REGULATIONS TO BE MET BY CONFORMITY ASSESSMENT BODIES

R1G

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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	5/14	Modification in consecutive assessment duration
1.2 Mar 2019	EGAC Quality manager	4/19, 5/19, 8/19, 9/19, 10/19, 14/19, 15/19 & 16/19	- Modification clauses: 1.3, 1.11 & 3.7 - Modification FSP accreditation requirements and conditions
1.3 / May 2019	EGAC Quality manager	4, 6, 7 & 8 / 19	- 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 Ashraf Saif Quality General Manager. And no changes needed.
1.4 / Jun 2021	Eng. Mohamed Osman Accreditation Director	3, 4, 5, 6, 7 & 8 / 19	- Small changes in the index page; - Add clause for purpose of the regulation; - Add 2 new definitions CABs & CABs activities; - Add EGAC policy on the application of an accreditation cycle; - Add reference to remote assessment - Add to EGAC authority to terminate accreditation of the CAB “CAB activities or persons effect the impartiality”. - Some adjustment in wording and formatting.

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1. PURPOSE

Regulations to be met by applicant/accredited conformity assessment bodies undertake conformity assessment activities and seek to have/maintain/renew accreditation by EGAC.

2. DEFINITIONS

2.1 **Conformity assessment body (CAB)**

Body that performs conformity assessment activities and that can be the object of accreditation.

2.2 **Conformity assessment activity**

Activity conducted by a conformity assessment body when assessing conformity. (Include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification. For simplicity, these are referred to as conformity assessment activities being performed by conformity assessment bodies).

2.3 The term "**certification**" is deemed to cover: certification of management system (quality management system, environmental management system, food safety management system, occupational health and safety management system, …etc), certification of product, certification of person and certification of halal.

2.4 The term "**inspection**" is deemed to cover examination of product, service, process, inspection of forensic service providers and determination of their conformity with specific requirements or on the basis of professional judgment and general requirements.

2.5 The term "**laboratory**" is deemed to cover organizations provide calibration, testing, medical activities.

2.6 The term "**proficiency testing Provider**" cover the organizations provide all types of PT schemes

3. GENERAL

3.1 These regulations apply to the accreditation of conformity assessment body 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.

3.2 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, relevant accreditation scheme and related national/international publication and guidelines;

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

(d) Gives such undertakings as EGAC may require.

3.3 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.

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

EGAC policy on the application of an accreditation cycle:

- EGAC select an accreditation cycle (4- years) for its accredited CAB.
- In the normal situations EGAC will plane for two consecutive assessment visit within the accreditation cycle
- In all cases the duration between the sequential assessment visits shall not exceed than 2 years.
- According to each accredited CAB case, EGAC may implement un-planned assessment visit during CAB accreditation cycle

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.

- EGAC Normally conduct on-site assessment, if it not possible to conduct on-site assessments for any reason, EGAC will conduct the assessment using a remote assessment technique. According to EGAC publication PB20G_Policy on Remote assessment which demonstrates the details for using remote assessment technique.

3.5 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.

3.6 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.

3.7 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.

3.8 **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;

(d) The CAB or any part of the same legal entity offer or provide or receive any service that affects its impartiality, such as:

a) Conformity assessment activities covered by accreditation which include but are not limited to testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification;

b) Consultancy, Any CABs persons be involved in any activities that may affect / diminish confidence in its competence, impartiality, judgment or operational integrity;

3.9 If the CAB made unreasonable or irresponsible use of subcontracting on its accredited activities (from EGAC point of view). EGAC will dealt with as a misuse of its accreditation.

3.10 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.

4. PRESCRIPTION OF RELEVANT ACCREDITATION CRITERIA

5.1 EGAC have the rights to specify the relevant accreditation criteria against which an applicant CAB shall be assessed.

5.2 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.

5. 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;

5.1 **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. F1WI4TCL_Self Assessment & Document Review of ISO-IEC17025-2017 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. Calibration/testing procedure for measurement uncertainty calculation;
8. A CAB CMC for each scope;
9. Measurement 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.

5.2 **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. F1WI7I_Self Assessment & Document Review of ISO-IEC 17020-2012 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.

5.3 **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. F1WI6C_Assessment checklist report of ISO-IEC 17021-1-2015 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.

5.4 **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. F1WI5M_Self Assessment & Document Review of ISO 15189-2012 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).

5.5 **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. F1WI8PT_Self Assessment & Document Review of ISO-IEC 17043-2010 for PT providers quality system implementation;
2. PT provider quality system documents;
3. PT schemes scope of which accreditation is sought.

5.6 **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. F1WI9Pd_Assessment checklist report of ISO-IEC 17065-2012 for product CBs and F1WI10Ps_Self Assessment & Document Review of ISO-IEC 17024-2012 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.

5.7 **Accreditation for forensic service providers according to ISO/IEC 17025:2017 and/or ISO/IEC 17020:2012 and ILAC – G19:Modules in a Forensic Science Process**

5.7.1 **For forensic testing laboratory:-**

The application should be submitted in electronic and hard copy and include the following:

- Locations to be covered by the accreditation
- Proposed scope of accreditation
- Quality system and associated operating procedures, however named that achieve EGAC and ILAC requirement's for ILAC – G19: Modules in a Forensic Science Process, ILAC-G24: Guidelines for the determination of calibration intervals of measuring instruments, EGAC Policy on Traceability for Measurements and Calibration R2G)
- Proficiency testing/inter-laboratory comparison activity (PB14G ; General policy for Forensic Services Provider Laboratories);
- Testing areas for which accreditation is sought
- Number of proficiency-tested in each testing area
- F1WI12FP self-assessment report
- Irrespective of whether the forensic unit implements ISO/IEC 17025 or ISO/IEC 17020, methods of examination/testing shall be fit for purpose. In demonstrating this, the forensic unit will need to refer to appropriate validation / verification data.
- Sample collection information;
- Plan for continuing participation in proficiency testing next year
- Calibration plan;
- Authorization list for different working shifts;
- Last management review meeting minuets;
- Outcome of last internal audit;
- Supporting reference documents/guidelines;
- Cross reference to CAB document or quality manual

Notes:

1. *EGAC accreditation activities shall be confined to the draft scope of accreditation agreed on during the opening meeting of the initial accreditation assessment.*
2. *Separate applications are required for each location to be accredited. Physical locations in close proximity can be considered one location (to be determined by EGAC).*
3. *EGAC reviews the application to determine if additional information is required. After final review,*
4. *Proficiency Testing:*

4.1 Irrespective of whether the forensic unit implements ISO/IEC 17025 or ISO/IEC 17020 Forensic testing laboratories and inspection body shall perform proficiency testing in order to verify the laboratory's performance. The frequency of proficiency testing shall be at least annually and at least one of these proficiency one of these PT should be from a recognized PT provider external to laboratory.

4.2 Proficiency –test samples should be representative of the laboratory's normal casework. Methodology required to perform proficiency tests should be in concert with the normally practiced in the laboratory.

4.3 Where no formal PT is practical or available, the Forensic testing laboratories and inspection body shall indicate suitable alternative means by which performance will be assessed and monitored. These may include activities such as intra laboratory comparisons, the use of reference materials or other comparisons. EGAC will consider these alternative arrangements as part of the laboratory's planned activities. It is the responsibility of CABs to provide the details of the plan and its justification to obtain approval from EGAC.

5.7.2 **For forensic inspection body shall be achieve:**

Any testing conducted as part of scene of crime investigation shall be carried out according to documented procedures and ISO/IEC 17020 may cover these procedures provided that the relevant clauses of ISO/IEC 17025 are considered.

A forensic unit can have one single management system to cover all of its activities and all the competence standards to which it works, i.e. ISO/IEC 17020 and ISO/IEC 17025 and achieve the requirement of ILAC-G19: Modules in a Forensic Science Process and ILAC-G27; Guidance on measurements performed as part of an inspection process.

The forensic unit may be undertaking testing, including but not limited to quantitative measurements and presumptive or screening tests, as part of a scene of crime investigation. If the unit is accredited to ISO/IEC 17025 then relevant requirements are covered in that particular standard. However, if a body is accredited to ISO/IEC 17020 and its inspection activity contains testing then it should meet the relevant requirements of ISO/IEC 17025.

Additional criteria needed to clarify proficiency testing requirements for inspection bodies have been added When tests and measurements are involved as part of the inspection process and measurement traceability is required.

In effect, EGAC accreditation at tests that an inspection body has demonstrated that:

a) it is competent to perform specific inspections or specific types of inspections; and

b) its quality system is documented, fully operational and addresses and conforms to all elements of ISO/IEC 17020:2012, ILAC P15 and any EGAC official applications of these standards;

c) it is operating in accordance with its quality system; and

d) it conforms to any additional requirements of EGAC or specific fields or programs necessary to meet particular user needs.

Accreditation is available for any type of inspection body. Typically, the scope of accreditation is identified in terms of standard inspection methods prepared by national, international, and professional standards writing bodies.

Inspection Body Structure Locations of offices were key activities take place will require separate scopes of accreditation and need to be assessed on Accreditation cycle. Key activities include:

- Policy formulation and approval;
- Development and approval of processes and procedures necessary for the operation of the certification of persons systems, including requirements for selection and appointment of examiners;
- Review of applications and of contractual arrangements associated with the assessment and certification of persons;
- Development, evaluation and maintenance of the examination(s) and of recertification;
- Decision on certification of persons, including signing or authorization of certificates;
- Development and approval of policies, processes and procedures for the resolution of appeals and complaints received from applicants, candidates, certified persons and their employers and other parties about the certification process and criteria;
- Final decision on appeals and complaints. Accreditation of main locations will cover satellite locations where the following is true:
- All inspections are in the same field;
- All inspectors operate under the same management system and management as the main inspection body. Inspectors need to be trained on the management system and included on the organizational chart;
- All 'key activities' (i.e. policy formulation, process and/or procedure development, process of initial selection of inspectors and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments) occur at the main location,
- All inspectors are able to have prompt supervisory oversight from the main location, when necessary, and;
- All inspectors must be included in the inspector witnessing plan
- Inspection scope of which accreditation is sought;
- Work instructions/SOPs;
- List of authorized inspectors;
- Last management review meeting minuets;
- Last internal audit;
- Supporting inspection methods/standards/regulations....;
- List of used instruments/equipment with appropriate calibration certificates.

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

6.1 **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.

6.2 **Conditions to be met by Certification Bodies (CBs):**

6.2.1 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.

6.2.2 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.

6.2.3 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.

6.2.4 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.

6.2.5 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.

6.3 **Conditions to be met by Inspection Bodies (IBs):**

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

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

6.3.3 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.

6.3.4 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.

6.3.5 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.

6.4 **Conditions to be met by Calibration and Testing Laboratories:**

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

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

6.4.3 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.

6.4.4 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.

6.4.5 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.

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

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

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

6.5.3 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.

6.5.4 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.

6.5.5 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.

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

6.6.1 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.

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

6.7 **Conditions to be met by forensic service providers (ISO/IEC 17025):**

Impartiality is defined as the "presence of objectivity" and it is noted that other terms useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, and balance.

Clauses 4.1.4 and 4.1.5 of ISO/IEC 17025 require that personnel conducting testing do so with integrity and without bias. When evaluating conformity with these requirements, the EGAC assessor will look for objective evidence that the laboratory and its personnel are aware of and comply with these ethical obligations.

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

6.7.2 Forensic service providers shall not allow persons or organizations external to lab to influence the results of calibrations or tests performed by lab.

6.7.3 Forensic service providers shall not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its calibration, testing activities, or PT providers.

6.7.4 Continuing Accreditation PT/ILC Requirements:-

6.7.4.1 Laboratories shall submit the results of PT to EGAC every years. Assessors shall verify during assessment and reassessment that up-to-date information is in EQM and shall ask that a completed PT/ILC Plan, be attached in each assessment.

6.7.4.2 Forensic Agencies must successfully complete a minimum of **one appropriate proficiency test from every major proposed scope** of accreditation prior to gaining accreditation.

6.7.4.3 An accredited laboratory shall successfully complete annually:

- A minimum of one appropriate proficiency test in each category of testing that appears on the scope of accreditation. Over a period of four years, this must include at least one proficiency test in each sub-category of testing within the scope of accreditation.
- Any PT requirements of field-specific standards pertinent to activities within the laboratory's scope of accreditation.

6.7.4.4 Successful completion means the testing results conformed to the expected results, or if discrepant results were obtained, the laboratory took corrective action appropriate to the severity of the discrepancy.

6.7.4.5 Unsatisfactory performance by an accredited laboratory in PT schemes can affect accreditation status. ANAB may continue accreditation subject to completion of corrective action or may suspend or withdraw accreditation for the relevant tests, depending on the specific issue and history of performance of the laboratory.

6.7.5 Separate applications are required for each location to be accredited. Physical locations in close proximity can be considered one location (to be determined by EGAC).

6.8 **Specific Conditions to be met by forensic service providers (ISO/IEC 17020):**

6.8.1 General Requirement's:

6.8.1.1 Impartiality and independence:-

6.8.1.2 The organization shall have clear and documented policies regarding pressures on individuals that may affect their judgment.

6.8.1.3 The organization shall have a policy and procedure that shall be followed if circumstance is discovered where there is a possibility that and individuals judgment has been compromised.

6.8.2 Confidentiality

6.8.2.1 The unit shall have a policy as any legal requirements of the agency as relates to confidentiality.

6.8.2.2 The policy shall have a policy on the confidentiality of the report.

6.8.3 Organization and management

6.8.3.1 The inspection body shall have an organization that enables it to maintain the capability and competence to perform its technical functions satisfactorily and take steps to keep it appropriately informed about applicable technical and/or legislative developments concerning its activities. This includes infrequently performed technical activities.

6.8.3.2 Any agency applying for accreditation shall show evidence of participation in at least one PT/ILC in each discipline of the proposed scope of accreditation prior to the granting of initial accreditation.

6.8.3.3 EGAC -accredited forensic service providers shall maintain proficiency test records for a minimum of one complete accreditation cycle. This shall include records of corrective action taken to address test results that do not conform to expected outcomes.

6.8.3.4 Each crime scene investigator and/or forensic examiner shall be observed (witnessed) and documented at least once per accreditation cycle.

6.8.3.5 All members of forensic staff, whose work influences the result(s) of the crime scene investigation and/or forensic examinations, shall have up-to-date records of training, development, and competence evaluation.

6.8.3.6 These records shall include academic and professional qualifications, external or internal courses attended, and relevant training (and retraining, where necessary) received while working in the forensic unit.

6.8.3.7 Visitors shall not have unrestricted access to the operational areas of the facilities.

6.8.4 Subcontracting

6.8.4.1 A subcontractor is one who is not part of the accredited organization and who performs services that are covered under the scope of accreditation.

6.8.4.2 If the evaluation of the competence of the subcontractor is based partly or in full on its accreditation, the forensic unit shall ensure that the scope of the subcontractor’s accreditation covers the activities to be subcontracted.

6.8.5 Handling inspection items and samples

6.8.6 A “chain of custody” record shall be maintained from the receipt of items/exhibits that details each person or body who takes possession of an item or alternatively the location of that item (e.g., if in storage).

6.8.7 The forensic unit should understand the significance of deviations with regard to the normal investigation and/or examination processes.

6.8.8 There shall be documented procedures that describe the measures taken to secure exhibits in the process of being examined which must be left unattended.

7. SIGNIFICANCE OF ACCREDITATION

7.1 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.

7.2 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).

7.3 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.

7.4 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.

7.5 Financial arrangements between a CAB and its clients are in no way the responsibility of, and are not subject to the control of EGAC.

8. NOTIFICATION OF CHANGE

8.1 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.

8.2 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.

8.3 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.

8.4 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.

8.5 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.

9. SUSPENSION AND WITHDRAWAL

9.1 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.

9.2 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.

9.3 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.

9.4 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.

9.5 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.

10. 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.

11. 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.