



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Procedures for Dealing with Adverse Decisions

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AMENDMENT SHEET

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1. SCOPE

The document is to define the procedures outlining the conditions to decide under which circumstances adverse decisions are taken. It also outlines the procedure and criteria to revoke the adverse accreditation status.

2. CLASSIFICATION OF ADVERSE DECISIONS

The various types of adverse decisions addressed in this document are:

A. Adverse decisions against Applicant Conformity Assessment Bodies (CABs)

1. Inactive
2. Closed
3. Denial of Accreditation
4. Debar from applying

B. Adverse decisions against Accredited Conformity Assessment Bodies (CABs)

1. Closed
2. Denial of Accreditation
3. Scope reduction
4. Suspension of Accreditation
5. Withdrawal of Accreditation
6. Debar from reapplying

Note:

1. *A showcase notice will be issued to CAB to reply within 10 days in case of initiation of any adverse action (except 'inactive' for applicant CABs and voluntary withdrawal of accreditation for accredited CABs, for which no showcase notice will be communicated to the CAB).*
2. *An opportunity will be given to the CAB's authorized representative to be present in person during the process of adverse decision making of that particular CAB.*

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3. PROCEDURE TO BE FOLLOWED FOR TAKING ADVERSE DECISIONS AGAINST THE APPLICANT CONFORMITY ASSESSMENT BODIES (CABs)

3.1 INACTIVE

Condition

1. When the CAB has not addressed the inadequacies of document review (Application and Quality Manual/ Management system document) done by NABL secretariat within 15 days from the date of communication of inadequacies to the CAB.
2. When CAB fails to propose the date of Pre-assessment (optional for testing / calibration / medical Laboratories) within 15 days of completion of document review.
3. When the Pre-assessment (If undertaken by CAB, as it is optional for testing, calibration and medical Laboratories) of the CAB has been conducted for which the non-conformities have been communicated by the assessment team at the time of Pre-assessment and the CAB has not submitted the satisfactory corrective actions to close the non-conformities within 15 days.
4. When the CAB fails to propose date of final assessment within 15 days from the successful completion of document review (Application and Quality Manual/ Management system document when it has not opted for pre-assessment) and / or date of closure of non-conformities raised during pre-assessment, if conducted.

Actions by NABL

1. The 'Inactive' status is imposed.
2. The CAB is notified.

Restoration to 'Active' status

1. The status of the CAB is changed to 'Active' if the CAB has satisfactorily resolved the issues raised by NABL within 30 days from the date of imposition of 'Inactive' status.
2. The effective date of application shall be considered the date of restoration to 'Active' status.

Note: *Applicant CAB can be put under "Inactive" category only once.*

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3.2 CLOSED

Conditions

1. When the CAB fails to restore the status to 'Active' within 30 days
2. When the CAB voluntary withdraws the application at any stage.
3. Takeover / merger / demerger / acquisition by any other organization.
4. When the CAB shifts to another district.
5. When there is evidence of fraudulent behaviour, when conformity assessment body intentionally provides false information or when conformity assessment body conceals information.

Actions by NABL

1. The application will be closed.
2. The decision will be formally communicated to the CAB by NABL

Procedure for re-enrollment

1. The CAB can apply afresh after three months (except condition no. 5) with relevant application form, quality manual/ Management system document and application fees applicable at that time along with outstanding charges (if any).
2. For condition no. 5, the CAB can apply afresh after one year with relevant application form, quality manual/ management system document and application fees applicable at that time along with outstanding charges (if any).

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3.3 DENIAL OF ACCREDITATION

Conditions

1. Non-submission of satisfactory corrective actions for the non-conformities raised during the initial (final) assessment within the stipulated time of 30 days.
2. Not providing satisfactory clarification as desired by NABL / showing inability to undergo proposed verification visit within 30 days from the formal communication from NABL.
3. Non adherence to terms & conditions for obtaining and maintaining NABL accreditation as mentioned in NABL 131.
4. The information provided in the application like personnel, internal audit, MRM particulars or with regard to availability of equipment, validation of test methods, availability of reference standards / materials / cultures vis-à-vis scope applied, is found to be false leading to withdrawal of scope during the assessment.

Actions by NABL

1. The accreditation will be denied.
2. The decision will be formally communicated to the CAB by NABL.

Procedure for re-enrollment

The CAB can apply afresh after three months with valid responses for the reason(s) on earlier denial, using relevant application form, quality manual/ management system document, application fees applicable at that time along with outstanding charges (if any).

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3.4 DEBAR FROM APPLYING

Conditions

1. When the CAB denies access to its facility during the assessments / visits scheduled by NABL or refuses to allow examination of documents and records relevant to form the decision on accreditation.
2. When the CAB misleads its users or brings NABL into disrepute in any manner.
3. When the CAB is found to be involved in any kind of fraudulent activities.

Actions by NABL

1. Debar status will be imposed.
2. The decision will be formally communicated to the CAB by NABL
3. Debar status will be imposed on the CAB for a minimum period of six months.
4. Debar status will be made available on NABL website.

Procedure for re-enrollment

The CAB can apply afresh after one year (cooling off period) with valid responses for the reason(s) on earlier debar, relevant application form, quality manual/ management system document, application fees applicable at that time along with outstanding charges (if any).

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4. PROCEDURE TO BE FOLLOWED FOR TAKING ADVERSE DECISIONS AGAINST THE ACCREDITED CONFORMITY ASSESSMENT BODIES (CABs)

4.1 CLOSED

Conditions

1. When NABL has not received the application of the CAB for renewal of accreditation before the expiry date.
2. When CAB has applied for renewal of accreditation and fails to take up re-assessment within two months from date of receipt of application in NABL.
3. When the CAB voluntarily withdraws the accreditation at any stage other than during adverse decision.

Actions by NABL

1. The application will be closed.
2. The decision will be formally communicated to the CAB by NABL.

Procedure for re-enrollment

The CAB can apply afresh with relevant application form, quality manual/ management system document, application fees applicable at that time along with outstanding charges (if any). The application will be treated as new application.

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4.2 DENIAL OF ACCREDITATION

A. RE-ASSESSMENT

Conditions

1. Non-submission of satisfactory corrective actions for the non-conformities raised during the re-assessment within the stipulated time of 30 days.
2. Not providing satisfactory clarification as desired by NABL / showing inability to undergo proposed verification visit within 30 days from the formal communication from NABL.
3. Non adherence to terms & conditions for obtaining and maintaining NABL accreditation as mentioned in NABL 131.
4. When there is evidence of fraudulent behaviour, when conformity assessment body intentionally provides false information or when conformity assessment body conceals information.
5. The information provided in the application like personnel, internal audit, MRM particulars or with regard to availability of equipment, validation of test methods, availability of reference standards / materials / cultures vis-à-vis scope applied, is found to be false leading to withdrawal of scope during the assessment.

Actions by NABL

1. The accreditation will not be renewed.
2. The decision will be formally communicated to the CAB by NABL

Procedure re-enrollment

1. The CAB can apply afresh after three months (except condition no. 4) with valid responses for the reason(s) on earlier denial, relevant application form, quality manual/ Management system document, application fees applicable at that time along with outstanding charges (if any). The application will be treated as new application.
2. For condition no. 4, the CAB can apply afresh after one year with valid responses for the reason(s) on earlier denial, relevant application form, quality manual/ Management system document, application fees applicable at that time along with outstanding charges (if any). The application will be treated as new application.

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B. CHANGE IN ACCREDITATION STANDARD AND/OR NABL REQUIREMENTS DURING THE ACCREDITED PERIOD

Condition

1. When CAB has declared that it has implemented the change in accreditation standard and/or NABL requirements but fails to demonstrate compliance in assessment conducted to verify the same.

Actions by NABL

2. The accreditation will be denied.
3. The decision will be formally communicated to the CAB by NABL.

Procedure re-enrollment

The CAB can apply afresh after one month (cooling off period) with declaration of effective implementation of the changed requirements, relevant application form, quality manual/ management system document, application fees applicable at that time along with outstanding charges (if any).

C. SCOPE EXTENSION

Conditions

1. Non-submission of satisfactory corrective actions for the non-conformities raised during the supplementary visit within the stipulated time of 30 days.
2. Not providing satisfactory clarification as desired by NABL within 30 days of the formal communication from NABL.
3. The information provided in the application like personnel, internal audit, MRM particulars or with regard to availability of equipment, validation of test methods, availability of reference standards / materials / cultures vis-à-vis scope applied, is found to be false leading to withdrawal of scope during the assessment.

Actions by NABL

1. The accreditation for additional discipline(s) / parameter(s) will be denied.
2. The decision will be formally communicated to the CAB by NABL

Procedure re-enrollment

The CAB can apply afresh for scope extension after three months (cooling off period) with valid responses for the reason(s) on earlier denial, relevant application form, quality manual/ Management system document, application (scope extension) fees applicable at that time along with outstanding charges (if any).

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4.3 SCOPE REDUCTION

Conditions

1. When the assessment team / NABL secretariat observes major non-conformities in the technical competence of specific test(s)/ calibration(s) / PTP / RMP area with reference to ISO/ IEC 17025: 2005 / 2017 or ISO 15189: 2012 or ISO 17034: 2016 or ISO/IEC 17043:2010 or NABL documents whichever is applicable, during desktop surveillance or surveillance of integrated assessment CABs or surveillance decided by NABL based on previous renewal assessment performance or renewal assessment which is expected to adversely influence the CAB results.
2. When a CAB is not able to close non-conformities within specified time after surveillance (including desktop) / re-assessment related to specific test(s)/ calibration(s) / PTP / RMP Area.
3. In the event of a CAB's performance in a proficiency testing programme being unsatisfactory or is declared an outlier or in terms of $|Z| \geq 3$ or $|En| > 1$ or any other criteria depending on the programme design and CAB does not take appropriate corrective actions within specified time on two consecutive occasions.
4. When a CAB voluntarily withdraws a part from the accredited scope at any stage during valid accreditation period.

Actions by NABL

1. The scope will be reduced.
2. The decision will be formally communicated to the CAB by NABL
3. Revised scope of accreditation shall be issued to the CAB by NABL.
4. NABL website shall be updated to reflect the scope reduction.

Procedure for restoration

1. When the CAB has fully addressed the deficiencies, which had originally led to scope reduction, it can apply after three months (cooling off period) from the decision of scope reduction, with requisite fees.
2. The CAB will not be allowed to apply for restoration of scope for a minimum period of three months which may be extended to one year (Cooling off period) if CAB withdraws scope in response to non-conformities raised during assessment.

Note: CAB shall return the original scope of accreditation, wherever applicable.

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4.4 SUSPENSION OF ACCREDITATION

Conditions

1. When a total system failure or gross negligence is identified at any point of time during the valid accreditation period.
2. Failure to undergo annual surveillance within stipulated time period.
3. Failure to submit the documents for the desktop surveillance for more than 30 days beyond the scheduled due date.
4. Violation of terms and conditions (NABL 131).
5. Outcome of investigation of Complaints and/ or surprise visit by NABL.
6. Outstanding amount of over three months of the accreditation / membership fees or assessment charges or any charges in response to the invoice(s) raised by NABL.
7. When accreditation is denied as per condition no. 1 and 2 of clause 4.2 A of this document but validity mentioned in accreditation certificate is not over.

Actions by NABL

1. The accreditation of the CAB will be suspended.
2. The decision will be formally communicated to the CAB by NABL.
3. The Conformity Assessment Body is informed not to use NABL symbol and / or claim accreditation.
4. The suspension status is imposed for a maximum period of six months for the scope of accreditation; however, the minimum suspension period is three months.
5. NABL will publish the status of suspension of accreditation on its website. The website is also updated by removing certificate of accreditation of the CAB and by removing the name of the CAB from relevant directory of CABs.
6. Processing of any application submitted by CAB will be stopped.

Procedure for Re-enrollment

1. To regain accreditation status during the suspension period (after three months of suspension), the CAB in 'Suspended' status must notify to NABL the corrective actions taken and its desire to undergo assessment, paying the assessment charges and other outstanding payments. 'Suspension' status will continue till assessment is completed and a decision is taken.
2. The new certificate of accreditation will be issued from the date of restoration of accreditation with earlier existing validity.
3. In cases, where the accreditation cycle has expired during the suspension period [even if, CAB has submitted the renewal application (but assessment not yet conducted) prior to placing the accreditation status under suspension category], following procedure to be followed:
 - i. Renewal application shall not be processed.
 - ii. After three months from the date of suspension, CAB shall submit evidences that all the issues are addressed and effectively implemented. After review of corrective actions by NABL, the CAB shall be notified about the decision for accepting the corrective actions. Once corrective actions are satisfactory, the date of acceptance of renewal application

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will be taken as the date of acceptance of corrective actions by NABL and the application will be processed further by NABL.

4. In cases where the accreditation cycle has expired during the suspension period but renewal application has been processed (assessment conducted) prior to the CAB being placed under suspension category, however decision has not been communicated to the CAB, a verification visit will be conducted after completion of the cooling off period and review of satisfactory corrective actions taken by the CAB. The decision on renewal of accreditation will be linked to the outcome of the verification visit (applicable both in case the cooling off period is over before expiry or after expiry of the accreditation certificate).

Note: CAB shall return the original certificate of accreditation, wherever applicable

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4.5 WITHDRAWAL OF ACCREDITATION

Conditions

1. When a CAB, remains in 'Suspended' category for six months and has not met the condition for revoking the suspension status even after six months within valid accreditation cycle.
2. When the CAB voluntarily withdraws their accreditation status during any adverse decision initiated.
3. When a CAB has been involved in fraudulent activities bringing disrepute to NABL.
4. When the CAB fails to comply with NABL time limits for the changes in Version of applicable standards, Specific criteria or any regulatory authorities' obligations.

Actions by NABL

1. The accreditation will be withdrawn.
2. The decision will be formally communicated to the CAB by NABL
3. NABL will publish the status of withdrawal of accreditation on its website. The website is also updated by removing certificate of accreditation of the CAB and by removing the name of the CAB from relevant directory of CABs.
4. CAB under withdrawal of accreditation category can apply for accreditation on completion of six months from the date of forced withdrawal.
5. Processing of any application submitted by CAB will be stopped.

Procedure for re-enrollment

On completion of six months (cooling off period), the CAB can be enrolled for accreditation by submitting afresh application along with corrective actions for reason(s) of imposing the withdrawal of accreditation status. The application will be treated as new application.

Note: CAB shall return the original certificate of accreditation, wherever applicable

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4.6 DEBAR FROM REAPPLYING

Conditions

1. If CAB misleads its users or brings NABL into disrepute in any manner including unwarranted use of NABL symbol and NABL Accredited CAB Combined ILAC MRA mark or mis-claim of NABL accreditation and NABL Accredited CAB Combined ILAC MRA mark.
2. Repeated valid complaints against the CAB.
3. Unethical practices by accredited CABs.
4. If CAB Intimidates / threatens NABL officials or assessors.

Actions by NABL

1. Debar status will be imposed.
2. The decision will be formally communicated to the CAB by NABL.
3. In case the 'debar' status is imposed on the CAB, the existing accreditation of the said CAB will stand invalid with immediate effect.
4. Once the debar status is imposed, CAB is not eligible to re-enroll for a minimum period of two years.
5. Debar status will be published on website.

Procedure for re-enrollment

The CAB can apply afresh after two years (cooling off period) with valid responses for the reasons on debar, relevant application form, quality manual/ Management system document, application fees applicable at that time along with outstanding charges (if any).

Note: CAB shall return the original certificate of accreditation, wherever applicable

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