IQAS-013

Adverse Decision Procedure

AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of Amendment	Reasons of Amendment	Amendment details	Remarks	Approved by
	--	--	28.10.2026	Periodic Review as per document control procedure	Detailing as part of periodic review	Replaces previous issue 01 dated 20.11.2023	R.S. Rana

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1. Objective:

Decision on status of accreditation of CABs.

2. Scope:

The decision covers the applicant and accredited laboratories.

3. Responsibility

The competent authority shall approve the decision based on the recommendation of the accreditation committee/complaint committee.

4. Reference

Clause 4.3.1 (c) and (e), 7.2.4, 7.7.1, 7.11.1,7.11.2, 7.11.3 of quality manual.

5. Procedure

5.1 There are two categories of laboratories

5.1.1 Applicant laboratories

5.1.2 Accredited laboratories

Probable adverse decisions are covered under two categories:

5.1.1 Applicant CABS

For applicant laboratories following adverse action may be initiated by IQAS based on the certain conditions:

Conditions for debarring and status restoration

1. If an applicant CAB does not address inadequacies raised during the adequacy check of the application and quality manual/management system document, within 15 days after communication of inadequacies by IQAS.
2. If the CAB is not able to propose the tentative assessment dates (pre-assessment-optional/ initial assessment) within 15 days after the completion of document review and request for assessment date by IQAS whichever is later.
3. In case, pre-assessment of the CAB has been conducted and CAB is not able to submit the corrective actions on NCs raised during the pre-assessment within 30 days of conclusion of pre-assessment,

4. When CAB is not able to take the corrective actions within 30 days for the NCs raised during initial assessment,
5. For any of the above condition the CAB may be placed under “inactive” category and decision is communicated to the CAB,
6. CAB is under the “inactive” category for 30 days and during these 30 days CAB may be made active if the appropriate action is initiated by the CAB.
7. The effective date of restoration of active status is the date of approval by the competent authority of IQAS,
8. in case the CAB does not take any action to remove the inactive status then IQAS may close the CAB application and decision is communicated to the CAB.
9. in case, the CAB after getting active status does not take further appropriate actions it is not put again under inactive category. The inactive status is given one-time only and next time the accreditation of CAB is closed.

Conditions for closure and restoration

1. When CAB is not able to restore to the active status within 30 days after inactive status has been revised.
2. When CAB voluntarily withdraws its application at any stage.
   Application is closed and the CAB is communicated formally. CAB can/shall apply afresh along with required application fee.

Conditions for scope reduction and restoration

1. When CAB is not able to perform specific calibration/testing/ medical testing due to technical competence of the personnel/due to non-availability of artifact/due to nonperformance of the master/related equipment etc.
2. When CAB is not able to take the corrective actions for concerned NCs raised during the assessment. The scope is reduced from the applied scope of accreditation.

3. When CABs performance is not satisfactory in PT/ILC repeatedly in the particular parameter the scope may be reduced from the accredited scope.
4. When CAB voluntary withdraws the specific scope or parameter, the scope is reduced from the accredited scope.
5. Revised scope of accreditation is issued to the CAB.
6. The revised scope of accreditation is uploaded on the website.
7. The CAB can restore reduced scope by taking corrective actions for which scope was reduced.
8. To restore the reduced scope, CAB to apply along with required fee.

Conditions for denial of accreditation:

1. When CAB is not able to submit the corrective actions within the 30 days or extended period if granted by IQAS.
2. When CAB is not able to address the clarification sought by IQAS within 30 days or extended period if granted by IQAS.
3. When CAB does not adhere to the terms and conditions (IQAS-006), agreed upon, to obtain and maintain IQAS accreditation.

The denial of accreditation is communicated to the CAB. CAB shall apply afresh by providing evidence of corrective action taken for the NC/clarification sought by IQAS along with the required fee.

Conditions for debarring from re-applying

1. When CAB refuses to allow the assessment team to perform assessment as scheduled by IQAS.

2. When CAB refuses to give access to various records and documents, which are required to perform the assessment.

3. When CAB is found to involve in activity to defame IQAS and/or involved in any fraudulent activity.

A debarred CAB can apply only after six months from the date of debarment.

5.1.2 Accredited CABs:

Conditions for closure:

1. When CAB has not applied, within the six months of expiry of accreditation.
2. When CAB has applied for renewal of accreditation and not able to take the assessment even after the six months of the expiry of accreditation.
3. When CAB withdraws accreditation at any stage other than adverse decision.
4. When CAB is not able to acquire the change in accreditation standard/or IQAS specific requirement during the accredited cycle period.

Application will be closed and the CAB is duly communicated. The CAB may reapply for getting the accreditation along with applicable fee.

Conditions for denial of accreditation:

1. When CAB is not able to submit corrective actions within the 30 days or extended period if granted by IQAS.
2. When CAB is not able to address the clarification sought by IQAS within 30 days or extended period if granted by IQAS.
3. When CAB has not adhered to the terms and conditions (IQAS-006), agreed upon, to obtain and maintain IQAS accreditation.

The denial of accreditation is communicated to the CAB. The CAB shall apply afresh by providing evidences of corrective actions taken for the NC/clarification sought by IQAS along with the required fee.

Condition for withdrawal of accreditation

When there is evidence of fraudulent behavior or the CAB intentionally provides false information or conceals information IQAS will initiate process for withdrawal of accreditation.

Conditions for scope reduction and restoration

1. When CAB is not able to perform specific calibration/testing/ medical testing due to technical competence of the personnel/due to nonavailability of artifact/due to nonperformance of the master/related equipment etc.
2. When CAB is not able to take corrective action for the NCs raised during the assessment. The scope is reduced from the applied scope of accreditation.
3. When CAB performance is not satisfactory in PT/ILC repeatedly in the particular parameter, the scope may be reduced from the accredited scope.
4. When CAB voluntary withdraws specific scope or a parameter, the scope is reduced from the accredited scope.

Revised scope of accreditation is issued to the CAB. The revised scope of accreditation is uploaded on the website. The CAB can restore reduced scope by taking corrective actions for which scope was reduced. To restore the reduced scope CAB has to apply along with required fee.

Conditions for suspension and lifting of suspension:

1. When there is system failure with respect to quality management systems and technical competence within the valid cycle of accreditation.
2. Violations of the terms and conditions, as per IQAS-006, to obtain and maintain accreditation.
3. Outcome of complaint against the CAB.
4. Outcome of surprise visit by IQAS

5. When outstanding amount raised by IQAS and CAB is unable to pay within 90 days of the outstanding amount being due.

The accreditation of the CAB will be suspended for 3 months. The CAB is formally informed. During the suspension period the CAB shall not use IQAS/claim accreditation. The suspension status of the CAB will be uploaded on IQAS website.

The suspension of the CAB can be uplifted after one month based on the corrective actions implemented by the CAB.

Once the suspension is uplifted a new accreditation certificate is issued from the approval date to the earlier date of expiry of accreditation.

In case, the accreditation of the CAB expires during the suspension period, the renewal of accreditation is entertained only after the corrective actions are verified by IQAS assessor at site and the assessment report is reviewed by the accreditation committee.

In case the CAB has applied for renewal of accreditation and assessment conducted but decision on accreditation is not communicated to the CAB, the CAB shall take the appropriate corrective actions for the uplifting the suspension after one month, only then the decision of renewal of accreditation is communicated to the CAB.

Conditions debarring from re-applying

1. When AB refuses to allow assessment team to perform assessment as scheduled by IQAS.
2. Refusal to give access to the various records and documents which are required to perform the assessment.
3. When CAB is found to involve in activity to defame IQAS and/or is involved in any fraudulent activity.

A debarred CAB can apply only after six months from the date of debarment.