CLSI Guidelines for Developing a Quality Management Plan

Background

In order to ensure the safety of patients and laboratory personnel and to ensure that accurate results are obtained and reported, the laboratory needs to maintain quality throughout its pre-analytical, analytical, and post-analytical path of workflow. A Quality Management Plan provides the infrastructure for maintaining quality in the laboratory.

The Quality Management approach included in these guidelines is based on the 12 Quality System Essentials (QSE) model developed by CLSI/NCCLS (refer to CLSI documents QMS01 ED5-2019, QMS02-A6, and CLSI QMS06-A3) and is mostly consistent with ISO standards (refer to ISO 15189). The 12 QSEs represent the most fundamental elements for maintaining quality, safety, and efficiency throughout the laboratory's path of workflow.

Description of the 12 QSEs:

- **QSE 1 – Organization and Leadership:** A strong commitment from top-level managers is essential for the success of the overall laboratory quality program. It is the leadership's responsibility for the laboratory's success in achieving and maintaining a systematic approach to quality and meeting regulatory, accreditation, customer, and internal requirements..
- **QSE 2 – Customer Focus:** This QSE describes how the laboratory need to identify its customers and their expectations. It should formalize agreements to provide laboratory services, to design work to meet those expectations and an applicable requirements. Also manage any customer complaints. There should be methods for seeking customer input to confirm expectations are met.
- **QSE 3 – Facilities & Safety Management:** This QSE describes how the physical space of the laboratory is maintained in a manner that ensures efficient workflow, accurate test results, and personnel safety. It describes how the laboratory supplies the materials and training necessary to ensure the safety of all personnel.
- **QSE 4 – Personnel Management:** The most important of the laboratory's resources is its personnel. This QSE describes how personnel are managed and provided with the tools needed to perform testing so that accurate and reliable test results are obtained. The laboratory identifies personnel resources needed for the new or changed services and acquires personnel with the necessary qualifications.
- **QSE 5 – Supplier and Inventory Management:** Availability of dependable and reliable test kits and supplies is essential. This QSE describes how reagents and supplies are procured, distributed, and managed to continue to keep up with performing the new or changed services.
- **QSE 6 – Equipment Management:** This QSE describes how equipment is selected, installed, identified, validated/verified, and maintained in order to ensure personnel safety and specimen and testing result integrity throughout the lifetime of the equipment in the laboratory. Also includes computer system (eg, information system) hardware and software.
- **QSE 7 – Process Management:** This QSE describes the activities and techniques that are carried out to ensure that the testing procedures are correctly performed, the

environment is suitable for reliable testing, and the testing methods work as expected to produce accurate and reliable results.

- **QSE 8 - Documents and Records Management:** This QSE describes the processes for creating standardized documents and records and maintaining documents and records so that they are up-to-date and accurate, readily accessible by laboratory staff, and protected from damage, deterioration, and unauthorized use.
- **QSE 9 – Information Management:** This QSE describes how patient-related and testing information are managed in order to maintain the accuracy, reliability, confidentiality, and accessibility of the data.
- **QSE 10 – Nonconforming Event Management:** This QSE describes how nonconforming events (occurrences) are detected, investigated, resolved, and tracked.
- **QSE 11 – Assessment:** This QSE describes the internal and external assessments that are conducted to evaluate the effectiveness of the laboratory's quality management system.
- **QSE 12 – Continual Improvement:** This QSE describes elements of a process improvement program that identifies and addresses opportunities for improvement and problems that impact patient care. Uses a defined strategy to eliminate process problems, enhance customer satisfaction, reduce waste, and lower cost.

Purpose

This document and the appendices provides guidance for developing a Quality Management Plan for a laboratory. The policies, processes, and procedures outlined in these guidelines and appendices are **only suggestions.** Each individual laboratory is responsible for developing a Quality Management Plan that is consistent with its path of workflow, needs and responsibilities, protocols specific to the laboratory, and any organizational, accreditation, governmental, or other regulations with which it must comply.

Terms

Document - For these guidelines, the term document will refer to any written policy, process, procedure, form, or job aid.

Facility - For the purpose of these guidelines, the term facility will refer to the laboratory's parent organization, including, but not limited to, hospitals, universities, or other institutions.

Policy Documents - Provides a statement of the intent and direction for accomplishing tasks.

Process Documents - Depicts/describes how related activities are sequenced across time.

Procedure Documents - Presents step-by-step instructions that a single individual needs to take to successfully complete one activity in a process.

Record - Laboratory records may be paper or electronic. Laboratory records include, but are not limited to: examination requisitions; worksheets and instrument printouts; quality control results and actions taken; external quality assessment (proficiency testing); equipment calibration and maintenance; examination method verification; software verification; patient examination reports; staff training and competence; internal and external audits and inspections; and occurrence, nonconformance, and complaint records and actions taken.

Policies and Processes

The policies and processes related to each QSE are described in the following appendices.

Appendices

A. QSE 1 – Organization and Leadership
B. QSE 2 – Customer Focus
C. QSE 3 – Facilities and Safety Management
D. QSE 4 – Personnel Management
E. QSE 5 – Supplier and Inventory Management
F. QSE 6 – Equipment Management
G. QSE 7 – Process Management
H. QSE 8 – Documents and Records Management
I. QSE 9 – Information Management
J. QSE 10 – Nonconforming Event Management
K. QSE 11 – Assessment
L. QSE 12 – Continual Improvement

References

1. CLSI. Quality Management System – A Model for Laboratory Services, 5th Edition, CLSI QMS01-ED5:2019. 950 CLSI West Valley Road, Suite 2500, Wayne, PA, 19087
2. CLSI Quality Management System: Development and Management of Laboratory Documents: Approved Guideline, 6th Edition, CLSI QMS02-A6.CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087,
3. CLSI Training and Competence Assessment, CLSI QMS03 4th Edition. CLSI QMS02-A6.CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087,
4. ISO. *Medical laboratories – Particular requirements for quality and competence.* EN/ISO15189. Geneva: International Organization for Standardization.
5. CLSI Laboratory Design, CLSI QMS04 3rd Edition. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
6. CLSI Qualifying, Selecting, and Evaluating a Referral Laboratory: Approved Guideline, 3nd Edition. CLSI QMS05-ED2:2020. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
7. CLSI Quality Management System: Continual Improvement: Approved Guideline, 3rd Edition, CLSI QMS06-A3. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
8. CLSI Nonconforming Event Management 2nd Edition, CLSI QMS11 2nd Edition. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
9. CLSI Developing and Using Quality Indicators for Laboratory Improvement, CLSI QMS12 2nd Edition. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087

10. CLSI Quality Management System: Equipment, 1st Edition, CLSI QMS13-A: 2011. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
11. CLSI Quality Management System: Leadership and Management Roles and Responsibilities: Approved Guideline, CLSI QMS14-A. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
12. CLSI Laboratory Internal Audit Program, CLSI QMS15 2nd Edition. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
13. CLSI External Assessment Audits, and Inspections of the Laboratory 1st Edition, CLSI QMS17-ED1:2016. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
14. CLSI Process Management, 2nd Edition, CLSI QMS18-ED2:2023. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
15. CLI Customer Focus in a Quality Management System, 1st Edition, CLSI QMS19-ED1:2017. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
16. CLSI Purchasing and Inventory Management, CLSI QMS21 1st Edition. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.
17. CLS Managing Laboratory Records, CLSI QMS26 1st Edition. CLSI 950 West Valley Road, Suite 2500, Wayne, PA, 19087.