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Laboratory Management System and Competency of Accredited Laboratories

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Abstract

ISO/IEC-17025 is one of the most important standard for testing and calibration laboratories the world. By implementation of this standard, an ideal laboratory management system can be established. The standard is a single most important tool for showing the competence of testing and calibration laboratories which is accepted by everyone in the world. Accreditation of the testing and calibration laboratories is an independent system to show the confidence in the customer by choosing accredited laboratory. ISO/IEC 17025 is the symbol of Quality and competence in the testing & calibration laboratory. All over the world quality has become significant subject in life. ISO/IEC-17025 accreditation provides the assurance regarding calibration and testing laboratories for providing best services and maintaining the records with all evidences. ISO/IEC-17025, accreditation help to the laboratories to reduce the risk, ensuring that customers have chosen a technically competent laboratory that has quality management system in terms of competent personnel, equipment, PT/ILC, MU, method validation etc.

Keywords: *Accreditation, Competence, ISO, Quality, PT/ILC, MU.*

Introduction

Accreditation of testing and calibration laboratories according to ISO/IEC-17025 standard is not easy task, mainly for those laboratories located at teaching and research institutions (Mijrab, *et al*., 2016). In order to become efficient and competitive in today's business environment, the majority of organizations are being encouraged not only to change their old operation habits, but also to develop better ways to ensure that customers are satisfied with the quality of products and services (Magd 2010). ISO/IEC 17025 is the global quality standard for testing and calibration laboratories. Today's competition is quite tough and the quality

of the products on the market needs to satisfy some kind of need expressed by potential customers. International Organization for Standardization and International Electro technical commission, both has endorsed the ISO/IEC-17025 standard with the aim of bringing global approach for acceptance of testing and calibration laboratories**.** The objective of the ISO is to develop standards that have economic and technical impact on countries around the world (Boyer and Verma 2010). ISO is an independent, non-governmental organization with a membership of 164 national standards bodies. Through its members, ISO brings together experts to share knowledge and develop voluntary, consensus- based, market-relevant International Standards that support innovation and provide solutions to global challenges. ISO has published more than 21,500 International Standards and related documents, covering almost every industry, from technology to food safety, to agriculture and healthcare (ILAC). Standard is a technical document, established by consensus that provides rules, guidelines or characteristics for activities or their results (ISO /IEC, 2004). This is a voluntary, third party reviewed process that ensures laboratory's quality management system is thoroughly evaluated on a regular basis to guarantee continued, technical competence and compliance with ISO/IEC-17025 (www.standards.org).

International standards with a slogan "make things work"; they provide specifications for products, services and systems to ensure quality, safety and efficiency (ISO, 2017). Implementing an ISO/IEC-17025 laboratory management system is a means to ensuring the competency ~~in~~ of calibration and testing laboratories. A laboratory that establishes a laboratory management system compliant with ISO/IEC 17025 joins the growing world partnership of accredited laboratories (PJLA, 2009). One of the main advantages is that a laboratory will gain international recognition for its commitment to quality, competency and reliable results. In addition, ISO/IEC-17025 accreditation will signify that you comply with an internationally recognized standard, thus easing the global exchange of valuable information. This is only one example of what ISO/IEC-17025 accreditation can do for your company. There are many other reasons to pursue accreditation (PJLA, 2009). Standards are very important tools for gaining and establishing economic and trade performance worldwide, meanwhile these standards create a reliable base for trade and increasing customer satisfaction. One important accreditation benefit is that any test or calibration certificate issued by laboratory that is accredited by AB that is a signatory and signed Mutual Recognition Agreement (MRA) is accepted throughout the World. The laboratory, thus, gains international recognition for its commitment to quality, competency and reliable results. On 31st January 2001, the ILAC MRA was signed including both calibration and testing laboratories. In October 2012, the ILAC MRA further expanded to incorporate the accreditation of inspection bodies. In May 2019, the ILAC MRA was further extended to include the accreditation of proficiency testing providers. In 2018, almost 76,500 laboratories and over 10,500 inspection bodies were accredited by ILAC MRA Signatories (ILAC/IAF 2018). Accreditation of laboratories plays an essential role on the international stage as it minimizes barriers to trade. With accreditation, test results produced in one country is accepted everywhere. Accreditation of the laboratories as per ISO/IEC-17025 is an effective marketing tool for testing, calibration laboratories and a passport to submit tenders to contractors that require independently verified laboratories. Laboratory accreditation provides a benchmark for performance, a range of marketing advantages and international recognition of technical competence. Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence. 80% (04 trillion US$/annual) of world trade involves some level of conformity assessment. UNIDO has also published information to demonstrate how standards and accreditation can support the achievement of the United Nations sustainable development goals (ILAC/IAF 2018). The main reason of accreditation ISO/IEC 17025 according to (Catini, *et al.*, 2015) is to prevent many deviations from occurring and to give the laboratory's customers confidence in the quality of the services provided by the laboratory. (Catini, *et al.*, 2015) Describes that there is also the financial situation affecting the quality of the laboratory in the management of all materials and service requirements, hence workers and their performances are key to organizational effectiveness. ISO/IEC 17025 allows firms, on the one hand, to obtain a high degree of professionalism, and strengthening customers' confidence on test / calibration results, and on the other, reduce costs by preventing mistakes and time wasting and allowing improvements in the corporation's process. However, in spite of its advantages, the problems can be also found in its implementation (Gharibi and Abdullah, 2017)

(Khodabocus and Balgobin 2011). Hence, for successful implementation, laboratories must find out what activities or factors will affect the results that laboratories expect based on their culture and their goal. Laboratory management is a very important element in ISO/IEC-17025. Especially when it involves practical work for testing and calibration laboratories. Findings (Mijrab *et al.,* 2016) on performance evaluation of labs were based on factors that correlate with economy such as price, quality and delivery time Quality has a cost, it is not free, is the cost spent on assuring quality justified? Does it raise the price of services delivered? Are huge savings possible by implementing continual improvement efforts. These answers may not be obvious as many times the effect of an efficient quality system is seen gradually. However quality is measurable, as are its costs. The cost of quality is "the expense of non-conformance, the cost of doing things wrong." Some prefer the term "cost of poor quality" because that implies what happens when continual improvement efforts are derailed or postponed. What is often seen is the cost spent on assuring quality and not the cost of correcting errors that may happen due to lack of a consistent quality system. So quality assurance is the essential organizational infrastructure that underlies all quality measurements. This would include all aspects of a laboratory like staff training and management, adequacy of lab equipment and environment, safety, storage, integrity and identity of samples, record keeping, maintenance and calibration of instruments, use of validated methods and standard reagents, which ultimately translates into quality of analytical measurements. Failure in any of these areas would reflect adversely in achieving the desired quality (Philip, 1996).

Discussion

The Philosophy of ISO/IEC-17025 standard is to generate authentic results, assurance, consistency, objectivity, independence and impartiality during all testing activities.

Benefits of ISO/IEC-17025 STANDARD (Panhwar *et al.,* 2020)

- National and international reputation and recognition.
- Strong interaction between laboratory and customer.
- Confidence of customers.
- Reduction of testing cost.
- Systematic & professional operational approach and environment
- Upgrading of laboratory testing environment.
- Documentation of all testing activities in laboratory.
- Boosting self-confidence, confidence and capability of employees.
- Regular trainings of laboratories personnel
- Well-organized working structure of laboratories, development of quality culture and edge of marketing
- Validity of test methods and providing accurate data.

Human factor is also reason of the inefficiency of top management in case of weaknesses is not addressed. To increase effectiveness of the management, quality management should evaluate all aspects of laboratory management through assessment. An evaluation mechanism should be established through a number of key criteria in terms of documentation, security, environment and equipment. This assessment should be evaluated by customers who use the laboratory. The evaluation or findings are then reported in terms of percentage of achievement. Service quality begins by the dedication of the top management. The Management should also provide ongoing advice and training to clients and staff in conducting customer relations. Training should be implemented at various levels /methods of management training, leadership, teamwork training, personality training. This is useful in linking supervisors, lecturers, lab supervisors, technicians and students together to understand the roles of each other within the organization (Mohamad *et al.,* 2012). Improvement continuously is an important element in a successful quality strategy. Stop improving means there is no positive changes which soon lead to being less successful. The basic rule for

continuous improvement is that it is always possible to improve processes, products or services in a way the input resources is reduced, quality of output is increased or cost is lowered. The challenge is to find the right way to change to improve. Another vital aspect is the mind-set that everything can be improved; get a better match of customers' needs with fewer resources (Victor 2012). The laboratory system can be improved with the implementation of ISO/IEC-17025, the laboratory, personnel and the customer enjoyed a range of benefits like increase in export, improvement in quality of food and non-food items. Good traceability, participation of personnel in all laboratories processes, acknowledgement of analytical competency, benchmarking for performance in proficiency testing, advertising benefits, international recognition, minimization of risks, customers's satisfaction and reduction of cost in testing. The achievement of the laboratory management system implementation, based on ISO/IEC-17025, is achievable if availability of adequate resources and commitment from top management of organization in government and private sector. Internal and external audits can also be used as a tool to assess and to maintain Quality. An internal audit is a requirement of ISO/IEC-17025. An audit is a systematic independent examination of the entire quality management system. This in turn can verify analytical quality (Victor 2012).

Audits also help in recognizing problems, taking corrective action and initiating preventive actions. Quality Indicators: It is advised for each laboratory to set up a list of quality indicators which will determine and monitor as well as the analytical quality of the Laboratory as the overall Quality System performance. It is vital, not only for individuals and organizations but for national and international economic health, that products and services can cross borders to meet global demand without causing undue risk to the health and security of individuals or the environment. Management should always strive to adhere to customers' satisfaction by conducting research every year. Research can be considered as a journey of discovery and whether anything is discovered or not-the essential feature is that it should make an original contribution to knowledge. Considering the discussion and conclusion, it is vital to make the quality management system specific to the organization's needs and resources. The three principles; process view, continuous improvement and commitment from everybody should be considered and implemented (Victor 2012).

Customer satisfaction is adopted as a strategic objective for most organizations. It is not only acknowledged in the private sector, but also in the public sector. The customers who receive services from the laboratories request the implementation and accreditation to laboratory standards as a means of quality assurance (Srivastav, 2009). (Robinson, 2005) Eludes that test or calibration reports issued by non-accredited laboratories may lack credibility and they do not carry much legal weight if the results are presented to resolve any disputes that may arise. Some extent accreditation can increase paper work and work load, internal quality control and running costs of operating the laboratory. The benefits associated to accreditation can be analysed from three different angles; the laboratory's personnel, the laboratory itself and the clients. With the use of appropriate procedures, staff will be more confident about their work. They can easily identify errors and their sources. Thus they can implement necessary corrective actions. Competition in the global economy and the market today also demands that service companies create well-designed quality management system and implement them effectively (Psomas, *et al.,* 2013).

Conclusion

Laboratory Management System is the only way to improve the performance of the laboratories and confidence of customer. LMS is process in which laboratory develop documentation as per international standard, and through implementation, can get reliable results of testing ad calibration laboratories. Laboratory management system which is only possible, if followed appropriate procedures and management methods, then human error will be minimal. Through implementation of the laboratory management system it can show that the quality of test results of the laboratory are authentic and reliable. With existence of the laboratory management system, the laboratory carried out its quality assurance activities including measurement traceability record, error prevention, and corrective actions.

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