REGULATIONS TO BE MET BY CONFORMITY ASSESSMENT BODIES

R1G

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1. GENERAL

1.1 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 (CABs) undertaking testing, calibration, certification, inspection and proficiency testing.

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 persons, certification of food safety management system, occupational health and safety management system specification involved in quality verification and halal product conformity certification ".

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

1.2.3 The term “laboratory” is deemed to cover calibration, testing, medical laboratories including the calibration and testing laboratories of forensic service providers (FSP).

1.2.4 The term “proficiency testing” cover the CABs provides PT schemes for all types of laboratories.

1.2.5 The terms “applicant CABs” and “accredited CABs” are deemed to cover laboratories, certification bodies, inspection bodies, PT providers and forensic service providers.

1.3 These regulations apply to the accreditation of certification bodies against:

- ISO 15189:2012 for medical laboratories;
- ISO/IEC 17020:2012 for inspection bodies including FSP inspection bodies;
- ISO/IEC 17021-1:2015 for certification of management systems;
- ISO/IEC 17024:2012 for person certification;
- ISO/IEC 17025:2017 for testing and calibration laboratories including FSP labs;
- ISO/IEC 17043:2010 for proficiency testing providers;
- ISO/IEC 17065:2012 for product conformity certification;
- UAE S 2055-2:2016 for halal products conformity certification.

These standards shall be followed along with any other relevant criteria of competence specified by EGAC.

1.4 Granting, maintenance, extension and renewal of accreditation will be afforded only to the CAB which:

(a) Is legally identifiable
(b) Demonstrates compliance with these EGAC requirements, relevant standard and related national/international publication and guidelines;
(c) Pays such fees as are due to EGAC;
(d) Gives such undertakings as EGAC may require.

1.5 Applicant CABs for accreditation will undergo initial assessment as required by EGAC to enable EGAC assessors to determine the competence of CAB and its compliance with criteria for which accreditation is sought. In the event that accreditation is awarded, an accreditation certificate and accreditation schedule defining the scope of accreditation will be issued to the accredited CAB.

1.6 EGAC will indicate how continuing compliance with these regulations and relevant criteria will be monitored.

The frequency with which accredited CAB is normally subject to consecutive assessment and reassessment will be prescribed by EGAC. 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.
If the 1st, 2nd and 3rd assessment showed that the CAB needs more frequent visits then EGAC relative accreditation manager in consultation with EGAC accreditation director would decide on more 4th un-planned assessment visit. The reassessment will be every 4 years, reassessment preparations will start by inform EGAC its CAB within11 months before the expiry date of the accreditation certificate.

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

1.8 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, withdrawn or reinstated.

1.9 EGAC may suspend or withdraw accreditation, reduce the scope of an accreditation, extent or reassessment, if:

(a) There is any change in any aspect of accredited CAB's status or operation that affects compliance with these regulations and relevant criteria or affects accredited CAB's capability or scope of activity; or
(b) The CAB fails to comply with the requirements of these regulations and/or relevant criteria specified by EGAC.

1.10 EGAC has authority to terminate accreditation if accredited CAB:

(a) Being owned by an individual, such individual is declared bankrupt or enters into a composition with his creditors; or
(b) 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) Fails in any respect to comply with the law of the country;

1.11 Made unreasonable or irresponsible use of subcontracting from the reasonable view of EGAC.

1.12 All information gained by EGAC and its representatives in the granting, maintenance and renewal of accreditation will be treated as confidential between the CAB 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 country, be discloses without the express written instructions of the CAB's management.

2. PRESCRIPTION OF RELEVANT ACCREDITATION CRITERIA

2.1 EGAC have the rights to specify the relevant accreditation criteria against which an applicant CAB 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 CAB but additional or alternative criteria may be prescribed at the discretion of EGAC.

3. DOCUMENT HAS TO BE SUBMITTED BY THE Conformity Assessment Bodies (CABs)

General:

All CABs shall submit the following updated documents at its assessment or re-assessment case to EGAC relevant department:

1. Fully completed F1P9G_EGAC application form (soft and hard);
2. Two original copies of F2P9G_EGAC CAB agreement;
3. Application fee according to R3G;
4. Commercial registration/legal entity;

3.1 Accreditation testing and/or calibration labs according to ISO/IEC 17025:2017 shall submit the following documents electronically at initial assessment or re-assessment case to EGAC testing/calibration labs accreditation departments:

1. Assessment checklist report F1WI4TCL (self-assessment) for testing and/or calibration labs quality system implementation;
2. Updated quality manual (if applicable) with updated organization chart indicating where the lab is included within parent organization;
3. Management procedures and arrangements that address ISO/IEC 17025:2017 management requirements;
4. Technical procedures and arrangements that address ISO/IEC 17025:2017 technical requirements;
5. Testing and/or calibration scope of which accreditation is sought;
6. Work instructions/SOPs;
7. Cal/test procedure Uncertainty calculation;
8. A CAB CMC for each scope;
9. Uncertainty calculation for each scope;
10. An updated proficiency testing (PT) report for each scope with satisfactory result with a scope covering plan;
11. A list of used equipments standard with a copy of last "non-expired" calibration certificate for each one;
12. Calibration plan;
13. A list of involved employees for each scope.

3.2 Accreditation for inspection according to ISO/IEC 17020:2012 shall submit the following documents electronically at initial assessment or re-assessment case to EGAC inspection body's accreditation departments:

1. Assessment checklist report F1WI7I (self-assessment) for inspection body quality system implementation;
2. Updated quality manual with updated organization chart indicating where the lab is included within parent organization;
3. Management procedures and arrangements that address ISO/IEC 17020:2012 management requirements;
4. Technical procedures and arrangements that address ISO/IEC 17020:2012 technical requirements;

5. Inspection scope of which accreditation is sought;
6. Work instructions/SOPs;
7. List of authorized inspectors;
8. Last management review meeting minuets;
9. Last internal audit;
10. Supporting inspection methods/standards/regulations....;
11. List of used instruments/equipment with appropriate calibration certificates.

3.3 Accreditation for certification bodies of management system according to ISO/IEC 17021-1:2015 or halal products according to UAE S 2055-2:2016 shall submit the following documents electronically at initial assessment or re-assessment case to EGAC certification bodies accreditation departments:

1. Assessment checklist report F1WI6C (self-assessment) for management system CBs or F1WI11H (self-assessment) for management system CBs quality system implementation;
2. Legal entity documents of the CAB (company);
3. Latest version of CAB documents (company's distinguished documents);
4. Quality manual;
5. Administrative procedures and technical procedures;
6. List of accredited auditors;
7. A list of the countries and activities in which the company operates and wishes to use accreditation symbol of EGAC.

3.4 Accreditation for medical labs, according to ISO 15189 shall submit the following documents electronically at initial assessment or re-assessment case to EGAC medical labs accreditation departments:

1. Assessment checklist report F1WI5M (self-assessment) for medical labs quality system implementation;
2. Information on safety (manual);
3. Sample collection information (manual);
4. Management procedures and arrangements that address ISO 15189:2012 management requirements of clause 4;
5. Technical procedures and arrangements that address ISO 15189:2012 technical requirements of clause 5;
6. Medical scope of which accreditation is sought;
7. SOPs in scope of accreditation;
8. 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.
9. Plan for continuing participation in proficiency testing;
10. Calibration plan;
11. Authorization list for different working shifts;
12. Last management review meeting minuets;
13. Outcome of last internal audit;
14. Supporting reference documents/guidelines;
15. List of sample collection sites/facilities (if any).

3.5 Accreditation for proficiency testing providers, according to ISO/IEC 17043:2010 shall submit the following documents electronically at initial assessment or re-assessment case to EGAC PT providers accreditation departments:

1. Assessment checklist report F1WI8PT (self-assessment) for PT providers quality system implementation;
2. PT provider quality system documents;
3. PT schemes scope of which accreditation is sought.

3.6 Accreditation for product or person certification bodies, according to ISO/IEC 17065:2012 or ISO/IEC 17024:2012 shall submit the following documents electronically at initial assessment or re-assessment case to EGAC PT providers accreditation departments:

1. Assessment checklist report F1WI9Pd (self-assessment) for product CBs and F1WI10Ps (self-assessment) for person CBs quality system implementation;
2. Electronic copies of the applicant's management system and relevant associated documentation;
3. List of all forthcoming evaluation activities (the fields and types of activity, the assigned evaluators and client details);
4. Evidence of the identity of the legal entity applying for accreditation.

3.7 Accreditation for forensic service providers according to ISO/IEC 17025:2017 and/or ISO/IEC 17020:2012 shall submit the following documents electronically at initial assessment

1. Assessment checklist report (self-assessment) using the forms F1WI4TCL for testing/calibration labs and/or F1WI7I for inspection bodies to demonstrate quality system implementation;
2. FSP quality system documents;
3. If applicable, additional requirements (e.g., FBI Quality assurance standards, ABFT requirements, NAME requirements)
4. Within each discipline, a complete listing of the types of testing, calibration, or inspection in which accreditation is being sought;

4. CONDITIONS TO BE MET BY CONFORMITY ASSESSMENT BODIES (CAB):

4.1 The accredited CAB shall:

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

(b) Referring to accreditation only for activities which are defined in the schedule of accreditation and which are carried out in accordance with these regulation and the relevant criteria prescribed by EGAC;

(c) Pay promptly all fees due to EGAC, in accordance with the current fee structure R3G;

(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 withdrawn of accreditation (however determined) forth with discontinue its use of accreditation and all advertising matter which contains any reference thereto;

(f) 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;

(g) 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 CAB.

(h) 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 (CBs):

4.2.1 CB shall offer to all its clients a quality of service consistent with these regulation and related standard to which it has been accredited. A CB shall not offer to client's non-accredited certification within its accredited scope.

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

(a) Permitting scrutiny by EGAC and its representatives of:
   i. Certificates and other records relevant to accredited activities;
   ii. The results of CB's own internal quality system audits

(b) Assisting EGAC and its representatives in the investigation and resolution of any properly authenticated complaints made by third parties about CBs accredited activities.

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

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

4.3 Conditions to be met by Inspection Bodies (IBs):

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

4.3.2 IB shall not allow external persons or organizations to influence the results of inspections performed by IB.

4.3.3 IB 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 IB shall afford EGAC and its representatives such reasonable accommodation and co-operation as necessary, to enable EGAC to monitor compliance with these regulation and

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:

i. Inspection certificates and reports and other records relevant to accredited activities;
ii. The results of IB's own internal quality system audits;

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

4.4 Conditions to be met by Calibration and Testing Laboratories:

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

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

4.4.3 Lab 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 Lab shall afford client or his representative reasonable cooperation to enable him to monitor the performance of lab in relation to his contract. This cooperation shall include:

(a) Undertaking any reasonable check calibrations or tests to enable client to verify the calibration or testing capability of the lab;

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

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

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

(a) Affording EGAC and its representatives access to relevant areas of lab, for witnessing of calibrations or tests;

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

(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:

i. Calibration certificates, test reports, and other records relevant to accredited activities;
ii. The results of lab's own internal quality system audits, measurement audits or proficiency tests;

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

4.5 Conditions to be met by Proficiency Testing Providers (PT providers)

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

4.5.2 PT providers shall not allow persons or organizations external to PT providers to influence the results of tests performed by the participated labs.

4.5.3 PT 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 PT providers shall afford client or his representative reasonable cooperation to enable him to monitor the performance of lab in relation to his contract. This cooperation shall include:

(a) Undertaking any reasonable check statistical to enable client to verify the testing capability of the its lab;

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

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

(a) Affording EGAC and its representatives access to relevant areas of PT provider, for the witnessing of PT;

(b) Undertaking any reasonable check PT to enable EGAC to verify the process capability of PT provider

(c) Permitting scrutiny by EGAC and its representatives of:

i. PT reports, and other records relevant to accredited activities;

ii. The results of PT provider's own internal quality system audits.

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

4.6 Conditions to be met by Medical Laboratories

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

4.6.2 Lab should, when relevant, comply with international standard ISO 15190:2003 which specifies requirements for safe practices in medical lab.

5. SIGNIFICANCE OF ACCREDITATION

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

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

5.3 Accreditation of testing/medical labs should not be considered as guarantee for the correctness of

these labs' testing/medical reports or certificates. Labs should strive to achieve the highest levels of their service standards.

5.4 CBs and their certified suppliers may only claim product certification after CB 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 a CAB 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 CAB shall inform EGAC immediately of changes bearing on CAB's compliance with these regulation and relevant standard, or otherwise affecting CAB's capability or scope of accreditation.

6.2 The CAB 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 CAB will be given due notice of any intended changes in these regulation, 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 CAB shall notify EGAC when such adjustments have been completed.

6.4 Accreditation may be relinquished by CAB 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 regulation by EGAC shall be deemed to be duly given or sent if sent by recorded delivery post to the address of CAB 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 CAB 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 two cases of suspension:

- Voluntary suspension.
  This process begins when a CAB request in writing to EGAC for voluntary suspension due to failure to comply with accreditation requirements or any other reason. EGAC shall suspend CAB's accreditation for maximum of 6 months.
- Imposed suspension:
  If the CAB fail in one of the following:
  - Suspension for non-payment of fees.
    When a CAB fails to pay accreditation fees within 3 months of the date of the original invoice, EGAC shall suspend the CAB's accreditation for maximum of 3 months.
  - Suspension for non-compliance with requirements.

When a CAB fails to clear the reasons of non-compliance to accreditation requirements within 30 days of the date of receiving findings, corrective actions and clearance report from EGAC, EGAC shall suspend the CAB's accreditation for maximum of 3 months.

- Suspension for failure of conducting consecutive assessment/reassessment visit.
  This process begins when a conformity assessment body fails to arrange for the consecutive assessment /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 R5G.

7.2 Extension of suspension period

Due to unforeseen circumstances the suspension period may be extended with the necessary justification to other 3 months (except for voluntary suspension).

If EGAC management finds that the delay in the response of the CAB is out of its control or due to out of control of EGAC then EGAC management may extend the suspension period with the necessary justification which is to be approved by EGAC executive director. This justification should take into consideration cases of actual commitment of the CAB for the accreditation conditions such as:

- CAB participates in a PT but its report was delayed for some reason.
- The process of approval of the CAB granting of accreditation is delayed for some reason.

7.3 Re-instatement of accreditation

Should the 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. 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.

7.4 Reduction of scope of accreditation

There are two cases of reduction of scope:

- Voluntary reduction of scope.
  This process begins when a CAB 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.
- Imposed reduction of scope.
  Should the CAB 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.

7.5 Withdrawal of accreditation

There are two cases of withdrawal:

- Voluntary withdrawal.
  This process begins when a CAB 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.
- Imposed withdrawal.
  Should the CAB 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.

8. APPEALS

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

Appeals against a decision relating to the granting, maintaining, extending, reducing, suspending or terminating of accreditation, and disputes concerning the interpretation of these regulation and the specified criteria of competence or otherwise arising in the operation of EGAC will be considered by an appeals committee according to PB3G - Guidelines for dealing with complain and appeal and EGAC procedure for dealing with complain and appeal.

9. COMPLAINTS

Any complaints about EGAC or its operation should be addressed to EGAC executive director in writing, according to PB3G - Guidelines for dealing with complain and appeal.