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Guide to Quality Management Systems and Quality Manual

Purpose

This document from the Diagnostic Accreditation Program (DAP) provides guidance for organizations on fulfilling the Laboratory Medicine Accreditation Standards.

If you have questions about items in the standards, please email them to laboratorymedicine@cpsbc.ca.

Introduction

This document describes the objective of a quality management system (QMS) and the requirements for a quality manual. The quality manual forms the basis of the evidence submission required by assessors in advance of the on-site assessment.

Objectives

The objectives of this document are to

- familiarize assessors with the concept of a QMS, and to
- introduce the laboratories to the structure of a QMS and quality manual.

Quality management systems and quality manual

A QMS is the infrastructure built to support quality in an organization. Quality is the focused effort of understanding the policies, processes and procedures that work together to deliver services in an organization. A QMS is defined as the "coordinated activities to direct and control an organization with regard to quality."

A QMS is designed to provide a common understanding of the coordinated quality activities in an organization and form the basis for continual improvement. Continual improvement of systems and services is the definitive goal of a successful QMS.

Every organization needs to understand their definition of quality and consider how they will best achieve it. The definition of quality is embedded in the quality policy in the form of objectives which should be measurable and monitored to ensure that the organization is delivering what it says it will. These measures usually form part of the organization's key performance indicators or quality metrics.

There are many models for developing a QMS. The two that are most often used in diagnostic services are as follows:

- The ISO 9000 series of documents is a set of standards that specify requirements for quality systems. In essence, they provide a roadmap based on international expert consensus for the

delivery of a comprehensive QMS. ISO 15189 is a technical standard for medical laboratory testing based on ISO 9001:2015-Quality Management Systems.

- The Clinical and Laboratory Standards Institute (CLSI) document *Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition (QMS01-A4)* provides another excellent reference on building a QMS. This document was written as a roadmap for QMS development in a medical laboratory but is equally applicable to all diagnostic services and healthcare organizations.

The language of these two references differs slightly, but the fundamental requirements are the same. The building block policies of a QMS for a diagnostic service are described in Table 1.

Table 1: Quality management policies

CLSI QMS01-A4	ISO 15189:2012(E)
Organization structure	4.1 Organization and management responsibility 4.2 Quality management system
Facilities and safety	5.2 Accommodation and environmental conditions
Personnel	5.1 Personnel
Purchasing and inventory	4.4 Service Agreements 4.6 External services and supplies 4.7 Advisory services
Equipment	5.3 Laboratory equipment, reagents and consumables
Process management	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results processes 4.5 Examination by referral laboratories 5.7 Post-examination processes
Documents and records	4.3 Document Control 4.13 Control of records
Information management	5.8 Reporting of results 5.9 Release of results 5.10 Laboratory information management
Nonconforming event management	4.9 Identification and control of nonconformities
Assessment	4.14 Evaluation and audits 4.15 Management review
Continuous improvement	4.10 Corrective action 4.11 Preventive action 4.12 Continual improvement
Customer focus	4.8 Resolution of complaints

A successful QMS is often described using the four principles: ***Say what you do; do what you say; prove it; then improve it.***

Say what you do:

- document policies, processes and procedures
- make intentions transparent

Do what you say:

- provide training and support to understand and follow the procedures
- use the processes and procedures as the basis for the training

Prove it:

- audit the processes and system
- check the results/records for evidence of compliance

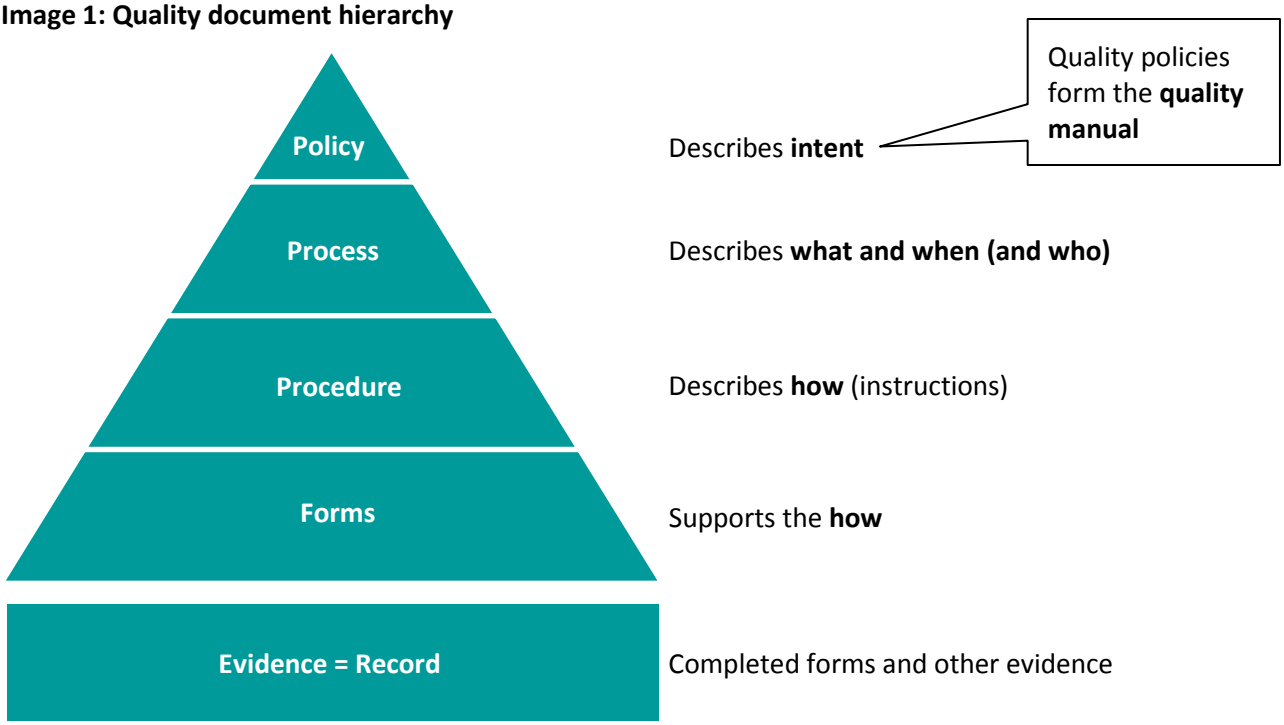
Improve it:

- audit the system for efficiencies and opportunities for continuous improvement
- correct the things that don't turn out the way they were designed to and prevent them from recurring in order to continuously improve the system

The first principle above addresses the need to document how you intend to assure quality in the organization. These quality intentions are explicit in the organization's quality management policies for each of the building blocks described in Table 1: Quality management policies. Collectively, these quality management policies are referred to as the **quality manual**.

The purpose of the quality manual is to communicate information to the organization about the organization's intention regarding quality. It sits at the top of the organization's document hierarchy.

Image 1: Quality document hierarchy



Although this collection of QMS policies has been long referred to as a "manual," there is no requirement for a facility to have these assembled together in a single document, binder or collection. It can be presented as one document addressing all elements or as a group of documents where each is dedicated to a single quality policy. Many facilities now use application software to meet their document control needs and may organize their policies in a more distributed manner; for example, the policy may be associated in a folder or directory accompanied by its related processes and procedures.

It is also understood that not all policies may be under direct control of the diagnostic service. For example, human resources (HR) policies and employee files may be retained by a centralized HR department. The need remains for these policies to be readily available to an organization's personnel and, upon request, must be submitted to the DAP for evaluation by assessors.

Quality manual documentation

Quality manual documentation should include the following:

- a description (and brief history if possible) of the organization including the scope of examinations available
- a glossary of terms used in the quality systems documentation (this is considered a best practice)
- the quality policy statement
- quality management policies
- quality management processes or references to processes used by the organization to deliver quality

One of the activities that the assessor evaluating the QMS will undertake before the on-site assessment is to review a facility's quality management policies in preparation for the on-site assessment. In this way, the assessor understands what they expect to observe at the facility with respect to quality and can focus their questions and observations accordingly. Opportunities to observe QMS practices occur in numerous assessment protocols during the on-site assessment. It is important to note that organizations must adhere to the policies and processes they have developed. Part of the assessor's observation is to verify that a diagnostic service is operating in the way the policies state.

The DAP has developed a series of criteria to help assessors evaluate the quality manual. This evaluation tool can be found in Appendix A. Although the policies have been grouped together in the format prescribed by the CLSI document *Quality Management System: A Model for Laboratory Services; Approved Guideline-Fourth Edition (QMS01-A4)*, the diagnostic service can group the quality policies in any manner appropriate for their operation and functional design. The only requirement is that all quality policies be documented and available to personnel.

References

1. International Organization for Standardization. Quality management systems – fundamentals and vocabulary. 4th ed. Geneva: International Organization for Standardization; 2015. 51 p. ISO 9000:2015.
2. Clinical and Laboratory Standards Institute. Quality management system: a model for laboratory services; approved guideline. 4th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2011. 220 p. CLSI document QMS01-A4.
3. Diagnostic Accreditation Program. Accreditation standards 2015: laboratory medicine - version 1.3 [effective 2017 Feb 1]. Vancouver: College of Physicians and Surgeons of British Columbia; 2016.
4. International Organization for Standardization. Medical laboratories - requirements for quality and competence. 3rd ed. Geneva: International Organization for Standardization; 2012. 53 p. ISO 15189:2012.

Appendix A: Checklist for DAP quality manual assessment (DAP Accreditation Standards – Laboratory Medicine, version 1.4)

Quality Manual Attribute	DAP	Yes	No	Comment
1. Quality policy included	QMS1.4.2			
• Commitment to standards	QMS1.1.2			
• Quality objectives and indicators identified	QMS1.1.3			
• Authority for issue (medical director)	QMS2.2.5			
2. QMS introduction and scope	QMS1.4.3			
3. Organizational chart	ORG2.1.2			
4. Safety policy	**SAF1.0**			
5. Personnel/human resources policy	**ORG4.0**			
6. Qualifications	ORG4.2.1			
• Training and competency	ORG8.2			
7. Purchasing and inventory policy	ERS1.1.1			
• Equipment validation and verification policy	ERS3.2.4			
• Referral laboratory policy	QMS3.1.1			
8. Information management policy	**IMI4.0**			
• Patient confidentiality	IMI1.4.1			
9. Document management/control policy	QMS2.1.1			
• Assess policy document for: title	QMS2.2.1			
• Assess policy document for: document identifier	QMS2.2.2			
• Assess policy document for: revision number	QMS2.2.3			
• Assess policy document for: page n of total	QMS2.2.4			

Quality Manual Attribute	DAP	Yes	No	Comment
• Document review frequency (1-3 years)	QMS2.1.4			
10. Records management policy	QMS2.3.1			
• Records retention schedule	QMS2.3.6			
11. Nonconforming event management	QMS5.1.2			
12. Customer focus – complaints and feedback	QMS4.2.1			
• Advisory services and interpretive services	QMS4.1.1			
13. Internal audit/assessment policy	QMS6.3.1			
14. Continuous improvement policy	QMS6.2.3			
15. Management review policy	QMS1.2.6			
16. Process management policy – sample collection	**SCT1.0**			
• Process management policy – pre-examination	**PRE1.0**			
• Process management policy – examination	**EXA1.0**			
• Process management policy – PT/QC	**QUA1.0**			
• Process management policy – post-exam	**POS1.0**			

Bold (XXXn.0) *indicates that there are multiple requirements for this policy included in the standards.*