EVALUATION OF QUALITY CONTROL MEASURES AND COMPETENCY OF THE STAFF IN NON-ACCREDITED TESTING LABORATORIES IN SRI LANKA

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Abstract

The purpose of this research was to identify the quality control measures adopted by non-accredited testing laboratories (excluding medical and calibration laboratories) in Sri Lanka and to examine the competency of the staff in conducting the tests in non-accredited laboratories using ISO 17025 as the guidance.

A field study based on a structured questionnaire and personal interviews was carried out in ten (10) non-accredited laboratories in Sri Lanka. Eighteen test methods (18), twenty one (21) actual tests were observed and twenty four (24) employees were given a structured examination.

The study analyzed non-accredited laboratories based on management and technical requirements of ISO 17025. Several specific clauses stipulated in ISO 17025 were considered for the assessment. Each clause selected was subdivided in to a set of objective requirements which was examined in each laboratory/test method/test. The laboratory was decided to have complied with minimum quality control procedures related to the clause if these requirements are met as per the acceptance criteria developed by the researcher.

The study identified that less than 40% laboratories observed, used adequate quality control methods in conducting the tests in aspects related management system, equipment and reporting results. Less than 70% laboratories observed, used adequate quality control methods in conducting the tests in aspects related to internal audit, organizations and laboratory environment. Erroneous procedures and deficiencies in conducting the test were observed in many aspects. Ignorance of conditions laid down in the relevant test method/standard, inappropriate handling of testing equipment or standards by the staff, non-use of quality control samples when required and errors in documentation and issuing of the test report were the four major shortcomings observed in test methods. Three major deficiencies in laboratory quality control included calibration issues, not enough facilities to monitor the test environment and lack of documentation in quality procedures. The study also revealed the poor competency and knowledge of the laboratory staff in general quality principles. Although 56% of the employees examined had sufficient technical knowledge to carry out the given test, only 30% had satisfactory understanding of general quality management policies laid down in ISO 17025.

The outcome of this research is that due to inadequate level of quality control procedures implemented in most of the non-accredited laboratories and due to the lack of knowledge of the staff in these testing laboratories in quality assurance principles, the ability of non-accredited laboratories to consistently deliver reliable and valid results is highly doubtful. Finally, this paper presents recommendations for an effective and reliable laboratory network in Sri Lanka.

Key words: Non-accredited testing laboratories, ISO 17025, Laboratory quality control

Introduction

Quality control is an important part of every laboratory test. Quality has been defined as "conformance to requirement" (Crosby) or "satisfying customers' needs" (Deming). Appropriate quality control practices will maximize the accuracy of results provided as well as possibly provide early signals of potential problems. Any testing or calibration laboratory that wishes to generate technically valid data and quality results and ensure that defined quality levels required for producing such results are continuously maintained, should implement a well-defined quality system operated by

technically competent personnel. (National Foreword, SLS ISO 17025:2015). ISO 17025:2015 provides the basis and all requirements that have to be met by testing laboratories.

Realizing the importance of quality control in laboratory tests, Sri Lanka Accreditation Board for Conformity Assessment (SLAB) was established under Act. No. 32 of 2005. It has accredited 20 chemical laboratories, 13 mechanical, electrical and biological testing laboratories (organizations) in Sri Lanka up to October 2013. However, compared with the number of laboratories offering testing services in Sri Lanka, this number is relatively small though increasing at a rapid rate. Though the number of total testing laboratories in Sri Lanka is difficult to estimate, according to the statistics of Sri Lanka Association of Testing Laboratories (SLATL), only 39% of their membership is accredited out of 84 member laboratories.

As can be seen from the above, non-accredited testing laboratories play a critical role in laboratory network in Sri Lanka. However, no proper mechanisms are in place to control the level of quality maintained in non-accredited laboratories and little research is carried out about these laboratories and their ability to provide valid results.

However due to low cost of testing for the customer, speed of delivering results, high acceptability in local society due to non-awareness on accreditation process and its benefits to final customer, convenience (place, long term relationships etc.), a large number of tests are carried out in these testing laboratories.

Objectives of the Study

This research analyzes several non-accredited testing laboratories in Sri Lanka and derives conclusions from observations of several tests conducted in these laboratories to identify the adequacy quality control measures adopted by non-accredited testing laboratories. The study also investigates the technical and managerial skills possessed by the staff related to a laboratory. This research aims to evaluate and comment on the ability of those laboratories to consistently deliver reliable results using the results on above aspects.

Literature Survey

The results of non-accredited tests pose a question mark as theses laboratories have not undergone a rigorous external quality check. While most laboratories follow instructions stipulated in testing method/standard, general adherence to laboratory quality framework laid down in ISO 17025 is rare. Such issues are common for most developing countries.

Attempts to improve laboratory quality management and to get accredited encounter various problems. Typical for a developing country, insufficient lab personnel, inadequate maintenance of lab equipment and budget constraints due to inconsistent financial support are primary problems. International financial assistance does not ensure long-term sustainability (Siddiqiet al., 2005; Sriinsut, 2009).

In a research carried out in Thailand, Suvagandha (2009) found laboratory management skills in Thailand (57 percent) are not as good as technical skills (70 per cent), which suggests there are more management than technical problems. Solving technical problems is not difficult whereas solving management problems does not have any standardized approach because management issues are context specific. An example of management problems was found in the study of Manoromana & Wattanasri (2007). They found one management requirement of control of non-conformity received the lowest score (43 per cent), which meant many laboratory personnel did not clearly understand how to respond to non-conformity according to the standard required. In addition, they did not have policies and procedures to review and analyzed on-conformities or identify eligible personnel to correct procedures and develop preventive measures.

The common obstacles for large private firms to apply for ISO registration are too much document work, difficulty in con-trolling documents, lack of co-ordination between departments, lack of communication between management and employees, and resistance to change. Although SMEs have simple organization structures so that the first four road blocks can be overcome (Industry Department

(Hong Kong), 1996), they have problems of limited resources such as time, manpower and technical knowledge which eventually lead to appreciable capital investment (Spendlove, 1997)

Methodology

A field study based on a structured questionnaire and personal interviews was carried out in ten non-accredited laboratories in Sri Lanka to collect data that included eight physical testing laboratories and two chemical testing laboratories. Eighteen test methods and twenty one actual tests were observed to gather data. Twenty four employees were given a structured examination and interviewed.

In this research attention was drawn to investigate whether the laboratories have implemented adequate level of quality control methods using ISO 17025 as the basis. Specific clauses stipulated in the requirements of ISO 17025 were considered for the assessment. These were specifically chosen because the existence of these requirements implies that the laboratory/organization has been able to construct the basic work for accreditation in a future date.
Each clause selected was subdivided in to a set of objective requirements which was examined in each laboratory/test method/test. The laboratory was decided to have complied with minimum quality control procedures related to the clause if these requirements are met as per the acceptance criteria developed by the researcher.

Results and Discussions

The following table summarizes the information about the test methods observed in this research. Out of eighteen test methods five test methods covered chemical testing area where as thirteen were in the area of physical testing.

Table 1 - Information about the test methods and actual tests observed

Test Method	Test Type	Number of Test Methods Observed	Number of Tests Observed
Latex testing	Chemical	4	5
Composition in metal using AS	Chemical	1	2
Hardness of Rubber using SHORE A/IRHD N/IRHD M	Physical	3	4
Tensile test of Rubber/Metal/Plastics	Physical	4	4
Abrasion Resistance of Rubber	Physical	1	1
Density of Rubber	Physical	1	1
Determination of maximum force and elongation at maximum force for Textiles and Garments, plastics	Physical	2	2
Sole adhesion test for footwear	Physical	1	1
Thickness of polyethylene	Physical	1	1
Total		**18**	**21**

Analysis of Quality Control Methods in Laboratories

The study analyzed non-accredited laboratories based on management and technical requirements of ISO 17025. The following table summarizes the information about the clauses developed.

Table 2 – Acceptance Criteria for the research

Class of requirement as per ISO 17025	Relevant clause in ISO 17025	Set of Requirements examined to decide whether the laboratory can be considered as achieved requirements in clause	Acceptance criteria
Management Requirements of ISO 17025	*Organization* Clause 4.1.4 – The responsibilities of key personnel shall be defined including appointing a member of staff as Quality Manager (however named)	1. Presence of a high level officer that has formal responsibility of overall quality management process 2. Responsibility for signing reports and the authority for carrying out tests is identified	All requirements in column three must be satisfied
	Management System Clause 4.2.2 – The laboratory shall document its policies, systems, procedures and instructions to the extent necessary to assure quality of test	1. Presence of a Quality Manual, Method Manual/Procedure Manual or Instruction Manual (however named) 2. Operating/Safety instructions are visible near the equipment	All requirements in column three must be satisfied
	Control of Records Clause 4.13.1.3 – All records shall be legible and shall be retained is such a way that provide a suitable environment to prevent damage during established retention time	1. Retention time of reports are formally documented 2. Past test results, reports and other important records are stored in a safe manner in a safe place	All requirements in column three must be satisfied
	Clause 4.14.1 – The laboratory shall periodically with a predetermined schedule and procedure conduct internal audits	1. The laboratory has a developed procedure to audit their own procedures and verify compliance 2. Responsible persons for verifying compliance with existing laboratory procedures are recognized officially	At least one requirement in column three must be satisfied
	Personnel Clause 5.2.1 - Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience or other	1. The officer who is conducting the test and calculating the result should be sufficiently capable of handling the test and doing the calculation evaluated based on his past	Requirement in column three must be satisfied (a matter of opinion is needed)

	demonstrated skills as required	education, training or experience	
	Accommodation and environment Clause 5.3.1 - The laboratory shall ensure that environment conditions do not invalidate results or adversely affect the required quality of measurement	1. A method for monitoring environmental factors such as temperature and humidity if specified in the test standard is present	Requirement in column three must be satisfied
Technical Requirements of ISO 17025	*Selection of methods* Clause 5.4.2 - The laboratory shall use methods which meet the needs of the customer and appropriate preferably international or national standards and the latest version Clause 5.9.1 – The techniques are used to determine the performance of a method/laboratory	1. Use of reference materials as specified in the standard 2. Use of proficiency/inter-laboratory tests 3. Uncertainty calculations are done 4. Duplicate tests are done as per the standard	At least two requirements in column three must be satisfied
	Equipment Clause 5.5.2 - Calibration programs need to be established and checked before use. Equipment shall be operated by authorized personnel only	1.Calibration schedule/plan (However named) is present 2.Authority to operate equipment in a laboratory is documented 3. Access to a laboratory is limited to authorized persons	At least two requirements in column three must be satisfied
	Reporting the results Clause 5.10 - The results of each test shall be reported accurately, clearly and objectively in accordance with the standard method.	1.The final report are going through a formal and documented checking process before dispatch*(1) 2. The report states the important aspects of the test*(2)	All requirements in column three must be satisfied

* (1) These include unique identification of sample, details of customer, test method, conditions of the test, a valid signature with the designation

* (2) Some laboratories have fulfilled this condition partially. For example some test reports issues by the laboratory had stated all important aspects mentioned in (1) above whereas some reports did not. In such circumstances, if the laboratory issues majority of test reports with the required details, such laboratories were considered to conform with the requirement.

The following result was observed after the research on above aspects. The laboratories which have achieved the minimum quality control procedures successfully are given as a percentage of total number of laboratories researched.

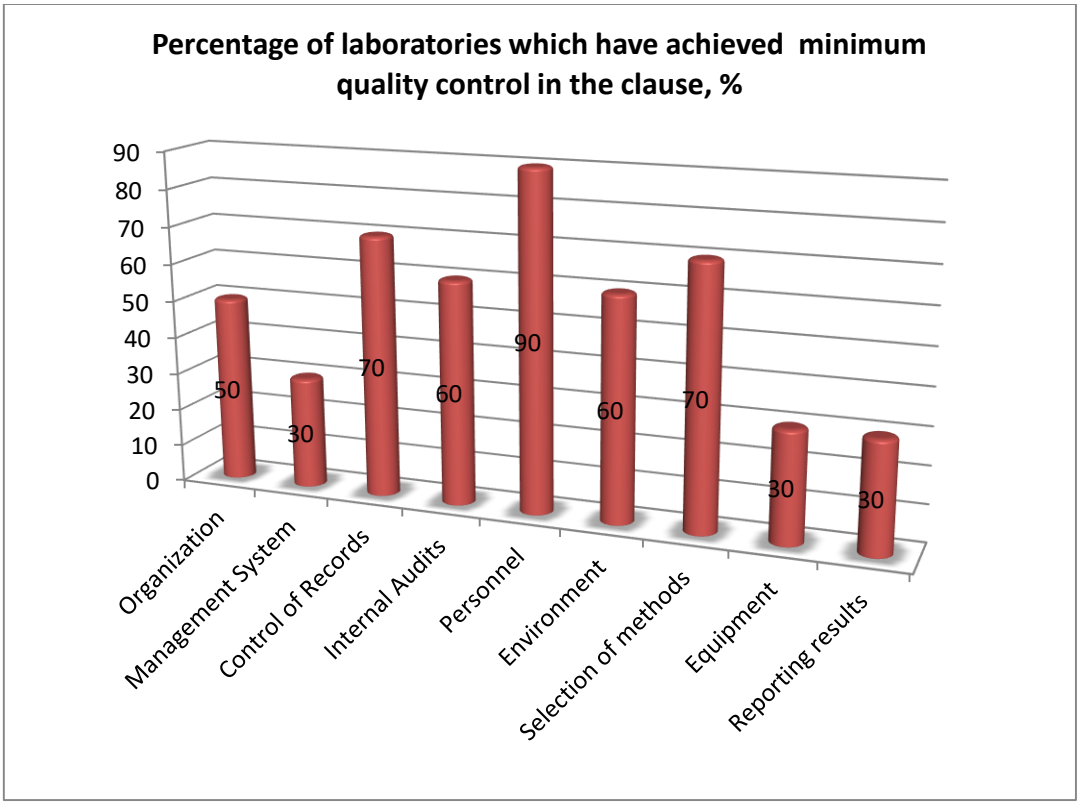

Figure 1: Laboratories which achieved minimum standard

The study identified that less than 40% laboratories observed, used adequate quality control methods in conducting the tests in aspects related management system, equipment and reporting results. Less than 70% laboratories observed, used adequate quality control methods in conducting the tests in aspects related to organization, internal audits and laboratory environment. Only one laboratory had fulfilled all the nine requirements.

Erroneous procedures and deficiencies in conducting the test were observed in many aspects. Ignorance of conditions laid down in the relevant test method/standard, inappropriate handling of testing equipment or standards by the staff, non-use of quality control samples when required and errors in documentation and issuing of the test report were the four major shortcomings in test methods. Three major deficiencies in laboratory quality control included calibration issues, not enough facilities to monitor the test environment and lack of documentation in quality procedures.

In some laboratories, employees are under pressure from their supervisors to work with numerous documents for laboratory quality management. These records or document sometimes had become their first priority whereas providing reliable and accurate testing should be.

Technical Competency and Laboratory Management Skills of the Staff

A structured test was given for 24 employees who are working in the 10 laboratories of the research to find out the technical competency and laboratory management skills of the staff. The structure of the test is as follows.

The class of question	Explanation
Two questions on the specific test method adopted based on the relevant standard. These two questions were changed depending on the test method being evaluated.	The objective of these questions is to test the technical competency of the employee. It questions about specific technical details of the standard that are compulsory to carry out the test. The employees were allowed to refer to the standard. Example questions were: 1. How many reading should be taken to express Rubber Hardness IRHD-N? 2. What accuracy should you express the final result (number of digits)
Five MCQ type questions that are common to all employees that assess the general laboratory quality management knowledge and skills as per ISO 17025	It questions about some important concepts/terminology of laboratory quality management that are useful or compulsory to deliver reliable results. Five questions were 1. The standard that deals with laboratory quality management is, 2. Calibration is a process of, 3. Proficiency tests are, 4. What is understood by the term “reference sample”? 5. What do you do if you suspect that equipment is giving faulty results?

From the evaluation the following results were obtained.

Question	Percentage of employees who answered successfully to the question out of the total number of employees evaluated
1.	82%
2.	91%
3.	45%
4.	64%
5.	23%
6.	60%
7.	57%

Although 56% of the employees examined had sufficient technical knowledge to carry out the given test, only 30% had satisfactory understanding of general quality management policies laid down in ISO 17025. As accreditation bodies that recognize the competence of testing laboratories use ISO 17025 as the basis for accreditation and adherence to ISO 17025 standard increases the possibility of generating technically valid data, low knowledge and skills of the principles of the above standard raises a major issue about the standard of the non-accredited laboratories.

Conclusion

The primary conclusion to be drawn from the foregoing study of non-accredited testing laboratories are that due to inadequate level of quality control procedures implemented in most of the non-accredited laboratories and due to the lack of knowledge of the staff in these testing laboratories in quality assurance principles, the ability of non-accredited laboratories to consistently deliver reliable and valid results is highly doubtful.

When evaluated on nine clauses of ISO 17025, the study identified that less than 40% laboratories observed, used adequate quality control methods in conducting the tests in aspects related management system, equipment and reporting results. Less than 60% laboratories observed, used adequate quality control methods in conducting the tests in aspects related to internal audits and laboratory environment.

Ignorance of conditions laid down in the relevant test method/standard, inappropriate handling of testing equipment or standards by the staff, non-use of quality control samples when required and errors in documentation and issuing of the test report were the four major shortcomings in test methods. Three major deficiencies in laboratory quality control included calibration issues, not enough facilities to monitor the test environment and lack of documentation in quality procedures.

Turning to the competency and knowledge of the employees of non-accredited laboratories, although 56% of the employees examined had sufficient technical knowledge to carry out the given test, only 30% had satisfactory understanding of general quality management policies laid down in ISO 17025. Low knowledge and skills of the principles of the ISO 17025 standard possessed by the employees further augments the doubts about the standard of the non-accredited laboratories.

As in most circumstances, the results are used for an important purpose in the industry such as to assess the quality of a product, research and product improvements purposes, etc. immediate action is needed rectify the above situation if we are to make our laboratory tests reliable and internationally acceptable.

Recommendations

The following recommendations are provided to improve the standard of the Sri Lankan laboratory network and able both accredited and non-accredited laboratories to produce results that are accepted internationally.

The policy makers should develop less rigorous basic acceptance criteria for non-accredited testing in Sri Lanka similar to a one developed in this research using ISO 17025 standards as the base document. Once developed, it can be used to check as to whether laboratories comply at least the basic requirements of the ISO 17025. If not such laboratories must be forced to improve the quality standards by various means as these laboratories give non reliable results. Practicing universal precautions must be maintained at all times, e.g. do not drink, eat or keep food in the laboratory.

As highly knowledgeable and experienced lab personnel are required to carry out testing procedures such technical and non-technical competency must be developed through regular training programs and workshops. The accreditation officials of Sri Lanka need to provide non-accredited laboratories with the required expertise and resources in order to improve the competency of the laboratory employees. More accent should be given to improve the knowledge on quality framework of laboratories as this research suggests that most of the employees already possess technical skills related to testing and since most non accredited laboratories have already fulfilled minimum requirements laid down in “Personnel” clause, the potential for improvement of staff in these laboratories are evident. On-line technical training via country laboratory quality websites is an option available to government to educate any lab personnel without any cost to the laboratory. Knowledge sharing after outside training has been initiated in many laboratories which allows staff who has not had the opportunity to be trained elsewhere, to benefit from outside training with minimal extra expense.

Vision, mission and policy of the organization/laboratory should be clear. The top management needs to encourage staff to embrace and develop quality management procedures step by step through employee motivations and appraisal schemes targeting quality improvements. The top management of these organizations should be educated on the accreditation process and benefits of accreditation and the high responsibility lie on a laboratory.

Consistent financial support need to be provided as adopting quality management systems gives long term benefits and initial high costs. Calibration, Proficiency and inter-laboratory testing, reference samples, environment monitoring equipment are costly and compared with the income such quality principles may be difficult to be adopted by these laboratories with often small and medium scale investments. The government of Sri Lanka needs to give assistance to these laboratories through sustainable programs. Some suggestions may be:

- Calibration process is carried out for a special discounted cost for SME sector
- Encourage participation in inter laboratory testing with the leadership of already accredited renowned government laboratories
- Start a proficiency testing program in Sri Lanka which would reduce the cost of proficiency programs conducted abroad at the moment by 1/3rd
- Distribute reference samples at an affordable price for SME sector for critical testing parameters of national importance

High work load, insufficient and demotivated staff is a critical reason for low adoption of quality principles as staff lack time to engage in activities that are concerned with laboratory quality. The staff must be allowed and encouraged to engage in quality and continuous improvement activities regularly in addition to day to day work.

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