Procedure for Operating Approval Body

(STQC/SAB/D01) Issue :01



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



D01 – Procedures for Operating Approval Body

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0.1 Approval and Issue

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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.



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0.2 Amendment Record

S1. No.	Date	Issue	Reason of Change / Change Details
1.	23-02-21	01	First Issue



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1.0 Purpose

This procedure is for operation of STQC Approving Body in respect of

- Control of Documents
- Control of Records
- Non-Conformance
- Corrective Actions
- Preventive Actions
- Internal Audit
- Management Review

2.0 Scope

This procedure is applicable to Approving Body only.

3.0 Reference Documents

STQC/ITeGov/D00 Quality Manual

STQC/ITeGov/F01 Master List of Documents

STQC/SAB/D01 Rule & procedure for SAB

4.0 Procedure

4.1 Control of Documents

PURPOSE: To ensure a procedure for control of documents & records

SCOPE: Control of Approving Body Management system documents &

Approval Scheme Records

RESPONSIBILITY: Refer document STQC/ITeGov/D06 for Responsibility

Matrix

PROCEDURE

Management System Documents:

All Approving Body management system documents are numbered uniquely for easy identification as defined in the Responsibility Matrix document.

Document format:

All documents will have Title page with name and address of the organization, document name and document no. and Version No.

Other pages will have footer information consists of document no., document name, Issue no., Issue Date, Revision no., Revision Date, page no. & total no. of pages.



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The procedures will have topics such as Purpose, Scope, Responsibility, Abbreviations / Definitions, Details and Records as relevant. Assessment Forms have defined in STQC/SAB/F02.

All enclosures and Annexure to the management system document are also controlled through header & footer formats of the respective document.

Document Issue and control: Issues are controlled as follows:

- A complete or major changes of the manual/document is termed as a new issue
- More than 10 amendment numbers in the Amendment Record, Issue no. is incremented.
- In the next issue all page revisions are reset to 0 for the internal documents.
- For every document amendment, the changed page/s is identified with incremented revision number and incorporating the changes in the Amendment Record of updated document.

Preparation, Review, Approval & Issue authority of management system documents is detailed in STQC/ITeGov/D06. A master list STQC/IT&eGov/F01 & master copies of controlled documents will be maintained by Scheme Representative. Documents updated periodically as and when amendments are issued based on change request. Soft copy of documents in published on website www.stqc.gov.in. Photocopies issued to others upon requirement with due approval from Head-Approving body are treated as uncontrolled stamp on such copies before issue. Such copies are neither listed nor updated. Use of uncontrolled copies or photocopies of controlled documents is not permitted by the personnel operating the Approval Scheme.

Master copies of obsolete documents may be retained for the purpose of knowledge preservation and archived identified with 'OBSOLETE' stamp while all other obsolete copies be destroyed by the user. Documents are issued on electronic media (on intranet). In case of electronic media, control shall be exercised in a similar way as defined in STQC/ITeGov/D06 to ensure the correctness of the matter within, identification of documents and prevention from unauthorized changes. The issuing authority only is authorized to maintain the current status of documents. Periodic review of documents shall be done once at least in 3 years (from initial issue date) and if required, necessary changes may be incorporated. Scheme Representative shall initiate the periodic review process and all review committee nominated by Approving body shall give their inputs on suitability of document and improvements that can be brought in. The changes shall be recorded and review, approval and



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issue shall be carried out as per regular process. In case of no changes, the same shall be recorded as reviewed and no changes proposed. Documents of external origin are controlled as given in STQC/ITeGov/D06.

Document Changes:

Any person in the SAB can propose document changes for improvement.

A change may also be necessitated, if found inadequate during audits, complaints or any other stages based on objective evidences.

Any changes to the document shall be initiated through Change Request Form and submitted to Head, SAB.

All reference documents are stored safely and maintained.

SETL documents:

SETL Documents such as Application for Approval, Lab management system documents are to be maintained & retained in the respective job folder with due identification of Client number on the same. Approval agreements/changes in the Approval agreement during the validity period &. All SETL documents will be maintained by Scheme Representative.

4.2 Control of Records:

PURPOSE:

To detail the elements of Records management like identification, indexing, access, collection, filing, storage, location, retention & disposition

SCOPE:

This procedure is applicable for all management system records and technical records of Software Test Laboratory.

RESPONSIBILITY:

As identified in the table enclosed.

DETAILS:

Scheme Representative has overall responsibility of management of records related to Approval scheme of IT Testing Laboratories as SETL.

All types of records are identified & maintained in the following table.



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Users of the Approval scheme can have only access to these records with authorization of Technical Operations Manager/Head-Approving Body based on status of records. Records may be maintained on softcopy or hard copy or both. Confidentiality of records to be ensured.

RECORDS:

Sr. No.	Type of Record	Responsibility	Retention Period
1.	Customer SETL files with related	Scheme	5 Year
	documents from Application till	Representative	
	Approval certification including		
	assessment records and reports		
2.	Customer correspondence	Scheme	5 Year
	-	Representative	
3.	Administration and accounts related -	Scheme	Till Financial
	Finance papers related to Customer	Representative	Audit
	service		
4.	Assessor related records like	Scheme	Till
	empanelment, training, competence,	Representative	empanelment
	feedback etc.		period
5.	Document Control, Internal Technical	Scheme	5 Year
	Operations audit, Corrective &	Representative	
	preventive actions	_	
6.	Management review Records, records	Scheme	5 Year
	related to Approval Committee,	Representative	
	Technical Advisory Committee,		
	management Committee etc.		
7.	Copies of Approval Certificates	Head, SAB	5 Year

4.3 Internal Audit:

PURPOSE:

To ensure that internal audits are carried out at least once a year and to verify that the operations and activities under Approval Scheme continue to comply with the requirements of the management system and its effectiveness.

SCOPE:

All areas of the Approving body management system as defined in the management system documents

RESPONSIBILITY:



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Scheme Representative is responsible for planning, organizing and subsequent follow-up for closure of non-conformities of audit within a time frame. Head, SAB is the Authority of audit process.

PROCEDURE:

Sr. No.	Activity	Responsibility
1.	The schedule for the internal audit, nomination of auditors is prepared and approval of the Head-Approving Body is obtained.	representative
2.	Auditors selected for the purpose shall be trained and qualified staff and shall not have any direct relationship with the area being audited. If required, external auditors with technical expertise may be drawn.	
3.	All activities under the scope of management system shall be informed about the internal audit schedule well (one week) in advance.	Auditors
4.	Internal Technical Operations audit shall be carried out as per the schedule at the locations of STQC Approving body &Technical Operations	
5.	If audit could not be conducted as per the schedule due to unavoidable reason, the auditors shall inform the next date to the auditee after approval for the deviation from Technical Operations Manager	Auditors
6.	Record the findings including both conformities & non-conformities in the Noting sheet Form. During audit, information received verbally shall be checked against actual operations by observations & non-conformities shall be raised only when objective evidence is established. Auditors to conduct Witness testing also during internal audit.	Auditors
7.	All the non-conformities raised shall be related to the particular clause of the management system documents and recorded in the NC format.	
8.	Time required for corrective action is ascertained from the activity Head/Manager concerned and it is indicated in the same form.	Auditors
9.	Copy of the Corrective action request form complete in all respect is handed over to the concerned activity Head/Manager for initiating corrective actions.	Auditors
10.	Corrective actions is completed in agreed time frame and intimated to auditors	Activity Head/Manager
11.	Corrective actions are verified for its effectiveness and non-conformities are closed	Auditors
12.	Monitor for the non-conformities that are not been carried beyond the agreed time frame and follow up	Scheme representative



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	with both the auditors and audittee for early action.	
13.	Analyze the non-conformities & prepare report on each	Scheme
	audit for the managerial review meeting.	representative
14.	Special or process audits may be organized depending	Scheme
	on the importance of the activity or more non-	representative
	conformity is observed based on customer complaints	
	or when new activity is established. However, this will	
	be done after the approval from the Head-Approving	
	Body.	

FORMS USED:

Internal Audit Noting sheet; NC Form

RECORDS:

Internal Technical Operations Audit Schedule; Internal Audit Reports; Internal Audit Noting Sheets

4.3 Management Review

PURPOSE:

To evaluate the status, effectiveness of the Management System and to analyze the corrective actions.

SCOPE:

To review entire Approval Scheme Management system

RESPONSIBILITY:

as defined in table below

DETAILS:

Management review is conducted at least once a year to verify that the operations of the Approving body are in line with management system, to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements as required.

Management Review is conducted by Management Committee, MC, with Technical Operations Manager as Member secretary and DG,STQC as Chairperson.

The activities & responsibilities given below:



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Sr.	Activity	Responsibility
No.		
1.	Organizing Managerial Review, MR, meeting at least once in a year with intimation to all members of MC through Note	Technical Operations Manager
2.	Analysis of approving body activities, customer complaints to be presented to MR	(Scheme Representative)
3.	Follow up of action points of previous minutes of MR	
4.	 Review of agenda points: Suitability of Policy and objectives and procedures. Follow up of points from action points of previous review Outcome of internal audits Trend of Nonconformities Status of Corrective and preventive actions New Approval areas Feedback from Interested parties Fulfilment of objectives Improvement / changes in Technical Operations system Appeals Resources / Training Performance report/analysis of complaints 	Management Committee
	Any other point	
5.	Preparation of minutes of MR meeting together with instruction on the action points, time limit & responsibility for implementation.	Technical Operations Manager (Scheme Representative)
6.	Approval of minutes of MR meeting	Head, SAB
7.	Issue of minutes of MR meeting	Technical
8.	Follow up of action points of MR.	Operations
9.	The action resulting from review shall be communicated to appropriate authority for effecting necessary changes in the system/methods/procedures, if called for	Manager (Scheme Representative)
10.	Records of review to be maintained for the stipulated period of retention	

4.4 Non-Conformities, Corrective and Preventive Actions: PURPOSE:

This document describes the initiatives to be taken to identify and control of non-conformities across the laboratory and outlines the procedure for selection and implementation of corrective and preventive actions.

SCOPE:



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This procedure is applicable when any aspect of testing executed by the laboratory does not conform to laid down procedures or agreed requirements of the customer and if any deviations are observed in the implementation of policies, procedures, methods and Management system as per ISO/IEC 17025: 2005.

RESPONSIBILITIES:

All officials working for the Approval scheme are required to understand and implement management policy, objectives and procedures implementation of Management system and shall report any deviations observed. Technical Operations Manager shall review the non-conformances for confirmation and evaluate their significance and possible impact. Technical Operations Manager shall decide on withholding or resumption of the activity based on evaluation of the significance of the impact where relevant. Technical Manager and Head Approving body together shall take up root cause analysis and identify the appropriate corrective action. Activity Head /Managers responsible for implementing corrective action in their areas. Technical Operations Manager shall monitor effectiveness of corrective / preventive actions initiated in the laboratory &shall maintain records and make them available for audits and reviews.

CONTROL OF NON CONFORMITIES

The Approving body shall implement the following activities to detect non conformities in management systems, approval operations, and Customer Services based on deviations from management policy, objectives, documented procedures and customer requirements.

- o Internal Technical Operations audits
- Customer complaints / feed back
- o Routine monitoring/supervision of work
- Staff observations
- o Approval Report verification
- o Management review
- Other such activities

Non-conformities reported from above said activities shall be reported to Technical Operations Manager.

Technical Operations Manager shall review and evaluate the significance and possible impact on the ongoing approvals.

If the significance of the non-conformity is of major concern (eg: Improper evaluation of scope of Approval) and where immediate action to rectify the



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nonconformity cannot be decided or taken, the concerned activity shall be withheld by Technical Operations Manager.

The procedure stated above on initiating and implementing the corrective action shall be followed.

On successful implementation of the appropriate corrective action, the decision about resumption of the activity will be taken by Technical Operations Manager.

If non-conformity is of minor significance and does not affect the validity of approval, the Technical Operations Manager shall take the decision about the acceptability of the non-conforming work.

If non-conformity is found in Approval reports or Certificates issued to customer, such reports/certificates shall be recalled, reviewed and amended reports/certificates shall be re- issued. The decision for recalling and issuing the amendments shall be taken by Technical Operations Manager and records maintained.

If any nonconformity is detected in implementation of management system, such nonconformities shall be brought to the notice of Technical Operations Manager for immediate redressal.

If it is required to accept a deviation to overcome the non-conformity, the customer shall be notified, about the non-conformity and approval of the customer shall be obtained

CORRECTIVE ACTION:

On detection of non-conformity, Review Committee consisting of Technical Operations Manager and Head Approving body shall take up root cause analysis and identify the potential causes of the problem.

However, in case of non-conformity detected during Internal audit, verification of ongoing approval activities etc. the identification of corrective action will be done by concerned persons as designated in respective procedures.

As part of root cause analysis, the problems may lie in areas/ activities like Interpretation of customer requirements/ documents, Methods & Procedures, Competence of the personnel and shall be examined to arrive at possible/ actual cause of the problem.

The analysis shall take into account the impact of non-conformance and measures that shall be taken to prevent its reoccurrence.



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The Review Committee shall identify appropriate corrective action, which would overcome the problem that has been originally identified. Any changes in the management system documents resulting from corrective actions shall be implemented as per 4.1 above.

Technical Operations Manager shall monitor the effectiveness of the corrective actions initiated and maintain the records. The corrective actions initiated and its effectiveness shall be reviewed in Management Review Meeting.

PREVENTIVE ACTION:

The Approving body to look for opportunities for improvements and overcome the potential sources of non-conformities either in technical operations or in Management System.

The action plan for bringing improvements shall include but is not limited to Periodic review of management system documents, Maintenance of Competence of Assessors & improvements to approval scheme.

Based on non-conformities and trend analyses carried out, the potential or frequent non conformities which could occur in specific areas of Approval scheme operations or activities shall be identified and action plan shall be initiated accordingly by Technical Operations Manager.

Technical Operations Manager shall monitor the action plan initiated and will evaluate effectiveness of preventive action taken in reducing the likelihood of the occurrences of non- conformities & advantage of the opportunities in bringing improvements.

Records related to preventive actions are maintained by Technical Operations Manager and made available for management review.

4.5 Other processes: Refer to following documents

- 1. Assessor Empanelment refer to STQC/SAB/D03
- 2. Policy on Use of STQC Approved Laboratory Logo refer to STQC/IT&eGov/D02
- 3. Handling Customer Complaints refer to STQC/IT&eGov/P02
- 4. Assessor Guide refer to STQC/SAB/P03
- 5. Adverse Decisions of Approving body refer to STQC/SAB/P02