

Adverse Decisions by Approving body

(STQC/SAB/P02)

Issue :01



STQC Approval Body, STQC Directorate,
MeitY, Government of India
INDIA



| | | |
|---|--|-------------------|
|  | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | Page : 2 of 10 | |

Table of Contents

| | | |
|-----|---|----|
| 0.1 | Approval and Issue | 3 |
| 0.2 | Amendment Record..... | 4 |
| 1. | STQC Approval Body takes adverse decisions/actions on the applicant/Approved Laboratory if..... | 5 |
| 2. | The adverse decisions against Applicant Laboratory are | 5 |
| 2.1 | Not processed for Approval: | 5 |
| 2.2 | Case Closed with intimation: | 5 |
| 2.3 | Revoking the closed status of Applicant Laboratory | 6 |
| 2.4 | Re-enrollment by laboratory..... | 6 |
| 3. | The adverse decisions against STQC Approved Laboratory: | 6 |
| 3.1 | Denial of Approval | 6 |
| 3.2 | Scope Reduction | 7 |
| 3.3 | Restoration of Scope | 7 |
| 3.4 | Abeyance | 8 |
| 3.5 | Suspension | 8 |
| 3.6 | Withdrawal of Certificate of Approval | 10 |

| | | |
|---|--|-------------------|
|  STQC ॥ गुणोत्कर्षं समृद्धिः ॥ | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | Page : 3 of 10 | |

0.1 Approval and Issue


This document is the property of STQC Approval Body (SAB) and should not be reproduced in part or full without the written consent.

Reviewed by : Scheme Representative

Approved by : Head, SAB

Note:

- Scheme Representative is responsible for issue and distribution of this document including amendments.
- Holder of this copy is responsible for incorporation of all the amendments and currency of the document.

| | | |
|---|--|-------------------|
|  | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | Page : 5 of 10 | |

1. STQC Approval Body takes adverse decisions/actions on the applicant/Approved Laboratory if

- Not Meeting Approval Body requirements
- non-adherence to Terms & Conditions of obtaining & Maintaining Approval
- Misuse of STQC Approved Laboratory Logo
- Customer Complaints
- Inputs from stakeholders on activities of laboratory bringing disrepute to the STQC Approving Body
- Other significant data/information received

2. The adverse decisions against Applicant Laboratory are

2.1 Not processed for Approval:

2.1.1 When the laboratory has not responded nor submitted the completed application within three months' time after the deficiencies in information provided has been communicated to the laboratory.

2.1.2 If the Applicant laboratory has not closed the Stage-1 observations & absence of intimation on closure the case is not processed for approval.


2.1.3 If the Applicant laboratory has not provided root cause analysis, proposed correction/corrective/preventive actions and evidence of closure of proposed actions within stipulated time during stage-2 assessment & no communication in this regard is received for the delay the case will not be processed for approval.

2.2 Case Closed with intimation:

2.2.1 When the laboratory continues to be in the 'inactive' status for 3 months.

2.2.2 When the adequacy audit of the laboratory has been conducted for which the comments/ deficiencies have been communicated and the laboratory has not taken action on them within a maximum of two months

2.2.3 When the pre-assessment of the laboratory has been conducted for which the non-conformities have been communicated and the

| | | |
|---|--|-------------------|
|  | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | | Page : 6 of 10 |

laboratory has not taken proper corrective actions to close the non-conformities within maximum of three months.

2.2.4 When the laboratory does not co-operate with the Approval Body or refuses to allow examination of documents and records or denies access to testing areas or misleads its users or brings Approval Body into disrepute in any manner.

2.2.5 When the assessment report has been evaluated by Approval Committee for which clarifications have been sought or verification visit has been planned and the laboratory has not provided appropriate clarifications/ agreed for verification visit with in a maximum period of two months

2.2.6 When the laboratory voluntary withdraws the application

2.3 Revoking the closed status of Applicant Laboratory

2.3.1 The status of the laboratory is changed from closed to active after the laboratory has satisfactorily resolved the issues raised by STQC Approval Body within 03 months from the date of imposition of case closure. More than three months the case can be revoked with the authorization from the Head-Approval Body.

2.3.2 The laboratory need not pay additional application fees, when the case is reopened.


2.3.3 The Lab ID remains the same. However, the effective date for application shall be the date of restoration from closed case.

2.4 Re-enrollment by laboratory

2.4.1 More than 6 months of closure of case if the Applicant laboratory wants to pursue approval then the laboratory shall apply afresh with relevant application forms, quality manual and application fees applicable at that time along with any other outstanding charges.

3. The adverse decisions against STQC Approved Laboratory:

3.1 Denial of Approval

| | | |
|---|--|-------------------|
|  | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | Page : 7 of 10 | |

- 3.1.1 When the Accreditation Committee has not recommended accreditation based on the recommendation of the assessment team.
- 3.1.2 When the Accreditation Committee has not recommended accreditation though same was recommended by the assessment team.
- 3.1.3 In such case the laboratory is notified in writing giving reasons of denial and file shall be closed. The Laboratory is instructed not to use Approved Laboratory Logo/claim of approval. The Approval Body will remove the name of the Laboratory from the list of Approved Laboratories. For Re-enrollment refer to 2.4.


3.2 Scope Reduction

- 3.2.1 When the assessment team during assessment or surveillance or re-assessment observes major non-conformities in the technical competence of specific test(s) with reference to the applicable Approval Criteria which is expected to adversely influence the test results.
- 3.2.2 When a laboratory is not able to close non-conformities within specified time after Assessment/Surveillance / re-assessment related to specific test(s).
- 3.2.3 When a laboratory voluntarily withdraws test(s) from the approved scope.

In such case Decision on scope reduction will be formally communicated to the laboratory. Revised Scope of Approval will be issued to the Laboratory withdrawing the earlier scope. STQC website will be updated to reflect scope reduction.

3.3 Restoration of Scope

- 3.3.1 When the laboratory has fully addressed to the deficiencies which had originally led to scope reduction, it may make a request the Approval Body and undergo a fresh assessment, at additional cost. If granted, the scope of approval is appropriately amended indicating the effective date. The effective date is based on the date of approval by the Approval Body.
- 3.3.2 In all cases of scope restoration, the expiry date of the certificate will remain same

| | | |
|---|--|-------------------|
|  | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | Page : 8 of 10 | |

3.3.3 The web-site will be updated to reflect the scope restoration.

3.4 Abeyance

3.4.1 When a total system failure or gross negligence in technical aspects is identified at the time of surveillance or re-assessment.

3.4.2 When a laboratory had undergone a surveillance or re-assessment and has not taken any corrective action within 3 months after surveillance/re-assessment.

3.4.3 When a laboratory has not paid the relevant approval charges in response to bill raised by the Technical Operations Manager.

3.4.4 When a laboratory has not appropriately responded to the queries as requested by the Approval Body, even after repeated reminders.

3.4.5 When there is no approved authorized signatory available with the laboratory for more than 30 days.


In such cases the laboratory is notified in writing. The laboratory is informed not to use Approved Laboratory Logo and claim accreditation during 'abeyance' status. The 'abeyance' status is given to a laboratory for no longer than three months, before further action is taken.

The 'abeyance' status is not published in STQC website, however if enquiries are received the laboratory is referred to as under 'abeyance' and working towards re-approval.

Re-enrollment by laboratory is feasible only after Reassessment. In cases where the validity of Certificate of Approval has been expired during the abeyance period; the laboratory while applying for renewal of approval shall submit evidences that all the issues to invoke the abeyance are addressed and effectively implemented.

The validity date remains unchanged after accreditation is restored, however the issue date shall be the date of revoking the Abeyance status. Where accreditation cycle expired in the abeyance period new accreditation cycle will be given after re-enrollment.

3.5 Suspension

| | | |
|---|--|-------------------|
|  | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | Page : 9 of 10 | |

3.5.1 When a laboratory continues to be in 'Abeyance' status for three months.

3.5.2 The laboratory can be suspended in view of following reasons


- non co-operation with Approval Body
- refusal to allow scrutiny of documents & records
- denial of access to testing areas
- wrong representation of scope of approval
- willful and/ or repeated misuse of Approved Laboratory Logo
- misleading reporting of facts
- brings disrepute to Approval Body in any manner etc.
- repeated valid customer complaints against the laboratory.
- actions taken by Statutory / regulatory bodies against laboratory

In such cases a show cause notice is issued to the laboratory by the Approval Body to be replied within 10 working days. If the reply is found unsatisfactory (or) laboratory has not responded, a suspension letter is issued. The laboratory is informed not to use Approved Laboratory logo or claim accreditation.

The 'suspension' status is imposed for a maximum period of three months for the entire laboratory activities under approval, however the minimum suspension period is one month.

STQC Approval body will announce the suspension of approval on the web-site removing the scope of the laboratory and by removing the name of the laboratory from relevant List of approved laboratories.

Re-enrollment by laboratory is feasible only after Reassessment. In cases where the validity of Certificate of Approval has been expired during the suspension period; the laboratory while applying for renewal of approval shall submit evidences that all the issues to invoke the suspension are addressed and effectively implemented.

| | | |
|---|--|-------------------|
|  | STQC Approval Body (SAB) | |
| | P02 – Adverse Decisions by Approving body | Issue : 01 |
| | | Date : 01/03/2021 |
| | Page : 10 of 10 | |

The validity date remains unchanged after accreditation is restored, however the issue date shall be the date of revoking the suspension status. Where accreditation cycle expired in the suspension period new accreditation cycle will be given after re-enrollment.

3.6 Withdrawal of Certificate of Approval

3.6.1 When a laboratory remains in 'suspended' status for three months and has not met the condition for lifting the suspension even after three months.

In such cases the laboratory is notified in writing by the Approval Body. The laboratory is informed not to use the logo or claim accreditation. The withdrawal status is published on STQC website. In case the 'forced withdrawal' status is imposed on the laboratory, the laboratory is debarred from re-applying for a minimum period of one year. **Re-enrollment** is only through fresh application for approval.
