Research Article
Volume 10:4, 2021

Industrial Engineering & Management

ISSN: 2169-0316 Open Access

Non-conformities against ISO/IEC 17025:2017 in Pakistani labs: A study based on Auditing Body Reports

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Abstract

ISO/IEC 17025:2017 deals with the "General requirements for the competence, impartiality and consistent operation of testing and calibration laboratories" (Standardization, Publications and products, 2017) by focusing on both management and technical requirements of laboratories. Management requirements relate to lab operations, auditing, and management review etc. while technical related to testing activities and handling of lab technical resources. Purpose of this article to present the significant non-conformities that testing/calibration labs face during ISO/IEC 17025:2017 accreditation process.

Keywords: ISO/IEC 17025 Challenges, Lab Accreditation Challenges, Lab Audit Handling, Common Audit Findings.

Method

For research purpose; Pakistan National Accreditation (PNAC) final audit reports of 1st time accreditation (26 labs) are analyzed and significant (major) non-conformances are highlighted to identify common critical concerns. Analysis of non-conformances are done by taking percentage of significant non-conformances.

Results

According to this study, target laboratories are facing difficulty in true implementation of Quality Assurance Program (Ensuring the validity of results) especially in Proficiency Testing (PT); 69% of laboratories are facing problems in PT/ILC process; similarly, 50% of the laboratories are facing problems in non-conformance significance evaluation.

Introduction

ISO/IEC 17025 replaced ISO Guide 25 in 1999, till 2020 this standard has been revised twice in 2005 and 2017. (ISO, n.d.) Pakistan National Accreditation Council (PNAC) is the only public sector body in Pakistan with authorization of giving accredited status after successful completion of assessment. PCSIR Karachi, is the first laboratory to achieve accreditation status by PNAC on 30th Jan 2004. After this; a new chapter of accreditation is opened in Pakistan. (Council, 2020) PNAC has a Mutual Recognition Arrangement (MRA) from International Laboratory Accreditation Cooperation for testing and calibration laboratories. This MRA ensures that labs' accreditation status by PNAC is recognized internationally as well, and not just locally. Laboratories are the first and final check for receiving of raw material or passing out product to end user. If the raw material used in product manufacturing is not as per standard then it will ultimately effect the final product or if final product is not as per mark (due to variation in process) irrespective of raw material quality then it will effect end user. In both cases, society will suffer the result of non-conformance product. There are many cases when products failed to meet the requirement as a result society suffered from it. According to market research on drugs sample in under developing countries, around 13.6% of drugs found substandard or falsified as a result these countries suffered from financial loss of $10 billion to $200 billion. (Ozawa S, 2018) As per report of Federal Road Safety Corps (FRSC); 772 out of 9000 reported road side accidents in 2015 were due to sub-standard or expired tyres. (Ajibola Hamzat (Features Editor), 2016) As per public reports, around 24 bike riders lost their lives in Karachi due to usage of sub-standard helmets as the helmets could not save them from serious head injuries. (Abbas, 2019) ISO/IEC 17025 deals with the "General requirements for the competence, impartiality and consistent operation of testing and calibration laboratories" (Standardization, 2017) Laboratory Accreditation is the confirmation by a competent body, on basis of demonstrated objective evidence that a laboratory's management system operates in compliance with the relevant standard (ISO/IEC 17025). During this implementation and operation process of ISO/IEC 17025, laboratories face the number of challenges during system development, implementation and its maintenance (or even further improvement). This study is based on such challenges, highlighted in the form of Non-conformances in PNAC 1st time final assessment reports for ISO/IEC 17025 accreditation. Similar, research has been conducted in Hong Kong for ISO 15189 (Medical Laboratories requirement for quality and competence) by Bella Ho & Eric Ho back in 2012; according to research findings most frequent non-conformities are reported against quality & technical records in management section and examination procedures, equipment, & assuring quality of examination procedures in technical section. (Bella Ho, 2012) According to research, conducted in 500 labs of Brazil from 2008-12; most NCs of ISO/IEC 17025 were recorded against clause 4.3 & 4.13, "Document & Record Control" in management section and clause 5.4 "Test and calibration methods and method validation" & 5.5 Equipment Management. Out of 500 labs, 270 labs have NC in clause 5.4 & 174 labs in clause 5.5 (Morgana Pizzolato, 2015) Denis Glavi ˇc-Cindro & Matic Korun have conducted statistical analysis of ISO/IEC 17025 Assessment (4), External Audit (5) & Internal Audit (32) reports of gamma-ray spectrometry lab from 1998 to 2004; according this assessment, most NCs are reported in clause 5.5 Equipment & 5.9 Assuring quality of test results. (ˇc-Cindro, 2006) From last 3-5 years in Pakistan market, Accreditation of laboratory management system (ISO/IEC 17025) become precarious issue especially for pharmaceutical, electrical, pesticide & automobile due to following reasons:

- In pesticide sector, number of complaints were raised against

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Received 29 October 2020; **Accepted** 23 April 2021; **Published** 30 April 2021

pesticide companies passed product that failed to reproduce the results in government or appellate laboratories which ultimately led to FIRs (First Information Report) against companies' CEO. From 31st May 2018 onward it became compulsory for pesticide companies in the province of Punjab, Pakistan to get their lab ISO certified (The Punjab Gazette, 2018).

- Accreditation of laboratory management system ISO/IEC 17025 became mandatory requirement for electrical transmission vendors in order to participate in tenders due to non-quality testing of vendors. (Waleed, 2019) Transmission department auditors were not able to reproduce all test in their laboratories; so it was decided to perform onsite inspection of electrical products at vendor laboratories and based on the results achieved, the vendors' products are accepted or rejected.

- In pharmaceutical sector; if QC passed products failed in appellate laboratories then it may lead to FIRs getting registered against companies' CEO, Production Manager & QC Lab. In 169th meeting of Provincial Quality Control Board (PQCB), 65 cases of substandard drugs were identified out of which 26 cases were referred to drug court for prosecution. (26 cases referred to drug court, 2017).

- Foreign customers are losing trust on local laboratories because there are many cases where samples failed to reproduced results in customers' or international labs. (Ibraz, 2018).

- In 2018, more than 50 companies' ghee and cooking oil samples were failed by Punjab Food Authority that had been passed by internal labs of the companies, own lab which ultimately led to legal actions. (Authority, 2018).

ISO/IEC 17025 Lab Management System is internationally developed standard of International Organization for Standardization that focusing on improving the quality of test results by targeting following: (ISO, 2017).

i. Lab Personnel requirement mainly focuses on Education, Qualification, Training, Experience, Technical knowledge & Skill lab personnel. On the basis of these requirements authorization for tests are assigned to lab Personnel. Having proper system for managerial & technical personnel selections and personnel development is the key for running effective lab management system. (Sari, 2018) All authorized personnel should act as impartial and secure confidentiality in their scope of work.

ii. Lab Environment for testing/calibration including but not limited to humidity, temperature, microbial contamination, particles, vibrations, dust, air, electromagnetic disturbance, electrical supply and sound, also contribute in test results. For example, in chemical testing laboratories technical/actives are used in minor quantities (mg) for testing activities, for this purpose sensitive weighing balance are used. The reading of the balance may fluctuate with vibration, analyst's breathing, and even sound etc.

iii. Latest and valid test methods that are published by International, national & regional bodies, methods developed by reputable organization or published in relevant science journal or specified by equipment supplier. Irrespective of this; methods need to be verified prior to use in routine testing. Internationally developed methods are verified in laboratory and modified or lab-developed methods require through validation by the laboratory.

iv. Material/Reagents that are directly used in testing or calibration activities should be standardized having proper Certificate of Analysis, to manufacturer.

- Equipment should be calibrated from accredited lab having proper meteorological traceability to national and international standards. Where meteorological traceability is not possible; it should be traceable to consensus standards or competent producer/manufacturer.

- Management System (ISO 9001:2015) to manage the quality of operations related to testing or calibration of laboratories

Accreditation is provided by national accreditation bodies; they are a signatory of ILAC, and the MRA (Mutual Recognition Arrangement) provides an opportunity for international acceptance of the laboratory's results (Karthiyayini Nagarajan, 2016) As per research, countries with high GPD have more accredited laboratories than the countries having low GDP. (Grochau, 2017) In (**Figure 1)** comparison of number of accredited laboratories and GDP are shown.

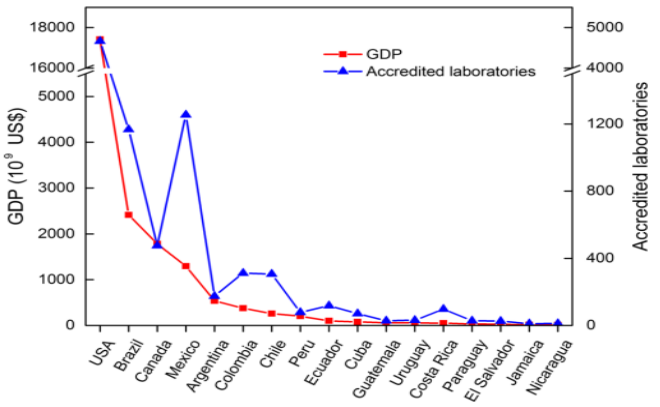

Figure 1: Number of Accredited Laboratories and GDP of the Country.

Moreover, due to system documentation, lab is able to perform and document most of the tasks; due to which internal and external issues of lab are resolved (Elhuni, 2016) Lab Accreditation increases the awareness of lab staff; enhance their technical knowledge skills, credibility, reliability & confidence on test results. Customers receive detailed reports as per guidelines of ISO/IEC 17025 standard. (Abdel-Fatah, 2010) In Pakistan, there has been an abrupt rise of 40% in lab accreditation, in the year of 2018 (PNAC, 2019) which is signifies increase in awareness regarding ISO/IEC 17025 among Pakistani labs.

Methodology

Data for this study is collected from respective labs and field consultants. Accreditation body final audit report of 26 testing & calibration labs including 10 chemicals (pesticides & pharmaceutical), 6 electrical (transformer), 3 livestock, 3 rubber testing and 4 calibration (temperature, volume & pressure) labs from the time period of mid-2017 to 2019 was analyzed in order to extract the required information. Name and any other identification of labs are kept confidential. Final audit reports are completely analyzed and highlighted major non-conformances (NC) are noted based on ISO/IEC 17025 clauses requirement. Only highlighted major non-conformance (defined as "Finding does not meet the requirement of the subsequent clause, neither in form of implementation, nor in documentation which effects the validity of test results") are segregated based on standard clauses requirement as mentioned in table 1. Major NCs of specific clauses are noted and NC percentage (out of 26 labs) has been taken based on "Documents & Non-Conformance Points" as mentioned in column 3 of **(Table 1)**.

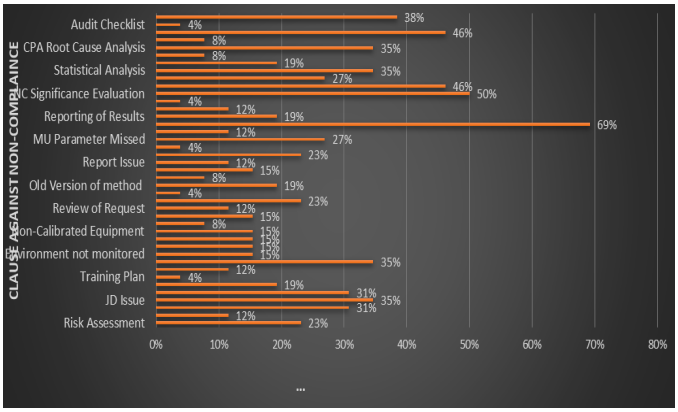

Figure 2: Percentage Non-Compliances during Accreditation Audits.

Table 1: Standard Clauses and Issues Area.

Cls.17025	Clause title	Documents & Non-Conformance Points
4.1 & 8.5	Impartiality and Confidentiality	Policy & Procedure for Risk Assessment is not defined or not followed properly. Risk Related to Lab Activities are not identified
4.2 & 8.5	Impartiality and Confidentiality	No action has been taken against identified risks
5	Structural Requirement	• Organogram is not developed or conflict of interest identified in organogram comparison to on-floor reality. Lab Internal customers have influence on lab activities. • Job Descriptions are not properly defined or conflict in JDs in comparison to on-ground activities
6.2	Personnel	• Lab Authorization Permits are not developed or properly followed • Training Need Analysis (TNA) is not conducted • Training Plan is not developed or followed • Training Effectiveness is not analyzed or system does not exist
6.3	Facilities and Environment condition	• Un-controlled testing Environment • Environmental conditions are not monitored
6.4	Equipment	• Equipment Documentation like Log Books, manual related issues • Equipment Corrective & Preventive Maintenance Plan related issues • Non-Calibrated Equipment or Correction Factors are not considered during testing activities
6.5	Meteorological Traceability	Calibration from non-accredited lab or lack of availability of traceable Certified Reference Material
6.6	Externally provided product and services	Product as well as services supplier selection criteria is not defined or followed
7.1	Review of Request, tenders and contracts	Review of Request system does not exist or sample traceability issue
7.2	Selection, verification of methods	• Test Method Verification is not being performed • Non-Standard Test Method is in practice or amendment is done in internationally developed methods • Old Version of testing method is in practice
7.3	Sampling	• Sampling Plan or international method is not followed
7.4	Handling of test or calibration items	Test items are not handled properly. No system for sample retention and disposal
7.5	Technical Record	• Technical data (rough readings, log books) are not maintained
7.6	Evaluation of Measurement Uncertainty (MU)	• Training on Uncertainty Calculation is not conducted. Lab personnel are not aware of it • Uncertainty measurement is not calculated or complete • parameters that are affecting the results are not incorporated during calculation
7.7	Ensuring the validity of test results (PT/ILC)	• Equipment Intermediate checks system does not exist or no Certified Reference Material is available • PT/ILC of test in the scope, is not conducted or results do not qualify
7.8	Reporting of Results	• Report format is not as per ISO/IEC 17025 or in case of simplified report, lab is not maintaining complete information required on in ISO/IEC 17025
7.9	Complaints & Feedback	• Customer Feedback is not collected or its analysis is missing • Complains of customers are not recorded or addressed properly
7.10	Non-conforming Work	Non-Conformance Significance Evaluation is not addressed in SOP or not followed due lack of awareness
7.11	Control of data and information management	Control of data and information management issues i.e back up, disposal, handling etc.
8.3 & 8.4	Management System Documentation & Records	SOP not followed or un-approved documents in practice
8.6	Improvement	• No Statistical Analysis of lab related activities is performed to identify improvement opportunities • Objectives to bring improvement in lab are not communicated or properly tracked
8.7	Corrective Actions	• Corrective Action Request system does not exist in lab • Corrective Action Request Root Cause Analysis is not properly done by lab
8.8	Internal Audit	• Internal Audit system is does not exist or followed. Internal Audit plan is not developed or shared with auditee • Internal Audit is conducted but all activities like testing, sample handling are not covered in it • Audit Checklist is not properly maintained, incomplete or followed
8.9	Management Review Meeting (MRM)	MRM meeting Agenda is not circulated timely or during meeting minimum agenda points as per ISO/IEC 17025 are not discussed

Results Analysis

For graphical analysis of results; bar graphs are used against each clause as mention in table 1. Percentage non-compliance (major) are given in **(Figure 2).**

Analysis results in figure 2, show the weightage of major non-conformances in in selected laboratories. As per these results, 69% (18) laboratories have faced problem in Proficiency Testing/Inter lab comparison activities (Ensuring the validity of Test Results/Quality Assurance Program) , similarly 50% (13) are facing problem in Non-conformance significance evaluation, 46% (12) in Control of data & information management and Internal Audit Execution, 38% (10) in Management Review Meeting and so on. According to a study conducted by Vongsheree in 2018, newly accredited labs have more non-conformances as compare to labs that are already accredited. (Vongsheree, 2018)

Conclusion

ISO/IEC 17025 has been developed for testing & calibration labs. In this paper, analysis of ISO/IEC 17025 major non-conformities has been presented. Out of 26 labs, 18 labs are facing problems related to Proficiency Testing/Inter lab comparison activities which is mandatory requirement of "Quality Assurance Program/Ensuring the validity of test results" and this is one of the external issue of labs In order to search out ISO 17043 Accredited Proficiency testing provider web browsing expertise are required; this problem has been resolved after development of eptis search engine, dedicated to PT providers. But in some cases, instead of availability of PT providers; the PT provider refuses to provide PT program due to some constraints either due to regional restrictions, geographical limits, or they are reluctant to send samples when it is equipment or device; laboratories need to send back the PT sample to the service provider. (Li, 2018) Awareness regarding this area are being rising day by day that's why till May 2019, four Proficiency Testing providers (PNAC, 2019) have been accredited in Pakistan who cover water, microbial, petroleum, pharmaceutical & limited textile (Socks/yarn) testing. For other sectors like electrical, material mechanical testing, calibration, chemical testing etc. local laboratories are working to get ISO 17043 Accreditation. Other frequent non-conformances; NC significance evaluation, Control of data & information management, Internal Audit Execution and Management Review Meeting are related to internal issues of labs that can be addressed through proper trainings and taking some physical actions against them.

Potential Conflict of Interest

None declared.

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How to cite this article: Yousaf Ayub, Zahid Anwar, Zahid Abbas Shah, Muhammad Mudassar Sharif. "Non-conformities against ISO/IEC 17025:2017 in Pakistani labs: A study based on Auditing Body Reports." *Ind Eng Manage* 10 (2021): 293.