

Document and Records Control System

APHL Quality Management System (QMS) Competency Guidelines

This course will help staff recognize what a Document and Records Control System is and its importance in a laboratory committed to ensuring the consistent quality of the tests performed, the products created, the data generated, and the results reported.

Objectives:

1. Participant will understand what the document and records control system covers, and why a laboratory must adhere to it.
2. Participant will appreciate the need for traceability in the QMS.
3. Participant will appreciate the benefits of a good document and records control system in the laboratory.
4. Participant will comprehend why a document and records control system is needed in a good Quality Management System.

A Document and Record Control System is a way for management to provide information to staff in way that is useful and ensure this information is kept up to date.

Public health laboratory competency guidelines: General (GEN) domain

QMS 8.00 Documents and records: ensures that there is an effective system to control and manage documents and records.

QMS 8.01. Document management system

Describes how the laboratory controls and manages documents
Applies the policies, processes, and procedures for controlling and managing documents

Develops the policies, processes, and procedures for controlling and managing documents

Oversees the document management system

What is a Document and Records Control System?

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A document and records control system is the way management communicates with staff what their responsibilities are and what procedures and policies to follow. A Document and Record Control System is the way management ensures that all documents used to guide staff in their work have been authorized, are accurate, and safeguards that the work being done remains consistent.



to ensure staff compliance with internal policies, external regulations, and accreditation* requirements

QMS 8.02. Records management system

Describes how the laboratory controls and manages records

Applies the policies, processes, and procedures for controlling and managing records

Develops the policies, processes, and procedures for controlling and managing records

Oversees the record management system to ensure staff compliance with internal policies, external regulations, and accreditation requirements

Safety documents and records (SDR) domain

SDR 1.01. Safety document management

Describes procedures for safety document management

Adheres to procedures for safety document management

Manages safety document management process

Designs the safety document management system

Informatics (INF) domain

INF 11.01. Document management systems

Describes centralized electronic document management systems that track and store grants, contractual instruments, and project management* materials

Verifies the entry and timeliness of laboratory program deliverables into document management systems

Evaluates document management systems to recommend improvements and efficiency and to meet contractual and grant obligations

Develops enterprise-wide workflows and communications to ensure an automated and secure document management system for grants and contractual instruments

