© September 2024 | IJIRT | Volume 11 Issue 4 | ISSN: 2349-6002

International Standards for Clinical Laboratories: A Comparison and the Relevance of Quality Management Systems

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Abstract: A quality management system (QMS), controls, and advances the elements that influence a laboratory's success in achieving the desired results and customer satisfaction. There are various standards that establish requirements for the implementation of a quality management system for laboratories, such as ISO 9001, ISO/IEC 17025, and ISO 15189, and a cross-comparison between them is revealed. Furthermore, proficiency testing (PT) program provide numerous advantages to laboratories, including method verification, inter-laboratory comparison, monitoring Quality Indicators, and integrity testing. These programmes are a tool for keeping the laboratory procedures and every variable involved (man, machine, and method) well controlled in order to control the quality of the procedures. Previous benefits, on the other hand, will be realized only if the reported results for each programme are thoroughly examined. As there are additional benefits to incorporate PT results into the laboratory's quality management system, a procedure is usually proposed. Furthermore, the results of PT programs validate the utility of the laboratory's internal controls, which are part of its quality management system.

Keywords: QMS, PT program, internal quality control, laboratories, harmonization, quality indicators, ISO standards

1. INTRODUCTION

A quality management system (QMS) is composed of a number of coordinated tasks that are completed on a number of components to ensure the quality of goods or services that are made available to customers or users. The quality of a laboratory is determined by the precision, dependability, and promptness of the analytical results, and all aspects of analytical operations should be controlled (WHO, 2016). The elements that affect meeting user requirements and satisfaction are also planned for, controlled, shared, and improved by the QMS (Rafael and Mateo 2009). According to the quality management system—fundamentals and vocabulary section of the ISO 9000:2015 standard, a different way to define a QMS is by the meaning of each word individually: *Quality*: is the sum of all the features and qualities that affect a product's or service's capacity to satisfy the stated or implied needs of the customer. *Management*: coordinated activities to direct and control an organization. *System*: a set of interrelated or interacting elements.

It is clear from these three sentences that a QMS refers to the business, planning, and regulatory activities accomplished on a set of elements to achieve quality. To guarantee the accuracy, integrity, reliability, and traceability of the results and prevent any errors from impacting the users, many processes are carried out in laboratories. A quality management system that controls, detects, and tracks all the processes is essential.

2. INTERNATIONAL STANDARDS FOR LABORATORIES

The most common international standards utilized by laboratories for documentation are those from

ISO 9001, which are requirements for the implementation and certification of quality management system. ISO 9000 documents offer recommendations for service and manufacturing quality that can be used by various organizations. The general requirements for integrating a quality management system (WHO 2016) into business operations across a variety of productive sectors, including medical testing laboratories regardless of size and while maintaining organizational characteristics, are covered by ISO 9001. The hallmark of ISO 9001 is its process-based methodology, which establishes standard procedures for any organization or activity, product development, or service delivery (e.g., document control, equipment maintenance, traceability, or staff competency and training). According to ISO 9001:2015, the following issues must be documented:

- Quality management system and its processes
- Quality objectives
- Monitoring and measurement of resources
- Competition
- Monitoring, measurement, analysis, and evaluation
- Internal audit
- Review of management
- Nonconformity and corrective actions

Additionally, there are two ISO standards, ISO/IEC 17025:2005, that are specifically geared toward laboratory accreditation. General requirements for testing and calibration laboratories' competence and ISO 15189:2012 Medical laboratories' quality and competence requirements (Geneva: International Organization for Standardization). A higher level of quality than certification, accreditation is also a volunteer activity. Anyway, ISO standards were developed to standardize various processes in order to produce high-standard goods and services. They are international voluntary norms. However, a number of government organizations already require accreditation in order to register laboratories. As a result, voluntary norms may now be enforced in some nations and in some productive sectors in developing nations (Schneider et al.,2017).

The Clinical and Laboratory Standards Institute (CLSI), with input from numerous stakeholders, including the international laboratory community, has created and made available additional significant international standards for laboratories. These CLSI consensus-based medical laboratory standards are addressed in order to continuously improve the testing quality, safety, and effectiveness while promoting the highest calibre of medical care. The CLSI-developed model for a quality management system is based on 12 essential components and is completely compliant with ISO standards for laboratories (WHO 2016). There are two well-known references for the clinical laboratory that the CLSI has published:

- The alignment of GP26-A4 with a number of laboratory and accreditation standards makes it simple to implement, which aid laboratories in complying with regulatory requirements (Jane Keathley 2012). GP26-A4 Laboratory Service Quality Management System Model Application (fourth edition). The term "Good laboratory practices" (GLPs) refers to a quality management system that links organizational procedures and standard operating procedures to the planning, execution, control, documentation, archiving, and information-gathering of nonclinical health and environmental safety studies. The primary goals of GLPs are:

- Optimizing resources;
- safeguarding people, the environment, and experimentation animals;
- establishing standardized operating procedures;
- ensuring the validity and reliability of study findings.

GLPs, however, does not prioritize ongoing development (Vives et al., 2015). The World Health Organization (WHO) developed a number of standards for laboratories, and some nations have even provided national quality standards for laboratories; however, these standards are outside the purview of this review and there are numerous other standards for laboratories that are conducted only to specific laboratory areas, analyses, or programmes and zones.

3. ISO SPECIFICATIONS THAT APPLY TO LABORATORIES

The following standards are accredited and are more frequently used by laboratories that wish or need to demonstrate their proficiency than ISO 9001 certification, as was previously mentioned.

3.1 ISO 15189: Medical laboratories' – Requirements for quality & competence

All of the requirements specified in ISO 15189 must be met by medical laboratories that analyse human biological samples in order to ensure that they are: technically competent; able to produce results that are technically valid. Similar to ISO 17025, this standard does not certify but rather accredits particular testing techniques based on the requirements of the laboratory. By achieving ISO 15189, clinical laboratories prove in an unbiased manner and attest to their technical competence, quality, and proper laboratory operation. The processes in an ISO 15189 laboratory are under control and meet the technical standards to ensure clinical diagnosis information, establishing a framework of trust between society, patients, and medical professionals.

When ISO 9001, ISO/IEC 17025, and ISO 15189 are compared (Table 1), ISO/IEC 17025 mandates the documentation of "technical requirement" processes. In other words, the staff, environmental conditions, equipment, and samples are just a few examples of the factors that must be noted in order to ensure the accuracy, reliability, and validity of tests and calibrations. Due to the sensitivity and specificity of test and calibration, there are requirements related to human resource management, specifically in terms of qualification and competence, or infrastructure (to ensure test conditions).

3.2 ISO/IEC 17025: Testing and Calibration Laboratories Competence

The requirements set forth by ISO 17025, including sampling, must be complied with by organizations conducting tests and/or calibrations. Labs that want to develop and implement a quality management system for their services and receive laboratory accreditation use this standard. It creates a framework for assessing the laboratory's technical proficiency through an external audit. A laboratory must adhere to ISO 17025 regardless of how many employees, what kind of testing or calibration activities are being performed, for whom, or even for their own organization. It includes experiments that make use of unconventional, conventional, or lab-developed techniques.

ISO 17025 was made based on two sets of requirements such as • *Management requirements:* These pertain to the quality management of the laboratory and are very similar to ISO 9001. Technical requirements: elements that have a direct impact on the outcomes of calibration and testing activities in laboratories. Analysts are aware of the advantages of working within a QMS of this type due to the growth in laboratory business revenue (Honsa and McIntyre 2003).

ISO 15189 : 2012	ISO 15189: 2022	ISO/IEC 17025:2017	ISO 9001
Foreword	Foreword	Foreword	Foreword
0 Introduction	Introduction	0 Introduction	0 Introduction
1 Scope	1 Scope	1 Scope	1 Scope
2 Normative references	2 Normative references	2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions	3 Terms and definitions	3 Terms and definitions
4 Management requirements	4 General requirements	4 General requirements	4 Context of the organizations
4.1 Organization and management responsibility	4.1 Impartiality	4.1 Impartiality	4.1 Understanding the organization and its context
4.2 Quality Management system	4.2 Confidentiality	4.2 Confidentiality	4.2 Understanding the needs and expectations of interested parties
4.3 Document control			4.3 Determining the scope of the quality management system
4.4 Service Agreements			4.4 Quality management system and its processes
4.5 Examination of referral laboratories			

ISO 15189 : 2012	ISO 15189: 2022	ISO/IEC 17025:2017	ISO 9001
4.6 External services and supplies			
4.7 Advisory services			
4.8 Resolution of complaints			
4.9 Identification and control of nonconformities			
4.10 Corrective action			
4.11 Prevention action			
4.12 continual improvement			
4.13 Control of records			
4.14 Evaluation and audits			
4.15 Management reviews			
5 Technical requirements	Structural and Governance requirements	5 Structural requirements	5 Leadership
5.1 Personnel	5.1 Legal Entity		5.1 Leadership and commitment
5.2 Accommodation and environmental conditions	5.2 Laboratory Director		5.2 Policy
5.3 Laboratory equipment, reagents, and consumables	5.3 Laboratory Activities		5.3 Organizational roles, responsibilities, and authorities
5.4 Pre-examination processes	5.4 Structure and Authority		
5.5 Examination processes	5.5 Objectives and Policies		
5.6 Ensuring quality of examination results			
5.7 Post-examination processes			
5.8 Reporting of results			
5.9 Release of results			
5.10 Laboratory information management			
	6 Resource requirements	6 Resource requirements	6 Planning
		6.1 General	6.1 Actions to address risks and opportunities
	6.2 Personal	6.2 Personnel	6.2 Quality objectives and planning to achieve them
	6.3 Facilities and environmental conditions	6.3 Facilities and environmental conditions	6.3 Planning of changes
	6.4 Equipment	6.4 Equipment	
	6.5 Equipment Calibration and Metrological traceability	6.5 Metrological traceability	
	6.6 Reagents and Consumables	6.6 Externally provided products and services	
	7 Process requirements	7 Process requirements	7 Support

ISO 15189 : 2012	ISO 15189: 2022	ISO/IEC 17025:2017	ISO 9001
	7.1 General	7.1 Review of requests, tenders and contracts	7.1 Resources
	7.2 Pre-examination Processes	7.2 Selection, verification and validation of methods	7.2 Competence
	7.3 Examination Process	7.3 Sampling	7.3 Awareness
	7.4 Post Examination Process	7.4 Handling of test or calibration items	7.4 Communication
	7.5 Nonconforming Work	7.5 Technical records	7.5 Documented information
	7.6 Control of data and information management	7.6 Evaluation of measurement uncertainty	
	7.7 Complaints	7.7 Ensuring the validity of results	
	7.8 Continuity and emergency preparedness planning	7.8 Reporting of results	
		7.9 Complaints	
		7.10 Nonconforming work	
		7.11 Control of data and information management	
	8. Management system requirements	8. Management system requirements	8 Operation
	8.1 General requirements and options	8.1 Options	8.1 Operational planning and control
	8.2 Management system documentation	8.2 Management system documentation (Option A).	8.2 Requirements for products and services
	8.3 Control of management system documents	8.3 Control of management system documents (Option A)	8.3 Design and development of products and services
	8.4 Control of records	8.4 Control of records (Option A)	8.4 Control of externally provided processes, products, and services
	8.5 Actions to address risks and opportunities for improvement	8.5 Actions to address risks and opportunities (Option A)	8.5 Production and service provision
	8.6 Improvement	8.6 Improvement (Option A)	8.6 Release of products and service
	8.7 Corrective action	8.7 Corrective actions (Option A)	8.7 Control of nonconforming outputs
	8.8 Evaluation	8.8 Internal audits (Option A)	

ISO 15189 : 2012	ISO 15189: 2022	ISO/IEC 17025:2017	ISO 9001
	8.9 Management review	8.9 Management reviews (Option A)	
			9 Performance evaluation
			9.1 Monitoring, measurement, analysis, and evaluation
			9.2 Internal audit
			9.3 Management review
			10 Improvement
			10.1 General
			10.2 Nonconformity and corrective action
			10.3 Continual improvement
Annex A (informative) Correlation with ISO 9001:2008 and ISO/IEC 17025:2005	Annex A (normative) Additional requirement for Point-of –Care Testing (POCT)	Annex A Nominal cross-references to ISO 9001:2000	Annex A Clarification of new structure, terminology, and concepts
Annex B Comparison of ISO 15189:2007 and ISO 15189:2012	Annex B (informative) Comparison between ISO9001 :2015 and ISo 15189: 2022	Annex B Guidelines for establishing applications for specific fields	Annex B Other international standards on quality management and quality management systems developed by ISO/TC 176
	Annex C (informative) Comparison between ISO 15189: 2012 and ISO 15189: 2022		
Bibliography	Bibliography	Bibliography	Bibliography

Table 1: Comparison of Structure and components of all three standards ISO 15189:2012 & 2022, ISO/IEC 17025:2017, and ISO 9001:2015

In order to establish communication channels between patients, medical personnel, and the laboratory, ISO 15189 expands its scope to include the analytical, pre-analytical, and post-analytical phases. The decision between certification (ISO 9001) and accreditation (ISO 17025 standard for testing or calibration laboratories or ISO 15189 when it is a clinical laboratory), on the other hand, will depend on the demands from current or potential customers, regulatory boards, or the anticipated growth and development of the laboratory (Gimeno 2003; Datema et al., 2011).

CERTIFICATION AND ACCREDITATION: SIMILARITIES AND DIFFERENCES.

The best option is matching laboratory certification for the required tests because it enables determining the validity of their tests, which is crucial when clients demand international recognition of their results or the laboratory wishes to include users with international criteria. If customers need to ensure sample traceability from sample collection to result delivery, they should utilize ISO 9001 because it is the most straightforward and affordable quality management system to adopt. The ISO 9001 certification could be adequate at the local level to reassure clients about the calibre of the products or services offered, to differentiate themselves from the competitors, and to accomplish a number of objectives like winning market share and government contracts.

In contrast, the laboratory's mission, vision, and policy may include matters relating to market positioning, so specific goals should be established for each case with regard to certification and accreditation.

Table 2 (Valeria 2017) lists the advantages of implementing ISO 9001, ISO/IEC 17025, and ISO 15189 in the laboratory.

Benefits	ISO 15189	ISO/IEC 17025	ISO 9001
Enhancing the company's reputation	X	X	X
Permit market share to increase	X	X	X
Increasing business effectiveness	X	X	X
Enhancing qualifications for accessing bids	X	X	X
Process improvement internally	X	X	X
Accomplishment of strategic goals	X	X	X
Creation of systems for service quality improvement that is ongoing	X	X	X
Obtaining consumer contentment	X	X	X
Customer adherence	X	X	X
Formally acknowledge technical proficiency	X	X	
Trials are recognized internationally	X	X	
Staff dedication to fulfilling consumer needs	X	X	
Building staff competencies	X	X	
Met the criteria for the laboratory's registration with governmental bodies.		X	

EXTERNAL PROGRAMMES FOR QUALITY CONTROL

Programs for "external quality assurance or assessment" (EQA) are a resource developed by a number of providers (usually medical or scientific societies) with the aim of instructing, assisting, and training individuals. They make it possible to compare the analytical performance for each of the important variables to the actual results (staff, apparatus, reagents, and method). EQA programme function similarly as a teaching tool to evaluate the laboratory's competence in relation to specific variables. In the quality management system, EQA is a supplement to internal quality control (IQC). An option is proficiency testing (PT), which is used for external quality assurance when licensing and/or accrediting laboratories for regulatory purposes (James et al., 2014).

With the aim of achieving harmonization, EQA programs enable the comparison of laboratory results and the reporting of worldwide variation. This goal is essential since it's common practice in medicine to compare analytical outcomes to the passage of time or a reference interval (Jones 2017). International societies are aware of the importance of this kind of EQA offering (De la Salle et al., 2017). The World Health Organization has a booklet available that provides guidelines on how to build up a national EQA programme based on ISO 17043:2010 Conformity assessment—general standards for proficiency testing and ISO 13528:2015 for health laboratories and other testing facilities. Proficiency testing for inter laboratory comparison using statistics. Contrary to expectations, there aren't enough accounts of how EQA involvement has improved the quality of analytical performance (Stavelin and Sandberg 2017).

An overview of the EQA participation procedure is shown in Figure 2. Samples are prepared by the EQA supplier and sent to the labs for analysis. The laboratory considers these samples of unknown nature from their arrival till report emission as regular samples while striving to include each analyser in the entire programme (James 2014). The EQA provider creates a confidential report explaining any discovered deviations from the given values after obtaining the analytical findings from all laboratories (Kristensen and Meijer 2017). Optionally, the report may specify the given value's acceptance criteria in accordance with the demands of analytical performance (Jones et al., 2017a) and offer details on the efficacy of the numerous participant-used techniques.

PARTICIPATION IN THE EQA

• *Monitoring:* to find labs that do analyses incorrectly. Statistically, the similarity of a result to those produced using the same process determines whether it is considered acceptable. The disadvantage of this kind of acceptance limit is that it varies between approaches. • *Clinical:* based on choices made by doctors.The laboratories should select the proper bounds for the specified objective when taking part in non-regulatory EQA. The "fitness for purpose" acceptance limit must be expressed in terms of external requirements when it is employed (Coucke and Soumali 2017). Targeted, high-quality schemes with sufficient sample sizes are preferred to numerous, high-risk schemes, even if the optimal frequency for EQA participation has not yet been established.

The quality of an EQA programme is determined by the design elements (Miller et al., 2011). It is common practise for an EQA programme to assign values based on reference measurement processes or by comparison with approved reference materials using validated commutable samples. The EQA sample is commutable when the result of analysis using a range of procedures is equivalent to the result obtained from patient samples with the same quantity of analytes. In other words, results obtained using different approaches are equivalent since commutable samples do not show matrix-related biases (Miller et al., 2006; Miller and Myers 2013). However, commutability is not always feasible since a significant number of EQA samples must be created under stable, homogenous settings with appropriate concentrations. To use biological samples as reference materials, it is also necessary to have precise knowledge about their processing, purity, characterization, "fitness for purpose," homogeneity, and stability, as well as their initial clinical, biological, and pathological diagnosis. Only in this way can the requirements of ISO Guide 34 for the preparation of reference material be applied.

In the absence of commutable samples, technique accuracy cannot be evaluated. In this sense, peer groups are employed to rate and classify laboratories because it is impossible to compare outcomes to a single set value. The approach and bias associated to the matrix are the same across peer groups. The assigned value is the group mean or median after outliers have been eliminated or deviation has been computed using trustworthy statistical procedures. It is significant to remember that a smaller peer group than a bigger one would have greater uncertainty in the projected assigned value (Kristensen and Meijer, 2017).

Another problem is that peer group evaluation cannot differentiate between a bad performance outcome when all participant reagents are affected. Due to this, the manufacturer should be informed when batch effects are observed, and the batch number of the reagents should be noted and considered during the EQA provider's evaluation (Miller 2016; Stavelin et al., 2016). The quality of the results can be compared to the method and the other laboratories in the same group, notwithstanding past limitations, thanks to this type of EQA. Regardless of sample commutability, previous analysis techniques are inappropriate for semi-quantitative measures, measurements reported on a discontinuous scale, or circumstances where dichotomous answers are provided for a continuous parameter (Coucke and Soumali 2017).

International EQA programmes are suggested, ideally with the aforementioned goal of harmonising laboratory results. They are too expensive and complicated to be useful for everyday usage, which makes it difficult for EQA providers to come up with creative solutions and get beyond design-related limitations (Miller et al., 2011). A new option has been proposed in the interim (Jones 2017b) would be to put up a global EQA with a special design (verified commutable samples and assigned value by references) for a few representative labs from different nations. These labs would then participate in more focused national or regional programmes that were created especially for reference labs in a later phase. As part of this endeavour, the EQA results should be reviewed by a qualified, worldwide advisory board to identify the root causes of any global variances.

One type of testing is point-of-care (POC) technologies, which introduce a decentralized approach and have the highly noticeable benefit of improving the population's access to diagnostics. However, from the standpoint of the EQA programme, POC analytical performance improves in a manner similar to that of the design difficulty: many EQA samples are needed for several testing points, where nonspecialized staff is available with a poor and delayed participation (Stavelin and Sandberg 2017). Connected devices to a central database for POC technologies have been developed to solve this problem and construct an efficient and quick EQA workflow. Unique IDs assigned to send EQA samples make each phase of the process less complicated, less expensive, and less error-prone (Cheng et al., 2016).

To be clear, taking part in EQA does not directly increase quality, but it does help to spot and monitor problems with inferior performance. Since an EQA manager should be available, it is essential that proactive involvement be incorporated in the lab (James et al., 2014). Based on the various EQA designs and its specific requirements for quality control or assistance, the laboratory must choose an EQA organizer. This selection procedure needs to be described and backed up by facts. The choice is easier when competence testing is necessary for legal requirements. Use EQA companies that have professional committees and accredited labs whenever possible. To do this, the EQA supplier is required to offer consumers with information regarding the designs of EQA programme, in particular the analytical performance criteria applied in each case. This information will allow comparisons between different EQA programme because analytical performance criteria for the same analyte are not uniform.

The laboratory must also take a proactive approach for proper and prompt EQA report review; in the case of accreditation, this is even obligatory. EQA provider auditor reports are commonly utilised as a quality control tool. The laboratory staff should be notified of the outcomes of the EQA analytical performance through formal communications (James et al., 2014). There should be three different types of reports available (Coucke and Soumali 2017): • A private, detailed report for each laboratory, including outliers, detailing its divergence from the allocated value and typically the accepted limits. Reports may also include participant numbers, countries of origin, and distribution of results to enable comparisons between them and even the laboratory's performance history. Periodic reports can also be provided to emphasize the most important findings. • Summary reports at the end of each scheme or programme with global and anonymized information regarding analytical performance variation for various analyses. Graphical representations are a crucial supporting component for the evaluation in the reports and are needed by international standards. Graphs are effective tools for displaying combined data from numerous analyses using various samples, time periods, or other pertinent variables. Only if adjustments are made to the deviating procedures will it be able to improve the laboratory's quality following EQA participation. EQA providers should assist and work together with the laboratory throughout this phase as part of their duties in education, training, and assistance.

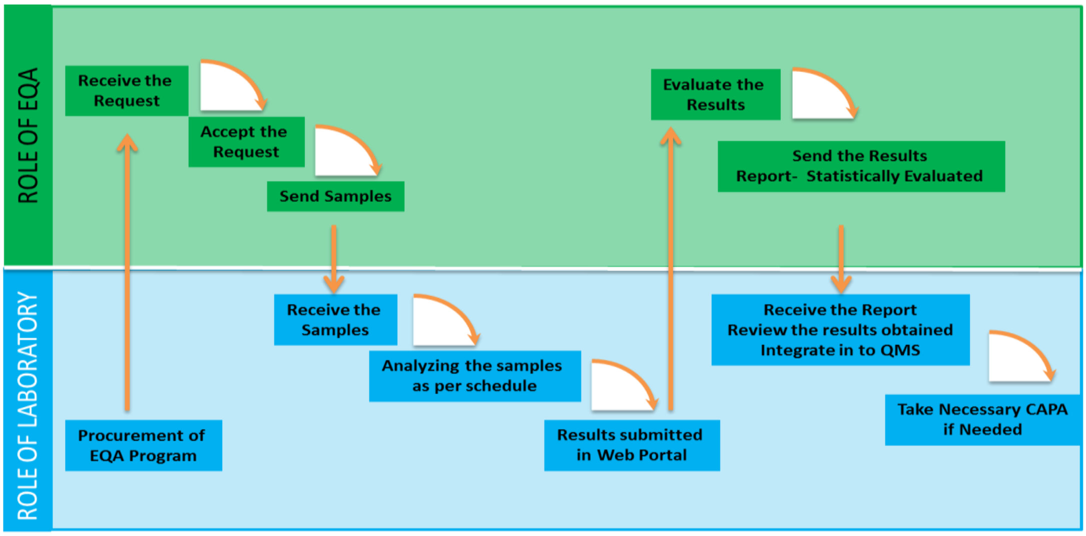
The efforts taken to identify the cause of the deviation and address its effects must be included in the proposed corrective actions' documentation. The Norwegian Clinical Chemistry EQA Program (NKK) and the External quality Control of diagnostic Assays and Tests (ECAT) Foundation have created a flowchart with extra remarks as a troubleshooting aid for EQA about analytical (Kristensen and Meijer 2017). It is a public tool, solely valid for quantitative analysis, that suggests corrective and preventative action (CAPA) documentation or root cause analysis (RCA) measures be taken once an EQA identifies a deviation. The flowchart and related remarks take into account four points: the likely source of deviation, the associated accountability for this cause, a concise explanation, and lastly a thorough explanation about the proposed actions.

The preceding points are grouped in accordance with the sequential EQA participation steps as follows (Table 3):

S. No	Particulars	
1	Transcription errors	This is the most typical reason.
2	Pre-survey concerns	This is not laboratory-related. Sadly, sample reanalysis is required.
3	Sample receipt or handling	This caused by inaccurate address information, a failure to grasp the EQA provider's instructions, a sample's lack of integrity, or a lack of records.
4	Test performance	New or recurring factors that necessitated determining who, when, and how as well as looking at internal quality control data (IQC) and searching for consistent departures from various participations throughout time.
5	Data handling by the EQA provider	These inaccuracies are related to the statistical procedure, and the laboratory has a difficult in identifying them.

Reporting and analysis

In conclusion (Figure 3), (Miller and Jones 2011) the process for integrating the EQA data in the laboratory's QMS is as follows:



Interpretation of a report, putting in motion documented remedial and preventative measures when possible. To compile data on who, when, and how EQA participation occurs in relation to IQC data, past EQA results, and the overall EQA results. To determine what caused the discrepancy. Keeping track of the steps taken. A fresh examination of the last stored aliquot of the EQA sample. Modification of EQA programme choice

Linking QMS with the EQA results in laboratory's

Although EQA has typically been used to improve analytical performance, the pre-analytical phases should be met by the EQA method as well. There have been numerous attempts to address these, and three different pre-analytical EQA techniques have been identified (Kristensen et al., 2014). Type I: Questionnaires are used to register procedures. A minimal amount of resources are required to arrange and take part, and pertinent suggestions might be offered. Sample analysis with simulated problems is Type II. Pre-analytical deviations can be induced, but only to a certain extent. Type III: Incidence registration. This type of pre-analytical EQA scheme gives EQA suppliers the chance to harmonize quality indicators (QIs). Although pre-analytical EQA schemes are more challenging to standardize, making progress in this area is worthwhile because these stages are more prone to mistakes. Due to two key factors—the high prevalence of errors connected with these phases, as well as the definition of a quality management system (QMS) discussed at the beginning of this chapter—the seeking and reporting diagnostic phases should also be covered by EQA programmes (Badrick et al., 2017). To get valuable information, such applications' designs should be properly constructed. The activities of clinical laboratories are supported by evidence from research (Jones 2017).

CONCLUSION

Every laboratory must look into the existence of national regulatory standards. These are the ones that are most closely aligned with the requirements of the nation's laboratories. A laboratory has to consistently employ both guidelines and standards: guidelines delineate how quality management might be incorporated into laboratory procedures, while standards enumerate the prerequisites for a quality management system.

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