



**National Accreditation Board for
Testing and Calibration
Laboratories (NABL)**



**Procedures for Dealing with
Adverse Decisions**

AMENDMENT SHEET

Sl no	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QM	Signature CEO
1	9/14	4.2	08.06.16	A line removed	Typo error	Sd/-	Sd/-
2	11/14	4.4	20.03.17	Additional condition for Abeyance	Clarity on Abeyance in case of outstanding payment with CAB	Sd/-	Sd/-
3	12/14	4.5	19.02.2018	Inclusion of cond. under suspension-repeated valid complaints against CAB within a year	Feedback from Complaints Manager	Sd/-	Sd/-
4	4/14	3.1		Shifting of conditions from Closed category to Inactive category	Feedbacks from Resource Review Cell		
5	7/14	3.4		added as highlighted	Internal review		
6	10/14	4.3		Inclusion of Abeyance as a cond. under Scope reduction	Internal review		
7	11/14	4.4		Inclusion of Non-functioning of equipment as an additional cond. under Abeyance & as highlighted	Internal review		
8	11, 12 & 14 /14	4.4, 4.5 & 4.7		a condition added and procedure for enrolment as highlighted	Internal review		
9	4/14	3.1	23.05.2018	Condition from Closed shifted to Inactive category as highlighted	Change in timelines for process	Sd/-	Sd/-
10	6/14, 9/14, 11/14	3.3, 4.2, 4.4	23.05.2018	timelines for submission of corrective action is 30 days from 60 days and change in cond. for abeyance i.e. discipline replaced by part of the accredited scope under as highlighted	Change in timelines for process & cond. for abeyance due to internal feedback	Sd/-	Sd/-
11	14/14	4.7	02.01.2019	Inclusion of action as highlighted once debar status is imposed	For clarity in line of action by NABL	Sd/-	Sd/-

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1. SCOPE

The document lists the adverse decisions, the conditions under which these decisions are taken, the procedure for taking such decision as well as the procedure to revoke the adverse accreditation status.

2. CLASSIFICATIONS 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. Debarring from reapplying to NABL for accreditation.

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

1. Closure of Renewal application
2. Denial of accreditation
3. Scope reduction
4. Abeyance
5. Suspension
6. Forced withdrawal
7. Debar of the CAB from reapplying to NABL for accreditation.

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) done by NABL secretariat within 15 days from the date of communication of inadequacies to the CAB.
2. When CAB has expressed to undertake the Pre-assessment and later unable to accept the Pre-assessment within 30 days.
3. When the Pre-assessment (If undertaken by CAB as it is solely optional) 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 corrective actions to close the non-conformities within 15 days.
4. When the CAB shows inability to undergo initial assessment within 30 days from the successful completion of document review (Application and Quality Manual) and date of closure of non-conformities raised during pre assessment.

Actions by NABL

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

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. For the purpose of calculating the time for granting the accreditation, the effective date for application shall be the date of restoration to 'Active' status.

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.

Actions by NABL

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

Procedure for re-enrollment

1. The CAB can apply afresh with relevant application forms, quality manual and application fees applicable at that time along with outstanding charges (if any).

3.3 DENIAL OF ACCREDITATION

Conditions

1. NABL has not granted the accreditation in line with the recommendation of the assessment team.
2. NABL has not granted though the same was recommended by the assessment team.
3. Non submission of corrective actions for the non conformities raised during the initial assessment within the stipulated time of 30 days.
4. Not providing satisfactory clarification as desired by NABL / shows inability to undergo proposed verification within 30 days of the formal communication from NABL.
5. Failure to adhere the terms & conditions as mentioned in NABL 131.

Actions by NABL

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

Procedure for re-enrollment

1. The CAB can apply afresh by submitting a new application with application fees and quality manual along with valid responses for the reasons on earlier denial.

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3.4 DEBAR FROM REAPPLYING

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.

Actions by NABL

1. The decision will be formally communicated to the CAB by NABL
2. In case the 'debar' status is imposed on the CAB, the CAB is not eligible to re-enroll as an applicant for a minimum period of six months.

Procedure for re-enrollment

1. On completion of debar period, the CAB can apply afresh by submitting a new application by paying full application fees subject to clearance of outstanding fee (if any).

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

4.1 CLOSURE

Conditions

1. When NABL has not received the application of the CAB for renewal of accreditation even after 6 months of expiry of accreditation.
2. When CAB has applied for renewal of accreditation and fails to take up re-assessment for six months.
3. When the CAB voluntarily withdraws the accreditation at any stage other than during Adverse Decisions. (e.g. abeyance, Suspension etc.)

Actions by NABL

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

Procedure for re-enrollment

1. The CAB can apply afresh with relevant application forms, Quality manual and application fees applicable at that time along with outstanding charges (if any).

4.2 DENIAL OF ACCREDITATION (Re-assessment)

Conditions

1. When NABL has not renewed accreditation to CAB based on the recommendation of the assessment team and the accreditation is already expired. In cases, where the validity of existing certificate is still valid, status of accreditation of CAB will be put under Abeyance till the accreditation is renewed.
2. When NABL has not renewed accreditation to CAB though same was recommended by the assessment team and the accreditation is already expired. In cases, where the validity of existing certificate is still valid, status of accreditation of CAB will be put under Abeyance till the accreditation is renewed.
3. Non submission of corrective action against the non conformities within the stipulated time of 30 days.
4. Not providing satisfactory clarification as desired by NABL / shows inability to undergo proposed verification within 30 days of the formal communication from NABL.
5. Failure to adhere the terms & conditions as mentioned in NABL 131.

Actions by NABL

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

Procedure re-enrollment

1. The CAB can apply by submitting a new application with application fees and Quality manual along with valid responses for the reasons on earlier denial.

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 or ISO 15189: 2012 or ISO 17034: 2016 or ISO/IEC 17043:2010 or NABL documents whichever is applicable, during surveillance (including desktop) or re-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.
5. When a CAB is unable to revoke the Abeyance status for part of the accredited scope for the reasons as specified under Cond. 6 of clause 4.4.

Actions by NABL

1. The decision will be formally communicated to the CAB by NABL
2. The CAB will be required to return the original annexure and a new scope will be issued with reduced scope
3. NABL website will be updated to reflect the scope reduction.

Procedure for restoration

1. When the CAB has fully addressed to the deficiencies which had originally led to scope reduction, it may apply with requisite fee and procedure for scope addition will follow.
2. In all cases of scope restoration, the expiry date of the certificate will remain same.
3. NABL web-site will be updated to reflect the scope restoration.

4.4 ABEYANCE (for surveillance and other visits except re-assessment)*

Conditions

1. When a total system failure or gross negligence in technical aspects is identified at the time of surveillance, desktop surveillance or supplementary visit.
2. Failure to undergo surveillance within stipulated time period.
3. Failure to submit the documents for the desktop surveillance for more than 60 days beyond the scheduled due date.
4. When the surveillance of the CAB has been conducted and the CAB has not taken satisfactory corrective actions to close non conformities within 30 days.
5. Not providing satisfactory clarification as sought by NABL / shows inability to undergo proposed verification within 30 days of the formal communication from NABL.
6. When there is no NABL approved authorized signatory available with the CAB and (or) non-functioning of equipment for more than 30 days.
7. Outstanding amount of over 3 months of the Accreditation / Membership fees or assessment charges or any charges in response to the bills raised by NABL

Abeyance' can also be imposed for part of the accredited scope.

Action by NABL

1. The decision will be formally communicated to the CAB by NABL
2. The 'abeyance' status is not published, however if inquiries are received the CAB is referred to as under 'abeyance' and working towards re-accreditation.
3. CAB shall be communicated not to use NABL symbol/ claim accreditation during the abeyance period

Procedure for re-enrollment

1. To regain accreditation status, the CAB under 'abeyance' status must notify to NABL of its desire and agree to undergo assessment or supplementary visit after taking appropriate corrective actions. 'Abeyance' status will continue till assessment or supplementary visit is completed and a decision is taken by NABL.
2. In cases, where the accreditation cycle is expired during the abeyance period while applying for renewal of accreditation, CAB shall submit evidences that all the issues to invoke the abeyance are addressed and effectively implemented. The decision for accepting the renewal application will be taken by NABL based on the reply of CAB and will be verified through the verification visit, if necessary. In case, where the CAB is unable to revoke the abeyance status; the CAB shall apply for renewal of accreditation only after 10 months from the expiry of accreditation.
3. Abeyance shall directly be revoked without any assessment if CAB makes the payment in line with condition No. 7 i.e. outstanding amount as mentioned above.

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4.5 SUSPENSION

Conditions

1. When a CAB fails to address the issues satisfactorily which lead to abeyance within 60 days.
2. When a major system failure or gross negligence identified at the time of supplementary visit verification visit conducted to restore the abeyance status.
3. Violation of terms and conditions (NABL 131).
4. Outcome of investigation of complaints by NABL.
5. Repeated valid complaints against the CAB.

Actions by NABL

1. The decision will be formally communicated to the CAB by NABL and CAB shall return the accreditation certificate to NABL.
2. The Conformity Assessment Body is informed not to use NABL symbol or claim accreditation.
3. The 'suspension' status is imposed for a maximum period of 60 days for the entire CAB activities under accreditation; however the minimum suspension period is 30 days.
4. NABL will publish the status of suspension of accreditation on its website. The website is also updated by removing the scope of the CAB and by removing the name of the CAB from relevant directory of CABs.

Procedure for re-enrollment

1. To regain accreditation status during the suspension period (ie. within 60 days 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 expired during the suspension period, while applying for renewal of accreditation, CAB shall submit evidences that all the issues to invoke the suspension are addressed and effectively implemented. The decision for accepting the renewal application will be taken by NABL based on the reply of CAB and the same will be verified through verification visit, if necessary. In case, where the CAB is unable to revoke the 'Suspension' status; the CAB shall apply for renewal of accreditation only after 10 months from the expiry of accreditation.

4.6 FORCED WITHDRAWAL

Conditions

1. When a CAB remains in 'Suspended' category for 60 days and has not met the condition for revoking the suspension status even after 60 days.
2. When the CAB voluntarily withdraws their accreditation status during any adverse decision initiated.
3. 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 decision will be formally communicated to the CAB by NABL
2. The forced withdrawal' status is imposed on the Conformity Assessment Body and status will published in website
3. CAB under forced withdrawal category can apply for accreditation on completion of six months from the date of forced withdrawal.

Procedure for re-enrollment

1. On completion of six months, the CAB can be enrolled for accreditation by submitting fresh application along with corrective actions for reasons the status of forced withdrawal was imposed.

4.7 DEBAR OF THE CAB FROM REAPPLYING

Conditions

1. If CAB misleads its users or brings NABL into disrepute in any manner.
2. Outcome of investigation of Complaints by NABL.

Actions by NABL

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

Procedure for re-enrollment

1. On completion of the debar period the Conformity Assessment Body can apply a fresh by submitting a new application by paying full application fees and assessment charges applicable at that time subject to clearance of outstanding fee (if any).

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