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QUALITY MANAGEMENT SYSTEM AUDIT AND ITS IMPACT ON COMPANY'S PERFORMANCE

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ABSTRACT

The purpose of this paper is to find out the impact of Quality Management System (QMS) ISO/IEC 17025:2005 certification audit on company's Performance. Libyan petroleum Institute has been certified ISO/IEC 17025:2005 for 8 years. Therefore, it is necessary to study and analyze the impact of that certification on its performance. Survey study has been done by distributing a questionnaire by handing it personally to qualified staff in the 15 accredited laboratories in the institute. The response rate was 66.6%. The statistical operations with the results of analytical study have been done to achieve the goal and objectives of the research. Finally, ISO/IEC 17025:2005 certification audit is found to have a positive effect on the institute's performance.

Keywords: auditing process, ISO/IEC 17025:2005, quality management system, Libyan Petroleum Institute

I. INTRODUCTION

Laboratory accreditation assesses the competencies of all types of laboratories in terms of performing specific tests and calibrations. ISO and the international Electro-Technical Commission (IEC) introduced ISO/IEC 17025 standard due to the growing importance of accreditation and international recognition. The assessment of the facilities that calibrate and test equipment is crucial to monitor accuracy of measurement and testing [1]. ISO 17025 is a laboratory standard equivalent to more generic ISO 9000. The standard can be applied by all organizations performing tests and/or calibrations and it can harmonize laboratories worldwide (ISO-9000, 2010). ISO 17025, as all ISO standards, heavily focuses on documenting the process of any analysis performed by a laboratory. It includes the quality management system and technical requirements of the accreditation process.

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The management requirements section of the standard evaluates the organization of the laboratory; its quality system; document control; review of requests; tenders and contracts; subcontracting of tests and calibrations; purchasing services and supplies; service to the customer; complaints; control of nonconforming testing and/or calibration work; corrective actions; preventive actions; improvement; control of records, internal audits and management reviews. This section adapts the ISO 9000 quality management criteria into a laboratory context. The technical requirements section of the ISO 17025 standard evaluates personnel; accommodation and environmental conditions; test and calibration methods and method validation; equipment; measuring traceability; sampling; handling of test and calibration items; assurance of the quality of test and calibration results, and reporting the results. A laboratory must identify both the management requirements and technical requirements of the standard in order to produce a good product and satisfy its customer (ISO/IEC-17025, 2010). Although ISO standards and total quality management implementations have the same objective of improving competitiveness of the organization, they are not interchangeable. They are compatible with and support each other. However, the majority of ISO certified organizations do not fully implement total quality [2].

Nowadays, a wide range of socio-economic activities depend on measurements. Food safety, health and environmental protection are dependent on chemical analyses. As we rely heavily on them, our confidence in chemical measurements can only be boosted by their accuracy. Laboratory accreditation, achieved through the implementation of the ISO/IEC 17025:2005 standard is the process which determines the competence of laboratories in delivering accurate results. On the global scale, with the economic crisis, manufacturers and suppliers need to reduce their operating costs. Using accurate and reliable data, emanating from internationally recognised accredited laboratories, eliminates the need for retesting, thus, reducing costs and minimising technical barriers to trade.

In Libya, the use of quality management systems and laboratory accreditation are acquiring significance in various sectors. Companies are now aware of the benefits of implementing quality management systems and acquiring accreditation. Though the implementation and maintenance processes involve major investment, organisations are conscious of the fact that customer satisfaction is an important asset to their business. Moreover, international companies are more likely to seek the services of an accredited laboratory knowing that their decisions will be based on accurate and reliable data.

II. LITERATURE REVIEW

ISO 9001 is the general standard which specifies the requirements for a quality management system, whereas ISO/IEC 17025 states the requirements for the competence of testing and

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calibration laboratories. Clients look for laboratories which can supply them with accurate and reliable results and the ISO 9001 standard does not cater for the technical competence of a laboratory. On the other hand, a laboratory accredited to the ISO/IEC 17025 standard has been evaluated for compliance to specific factors relevant to the laboratory's ability to deliver precise and accurate data. Some of these factors are: Technical competence of staff; validity of methods; calibration and maintenance of equipment; traceability of measurements; estimation of measurement uncertainty; quality assurance of test or calibration results.

Laboratory accreditation can help laboratories to produce consistent results by means of implementing the framework of a documented quality system [1]. [3] presented the current status of accreditation of hair testing laboratories based in Europe. They found 48 percent of the laboratories accredited and 31 percent of the laboratories accredited to ISO 17025. [4] found approximately 67 percent of government or police laboratories were not accredited. They claimed there was ambiguity of perceptions about the meaning, purpose, and principles of quality assurance and accreditation among European forensic science laboratories. The personnel of some laboratories did not know the fact that a laboratory without having a quality management system cannot get accredited. This problem is attributed to "lack of awareness syndrome." There are mixed results about the relationship between ISO 17025 accreditation and laboratory performance. [5] claims the improper use of quality management tools in the laboratory has a negative effect on laboratory activity especially on continuous improvement implementation. This also always a negative effect on the customer. [6] Performed proficiency test for heavy metals in feed and food of 31 laboratories, 28 of which were ISO 17025 accredited laboratories, in Europe. They found low laboratory performance and claimed the errors in measurement uncertainty might be the reason of failure of the laboratories. [7] conducted proficiency testing of chemical oxygen demand measurements and found low laboratory performance. They claimed the failure might come from heterogeneity of the samples, measurement errors, and the differences in the analysis methods [8] made an analysis of the causes of discrepant results in proficiency tests in a testing laboratory and investigated the reasons of erroneous laboratory results in the years of 2003 and 2007. [9] investigated accreditation process and standardization of Pathology Laboratories in Pakistan. They claimed physical conditions and limited qualified workforce were the reasons of current insufficient accreditation status in Pakistan. [10] explained quality regulations and accreditation standards for clinical chemistry in Turkey. He mentioned insufficient accreditation status in clinic laboratories and emphasized the importance of having a necessary infrastructure and directions in the healthcare in Turkey. On the other hand, there are successful implementations of accreditation reported in the literature. [11] showed accreditation process of the Quality System by ISO 17025 standards in a national reference laboratory of Argentina. They found the implementation improved systematic recording and control of the tasks, robustness of the traceability chain and

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external recognition of quality of the laboratory. [12] found accredited laboratories had more satisfactory and less suspicious and unsatisfactory laboratory performances than non-accredited laboratories. Thus, they claimed accredited laboratories were more successful than non-accredited laboratories. [13] have explained implementations of ISO 17025 accreditation of a laboratory within racing chemistry in Britain. They reported successful results in spite of difficulties of implementation of accreditation. [14] presented implementation and maintance of the ISO 17025 quality assurance system in the General Chemical State Laboratory of Greece.

The laboratory could prove the reliability of the test results and technical competence to clients and regulators. They experienced that accreditation and international quality standard of the laboratory improved its competitiveness. The laboratory could fulfill the requirements of clients and regulators. The laboratory could effectively analyze, solve and reduce operational problems with the adoption of a quality culture. The laboratory obtained employee fulfillment with the personnel training and teamwork.

III. METHODOLOGY

The methodology used in this paper is Quantitative technique since the expected information from the field involved factual elements that would be presented using descriptive statistics. The target populations of this study all professional laboratories staff in credited laboratories. The research instrument used was questionnaire contains references clauses of the ISO/IEC 17025 standard. The field survey was conducted in credited laboratories. A total of 60 structured questionnaires were distributed to 15 laboratories in various departments at LPI. The survey consists two parts:

Part I: General details

The first part of the questionnaire was intended to determine fundamental issues, such as business category, work experience involvement in quality management, size of the company, the position of the respondent in the company. The aim of this section is to provide information regarding the respondents' experience, and therefore indicate the degree of reliability of the data provided by respondents.

Part II: Assessment checklists

The purpose of the second part of the questionnaire is to assess the efficiency of the quality management system and the level of its performance in the LPI. Laboratories must examine the context of actual work practice and how to achieve the requirements of ISO/IEC 17025 standard.

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IV. ANALYSIS RESULTS

a. Response rate: In the study, a total of 60 questionnaires were issued of which 40 were successfully filled, returned and taken as valid samples as presents in table (1).

Table 1: Response rate

Questionnaires issued	Returned	% return rate
60	40	66.66%

b. Reliability analysis: An internal consistency analysis for reliability analysis Cronbach's alpha was calculated by application of SPSS. Table (2) lists The Cronbach alpha for reference clauses. Value of the alpha coefficient ranges from 0 to 1 and may be used to describe the reliability of factors extracted from dichotomous (that is, questions with two possible answers) and/or multi-point formatted questionnaires or scales (i.e., rating scale for nonconformity: 0 = not applicable, 1= no, 2= non critical, 3= critical). A higher value shows a more reliable generated scale. [15] has indicated 0.7 to be an acceptable reliability coefficient. As the alpha coefficients were all greater than 0.7, a conclusion was drawn that the instruments had an acceptable reliability coefficient and were appropriated for the study.

Table 2: Internal consistency analysis

Reference Clauses	Cronbach alpha	Number of items
4. Management Requirement		
4.1 Organisation	0.754	6
4.2 Quality System	0.802	7
4.3 Document Control	0.812	3
4.4 Review of request, tenders and contracts	0.711	5
4.5 Subcontracting of test and calibration	0.7036	4
4.6 Purchasing services and supplies	0.801	4
4.7 Service to client	0.825	2
4.8 Complaints	0.745	1
4.9 Control of nonconforming	0.845	2

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testing / work		
4.10 Corrective Action	0.823	5
4.11 Preventive Action	0.798	2
4.12 Control of records	0.836	2
4.13 Internal Audits	0.745	4
4.14 Management reviews	0.812	2
5. Technical Requirements		
5.1 Personnel	0.921	5
5.2 Accommodation and environnemental condition	0.814	5
5.3 Test method and method validation	0.769	7
5.4 Equipment	0.812	12
5.5 Measurement traceability	0.914	3
5.6 Sampling	0.879	3
5.7 Handling of test items	0.777	4
5.8 Assuring the quality of test result	0.825	2
5.9 Reporting the results	0.768	9

V. RESULTS DISCUSSION AND CONCLUSION

1) Management Requirement

A. Organisation

1. LPI organization quality system policies and objectives is defined and documented in the organization quality manual.
2. LPI is the legal entity registered in state of Libya is legally responsible.
3. LPI has fulfilled the requirement of the standard, need of the client, regulatory authorities and organization that provide recognition.
4. Organization has appointed Quality Manager and Technical Manager with the authority to execute duties related to quality system and laboratory technical matters.
5. Organization requires all its employees to sign a disclaimer letter to avoid internal and external pressure to avoid conflict of interest.
6. Client confidential information and proprietary requirements has been clearly defined. (Adequate and satisfactory).

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7. Organization and management structure clearly documented.
8. Responsibility, authority and interrelationship of personnel is clearly documented.
9. Adequate supervision is available to handle all the training needs and competence staff is made available to train new staff on board.
10. Organization has appointed Technical Manager to be overall responsibility for the technical operation to ensure quality of laboratory operations.
11. Organization has appointed the Quality Manager to be the person responsible for the development, establishment and implementation of the laboratory quality system. Quality Manager job description has define its access to the top management

B. Quality system

1. Quality system are implemented by all the personnel and found to be adequate and satisfactory.
2. Quality policy statement is issued under the authority of the Chairman Management Committee (CMC).
3. Roles and responsibilities of technical and quality manager is clearly defined and documented in the quality manual

C. Review of requests, tenders and contracts

1. Organization quality system procedure clearly defines and documents the requirement procedures for the review of requests, tenders and contracts.
2. Team feasibility is carried out by the multi cross functional team from QSO/SRO/LAB/MAC/FIN before an acceptance of an order.
3. Team feasibility has been adequately carried out to review the requirement of the client and this meet the intent of the requirement
4. Sample recipient office initiate quotation process for successful team feasibility review has been verified.
5. Sample recipient office maintained records of review of all new enquiry or changes to the existing contract found to be adequate and satisfactory.
6. Team feasibility has considered review of subcontracting requirement has been verified.
7. Any deviation occurred after the acceptance of contract; sample recipient office resolved the issues with the customer. Records of communication is been maintained. When major amendment in the contract , the review process shall be repeated

D. Subcontracting of tests and calibrations

1. Organization subcontract work to the competent subcontractor which compiles to the international standard has been verified.

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2. Organization uses subcontractor approval form to obtain approval from its client for the work subcontracted out in the event the laboratory does not have the capability to conduct the testing.
3. Team feasibility review checklist, whereby the requirement of subcontracting was reviewed prior acceptance of client work. Ref doc no :
4. Generally the laboratory accepts the responsibilities for the subcontractor work when the laboratory selects the subcontractor otherwise when the clients identify or select the subcontractor the laboratory is not responsible for the subcontractor work.
5. Approved supplier list and the supporting document of the entire key competent subcontractor are registered.

E. Purchasing services and supplies

1. LPI has established policy and procedure for selection and purchasing of services and supplies.
2. Laboratory uses incoming receiving inspection to carry out inspection on reagent, material and consumable product that affect the quality of test.
3. Verified and seen incoming receiving inspection record. There is no case recorded whereby any nonconformities detected during the incoming inspection verification
4. Verified and seen record of evaluation maintained by the material department for the above subcontractor

F. Service to the client

1. LPI has established a policy and procedure to address service to client requirement.
2. Organization customer visit report whereby has been verified, organization has afford the client reasonable access to the organization facilities.
3. Communication record with the client is maintained throughout the work for any delays or major deviation in the performance.
4. Deviation from the test method or test result is communicated with the client using customer communication record or deviation authorization.

G. Control of nonconforming testing and/or calibration work

Organization has assigned the Quality Manager as the responsible person who has the authority for management of nonconforming work. The other entire person who detects nonconforming shall report to the quality system office for further action since the implementation of the ISO/IEC 17025.

2) Technical requirements

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A. Personnel

1. LPI has develop and established procedure for measurement uncertainty and laboratory maintained competency matrix for each of the laboratory staff who operates equipment, perform test, evaluate result and sign test report.
2. Laboratory Supervisor and its Deputy Supervisor are responsible to provide on-job training to all staff undergoing training. Upon completion of the on-job training , evaluation is carried out to verify the competency and the result of the verification is updated in the individual training record
3. Verified and seen how laboratory determine the competency requirement for the laboratory staff that performed specific or special task. Training record and competency matrix clearly documented this requirement.
4. Verified and seen organization training plan whereby the goals are formulate respect to education, training, and skills of the laboratory personnel
5. Organization training policy and procedure are clearly define and documented.
6. Organization training programme are relevant to the current anticipated task of the laboratory
7. Organization laboratory comprises contract and permanent employee but the quality system are applied to both category. Training manifest are developed , established and implemented for contracted staff who undergoing training
8. Job Description for each position in the laboratory. Updates of JD of IL06 lab supervisor is verified and seen
9. Organization maintain competency matrix and other supporting document from the quality manual, whereby this authority on performing specific or special task has been approved by the General Manager.

B. Accommodation and environmental conditions

1. LPI has considered all factors contributing to environmental condition to facilitate correct performance of the test.
2. All laboratories perform weekly and monthly verification to ensure all factors of accommodation does not affect the test result.
3. Organization maintains environmental condition for work carried out at permanent facilities and for onsite sampling activities. For work carried out in permanent facilities, the environmental condition are recorded in the testing raw data and meanwhile for sampling carried out at onsite, chain of custody form is attached with the environmental condition.

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4. Organization accommodation and environmental condition are clearly documented and using verification checklist.
5. Some cases recorded whereby on the RH/TH was out of control limit and the laboratory has stopped all the testing work and carried out necessary corrective action to bring back the RH/TH back to control.
6. Organization laboratory does not conduct any incompatible activities within the same laboratory. All activities of incompatible are carried out in the different laboratory to prevent cross contamination.
7. Organization laboratory access control are clearly defined and documented. Organization uses access control list to limit the access.

C. Test and calibration methods and method validation

1. All method adopted by the laboratory are recognized nationally or internationally, there for the use of non standard method are unlikely.
2. LPI laboratories using latest valid edition of the American Society for Testing and Materials (ASTM) method and other recognized method for scope of accreditation.
3. All accredited laboratories have individual equipment operating instruction and well as sample handling and preparation.

D. Equipment

1. Organization quality system procedure has clearly defined and documented the calibration programme.
2. Laboratory equipment master list whereby all equipment required for sampling and testing is made available.
3. LPI laboratories use equipment tracking list to control equipment going out site of the permanent laboratory.
4. Calibration programme of the laboratory ensures equipment and software achieved the required accuracy.

E. Measurement traceability

1. Organization quality system procedure clearly defined the laboratory calibration program.
2. There is laboratory equipment calibration master schedule against equipment in the laboratory to ensure only calibrated equipment are used for testing.
3. Organization uses external calibration services for its calibration needs. This external calibration sub-contractor is accredited to ISO/IEC 17025 and traceable to national and international institute.

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4. Calibration certificate received from the external calibration sub-contractors; the SI units are traceable to the national and international institute.
5. For internal calibration of equipment where the equipment manufacture specifies use of certified reference material (CRM) for calibration, the laboratories used CRM which is certified and established by reputable body.
6. The organization quality system procedure clearly defined the monitoring, measurement and calibration programme required for reference standard and certified reference material. Laboratories maintained master schedule for calibration of reference standard and certified reference material.

F. Sampling

1. All organization sampling activities are governed by the quality system procedure. Manual sampling for petroleum products and laboratory work instruction used for sample preparation and sampling.
2. LPI used appropriate statistics sampling specified by the ASTM and sampling method which is recognized by national and international for its sampling activities.
3. Organization has a system in placed to handle deviation or exclusion for sampling.

G. Assuring the quality of test and calibration results

1. LPI has developed and established quality system procedure for assuring the quality of tests
2. Some laboratories have implemented control chart for some of the test method to monitor the trend
3. As a part of quality control activities, LPI laboratories use certified reference material to carry out intermediate checks.
4. LPI using proficiency test for result comparison matrix. The proficiency test result from over 200 international laboratories participated to compare the LPI test result.

H. Reporting the results

The test reports meet the intent of the ISO/IEC 17025 requirement.

1. Results at LPI are reported accurately, clearly, unambiguously, objectively, in accordance with method (s).
2. Reports include information requested by client, necessary for interpretation of results, all information required by method(s) used.
3. Simplified reports for internal clients, written agreement with the client.
4. Availability of information.

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VI. CONCLUSION

This study examined the effect of ISO 17025 accreditation on laboratory performance in Libya. The results show statistically positive or significant effects on laboratory performance. When a laboratory adopts ISO 17025 accreditation for merely gaining a marketing advantage, this correct motivation brings the laboratory positive outcomes such as high satisfactory and suspicious laboratory measurements and low satisfactory laboratory measurements. On the other hand, the laboratory adopts ISO accreditation for such purposes of improving quality, reliability, accuracy and consistency of its products, services and processes, and customer satisfaction, the laboratory can improve its laboratory performance, customers' loyalty and competitiveness in the market.

We suggest that the accreditation body should control and assess competency and honesty of the organization and personnel of the certification bodies in audits more strictly and frequently to improve credibility, fairness, and effectiveness of ISO accreditation. In addition, we suggest that the accreditation body, certification bodies, and laboratories should more emphasize such issues as ethics, quality, and continual improvement in their guiding principles to improve the impartiality and competency of the audits as well as to have good motivations for ISO adoption, and to increase quality, reliability, accuracy, and consistency of laboratory measurements.

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