

Quality and Accreditation Institute
Centre for Laboratory Accreditation



Change Adapt Improve

**POLICIES AND PROCEDURES
FOR DEALING WITH ADVERSE
AND OTHER DECISIONS**

Issue No.: 01

Issue Date: February 2019

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Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 022	Policies and Procedures for Dealing with Adverse and Other Decisions	
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CHANGE HISTORY

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1. Objective

This document describes various policies and procedures of QAI for dealing with adverse decisions against applicant and accredited Conformity Assessment Body (CAB).

2. Scope

QAI Secretariat shall monitor the CAB for compliance with the requirements applicable from time to time. The issues that fall under the scope of this document are related to situations wherein applicant or accredited CAB has not complied with one or more terms and condition as well as any of the applicable requirement.

3. Policies and Procedures for Dealing with Adverse and Other Decisions Against CAB

QAI Secretariat shall monitor the CAB of any information that casts doubt on the suitability of awarding or maintaining accreditation of CAB. QAI may consider an appropriate action in each case, taking into account the objective evidence against and facts available and comparing them with the related clauses as mentioned in this document.

Various categories of decisions are as follows:

Adverse decisions against applicant CAB

- Inactive and Closed

Adverse decisions against accredited CAB

- Shifting of Renewal Date
- Expiry of Accreditation
- Abeyance
- Suspension
- Forced Withdrawal
- Scope reduction

Other decisions against accredited CAB

- Voluntary Withdrawal
- Extension of Validity of Accreditation Certificate

4. Policy and Procedure for Dealing with Adverse Decisions Against Applicant CAB

4.1 Inactive and Closed

• Conditions:

- When a CAB has submitted incomplete application and has not submitted required information, application fee etc. within three months even after a reminder is sent.
- When CAB has not undergone final assessment within six months of application.
- When the assessment of the CAB has been conducted and CAB has not submitted action plan, if required for non-conformities within one month.
- When an applicant CAB does not adhere to terms and conditions including misrepresentation of facts like use of QAI logo or accreditation mark.

• Action by QAI

- A communication to be sent to the CAB that it has been put under "Inactive" category and application will be closed. Against the name of the CAB, "application closed" status shall be mentioned under applicant category on QAI website. Fee paid once are non-refundable as per QAI rules. CAB has to apply afresh and it is treated as a

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new CAB and has to pay all fees, as applicable at that time. However, unique registration number will remain same.

- For a condition mentioned above, a warning letter shall be sent to adhere to the conditions, to obey within 30 days failing which application will be closed. The CAB will be treated as a forced withdrawal case. There will be no provision for appeal in this case. CAB has to apply afresh and it is treated as a new CAB and has to pay all fees, as applicable at that time. However, unique registration number will remain same.

5. Policy and Procedure for Dealing with Adverse Decisions Against Accredited CAB

5.1 Shifting of Renewal Date

- **Condition:**

- If an CAB has not applied 6 months prior to the expiry of accreditation and is unable to complete formalities for re-accreditation before the expiry of accreditation.

- **Action by QAI**

- The CAB will not remain in accredited category and cannot use QAI Accreditation Mark. If CAB continues to use the QAI accreditation mark and claim accreditation status, it will be debarred from QAI accreditation process for six months. CAB will be treated as a forced withdrawal case. There will be no provision for appeal in this case. CAB has to apply afresh and it is treated as a new CAB and has to pay all fees, as applicable at that time. However, unique registration number will remain same.
- Accreditation status will be granted when the CAB undergoes the re-assessment; is able to complete the corrective actions on the non-conformances after Re-assessment and the Assessment Team recommends renewal of accreditation. The renewal date of Accreditation certificate, in case it is after the expiry of accreditation certificate, shall be the date on which the approving authority approves it. The certificate shall be valid for a period of two years.

5.2 Expiry of Accreditation

- **Condition:**

- When the CAB has not submitted the application for renewal before expiry of accreditation.

- **Action by QAI**

- When the CAB has not submitted the application for reassessment, QAI Officer shall inform the CAB at least one month before expiry of accreditation that it shall not claim accreditation status after expiry of accreditation.
- HCF shall not use QAI Accreditation Mark in letterheads, publicity matters, other documents etc. once the accreditation cycle is over.
- After the date of expiry of accreditation, QAI website will be updated to show the expired status.
- The HCF shall have to apply afresh depositing application fees and other outstanding charges and undergo fresh assessment, as a new applicant CAB.
- The unique Registration number will remain same, for the purpose of identification and tracking of earlier records.
- The CAB will have a new certificate date, if successfully get accredited.
- The status shall be published on QAI website, thereafter.
- If CAB continues to use the QAI accreditation mark and claim accreditation status, it will be debarred from QAI accreditation process for one year. CAB will be treated as a

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forced withdrawal case. There will be no provision for appeal in this case. CAB has to apply afresh and it is treated as a new HCF and has to pay all fees, as applicable at that time. However, unique registration number will remain same.

5.3 Abeyance

- **Conditions:**

- When a CAB had undergone Re-assessment visit and has not submitted a valid action plan to QAI within one month of Re-assessment visit.
- When an CAB has not paid the Accreditation fees and the accreditation expenses, beyond three months of the due date.
- When an CAB does not appropriately respond to the queries as requested by QAI, even after two reminders.
- When a total system failure or gross negligence in technical aspects is identified at the time of Re-assessment visit.
- If the CAB is not maintaining the terms and conditions of accreditation or has breached the provision of the standard agreement between CAB and QAI.
- When the CAB fails to submit corrective actions as per accepted and committed action plan for addressing the non-compliances.

- **Action by QAI**

- The CAB is notified in writing about its change in accreditation status as abeyance.
- The abeyance status is given to an CAB for no longer than three months.
- The CAB in abeyance status is not published, however if inquiries are made the CAB is referred to as under abeyance and working towards restoration of accredited status.
- To regain accreditation status, the CAB in abeyance status must notify to QAI of its desire and lift the conditions for which it was put into abeyance (agree to undergo verification assessment, paying the assessment charges and other outstanding payments etc.). Abeyance status will continue till verification assessment is completed and a decision is taken. Restoration of accredited status must happen before three months from the date CAB has been put under abeyance.
- After verification assessment, assessment report is to be reviewed and decision taken.
- The certificate date remains unchanged, after accreditation is restored.
- If the CAB does not proceed further or respond or notify QAI about its inability to undergo verification assessment and restore accredited status within three months of the abeyance status, action shall be initiated to suspend the accreditation of the CAB.
- In case of total system failure and gross negligence in technical aspects, observed during re-assessment, QAI will immediately put the CAB under 'Abeyance' category and ask the CAB to stop claiming accreditation status. (If this is applicable, report may be directly placed to CEO- QAI for further action).

5.4 Suspension

- **Conditions:**

- When an CAB continues to be in 'Abeyance' status for three months.
- When an CAB violates the standard agreement conditions of maintaining accreditation such as, but not limited to:
 - non co-operation with QAI
 - refusal to allow examination of documents & records
 - denial of access to QAI & its assessor to its services and patient care areas
 - wrong representation of scope of accreditation
 - misuse of accreditation mark

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- misleading reporting of facts
- brings QAI into disrepute in any manner etc.
- result of complaint analysis or any other information, which indicates that the CAB no longer complies with requirements of QAI.

- **Action by QAI**

- The CAB is notified in writing, about the concerns and asked to reply with evidences.
- After 30 days, of the above notification if issues are not resolved, a suspension letter is issued.
- The suspension status of CAB is published.
- An CAB can remain in suspension status for a maximum period of three months.
- If the CAB does not respond to the suspension letter or refuses to meet the conditions to lift the suspension, 'Forced Withdrawal' action is initiated. If, even after suspension, the CAB continues to violate the conditions of accreditation, an action on Forced withdrawal of accreditation shall be initiated by QAI.
- If CAB continues to use the QAI accreditation mark and claim accreditation status, it will be debarred from QAI accreditation process for minimum one year. CAB will be treated as a forced withdrawal case. There will be no provision for appeal in this case. CAB has to apply afresh and it is treated as a new CAB and has to pay all fees, as applicable at that time. However, unique registration number will remain same.
- To regain accreditation status, the CAB in suspension status must notify to QAI of its desire and agree to undergo verification assessment, paying the assessment charges and other outstanding payments. Suspension status will continue till verification assessment is completed and a decision is taken. Restoration of accredited status must happen before three months from the date CAB has been put under suspension.
- After verification assessment, assessment report to be placed to accreditation committee or further recommendation.
- The CAB, during the period of suspension cannot use QAI accreditation mark and claim accreditation.
- QAI website will announce the suspension of accreditation.
- QAI shall inform to the competent authorities e.g. ECHS, CGHS, respective state, etc. about the status of CAB.

5.5 Forced Withdrawal

- **Condition**

- When an CAB remains in 'Suspended status' for three months and have not met the condition for lifting the suspension even after three months.

- **Action by QAI**

- The CAB is notified in writing.
- QAI website will announce the withdrawal status of accreditation.
- QAI shall inform to the relevant competent authorities about the status of CAB.
- In case the CAB has been withdrawn from the accreditation programme it is debarred to participate in the accreditation programme for at least one year. The CAB can be re-enrolled in the programme by applying as a new CAB and paying full fees and assessment charges, applicable at time.
- After the CAB accreditation status is withdrawn, the CAB shall not use accreditation mark or claim accreditation.

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- If CAB continues to claim accredited status or uses QAI mark, financial and non-financial penalty may be imposed to CAB. Decision shall be taken on case to case basis by the Board.

5.6 Scope Reduction

- **Condition**

- When a CAB fails to demonstrate capability and competence in a specific scope of accreditation. These may include but not limited to non-availability of required equipment, failure in proficiency testing etc.

- **Action by QAI**

- The CAB is notified in writing.
- The scope of accreditation is revised

6. Policy and Procedure for Dealing with Other Decisions Against Accredited CAB

6.1 Voluntary Withdrawal

- **Condition:**

- When an CAB does not wish to continue their accreditation and voluntarily request in writing that their accreditation be terminated.

- **Action by QAI**

- QAI will accept the same and maintain the record under 'Voluntary Withdrawal Category'.
- A communication is sent to the CAB that it has been put under Voluntary Withdrawal category.
- The Voluntary withdrawal status is published on QAI website.
- If an CAB decides to regain the accreditation status, after it has sought voluntary withdrawal, it is treated as a new CAB and has to pay all fees, as applicable at that time. However, unique registration number will remain same.
- A new certificate with current date and number is issued based on fresh assessment.
- Between voluntary withdrawal and fresh accreditation if any, CAB cannot claim accredited status or use QAI accreditation mark. If CAB continues to claim accredited status or uses QAI mark, financial and non-financial penalty may be imposed to CAB. Decision shall be taken on case to case basis by Board.

6.2 Extension of Validity of Accreditation Certificate

- **Conditions:**

If an CAB has applied for renewal of accreditation six months before expiry of accreditation, extension of validity of accreditation may be granted for any of the following reasons:

- Where re-assessment has been completed, but the decision could not be taken for a reason beyond the control of QAI-CLA.
- Where there is delay in conducting re-assessment for reasons beyond the control of QAI-CLA.

- **Action by QAI**

- An extension to accreditation validity period is granted to the CAB and a letter is sent allowing the CAB to claim QAI Accreditation status and use of QAI Accreditation Mark till a final decision on renewal of accreditation is taken. In the event of accreditation

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to the CAB is not renewed, the CAB shall be informed, immediately, to stop claiming QAI accreditation status & use of QAI Accreditation Mark. The website will also be updated to show the expired status.

Note: Whenever an adverse decision is likely to be taken on an CAB, the Officer shall first verbally inform the CAB, explaining them the consequences and then follow it up with a letter. The final letter of adverse decision shall be sent by CEO- QAI.

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