Information sheet

Document G_10_Info_5_A, Author: C Allen, Authorised: W Porau, 5/9/22 Review: 5/9/24

Document Control and Records Management

What are documents?

Documents provide written information about policies, processes and procedures. Some examples of documents include a quality manual, standard operating procedures and job aids.

What are records?

Records are the collected information produced by the laboratory in the process of performing and reporting a laboratory test. Some examples of records include completed forms, charts, sample logs, patient records, quality control information and patient reports.

What does it mean to 'control' a document?

Document control refers to a series of practices for distributing, changing and approving documentation as well as designating those who will be responsible for implementing these practices.

Why is it necessary to control documents and records?

It is an ISO-15189 Medical laboratory requirement to ensure all documents and records are accessible, up-to-date, accurate, checked and formally approved before distribution. Having document control means that staff are following the most up-to-date and authorised versions of SOPs etc.

How do I recognise a controlled document?

Look for the document header or footer to see the document number, version, author, authoriser, date of issue and date for next review. SOPs will have a revision table indicating the changes made with each version.

Who manages documents in my lab?

For nationally issued documents, the Chief Pathologist's office manages the documents aided by local lab. managers and quality officers.

For locally authorised documents, the quality officer (if appointed) is responsible for document control. Otherwise the laboratory manager has this responsibility.

What happens when a document becomes out of date or updated?

Out of date documents or documents requiring additions or amendments need to be assigned to a reviewer and then revised before reissue. At least one electronic or printed version of the previous version must be archived and all other copies destroyed.

Are external produced documents or references controlled?

Yes, this includes both hard (printed) and soft (computer) copies.

In summary:

What: The management of documents and records is an ISO-15189 Medical Laboratory Requirement for Quality and Competence.

Document control is the set of measures taken to regulate everything about documents.

- preparation and review
- approval and release
- distribution and access
- storage and security
- alteration and change
- withdrawal and disposal

Why: Document Control is essential for ensuring accuracy and consistency in the laboratory.

- ensures that the most current version of any document is the one that is in use
- ensures availability and ease of use when a document is needed at point of use
- provides for the appropriate archiving of documents when they need to be replaced
- provides a method for formatting documents so that they are easily managed/standardised
- sets up processes for maintaining the inventory of documents
- must include all internal and external documents, both hard and soft copies

Risks to be avoided by using a Document Control and Record Management System

- loss of data in the event of a disaster
- time wastage and cost increases
- communication gaps
- poor or wrong decisions resulting in laboratory errors
- missing the opportunity to satisfy customers (clinicians, patients)
- loss of reputation
- failure to comply with legal requirements

Recommended online training on document management

- **WHO eLearning course on LQMS** , module on Documents and records - access via this page.

Where can I read more about document control?

- WHO Laboratory Quality System stepwise tool: Set up a document control system handbook https://extranet.who.int/lqsi/activities/2/33
- WHO Laboratory Quality System handbook https://www.who.int/ihr/publications/lqms/en/