



**Accreditation Education Research & Scientific Service Center,
Nepal**

Procedure for Dealing with Adverse Decisions

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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)

- i. Closed
- ii. Denial of Accreditation

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

- i. Closed
- ii. Denial of Accreditation
- iii. Scope reduction
- iv. Suspension of Accreditation
- v. Withdrawal of Accreditation

3. Adverse Decisions Against the Applicant Conformity Assessment Bodies (CABs)

3.1 Closure of Application

Condition

- (a) When the CAB has not addressed the inadequacies of document review (Application and Quality Manual/ Management system document) done by the AERSSC
- (b) When the Pre-assessment (If undertaken by CAB, as it is optional for testing, 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.
- (c) When the CAB fails to accept the date of final assessment.
- (d) When there is evidence of fraudulent behavior, when the conformity assessment body intentionally provides false information, or when the conformity assessment body conceals information.

Actions by AERSSC

- (a) The application will be closed.
- (b) The decision will be formally communicated to the CAB by AERSSC

3.2 Denial of Accreditation

Condition

- (a) Non-submission of satisfactory corrective actions for the non-conformities raised during the initial (final) assessment within the stipulated time.
- (b) Non-adherence to terms & conditions for obtaining and maintaining AERSSC accreditation as mentioned in AERSSC 37 'Agreement between AERSSC and CAB'.

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- (c) When the CAB denies access to its facility during the assessments/visits scheduled by AERSSC or refuses to allow examination of documents and records relevant to form the decision on accreditation.
- (d) When the CAB misleads its users or brings AERSSC into disrepute in any manner.
- (e) When the CAB is found to be involved in any kind of fraudulent activities.

Actions by AERSSC

- (a) The accreditation will be denied.
- (b) The decision will be formally communicated to the CAB by AERSSC.

4. Adverse decisions against the Accredited Conformity Assessment Bodies (CABs)

4.1 Closure of Application

Conditions

- (a) When AERSSC has not received the application of the CAB for renewal of accreditation before the expiry date.
- (b) When CAB has applied for renewal of accreditation and fails to take up re-assessment within two months from the date of receipt of application in AERSSC.
- (c) When the CAB voluntarily withdraws the accreditation at any stage other than during an adverse decision.

Actions by AERSSC

- (a) The application will be closed.
- (b) The decision will be formally communicated to the CAB by AERSSC.

4.2 Denial of Accreditation

Conditions

- (a) Non-submission of satisfactory corrective actions for the non-conformities raised during the re-assessment within the stipulated time.
- (b) .
- (c) Non adherence to Agreement between AERSSC and CAB as mentioned in AERSSC 37.
- (d) When there is evidence of fraudulent behaviour, when conformity assessment body intentionally provides false information or when conformity assessment body conceals information.
- (e) 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

Actions by AERSSC

- (a) The accreditation will not be renewed.
- (b) The decision will be formally communicated to the CAB by AERSSC

4.3 Scope Reduction

Conditions

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- (a) When the assessment team / AERSSC secretariat observes major non-conformities in the technical competence of specific test(s) area with reference to ISO/ IEC 17025:2017 or ISO 15189:2012 /ISO 15189:2022
- (b) When a CAB is not able to close non-conformities within the specified time after surveillance / re-assessment related to specific test(s) Area.
- (c) When a CAB voluntarily withdraws a part from the accredited scope at any stage during valid accreditation period.

Actions by AERSSC

- (d) The scope will be reduced.
- (e) The decision will be formally communicated to the CAB by AERSSC
- (f) Revised scope of accreditation shall be issued to the CAB by AERSSC.

4.4 Suspension of Accreditation

Conditions

- (g) When a total system failure or gross negligence is identified at any point of time during the valid accreditation period.
- (h) Failure to undergo annual surveillance within the stipulated time period.
- (i) Violation of terms and conditions (AERSSC 37).
- (j) Outcome of investigation of Complaints by AERSSC.
- (k) 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 AERSSC.

Actions by AERSSC

- (l) The accreditation of the CAB will be suspended.
- (m) The decision will be formally communicated to the CAB by AERSSC.
- (n) The Conformity Assessment Body is informed not to use AERSSC symbol and / or claim accreditation.
- (o) 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.
- (p) AERSSC will publish the status of suspension of accreditation on its website. The website is
- (q) also updated by removing certificate of accreditation of the CAB and by removing the name of the CAB from relevant directory of CABs.
- (r) Processing of any application submitted by CAB will be stopped.

Procedure for Re-enrollment

To regain accreditation status during the suspension period (after three months of suspension), the CAB in ‘Suspended’ status must notify to AERSSC 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.

4.5 Withdrawal of Accreditation

Conditions

- (s) 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.

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- (t) When the CAB voluntarily withdraws their accreditation status during any adverse decision initiated.
- (u) When a CAB has been involved in fraudulent activities bringing disrepute to AERSSC.
- (v) When the CAB fails to comply with AERSSC time limits for the changes in the Version of applicable standards, Specific criteria, or any regulatory authorities' obligations.

Actions by AERSSC

- (w) The accreditation will be withdrawn.
- (x) The decision will be formally communicated to the CAB by AERSSC
- (y) AERSSC 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.