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		Date	01-08-2018

Quality Manual

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Designation	Quality Manager	CEO	Quality Manager

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This Quality Manual is released under the authority of

Mr. G. Kameswara Rao,

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Indian Cotton Solutions.com Pvt. Ltd.

having its address as follows:

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1.3		Glossary Of Terms (Abbreviations)	
Sr. No.	Abbreviation	For	
1.	ICSCPL	Indian Cotton Solutions.com Pvt. Ltd.	
2.	MGT	Management	
3.	CEO	Chief Executive Officer	
4.	QM	Quality Manual	
5.	QP	Quality Procedure	
6.	NCR	Non-Conformity Report	
7.	IANCR	Internal Audit Non-Conformity Report	
8.	AEPL	Approved External Provider List	
9.	CAR	Corrective Action Report	
10.	W	Work Instruction	
11.	E	Exhibit	
12.	F	Formats	
13.	QMS / SYS	Quality Management System	
14.	LMS	Laboratory Management System	
15.	MKT	Marketing	
16.	OPN	Operation	
17.	PUR	Purchase	
18.	QCD	Quality Control	
19.	TRG	Training	
20.	INT	Intermediate	

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Chapter → 2.0 Authorization Statement and ICSCPL Profile

2.1 Authorization Statement

ICSCPL is committed to the establishment and maintenance of management system given in this manual and implemented by the ICSCPL, to meet the requirements of ISO/IEC 17025:2017.

The members of the **ICSCPL** strictly adhere to the various quality procedures and work instructions / standard operating procedures, as supported by the policies outlined in this manual.

Ms. G. Kastury has been appointed as **Quality Manager** and **Mr. G. Kameswara Rao** himself has been appointed as **Technical Manager** of **ICSCPL**. The Quality Manager is responsible for ensuring compliance with the quality requirements stipulated in this manual. Quality Manager is authorized to ensure that the management system is established, implemented, and maintained by the **ICSCPL**, CEO, Technical Manager, and **ICSCPL** employees give full support and co-operation to Quality Manager. Technical Manager assumes responsibility of Quality Manager and Quality Manager assumes the responsibility of Technical Manager in their absence. Technical Manager is responsible for ensuring compliance with the technical requirements in the testing activities.

Mr. G. Kameswara Rao
CEO
Indian Cotton Solutions.com Pvt. Ltd.

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2.2	Company Profile
<p>This is an innovation, a concept designed mainly with a "cotton farmer" orientation and balancing the thoughts of the entire Textile industry chain from Farmer to Weaver. In India cotton farmers are not being encouraged and are also not getting the benefits comparatively in the Textile chain. The capital-intensive spinning sector of cotton industry is also not happy with lot of cotton price fluctuation because there is one negative year in every 3 years in the market; due to this all cash-rich companies are affected heavily. In the supporting process, ginning mills are also not happy due to heavy fluctuations of industry. Here in this design, cotton farmer has great importance because they are cotton producers with their maximum efforts. India takes pride in being number one in cotton production in the world. This position is continuing from 2014. As new generation engineers we have developed this concept mainly by keeping in mind that Indian cotton farmer should get maximum advantage because their efforts are high and they are the key for India being in the 1st position of cotton producing. Indian government support is enormous by adopting the MSP (minimum support price) system for raw cotton and purchasing through CCI (cotton corporation of India). It is a great incentive but as per our observation so far, no special initiative from Indian Textile Industry to support cotton farmers directly. Considering all of this we developed this innovative concept focusing on the support to cotton farmers as our obligation. The farmers have put in a lot of effort and brought up India to 1st position among the cotton producing countries. So, now it is the duty and responsibility of every promoter of Indian textile industry to sustain the growth of cotton production and in turn develop the whole industry rather than the personal development and personal growth. As a helping hand to the cotton sector from cotton to yarn we came up with this solution of "Indian Cotton Solutions."</p> <p>We have mobile facilities for the testing of cotton, which gives proper rate of cotton to farmer. The laboratory is having state of art technology equipments for testing of quality of cotton.</p>	

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2.3	Context of organization
Internal issues	
1.	Impartiality to the laboratory activities
2.	Reporting statement of conformity against defined risk
3.	Nonconforming testing work
4.	Maintaining competence of testing personnel as well as employees' turnover
External issues	
1.	Confidentiality of customer's information
2.	Customer dissatisfaction
3.	Market reputation
4.	Legal issues

2.4	Testing facilities covered in ISO/IEC 17025:2017 Scope
1.	Cotton
	Scope of Accreditation
	The detailed scope of accreditation with the details of the products / materials, specific tests or types of test performed, specification, standard (method) or techniques used and range of testing / limit of detection is given in E/SYS/07.

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3.0	Controls And Distribution
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3.1	Structure Of Quality Manual
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This manual is prepared according to the table of contents. Cover page begins with page no. 1 and the numbering continues throughout the manual.

The manual is supported by documented management system covering Quality Procedures (QP) and work instructions or test methods. The procedure is referred in the relevant chapters of this manual. In addition, a separate list of chapter-wise procedures referred in this manual is given in Annexure-1 and a glossary of terms is given in clause no. 1.3.

The manual is issued in loose paper sheets and is accessible to the staff and customers.

The implementation of this manual and related quality procedure is mandatory for all departments. Any changes made in this manual shall be effected through the document control procedures and must be approved by the **CEO**.

3.2	Responsibility
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CEO approves all the pages of the Quality Manual. The control and maintenance of this manual is the responsibility of Quality Manager, who is maintaining master list of documents for quality manual.

3.3	Reference
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	ISO/IEC 17025:2017	General requirements for the competence of Testing and Calibration Laboratories
	Quality Procedure	QP/01 to QP/21

3.4	Distribution
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Quality Manuals are distributed to various departments on a "controlled" basis. Controlled copies are the one, which are subject to incorporation of "revisions".

"Controlled" copies of the quality manual are stamped "**Controlled Copy**" on all pages and are given a unique copy number for maintenance purpose.

Distribution list of Quality Manual is given on the next page.

Quality Manager, through a "change note" issues amendments and revised pages of quality manual to holders of controlled copies of the manual. Upon receipt of such revisions, the recipient will replace the pages by the revised ones.

"Uncontrolled" copies may be issued by the Quality Manager to the customers on request of the Technical Manager, or Functional Head to all employees but the recipient shall not be issued the amendments / revisions.

Quality Manager is responsible to fill-up amendment sheet in line with any amendment and put "Controlled Copy" Stamp on the amendment sheet as well as table of contents. All the information regarding revisions is distributed to Copy Holders. If any amendment due to change in page number is done then the table of contents is amended accordingly.

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3.5	Distribution list of Quality Manual			
	Copy No.	Type of document	Distributed to	
	1	Controlled Copy	CEO	
	2	Master Copy	Quality Manager	
	3	Controlled copy	Technical Manager	
	4	Controlled copy	Mobile Lab copy	
	=====	Uncontrolled copy	Accreditation body	
3.6	Numbering and document control for Quality Manual			
(1.)	The number for Quality Manual is given as QM/01, where QM stands for Quality Manual and 01 stands for 1 st level document.			
(2.)	When any amendment becomes necessary, it is the affected page that is replaced and not the whole chapter. The revised page is given amendment no. and amendment date in the footer as well as in the amendment record sheet of Chapter –1.			
(3.)	Revised pages of the Quality Manual are subject to the same approvals and controls as per the original one. In case of amendments to the particular page the amendment no. and amendment date for the particular page is identified on the footer of the amended page. After more than nine amendments in a single page the whole issue number of Quality Manual is revised with new issue number with amendment no. as 00.			
3.7	Reference to related documents			
1.	Amendment record sheet (Clause No. 1.2)		–	Chapter – 1.

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4 General requirements

4.1 Impartiality

4.1.1 **Laboratory activities** are undertaken impartially and they are structured and managed, so as to safeguard impartiality. To ensure impartiality, the testing personnel and administration personnel are separate. The organization structure is given on the next page, which ensures that impartiality related to work is carried-out by the laboratory. The Quality Manager ensures impartiality by the laboratory during the laboratory subcontractors' and employees' relation with customers during execution of the work.

4.1.2 **ICSCPL** management is committed to impartiality and impartiality policy (E/SYS/05) is prepared and communicated to all. Procedure (QP/01) is prepared for maintaining impartiality of laboratory activities and is followed to maintain impartiality.

4.1.3 **ICSCPL** is independent laboratory, dealing in the cotton testing. **ICSCPL** is responsible for the impartiality of its activities and the matter related to commercial, financial or other pressures to compromise impartiality is handled by the personnel other than the testing personnel. Testing person is not in the direct contact with the customer. Receipt of sample, billing, payment collection, etc. activities is undertaken by administration personnel. Employees are not given more work which can create pressure on them to ensure no compromise in the testing activities.

4.1.4 **ICSCPL** has identified risks to its impartiality on an on-going basis from customer, employees and suppliers. This includes those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships are not necessarily present at **ICSCPL** with a risk to impartiality. A relationship that threatens the impartiality of **ICSCPL**, is on ownership (as the **Head of ICSCPL** does not have any other business, he is engaged in the testing activities only), governance, management, personnel (technical and administration personnel are separate), shared resources (all resources for the testing are owned by laboratory; as a policy, it is decided that the resource of customer will not be used in any case for undertaking the customer's testing job), finances (separate and dedicated finance is allotted for testing laboratory), contracts, marketing (including branding etc. not applicable). The other activities like, payment of a sales commission or other inducement for the referral of new customers etc. are not done as a part of policy. Impartiality policy, its requirements and its norms are communicated to all laboratory personnel by:

- To all employees → By providing training related to requirements of impartiality,
- To all sub-contractors / external service providers → By signing the confidentiality and impartiality agreement (F/PUR/07).

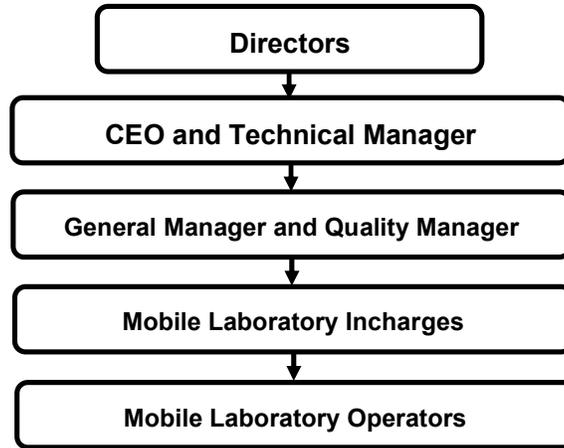
4.1.5 If a risk to impartiality is identified, **ICSCPL** will take appropriate action to eliminate or minimize such risk by deploying separate personnel, by providing separate or dedicated resources etc. **CEO** initiates the immediate actions to overcome and take action to maintain impartiality.

Reference documents	
QP/01	Procedure for Maintaining impartiality of laboratory activities
E/SYS/05	Impartiality policy
F/PUR/07	Sub-contractor's / External service provider's agreement
F/SYS/17	Impartiality check report

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Organization Chart



Remarks

- Technical Manager is nominated as Deputy Quality Manager.
- Quality Manager is nominated as Deputy Technical Manager.

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4.2 Confidentiality

- 4.2.1 The confidentiality agreement is made with the employees and other parties to ensure protection of its customers' confidential information, proprietary rights as well as test results. All care is taken to ensure files are transmitted in non-edited form to the customer and all care for confidentiality is taken in electronic storage and transmission of results. **ICSCPL** is responsible, through legally enforceable commitments (based on the contract made with the customer, either in customer order or in the Sample test request slip – F/QCD/02), for the management of all information obtained or created during the performance of **Laboratory activities**. **ICSCPL** informs the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between **ICSCPL** and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and is regarded as confidential. All employees of the laboratory activities have signed confidentiality agreement (F/TRG/06) to ensure that confidentiality of customer's information is maintained. All sub-contractors / external service providers have signed confidentiality and impartiality agreement (F/PUR/07).
- 4.2.2 When **ICSCPL** is required by law or authorized by contractual arrangements to release confidential information, **ICSCPL** will inform the details of information shared to the customer or individual concerned. The customer is informed in writing for such incidence.
- 4.2.3 Information about the customer, obtained from sources other than the customer (e.g. complainant, regulators), is kept confidential between the customer and **ICSCPL**. The provider (source) of this information is kept confidential to **ICSCPL** and is not shared with the customer, unless agreed by the source.
- 4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on behalf of **ICSCPL**, ensure that all information obtained or created during the performance of **Laboratory activities**, except as required by law, are strictly kept confidential.

Reference documents	
E/SYS/03	Secrecy rules
F/TRG/06	Confidentiality agreement
F/PUR/07	Sub-contractors / External service provider's agreement

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5 Structural requirements

5.1 **ICSCPL** is registered as Private Limited company as a legal entity. The legal registration details of the **ICSCPL** are as below;

ICSCPL is legally registered as a Private Limited company as below:

Registered with	Registrar of Companies, incorporated under the Companies Act, 1956 (No. 1 of 1956)
Registration no.	U17200AP2014PTC095890
Registration date	24-12-2014

5.2 **CEO** (as a Head of Laboratory) has overall responsibility for **Laboratory activities** carried-out at the mobile facility. As **ICSCPL** is conducting the testing in the mobile laboratory only, hence the requirements of permanent facility and site testing is not applicable.

5.3 **ICSCPL** has defined and documented the range of **Laboratory activities**, such as testing of Cotton at mobile facility. Permanent facility and site testing is not applicable. All such details are given in E/SYS/07. All activities carried-out comply with the requirements given in ISO/IEC 17025 (this document). **ICSCPL** claims conformity only for the defined scope of accreditation, which excludes externally provided activities on an ongoing basis.

5.4 **Laboratory activities** are carried-out in such a way as to meet the requirements of ISO/IEC 17025, relevant test standards, customer requirements, regulatory authorities and organizations providing recognition / accreditation, such as Accreditation Body. This includes **Laboratory activities** performed in mobile facilities only. No testing is carried-out at permanent facility as well as site, and hence, the requirement is not applicable.

5.5 **ICSCPL** has:

- defined the organization and management structure of **ICSCPL**, and the relationships between management, technical operations and support services. The organization structure is given at the end of clause no. 4;
- specified the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of **Laboratory activities**. Detailed job description and specifications (F/TRG/04) are prepared for each level of employees and communicated to all personnel within the laboratory. The responsibilities and authorities of key personnel are given at the end of clause no. 5.0.
- documented its procedures as identified in successive clauses, to the extent necessary, to assure the consistent application of its **Laboratory activities** and the validity of the results reported to the customer for the materials.

5.6 **ICSCPL** have personnel (Quality Manager and Technical Manager) who, irrespective of other responsibilities, have the authority and resources needed to carry-out their duties, including:

- implementation, maintenance and improvement of the management system as per ISO/IEC 17025;
- identification of deviations from the management system or from the procedures for performing **Laboratory activities**;

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- c) initiation of actions to prevent or minimize such deviations;
- d) reporting to **ICSCPL** management on the performance of the management system and any need for improvement;
- e) ensuring the effectiveness of **Laboratory activities**.

5.7 ICSCPL management ensures that:

- a) communication (through written communication as per the E/SYS/04) takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements. Method of communication is effectively implemented related to management system within the laboratory. In majority of the cases, the communication is done through routine records for effective implementation and e-mail to the concerned.
- b) the integrity of the management system is maintained when changes to the management system are planned and implemented. Also it is ensured that the integrity of management system is maintained, when changes are planned and implemented in the system. In key position, the deputies are nominated to take care of the person related issues.

Reference documents	
E/SYS/04	Communication process
E/SYS/07	Scope of accreditation
F/TRG/04	Job description and specification

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Responsibility and authority of the Top Management (CEO)	
Responsibility	
<ul style="list-style-type: none"> • To provide resource for effective implementation of the system. • To conduct the management review meeting periodically, and to ensure that the system is effectively implemented within the laboratory. • To nominate Quality Manager and Technical Manager as per the requirements of the system. • To prepare and review Quality Policy periodically, and to ensure that the same is in line with the present circumstances. • To provide evidence of commitment to the development and implementation of management system and continual improvement and its effectiveness. • To communicate the importance of meeting customer as well as statutory and regulatory requirements within the organization. • To ensure that the integrity of the management system is maintained during changes to the management system as planned and implemented. 	
Authority	
<ul style="list-style-type: none"> • To stop the activity, if found any non-conformity related to testing, accommodation and environment. 	

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Responsibility and authority of Quality Manager

Responsibility

- To review and approve the management system documents.
- To ensure that a management system is established implemented and maintained in accordance with the ISO/IEC 17025 management system standards.
- To ensure that the continual improvement is going on after implementing the system.
- To liaise with Accreditation Body for all the matters related to accreditation.
- To record the minutes during the management review meeting.
- Overall responsible for the document control.
- To establish control over document and data, including documents of external origin (such as **Indian Standards / International Standard**, etc.).
- To schedule and arrange internal audits on the basis of status and importance of the functions.
- To establish control system on quality and technical records.
- To identify causes of non-conformities and take necessary corrective actions to remove the cause.
- To identify training needs of employees for the management system.
- Overall responsible for maintaining of training records in consultation with Technical Manager.
- To prepare records of technical training of the employees.
- To identify the corrective action based on the analysis of complaints.
- To do data analysis and identify fruitful results for the further improvement.
- To conduct the analysis of customer feedback and to identify the customer satisfaction level.
- Overall responsible for establishing and maintaining of system based on ISO/IEC 17025.

Authority

- To stop the activity, if found any non-conformity related to testing, accommodation and environment.
- To review all the non-conformities raised during the audit and issue report to the auditee for taking actions.
- To approve the actions taken by the auditee as a basis to resolve non-conformities.
- To suggest corrective actions related to the system improvement.
- To monitor whole documented system and suggest preventive actions, if anything goes wrong.

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Responsibility and authority of Technical Manager

Responsibility

- To ensure that the documented test methods / reference standards are followed during the testing.
- To prepare four-year plan and to follow the requirements for ensuring the validity of results.
- To identify the training needs of the employees and provide the same in consultation with the Quality Manager.
- To ensure that proper accommodation and environment is maintained in the testing area as per the requirements of the relevant test standards.
- To initiate corrective actions based on the feedback of the testing activities.
- To ensure periodic monitoring of the environment to maintain records as per the documented procedure.
- To ensure that all the available literatures, including manufacturers manual, are maintained.
- To prepare preventive maintenance schedule and intermediate checks schedule for all the instruments and to ensure that the employees follow the same.
- To verify and review test records.
- To ensure that calibration of all the equipments are traceable to the national / international standards and having valid relationship.
- To re-calibrate the equipments used in the testing before the validity expires.
- To ensure optimum use of available resources.
- To ensure that the proper records are maintained at all stages of testing and quality control.
- To review and authorize daily records of the laboratory.
- To ensure safe and proper handling of the samples / materials throughout the laboratory.
- To review the print-out from the equipment of each testing after completion of necessary testing work.
- To provide technical training to the testing personnel, as identified.
- To ensure that uncertainty of measurement is calculated periodically for each test parameter.
- To identify or receive the requirements for consumable purchase from the concerned employees and to procure the same.
- To handle all the complaint and analyse the same.

Authority

- To review and authorize the routine records of the laboratory.
- To review and authorize the Test Report before it is issued to the customer.
- To review and approve records of employees' competence, skills, etc.
- To review Calibration Certificates of equipments, received from the outside calibration agency.
- To stop the testing activities, if proper environment condition is not maintained and achieved.
- To take corrective actions identified based on analysis, related to the complaint or results of testing.
- To issue Test Report.

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Responsibility and authority of testing personnel

Responsibility

- To check the physical condition of samples received for testing.
- To make sample ready for testing as per the defined test method.
- To do testing of samples as per the documented test method given in the related Standards.
- To use equipments for testing as referred in the related Standards.
- To ensure that the test methods / Standards for testing are available where testing activities are performed.
- To conduct the uncertainty of measurement of the samples as per the defined periodicity for the identified parameters.
- To ensure that all required information related to test conducted is adequately available in the print-out or on the display of computer for High Volume Instrument. Also to ensure that the test data related to raw cotton is available in the work sheet.
- To ensure that HVI test data and work sheet are reviewed by Technical Manager.
- To ensure that the equipment used for testing is having valid calibration.
- To conduct preventive maintenance of the equipments.
- To initiate inter-laboratory comparison and to evaluate the results of inter-laboratory comparison.
- To handle breakdown maintenance of the equipment, as soon as possible.
- To place the remaining samples retained for the re-test in the sample preservation area and ensure that the sample is preserved for specified retention period. However, it may be stored for longer period, if requested by the concerned user / section.
- To ensure proper disposal of the sample after retention period as well as after testing, after receipt of approval from the Technical Manager.
- To ensure that the proper records are maintained at all stages of testing and ensuring the validity of results.
- To monitor the environment condition regularly and record the same periodically during the testing activities are carried-out.
- To handle the samples throughout the testing and preservation in such a way that it does not create any problem in testing.
- To ensure stringent follow-up of the ISO/IEC 17025 system in the lab.
- To analyse the complaint by reviewing the related records as per the complaint given by the Technical Manager.
- To report to the Technical Manager on day-to-day functioning / activities.
- To use available resources on optimum basis to achieve maximum output during the testing.
- To reduce wastage of available resources.

Authority

- To stop the testing activities, if proper environment condition is not maintained / achieved.

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6 Resource requirements

6.1 General

ICSCPL has available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities related to testing of cotton.

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, are competent and work in accordance with the laboratory's management system. **Impartiality policy (E/SYS/05)** is prepared and is communicated to all employees to ensure that all employees act impartially.

6.2.2 ICSCPL has documented the competence requirements based on the specific criteria defined by accreditation body, for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. All such criteria are documented in the employee competence report (F/TRG/08).

6.2.3 ICSCPL ensures that the personnel have the required competence (F/TRG/08), to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The management of the laboratory communicates to personnel their duties, responsibilities and authorities in the job descriptions and specifications (F/TRG/04).

6.2.5 ICSCPL has procedure for the personnel and training (QP/02) and retain records for:

- a) determining the competence requirements, considering the requirements of relevant test parameters covered under the scope of accreditation;
- b) selection of personnel for all activities carried-out by laboratory;
- c) training of personnel considering the skill and competence requirements;
- d) supervision of personnel;
- e) authorization of personnel based on the skill and competence;
- f) monitoring of competence of personnel.

6.2.6 ICSCPL has authorized specific personnel to perform specific laboratory activities, including but not limited to, the following:

- a) development, modification, verification and validation of methods; the details of all such authorization is maintained in the skill matrix (F/TRG/05);
- b) analysis of results, including statements of conformity or opinions and interpretations; the details of all such authorization is maintained in the skill matrix (F/TRG/05);
- c) report, review and authorization of results; the details of all such authorization is maintained in the skill matrix (F/TRG/05);

Such authorization is given based on their competency and details recorded.

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Reference documents	
QP/02	Procedure for personnel and training
F/TRG/01	Training Calendar
F/TRG/02	Training Report
F/TRG/03	Induction Training Report
F/TRG/04	Job Description
F/TRG/05	Skill Matrix (Authorization)
F/TRG/07	Appointment Letter
F/TRG/08	Employees Competence Report
F/TRG/09	ISO/IEC 17025 Effectiveness Check Report
F/TRG/10	Technical Training Effectiveness Check Report
F/TRG/11	Interview Report
F/TRG/12	Self study report for trainer

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6.3 Facilities and environmental conditions

6.3.1 ICSCPL has provided the required facilities and environmental conditions suitable for the mobile testing laboratory activities, considering the tests carried-out, and it is ensured that it does not adversely affect the validity of results. The following parameters are controlled considering the validity of test results, such as dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration. The following conditions are maintained in the mobile laboratory;

Sr. No.	Parameter	Limits
1.	Temperature in °C	23 ± 2
2.	Humidity in % Rh	65 ± 5

6.3.2 The requirements for facilities and environmental conditions (as above) necessary for the performance of the mobile laboratory activities are documented.

6.3.3 ICSCPL monitors, controls and records environmental conditions in accordance with relevant specifications, methods or procedure (QP/03) or where they influence the validity of the results. The records of environmental condition monitoring are maintained.

6.3.4 Measures to control facilities are implemented, monitored and reviewed at every **month** and these include, but not limited to:

- a) access to and use of areas affecting mobile laboratory activities;
- b) prevention of contamination, interference or adverse influences on mobile laboratory activities;
- c) effective separation between areas with incompatible mobile laboratory activities.

6.3.5 Site testing is not done by **ICSCPL** and hence requirement of site testing is not applicable. The facility provided at mobile laboratory are already documented in 6.3.1 to 6.3.4.

Reference documents	
QP/03	Procedure to maintain laboratory environmental condition
F/QCD/08	Environment condition monitoring report
F/QCD/07	Facility supervision checklist

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6.4 Equipment

6.4.1 ICSCPL has access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus, which is required for the correct performance of laboratory activities and which can influence the result. A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. Reference materials from producers meeting the requirements of ISO 17034 come with a product information sheet / certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

6.4.2 No equipment is used outside the permanent control of mobile laboratory and hence a requirement of this clause is not applicable.

6.4.3 Procedure (QP/04) for handling, transport, storage, use and planned maintenance of equipment is prepared and implemented to ensure proper functioning and in order to prevent contamination or deterioration. It is strictly followed by all persons, during routine activities.

6.4.4 ICSCPL verifies that equipment conforms to specified requirements before being placed or returned into service. The details of checks conducted are recorded in the equipment history card (F/OPN/01). Equipment history cards are maintained for all the equipments used in the testing.

6.4.5 Equipments used for testing (measurement) are capable of achieving the required accuracy or measurement uncertainty to provide valid test results and have complied with specifications relevant to testing. Calibration schedule (F/SYS/10) is established for all equipments, where these properties have a significant effect on the results. Before being placed into service, equipment are tested or checked to establish that it meets the specification requirements of **ICSCPL** and complies with the relevant standard specifications. All such calibration details of equipments are reviewed before use.

6.4.6 Measuring equipment are calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the reported results, or
- calibration of the equipment is required to establish the metrological traceability of the reported result.

Types of equipment having an effect on the validity of the reported results can include:

- those used for the direct measurement of the measurand, for example, use of a automatic equipment for cotton tests;
- those used to make corrections to the measured value, for example, measurement of temperature and humidity of mobile laboratory, which may affect the measurement;
- those used to obtain a measurement result calculated from multiple quantities.

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- 6.4.7** ICSCPL has established a calibration programme (E/SYS/02 and F/SYS/10), which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.
- 6.4.8** All equipment requiring calibration or which has a defined period of validity are labeled with the calibration status sticker having identification no., date of calibration, and due date of calibration. This helps to allow the user of the equipment to readily identify the status of calibration or period of validity.
- 6.4.9** Equipment, which is subjected to overloading or mishandling and gives suspected results, if showing to be defective or outside specified limits, is withdrawn from operations. It is isolated to prevent its use and clearly labeled or marked as being “**out of service**” until it has been repaired and shown by testing to perform correctly within defined acceptance criteria. ICSCPL examines the effect of the defect or departure from specified limits on previous testing, and after that, the same is followed as per the procedure for management of non-conforming work.
- 6.4.10** Defined intermediate check points are established, implemented and are followed as per the Procedure (QP/05) to maintain confidence in the calibration status of equipment and testing performed by the same equipment. Records of such intermediate checks are maintained.
- 6.4.11** When calibration and reference material data include reference values or correction factors, ICSCPL ensures the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.
- 6.4.12** ICSCPL takes practicable measures to prevent unintended adjustments of equipment from invalidating results.
- 6.4.13** Records are retained for equipment that can influence laboratory activities in the equipment history card (F/OPN/01), preventive maintenance schedule (F/OPN/02) and calibration status of equipments (F/SYS/10). The records include the following, where applicable:
- the identity of equipment (name of equipment), including software and firmware version;
 - the manufacturer's name, type identification, and serial number or other unique identification;
 - evidence of verification that equipment conforms with specified requirements;
 - the current location;
 - calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
 - documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
 - the maintenance plan and maintenance carried-out to date, where relevant to the performance of the equipment;
 - details of any damage, malfunction, modification to, or repair of, the equipment.

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Reference documents	
QP/04	Procedure for handling, transport, storage, use and planned maintenance of equipment
QP/05	Procedure for intermediate checks
E/SYS/02	Calibration periodicity
F/OPN/01	Equipment history card
F/OPN/02	Preventive maintenance schedule
F/OPN/03/XX	Equipment-wise preventive maintenance check points
F/QCD/10	Intermediate check report – Weighing balance
F/SYS/10	Calibration status of equipments

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6.5 Metrological traceability

6.5.1 ICSCPL has established and maintained metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. All equipment used for sampling, testing, including equipment for subsidiary measurements (e.g. for environmental conditions), having a significant effect on the accuracy or validity of the results, are calibrated before being put into service. **ICSCPL** has an established program and procedure for the calibration of equipment (F/SYS/10), procedure no. QP/06 is established and implemented. The procedure covers details like selection, use, calibration, checking, controlling, and maintenance of measurement standards, and reference standards for measuring equipment.

6.5.2 ICSCPL ensures that measurement results are traceable to the International System of Units (SI) through ensuring the followings:

- a) calibration provided by a competent laboratory (ISO/IEC 17025 accredited calibration laboratory);
- b) certified values of certified reference materials provided by a competent producer (ISO 17034 accredited CRM producer or by committee) with stated metrological traceability to the SI;
- c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

6.5.3 When metrological traceability to the SI units is not technically possible, **ICSCPL** demonstrates metrological traceability to an appropriate reference, such as:

- a) certified values of certified reference materials provided by a competent producer; or
- b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

Reference documents	
QP/06	Procedure for measurement traceability and calibration
F/SYS/10	Calibration status of equipments

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6.6 Externally provided products and services

6.6.1 ICSCPL ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- a) are intended for incorporation into the laboratory's own activities, such as used in the testing of samples;
- b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
- c) are used to support the operation of the laboratory, such as equipments and consumables, etc.

Products include measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services include, calibration services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services taken from external provider.

6.6.2 ICSCPL has implemented procedure (QP/07) for purchasing of externally provided products and services and retain records for:

- a) defining, reviewing and approving the requirements for externally provided products and services;
- b) defining the criteria for evaluation (F/PUR/04), selection, monitoring of performance and re-evaluation (F/PUR/06) of the external providers;
- c) ensuring that externally provided products and services conform to the **ICSCPL's** established requirements, or when applicable, to the relevant requirements of ISO/IEC 17025, before they are used or directly provided to the customer;
- d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 ICSCPL communicates its requirements to external providers, for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of personnel;
- d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

All the above details are incorporated in the Purchase Order (F/PUR/01) and then the purchase order is approved by Technical Manager before its issue to Approved External Provider. Products and services are procured only from the external provider included in the Approved External Provider List (F/PUR/03).

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Reference documents	
QP/07	Procedure for procurement of externally provided products and services
F/PUR/01	Purchase Order
F/PUR/02	Indent (Purchase requisition)
F/PUR/03	Approved External Provider List
F/PUR/04	Supplier Registration Form
F/PUR/05	Open Purchase Order
F/PUR/06	Supplier Evaluation Report
F/QCD/06	Inspection Report

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7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 ICSCPL has procedure (QP/08) for the review of requests, tenders and contracts. The procedure ensures that:

- a) the requirements related to testing are adequately defined, documented and understood, and are referred in Sample test request slip (F/QCD/02).;
- b) the **ICSCPL** has the capability and resources to meet the requirements, including the requirements of test methods to be followed, such as **Indian Standards / International Standard**;
- c) no external providers are used (at present, subcontracting for testing is not done by **ICSCPL**, hence, the requirements of this clause is not applicable);
- d) The appropriate test methods are selected and are capable of meeting the customers' requirements, which are based on **Indian Standards / International Standards**.

7.1.2 Customer will be immediately informed by **ICSCPL**, when the method requested by the customer is considered to be inappropriate or out of date.

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test (e.g. pass / fail, complies / does not complies, in tolerance / out of tolerance) the specification or standard, and the decision are clearly defined in the Sample test request slip (F/CSD/02). Unless inherent in the requested specification or standard, the decision rule selected is communicated to, and agreed with, the customer. Records of such decision are maintained in the Sample test request slip (F/CSD/02).

7.1.4 Records of acceptance of each contract are maintained in the contract made with the customer, including details of sampling plan and procedure, where applicable, by **ICSCPL**. It is ensured that the difference between the requirements and capabilities are resolved before finalization of contract. Records of reviews, including any significant changes, are maintained in contract / Sample test request slip (F/QCD/02). Records are also maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract, if any. Sample test request slip (F/QCD/02) is signed by customer or his representative and by Technical Manager as an acceptance of contract. Deviations requested by the customer do not impact the integrity of the laboratory or the validity of the results.

7.1.5 The customer will be informed immediately, in case of any deviation from the contract.

7.1.6 If a contract needs to be amended after work has commenced, the same contract review process will be repeated as described above. In such cases, either amended Sample test request slip (F/QCD/02) or amended contract is prepared and is signed by **ICSCPL** representative and customer representative as an agreement of acceptance of amended testing work with all technical details. Details of amendments are communicated to all affected personnel.

7.1.7 ICSCPL cooperates with customers or their representatives in clarifying the customer's request and in monitoring the **ICSCPL**'s performance in relation to the work performed. The cooperation can include:

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- a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities; it means witnessing the testing performed for customer's sample;
- b) method followed for preparation, and dispatch of items needed by the customer for verification purposes.

7.1.8 Records of reviews, including any significant changes, are retained. Records are retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities in the Sample test request slip (F/QCD/02).

Reference documents	
QP/08	Procedure for Review of requests, tenders and contracts
F/QCD/02	Sample test request slip
F/QCD/09	Inward Register

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7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 **ICSCPL** uses appropriate methods and procedures for all laboratory activities (testing work carried-out for the materials covered under the scope of accreditation) and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. These also include handling, transport, storage, and preparation of items to be tested.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, are kept up-to-date and are made readily available to personnel, where the laboratory activities are carried-out.

7.2.1.3 It is ensured that, the latest valid version of a method is used during the laboratory activities, unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application. **ICSCPL** uses **Indian Standards / International Standards** or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities. The copies of those standards are being issued to laboratory personnel for conducting the laboratory activities. For smooth operation, additional documentation for optional steps in the method or additional details are provided considering the equipment to be used for the laboratory activities for maintaining accuracy in the laboratory activities. Method prepared, documented and issued for implementation are having following information as minimum:

- a) Identification No.,
- b) Scope of activity,
- c) Description of item to be tested,
- d) Parameters etc.,
- e) Equipment requirements, including technical performance requirements,
- f) Reference of standards / materials on which basis the method is prepared,
- g) Sample preservation methods / condition,
- h) Description of Test Method, including
 - I. Checks to be done before commencement of testing
 - II. Method for recording observation / print-out from the equipment
 - III. Safety precautions to be taken before and during testing
- i) Criteria for “Conformance / Compliance or Non-conformance / Non-compliance” are provided based on acceptance norms as agreed with customer.
- j) Test Report preparation method

7.2.1.4 When the customer does not specify the method to be used, **ICSCPL** selects an appropriate method (considering the product / material under the test and its test parameters) from the scope of accreditation and informs the customer of the method chosen. The details of method selected for the test is clearly identified in the Sample test request slip (F/QCD/02). Methods published either in **Indian Standards / International Standard, or by reputable technical organizations**, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment is recommended. Laboratory-developed or modified methods are not used in the laboratory activities performed by **ICSCPL**.

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7.2.1.5 **ICSCPL** verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Record of the verification of method performance is retained in terms of method verification report (F/QCD/14) and filled print-out from the equipment. If the method is revised by the issuing body, verification is repeated considering its impact on the accuracy of the test results.

7.2.1.6 When method development is required, this is planned activity and is assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review is carried-out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan is approved and authorized.

7.2.1.7 Deviations from methods for all laboratory activities occurs only if the deviation has been documented, technically justified, authorized, and accepted by the customer. Customer acceptance for the identified deviation is agreed in the Sample test request slip (F/QCD/02), if any.

7.2.2 Validation of methods

7.2.2.1 **ICSCPL** validates non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation is as extensive as is necessary to meet the needs of the given application or field of application. Method validation includes procedures for handling and transportation of test items. The techniques used for method validation can be one of, or a combination of, the following:

- a) evaluation of bias and precision using reference standards or reference materials;
- b) systematic assessment of the factors influencing the result;
- c) testing method robustness through variation of controlled parameters, such as oven temperature, volume delivered, etc.;
- d) comparison of results achieved with other validated methods;
- e) inter-laboratory comparisons;
- f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

7.2.2.2 After validation of methods, if changes are made to a validated method, the influence of such changes is determined and where they are found to affect the original validation, a new method validation is performed.

7.2.2.3 The performance characteristics of validated methods are assessed for the intended use, relevant to the customers' needs and consistent with specified requirements. Performance characteristics includes, but are not limited to, the measurement range, accuracy, the measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

7.2.2.4 **ICSCPL** retains the following records of validation:

- a) the validation procedure (QP/09) used;

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- b) specification of the requirements;
- c) determination of the performance characteristics of the method;
- d) results obtained;
- e) statement on the validity of the method, detailing its fitness for the intended use.

Reference documents	
QP/09	Procedure for method verification and validation
F/QCD/14	Method verification report
F/QCD/15	Method validation report

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7.3 Sampling

ICSCPL is not doing sampling of samples. Samples are received from customer at our mobile testing laboratory and hence a requirement of this clause is not applicable.

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7.4 Handling of test items

7.4.1 ICSCPL has procedure (QP/10) for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test items, including all provisions necessary to protect the integrity of the test item, and to protect the interests of the laboratory and the customer. Precautions are taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing / waiting, and preparation for testing. Handling instructions provided with the item are followed. All employees are made aware regarding the requirements of handling of test items and any special care, if any.

7.4.2 ICSCPL has a system for the unambiguous identification of test items. All samples upon receipt are identified by inward number / test number and the same is in numeric digit in continuation. The identification no. is retained while the item is under the responsibility of the laboratory. All samples received for the testing are retained for the period of **1 day** after completion of testing. The system of identification of test item ensures that test items will not be confused physically or when referred to in records or other documents.

7.4.3 Upon receipt of the test item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for test, or when an item does not conform to the description provided, the **ICSCPL** consults the customer for further instructions before proceeding and records the results of this consultation. When the customer requires the item to be tested acknowledging a deviation from specified conditions, **ICSCPL** include a disclaimer in the report indicating which results may be affected by the deviation. Samples are disposed off in such cases.

7.4.4 When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded.

The process followed for sample collection, sample handling and storage are well-defined, and the sample quantity required for each testing is also defined.

The sample is received in laboratory with Sample test request slip (F/QCD/02).

Sample is checked during receipt for:

- a) Physical condition,
- b) Sufficient quantity / volume of sample to ensure completion / adequacy of sample for satisfactory completion of all tests,
- c) Parameters to be tested.

Upon completion of retention period, the sample will be disposed off. The details of samples disposed and date of disposal is recorded in the inward register (F/QCD/09).

Reference documents	
QP/10	Procedure for transportation, receipt, handling, protection, storage, retention, and disposal or return of test items
E/SYS/06	Sample receipt checklist
F/QCD/02	Sample test request slip
F/QCD/09	Inward Register

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7.5 Technical records

7.5.1 ICSCPL ensures that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical record includes the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made in the relevant records and are identifiable with the specific task. The record includes the identity of personnel responsible for the performance of each testing and checking of results.

7.5.2 ICSCPL ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files are kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations. When mistakes occur in records, each mistake is crossed-out and not erased, made illegible or deleted, and the correct value is entered alongside. All such alterations to records are signed or initiated by the person making the correction. In the case of records stored electronically, possible care is taken to prevent loss or change in the original data. Any alteration made in computer / electronic media are identified with amended copy. Original one is also maintained.

Reference documents	
=====	Print of results as an output from testing machine
	Work sheet – Raw cotton

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7.6 Evaluation of measurement uncertainty

7.6.1 ICSCPL has identified the contributions to measurement uncertainty. When evaluating measurement uncertainty all contributions, which are of significance, including those arising from sampling / filling, are taken into account using appropriate methods of analysis.

7.6.2 Being a testing laboratory, the requirements of this clause is not applicable.

7.6.3 ICSCPL performs testing and evaluates measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty (F/QCD/04), estimation is made based on an understanding of the theoretical principles or practical experience of the performance of the method. In some cases, well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, **ICSCPL** is considered to have satisfied by following the test method and reporting instructions.

ICSCPL has documented procedure QP/11 for estimating uncertainty of measurement. The components for estimation of uncertainty are identified and included in the nature of test method, which precludes rigorous, metrological, and statistically valid calculation. The form (F/QCD/04) of reporting of results is clear and it does not give any wrong impression of the uncertainty. The estimation of uncertainty is based on knowledge of the performance of the method and on the measurement scope, including previous experience and validation data. All such uncertainty calculations are done based on the guidelines given in ISO Guide 98-3.

For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result, if the laboratory can demonstrate that the identified critical influencing factors are under control.

Reference documents	
QP/11	Procedure for evaluation of measurement uncertainty and statistical techniques for analysis of data
F/QCD/04	Uncertainty of measurement calculation sheet

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7.7 Ensuring the validity of results

7.7.1 ICSCPL has a procedure (QP/12) for monitoring the validity of results. The resulting data are recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but not limited to:

- a) use of reference materials or quality control materials;
- b) functional check(s) of measuring and testing equipment prior to starting the test by comparing with the known value materials;
- c) use of check or working standards with control charts, where applicable;
- d) intermediate checks on measuring equipment, such as weighing balance etc.;
- e) replicate tests using the same or different methods;
- f) re-testing of retained items;
- g) correlation of results for different characteristics of an item;
- h) review of reported results;
- i) intra-laboratory comparisons;
- j) testing of blind sample.

7.7.2 ICSCPL monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned (Four-year plan (F/QCD/01) is prepared) and reviewed and include, but not limited to a selection from the following list:

- a) participation in proficiency testing (it is ensured that the PT Provider must have ISO/IEC 17043 accreditation);
- b) participation in inter-laboratory comparisons other than proficiency testing, through accredited testing laboratories in the similar materials and its parameters.

7.7.3 Data obtained from above monitoring activities are analyzed and used to control, and if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate actions are taken to prevent incorrect results from being reported. The pre-defined criteria for the monitoring are as below:

Type of internal quality checks	Acceptance criteria
Self-initiated Inter-Laboratory Comparison	Z Score between ± 2.0 (Means -2.0 to 2.0)
For re-test / replicate test / intra-laboratory comparison	Difference between the results must fall between the acceptance criteria given in E/SYS/08

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Reference documents	
QP/12	Procedure for ensuring and monitoring of validity of result
E/SYS/08	Acceptance criteria for internal quality checks
F/QCD/01	Four-Year Plan for Quality Control
F/QCD/03	ILC Analysis Report
F/QCD/05	Re-test analysis report

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7.8 Reporting of results

7.8.1 General

7.8.1.1 The results of test are reviewed and authorized prior to release.

7.8.1.2 The results are provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. test report), and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports are retained as technical records.

For the purpose of ISO/IEC 17025, test reports are sometimes called test certificates. **ICSCPL** issues test report in the form of hard copy only. For HVI and ICC mode testing of cotton, the test report is directly generated from the HVI Machine. After that the same is authorized by authorized personnel and then uploaded on the web site. For raw cotton, the test certificate is prepared in computer and then print of test certificate is taken, after authorizing the test certificate the same is scanned and uploaded on the web site. Customer can enter with their login details and they can view the test report in PDF format and can take print. All such process is followed in the non-editable format and hence there are no chances of changes later on by user or anyone else.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 which is not reported to the customer is made readily available, when the simplified report is issued.

7.8.2 Common requirements for reports (test)

7.8.2.1 Each test report includes at least the following information, unless the **ICSCPL** has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

- a) a title (e.g. "Test Report");
- b) the name and address of the **ICSCPL** in detail including the mobile lab vehicle registration number;
- c) the location of performance of the laboratory activities (Such as Mobile testing identification by identifying the vehicle number),
- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- e) the name and contact information of the customer;
- f) identification of the test method used in the testing of each parameter of product / material;
- g) a description, unambiguous identification, and, when necessary, the condition of the item during receipt;
- h) the date of receipt of the test item(s),
- i) the date(s) of performance of the laboratory activity;
- j) the date of issue of the report;
- k) a statement to the effect that the results relate only to the items tested,
- l) the results with, where appropriate, the units of measurement;
- m) additions to, deviations, or exclusions from the method;
- n) identification of the person(s) authorizing the report; and
- o) proprietary of test report, such as **"the report shall not be reproduced except in full, without approval of the laboratory"**.

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7.8.2.2 **ICSCPL** is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer are clearly identified. In addition, a disclaimer is addressed on the report when the information is supplied by the customer and can affect the validity of results.

7.8.3 Specific requirements for the test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, if specifically asked by the customer, the test results include the following details:

- a) information on specific test conditions (Temperature and humidity maintained during the testing), such as environmental conditions maintained during the testing considering the requirements of test standard;
- b) where relevant, a statement of conformity with requirements or specifications, if specifically asked by customer;
- c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
 - it is relevant to the validity or application of the test results;
 - a customer's instruction so requires, or
 - the measurement uncertainty affects conformity to a specification limit;
- d) where appropriate, opinions and interpretations;
- e) additional information which may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2 As sampling is not done, hence requirement of this clause is not applicable.

7.8.4 Specific requirements for the calibration certificates

Being a testing laboratory, the requirements given in the clause no. 7.8.4 and its sub-clauses are not applicable.

7.8.5 Reporting sampling – specific requirements

As sampling is not done, hence requirement of this clause is not applicable.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, **ICSCPL** document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule. In such case Technical Manager Review the risk register and the results of uncertainty of measurement is also considered in making the decision rule as well as ensure that same decision rule which is agreed at contract review stage is applied and such statement is made. Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 **ICSCPL** reports on the statement of conformity (based on customer request) such that the statement clearly identifies:

- a) to which results the statement of conformity applies;
- b) which specifications, standards or parts thereof are met or not met; and
- c) the decision rule applied

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7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, **ICSCPL** ensures that only Technical Manager, who is authorized for the expression of opinions and interpretations, releases the respective statement. **ICSCPL** documents the basis upon which the opinions and interpretations have been made. This interpretation and opinion are drawn based on reference **Indian Standards / International Standards and customer specification**. Such opinion and interpretation are clearly marked in a test report.

7.8.7.2 The opinions and interpretations expressed in reports are based on the results obtained from the tested item and are clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue is retained by mentioning the details for the same in the Sample test request slip (F/QCD/02).

7.8.8 Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change is included in the report.

7.8.8.2 Amendments to a report after issue is made only in the form of a further document, or data transfer, by following method:

- a) Title is identified as "Test Report- Amended"
- b) Date of issue is changed considering amendment issue date
- c) Certificate no. is kept same
- d) Reason for amendment alongwith the date of original issue of certificate.
- e) Details of original report, such as original issue date of the same test report is clearly identified in the Amended test report.

7.8.8.3 When it is necessary to issue a complete new report, this is uniquely identified and contains a reference to the original that it replaces.

Reference documents	
F/QCD/02	Sample test request slip
=====	Test report

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7.9 Complaints

- 7.9.1** ICSCPL has a documented process (QP/13) to receive, evaluate and make decisions on complaints.
- 7.9.2** A description of the handling process for complaints is available to any interested party on request. Upon receipt of a complaint, **ICSCPL** confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, deals with it. **ICSCPL** is responsible for all decisions at all levels of the handling process for complaints. The complaint is recorded and the complain report (F/QCD/12) is prepared for its further investigation.
- 7.9.3** The process for handling complaints includes at least the following elements and methods:
- a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
 - b) tracking and recording complaints, including actions undertaken to resolve them;
 - c) ensuring that any appropriate action is taken.
- 7.9.4** **ICSCPL**, on receiving the complaint, is responsible for gathering and verifying all necessary information to validate the complaint.
- 7.9.5** **Quality Manager** acknowledges receipt of the complaint, and provides the complainant with progress reports and the outcome through e-mail.
- 7.9.6** The outcomes communicated to the complainant is made by, or reviewed and approved by **Quality Manager / Technical Manager** not involved in the original laboratory activities in question.
- 7.9.7** Whenever possible, the laboratory gives formal notice of the end of the complaint handling to the complainant.

Reference documents	
QP/13	Procedure to receive, evaluate and make decisions on complaints
F/QCD/12	Complain report

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7.10 Non-conforming work

7.10.1 ICSCPL has documented and implemented procedure (QP/14) when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure (QP/14) ensures that:

- a) Technical Manager is responsible and authorized for the management of nonconforming work once defined;
- b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
- c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
- d) a decision is taken on the acceptability of the nonconforming work;
- e) where necessary, the customer is notified and work is recalled;
- f) Technical Manager is authorized for resumption of defined work.

7.10.2 Records of nonconforming work and actions taken on it as specified in 7.10.1, b) to f) is maintained and retained in the Disposal of non-conforming work (F/QCD/13).

7.10.3 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory implements corrective action against the nonconforming work.

Reference documents	
QP/14	Procedure for control of nonconforming work
F/QCD/13	Disposal of non-conforming work

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7.11 Control of data – Information management

- 7.11.1 ICSCPL** has access to the data and information needed to perform laboratory activities in terms of testing of products / materials.
- 7.11.2** The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data are validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the **ICSCPL** before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they are authorized, documented and validated before implementation.
- 7.11.3** The laboratory information management system(s) are:
- protected from unauthorized access, computers used in maintaining laboratory activities data are controlled by password protection;
 - safeguarded against tampering and loss;
 - operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription of data;
 - maintained in a manner that ensures the integrity of the data and information; and
 - includes recording system failures and the appropriate immediate and corrective actions.
- 7.11.4** When laboratory information management system(s) are managed and maintained off-site or through an external provider, **ICSCPL** ensures that the provider or operator of the system(s) complies with all applicable requirements of ISO/IEC 17025.
- 7.11.5 ICSCPL** ensures that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.
- 7.11.6** Calculations and data transfers are checked in an appropriate and systematic manner to ensure validity of data and its transfer. Procedure (QP/15) is implemented for control of data and its transfer.

Reference documents	
QP/15	Procedure for control of data

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8 Management system requirements

8.1 Options

8.1.1 General

ICSCPL has established, documented, implemented and maintained a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025 and ensuring the quality of the laboratory results. In addition to meeting the requirements of clauses 4 to 7 of ISO/IEC 17025, **ICSCPL** has implemented a management system in accordance with **option A**.

8.1.2 Option A

As a minimum, the management system of the laboratory addresses the following as a part of management system requirements:

- management system documentation (as per 8.2)
- control of management system documents (as per 8.3)
- control of records (as per 8.4)
- actions to address risks and opportunities (as per 8.5)
- improvement (as per 8.6)
- corrective action (as per 8.7)
- internal audits (as per 8.8)
- management reviews (as per 8.9)

8.1.3 Option B

ICSCPL has implemented the requirements of Option A, and hence, requirements of this clause are not applicable.

8.2 Management system documentation (Option A)

8.2.1 ICSCPL has established, documented, and maintained policies and objectives for the fulfillment of the purpose of ISO/IEC 17025 and ensures that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization. The detailed Quality Policy is given as below:

8.2.2 The policies and objectives address the competence, impartiality and consistent operation of the laboratory.

8.2.3 ICSCPL provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

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Quality Policy

ICSCPL is committed to achieve total customer satisfaction for the testing services that we offer.

ICSCPL will achieve this by:

- a.) Establishing good professional practices and providing quality services to customers,
- b.) Maintaining accuracy, precision, and reliability of testing services through maintaining standards,
- c.) Maintaining competence, impartiality and consistent operation of laboratory activities,
- d.) Adoption and maintenance of an laboratory management system for our laboratory testing activities in accordance with ISO/IEC 17025,
- e.) Encouraging and welcoming customer feedback to proactively improve our performance and quality of services,
- f.) Familiarizing all employees with relevant documents,
- g.) Complying with ISO/IEC 17025 and continually improving the effectiveness of the management system through regular review.

Mr. G. Kameswara Rao – CEO	1st August 2018
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Quality Objectives

Mistake in the report identified during the review	1 Max. / Quarter
Customer complaint related to testing service provided to them	1 Max. / Quarter
Customer satisfaction level achievement	90 % Min.

8.2.4 All documentation, processes, systems, and records related to the fulfillment of the requirements of ISO/IEC 17025 are included in, referenced from, or linked to the management system. The hierarchy of documentation prepared, implemented and cross-referred in the lab are as under;

Tier	Name of Documents	Cross-referred in
1 st	Quality Manual	=====
2 nd	Quality Procedure	Quality Manual
3 rd	Work Instructions / Test Methods	Quality Procedures
4 th	Formats	Quality Manual, Quality Procedures and Work Instructions / Test Methods

8.2.5 All personnel involved in laboratory activities have access to the relevant parts of the management system documentation and related information that are applicable to their responsibilities.

Reference documents	
F/SYS/05	Quality objective monitoring report

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8.3 Control of management system documents (Option A)

8.3.1 ICSCPL controls the documents (internal and external) that relate to the fulfillment of ISO/IEC 17025. **ICSCPL** has established and maintained procedure (QP/16) to control all documents that have formed part of management system, such as regulations, standards, other normative references, test methods, specifications, instructions, manuals and others used as references are covered in the document control system.

Internal documents	All documents prepared by the ICSCPL to fulfill the requirements of ISO/IEC 17025 as well as other reference standards.	
External documents	Customer documents	Indian Standard
	Supplier documents	International Standard
	Manufacturer's manual	Testing guidelines

8.3.2 ICSCPL ensure that:

a) All documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use by authorized personnel prior to issue as per the details given below. A master list and distribution list of documents (F/SYS/01) is maintained for all tiers of documents, showing current revision status and distribution of documents.

Responsibility Matrix For Documents					
Type of document	Authority to				
	Prepare	Review	Approve	Issue	Maintaining Master list and issuing as per distribution
1. Quality manual	Quality Manager	CEO	CEO	Quality Manager	Quality Manager
2. Quality procedure	Quality Manager	CEO	CEO	Quality Manager	Quality Manager
3. Applicable reference standards (external)	=====	Quality Manager	=====	=====	Quality Manager
4. Formats, work instructions	Quality Manager	CEO	CEO	Quality Manager	Quality Manager
5. Exhibits, reference documents and data					
6. Customer specifications, and documents of external origin	=====	Quality Manager	Quality Manager	=====	Quality Manager

b) All documents (such as Quality Manual, Quality Procedures, Work Instructions / Test Methods, Formats, etc.) are reviewed every year (mainly during management review meeting) and, where necessary, are revised to ensure continuing suitability and compliance with applicable requirements to ensure its compliance with laboratory's current practices; documented information are retained for such periodic review of documents in the F/SYS/16.

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- c) Changes / amendments done in any documents are identified; such latest changes are identified by putting asterisk (*) or suitable marking on right or left hand of particular text / paragraph affected along with the underlining of the affected text / paragraph etc. Such marking indicates the latest changes and all personnel of laboratory are acquainted of the same. Changes are supported by change note (F/SYS/02), which is maintained by Quality Manager.
- d) Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; details of distribution of documents are controlled, and are maintained by Quality Manager.
- e) Documents are uniquely identified, as per the numbering system described in the next table.
- f) Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use by putting stamp of “**Obsolete Copy**” on such documents. Obsolete documents are retained for legal or knowledge preservation purposes marked as “**Obsolete Copy**” and are maintained with Quality Manager for **three years**.

Reference documents	
QP/16	Procedure for document and data control
F/SYS/01	Master list and distribution list of documents
F/SYS/02	Change Note
F/SYS/16	Periodic document review report

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All documents are identified by unique document numbering system as per the details given below:

Numbering System for Documents		
A.	Numbering System for Quality Procedure	
	QP/XX	
	QP	Quality Procedure
	XX	Stands for continuous sl. no. of procedure
B.	Numbering System for Work Instruction or Standard Operating Procedure	
	W/AAA/XX or SOP/AAA/XX	
	W	Work instruction
	SOP	Standard Operating Procedure
	AAA	Stands for 3-digit department code as per E/SYS/01
XX	Stands for continuous sl. no. of work instruction or standard operating procedure	
C.	Numbering System for Exhibit	
	E/AAA/XX	
	E	Exhibit
	AAA	Stands for 3-digit department code as per E/SYS/01
XX	Stands for continuous sl. no. of exhibit	
D.	Numbering System for Formats	
	F/AAA/XX	
	F	Formats
	AAA	Stands for 3-digit department code as per E/SYS/01
XX	Stands for continuous sl. no. of format	

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8.4 Control of records (Option A)

8.4.1 ICSCPL has established and retained legible records to demonstrate fulfillment of the requirements of ISO/IEC 17025.

8.4.2 ICSCPL has established and maintained procedure for control of records (QP/17) considering identification, collection, indexing, access, filing, storage, protection, back-up archive, retrieval, retention time, maintenance, and disposal of quality and technical records. Quality records also include reports from internal audits and management reviews as well as records of corrective actions, etc. **ICSCPL** retains records for a period consistent with its contractual and legal obligations. Access to these records is consistent with the confidentiality commitments and records are made readily available. The procedure also covers the details of protection and back-up of records stored electronically and to prevent unauthorized access to or amendment of these records. All records maintained in computer are safeguarded from virus, having password protection and back-up of all such data / records are taken on monthly basis by users. Retention times of records are established and recorded in the Master List of Records (F/SYS/04). Master list of records with their retention period is also included at the end of this clause.

Reference documents	
QP/17	Procedure for control of records
F/SYS/04	Master List of Records

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8.5 Actions to address risks and opportunities (Option A)

8.5.1 ICSCPL has considered the risks and opportunities associated with the laboratory activities in order to:

- a) give assurance that the management system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the laboratory;
- c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; and
- d) achieve improvement.

8.5.2 ICSCPL has planned:

- a) actions to address these risks and opportunities;
- b) how to:
 - integrate and implement the actions into its management system;
 - evaluate the effectiveness of these actions.

8.5.3 Actions are taken to address risks and opportunities. It is ensured that the same are proportional to the potential impact on the validity of laboratory results. Risk and opportunities related to laboratory activities are identified and are implemented in the Risk assessment sheet (F/SYS/09). Procedure (QP/18) is prepared for the Risk assessment. Risk assessment sheet is prepared and is reviewed annually during the management review meeting.

Reference documents	
QP/18	Procedure for Risk assessment
F/SYS/09	Risk assessment sheet

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8.6 Improvement (Option A)

8.6.1 ICSCPL has identified and selected opportunities for improvement and implemented necessary actions for the improvement in the laboratory activities. Opportunities for improvement are identified through:

- review of the operational procedures,
- the use of the policies,
- overall objectives,
- audit results,
- corrective actions,
- management review,
- suggestions from personnel,
- risk assessment,
- analysis of data, and
- proficiency testing results.

Improvement log is maintained as soon as it is identified.

8.6.2 After providing the testing services to the customer, the customer feedback form (F/QCD/11) is submitted to customer alongwith the test report for taking feedback, both positive and negative, from customer related to service provided. Quality Manager follows-up with the customer for the collection of filled customer feedback form in time. Upon receipt of customer feedback form, the same is reviewed for the comments given by customer. If the feedback given by customer is Average or Poor, then customer is communicated about such ranking and necessary actions are initiated by the Quality Manager, based on customer's comments. Also, actions initiated for the same are informed to the customers. **Every year**, customer feedback is analyzed and percentage satisfaction level of customer is identified.

Reference documents	
F/SYS/15	Improvement log
F/QCD/11	Customer Feedback Form

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8.7 Corrective action (Option A)

8.7.1 Procedure (QP/19) is documented and implemented for the corrective action. When a nonconformity occurs, the **ICSCPL**:

- a) reacts to the nonconformity and, the nonconformity is reported in the non-conforming work (F/QCD/13):
 - immediate action is taken to control and correct the nonconformity. As a policy decision, all employees have been informed to stop the work immediately as soon as nonconformity is identified;
 - the consequences of nonconformity are addressed and then appropriate actions are taken;
- b) conducts further root cause analysis to evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - reviewing and analysing the nonconformity;
 - determining the causes of the nonconformity;
 - determining if similar nonconformities exist, or could potentially occur;
- c) implements identified corrective action (F/SYS/03) needed to prevent recurrence of the nonconformity;
- d) reviews the effectiveness of any corrective action taken after defined implementation period to ensure that the corrective action taken is effective and similar types of nonconformity is not repeated after implementation of corrective action;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the management system documentation based on the corrective action, if necessary.

8.7.2 Corrective actions are initiated / taken appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory retains records as evidence of:

- a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
- b) the results of any corrective actions.

Reference documents	
QP/19	Procedure for corrective action
F/SYS/03	Corrective action report

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8.8 Internal audits (Option A)

8.8.1 ICSCPL has documented and implemented procedure (QP/20) for internal audit. **ICSCPL** conducts internal audit **at least once in six months** to provide information on whether the management system:

- a) conforms to:
- the laboratory's own requirements for its management system, including the laboratory activities;
 - the requirements of ISO/IEC 17025;
- b) is effectively implemented and maintained within the laboratory.

8.8.2 ICSCPL:

- a) plans, establishes, implements and maintains an audit program (F/SYS/06), including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;
- b) defines the audit criteria and scope for each audit, and addresses them in the audit plan / schedule (F/SYS/06);
- c) ensures that the results of the audits, in terms of audit findings and internal audit non-conformity report (F/SYS/07), are reported to relevant management;
- d) implements appropriate correction and corrective actions without undue delay and retains documented information in the form of internal audit non-conformity report (F/SYS/07);
- e) retains records as evidence of the implementation of the audit programme (F/SYS/06) and the audit results (F/SYS/07).

Reference documents	
QP/20	Procedure for internal audit
F/SYS/06	Audit Plan / Schedule
F/SYS/07	Internal Audit Non-Conformity Report
F/SYS/08	Clause-wise document-wise audit review report
F/SYS/11	Clause-wise audit report – Management requirements
F/SYS/12	Clause-wise audit report – Technical requirements

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8.9 Management reviews (Option A)

8.9.1 The Top Management reviews management system at least **once in six months**, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of ISO/IEC 17025 requirements. Procedure (QP/21) is documented and implemented for planning and conducting management review meeting.

8.9.2 The inputs to management review (Circular – called as MRM Agenda, F/SYS/13) are defined and recorded, and include information related to the following:

- a) changes in internal and external issues that are relevant to the laboratory;
- b) fulfillment of objectives;
- c) suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) outcome of recent internal audits;
- f) corrective actions;
- g) assessments by external bodies;
- h) changes in the volume and type of the work or in the range of laboratory activities;
- i) customer and personnel feedback;
- j) complaints;
- k) effectiveness of any implemented improvements;
- l) adequacy of resources;
- m) results of risk identification;
- n) outcomes of the assurance of the validity of results; and
- o) other relevant factors, such as monitoring activities and training.

8.9.3 During the management review meeting, Quality Manager records the outputs from the management review in terms of decisions and actions related to at least:

- a) the effectiveness of the management system and its processes;
- b) improvement of the laboratory activities related to the fulfillment of the requirements of this document;
- c) provision of required resources;
- d) any need for change.

Detailed minutes of meeting are prepared by Quality Manager along with the review meeting output and are approved by the Top Management. Minutes of meeting is circulated to all concerned for taking timely actions on it as per the action plan. Quality Manager keeps track of the action plan and ensures that the actions are taken in a timely manner.

Reference documents	
QP/21	Procedure for management review meeting
F/SYS/13	Circular – MRM Agenda
F/SYS/14	Minutes of management review meeting

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Annexure – 1 List of documents

Quality Procedures			
Sr. No.	ISO/IEC 17025 Clause Number	Title of Procedure – Procedure For	Quality Procedure Number
1.	4.1	Maintaining impartiality of laboratory activities	QP/01
2.	6.2	Personnel and training	QP/02
3.	6.3	Maintain laboratory environmental condition	QP/03
4.	6.4	Handling, transport, storage, use and planned maintenance of equipment	QP/04
5.	6.4	Intermediate checks	QP/05
6.	6.5	Measurement traceability and calibration	QP/06
7.	6.6	Procurement of externally provided products and services	QP/07
8.	7.1	Review of requests, tenders and contracts	QP/08
9.	7.2	Method verification and validation	QP/09
10.	7.4	Transportation, receipt, handling, protection, storage, retention, and disposal or return of test items	QP/10
11.	7.2.1.1 / 7.6	Evaluation of measurement uncertainty and statistical techniques for analysis of data	QP/11
12.	7.7	Ensuring and monitoring of validity of result	QP/12
13.	7.9	Receive, evaluate and make decisions on complaints	QP/13
14.	7.10	Control of non-conforming work	QP/14
15.	7.11	Control of data	QP/15
16.	8.3	Document and data control	QP/16
17.	8.4	Control of records	QP/17
18.	8.5	Risk assessment	QP/18
19.	8.7	Corrective action	QP/19
20.	8.8	Internal audit	QP/20
21.	8.9	Management review	QP/21

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Technical Documents – Exhibits

Sr. No.	ISO/IEC 17025 Clause Number	Title of documents	Document Number
22.	8.3	Codification system	E/SYS/01
23.	6.5	Calibration periodicity	E/SYS/02
24.	4.2	Secrecy rules	E/SYS/03
25.	5.7	Communication process	E/SYS/04
26.	4.1	Impartiality policy	E/SYS/05
27.	7.4	Sample receipt checklist	E/SYS/06
28.	5.3	Scope of accreditation	E/SYS/07
29.	7.7	Acceptance criteria for internal quality checks	E/SYS/08
30.	6.2	Skill requirements	E/HRD/01

Technical Documents – Work Instructions

31.	6.4 and 7.2	Standard operating procedures	SOP/OPN/XX
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