

# Clinical Laboratories Accreditation based on ISO Standards

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**Abstract-** clinical laboratories' tests are an essential parameter affecting patient's diagnosis and treatment. Significantly, 60% of medical cases are diagnosed based on laboratory tests. Quality control system and ISO guidelines aim to improve clinical laboratories work process. In addition to that, accreditation authority plays an important role to guarantee continuous improvement and audit.

**Index Terms-** ISO, Accreditation, Quality Management of Clinical Laboratories

## I. INTRODUCTION

Recently, medical laboratories tests play a significant role in diagnosis and decision making for therapeutic and treatment. Tests results are the most frequent data used by therapeutic, where more than 60% of medical decision are made according to clinical laboratories tests [1]. Quality of laboratories tests consider as an essential factor influencing the quality of total healthcare services. Therefore, the demand of quality assurance in clinical laboratories require a great deal of compliance and standardization by applying internal or national standards. The International Organization for Standardization (ISO) is a global authority aims to develop settings or standards guidelines for different type of facilities including healthcare facilities. In clinical laboratories, ISO focus to perform global harmonization of clinical laboratories around the world, including technical competence requirements and quality management system. Leading to accredit consistency of valid results by applying regulations and requirements for quality policy. ISO declared two protocols; ISO 15189 and ISO 17025 that described the quality management system and terminology. As well as, ISO guidelines improves the ability of clinical laboratories to produce reliable test results and enhance customer satisfaction [2].

During the last decades, the quality management system in clinical laboratories started with implementation of internal quality control followed by external quality control in daily and routine laboratories practice. One of the fundamental guidelines for internal quality management is the European standard (EN 45) for specifying general requirements of work process during laboratories tests. In parallel to that, ISO 15189 and ISO 17025 are an international standard for external quality management in clinical laboratories specifying the requirements for competence testing and calibration which is widely used around the world. However, guidelines for clinical laboratories standardization

include national and international standards applied in specific countries such as; Joint Commission International (JCI), Clinical Pathology Accreditation (CPA) which mainly applied in UK, College of American Pathologists (CAP) in USA and the CCKL guidelines of Practice in the Netherlands or standards based on the International Society for Quality in Healthcare (ISQU). Significantly, the common factor between all these standards is focusing on clinical laboratories accreditation based on ISO 15189 guidelines which precisely describing harmonization of clinical laboratories and define the requirements of quality management of work process and customer satisfaction.

## II. METHODOLOGY

International guidelines for clinical laboratories accreditation were extensively studied based on standard protocols of ISO. Firstly, accreditation can be defined as a procedure by which an authoritative organization gives or issues a formal confirmation to recognize that certain healthcare facility or clinical laboratory is competent and capable to perform specific work process and clinical tests under certain requirements and regulations [3]. We found that the gold and the most recognized standard for clinical laboratories accreditation is ISO 15189. Specifically, the last version of ISO 15189 declared in 2012 has more and better structure toward work process, definitions of settings and associated with patient's safety. Therefore, the responsibility of laboratory manager is to define the job duties of each member and develop a strategic plan including prepare, practice and performance evaluation to be applied in harmony for successful implementation of ISO.

## III. DISCUSSION

ISO 15189 is a significant tool to meet clinical lab accreditation. Mainly, the requirement for quality and competence by ISO 15189 strives to develop work process which is failure resistance as possible and enabling to detect errors before they become serious problem and to reduce the opportunity of mistakes. Also, the continuous improvement of work process is a key stone which is required to defined in synchronization to involve all staff in accreditation. Members of clinical laboratories must know exactly what to do, how to do, who is in command of a process and how to find all information necessary to achieve their responsibilities [4].

In the beginning, clinical laboratories arrangements, practices and procedures have to be intensively investigated and

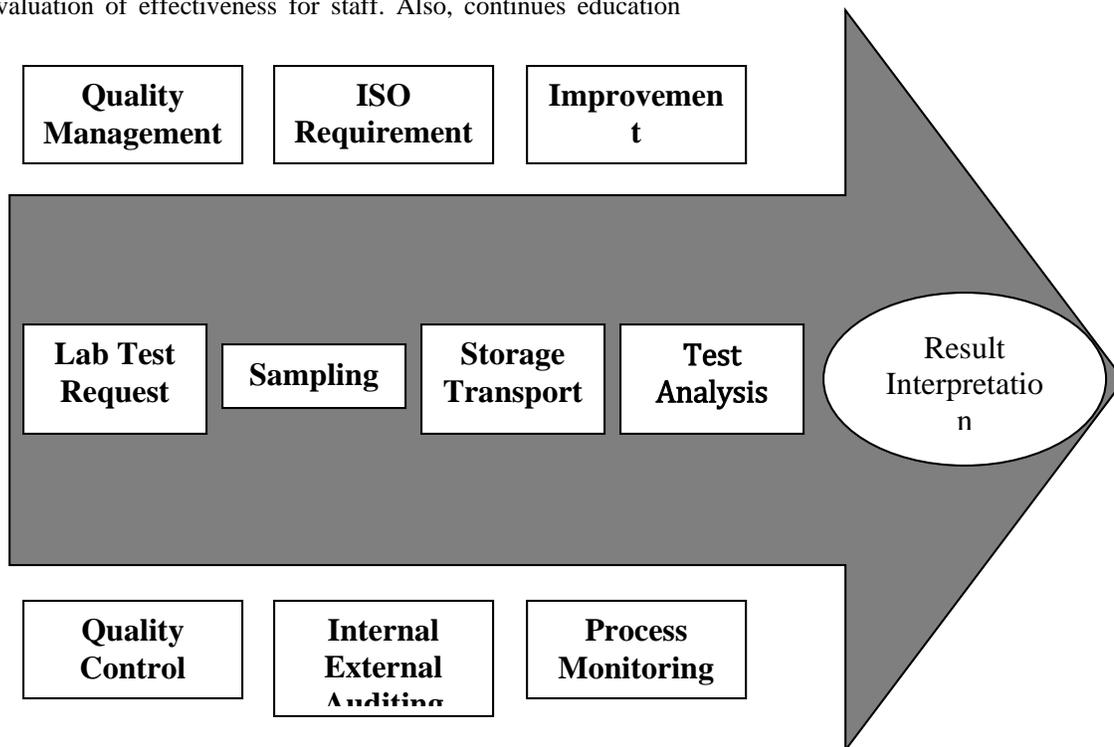
examined to determine whether they meet requirement of standardization or not. Therefore, ISO 15189 categorized the requirements for accreditation into three main parts; management requirements, technical requirements and quality system essentials [2].

The management requirement of ISO demands regular reviews and internal audits to assure that work process and procedures are adhere and effective according to quality management system and continuously meet the clients needs. As well as, identification of continues improvement has to take place according holistically reviews based on suitability, performance of testing, relation to supplier, patients' satisfactions and implementing effective solution such as develop root cause analysis [5].

Besides that, technical management significantly focuses on precise job description and responsibilities with continuous evaluation of effectiveness for staff. Also, continues education

program should be performed to improve skills and knowledge of all members. In addition to that, accommodation and environmental conditions are essential in risk management to reduce risk of injuries and infections. Medical laboratory equipment and reagents should be suitable and compatible to achieve specific tests perfectly. Quality controller materials should be run periodically and documented to facilitate traceability [6].

The accreditation plan significantly focusses on main criteria that should be followed toward laboratories accreditation, including; establishment of well-educated team which should be keen with quality management procedures, methodology to apply accreditation plan which should describing the over all process of clinical laboratory tests, developing and improving strategies that can be updated continuously to over come any error source or limitation during the all process. Figure 1 represents the scope of accreditation process [7].

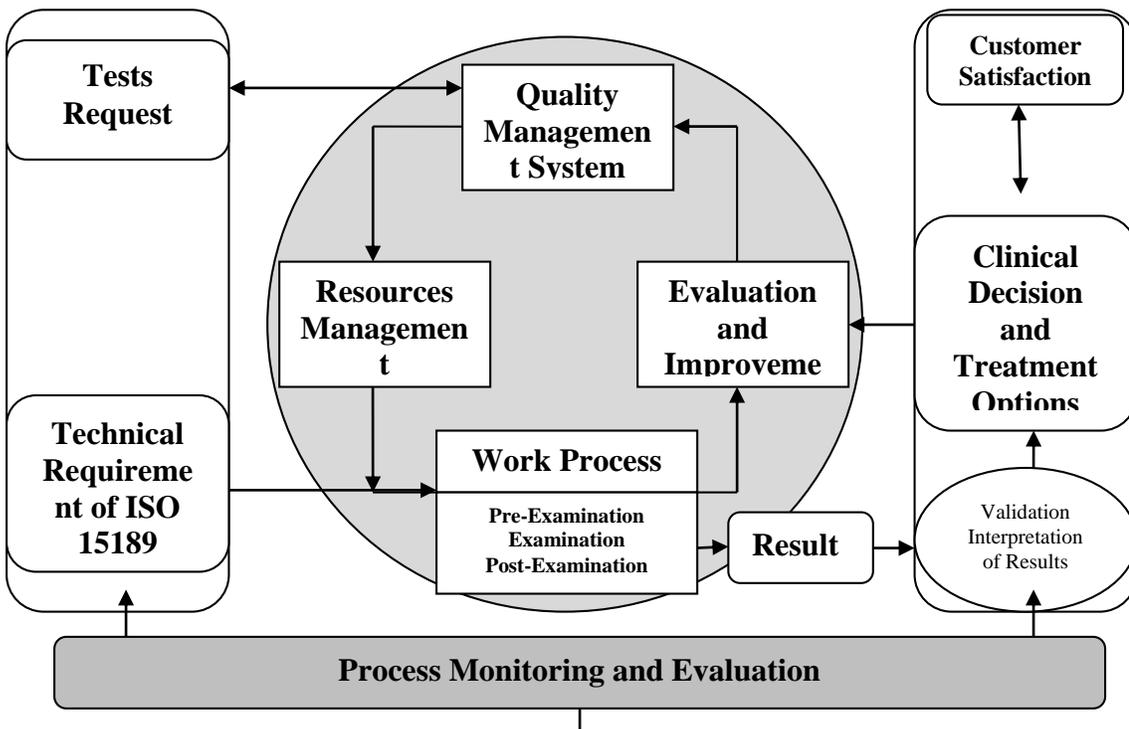


**Figure 1: Scope of Accreditation Process**

Significantly, ISO 15189 directed the framework of medical laboratories toward total quality management (TQM) system by using technical specifications that can be applied to achieve management requirements. Therefore, the quality cycle of clinical laboratories accreditation under the roles of ISO 15189 is applicable to cover all related field of clinical lab work process including; staff team, accommodation, laboratories' equipment, consumables and equipment's reagents, environmental condition, safety procedures, pre-examination and examination process [8]. Figure 2 shows the approaches of quality cycle of clinical laboratories based on ISO 15189. Firstly, the quality cycle describes the customer of clinical laboratories as patients or blood donors. Qualified staff team who achieve their job precisely at certain time to perform competence assessment. Also,

accommodation and environmental condition have been described as appropriate tools and facilities that should be undertaken to achieve TQM. Clinical laboratories' equipment, consumables and reagents are an essential part of TQM which have to be managed according to manufacturer's regulations including calibration, maintenance, storage and shelf life. All information should be documented and reported through the work process.

In addition to that, pre examination process should cover all patient and clinical tests information including sample collection, storage or transportation and handling. As well as, examination process should determine the optimal methodology to perform the requested laboratory tests and guarantee verification and analysis procedures according to biological references. Furthermore, post examination process focusses to apply quality control procedures to verify quality of control data, control materials, analysis and interpretation of results.



**Figure 2: Quality Cycle of Clinical Laboratory Under ISO 15189**

The continuous monitoring and evaluation of total work process can be designed based on internal and external quality assessment. Most of internal quality control design can be performed according to Westgard Rules or Levey-Jennings charts [9, 10]. Which suggested quality control design based on statistical and sigma metrics approaches [11]. On the other hand, external quality control suggested that clinical laboratories' work flow system should have the ability to perform corrective procedures when outcomes results consider as out of control or non-accurate.

#### IV. CONCLUSION

Accreditation of clinical laboratories promotes improvement of management system and technical capabilities for participated laboratories. As well as, the competitiveness level of clinical laboratories according to special specifications and guidelines issued by ISO 15189 would increase to achieve accurate and validated clinical tests that significantly improve clinical diagnosis, clinical decision and treatment options. However, accreditation body is a formal third-party authority that guarantee meeting the requirements of accreditation and perform periodic audits.

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