

**ACCREDITATION PROCESS TIME LIMITATIONS AND
RESPONSE ACTIONS TO THE NONCONFORMITIES OF THE CABS**

R05G

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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 the CABs in initial assessment and in surveillance/reassessment. Whenever testing laboratories are mentioned it includes medical ones.

2. Grading of Findings in EGAC:

The grading of the finding 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 Assessor 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 (test/calibration results or certificates). This may be 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.

3. 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 a “***non-conformity***”, the CAB will be required to answer the non conformity with a root cause analysis and a proposed corrective action ,then complete this corrective action when approved according to form (F06P12L).
- Accreditation of the CAB or the affected activity may eventually be rejected in initial assessment or suspended in surveillance/reassessment if the corrective action is not satisfactorily completed.
- Corrective action must be completed within the specified time interval as shown in the following table 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.

4. Accreditation Process time limitation

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

SN	Activity	Activity Description	Time limits for initial assessment	Time limits for extension of scope	Time limits for surveillance	Time limits for reassessment
1	Start of the accreditation process	The CAB needs to know and plan accordingly that it should start the process before the time assigned for the assessment by the following limits in order to finish in time	9 month before accreditation is required	3.5 months before the date of surveillance	3.5 months before the date of surveillance	9 months before the expiry date of accreditation certificate and CABs will be encouraged to apply for reassessment 2 months before that
2	Submitting Application	The CAB is required to submit an application for assessment/ reassessment early:	9 month before accreditation is required	3.5 months before the date of surveillance	NA	9 months before the date of reassessment and up to 8 months before expiry date
3	Acceptance of Assessment Team	After receiving the letter of notification of the appointment of the assessment team, the CAB is required to send its acceptance / justified rejection on assessment team	Within 7 W. Days maximum from receiving EGAC's notification letter.	Within 7 W. Days maximum from receiving EGAC's notification letter	Within 7 W. Days maximum from receiving EGAC's notification letter.	Within 7 W. Days maximum from receiving EGAC's notification letter
4	Answer to document review	After receiving the document review non-conformities, the CAB is required to send the required changes / corrections	Within 3 months maximum from receiving document review report	Within 2 weeks maximum from receiving document review report	---	Within 2 weeks maximum from receiving document review report
5	Agreement on assessment visit date	After receiving the letter of notification of the assessment visit date, the CAB is required to send its acceptance / justified request for delay	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.

SN	Activity	Activity Description	Time limits for initial assessment	Time limits for extension of scope	Time limits for surveillance	Time limits for reassessment
6	Rescheduling of assessment visit date	if the assessment visit date is not accepted, a justified request for delay shall be sent by the CAB including a new proposed assessment date that is:	Within 3 months maximum from receiving EGAC's notification letter.	Within 1 months maximum from receiving EGAC's notification letter.	Within 1 months maximum from receiving EGAC's notification letter.	Within 1 months maximum from receiving EGAC's notification letter.
7	Root cause & proposed corrective action	After receiving the assessment report with the corrective action requests for the non-conformities arising during the assessment the CAB is required to send the root causes and proposed corrective actions	Within 7 W. Days maximum from date of assessment visit.	Within 7 W. Days maximum from date of assessment visit.	Within 7 W. Days maximum from date of assessment visit.	Within 7 W. Days maximum from date of assessment visit.
8	Completed corrective actions	After receiving the assessment report with the corrective action requests for the non-conformities arising during the assessment the CAB is required to send corrective actions with its evidence of completion.	Within 3 months maximum from date of assessment visit.	Within 4 weeks maximum from date of assessment visit.	Within 4 weeks maximum from date of assessment visit.	Within 4 weeks maximum from date of assessment visit.
9	additional corrective actions	If the corrective actions introduced from the CAB were found to be unsatisfactory, the CAB is required to introduce and complete the additional corrective actions	Within 1 month maximum from date of receiving the refusal of corrective actions letter.	Within 6 weeks maximum from date of assessment visit.	Within 6 weeks maximum from date of assessment visit.	Within 6 weeks maximum from date of assessment visit.
10	Committee corrective actions	If any of the committees introduced any corrective actions during their review, then it should be completed by the CAB and introduced to EGAC with evidence of completion	Within 4 weeks from the time of giving the notice to the CAB	Within 4 weeks from the time of giving the notice to the CAB	N/A	Within 4 weeks from the time of giving the notice to the CAB

5. Consequences and Rewards:

a. *Initial assessments / extension of scope:*

- 1) The **CAB** is required to submit its application for extension of scope to EGAC at least 3.5 months before the next scheduled visit.
- 2) If the **CAB** fails to abide by the required time limits of any of the activities mentioned above, EGAC may reject the accreditation/extension of the CAB according to the evaluation of the 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.
- 3) **EGAC** will inform the CAB with its decision.

b. *Surveillance:*

- 1) If the **CAB** fails to abide by the required time limits of any of the activities mentioned above, 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 be withdrawn. These actions will be in accordance with EGAC's R01G "Regulations to be met by CABs", item "6. Suspension and Withdrawal".
- 2) In all cases **EGAC** will inform the CAB with its decision.

c. *Reassessments:*

- 1) Any CAB that applies for reassessment before the expiry date of its accreditation certificate by 270 days up to 240 days at the most:
 - a) Shall be exempted from the application fees.
 - b) If its reassessment process and the issuance of its new accreditation certificate took more than the expiry date of its old accreditation certificate, without any cause from the CAB's side, then EGAC will issue an official letter to extend the CAB's accreditation beyond the expiry date of its old accreditation certificate and until the issuance of its new accreditation certificate.
- 2) Any CAB that applies for reassessment before the expiry date of its accreditation certificate by less than 240 days:
 - a) Shall not be exempted from the application fees.



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- b) If its reassessment process and the issuance of its new accreditation certificate took more than the expiry date of its old accreditation certificate, then the CAB will **have to apply as initial accreditation.**
- 3) Any CAB that **doesn't** apply for reassessment **till** the expiry date of its accreditation certificate and it will have to apply as initial accreditation.
- 4) If the CAB fails to abide by the required time limits of any of the activities mentioned above, 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 be withdrawn. These actions will be in accordance with EGAC's R01G "Regulations to be met by CABs"; clause "6. Suspension and Withdrawal".

6. Actions for insuring the CAB status before withdrawal

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