Meeting the needs of Mediterranean nations: improving efficiency in laboratory medicine

The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine

eJIFCC

This is a Platinum Open Access Journal distributed under the terms of the Creative Commons Attribution Non-Commercial License which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

Which skills are needed and how they should be gained by laboratory medicine professionals for successful ISO 15189 accreditation

Diler Aslan

Department of Medical Biochemistry, Medical Faculty, Pamukkale University, Denizli, Turkey

ARTICLE INFO

Corresponding author:
Diler Aslan
Department of Medical Biochemistry
Medical Faculty
Pamukkale University
Denizli
Turkey
E-mail: daslan@pau.edu.tr

Key words:
ISO 15189, accreditation, training

ABSTRACT

Clinical laboratories worldwide are accredited according to the "ISO standard, 15189:2012: Medical Laboratories—Requirements for Quality and Competence."

Seeking accreditation has many challenges. Success requires the right competencies and knowledge and the right technical expert and trainer to lead the laboratory through the process. The right competencies and knowledge typcially are beyond the core knowledge, skills and attitudes gained during education of laboratory professionals. The main objective of this paper is to discuss what competencies, knowledge and expertise are essential for laboratories to meet accreditation challenges and gain ISO 15189:2012 accreditation.

INTRODUCTION

The "ISO 15189 Standard: Medical Laboratories–Requirements for Quality and Competence" is an internationally accepted accreditation standard based on a series of requirements (1). Like other ISO Standards, ISO 15189 identifies what laboratories need to do, but not how to do. Each laboratory specifies the "how" for its situation using knowledge thought to be acquired during the training of medical laboratory specialists and included in the core curricula/syllabi published by scientific, professional and government authorities (2,3). However, ISO 15189 accreditation typically requires knowledge and competencies beyond the educational scope. A key to ISO 15189 accreditation is the quality management system. In this context, it is useful to understand and apply concepts from "ISO 9001:2015 Quality Management Systems-Requirements," and the CLSI Guideline, "GP26-A3: Application of a Quality Management System Model for Laboratory Services (4,5). This paper presents the main areas and basic tools for gaining the competencies required by ISO 15189:2012 and to share my experiences of the ISO 15189 technical expert and trainer.

MAIN AREAS AND BASIC TOOLS FOR SUCCESSFUL ACCREDITATION WITH ISO 15189:2012

The medical laboratory environment is rapidly changing. In order for effective management, the laboratory directors must be technically and clinically competent in their defined specialty areas, and also have relevant and common managerial, statistical and computer knowledge and skills. These attributes can be collected under the main topics such as "Quality Management",

Figure 1 Areas and topics for competencies required for the ISO 15189:2012

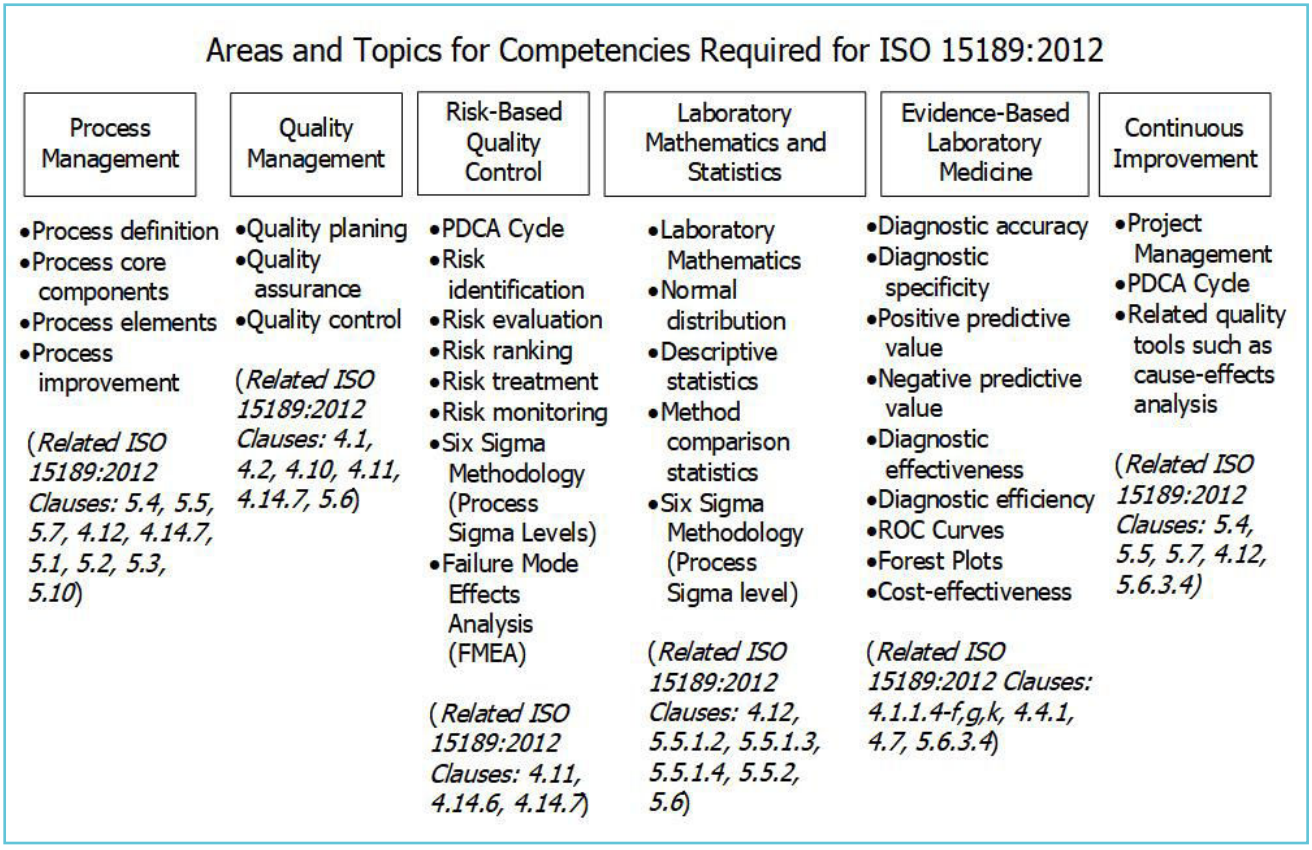
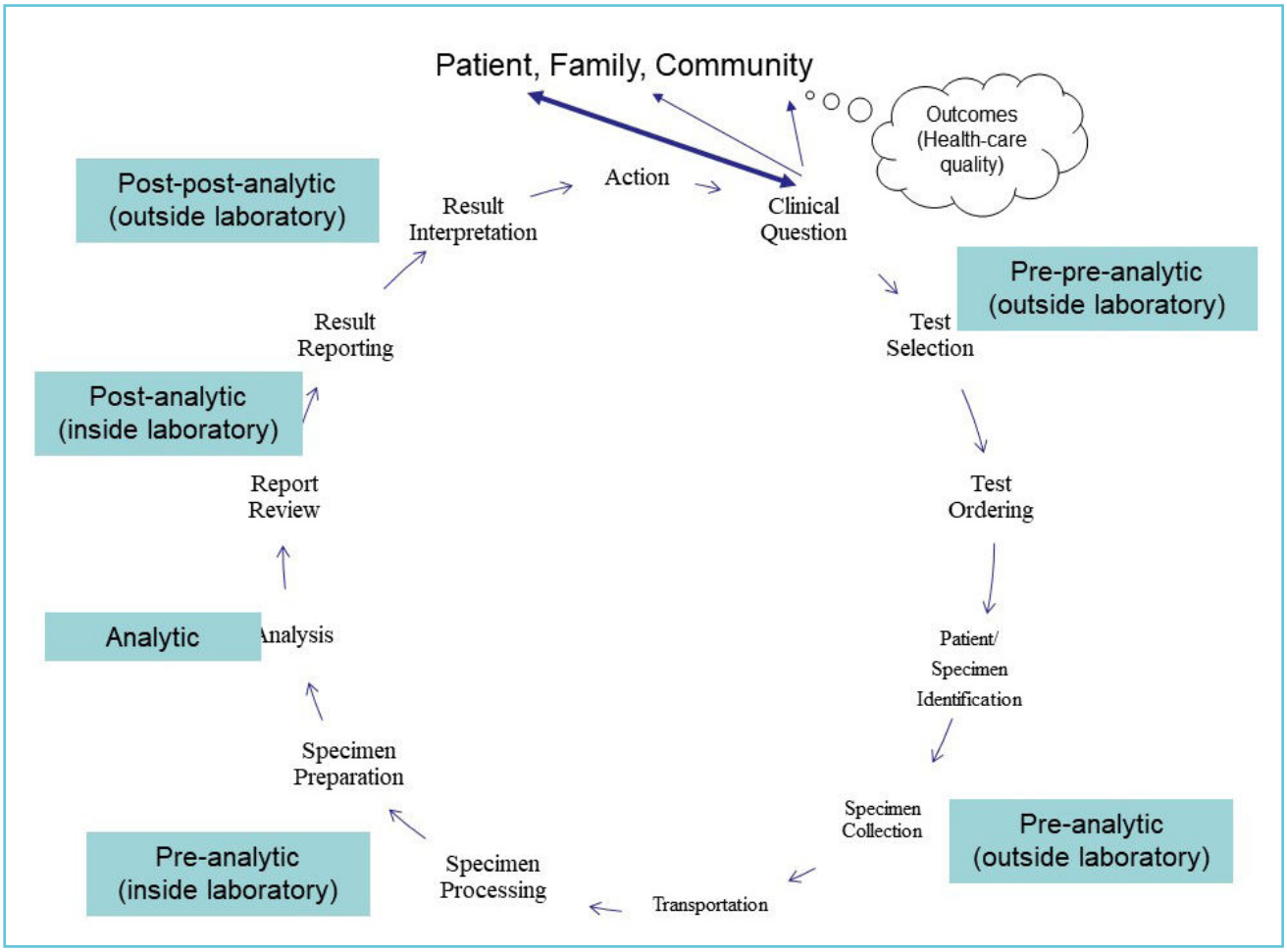


Figure 2 The medical laboratory total testing process



Adapted from:
https://ftp.cdc.gov/pub/cliac_meeting_presentations/pdf/addenda/cliac0314/16a_west_cdclabtoolkit2013_handout.pdf.

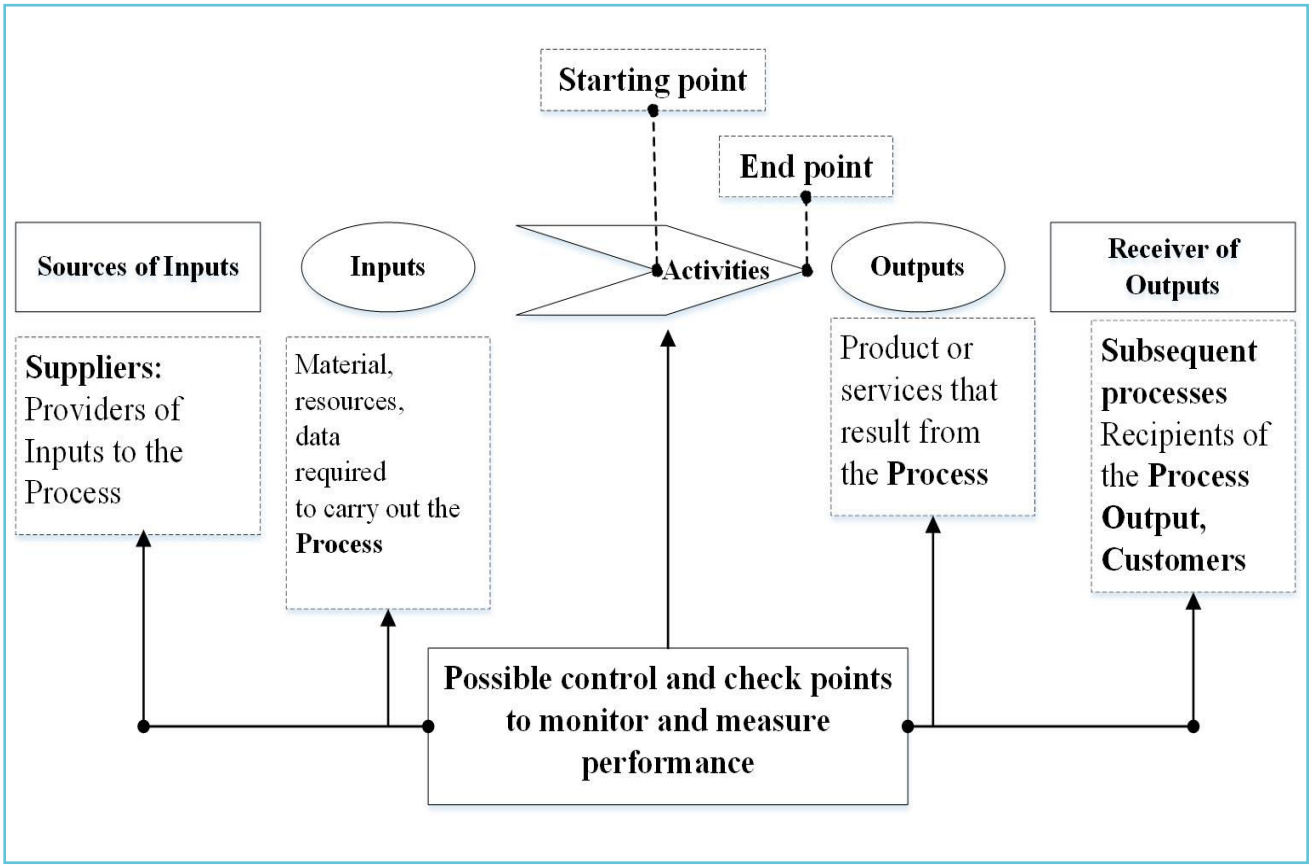
"Process Management", "Risk– Based Thinking", "Laboratory Mathematics and Statistics", "Evidence-Based Laboratory Medicine" and "Project Management" (Figure 1) (6–10).

The clauses' numbers of the ISO 15189: 2012 Standard that are related to the competencies that should be gained by laboratory professionals are listed under the competency topics in Figure 1.

To establish a quality management system requires a systematic, process-oriented approach so that quality objectives/requirements are achieved. The sub-processes of the total testing process of a medical laboratory seen in Figure 2 can be managed according to the simple work flow shown in Figure 3 in regard to the process core components (e.g., inputs, outputs, resources, activities and controls), and its elements (e.g., personnel, methods, materials, equipment, environment and measures).

Since continuous improvement is one of the key requirements of the ISO 15189, the methodologies and standards such as the "Plan, Do, Check, Act (PDCA)" Cycle, Six Sigma, Lean, Lean Six Sigma, total quality management, statistical process control and cause-effect analysis are the improvement tools used widely as listed in Figure 1 (6,8,11,12).

Figure 3 A process approach



Adapted from the ISO 9001:2015.

In addition to the topics mentioned in the previous paragraph, knowledge of quality management sub-processes is important to provide a systematic initiation. Such that establishment the QMS is composed of three processes; quality planning (QP), quality assurance (QA), and quality control (QC) (Figure 4) (6).

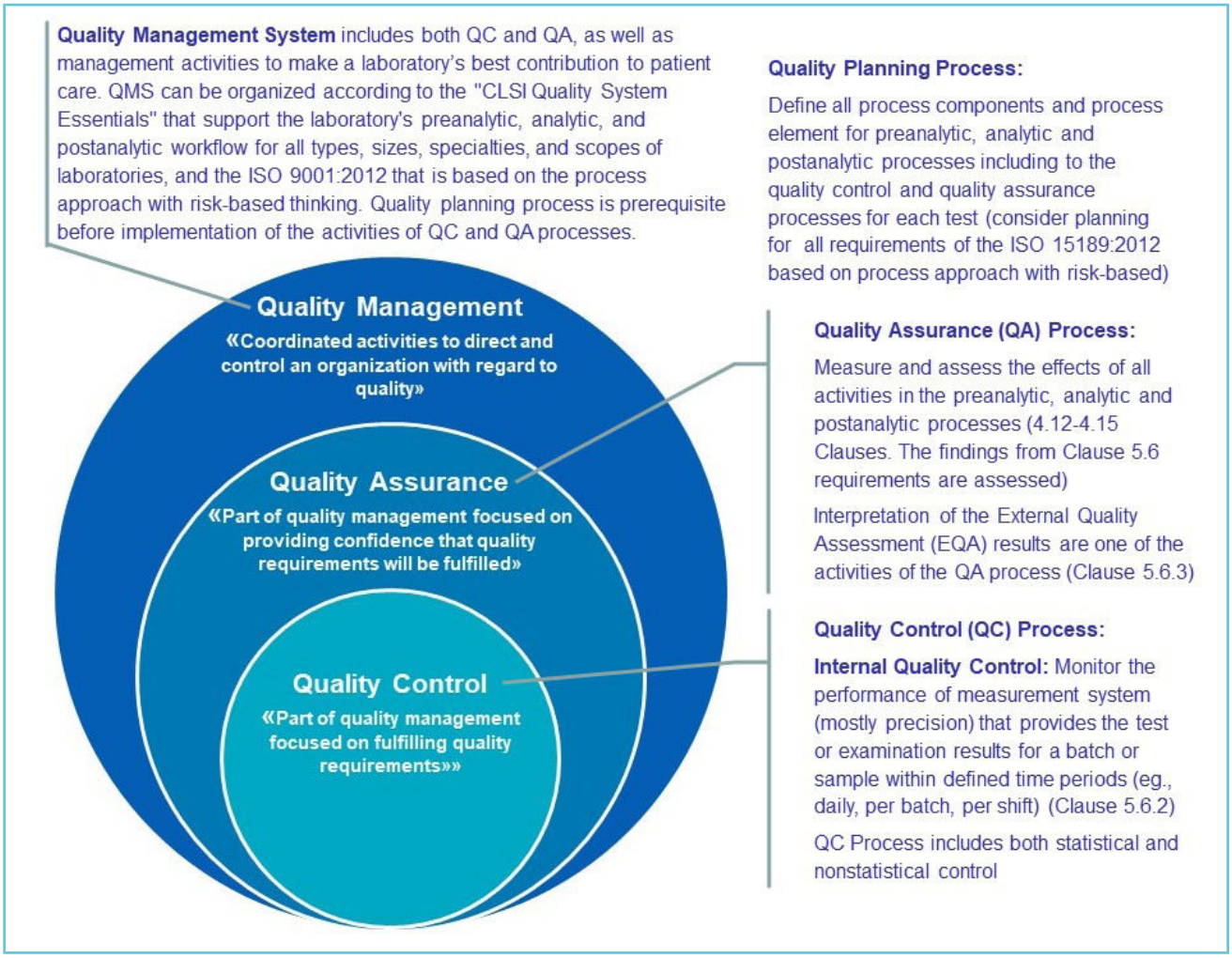
In the QP process, the managerial, operational and functional (supportive) processes of total testing process of a medical laboratory as required by ISO 15189 are defined, the resources according to each test system are allocated, and quality objectives and quality indicators of each subprocess are defined considering each test (Figure 5).

QC process covers the operational process control techniques to fulfill quality requirements defined for each test in order to achieve each subprocess (analytical and non-analytical processes) performance.

QA process is composed of planned and systematic activities to provide evidence-based information that a medical laboratory fulfills quality requirements defined as quality objectives and quality indicators for each sub-processes in the QP stage, and provides the report for continuous improvement activities (Clause 4.12). Learning resources, required knowledge, skills and competencies for each activities in the subprocesses are summarized in Figure 5.

The important common issue in preparation for accreditation is confusion about the differences between quality system certification and accreditation.

Figure 4 Quality levels that define the quality management processes required to establish a quality management system



DIFFERENCE BETWEEN ACCREDITATION AND QUALITY SYSTEM CERTIFICATION

It is important to realize the difference between the ISO 9001 quality system certification and the ISO 15189 accreditation. The ISO 9001 certifies the consisted business processes are being applied, but it is not guarantee the quality of the end products and services such as the ISO 15189 that focuses on the technical and clinical competencies for reliable and cost-effective test results (1,4). The first part of the ISO 15189 (Clause 4 Management Requirements) is based on the ISO 9001. However, there are correlations of the second section of the ISO 15189 (Clause 5 Technical Requirements) with the ISO 9001:2015 that uses process approach and risk-based thinking (1,4). In this context, the ISO 9001:2015, especially risk-based process approach, should be well understood before accreditation process. Although there are correlations between two standards, it is crucial to keep in mind the differences because accreditation is deserved for specific activities such as to provide effective and efficient test results whereas certification relates to the whole organization.

Figure 5 The decision, design and implementation processes for a new analyte, and required knowledge, skills and competencies

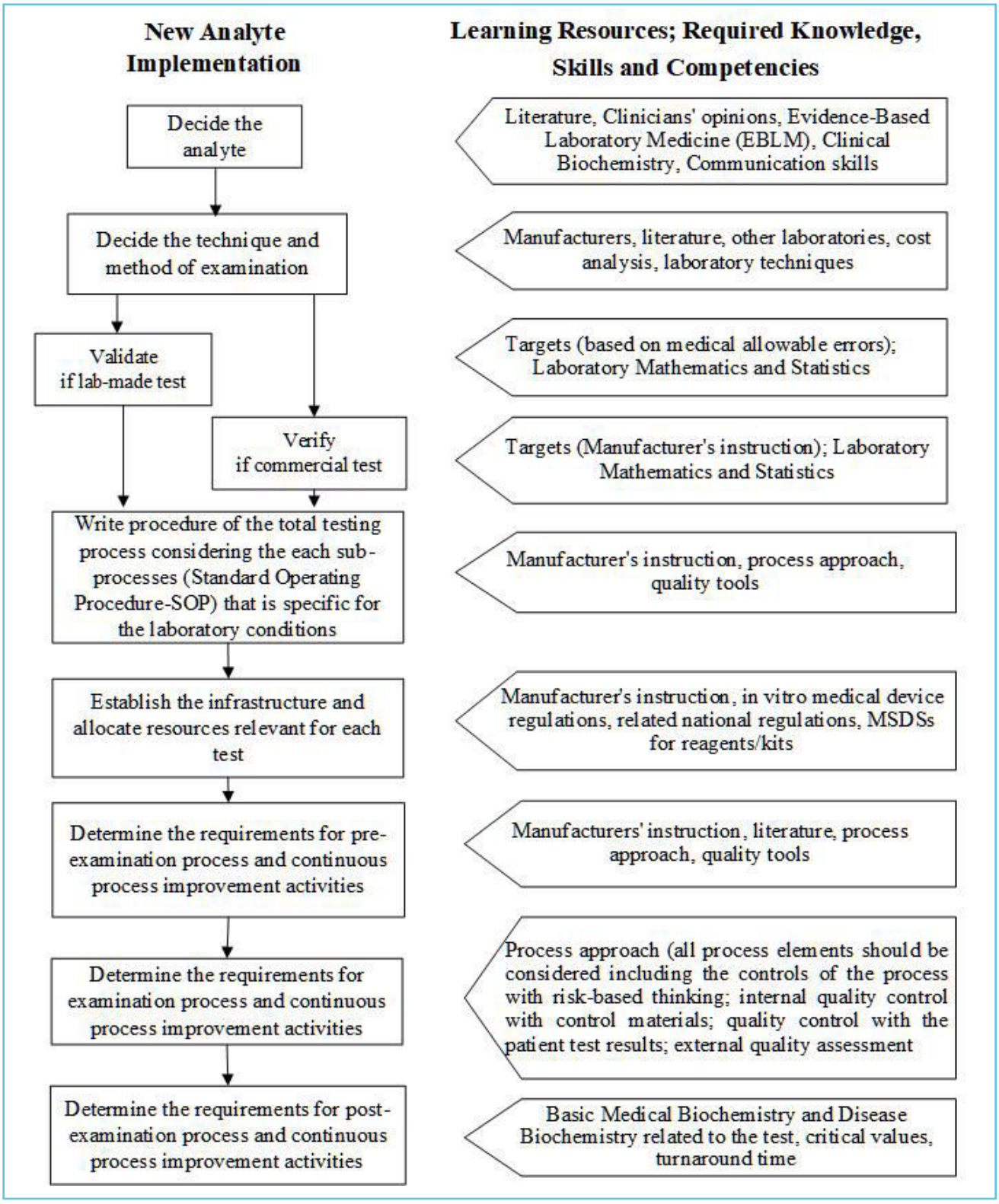


Table 1 Correlations between "NCCLS (CLSI) GP26-A3 Application of a Quality Management System Model for Laboratory Services; Approved Guideline — Third Edition (2004)" with the ISO 15189:2012

GP26-A3	ISO 15189:2012
Documents and Records	4.3 Document control
	4.13 Control of records (quality and technical records)
Organization	4.1 Organization and management responsibility
	4.1.1.3 Ethical conduct
	4.2 Quality management system
	4.15 Management review
Personnel	5.1 Personnel
Equipment	5.3.1 Laboratory equipment
	5.10 Laboratory information management
Purchasing and Inventory	4.4 Service agreements
	4.5 Examination by referral laboratories
	4.6 External services and supplies
Process Control	5.4 Pre-examination processes
	5.5 Examination processes
	5.6 Ensuring quality of examination results
	5.7 Post-examination processes
	5.8 Reporting of results
Information Management	5.10 Laboratory information management
Occurrence Management	4.11 Preventive action
	4.10 Corrective action
	4.14.6 Risk management

Assessment: External and Internal	5.6.2 Quality control (IQC)
	5.6.3 Interlaboratory comparisons
	5.6.3.2 Alternative approaches
	5.6.4 Comparability of examination results
Process Improvement	4.12 Continual improvement
	4.14 Evaluation and audits
	4.14.7 Quality indicators
	4.15 Management review
Customer Service	4.1.2.2 Needs of users
	4.7 Advisory services
	4.8 Resolution of complaints
	4.14.3 Assessment of user feedback
	4.14.4 Staff suggestions
	4.14.8 Reviews by external organizations
Facilities and Safety	5.2 Accommodation and environmental conditions

PREPARATION FOR ISO 15189 ACCREDITATION

The quality system essentials in the GP26-A3 can be used as framework with the process approach (5). Table 1 depicts the correlations between the QSEs and the ISO 15189. The QSEs are matching to the process core components and elements in Figure 3 of total testing process in Figure 1. As seen in Figure 5, all activities that are performed for decision of a new analyte and its application are also in between the requirements of the ISO 15189.

Preparation for the ISO 15189 accreditation is challenging, and requires comprehensive knowledge and competency (13). Learning the topics listed under the main areas related to the competencies required by the ISO 15189 accreditation summarized in Figure 1 may be helpful for successful accreditation.

The steps may be organized as:

1) Defining activities according to the quality levels (Figure 4);
2) Defining the process core components and process elements of the total testing process and its sub-processes for each test according to the process approach (Figure 3);
3) Defining all key process controls (key performance specifications and quality indicators) for each test process that is in the accreditation scope.

TRAINING PROGRAMS, PROFESSIONAL DEVELOPMENT AND CAREER PLANS

The main duty of a laboratory professional is to provide the reliable and accurate laboratory test results cost-effectively and timely. Besides this, there are responsibilities of laboratory in respect to the value-based health care (14,15).

Accreditation against the ISO 15189, if it is performed ideally, adds value to health care quality in respect to both human health, and the tracking and evaluation of in vitro diagnostic medical devices at the national level if the government establishes infrastructure for collecting the data. However, acquiring diverse knowledge and competencies that are growing exponentially is a challenging issue for a laboratory director.

The other challenging issue is that it is not possible to find a university or teaching hospital that has sufficient trainers who have all required knowledge and skills. One of the solutions may be the training courses organized by experts both in classroom and in distance-learning formats. The training programs should be competency-based in the concepts of “case-based”, “entrustable professional activities” and task-based (16,17).

Distance-learning courses (DLCs) can provide the rapidly increasing knowledge that should be learned and replace live on-site courses, which have high participation costs. However, the DLCs on the “Medical Laboratory Mathematics and Statistics” organized for the last 2 years encountered some challenges (18). These courses are 1.5 - 2 months long and require 3-hours of study per week. They contain texts, presentations, virtual classrooms and videos that enable the participants to practice with Microsoft Excel and SPSS calculations of problems and the assessment quizzes. However, it was observed that the laboratory specialists usually do not have enough time to work on the material.

Standardization of core knowledge of laboratory professionals required for the ISO 15189 accreditation can be established and online central examinations which would assess these requirements can be organized by the IFCC or the Regional Federations. Such initiatives will be helpful for laboratory professionals to decide what they need to learn and self-evaluate their knowledge.

REFERENCES

1. ISO. ISO 15189:2012 Medical laboratories — Requirements for quality and competence. 2012;

2. Greaves AUR, Smith JM, Greaves SEAUR, Florkowski C, Langman L, Sheldon J, et al. The IFCC Curriculum. 2017. http://www.ifcc.org/media/477173/2017-ifcc-curriculum.pdf

3. Wieringa G, Zerah S, Jansen R, Simundic A, Queralto J, Solnica B, et al. The EC4 European Syllabus for Post-Graduate Training in Clinical Chemistry and Laboratory Medicine : version 4 – 2012. Clin Chem Lab Med. 2012;50(8):1317–1328.

4. ISO 9001:2015 Quality management systems -- Requirements. International Organization for Standardization; 2015.

5. NCCLS. GP26-A3 Application of a Quality Management System Model for Laboratory Services ; Approved Guideline — Third Edition. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA; 2004.

6. Harmening DM. Laboratory Management, Principles and Processes. Third. St. Petersburg, Florida: D.H. Publish,ng and Consulting Inc.; 2013. 1-544 p.

7. Westgard JO, Sten A. Westgard. Basic Quality Management Systems Eessentials for Implementing Quality Management in the Medical Laboratory. Madison USA: Westgard QC, Inc.; 2014. 1-285 p.

8. Westgard JO. Six Sigma Risk Analysis: Designing Analytic QC Plans for the Medical Laboratory. Madison US: Westgard QC, Inc.; 2011. 1-296 p.

9. Christopher P. Price; Robert H. Christenson, editor. Evidence-Based Laboratory Medicine: From Principles to Outcomes. 2nd ed. AACC Press; 2003. 1-279 p.

10. P. Price C, Christenson RH, editors. Evidence-Based Laboratory Medicine: Principles, Practice, and Outcomes. 2nd ed. Washington, DC. US: AACC Press; 2007. 1-545 p.

11. The Proceess Approach in ISO 9001:2015. International Organization for Standardization. 2015. www.iso.org/tc176/sc02/public

12. Boutros T, Cardella J. The Basics of Process Improvement. CRC Press. 2016. p. 69–99.

13. David Burnett. A practical guide to ISO 15189 in laboratory medicine. ACB Venture Publications; 2013. 1-372 p.

14. Porter ME. What Is Value in Health Care? N Engl J Med. 2010;363(26):2477–81.

15. Schmidt RL, Ashwood ER. Laboratory Medicine and Value-Based Health Care. 2015;(September):357–358.

16. Ned-Sykes R, Johnson C. Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories. Centers for Disease Control and Prevention MMWR. 2015;64(1):1-81. http://www.ncbi.nlm.nih.gov/pubmed/25974716

17. McCloskey CB, Domen RE, Conran RM, Hoffman RD, Post MD, Brissette MD, et al. Entrustable Professional Activities for Pathology. Acad Pathol. 2017;4:1-9. http://journals.sagepub.com/doi/10.1177/2374289517714283

18. https://www.d-tek.com.tr/en/training/distance-learning-programs/ (Accessed on 12 October 2018)