

Management of laboratories and calibration systems according to international standards ISO17025

By

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Abstract

This research dealt with the presentation of the international standard ISO 17025: 2017, including how to design and prepare the procedures guide according to these requirements, how to register on it, and what are the benefits of obtaining a registration certificate, in order to provide an appropriate theoretical framework that enhances the main research contribution in providing a mechanism for preparing a guide. The procedures for the quality management system in accordance with the international standard ISO 17025: 2017 mentioned, helps health institutions, including laboratories, in preparing such guides, and encourages the adoption of the standard as a practical response in the direction of competition that it has become facing in light of the rapid development of the health sector. The study consisted of a number of conclusions that showed the poor knowledge of the Yarmouk Teaching Hospital laboratory administration about the importance of quality and the importance of documenting procedures in the ISO 17025: 2017 standard guide to be a tool used in developing the laboratory and moving towards its global accreditation.

Keywords: Laboratory management, calibration systems.

Introduction

Hospitals concerned with providing services in general and laboratories in particular face great challenges, represented by the increasing volume of demand for these services accompanied by the rapid change in those needs and the desire of customers to provide the best services according to high-quality specifications, in addition to that, health organizations touch the human aspects of their customers Representatives of patients in a way that exceeds other organizations, and they expect a lot from obtaining distinguished health services, and all of the above has made the organizations concerned with providing health services keen to provide a service that suits them and satisfies their customers by adopting international standards that serve as a competitive advantage for them.

The current research is an attempt to detect gaps in the management of laboratories and their calibration according to international standards, in which these laboratories are witnessing a number of changes and developments in providing high-quality services as a result of the intense competition between hospitals and in the increase as a result of the beneficiaries' need for these laboratories to provide their services, which makes it necessary for them to face these conditions By making the necessary arrangements to adopt the concepts of quality, calibration

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and correct management of these laboratories that enable them to achieve their goals efficiently and effectively, and to adopt new strategies, work policies and different approaches that help eliminate these gaps or reduce their severity.

The international standards for quality management systems are among the most important effective keys in the field of managing organizations in the modern era, given that they define the necessary conditions for establishing an effective and globally acceptable quality system that is applicable regardless of the size of the organization or its field of work.

Methodology

Research problem:

The importance of laboratory quality has become an interesting issue, as many organizations and sectors that have adopted laboratories have called the current era the era of quality, because quality has become a necessary and common requirement among all industrial and service sectors that are looking to compete in global markets, as well as to deal with health institutions that adopt In providing its services on internationally accredited specifications and standards, the international standard ISO17025 appeared in 2005 as one of the most important international responses towards achieving the goal of competition between laboratories, whether consulting or educational, and aimed at managing them to continuous improvement and achieving customer satisfaction.

In light of that international interest in the issue of quality, quality specifications developed, and in order to obtain a certificate of conformity with the international standard ISO / IEC 17025: 2017, it was necessary to calibrate to match what was stated in the international standard, which describes work procedures with documented and applied steps, and reflects each item of the standard For laboratories that aim to obtain a certificate of conformity to the international standard ISO / IEC 17025: 2017, so the Yarmouk Teaching Hospital laboratory, the study community, must document its operations because documentation is an important element of the laboratory management and calibration systems, as the documentation chain for laboratory management begins with the formation of a quality guide And a guide to procedures in laboratories by documenting and calibrating laboratory management systems.

From the foregoing, and through the researcher's communication with those in charge of these laboratories, the research community, the special problem of the research emerges, represented by: -

1. Although laboratories departments in the research community are familiar with the concepts of quality management in general and the calibration concept of the ISO/IEC 17025:2017 system in particular, its procedures and access mechanism may be difficult to reach in terms of documentation and application.
2. Lack of familiarity with the knowledge of laboratory management in the procedures manual for the ISO/IEC 17025:2017 standard system.
3. The absence of a skilled staff in the laboratories specialized in quality, capable of preparing procedure guides for the ISO / IEC 17025: 2017 standard system.
4. The management of the Yarmouk Teaching Hospital laboratory is aware of quality in terms of providing laboratory services only and by meeting quality requirements regardless of meeting the requirements of the ISO/IEC 17025:2017 standard system.

With the desire of the hospital to obtain a certificate of conformity with the ISO/IEC 17025:2017 standard system, this prompted the researcher to delve into this topic.

Research aims

The research seeks to achieve the following goals:

1. Calibration of laboratories for the ISO/IEC 17025:2017 standard according to its provisions, which are related to documentation and application, which constitutes a step towards obtaining the ISO/IEC 17025:2017 conformity certificate.
2. Proposing a mechanism that helps the hospital to follow a methodology that helps in preparing procedures guides for other activities in laboratories management and calibration.
3. Contribute to providing a theoretical framework for modern approaches to addressing the issue of quality and laboratory management, in particular with regard to the international standard ISO / IEC 17025: 2017, in a way that benefits those concerned in the Iraqi health sector in general and the Yarmouk Teaching Hospital laboratory in the study community in particular.

Research importance:

Despite these challenges, the Iraqi health sector has witnessed remarkable development in recent years, despite the country's general conditions, which makes conducting research in the field of laboratory management systems a significant matter in increasing the efficiency of these laboratories, which represent an important pillar of the life of society and the beneficiaries of Hospital services, which represent an important tributary in attracting health tourism, and the importance of this research can be indicated through the following:

A- The novelty of the topic of laboratory management and its standardization in local studies and research, which requires carrying out more studies with the help of laboratories in reaching successful management and its advantage.

B- Providing the Iraqi library with a scientific research contribution to the laboratory management system and calibration efficiency.

Theoretical framework

A. Definition of laboratories and their classifications:

Laboratories play an important role in the service of science and human life, as they are used to collect the necessary information and data to solve a specific problem related to a phenomenon. Specifically for conducting experiments and scientific research, either (Shahin and Hattab, 2005: 68) sees it as the process or set of operations carried out by individuals in clarifying or investigating knowledge through work. Whereas (Corter & et al., 2011: 2054) differed from the researchers in describing the laboratory and defined it as "the place where elegant scientific theories meet chaotic daily reality." And some similarities in definition with it (Al-Sayali, 2014: 15) are the place where all the practical preparations and equipment through which the examiner can perform a set of scientific experiments and operations.

As for (Gheraout & et al., 2018:86), he has his point of view differing in the description of the laboratory, as he sees it as a body that conducts tests, calibration, or sampling, related to the subsequent test or calibration." While he sees it (Putri & et al., 2019:1) Academic facilities and infrastructure used to support the implementation of education, research and community service, and are supported by approved and quality laboratory conditions.

From the foregoing, the laboratory is: the location or laboratory that meets the requirements of the infrastructure for conducting tests, calibration and conducting examinations.

The laboratories are classified into (Al-Zabin, 2016: 19):

- 1- Chemical laboratories: “In them, many chemical and physical tests are conducted on fodder, foodstuffs, industrial and medical gases, fuels, paints, mineral oils, fabrics, detergents, tobacco materials, as well as metals and industrial products.
- 2- Environmental laboratories: they conduct environmental tests in the fields of water, soil and wastewater. The main tasks of these laboratories are bacteriological and chemical analyzes of environmental samples.
- 3- Mechanical laboratories, including:
 - Metallurgical laboratories: "It conducts mechanical and physical examinations of metallic materials such as alloys and steel.
 - Plastic and rubber materials laboratories: "It conducts physical and thermal properties tests for manufactured and polymerized raw materials.
- 4- Destructive Laboratories (NDTL): “These laboratories provide services for measuring radioactive contamination in food and environmental samples.
- 5- Construction Materials Laboratory: "It conducts many chemical and physical tests for various construction materials such as concrete, cement, various building materials, insulation materials, ceramics, soil, raw materials, chemical building materials, asphalt, and rocks.
- 6- Water Efficiency Laboratory: “This laboratory provides testing services for the efficiency of water consumption for many means of water supply and various household appliances and tools.
- 7- Medical analysis laboratories: “are places where accurate tests of blood and various body fluids are conducted and are equipped with high-tech equipment to give accurate information about a person’s health status (whether sick or healthy) to reach an accurate diagnosis of his condition or early detection of diseases in some cases.” cases” (Abdul Majeed, 2017:15).
- 8- Laboratories of higher education institutions and research institutes for the activities of undergraduate and postgraduate programs (Grochau & et al., 2017: 2)

B. Technical competence of laboratories

The technical competence of laboratories depends on a number of factors, including: (ILAC B, 2019:1)

1. Qualifications of workers in terms of training, skills and experience.
2. Appropriate equipment, accurate testing and calibration, and regular maintenance.
3. Adequate procedures to ensure the quality of laboratories
4. Correct sampling practices
5. Correct methods and methods of testing
6. The extent to which measurement and calibration works conform to national standards
7. Accurate recording and reporting procedures and writing

As for (Ismail, 2:015), he defined it as follows:

- 1- “The technical competence of the workers.
- 2- “The validity and appropriateness of the examination methods used.

- 3- The type of sample and how to deal with it and transport it in the manner that preserves it.
- 4- "Measurement and calibration series for specified scales.
- 5- "The degree of suitability, calibration and maintenance of testing equipment.
- 6- "Environmental conditions surrounding the examination.
- 7- "The degree of application of appropriate ethical rules and values.

(Maqsood, 22:2019) showed that laboratories are efficient because they are of great importance to customers, producers and suppliers through:

- 1- "Reducing risk to a minimum.
- 2- "Avoid expensive re-examinations.
- 3- "Enhance the confidence of customers.
- 4- "Reducing costs and improving the acceptance of goods in foreign markets.

The researcher believes that "the most important thing that determines the technical competence of laboratories is the availability of human elements who possess high skills and are trained in dealing with different samples and in risky conditions.

C.The importance of laboratory efficiency

Being a competent laboratory is of great importance to customers, producers and suppliers: (ILAC B, 2019:1)

1. Reducing risk to a minimum

Customers around the world are currently striving to ensure that the products, materials or services they produce or purchase meet their expectations and meet their requirements. This often means that the product is sent to a laboratory to determine its characteristics against a specification. For the factory or supplier, resorting to one of the technically competent laboratories minimizes the risk of producing or supplying a particular product.

2. Avoid expensive re-tests

Product and material testing can be expensive and time consuming even to get it right the first time. If it is not performed correctly, the price and time required for re-testing may increase if the product does not meet specifications or expectations. Not only will the matter increase costs, but the reputation of the supplier or factory will also be affected. It is also possible that those responsible for the failure of the product will be held responsible, especially if it is related to public safety or a financial loss to a customer. Therefore, resorting to a technically competent laboratory reduces the possibility of requesting re-tests to a minimum. (ILAC, 2017:1)

3. Reliability in conducting the evaluation

Confidence in the product increases if customers know that someone has accompanied the tests with efficiency and reliability that have been comprehensively evaluated. This is especially true if it is proven to them that a third party has conducted an evaluation of the same laboratory and customers rely more on independent verification than simply accepting the supplier's statement that the product is "fit for purpose".

4. Reduce costs and improve the acceptance of your goods abroad

Through the system of international agreements, accredited laboratories with technical competence obtain one form of international recognition, which increases the ease of accepting their data in third parties. This recognition also helps reduce costs for producers and importers

whose products and materials are tested in accredited laboratories by reducing or eliminating the need for re-testing in the supplying country (ILAC B, 2017:1).

D. The main objectives of testing and calibration laboratories

Testing and calibration laboratories provide their customers with test reports to show the extent to which an item or product conforms to specific technical specifications and/or calibration certificates showing the validity of a reference standard and the measurement error associated with it. “In order for the reports and certificates provided by these laboratories to be recognized, they must be accredited. Because accreditation provides official recognition of the competence of laboratories that have such competence, and in doing so, it provides customers with a means to identify and choose reliable and reliable calibration, examination, testing and measurement services” (International Organization for Laboratory Accreditation, 2018). Accreditation is a tool for improving management systems in laboratories that conduct and issue tests. Quality reports (Okezue & et al., 2020:2).

The main objectives of the testing and calibration laboratories are as follows: (Al-Taher, 48: 2018)

- 1- “Consumer awareness and protection.
- 2- “Strengthening the economy.
- 3- “Improving the products and services provided.
- 4- Adopting the philosophy of quality assurance and implementing implementation.
- 5- “Commodity standardization.
- 6- “Quality control of exports and imports.
- 7- "Satisfaction of customers interested in laboratory testing.
- 8- “Achieving the quality of work within the examination laboratories.
- 9- “Training and awareness of workers and activities of workshops.

Errors in laboratory outputs

While (Cohen, 2010: 29) divided the errors in laboratory outputs into three stages:

- 1- The pre-examination stage, which includes (selection of examination, examination information, wrong request, sample collection, coding and transfer).
- 2- The examination stage, which includes (sample processing and preservation, quash preparation, equipment monitoring, and the method of performing the examination).
- 3- Post-examination stage, which includes (result control, quality audit, results report, interpretation and treatment)

(Looi, 2009:15) identified preventive measures to address errors in laboratory work, which can be clarified in the following paragraphs:

- 1- “System planning” for laboratories.
- 2- Training employees on risk management.
- 3- “Documentation of Plans”.
- 4- “Supplies Management.
- 5- “Review the laboratories system.

Laboratories accreditation

The accreditation process is a transparent and non-discriminatory procedure, and any laboratory that meets the accreditation requirements can obtain it, regardless of the field of examination or calibration.” International Standard ISO/IEC 17000,2004:4 describes it as an

endorsement by a third party related to the conformity assessment body. In it, it is formally indicated that this body is competent and capable of carrying out specific conformity assessment tasks. As (Al-Bayrakdar, 2016: 2) showed that the pillars of reliance are:

- 1- "A specific field of examination or calibration.
- 2- "Formal recognition by an authorized and impartial authority.
- 3- "Laboratory efficiency.

There are many definitions given by researchers regarding accreditation and schedule. Some of them see accreditation as "a set of procedures and operations carried out by the entity that grants accreditation to verify the availability of conditions and material and human capabilities in the organization. (Al-Jouhli, 2010: 76) It is a process through which quality is assured and verification that the organization (The laboratory) implements quality and adheres to it (Nassar & Abdel Qader, 2012: 209), or it is a recognition of the technical competence to implement conformity assessment activities (Barradas & Sampaio, 2017:406), Banifacio & et al., 2018:11)) and through it A continuous improvement process takes place, not a one-time goal, according to nationally and internationally accepted technical standards, and their efficiency is approved and reviewed at regular and specified periods (Kaynar, 2020:59).

The importance of laboratory accreditation

The importance of reliance on the benefits accruing to laboratories that have already obtained the accreditation certificate by reference to the international standard ISO 17025 lies in several points, including each of (Halawa, 2013: 3) (Milano & De Dona, 2017:5) (Oliver, 2018:64) as follows :-

- 1- "Ensuring the continuous improvement of the quality of the laboratory's administrative and technical system."
- 2- "Ensuring the control and control of all laboratory activities."
- 3- "Judgment by evidence whether the laboratory really possesses a competitive quality system and technical competence for its activities and obtains customer satisfaction."
- 4- "Raising the level of confidence in the measurement and calibration capabilities and technical performance of individuals."
- 5- "Material gains as a result of the increase in business volume and the growing demand to deal with the laboratory after obtaining accreditation in this internationally recognized standard."
- 6- "Permit and allow the possibility of exporting abroad the products that use these accredited laboratories in one of the manufacturing stages" (this part has become binding in many countries of the world)
- 7- "A high level of trust for customers and gaining credibility for test reports or calibration certificates issued by these laboratories, whether locally or internationally.
- 8- "Technological modernization of testing and calibration devices".
- 9- "A greater degree of safety for the results associated with each test."
- 10- "Achieving greater efficiency and effectiveness through testing activities."

Practical Framework

The reality of applying the laboratory efficiency system according to the standard (ISO / IEC 17025: 2017) in a laboratory

In this research, the actual reality of the laboratory competency system will be measured and evaluated in the laboratory according to ISO/IEC 17025:2017 using the checklist, and the

researcher will rely on personal interviews and actual observations to verify the appropriate information to fill it with the required information using heptatonic scale.

Item 4 Checklist (General Requirements)

A. Impartiality

- * Unbiased and orderly laboratory activities are conducted and managed in order to ensure impartiality
- * The laboratory management is committed to impartiality.
- * The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial or financial pressures or other forms of prejudice to impartiality.

B. Confidentiality

- * The laboratory shall be responsible, through legally enforceable obligations, for the management of all information that is obtained or generated in the course of performing the activities of the laboratory.
- * The laboratory informs the customer in advance of the information that it intends to put in the public domain. Except for information that the customer provides to the public or upon agreement between the laboratory and the customer (for example, for the purpose of responding to complaints), all other information is considered private information and must be considered confidential.

2- Structural requirements

- * The laboratory is a legal entity or a specific part of a legal entity and is legally responsible for its laboratory activities.
- * The laboratory determines the administration that bears the overall responsibility for the laboratory.

3- Resource requirements

General

The laboratory has the necessary staff, facilities, equipment, systems and support services to manage and perform its laboratory activities.

B. Personnel

All employees of the laboratory, whether internal or external, who may influence the activities of the laboratory, are obligated to act impartially, to be competent, and to work in accordance with the laboratory management system.

C. Equipment

The laboratory shall have a procedure for the handling, transportation, storage, use, and maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

4-Process requirements

A. Review of requests, tenders and contracts

The laboratory should have a procedure for reviewing applications, tenders and contracts

B. Selection and verification of methods

The laboratory uses appropriate methods and procedures for all laboratory activities, to assess measurement uncertainty checks as well as statistical techniques for data analysis where appropriate.

C. Sampling

The sampling method addresses the factors that must be controlled to ensure the validity of the results of subsequent calibrations or tests.

5- Management system requirements

General

The Laboratory shall establish, document, implement, and maintain a management system capable of supporting and demonstrating consistent achievement of the requirements of this specification and ensuring the quality of laboratory results. As well as meeting the requirements of Paragraphs 4 to 7, the Laboratory shall implement a management system” in accordance with Option A.

B. Actions to address risks and opportunities

Giving assurance that the management system achieves the desired results.

Prevent or reduce unwanted effects and potential failures in laboratory activities

Conclusions

- 1- One of the reasons for the discrepancy in the results of the tests is “the weakness in the specialized training programs for the laboratory workers in the field of laboratory tests, as well as the programs of workshops and practical lectures on which they are evaluated to determine their ability to perform the tasks entrusted to them.
- 2- Resistance to change by workers and their non-compliance with safety measures to preserve the environment through the waste resulting from the tests and the leakage of chemical and biological materials used in the tests into the sewage streams.
- 3- "Poor knowledge of the laboratory management of the concepts of the standard and its clauses in addition to their lack of knowledge of the continuous improvement mechanisms used, due to the lack of highly qualified workers to find opportunities through knowledge or submit proposals."
- 4- “Weakness in the procedures for identifying risks and opportunities during the planning process to identify the potential occurrence of cases of non-conformity, so when the problem is formed and exacerbated, corrective measures are taken instead of preventive, and the appropriate tools are not used to solve problems and identify the causes of cases of non-conformity.”
- 4- It was found that there was negligence in developing training plans for workers in light of the training needs and skills required for each job related to the quality of examinations.
- 6- “The laboratory does not adopt administrative review procedures for the system of efficiency of testing and calibration laboratories by the administration, as it deals with the inputs of the system according to the requirements of the standard to ensure the suitability and effectiveness of the system to diagnose appropriate opportunities for improvement and the need for changes in work.
- 7- “The laboratory suffers from a shortage of some devices required for examination and calibration, due to the lack of financial allocations, and some devices have exceeded their default operational life, and others are useless to repair, in addition to others that are inaccurate because they are supplied from unknown origins, in addition to the lack of an alternative. In addition to the lack of periodic and preventive maintenance programs.

Recommendations

- 1- The lack of training plans for workers in light of the training needs and skills required for each specialty related to the quality of examination and calibration, as well as the lack of availability and attraction of specialists to the laboratory and their involvement in intensive courses in the field of examinations.
- 2- “Providing safety equipment for laboratory workers and emphasizing adherence to it during testing and the need to comply with instructions and procedures for disposal of chemical test waste and destroying it without harming the environment by classifying waste according to its severity and training employees on how to deal with waste as well as following appropriate health guidelines.”
- 3- “Training employees on how improvement systems work and preparing individuals with multiple skills to use some methods to know the possibility and feasibility of making improvements and to determine whether there are risks, opportunities or needs that must be addressed as part of continuous improvement based on the results of the analysis and evaluation of the outputs of the audit outputs.”
- 4- Work on developing a methodology to identify the risks facing the work of the laboratory and how to address them and reduce their negative effects in order to achieve its objectives, as well as spreading a culture of risk-based thinking to identify and address risks and opportunities and provide assurance that the system of efficiency of testing and calibration laboratories achieves the desired results.
- 5- The need to provide a fair and rigorous evaluation of the suppliers of materials and services that affect the quality of tests and calibration and adhere to it, as well as the exclusion of default suppliers.
- 6- Carrying out more training programs for laboratory workers to achieve the requirements of the standard, especially in methods of estimating measurement uncertainty.

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