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A comparative study of legislative and normative frameworks in Morocco, France and U.S.A towards progressive and evolutionary quality management in Moroccan laboratories

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ABSTRACT

Introduction: Establishing and maintaining quality standards in medical laboratories is a significant challenge due to the rapid advancements in analysis techniques and technologies. In Morocco, the "Guide de Bonne Execution des Analyses'' (GBEA) is the primary regulation framework overseeing quality assurance in laboratories. However, it does not adequately address potential gaps that could compromise patient safety.

Methods: In this article, we compared five quality management systems through normative frameworks in Morocco, France, and the United States to develop an enhanced model adapted to the Moroccan context.

Results: The comparison reveals that the extensive roles and responsibilities of a laboratory director and the inability to delegate tasks to qualified staff members in the Moroccan GBEA pose a challenge to the effective leadership and detection of non-conformities. Adopting the French GBEA, the Clinical Laboratory Improvement Amendments CLIA and the International Standardization Organization ISO 15189 Documentation model that covers all analytical phases, process and procedure reviews, and robust quality control measures could serve as strengths in achieving successful accreditation without compromising the laboratory's technical, administrative, and financial stability. The principles of risk management and safety are increasingly important in the analytical process to ensure ongoing improvement and the safety of both staff and patients.

Conclusions: In this sense, adopting a progressive model, starting with detailed documentation, quality control, staff qualification and adaptation of requirements to the Moroccan context will enable medical laboratories to achieve quality without putting them in administrative and financial challenges while preserving continuous improvement.

Keywords: CLIA 88, Guide de Bonne Execution des Analyses, medical laboratories, patient safety, quality management

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INTRODUCTION

The quality management system (QMS) in medical laboratories has undergone various evolutions worldwide. Some countries have chosen to adopt a QMS adapted to their context, while others have established regulations and organizational plans in parallel with the International Standardization Organization (ISO). By 2015, over 60 countries had adopted ISO 15189 as their regulatory framework [1].

In this comparative study, we present the example of five QMSs in three countries with different experiences, address the regulatory and normative frameworks and finally explain the contrast between these systems.

In France, the QMS has gradually evolved from the GBEA to adopting ISO 15189 standards as a mandatory regulatory framework [2,3]. In the same context, the United States of America has quality assurance regulations in place since 1967. These regulations have undergone several modifications, notably the (CLIA 88) [4,5], which became a mandatory certification and accreditation standard, unlike ISO 15189, which remains optional. For Moroccan laboratories, the QMS integration is challenging given the new reforms adopted, especially the introduction of the new social protection system.

The requirement for accreditation presents significant challenges for medical laboratories. These challenges in-

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clude insufficient specialized technical and management training for staff, critical issues in risk management and patient safety, unclear regulations regarding delegating management responsibilities to qualified personnel, and an absence of established deadlines and procedures for external quality control. The lack of comprehensive documentation for most phases of the analytical process, as well as regular reviews, can impede continuous quality improvement. Addressing these obstacles is essential for success in achieving and maintaining accreditation.

This study aims to compare different quality management systems by outlining their technical and management aspects within medical laboratories. It will provide a comparative analysis of five distinct quality management systems, emphasizing their strengths and weaknesses. The objective is to draw inspiration from these systems to inform the development of an evolving model tailored for Morocco.

Quality management systems in Morocco

In Morocco, the GBEA is a regulatory and normative law of medical laboratories. It covers four main chapters:

- Chapter 1: Deals briefly with facilities, instrumentation, stock management, consumables and human resources.

- Chapter 2: Deals with laboratory operations and analysis, while briefly mentioning the requirements of the 3 stages of the analytical process [6].

- Chapter 3: Quality assurance QA, which is the responsibility of the laboratory director[7], who ensures that daily quality controls are carried out on the various quantifiable parameters. Internal and external quality controls are carried out at regular frequency and managed by a state institution or private non-profit organization.

- Chapter 4: This chapter deals with health and safety, precautions concerning hazardous products, cleanliness of premises and waste disposal.

The Moroccan accreditation service 'Service Marocain d'Accréditation' (SEMAC) is the only organization responsible for establishing and overseeing accreditation through the national standards institute Institute Marocain de Normalisation (IMANOR).

The Ministry of Industry and Trading has approved the 2022 version of ISO 15189 as the Moroccan standard Norme Marocaine (NM) ISO 15189. Medical laboratories will be accredited based on this version of the standard as part of the national accreditation system [8]. In Morocco, the number of ISO 15189-accredited laboratories is very limited compared with the total number (7/667). The majority are concentrated in the Casablanca-Settat region [9,10].

Besides these organizations, and since December 2023, the High Authority for Health 'Haute Autorité de la Santé' (HAS), based on Law 7-22, will oversee the quality assessment and accreditation of healthcare establishments in both the public and private sectors [11].

Quality management systems in France, from certification to accreditation

The first concepts of quality management were introduced in France in 1984 in toxicology laboratories through Good Laboratory Practice 'Bonne Pratique au Laboratoire' (BPL) to ensure the safety and effectiveness of products. Initially, medical laboratories were not included in these regulations, but new guidelines were issued after incidents involving blood samples. The GBEA, first introduced in 1994 and revised in 1999, became the primary document ensuring a quality approach, providing a regulatory and technical framework for the practice and control of laboratories [12]. In 1996, the 'Agence Nationale d'Accréditation et d'Evaluation en Santé' (ANAES) manual became a reference for accreditation, giving all laboratories in the private and public sectors a five-year deadline to comply [13,14]. Following the replacement of ANAES by HAS in 2005, the vocabulary changed from "accreditation" to "certification" [15,16]. In 2010, there was a significant revision of the regulations governing the practice and operation of medical biology laboratories, including the requirement for ISO accreditation. The regulation stated: "A medical biology laboratory may not perform medical biology examinations without accreditation" (L. 6221-1) [17].

The GBEA covers recommendations for analytical practices throughout the 3 phases of the analytical process and does not require precise analytical methods; on the other hand, it is often a reminder of everything useful for obtaining accurate results. Alongside Quality Control (QC), procedures and operating methods are a key element of quality assurance.

In contrast to the GBEA, the ISO 15189 standard takes a broader approach to quality, since the GBEA is concerned with quality assurance, which is the control of input and output analytical process, while ISO 15189 is concerned with quality management, which controls and aims for continuous improvement throughout the analytical process [18].

The International Laboratory Accreditation Cooperation (ILAC) recognized "15189" accreditation as a reference standard in 2006. Today, it is considered the only standard for medical laboratory accreditation worldwide [19]. The National Accreditation Body 'Comité Français d'Accréditation' (COFRAC) issues a provisional certificate to new laboratories, demonstrating that they meet the accreditation criteria before they start activity. Once the laboratory is officially operational, the COFRAC decides to accredit, suspend, or withdraw accreditation for that specific laboratory, [20]. Former laboratories that comply with the GBEA requirements can operate with

administrative authorization during a transitional phase. They must show that they have started an accreditation process by October 31, 2013, and obtain accreditation for all their activities by November 1, 2016, to continue operating (Art. L. 6221-6).

Several medical laboratories faced challenges during the accreditation process due to the large number of medical analyses, the need to comply with new requirements of the Territorial Hospital Group 'Groupement Hôspitalier Territorial' (GHT) (transport, logistics, IT system etc), and the obligation to certify the validation of all biological examinations [21–23]. In response to representations from the medical biology unions, the government decided to adapt the schedule and accreditation requirements to accommodate the needs of different laboratories and the challenges posed by the COVID-19 pandemic [24-26].

QMS in the U.S., evolving quality

The journey of laboratory quality in the U.S.A. began in 1967 with the federal regulation of clinical laboratories. This regulation was finalized in 1978 and included standards for quality control, staff competence, and test efficiency. Despite the federal government's efforts, the serious consequences of incorrect results on patient health continued to rise. This concern was highlighted by a series of articles in the Wall Street Journal, which drew the attention of Congress. This led to the "Clinical Laboratory Improvement Amendments" or CLIA. After the official announcement of the CLIA requirements in May 1990, a modified version was published in 1992 in response to public feedback. This version, used during the laboratory adaptation phase, underwent further modifications, resulting in a final extended form in 2003, [27].

Depending on the category, The Food and Drug Administration (FDA) classifies laboratories based on the type and complexity of their analyses, categorizing over 37,000 tests as waived, moderate, or highly complicated, a laboratory may perform one or more types of analysis. Every laboratory needs to possess one of the following CLIA certificates or be exempt from the CLIA (Section 493.2) [28,29]:

- Registration Certificate: A registration certificate is necessary. Initially, this will apply to all laboratories carrying out tests with moderate complexity (not including the subcategory of Provider-performed microscopy (PPM) procedures, high complexity, or both; additionally, it will apply to all laboratories holding a certificate for PPM procedures or Waived Analysis that plans to carry out tests with moderate or high complexity, or both, on top of the tests that are listed or designated as PPM procedures (Article 493.15 c).

- Waiver certificate: For labs or practices that want to carry out just Waived analyses as long as they follow and record manufacturer instructions.

- PPM Procedures Certificate: intended for labs or practices that want to do both PPM and Waived analyses.

- A registration certificate: Not necessary for laboratories that run PPM procedures, Waived testing, or any combination of these tests.

- Certificate of Compliance: This document pertains to all types of laboratories and states that they must notify the Department of Health and Human Services (DHHS) of any changes to the ownership, address, or other laboratory characteristics.

- The Accreditation Certificate is issued based on accreditations by an organization approved by the Centers for Medicare and Medicaid Services (CMS). It applies to laboratories performing a combination of waived, moderately complex and highly complex analyses. It expires in two years unless suspended by DHHS before then. In the event of non-renewal or suspension of accreditation, the laboratory must comply with the requirements of the certificate of conformity. (Article 493.61).

Accreditation to ISO 15189 does not meet the requirements of the US CLIA and does not replace CLIA-based certification. ISO 15189 can be selected as the quality management system for CLIA-accredited laboratories. Before applying for the College of American Pathologist Laboratory Accreditation Program (CAP LAP) (ISO 15189 accreditation, laboratories must first obtain accreditation from one of the independent bodies (CAP, COLA, the Joint Commission etc). In this research, we have taken the example of CAP LAP. When a laboratory applies for the CAP 15189 accreditation program, the assessment team first conducts an external review of the laboratory's documentation to assess the QMS components and the laboratory's readiness for accreditation. The laboratory also conducts internal audits to evaluate its readiness[30]. Laboratories have the option of carrying out gap tests before on-site accreditation testing. Gap assessments are detailed on-site evaluations against ISO 15189 standards and the conformity of the laboratory's QMS, revealing system deficiencies and issues that need to be resolved before certification can be achieved [1].

METHODS

In this comparative study, we have listed several legislative texts and normative guides to highlight the strengths of different quality management systems. The comparison includes 5 legislative and normative texts in three countries:

- Moroccan GBEA In Morocco, which is considered as the only official document dealing with the operation of medical laboratories;

- French GBEA is a regulatory framework that ensures the proper functioning of laboratories in France through requirements and recommendations;

- Federal guidelines, known as the Clinical Laboratory Improvement Amendments of 1988 (CLIA), are applicable to all U.S. facilities or sites that analyze human specimens for the purpose of assessing health or for the diagnosis, prevention, or treatment of disease;

- The latest update of ISO 15189:2022 is "General Requirements for the competence of medical laboratories." This standard will replace the third edition of ISO 15189: 2012 permanently;

- The College of American Pathologist (CAP) Accreditation Program offers accreditation to the ISO 15189 standard, which is an internationally recognized standard affirming the proficiency of medical laboratories in enhancing the quality of their services in compliance with CLIA.

The comparative tables illustrate differences in legislative and normative frameworks in the three countries using ISO 15189 CAP as a reference that encompasses the strengths of CLIA and ISO 15189. We have discussed the important aspects in 4 themes in chronological order (as cited in 15189 v 2022): Structural and governance requirements, Resource requirements, Process requirements, and Management system requirements. These themes were evaluated at three levels:

1. Non-covered: Requirements not mentioned in legislative or normative texts

2. Partially-covered: Includes requirements that are mentioned but not detailed or specified

3. Fully-covered: Includes requirements mentioned and detailed in the standard or legislative texts or technical and normative guides.

RESULTS

In the structure section, only 3/11 items in GBEA are fully covered and 1/11 is partially covered. Items concern director competencies, and responsibilities especially establishing technical procedures (Table 1).

Resource requirements include personnel, facilities and environmental conditions, equipment, reagents, and consumables. In the GBEA, only 3/23 items are fully covered (responsibility as general supervisor, sampling structure, and maintenance) and 6/23 are partially covered (Table 2).

The Process Requirements section covers all three phases of the analytical process. The pre-analytical phase is crucial in ensuring proper diagnosis and patient safety. The GBEA does not specify any item, in contrast to 8/39 (especially sample management, analytical procedures documentation, Internal Quality Assesement (IQA), and External Quality Assessment (EQA)) partially covered (Table 3).

The documentation aspect has only 1/18 item partially covered, it concerns documentation which is limited in procedures and archiving. This table confirms that Moroccan and French GBEA are standard frameworks that focus only on quality assurance (Table 4).

DISCUSSION

Structural and governance requirements

In the Moroccan GBEA, particularly regarding the laboratory director role, which is crucial for handling administrative, technical, and quality assurance tasks. However, this heavy responsibility can lead to issues such as excessive workload, lower detection rates of non-conformities throughout the analytical process, and decreased involvement of the laboratory staff. For the French GBEA, Specifying and delegating responsibilities helps establish a more efficient system through a participative approach.

CLIA and ISO 15189 stipulate that a laboratory must establish an organizational chart detailing the hierarchy and responsibilities of all staff members. Additionally, the laboratory should set specific, measurable objectives and evaluate them using quality indicators to ensure continuous improvement.

Table 1. Comparative table of the coverage of structure requirement and governance

Coverage of requirements	GBEA Morocco	GBEA France	CLIA	ISO 15189	ISO 15189 CAP Accreditation
LaboratoryDirector 5.2					
LaboratoryDirector Competencies 5.2.1	Full	Full	Full	Full	Full
Responsibilities of the Director 5.2.2	Full	Full	Full	Full	Full
Delegation of Responsibilities 5.2.3	None	Partial	Full	Full	Full
Advisory services 5.3.3	None	None	None	Full	Full
Structure and Authority 5.4					
Definition of the Organizational Chart 5.4.1	None	Partial	Full	Full	Full
Definition of procedures 5.4.1	Full	Full	Full	Full	Full
Definition of responsibilities 5.4.1	Partial	Full	Full	Full	Full
Quality management 5.4.2	None	None	Full	Full	Full
Quality objectives and policies 5.5					
Measurable objectives 5.5 (b)	None	None	None	Full	Full
Changes do not affect system integrity 5.5 (c)	None	None	None	Full	Full
Establishment of quality indicators 5.5 (d)	None	None	None	Full	Full

Abbreviations: CLIA- Clinical Laboratory Improvement Amendments, GBEA- Guide de Bon Exécution des Analyses, ISO- International Standards Organization.

Table 2. Comparative table of the coverage of resource requirements

Requirements	GBEA Morocco	GBEA France	CLIA	ISO 15189	ISO 15189 CAP Accreditation
Personnel 6.2					
Competency Requirements 6.2.2	Partial	Partial	Full	Full	Full
Reception and integration 6.2.1 (d)	None	Partial	Partial	Full	Full
Number of technicians by activity 6.2.1 (a)	None	Full	Full	Full	Full
Competency assessment 6.2.2 (c)	None	None	Full	Full	Full
Determination of Permissions 6.2.3	None	Partial	Full	Full	Full
Regular professional development program 6.2.4	None	Partial	Full	Full	Full
Definition of functions 6.2.5 (b)	Partial	Full	Full	Full	Full
Personnel Files 6.2.5	None	Full	Full	Full	Full
Technical Consultant	None	None	Full	None	Full
Clinical Consultant 493.1453, 1455, 1457	None	None	Full	None	Full
Technical Supervisor 493.1447, 1449, 1451	None	None	Full	None	Full
General Supervisor § 493.1459, 1461, 1463	Full	Full	Full	Full	Full
Structural Conditions and Environment 6.3					
Structure Controls 6.3.2	None	None	Full	Full	Full
Conservation Structure 6.3.3	None	Full	Full	Full	Full
Staff Space 6.3.4	None	None	Full	Full	Full
Sampling structure 6.3.5	Full	Full	Full	Full	Full
Equipment 6.4					
Equipment Requirements 6.4.2	None	None	Full	Full	Full
Equipment Acceptability Procedure 6.4.3	None	None	Full	Full	Full
Instructions for Use 6.4.4	Partial	Full	Full	Full	Full
Maintenance 6.4.5	Full	Full	Full	Full	Full
Incident Reporting 6.4.6	Partial	Partial	Full	Full	Full
Equipment Record 6.4.7	Partial	Partial	Full	Full	Full
Risk Assessment §493.1256 (d)	None	None	Full	None	Full
Metrological Calibration and Traceability 6.5					
Calibration 6.5.2	None	Partial	Full	Full	Full
Metrological traceability 6.5.3	None	Partial	None	Full	Full
Reagent and Consumable Management 6.6					
Receiving and Storage 6.6.2	Partial	Partial	Full	Full	Full
Acceptability Testing 6.6.3	None	None	Full	Full	Full
Inventory Management 6.6.4	None	None	Full	Full	Full
Instructions for use 6.6.5	None	Partial	Full	Full	Full
Adverse Event Reporting 6.6.6	None	None	Full	Full	Full
Records 6.6.7	None	Partial	Full	Full	Full
Risk assessment §493.1256 (d)	None	None	Full	None	Full
Service Contract 6.7					
Agreements with laboratory users 6.7.1	None	None	Partial	Full	Full
Point-of-Care Testing 6.7.2	None	None	Partial	Full	Full
Externally provided products and services 6.8					
External products and services adapted to laboratory users 6.8.1	None	None	Full	Full	Full
Reference laboratories and consultants 6.8.2	None	None	Full	Full	Full
External Service Contract Review 6.8.3	None	None	None	Full	Full

Abbreviations: CLIA- Clinical Laboratory Improvement Amendments, GBEA- Guide de Bon Exécution des Analyses, ISO- International Standards Organization.

Table 3. Comparative table of the coverage of process requirements

Requirements	GBEA Morocco	GBEA France	CLIA	ISO 15189	ISO 15189 CAP Accreditation
Pre-analytical process 7.2					
Information available to patients and users 7.2.2	None	None	Full	Full	Full
Sampling requirements 7.2.3	None	Partial	Full	Full	Full
Sample collection and processing procedure 7.2.4	None	Partial	Full	Full	Full
Transport of samples 7.2.5	Partial	Partial	Full	Full	Full
Sample receiving/ accepting procedures 7.2.6.1	Partial	Partial	Full	Full	Full
Sample preparation/ handling/ storage procedure 7.2.7	None	Partial	Full	Full	Full
Periodic review of requirements, appropriateness of procedures and requirements for samples	None	None	Full (not periodic)	Full	Full
Personal data management and intelligence 493.1241 (a)	None	Partial	Full	Full	Full
Analytical Process 7.3					
Verification of analytical methods 7.3.2	None	None	Full	Full	Full
Validation of analytical methods 7.3.3	None	None	Full	Full	Full
Evaluation of measures and uncertainties 7.3.4	None	None	Full	Full	Full
Biological reference intervals/ clinical decision limits 7.3.5	None	None	Full	Full	Full
Documentation of Analytical Procedures 7.3.6	Partial	Full	Full	Full	Full
Internal quality control 7.3.7.2	Partial	Partial	Full	Full	Full
External quality control 7.3.7.3	Partial	Partial	Full	Full	Full
Individualized quality control plan 493.1256 (d)	None	None	Full	None	Full
Quality control risk assessment	None	None	Full	None	Full
Quality control plan	None	None	Full	None	Full
Quality assessment plan	None	None	Full	None	Full
Comparability of results 7.3.7.4	None	None	Full	Full	Full
Post-analytical process 7.4					
Information on results analysis/ interpretation 7.4.1 (b)	None	Partial	Full	Full	Full
Delayed results patient information procedure 7.4.1 (c)	None	None	Full	Full	Full
Review of results prior to publication 7.4.1.2	None	Partial	Full	Full	Full
Critical results management procedures 7.4.1.3	None	Partial	Full	Full	Full
Specialconsiderations for results 7.4.1.4	None	None	Full	Full	Full
Sample retention and disposal 7.4.2 (a, d, e)	Partial	Partial	Full	Full	Full
Retention of samples for possible analysis 7.4.2 (b, c)	None	None	Full	Full	Full
Non-conformance management 7.5					
Defined NC management responsibilities 7.5 (a, g)	Partial	Partial	Full	Full	Full
Actions based on the risk analysis process 7.5 (b)	None	None	Full	Full	Full
Evaluation of the clinical significance of NC 7.5 (d)	None	None	Full	Full	Full
Acceptability of NC 7.5 (e)	Partial	Partial	Full	Full	Full
Examinations halted/ reviewed when necessary 7.5 (c, f)	None	None	Full	Full	Full
Data Control and Information Management 7.6					
Specification of authorities and responsibilities 7.6.2	None	Partial	Full	Full	Full
Information system management 7.6.3	None	Partial	Full	Full	Full
Information system outage plan 7.6.4	None	None	Partial	Full	Full
Claims Management 7.7					
Claims process 7.7.1	None	None	Full	Full	Full
Receipt of complaints 7.7.2	None	Partial	Full	Full	Full
Resolution of complaints 7.7.3	None	None	Full	Full	Full
Emergency Planning and Continuity 7.8	None	None	Full	Full	Full

Abbreviations: CLIA- Clinical Laboratory Improvement Amendments, GBEA- Guide de Bon Exécution des Analyses, ISO- International Standards Organization.

Table 4. Comparative table of the coverage of quality management requirements

Requirements	GBEA Morocco	GBEA France	CLIA	ISO 15189	ISO 15189 CAP Accreditation
Awareness of QMS 8.1.3	None	None	Partial	Full	Full
Management system documentation 8.2					
Competence and quality 8.2.2	None	None	Full	Full	Full
Proof of commitment 8.2.3	None	None	None	Full	Full
Documentation 8.2.4	Partial	Partial	Full	Full	Full
Personnel access to QMS 8.2.5	None	None	Full	Full	Full
Control of the management of documentation systems 8.3					
Document control 8.3.2	None	Full	Full	Full	Full
Recording Control 8.4	None	None	Full	Full	Full
Actions to Manage Risks and Opportunities for Improvement 8.5					
Identification of risks and opportunities 8.5.1	None	Partial	Partial	Full	Full
Intervention on risks and opportunities for improvement 8.5.2	None	None	Partial	Full	Full
ContinuousImprovement 8.6					
Continuous Improvement 8.6.1	None	None	Full	Full	Full
Feedback from patients, users and staff 8.6.2	None	None	Partial	Full	Full
Non-compliance and corrective actions 8.7					
Actions for non-compliance 8.7.1	None	None	Full	Full	Full
Effectiveness of corrective actions 8.7.2	None	None	Full	Full	Full
Records of nonconformances and corrective actions 8.7.3	None	None	Full	Full	Full
Evaluation 8.8					
Quality indicators 8.8.2	None	None	Partial	Full	Full
Internal audit 8.8.3	None	None	Partial	Full	Full
Management Review 8.9					
Review of input element 8.9.2	None	None	None	Full	Full
Review of output element 8.9.3	None	None	None	Full	Full

Abbreviations: CLIA- Clinical Laboratory Improvement Amendments, GBEA- Guide de Bon Exécution des Analyses, ISO- International Standards Organization.

Resource requirements

In Moroccan GBEA the laboratory director is the only one responsible for training and continuing education of the staff members. this highlights the need for a regular program of training and competence evaluation [31]. In France, the responsibility for quality management lies with the laboratory director and one or more qualified individuals. Staff members are required to maintain a comprehensive, documented record of their qualifications, training, internships, and accumulated experience. Furthermore, conducting certain specialized analyses requires specific qualifications and appropriate training. ISO 15189 accreditation requires continuous training for staff in their respective areas of expertise.

CLIA requires technical and management training for all personnel. The various accreditation bodies adopt Centers for Disease Control and Prevention (CDC) training programs dedicated to laboratory analysis staff. A regular skills assessment must be carried out every six months during the first year of employment for new members, and once a year for all staff, or in the event of a change in the laboratory's overall strategy. These assessments are carried out by the laboratory manager, the technical consultant or the technical supervisor, and the results (recorded in the personnel file) are subject to control by accredited auditors. This approach will enable the laboratory manager to monitor the staff and identify any deficiencies or difficulties at an early stage. It can be scheduled throughout the year so as not to affect staff performance. The assessment of workers' professional skills should include communication skills, inter-professional skills and development skills, and technology use. It should embody the culture of patient and staff safety by adopting continuously updated safety checklists [32,33].

Morocco has implemented a guide that outlines the technical requirements for facilities [34]. CLIA covers facility monitoring and control. Additionally, ISO 15189 requires the review of the laboratory facility to ensure

the quality of laboratory services and the safety of staff and patients. Therefore, the state should consider the challenges that older laboratories may encounter and grant them different accreditation deadlines from new facilities that comply with the latest requirements [35].

According to CLIA and ISO 15189, To ensure the effective use of equipment and reagents, the laboratory needs to have clearly defined selection criteria. It is important to establish validating analytic methods procedures, as well as documenting operating procedures that are tailored to the specific needs of the laboratory and align with international standards. Strengthening communication and coordination with suppliers is essential to minimize equipment breakdowns and enhance the quality of results.

Process requirements

Moroccan and French GBEA give laboratory directors an important responsibility in ensuring the quality of samples, and in deciding whether to accept or reject samples. Correct identity surveillance, transport and storage of samples are also important factors requiring special attention.

As far as CLIA is concerned, quality assessment of the pre-analytical phase is based on documented policies and procedures aimed at controlling, evaluating and correcting pre-analytical problems. The fourth version of ISO 15189 provides further details on sample collection and transport (referring to ISO 20658) [36], the pre-analytical phase should be subject to periodic review to ensure patient safety and continuous improvement [37].

To ensure the quality and accuracy of the analysis of biological samples, the Moroccan and French GBEA emphasizes the establishment of procedures, internal and external quality control, and the performance of analyses by qualified technicians.

Compliance with CLIA standards requires implementing procedures and manuals in paper or electronic form, and any changes must be carefully documented. In addition, it is necessary to control all analytical steps, with equipment and automated systems, calibration, internal and external quality control and inter-laboratory control being essential elements of this process. Despite the importance attached to the verification of reagents, equipment and automation components as part of quality system evaluation, the term metrology is not sufficiently defined. The analytical phase of the process also covers preventive and corrective maintenance, including the development of checklists for automated systems and water quality. Uncertainties and validation of analytical methods are detailed techniques.

Considering recent developments, the 2022 version of ISO 15189 has significantly enhanced technical aspects related to calibration, and uncertainty calculations (Reference to Standard ISO/TS 20914) [38], and method validation. Notably, it has integrated key requirements from the 2017 version of ISO/IEC 17025 [39], making it a robust standard. Moreover, the standard emphasizes the crucial aspects of document control management and periodic review. Both CLIA and ISO 15189 share commonalities :

- Ensuring that qualified personnel are informed of any changes by the supplier and are aware of procedures subject to periodic review.
- Strengthening the laboratory-supplier interface by consistently reviewing contracts and technical specification modifications.

In Morocco, IQA and EQA/Proficiency Testing PT are mandatory but not clearly outlined or documented. There are no regulatory guidelines for the procedures. EQA is conducted by an accredited public or private non-profit organization, authorized by the state or the Ministry of Health [2]. National Institute of Hygiene 'Institut National d'Hygiene' (INH) INH manages and controls EQA at the public laboratory. Labs that fail are requested to make changes without facing sanctions or inspections for subsequent failures or refusals.

In France, independent bodies conduct external quality control under the supervision of the HAS. Internal quality control is mandatory and must be documented. and is regularly reviewed and monitored by internal and external auditors. Quality Assurance (QA) monitoring primarily relies on the Levy-Jennings curve and Westgard rules.

In the United States, internal quality control is the responsibility of the General Manager [40]. According to CLIA, internal, external (Proficiency Test) or inter-laboratory (optional) quality control is not limited to QA testing and evaluation, but also constitutes a documented process known as the Individualized Quality Control Plan (IQCP).

The adoption of this model IQCP will enable Moroccan laboratories to continuously assess the quality of their analyses and also to [41,42]:

- Compare the performance of analyses to focus on areas requiring improvement [43];
- Optimize QC frequency, reduce costs, and make better use of QC materials and calibrators [44,45];
- Gain a better understanding and control of the analytical process;
- Engage suppliers of materials and reagents, to improve staff support for mastering the advantages and limitations of analysis;
- Better identify errors, especially in the pre-analytical and post-analytical phases, where most non-conformities occur. [46,47];
- Ensure that external quality controls are conducted under optimal conditions.

The Moroccan GBEA stipulates that this post-analytical phase is the exclusive and final responsibility of the laboratory director, who may accept or reject a result. It does not include any procedure for managing the validation and delivery of results. As for the French GBEA, validation is subject to documented procedures and consists of two stages: analytical validation by personnel under the director's responsibility, and exclusively biological validation.

CLIA and ISO 15189 have several points in common: the post-analytical phase is responsible for monitoring and assessing the overall quality of test results and specific patient data. Major non-conformities in the post-analytical phase can compromise patient safety. Laboratories are responsible for ensuring accurate and timely transmission of test results, from data capture to reporting. The post-analytical phase also includes complaint handling, continuity and emergency preparedness planning within the laboratory.

As a computerized laboratory management tool, LIS is playing an increasingly important role in all phases of laboratory analysis, from reception to results delivery, including stock management and documentation management (quality policies, procedures, technical data sheets, human resources files, etc.). In Morocco, regulations do not specify data management methods, unlike the French GBEA, which governs the use of IT tools in consultation with the (CNIL) Commission Nationale Informatique et Libertés, while limiting access to authorized persons in full respect of patient confidentiality and professional secrecy. Any modification by an authorized person must be documented, approved by the laboratory director and declared to the CNIL [48].

CLIA and ISO 15189 also emphasize the importance of information systems that manage patient data. Laboratories must plan for potential system failures to ensure continuous operation of the analytical process and assess the quality system to safeguard patient safety and data confidentiality [36].

Management system requirements

Moroccan laboratories need to adopt various approaches in order to achieve progressive quality improvement. In Managing their documentation system [31], the French GBEA can serve as a good intermediate phase for controlling documentation. Continuous improvement is crucial in both CLIA and ISO 15189 v22. This is accomplished through an assessable process and the establishment of quality indicators, which allow laboratories to assess their performance, strategize solutions for potential issues, and prioritize addressing the most common deviations in order to enhance the analytical process continuously.

Despite delegating the external audit service to various independent bodies, auditors and laboratory staff in France face several challenges in effectively managing audits and benefiting from them to correct deviations without them turning into inspections disguised as audits [49,50].

In contrast, managers in American laboratories (such as technical supervisors and clinical supervisors) have an equivalent level with external auditors due to their qualifications and training. This enables them to actively participate in the self-assessment and continuous improvement process through management reviews, documentation of personnel files, QMS documentation, and identifying gaps and solutions[39]. Similarly, Morocco is expected to set up a training program for managers in public and private laboratories to prevent the concentration of all management responsibilities on the laboratory director.

Safety and Risk management

The concept of health and safety is addressed in both versions of the GBEA (French and Moroccan) under the term 'hygiene and safety'; however, it does not encompass patient safety or risk management. In the ISO 15189, risk management and safety are vital aspects of strategic planning, aiming to address potential risks and capitalize on opportunities for improvement. safety It is part of the rigorous standards set out in ISO 15190 version 2022 [51]. Risk management, as laid down in ISO 22367 version 2020 [52], is crucial, with a focus on identifying and reducing risks to improve safety measures. While the tools and templates provided by manufacturers can be helpful, laboratories need to supplement them with their information to ensure a comprehensive risk assessment [53]. Requirements for sample collection and transport strictly adhere to current standards, thus guaranteeing patient safety [54]. Medical laboratories must also ensure the safety and protection of their staff to promote the well-being of laboratory users and patients.

CONCLUSIONS

This comparison demonstrates, through the advantages and disadvantages of each system, a progressive aspect starting from the French GBEA by delegating certain responsibilities from the laboratory director to qualified staff while emphasizing the importance of documenting procedures throughout the analytical process. As a second level, CLIA stresses the need for regular training and assessment programs tailored to each laboratory's specific requirements, based on the complexity of the analyses conducted. The implementation of IQCP and risk management in certain stages of the analytical process ensures a rigorous quality assessment. Ultimately, the updated version of ISO 15189 adopts a more integrated approach by covering various technical and management requirements, which are essential for the effective operation of a laboratory. This updated version places a strong

emphasis on reviews, risk management throughout the analytical process, and ultimately the concept of patient safety. Adapting these requirements to the Moroccan context will enable medical laboratories to achieve quality without imposing significant administrative and financial burdens while promoting continuous improvement.

ABBREVIATIONS

ANAES- Agence nationale d'accréditation et d'évaluation en santé

CAP LAP- College of American Pathologist Laboratory Accreditation Program

CDC- Centers for Disease Control and Prevention

COFRAC- Comité Français d'Accréditation

CLIA- Clinical Laboratory Improvement Amendments

CMS- Centers for Medicare and Medicaid Services

EQA- External Quality Assessement

FDA- Food and Drug Administration

GBEA- Guide de bon exécution des analyses

GHT- Groupement Hôspitalier territorial

HAS- La Haute Autorité de santé

INH- Institut National d'Hygiene

IMANOR- Institute Marocain de Normalisation

ISO- International Standardisation Organisation

IQA- Internal Quality Assessement

IQCP- individualized quality control plan

NM- Normes Marocaines

DHHS- the Department of Health and Human Services

PPM- Provider-performed microscopy

QA- Quality Assurance

QC- Quality Control

QMS- Quality Management System

PT- Proficiency Test

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AUTHORS' CONTRIBUTION

AK: conceptualization, methodology, investigation, writing, visualization.

SEF: review and editing, visualization.

MEF: review and editing, visualization.

MB: review and editing, visualization, validation

EAB: conceptualization, methodology, visualization, validation, supervision.

CONFLICT OF INTEREST

None to declare.

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