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RESEARCH ARTICLE

LABORATORY QUALITY IMPROVEMENT BY ISO/IEC-17025 ACCREDITATION: A CASE STUDY OF PCSIR

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ABSTRACT

ISO/IEC-17025 is an ideal International laboratory management system for testing and calibration laboratories. All over the world the testing and calibration laboratories are accredited as per ISO/IEC-17025 standard. Accreditation is an objective way to comfort your clients that you have established technical competency to issue authentic and correct results to enhance the reliability and confidence of the customer. PCSIR is the first ISO/IEC-17025 accredited testing laboratory in Pakistan, accredited in 2004 by Pakistan National Accreditation Council (PNAC). In 2007, PCSIR-KLC laboratories were also accredited by Norwegian accreditation, Norway. The laboratories have completed its 4 cycles of accreditation and 5th cycle 2019-2021 is in progress from PNAC. First cycle of accreditation was of 4 years and other 3 years each. At present more than 400 parameters are accredited and more than 100 technical personnel are involved in testing& calibration activities. The quality policy of the laboratory is to make sure accurate and appropriate analytical services to its customers particularly trade community/ exporters by meeting the needs of the customer from government and private sector. PCSIR is also largest testing and calibration laboratory and research organization of Pakistan, have active research in a number of areas. The number of scientist, engineers and technologist are keenly participating in research & testing activities as per records of the last decade. The personnel/scientists are experienced with higher degrees in related fields from highly ranked institutes. Distinguishing features of the laboratory including its infrastructure, area, size, equipment, trained personnel, implementation of ISO/IEC-17025 made the laboratory confident and reliable, to handle internal research, testing and calibration in the same laboratory.

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INTRODUCTION

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. ISO/IEC-17025is the only approved standard for testing and calibration laboratories around the world.ISO/IEC-17025 is comprised of 8 Clauses out of which first 03 are base for the implementation of other 05 clauses. Furthermore these 05 clauses are divided into two parts first management requirements and second technical requirements. Each clause contains in it the clear aspect about requirement of procedures, policies, and instructions to maintain the management system. Management requirements are connected to the operation of the laboratories and effectiveness of the laboratory quality management system and these have similar requirements as that of ISO 9001.

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Technical requirements address the competence of staff; testing methodology; equipment, quality; and reporting of the results (Dr. Ludwig Huber, 2009).The Philosophy of ISO/IEC-17025 standard is to generate authentic results, assurance, consistency, objectivity, independence and impartiality during all testing activities. A testing laboratory is a place where research, testing, measurements may be carried in a controlled environment. 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 (ILAC). Laboratory accreditation provides a benchmark for performance, a range of marketing advantages and international recognition of technical competence (ILAC). Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence. Accreditation is an objective way to assure your customers that you have demonstrated technical competence to provide reliable and accurate test or calibration results. Accreditation is objective because an independent, third party accreditation body performs annual assessments to verify whether your

system is meeting all of the requirements of ISO/IEC-17025. This independent evaluation is important to the customer, because it is an unbiased guarantee that your laboratory is performing at its highest level (PJLA, 2009). By having your laboratory management system accredited to ISO/IEC-17025, your company stands to gain a gold mine of benefits. One of the main advantages is that your 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 (PJLA, 2009). Pakistan National Accreditation Council (PNAC) is an accredited body which accredited testing, calibration and medical laboratories in Pakistan. Presently, more than 164 laboratories are accredited by PNAC.

According to ISO, it is estimated that across the world there are approximately 100,000 testing and calibration laboratories that are using the ISO/IEC-17025 standard as the main source for their laboratory accreditation (PECB). 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. Accredited conformity assessment is one tool that is helping businesses not only to comply efficiently and effectively with regulations and standards around the globe but also to gain competitive advantage from doing so and to expand into new markets, including those overseas(IAF/ILAC, 2018).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 (IAF/ILAC. 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. The data generated by accredited laboratories is more readily acceptable on the overseas market. By reducing or eliminating the need for retesting in the importing country, manufacturers and exporters can reduce costs (ILAC, 2001). Some extent accreditation can increase paperwork and work load, internal quality control and running costs of operating the laboratory and to maintain documentation procedures and records to operate the laboratory management system and the additional control of records to verify on tests carried out and calibration results. The validation for test methods is another additional load for laboratory staff (EURACHEM. 2008). Accreditation demonstrates the technical ability of a laboratory to carry out specific tests and thus provides a formal identification to competent laboratories. This recognition is a way for the customer to select reliable testing services suited to his needs. The logo of the accreditation body on the test reports of the accredited laboratory ensures the client about the results delivered (ILAC 2001). 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, 2013). Socio-economic activities cannot be separated from the measurement (Khodabocus, F and Balgobin, K, 2011). Food safety, health and environmental protection depend on chemical measurement analysis, so laboratory accreditation is required based on ISO/IEC-17025 standards to obtain accurate measurements (Khodabocus and Balgobin, 2011). There is no question that implementing and maintaining a quality system is costly to the testing laboratory. This cost is both a direct cost and in terms of the non-recoverable time people put into developing, testing and checking the system. (Karen Hullihen, 2008). A laboratory quality system is never complete, continuous improvement is a goal of our system and that of all other laboratories.

Through internal reviews and continuous monitoring changes have been made and continue to be made (Karen Hullihen, 2008). Estimation of uncertainty of measurement is also a mandatory requirement of the standard. As per guide 98-3, the uncertainty is defined, as a parameter associated to the measurement, which characterises the dispersion of the values that could be attributed to the measure and (ISO/IEC-2008*)*. In latest version of ISO/IEC-17025 new term of Decision Rule introduce to ensure validity of results, also a new term of Risk Assessment introduced in clause 8.5. The laboratory has to identify risk in all areas of activity and to initiate possible controls to eliminate risks and to ensure risk may not re-occur. .Measurement Traceability is also mandatory requirement, define as "Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties" (Eurachem 2003).

MATERIALS AND METHODS

Study design: This is a descriptive study, designed to compile the impact of execution of ISO/IEC-17025 in chemical testing and calibration laboratories of PCSIR, KLC.

Study area: Study was conducted in PCSIR laboratories complex, located in Karachi, a trade center and provincial headquarter of Sindh, Pakistan.

Data collection: Data was compiled through record of different accredited laboratories of PCSIR, laboratories complex, Karachi.

BENEFITS OF ISO/IEC-17025 STANDARD

- 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.

Table 1. Management and Technical Requirements.*[ISO/IEC-17025:2017]*

Technical Clauses	Management Clauses
6.1. Personnel	4.1. Impartiality
6.2. Facilities and Environmental conditions	4.2. Confidentiality
6.4. Equipment	8.2. Management system documents
6.5. Metrology Traceability	8.3. Control of management system documents
6.6. Externally provided products and services	8.4. Control of records
7.1. Review of request, Tenders and contracts	8.5. Action to address risk and opportunities
7.2. Selection, verification and validation of methods	8.6. Improvement
7.3. Sampling	8.7. Corrective action
7.4. Handling of test or calibration items	8.8. Internal audit
7.5. Technical records	8.9. Management review
7.6. Evaluation of measurement uncertainty	
7.7. Ensuring the validity of results	
7.8 Reporting of results	
7.9. Complaints	
7.10. Nonconforming work	
7.11.Control of data and information management	

Table 2. Different parameters in accredited scope

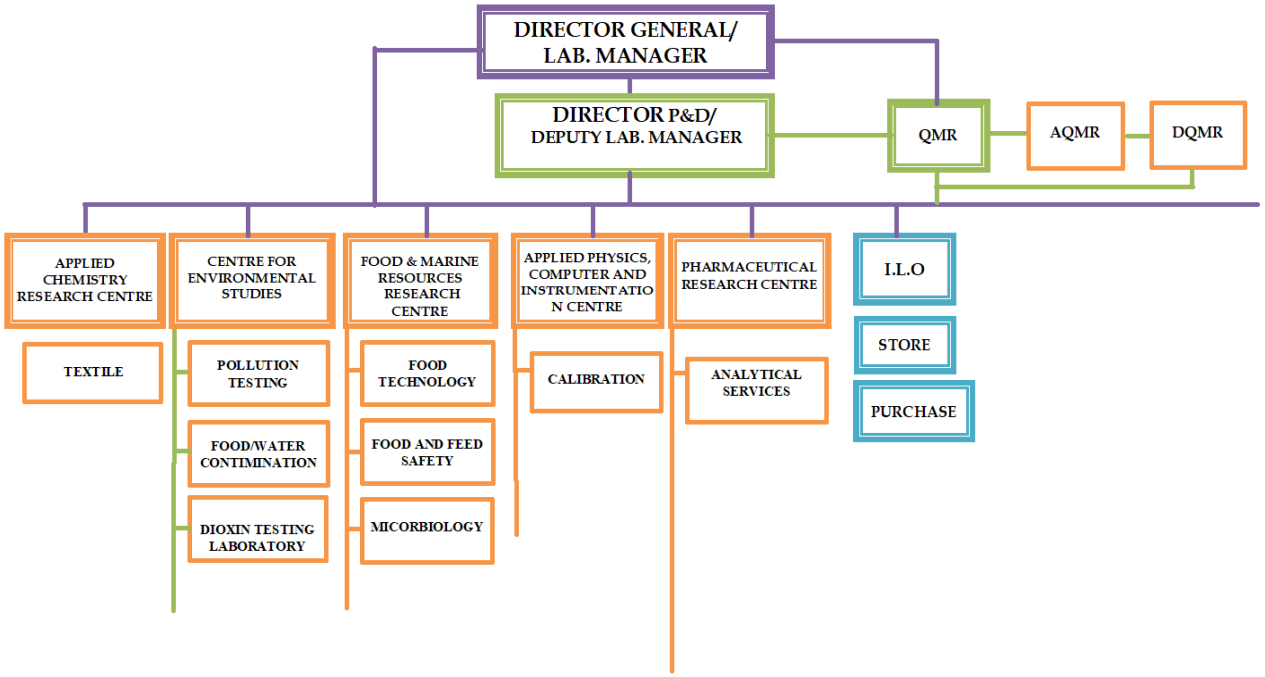
Products	Parameter
Agriculture commodities, Poultry Feed, Raw/Processed food	Protein, Fat, Calorific Value, Total Aflatoxin, Ochratoxin A, etc.
Environment	Water, Pesticides, Heavy Metals etc
Microbiology	Aerobic Plate Count, Total Coliforms, Faecal Coliforms, E.coli etc.
Pharmaceuticals	Vitamins, Sudan etc.
Calibration	Mass, Weighing, Length, , Temperature, RPM,Time, etc.
Textile	Fabric etc.

Table 3. Documentation in the Laboratory Quality Management System [PJLA-2009]

Document number and title	Purpose
Document Control	Outlining how your laboratory conforms to the standard.
Procedures	Describing how the system functions.
Work Instructions	Defining specific job activities affecting the quality of calibration or testing.
Quality Documentation	Documents, which explain how quality will be, managed for individual calibration or testing projects or contracts, as well as other types of specific documents;
Quality Records	Various records including charts, files, inspection and testing records, assessment results, and any other records of objective evidence

MANAGEMENT STRUCTURE OF THE LABORATORIES

Management Structure



CONCLUSION

This paper has summarized on the basis of our knowledge of 15 years in establishing and executing of an ISO/IEC-17025 compliant laboratory in a government sector. On the basis of this study it is concluded that the effect of the ISO/IEC-17025 is clearly visible, the laboratory system have been 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 labs 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.

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