Implementing Change from ISO/IEC Guide 25 to ISO/IEC 17025 and Beyond

Speaker Dr. S. L. Sarnot
Phone: +91-11-4363089; FAX: +91-11-4363083
e-mail sarnot@mit.gov.in
Authors: Dr. S.L. Sarnot and S.K.Kimothi
Phone: +91-11-4364165; FAX: +91-11-43643083
e-mail kimothi@mit.gov.in
Standardization, Testing and Quality Certification (STQC) Directorate
Department of Information Technology,Government of India
Electronics Niketan, 6 CGO Complex, Lodhi Road, New Delhi-110003 India

ABSTRACT

The laboratory accreditation bodies world over had formulated their general criteria for accreditation of testing and calibration laboratories based on ISO/IEC Guide 25:1990. The guide has now been replaced by a new standard ISO/IEC 17025:1999. The compliance to this standard demonstrates that the testing/calibration laboratories operate a quality system in line with ISO 9000: 1994, are technically competent and are able to generate technically valid results. The International Laboratory Accreditation Cooperation (ILAC) has formulated a transition plan which desires that all laboratory accreditation bodies should ensure that the accredited testing and calibration laboratories should upgrade their quality system for compliance to ISO/IEC 17025 before December 2002. Thus there are large number of accredited laboratories that will have to undergo the above transition. In the year 2000, the revised version of ISO 9000 series of quality management standards have been published. These standards have identified certain quality management principles whose application will result into improved performance of an organization. STQC has a chain of accredited testing and calibration laboratories which are in the process of incorporating changes in their quality system for compliance to ISO/IEC 17025. Some of the quality management principles from ISO 9000:2000 have also been implemented to achieve improved performance of the laboratories. The paper specifies the transition strategies and is based on experiences gained in implementing the above changes.

1. Introduction:

The role of testing and calibration laboratories in facilitating international trade is now getting more prominence. Mutual acceptability of laboratory data and results is an important step in removing technical barrier to trade. At the same time many of the testing and calibration laboratories are faced with the problem of sustainability and meager growth rate. For acceptability of test data produced by testing and calibration laboratories they should be technically competent which is a necessary condition for them to exist. However technical competence alone is not sufficient condition to ensure their sustainability and growth in the long run. For the success of a laboratory its management should work towards continuously improving its performance while addressing the needs of all interested parties viz. its customers, employees and other stake holders.

ISO/IEC Guide 25: 1990 has been used as a generic criteria document for the competence of testing and calibration laboratories. The Guide 25 also stipulates that laboratories meeting the requirements of the guide also comply with the requirements of ISO 9000 series of quality system standards when they are acting as suppliers producing calibration and test results. A number of ISO 9000 Certification Bodies started auditing laboratories against ISO 9000 standards and issued compliance certificates to that effect. This created confusion in the minds of users of services of testing and calibration laboratories whether a laboratory complying with ISO 9000 can also be considered to be technically competent. The Guide 25 is silent on this. This question has now been clearly answered in the new standard ISO/IEC 17025:1999.

2. ISO/IEC 17025: 1999, new standard for technical competence

ISO Committee on Conformity Assessment (CASCO) reviewed the requirements of Guide 25 for harmonization of conformity assessment practices. Based on the review, a new standard ISO/IEC 17025 have been published in 1999, which replaces all the existing standards on this subject. This standard has also harmonized the requirements of quality system for testing and calibration laboratories with those of the requirements of quality systems for manufacturing and service organizations as stipulated in ISO 9001: 1994. The following issues have also been cleared in the new standard.

i) ISO/IEC 17025 is a standard rather than a Guide. Conventionally the guides are generally not used for regulatory requirements like accreditation of testing and calibration laboratories

ii) Quality System Certification ensures compliance to the requirements of ISO 9000 standards whereas laboratory accreditation is based on its competence to carry out specific types of tests or calibrations. It is possible for a laboratory to comply with the requirements of ISO 9000 standards and still not be competent enough to carry out specific tests or calibrations. This position has been made very clear in the new standard , which states that laboratories complying with ISO/IEC 17025 also operate in accordance with ISO 9001 or 9002:1994. However certification against ISO 9001 or ISO 9002 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. The Guide 25 was silent on the second part of the above statement.

The new standard has stipulated two types of requirements which have bearing on the technical competence of laboratories. The first type of requirements have been defined as Management requirements and the second types of requirements as Technical requirements.

2.1 Management Requirements: These requirements mostly contain the quality system requirements which are in line with ISO 9001: 1994 generic requirements for quality system. The following aspects have been covered in Management Requirements:-

- Organization
- Quality system
- Document Control

- Review of requests, tenders and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Service to clients
- Complaints
- Control of non conforming test and calibration work
- Corrective action
- Preventive action
- Control of records
- Internal audit
- Management Review

2.2 Technical Requirements: Those factors that affect the technical functioning of the laboratories and quality of the test and calibration data are covered under technical requirements and the same are given below:

- General
- Personnel
- Accommodation and environmental conditions
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of tests and calibration results
- Reporting the results

A comparison of the above requirements with those of Guide 25 reveals that some of the existing requirements have been elaborated, some of the requirements have been modified, whereas some of the additional requirements have been included in the new standard.

3. STQC Network of Testing and Calibration Laboratories:

Standardization, Testing and Quality Certification (STQC) is an infrastructure established by Government of India for providing testing and calibration services to small and medium scale industries in electrotechnical sector. These services are provided through a network of 14 laboratories spread throughout the country with a strength of more than 500 technical employees, most of them having graduate and post graduate degrees in engineering or science. The calibration services provided by these laboratories include electrotechnical parameters, non electrical parameters like temperature, pressure and humidity and dimensional metrology. In the area of testing these laboratories are having technical facilities for testing of electrotechnical products to various specifications. Some of the laboratories are having specialised facilities for safety testing of products, compliance testing for electromagnetic interference/compatability and facilities for environmental simulations. Most of these laboratories have accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL) for testing as well as calibration functions. Some of the laboratories are also operating as independent test

laboratories under International Systems like IECQE and IEC CB Schemes. These laboratories are operating a quality system which has been meeting the requirements of Guide 25.

4. Upgrading Quality System from Guide 25 to ISO/IEC 17025:

International Laboratory Accreditation Cooperation (ILAC) has recommended a transition plan which desires that all accredited testing and calibration laboratories should upgrade their quality system to comply with the requirements of ISO/IEC 17025 before December 2002. All Laboratory Accreditation Bodies are expected to adhere to the above schedule. STQC laboratories are also in the process of implementing the change and are at various stages of implementation. A common methodology has been adopted by the laboratories. The upgradation of quality system is implemented based on the following activities:-

- Awareness creation about new standard
- Adequacy audit of existing quality system for compliance to ISO/IEC 17025
- Analysis of gap areas
- Upgrading Quality System documentation
- Implementing the upgraded quality system
- Auditing implementation of upgraded quality system and its effectiveness
- Review of effectiveness by laboratory management

4.1 Awareness Creation: The first step in implementation was awareness creation about the new standard in the laboratory. It started with a one day workshop which was attended by about twenty senior scientists of the laboratory. Though all the participants were aware of the requirements of the new standard, the thrust of the workshop was on evolving common understanding of the standard by all concerned. Ambiguities relating to the interpretation of the standard were resolved after detailed discussion among the participants. The awareness about the standard was also created among persons working at various levels.

4.2 Adequacy audit: The quality system of the laboratory was audited by audit teams consisting of trained and qualified internal auditors. The objective of the audit was to assess the limits of compliance of the existing quality system which is based on Guide 25 to the requirements of ISO/IEC 17025. The scope of the audit consisted of both the management and the technical requirements of the new standard, for all the testing and calibration activities of the laboratory. The general service process of the laboratory is as follows:-

1. Request for testing/calibration services are received at an interface between the customer and the laboratory called Customer Service Cell (CSC)
2. CSC translates the request into the job card and sends the item received for testing/calibration along with the job card to the concerned technical activity Head.
3. The job is performed in various technical sections. After completion of the job it is sent to CSC along with test/calibration report duly verified.
4. Inhouse quality assurance and quality control checks are carried out routinely as part of laboratory's quality system.
5. The item is returned to the customer by CSC along with the report/certificate duly signed by approved signatory

The adequacy audit was also conducted for the activities of the CSC. The audit findings from various technical activities were analyzed to find the gap areas

4.3 Analysis of gap areas: The audit findings from various testing and calibration activities were analyzed by a core group consisting of senior scientists and the quality manager of the laboratory. The observed inadequacies pertaining to the requirements of new standard have been listed and are given in the following table:

Table: Inadequacies against existing standard

ISO/IEC 17025 Clause reference & requirements	Remarks/Observations
4.3 Procedure for control of document	Not addressed adequately
4.4 Review of requests, tenders and contact	Not addressed at all
4.6 Purchasing of services & supplies	Issues pertaining to purchasing of services not addressed
4.7 Services to the client	Issues like monitoring of laboratory's performance by client not addressed. Practice of access to the laboratory for witness testing exists but not formalised in documentation
4.9 Control of non-conforming testing and/or calibration work	Not addressed at all
4.10 Corrective Action	Partially addressed
4.11 Preventive Action	Not addressed at all
4.12 Control of Records	Not addressed adequately
4.14 Management Review	Procedure exists but not adequate
5.2 Personnel	Systematic training programme does not exist and training needs are not identified.
5.4 Test and Calibration Methods and its validation	Method validation aspects not addressed
5.4.6 Estimation of Uncertainty of Measurements	Uncertainty is being reported for calibration jobs but the same is not being estimated and reported for testing jobs.
5.7 Sampling	The laboratory is not involved in sampling activity
5.10 Reporting the Results	Additional requirements for opinions and interpretations not addressed

4.4 Upgrading Quality System Documentation:

The existing quality system documentation of the laboratory consists of four tiers. The quality manual is the apex policy document. The next levels of documentation consist of technical and quality system related procedures followed by technical work instructions used for conduct of day to day testing and calibration. Before any change in the quality system was attempted it was decided to continue the existing documentation structure even with the new standard. The upgradation process of quality system documentation was attempted in two phases:

Phase I Upgrading Quality Manual
Phase II Upgrading other documentation

4.5 Upgrading Quality Manual:

In view of a number of changes involved due to additional and expanded requirements to be incorporated in the Quality manual, it was decided to bring out a new issue of the quality manual rather than amending the existing issue. The policies of the laboratory for the following additional requirements were formulated and included in the new issue of the Quality manual:

1. Review of requests, tenders and contracts: It is desired that the laboratory reviews all requests for testing/calibration for method to be used and unambiguous understanding of clients requirements. The laboratory also reviews its capability and resources to met these requirements.
2. Control of non conforming test and calibration: The objective is to ensure control on the quality of test data if testing or calibration work or the result do not conform to laboratory procedures or as agreed with the clients
3. Corrective Action: The objective is to lay policy for dealing with a situation when non conforming work or departure from policies and procedures in the quality system or technical operations have been identified.
4. Preventive Action: The objective is to initiate policy that ensures prevention of non-conformance in the quality system or technical operations of the laboratory
5. Service to the clients: This requirement desires that the laboratory shall formally afford the client cooperation for monitoring its performance or clarifying clients requests.

In addition to the above new requirements some of the existing practices as given in the quality manual were amended to bring them in line with the requirements of the new standards:

1. Document Control: Specific policy pertaining to document approval and issue, amendment to the documents and handling obsolete document was included
2. Purchase of services and supplies: Additional aspects pertaining to purchasing of services were also included in the quality manual.
3. Control of Records: The new standard has clearly defined the records in two categories viz. quality system related records and technical records. This aspect was included in the manual.

4. Management Review: The new standard has specifically identified the issues that need to be deliberated in management reviews and hence incorporated in the manual.
5. Training of personnel: The requirements for identification of training needs for personnel has been made specific in the standard and so was made as part of laboratory's policy.
6. Test and calibration method validations and uncertainty of test results: The laboratory generally uses standard test method. However the need for validation of test and calibration methods has been stipulated as a policy of the laboratory. The necessity for evaluation of uncertainty of test results as a policy has also been specified in the quality manual.
7. Opinions and interpretations: The laboratory's policy on these as per the new standard was also included in the quality manual.

4.6 Upgrading other Documentation:

The augmentation of the quality manual as per requirements of the new standard also necessitated the need for preparation of new procedures and modifications in some of the existing procedures. This involved the following procedures:

1. Control of documents
2. Purchasing of services and supplies
3. Corrective action
4. Preventive action
5. Control of Records
6. Training of personnel
7. Estimating uncertainty of test results

4.7 Implementing the upgraded quality system:

The new and amended quality manual and procedures are being implemented as part of the quality system of the laboratory. However one of the critical issue pertaining to implementation is estimation and reporting of Measurement Uncertainty of test results.

Estimation and reporting of measurement uncertainty of calibration result is an accepted practice with the calibration laboratories. However, it is not yet widely practiced by testing laboratories. In STQC laboratories also this aspect is being looked into. Procedures for estimating uncertainty of test results are being worked out, which will be broadly based on the method recommended in Guide for Estimation of Uncertainty of Measurement results published by International Organization for Standardization.

4.8 Auditing and Review of the upgraded quality system:

The implementation status of the upgraded quality system for compliance to ISO/IEC 17025 is audited as part of internal quality audit of the laboratory. A special audit for this purpose has been arranged. The effectiveness of the upgraded quality system is also audited as part of internal quality audit. The implementation and effectiveness related issue of upgraded

quality system are also reviewed as a part of the Management Review of the quality system of the laboratory

5. Journey beyond ISO/IEC 17025:

The management requirements specified in ISO/IEC 17025 are primarily based on generic requirements stipulated in ISO 9001:1994 standard. In the meantime International Organization for Standardisation (ISO) has been working on review of these standards. The new ISO 9000 standards on quality management has been published in 2000. Based on the experience gained with the operation of 1994 version of ISO 9000 family of standards the new standard has indentified eight quality management principles. The application of these quality management principles by the management is expected to lead the organization towards improved performance. These quality management principles are specified below:

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationship

STQC at overall organization level realized that the implementation of quality system as per ISO 17025 ensures technical competence which is an important element of laboratorys' operations. However this may not necessarily result into improved performance as envisaged in ISO 9000:2000 standard on quality management. A strategy was therefore evolved at corporate level to implement some of these quality management principles in the operations of the organization. The approach has been people focussed, customer focussed and establishing clear cut direction of the organization by the management. The application of these approaches at organization level has been applied in the following areas:-

1. Involvement of people: The persons working in laboratories were involved in decision making process at various levels. The business targets for the laboratories were prepared in consultation with them. The availability of resources, market and competition from other laboratories were considered while deciding the targets. The laboratory persons at operational level were engaged in Activity Business Groups which was evolved as a new concept to ensure peoples' participation in decision making. To give business focus to various testing/calibration and other support activities a number of activity business groups were formed. The membership of these groups was drawn from various laboratories consisting of persons engaged in similar activities. These groups meet at regular intervals and came out with definite recommendations for enhancing the productivity. As an extension of this activity a separate workshop on STQC calibration service was held which was attended by about 60 persons of various levels. More frequent formal meetings of the Heads of the laboratories were arranged for review of the progress and mutual exchange of views and ideas.

2. Customer focus: All the laboratories were requested to enhance their interaction with customers. The laboratories prepared their three year business plan after one to one interaction with a number of important customers. The augmentation of technical facilities in the laboratories were also planned keeping the future requirements of the customers in mind. The CSC were manned by persons with good communication skills and courteous in nature. The customer focus was not only confined to technical requirements but also service quality aspects.

3. Adoption of factual approach to decision making: A number of data bases in respect of personnel, technical facilities were prepared. Various clusters consisting of technical facilities and personnel were defined as cost and profit centres. The performances of various activities were closely monitored.

4. Leadership: The purpose and directions of the organization were unambiguously communicated to the laboratories. At corporate level the focus was shifted from hierarchical organizational working to comparatively flatter organization. This way the capabilities of the individuals could be better utilized.

5. Process review & continual improvement: Various technical and support activities of the laboratories were performed as processes with thrust on value additions. The performance of the processes and process owners were monitored regularly. The areas for continual improvements were identified which could result into improved performance. These pertain to easy accessibility of computers and other office automation equipment, improved work environment and laboratories ambience.

The upgradation of quality system with adoption of certain approaches from ISO 9001: 2000 has helped in enhancing the organisational productivity. A growth rate of 35 per cent in productivity has been achieved in a single year: A similar growth rate is expected to be achieved in the current year.

References:-

1. ISO/IEC 17025:1999 General requirements for the competence of testing and calibration laboratories,. International organisation for standardisation

2. ISO/IEC Guide 25: 1990: General requirement for the competence of calibration and testing laboratories; International organisation for standardisation

3. ISO 9000:2000 Quality Management System Fundamentals and Vocabulary; International Organization for Standardization.

The authors thankfully acknowledge the inputs provided by Mr. B.Basaviah, Director and Ms. Kaushal Singhal Scientist; Electronics Regional Test Laboratory (North), STQC New Delhi