



Handling of Application PB1G

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Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (cancelled)
1.1 / May 2019	Quality Manager	4/9	Modification in for self-assessment format name
1.2 / Aug 2020	Quality Manager	8/9	Update issuing date for some documents
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.



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1. INTRODUCTION

- To describe how EGAC deals with the applications for accreditation received from the conformity assessment bodies (CABs).
- This publication applies to all applications received from CABs requesting for accreditation or extending the scope of accreditation.

2. PROCESS DESCRIPTION

2.1 Request for Application

When an accreditation request from a CAB seeking accreditation or extension of accreditation, it will be forwarded to EGAC relevant accreditation manager who will ensure that the potential applicant is given the information pack by from EGAC premises or from EGAC web site which including:

- EGAC application form F1P9G;
- EGAC CAB agreement form F2P9G.
- Related self-assessment report for CABs quality system implementation;
- EGAC regulations and publications applicable to applicant's scope;
- EGAC scope related of areas to be accredited.

Applicants are advised to read all documents related to their scope of application prior to completing and submitting the EGAC application form (Annex 1 & 2. Describes most of documents needed to read before applying to accreditation), the documents contain all the requirements for accreditation.

The application form requires very comprehensive information on the applicant's CAB. This information is necessary to allow EGAC to judge the extent that the CAB's documented quality system satisfies EGAC accreditation requirements.

The applicant CAB is required to complete all sections of the application form. Part I & Part III are considered general for all applicants, Part II is specific for each selected accreditation scheme by applicant choice.

The application form requires the submission of applicant's quality system documents together with the application form which described in EGAC regulation R1G clause 3 (R1G - Regulations to be met by CABs) which is included in the information package and available on EGAC website too.

2.2 Receipt of Application Form.

On receipt of a completed application record for accreditation, EGAC relevant accreditation manager is assigned by EGAC accreditation director of EGAC to deal with the application. He/she shall check that all documents indicated on the application record have been attached with the application. In addition, he shall be verified that all sections of the application have been completed in full.

EGAC related accreditation manager will ask the applicant CAB representative to sign (form F3P9G_ List of documents received from applicant CAB unless if the CAB receive an official letter containing a list of its supplied documents.

By signing this form or initialing the official letter, EGAC related accreditation manager confirms the review and availability of the required resources to perform the accreditation.

EGAC related accreditation manager will also issue the payment order to the financial & administration manager for collecting the application fees.

Any section of the application that is not applicable to the applicant, shall be indicated as not applicable and justified by the applicant.

EGAC related accreditation manager shall examine the quality system to check that it addresses all the key elements as specified in the relevant standards.

He also shall check if the application fee has accompanied with the application and shall ensure that all necessary information is completed.

Should any additional information or documentation be required, this will be requested from the applicant. When EGAC related accreditation manager is satisfied that all the relevant information has been supplied the applicant shall be notified of receipt of application.

During the assessment visit, the assessors might find it necessary to acquire copies of some documents / records for the sake of the review of the technical committee.

Where the applicant has not forwarded the application fee with the completed application, EGAC related accreditation manager shall request the finance office to issue an invoice for the appropriate amount. The finance office shall issue such an invoice within a week of receipt of the request. EGAC related accreditation manager shall inform the applicant that the process is on hold until such time as the application fee and any outstanding information is received.

EGAC related accreditation manager shall administer the entire application process. The information received shall be used for the preparation of the on-site assessment and shall be treated with appropriate confidentiality.

Note:

All costs associated with the initial assessment must be paid prior to the assessment date.

Failure to receive payment shall stop the application process and the applicant shall be notified by telephone and in writing. The application process shall be re-started only after receipt of the full amount.

2.3 Process of Application

EGAC shall identify an appropriate assessment team (team leader, assessor/s and/or technical expert/s) according to their area of expertise to allow for pre-assessment visit (if required) and/or a full initial assessment of the applicant for the scope of accreditation.

All assessment team shall be totally independent of any connection whatsoever with the applicant to be accredited.

The appointed assessment team shall handle all applicant information in full confidential and impartial treatment.

EGAC shall notify the applicant in writing of the names and affiliations of the nominated assessment team. The notification shall seek the approval of the applicant to the nominated team.

Objection to any nominated team members shall be in writing, include a detailed justification from the applicant CAB to his objection, and shall be lodged with EGAC within seven working days of receipt of the nominations.

Failure by the applicant to object to any of the nominated team members shall be considered as acceptance of the team as a whole.

Objections from the CAB to any of the nominated assessment team will be investigated and



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justified to EGAC related accreditation manager.

If EGAC related accreditation manager is satisfied with the CAB's justification to his objection, he/she will change this nominated assessors, otherwise he/she shall inform the CAB that his objection is not accepted and EGAC will keep the nominated team.

Accreditation manager's decision shall be final.

All team members shall be informed of the proposed assessment. EGAC related accreditation manager shall give the both team leader and assessor/s a copy of the CAB quality system and relevant procedures for document review according to the relevant accreditation procedure.

3. REFERENCES

- ISO/IEC 17011:2017;
- EGAC requirements.

**Criteria and guidelines for
Testing laboratories, calibration laboratories & medical laboratories, proficiency testing
providers and forensic service providers to be accredited by EGAC**

S	Type of CAB	Criteria	EA / ILAC / EGAC Guidelines
1	Testing / Calibration Laboratories (including Testing / Calibration Laboratories related to Forensic service providers).	<ul style="list-style-type: none"> - For all: ISO/IEC 17025:2017; EGAC R1G, R2G, R3G, R4G, R5G & PB1G; - For doping laboratories: WADA ISL. 	<ul style="list-style-type: none"> - ILAC: G8, G18, G19, G21, G24, P9, P10, P13 & P14. - EGAC PB1G, PB3G, PB4TCL, PB14G & PB15TCL; - For Forensic Service Providers: <ul style="list-style-type: none"> - ILAC G19:2014 - EGAC PB13FP;
2	Medical Laboratories.	<ul style="list-style-type: none"> - ISO 15189:2012; - EGAC R1G, R2G, R3G, R4G & R5G. 	<ul style="list-style-type: none"> - ILAC: G18, G21, G26, P9, P10. - EGAC PB1G, PB3G, PB5M & PB14G.
3	PT Providers.	<ul style="list-style-type: none"> - ISO/IEC 17043:2010. - EGAC R1G, R2G, R3G, R4G & R5G. 	<ul style="list-style-type: none"> - EA: 2/13, 2/18; - ILAC: G21 & P13. - EGAC PB1G, PB3G & PB9PT.

ANNEX 2

Criteria and Guidelines for
Certification bodies, inspection bodies to be accredited by EGAC

A. General Criteria / Documents / Guidelines:

S	General Criteria / Documents / Guidelines
1	ILAC G21-09:2012 Cross Frontier Accreditation Principles for Cooperation;
2	IAF MD 12:2016 Assessment of Certification Activities for Cross Frontier Accreditation;
3	IAF MD 7:2010 Harmonization of Sanctions;
4	IAF/ILAC A5:07/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004
5	EA 2/13:2019 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members;
6	EA-3/01 M:2019 EA conditions for the use of accreditation symbols, text reference to accreditation and MLA signatory status;
7	IAF ML 2:2011 General Principles on Use of the IAF MLA Mark.
8	EGAC R1G, R2G, R3G, R4G, R5G, PB1G, PB3G & PB4G.

B. Specific Criteria / Documents / Guidelines:

S	Type of CAB	Criterion	EA / ILAC / EGAC Guidelines
1	Management System Certification Bodies.	- ISO/IEC 17021-1:2015; - ISO/IEC TS 17021-2:2016 (EMS); - ISO/IEC TS 17021-3:2017 (QMS); - ISO/IEC TS 17021-10:2018; - ISO/IEC 27006:2015 (ISMS); - ISO/TS 22003:2018 (FSMS); - ISO 50003:2014.	- IAF MD1:2018; - IAF MD2:2017; - IAF MD3:2008; - IAF MD4:2018; - IAF MD5:2019; - IAF MD8:2020 (ISO 13485); - IAF MD9:2017 (ISO 13485); - IAF MD10:2013 - IAF MD11:2013 - IAF MD15:2014' - IAF MD16:2015 (FSMS); - IAF MD17:2019 (QMS, EMS); - EGAC PB2C & PB7C.
2	Product Certification Bodies.	- ISO/IEC 17065:2012.	- EA-3/12:2020; - EA-6/02:2013; - EA-6/04:2011; - EGAC PB10Pd.
3	Persons Certification Bodies.	- ISO/IEC 17024:2012.	- EGAC PB11Ps & PB16Ps.
4	Inspection Bodies (including Inspection Bodies related to Forensic service providers)..	- ISO/IEC 17020:2012;	- EA-2/17; - ILAC P10 & P15; - EGAC PB8I & PB14G. - For Forensic Service Providers: - ILAC G19:2014 - EGAC PB13FP;



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Note:

- ILAC Mandatory documents are available in ILAC
website: <http://www.ilac.org/publications-and-resources>
- IAF Mandatory documents are available in IAF
website: http://www.iaf.nu/articles/Mandatory_Documents_/38
- EA Mandatory Documents are available in EA
website: <http://www.european-accreditation.org/publications>
- EA Regulations and Publications are available in EGAC
website: <http://www.egac.gov.eg>