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Purpose

To identify, collect, index, access, file, store, maintain, protect, backup, and dispose quality and technical records. To outline procedures for the protection and backup of data/records held on computers.

Scope / Field of Application

This procedure applies to all quality and technical records. Quality records include audit reports, management review, corrective action requests, and preventive action requests. Technical records include observations, calculations, derived data, calibration records, personnel records, and test reports.

Note - Forms are not records until they are completed.

Responsibilities

Technical Leader/Quality Manager shall:

- specify any alternative retention period
- ensure that records specified in the quality management system are handled in accordance with the requirements of this document

Quality Manager shall:

- ensure the unique indexing of records

All personnel shall:

- collect, store, and maintain records for the minimum retention period or the period designated by the Quality Manager
- ensure that records retained are legible

Materials Required


Complete Action Reports
FAR Forensic Analysis Reports
Technical, Quality Check documents and completed logs
Master Case File

Procedure

Identification

Records are appropriately identified by a descriptive title clearly labeling the record.

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Collection

The personnel/user identified for each record is responsible for collecting the record.

Accessing

Records are readily accessible to individuals requiring information contained in the record.

Records are available to clients as per general statutes and/or agency policy. Disseminated documents are uncontrolled once delivered.

Filing

Filing is considered the location where active records are kept. All records are physically or electronically filed by a method which enhances accessibility and retrieval by a user.

If electronic files are used, a backup system or other suitable measures to prevent record loss is implemented. Data may be stored on disks, tapes, or on the network. All disks, tapes, and printouts are maintained for a minimum of 10 years after data is reported.

Specifications:

- All systems backed up nightly as full (Subsets at 11:30pm and 2:30am) -Systems that can be virtually backed up by requirements are being performed nightly as full (Subsets at 11:30pm and 1:30am) *Performed to integrate with virtual infrastructure (clientless) and close down time window
- SQL Servers are backed up nightly as full and incremental throughout the day (8am-7pm) every hour
- Retention schedules are 60 days unless previously specified by System Administrator's or by individual request
- Retention schedules on archives are submitted by individual job from client in 1, 5, or 10 year increments where applicable
- The system is secured by login authentication to only a subset of individuals in MIS
- The file security on restore by default retains all previously placed permissions before backup
- An infrastructure back up report is issued quarterly by County MIS Department and placed in Lab Quality Documents by Quality Manager.

Retention


A record's "retention" time refers to how long it is kept before it is either discarded or destroyed, or sent to off-site for long-term storage. Records are retained on-site for the minimum retention time of 10 years and in accordance with state and local statutes. Records may be retained longer than the minimum retention time for the convenience of the laboratory. Retention times for work area-specific records are determined by the laboratory and stated in their quality management system documents.

Maintenance

All records are filed and stored in an office or laboratory environment unless specific media and/or special environmental control is specified to prevent damage, deterioration, or loss.

Disposition

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Records are disposed when the retention time has been exceeded. Disposition may be to discard or destroy the records, or as instructed by the Quality Manager. The Quality Manager may opt for long-term storage of records.

Storage

After the appropriate retention time, records are stored long-term as defined by the Quality Manager.

Documentation

Typical records maintained in the laboratory include:

- instrument and equipment maintenance log
- calibration record of instruments and analytical processes
- records associated with approved SOPs
- spreadsheets used to calculate accuracy and precision of instruments
- certified standards log
- sample log
- analyst case notes
- test reports
- Images and other supportive data

Reference Procedures

All quality management system procedures resulting in the production of records.

References

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



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REVISION HISTORY		
CURRENT VERSION	EFFECTIVE DATE	SUMMARY OF CHANGES
1	2016/07/01	Original version.
2	2018/02/14	Added to Materials Required section, change revision history table, Indexing section removed. Update specification ,filing and documentation sections
3	2018/04/01	Change issue date to effective date, rev# to ver#. Under retention added text to specific consideration of legal requirements.

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