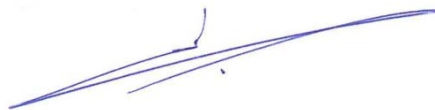


**Accreditation Process Time Limitations and Response Actions
To Findings of CABs**

R5G

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1. Scope

This regulation is set to determine accreditation activities time limits when CAB seeks accreditation or continuation of its accreditation for a certain scope from EGAC. It also determines EGAC's response actions to the nonconformities of CABs in initial assessment and in consecutive assessment/reassessment. Whenever testing laboratories are mentioned it includes medical ones.

2. Definitions

Accredited CAB: It means that the CAB was granted accreditation and premised to issue an accredited certificate with its accredited scope for its clients until its certificate will be expired, and it is identified at EGAC website with "Accredited" status.

Suspended CAB: It means putting temporary restrictions in place for all or part of the scope of accreditation for that CAB, until ending of its suspension period and it is identified at EGAC website with suspended status.

Withdrawn CAB: It means cancelling accreditation for the full scope of this CAB during its valid accreditation cycle and it is identified at EGAC website with withdrawn status.

Expired accreditation: It means stopping accreditation for the full scope of this CAB by the day of ending its accreditation date without any trend for delivering reassessment application.

Note

*EGAC has no relation with any CAB is not recorded in EGAC website with one of the explained previous status, for any CAB has an expiry date certificate shall be **omitted** "cancelled or vanished" from EGAC website i.e no more relation is considered with EGAC accreditation system.*

3. Grading of Findings in EGAC:

Grading of findings is determined by the assessment team in agreement with EGAC. Non-conformities shall be due to lack of application of requirements of the standard in the system or in the implementation of the system. This grading depends largely on the evaluation of the whole situation at the time. So, the examples given here are just for explaining; however we may have different grading in similar situations.

EGAC's grading is as follows:

- a. The finding is considered a "**Non-Conformity**" if assessment team finds a lack of application of requirements of the relevant standard, ILAC/IAF requirements, and EGAC requirement in the system or in the implementation of the system. The standard will be the accreditation criteria according to the type of the CAB for all levels of the scope standards, For EX. "ISO/IEC 17025, ISO/IEC 17021-1, ISO/IEC 17021-2 ...".
- b. The finding is considered a "**Comment**" if it does not affect the core activities of the CAB (ex: test/calibration results or certificates). This maybe the case if the validity of results were not in question and the management system was not in jeopardy. Ex.:
 - Where there is an isolated case of management system nonconformity. Like when:
 - One customer complaint had been acted upon but not been closed out.
 - A complaint received about something that is considered insignificant, so it was not treated in the complaint procedural way. Although other complaints are recorded and acted upon properly.
 - Where there is isolated case of technical recording or documented procedure nonconformity. Like when:

- A reference standard was not calibrated by the due date but no calibrations had been performed based on this item, after that date and until it was again recalibrated.
- One equipment not calibrated although it is not been used.
- A photocopy of an obsolete procedure was found in the drawer of one of the analysts.
- One staff member had no job personal description although there was a generic description for those in that position in the manual.

4. Actions taken by EGAC according to nonconformity grade:

a. *In dealing with corrective actions the following shall be considered:*

- Grading of non-conformities is based only on the findings recorded during the assessment.
- A finding would confirm whether it was a onetime event or a general statement whose corrective action should be implemented throughout the CAB. A corrective action request may ask the CAB to itself determine if the finding indicates a chronic problem.
- In all cases of nonconformity, assessors shall resist “approving” proposed corrective actions presented on the day of the assessment without a proper corrective action investigation by the CAB, because this may lead to issuing another CAR at the next assessment because the “approved” corrective action was not adequate.
- Findings should be evaluated together with the general picture / history of the CAB e.g. trust, ongoing improvement, staff competence, repetitive nature (from previous assessments)

b. *EGAC's actions will depend on the grading of finding as follows:*

- When the finding is considered “*non-conformity*”, the CAB will be required to answer the non conformity with a root cause analysis and a proposed corrective action, and then complete this corrective action when approved according to form (F10P9G_Finding, corrective action and clearance report).
- Accreditation of the CAB or the affected activity may eventually be rejected in initial assessment or suspended in consecutive assessment/re-assessment if the corrective action is not satisfactorily completed.
- Corrective action must be completed within the specified time interval as shown in (R5G clause 7) to avoid rejection of accreditation or suspension.
- Non-conformities may well need a follow-up on-site assessment to ensure they have been effectively corrected. However, if the assessment team agrees that the CAB understands the issues, written assurance of corrective action and the provision of objective evidence of the measures taken may be acceptable.
- When the finding is a “*Comment*”, it shall be answered by the CAB and cleared by the assessor.

5. Consequences and Rewards:

a. *Initial assessments / extension of scope:*

- 1) The CAB is required to submit its application attached with the supported documents for EGAC initial assessment / extension of scope to be completely reviewed and accepted by the relative department before its approval.
- 2) The CAB is required to submit its application for extension of scope to EGAC at least 3.5 months before the next scheduled visit and not at the last year of accreditation.
- 3) If the CAB fails to abide by the required time limits of any of the activities mentioned above (R5G clause 7), EGAC may reject the initial accreditation/extension of the CAB according to the evaluation of its provided justifications. Accordingly, CAB will lose its

application fees and it will be obliged to pay all fees of accreditation steps until date of rejection.

- 4) If a CAB seek for initial assessment and its application is submitted to EGAC relative department, and then no response (feedback) will be met by this CAB during the assessment process, this application will be cancelled after passing 3 months from its last step was acted on its assessment.
- 5) In all cases **EGAC** will inform the CAB with its decision.

b. Consecutive assessment:

- 1) A CAB should implement and complete the first assessment visit within maximum 12 months of granting accreditation.
- 2) If the CAB fails to abide by the required time limits mentioned above (R5G clause 7) of any of the consecutive assessment visits, EGAC shall suspend the accreditation of the CAB for a maximum of 3 months, according to the evaluation of its provided justifications. If the problem persists the CAB's accreditation will have an extension of suspension for another 3 months according to approval of justification provided to EGAC accreditation director, if the problem persists the CAB's accreditation will be withdrawn or its application (initial/extension) will be canceled.
- 3) In all cases **EGAC** will inform the CAB with its decision.

c. Reassessments:

- 1) For any CAB that applies for reassessment **before** the expiry date of its accreditation certificate up to 11 months or more at the most, Shall be exempted from the application fees.
- 2) For any CAB has to apply for reassessment in advance or up to 9 months before the expiry date of its accreditation certificate, EGAC give granting completing CAB reassessment process before the expiry date of its accreditation certificate if this CAB abide process time limits mentioned above (R5G item 5),
- 3) For any CAB applied for reassessment and the remaining time for the expiry date of its accreditation certificate **less than** "9 menthes", EGAC will accept CAB reassessment application and start the process until issuing a new accreditation certificate, if CAB accreditation date will be expired:
 - It must stop its accredited activity until granting a new accreditation;
 - A CAB submit a performance declaration to EGAC about that missed accredited period "from expiring to issuing a new one";
 - 1st accreditation date of this CAB will be changed and become the newer one;
 - A CAB new issued certificate date will start just the day after the decision of granting day.
- 4) If the CAB applies its reassessment application after the expiry date of its accreditation certificate, by logic it will be considered as an initial accreditation application with a new number of accreditation for this CAB.
- 5) For any CAB that complete its reassessment process "with the same previous accredited scope / with a modified accredited scope" before ending its accreditation cycle, then a new accreditation certificate with its same /new scope will be issued with the date just after the day of accreditation committee decision and withdrawing the previous issued certificate one.

6. Actions for insuring the CAB status before withdrawal

The CAB is required to submit a declaration of its complying with the relevant standard, ILAC/IAF requirements, and EGAC requirements in case of withdrawal without assessment visit.

7. Accreditation Process time limitation

EGAC and CABs that seek new/continued accreditation shall not to exceed time limits of assessment steps expressed below:

S	Activity	Activity Description	Time limits for initial assessment	Time limits for extension of scope	Time limits for consecutive assessment	Time limits for reassessment
1	Submitting application	Start when CAB communicate with the related manager to review his application & quality system and before acceptance application officially	Before acceptance application officially	3.5 months before consecutive assessment date	NA	≥ 9 months before accreditation certificate expiry date
2	Nomination of assessment team	Start with EGAC sending the notification letter and till CAB acceptance	Within 2 Weeks maximum from receiving EGAC's notification letter	Within 2 Weeks maximum from receiving EGAC's notification letter	Within 2 Weeks maximum from receiving EGAC's notification letter	Within 2 Weeks maximum from receiving EGAC's notification letter
3	Document review	Start with EGAC sending the report, till EGAC acceptance of CAB document review response	Within 3 months maximum from EGAC sending document review report	Within 1 month maximum from EGAC sending document review report	NA	Within 1 month maximum from EGAC sending document review report
4	Agreement on assessment visit date	Start with EGAC sending the proposal letter and till CAB acceptance	Within 2 weeks maximum from receiving EGAC's proposal letter	Within 2 weeks maximum from receiving EGAC's proposal letter	Within 2 weeks maximum from receiving EGAC's proposal letter	Within 2 weeks maximum from receiving EGAC's proposal letter
5	submitting the assessment report to CABs	Start from the date of assessment	One week	One week	One week	One week
6	Root cause & proposed corrective action	Start after the CAB receiving the assessment report till the CAB send the root causes and proposed corrective actions	Within 1 week maximum from assessment visit date	Within 1 week maximum from assessment visit date	Within 1 week maximum from assessment visit date	Within 1 week maximum from assessment visit date
7	Completed corrective actions	Start after the CAB receiving the assessment report till the CAB send corrective actions with its evidence of completion	Within 3 months maximum from assessment visit date	Within 4 weeks maximum from assessment visit date	Within 4 weeks maximum from assessment visit date	Within 4 weeks maximum from assessment visit date
8	Additional corrective actions	Start with EGAC letter to refuse the corrective actions introduced from the CAB till the CAB introduce and complete the additional corrective actions	Within 4 weeks maximum from the date of receiving refusal letter	Within 4 weeks maximum from the date of receiving refusal letter	Within 4 weeks maximum from the date of receiving refusal letter	Within 4 weeks maximum from the date of receiving refusal letter
9	Committee corrective actions	Start with EGAC notice to the CAB with committee needed actions till the CAB introduced evidence of completion	Within 4 weeks from receiving notice letter	Within 2 weeks from receiving notice letter	N/A	Within 4 weeks from receiving notice letter