDITATION

5.1 Accreditation should not be regarded as in any way diminishing the normal contractual responsibilities between the Accredited Body and its client. While accreditation will normally be a sound indicator of the integrity and competence of a Certified Body, Inspection Body or Laboratory and of the quality of service offered, it cannot be taken to constitute a guarantee by EGAC that the Accredited Body always maintains a particular level of performance.

5.2 Accreditation does not, of itself, qualify a Laboratory to approve any particular product (although accreditation may be a relevant factor enabling approval and certification authorities to decide whether to use a given laboratory in connection with their own activities, or whether to delegate

approval or certification authority to a particular laboratory).

5.3 Accreditation of testing (including medical) laboratories should not be considered as guarantee for the correctness of these laboratories' testing reports or certificates. Laboratories should strive to achieve the highest levels of their service standards.

5.4 Certification Bodies and their certified suppliers may only claim product certification after the Certification Body has been accredited to ISO/IEC 17065 and the supplier has been certified accordingly. Product certification must not be claimed on the basis of the certification of the supplier's quality management system.

5.5 Financial arrangements between an Accredited Body and its clients are in no way the responsibility of, and are not subject to the control of EGAC.

## 6. NOTIFICATION OF CHANGE

6.1 The Accredited Body shall inform EGAC immediately of changes bearing on the Accredited Bodies compliance with these Regulations and the relevant standard, or otherwise affecting the Accredited Body's capability or scope of accreditation.

6.2 The Accredited Body shall inform EGAC immediately of any change in its:

(a) Legal, commercial or organizational status;
(b) Organization and management, e.g. key managerial or technical staff;
(c) Policies or procedures
(d) Premises
(e) Personnel, equipment, facilities, working environment or other resources
(f) Authorized signatories
(g) Compliance with EGAC requirements.

6.3 The Accredited Body will be given due notice of any intended changes in these Regulations, the relevant criteria of competence, and any other requirements prescribed by EGAC and will also be given such time, as in the opinion of EGAC is reasonable, to carry out the necessary adjustments to its procedures. The Accredited Body shall notify EGAC when such adjustments have been completed.

6.4 Accreditation may be relinquished by the Accredited Body upon giving one month's notice (or other time period agreed upon between the parties) in writing to EGAC.

6.5 Any notice or other communication required to be given or sent under these Regulations by EGAC shall be deemed to be duly given or sent if sent by recorded delivery post to the address of the Accredited Body last known to EGAC and shall be deemed to be given at the time when the same would have been delivered in the ordinary course of post. Given email by the Accredited Body in its application, will also be considered as suitable means for communicating changes to the CAB.

## 7. SUSPENSION AND WITHDRAWAL

7.1 Suspension of accreditation:

There are four cases of suspension:

- Voluntary suspension.
  This process begins when a conformity assessment body request in writing to EGAC for voluntary suspension due to failure to comply with accreditation requirements or any other reason. EGAC shall suspend the CAB's accreditation for maximum of 6 months according to its procedure P17G.
- Suspension for non-payment of fees.

When a conformity assessment body fails to pay accreditation fees within three months of the date of the original invoice, EGAC shall suspend the CAB's accreditation for maximum of 3 months according to its procedure P17G.

- Suspension for non-compliance with requirements.
  When a conformity assessment body fails to clear the reasons of non-compliance to accreditation requirements within 30 days of the date of receiving the CARs from EGAC, EGAC shall suspend the CAB's accreditation for maximum of 3 months according to its procedure P17G.
- Suspension for failure of conducting surveillance/reassessment visit.
  This process begins when a conformity assessment body fails to arrange for the surveillance/reassessment visit for 90 days after the nominated date of the visit. EGAC shall suspend the CAB's accreditation for maximum of 3 months according to the accreditation process time frame regulation (R05G).

7.2 Re-instatement of accreditation

Should the conformity assessment body (CAB) clear the reasons of accreditation suspension within the time limits shown above, it shall be re-instated; otherwise, it will have its accreditation withdrawn or reduced in scope according to EGAC procedure P17G. If the accreditation of the CAB is withdrawn, then it will be required to submit a new application with all associated costs to EGAC for re-accreditation.

7.3 Reduction of Scope of Accreditation

There are two cases of reduction of scope:

- Voluntary reduction of scope.
  This process begins when a conformity assessment body request in writing from EGAC for voluntary reduction of scope of accreditation due to failure to comply with accreditation requirements in a part of its scope of accreditation. EGAC shall reduce the CAB's scope of accreditation according to its procedure P17G.
- Imposed reduction of scope.
  Should the conformity assessment body fail to clear the reasons of accreditation suspension within the time limits shown above in a way that affects only part of the accredited scope, it will have its accreditation reduced in scope. EGAC shall reduce the scope accreditation according to its procedure P17G.

7.4 Withdrawal of Accreditation

There are two cases of withdrawal:

- Voluntary withdrawal.
  This process begins when a conformity assessment body request in writing to EGAC for voluntary withdrawal of accreditation due to failure to comply with accreditation requirements or any other reason. EGAC shall withdraw the accreditation according to its procedure P17G.
- Imposed withdrawal.
  Should the conformity assessment body fail to clear the reasons of accreditation suspension within the time limits shown above in a way that affects all of the accredited scope; it will have its accreditation withdrawn. A new application with all associated costs will need to be submitted to EGAC to be re-assessed for new accreditation. If a withdrawal of accreditation is to be imposed, EGAC shall withdraw the accreditation according to its procedure P17G.

## 8. APPEALS

8.1 Appeals will be considered only against an accreditation decision made by EGAC

8.2 Appeals against a decision relating to the granting, maintaining, extending, reducing, suspending or terminating of accreditation, and disputes concerning the interpretation of these Regulations and the specified criteria of competence or otherwise arising in the operation of EGAC will be considered by an Appeals Committee

## 9. COMPLAINTS

Any complaints about EGAC or its operation should be addressed to the Executive Director of EGAC in writing.