Purpose

To control all quality management system documents (internally generated and from external sources).

To identify changes made to documents.

To identify reference naming in master electronic file.

To control Master Case File and Quality System Documents maintained in computerized systems to include DM (Document Management) and supportive data stored on the County redundant server infrastructure.

Document control ensures that:

- authorized editions of appropriate Technical and Quality procedures are available at all locations where operations essential to the effective functioning of the laboratory are performed. DM will only open the current version of technical and quality procedures
- documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements
- obsolete documents and procedures are saved as versions in DM, to assure against unattended use. Obsolete documents and procedures cannot be accessed without deliberate action, which prompts viewing of version labels of the out-of-date document or procedure. All versions are labeled with the effective date and end date
- new documents and procedures shall be current in DM with the effective date
- obsolete case file documents retained for either legal or knowledge preservation purposes are suitably marked and stored electronically in Master Case File

Scope / Field of Application

This procedure applies to the Quality Manual, test methods, and standard operating procedures. Also applies to externally generated quality management system documents.

Note – While there are standard formats for writing test methods and SOPs, documents may take on different formats. These formats may consist of signs, flowcharts, pictures, drawings, sketches, controlled forms, and bullet lists. Regardless of the format, all quality management system documents must be controlled through this procedure.

Definitions and Acronyms

Quality Manual – document stating the quality policy, quality management system, and quality

practices of an organization.

Quality System Procedure (QSP) – a document that specifies or describes how an activity is to be performed. It may include methods to be used and sequence of operations.

Technical Procedures – Section or Discipline specific procedures.

Document Management (DM) – Location on network (county redundant server infrastructure) that all quality documents are stored under controlled access.

Master Case File – All-encompassing documentation stored in Records Management System (RMS), image/data drives and hard case file for case documents, images, charts and supportive data cross referenced by master case number.

Responsibilities

Laboratory management ensures that this document control procedure is established, implemented and maintained. The Quality Manager or designee oversees the day-to-day operations of document control. Laboratory personnel are responsible for following this procedure in its entirety.

Materials Required

Master list

Procedure

The Quality Manager maintains a master list of all controlled documents.

Quality Manual:

1. The Quality Manual is approved by Quality Manager.

2. Only electronic copies are controlled.

Procedures:

1. Test methods and Technical procedures include the following:
   - the title of each procedure
   - the version number of each procedure
   - the effective date of each procedure
   - issuing authority
   - pagination
   - Suggested Uses and Documentation
   - Apparatus/ Materials and Equipment Required

- Reagent Preparation/if applicable
- Quality control check
- Expiration date/Not Applicable
- Procedure and Presentation
- Safety Measures
- References
- Revision History

2. QSPs are written with the following headings:
   - Purpose
   - Scope / Field of Application
   - Definitions and Acronyms
   - Responsibility
   - Materials Required
   - Procedure
   - Documentation
   - References
   - Revision History
   - Appendix (if applicable)

3. Procedures are peer-reviewed, authorized by management, copies uniquely identified, and made available in electronic form to users.

Note – The effective date (see header) is the effective date the document was issued.

4. Obsolete master copies are labeled, dated and archived for at least 10 years. All other draft copies are destroyed to prevent inadvertent use.

5. The Quality Manager maintains the master copies of the most current procedures.

6. The master list of procedures includes:
   - title
   - version number
   - effective date
   - date of last review

Document Review:

1. Quality manual and written procedures are reviewed annually in the month of January by the Quality Manager and Technical Leaders. Records are kept of this review by the Quality Manager.

Document Changes:

1. Changes to the Quality Manual or a procedure require the same review and approval that is performed at the original review and approval on the Document Approval Form # *4-3-1-F1, Document approval Form* . All affected personnel shall be required to sign the document approval form acknowledging they have read and understand the changes to the document.

Amendments by Hand: Are not permitted.

Computerized Documents:

1. Electronic copies of Quality Manual, Technical Procedures and other required documents for monitoring quality are maintained under the authority of the Quality Manager/Technical Leader. These documents are stored and maintained in DM Document Management of the County Server Infrastructure under controlled access.

2. Technical procedures affected by a DRF shall be archives at completion and moved to the archived folder. That procedure will be labeled with the DRF's title, effective date and end date.

Documentation

Revisions to Quality Manual sections and procedures are accompanied by Form # *4-3-1-F1, Document approval Form* which details the revisions.

Required Record	Custodian
Approved electronic master copies of Quality Manual and procedures	Quality Manager
Master list	Quality Manager
Document reviews	Quality Manager

References

Garfield, F.M., Kleska, E., Hirsch, J. 2000. Quality Assurance Principles for Analytical Laboratories. 3rd Edition. AOAC. Gaithersburg, MD.

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2016/07/01	Original Version
2	2018/04/01	Add updated definition of Master Case File, change revision history table, issue date to effective date, rev# to ver#
3	2019/11/18	Revised how obsolete documents are labeled, stored and saved in DM