

EGAC Policy on Cross Frontier and Cooperation PB4G

Prepared by: EGAC Quality General Manager
Ashraf Saif



Reviewed and
Authorized by: EGAC Accreditation Director
Mohamed Osman



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1. PURPOSE

The purpose of this document is to define the procedures and provisions for cross-frontier accreditation and cooperation with accreditation body's that are signatories to MLA/MRA/BLA agreements of AFRAC, ARAC, EA, IAF and ILAC.

2. SCOPE

This document is describes EGAC policy rules for the accreditation and assessment of CABs registered and/or acting outside the Egypt and for the assessment of CABs in Egypt on request of other (ABs).

3. REFERENCES

- 3.1 ISO / IEC 17011:2017;
- 3.2 ILAC-G21:2002 (Cross Frontier Accreditation - Principles for Avoiding Duplication);
- 3.3 IAF GD3:2003 (IAF Guidance on Cross Frontier Accreditation);
- 3.4 EA-2/13 M:2012 & EA-2-13-s1 (EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members).

4. DEFINITIONS

4.1 MRA Signatory Accreditation Bodies

ILAC is the international forum for laboratory accreditation bodies. The ILAC Mutual Recognition Arrangement (MRA) is designed to ensure that test reports and calibration certificates issued by accredited laboratories will be accepted worldwide. For this to be achieved, the Accreditation Bodies operate as a network, each providing an equivalent accreditation service. This is assured by the ILAC peer evaluation.

This MRA serves as a third party testimony that these Accreditation Bodies are working according to the guidelines of ILAC. No more investigation of competence will be necessary for these ABs.

4.2 EA region:

The geographical region covered by countries of the EA members, the countries which have been formally identified by the EU or EFTA as candidate countries for membership in the EU or EFTA and countries of accreditation bodies with which EA has signed a bilateral agreement is referred to as the "EA region".

4.3 Foreign accreditation body (FAB):

"Foreign Accreditation Body" refers to an Accreditation Body when it accredits a conformity assessment body which has sites with key activities in another country than the country of the accreditation body accrediting it.

4.4 Local accreditation body (LAB):

The term "Local Accreditation Body" refers to the national accreditation body of the country where the accredited conformity assessment body is established. The term also refers to the accreditation body of a country where there is a site included in an accreditation granted by an accreditation body in another country.

4.5 National accreditation body (NAB):

The term "National Accreditation Body" refers to the accreditation body in a country legally appointed by the government of that country.

5. RESPONSIBILITY

5.1 EGAC Executive Director

- 5.2 EGAC Accreditation Director
- 5.3 EGAC Quality Manager
- 5.4 EGAC Accreditation Managers
- 5.5 EGAC Finance & Administration Manager

6. General

In general EGAC shall comply with the Guidance document from IAF on cross frontier MD12:2016, the Guidance document from ILAC G21:2012, EA cross frontier policy 2/13-m:2012, EA-2-13-m-s1:2013 and EU regulation 765/2008 on all cross frontier processes in the following situations:

- When EGAC performs accreditation for a CAB located outside Egypt.
- When an MRA/MLA signatory Accreditation Body performs accreditation for a CAB located inside Egypt.

EGAC shall only consider accreditation outside Egypt if the CAB seeks its accreditation for the reasons stated in (8.1.1.b) mentioned IAF and ILAC documents and after it makes sure of the CAB's awareness of the local accreditation body and its equivalence.

EGAC accepts to perform any accreditation outside Egypt in a country with an accreditation body which is not EA member, and it may use its own assessors.

EGAC may conduct these accreditation with teams combined together with other Accreditation Body if requested and possible.

If EGAC is accrediting a CAB outside Egypt or inside Egypt but having critical locations outside Egypt, then an assessment program shall be made to assess these locations by EGAC.

These Critical Locations will be considered as such if they comply with the definition of the (critical location) in the above mentioned IAF document, EGAC may use the services of the local accreditation body for this assessment, EGAC's policy on sampling shall also apply for critical locations outside Egypt.

7. Cooperation

EGAC's cooperation with other MRA/MLA signatory Accreditation Bodies can be in the following ways:

- Use assessors of the local AB on its recommendation after discussing their qualification with it.
- EGAC may conduct a joint accreditation with local Accreditation Body.

EGAC's cooperation with other non-MRA/MLA signatory local Accreditation Bodies can be in the following ways:

- Use assessors of the local AB but take the responsibility for checking their qualification and training.
- EGAC may conduct a joint accreditation with local Accreditation Body.
- Have an assessor from the local AB as a team member in EGAC's assessment team.
- Have the local AB observe the process.

If EGAC accepts to perform any assessment outside Egypt in a country with an accreditation body which is EA member, EGAC policy is not to compete with other national accreditation bodies and EGAC will follow the applicable international guidance (EA cross frontier policy 2/13-m:2012 & EA-2-13-m-s1:2013).

8. PROCESS DESCRIPTION

EGAC is working in non-competitive manner with other EA AB's according to EC 765:2008.

8.1.1 Conditions for acceptance of CABs applications

8.1.1.a EGAC

- (i) Offers its services by priority to companies established on Egypt and operating under a

Egyptian legal entity;

- (ii) Does not compete with accreditation bodies (AB's) members of EA;
- (iii) Does not engage in any marketing of its services outside Egypt.

8.1.1.b Exceptionally, EGAC accepts CABs application for accreditation from foreign countries provided the following conditions are complied with:

- (i) There is no local AB or the local AB is under development, is not yet fully operational or it has absence of resources;
- (ii) The local AB is an EA member but not an EA-MLA signatory for the conformity assessment activities for which accreditation is sought;
- (iii) The local AB is not an EA member but a signatory of the AFRAC, ARAC, ILAC or IAF arrangements: however, the applicant especially requests for EGAC accreditation in order to fulfill specific expectations of the Egyptian market.

8.1.1.c Before accepting an application from a foreign CAB, EGAC:

- (i) Will enquire whether the applicant has considered to apply by the local accreditation body and why the application is put to EGAC. Where relevant, the advantages of applying to the local accreditation body and the equivalence demonstrated through the international multilateral arrangements will be pointed out;
- (ii) Will confirm with the local accreditation body that one of the conditions under 8.1.1.b applies;
- (iii) Will check through a comprehensive application review whether EGAC has the necessary understanding and specific competence to handle issues such as language, local laws and regulations, culture etc.... in addition to the normal technical competence requirements. In such cases, cooperation with the local accreditation body will be sought.

8.1.1.d EGAC reserves the right to reject CABs applications related to the following situations:

- (i) The application has been rejected or its accreditation has been withdrawn by the local accreditation body;
- (ii) The CAB applies for accreditation of a type of activity that is not accredited by the local body and that is not yet part of the EGAC scope of activities;
- (iii) The applicant has no justification to apply specifically to EGAC and the application is in the framework of a general tender.

8.1.2 Practical provisions for implementation

8.1.1a In case of accreditation of a foreign conformity assessment body, EGAC seeks for co-operation with the local accreditation body for exchange of information and competence resources. The local accreditation body is invited to provide assessment team members where appropriate or to take part in the assessments as observer.

In case where the local AB and EGAC have not been able to establish cooperation, EGAC will keep records of the reasons and the information shall be provided on request.

8.1.1.b When the conditions under 8.1.1.b are no longer met or at each re-assessment, EGAC reconsiders previously accepted justifications for providing cross-frontier accreditations. In case maintaining the EGAC accreditation is no longer justified, the accredited body is informed and is required to apply to the local accreditation body. EGAC cooperates with the local accreditation body in order to facilitate the transfer of the accreditation (see under point 8.1.3). The results of the review are formally recorded.

8.1.1.c EGAC keeps the local accreditation body informed of any significant element affecting the operation of the accredited body, such as any termination or suspension or complaint.

8.1.3 PRACTICAL PROVISIONS FOR THE TRANSFER OF EGAC ACCREDITATION TO ANOTHER ACCREDITATION BODY

8.1.3.1 Transfer due to the change of signatory status when the local accreditation body became a signatory (for EA members only)

When EGAC has granted accreditation to a CAB located abroad due to the fact that the local AB is not a signatory of the EA MLA/BLA agreement, EGAC informs its accredited CAB of the fact that it will have to transfer to the local AB as soon as these status change.

EGAC will not renew such an accreditation or extend in the same CAB accredited scheme after its local AB enters the EA MLA/BLA.

8.1.3.2 Change of accreditation body at the end of the validity term of the existing accreditation

When EGAC decides that an accreditation granted under the cross-frontier regime cannot be maintained at the end of an accreditation cycle or on request of the accredited body,

EGAC:

- (i) Informs the concerned accredited body at least 9 months before the expiry date of the certificate and invites the body to apply by the local accreditation body. The decision is motivated to be taken on time;
- (ii) Informs the local accreditation body about the reasons for the transfer and submits a copy of the EGAC accreditation documents, the last assessment report and a report on complaints if any;
- (iii) Offers its cooperation to the local accreditation body in order to facilitate the transfer through exchange of assessors or other practical provisions.

8.1.3.3 Assessment of activities performed outside Egypt by Egyptian CABs accredited by EGAC

Accredited CBs services provided outside Egypt by EGAC accredited CBs, it be managed through the head office in Egypt or through critical or non critical sites established abroad, are covered by the EGAC accreditation only in case these activities have been the subject of an appropriate evaluation. This evaluation may include assessment at the site offices and/or witnessing of conformity assessment activities.

EGAC may outsource assessments to be performed abroad to the local AB when this one is signatory of the EA, and has the specific technical competence to cover the accredited scope. The assessment procedure will be as agreed.

EGAC ensures that the local AB receives the necessary information to allow for a proper organization of the evaluation at least 3 months before the expected date for the visit; this information will include in particular the EGAC specific requests in terms of content and duration of the assessment as well as the content and language of the report.

In case the local accreditation body refuses to act on behalf of EGAC, EGAC organizes the evaluation.

The approach to the cooperation between EGAC and the local accreditation body differs, depending on the specific circumstances of the accredited body. There are 3 possible cases:

- (i) The EGAC accredited body has an operation site in a country where the site is itself a body accredited by the local accreditation body for an identical scope;
- (ii) The EGAC accredited body has an operation site in a country where the site is itself a body Accredited by the local accreditation body for a different scope;
- (iii) The EGAC accredited body has an operation site in a country where the site is not at all accredited by the local accreditation body.

The table in appendix 1 defines the principles of the cooperation between EGAC and the local accreditation body in the three cases. This table applies only if the local accreditation body has the appropriate competence for the work it is being asked to deliver.

In case of evaluation of critical sites, the provisions of ISO/IEC 17011 and ILAC/IAF A5 apply.

If the local accreditation body is not a signatory of the EA, ILAC or IAF relevant multilateral agreements, EGAC keeps the full responsibility for the organization of the evaluation but seeks for as much as possible cooperation with the local accreditation body (recourse to local assessors, joint assessments or participation of the local accreditation body as observer ...).

8.1.3.4 ACTIVITIES OF EGAC AS A SUBCONTRACTOR

On request of a foreign accreditation body signatory to the EA, ILAC or IAF multilateral agreements, EGAC will accept to act as a subcontractor to perform all or part of the assessment of a conformity assessment body accredited abroad and operating from critical sites located in Egypt, provided that the following conditions are complied with:

- (i) A specific arrangement or a framework agreement, with clear identification of the respective rights and obligations of both accreditation bodies, is in place;
- (ii) The activity to be evaluated is part of the scope of activities of EGAC;
- (iii) The evaluation will be performed according to the procedures of EGAC;
- (iv) The request for cooperation has been notified to EGAC at least 3 months in advance of the expected date for the evaluation;
- (v) EGAC has received the necessary information to allow for a proper organization of the evaluation; the scope of the requested assessment will be specified in such detail that the risk of misunderstanding is minimized.

8.1.3.5 COMPLEMENTARY PROVISIONS

EGAC and the foreign AB's exchange any valid and relevant information, such as outcome of assessments, complaints, market feedback etc concerning the CAB's when they are both involved.

The EGAC department managers are appointed as contact point for all communications concerning cross-border activities.

8.2 6.3 language

The language to be used during the assessment and in reports shall be agreed between the accreditation bodies involved and the conformity assessment body in advance of the assessment. The default language shall be English.

8.3 Assessment Terms

When a Foreign AB agrees to undertake assessments on behalf of a EGAC, the Foreign AB may use its own accreditation assessment procedures according to ISO/IEC 1711, systems and reports shall not be required to use the assessment procedures, systems or reports of EGAC.

The report shall, in any case, contain sufficient information about the findings and supporting evidence to ensure that a sound decision can be taken by EGAC.

EGAC shall specify the scope of the requested assessment in such detail that the risk for misunderstanding is minimized.

The Foreign AB shall ensure that it follows the instructions of the EGAC in such matters. EGAC shall provide the Foreign AB with all information needed to ensure effective assessment within the agreed time frame according to the agreement signed.

The Foreign AB shall inform EGAC with the outcome of the accreditation recommendation when it is made.

The Foreign AB and the Local AB shall exchange any valid and relevant information, such as outcomes of assessments, complaints, market feedback, etc, concerning CABs where they are both involved.