

1 Purpose

The purpose of this document is to provide management and technical personnel with requirements as well as guidance on the archiving, records management and disposal of data and information.

2 Scope and Applicability

This guideline is applicable to all manufacturing sites, functions departments and Marketing Companies undertaking work or providing support services, required to meet Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice(GMP)and/or International Organization for Standardization (ISO) standards and is independent of the medium used (paper, electronic, etc).

3 Definitions

3.1 Archives(1)

Records of the same provenance or origin accumulated by an organization or person in the course of conduct of business affairs, and preserved because of their enduring value.

3.2 Archives (2)

Physical space in which an organization or part of an organization manages the selection, acquisition, preservation and availability of one or more archive collections. Could also be known as Records Centre, Pre-Archive area or Short-term archive area.

3.3 Archiving - to Archive

To deposit a record into a storage medium and location which will ensure its storage for the appropriate retention period prior to disposal for long-term preservation.

3.4 Archivist

An individual who is responsible for appraising, acquiring, arranging, describing, preserving, and providing access to records of enduring value, according to the principles of provenance, original order, and collective control to protect the materials' authenticity and context. The value the archivist gives to the organization concerning the intellectual, logical and physical control of the records is both scientific and administrative.

3.5 Archives Manager

An appropriately qualified person appointed by management to operate and/or

instruments, data entered directly into a computer, either manually or through an instrument interface, data printed automatically from devices or through specimen preservation.

3.11 Metadata

Data describing context, content and structure of records and their management through time.

With respect to electronic records, metadata is information about the data in a computerized system that is not the data itself, e.g. audit trail, tabular definitions, etc. Both the data and associated metadata are necessary for the trustworthiness and reliability of records.

3.12 Records life cycle

The records lifecycle is the life span of a record from creation or receipt to its final disposition.

4 Responsibilities

4.1 Archives Management

Organization or part of an organization responsible for the retention, safe storage, availability and scheduled disposal of records required for regulatory compliance, legal or other reasons.

4.2 Technical Personnel

Are individually and collectively responsible for the generation and control of high quality active records. This also includes Supervisors. They ensure records are identified, indexed and transferred safely to archival storage in accordance with the Policy and associated procedures/guidelines.

4.3 Archive Managers

Are appointed by Management, and manage the archives and take responsibility for the preparation of written standard operating procedures (SOPs) for records management and good housekeeping. These SOPs must provide for orderly storage, expedient retrieval and, when appropriate, disposal of records in accordance with the relevant Policy and the Retention and Disposal Schedule. It is a GLP requirement to have a named person responsible for all aspects of the archive. In some functions, the Archives Manager has the title of Archivist.

Records provided for archiving must be arranged and indexed. Archivists, Archives Managers or Records Managers must conduct inventories of archived records and identify them according to the retention schedule.

Records must be suitably managed and organized (e.g. classification, titling, indexing, etc.) to enable lifecycle management and retrieval.

Periodic inventory checks of records held in archives are recommended.

Indexing systems for records can be manual or automated. If automated, the system must meet regulatory requirements for validation and electronic records compliance.

5.4 Segregation of Records for Information Protection

Where more than one copy or form of the same record is being retained (e.g. software programs, back-up tapes, or microfilm) then it is recommended that geographically separate archive/storage locations be used. Separation in this context should be by room, building or site.

Where several components of a common record or data set exist (e.g. histopathology: written or electronically held diagnosis, microscope slide, wax block, wet tissue, etc.) then it is again recommended that some sensible segregation of these occur, in order to minimize the overall potential loss of any data.

5.5 Loan of Records

It is recommended that Archive procedures prohibit or limit the loan of original records once archived. However, if such a stringent practice is adopted, then facilities should be available to provide a 'copy' as an exact image of the record required. This could be by means of photocopy, image scanning, microfilm/fiche review or loan, or access to a database (review and print only) record.

Where loan of original records is necessary or unavoidable (e.g. Regulatory Authority inspection) then procedures must be introduced to ensure:

- Reason for loan is approved by line management and/or Archive management
- Loan is formally documented
- Tracking of loan to ensure return occurs and overdue loans are followed up

5.6 Electronic Data Management

Archives Managers must be consulted prior to any transmittal of records on removable storage media to Archives. Some Archives may refuse to accept

can be established.

5.13 Disaster Prevention and Recovery Plan

The procedures to be followed in the event of a disaster befalling the archives must be detailed in an SOP. Whilst the facility design and location can help to minimize the risk of an occurrence, or the consequences of an actual event, a Disaster Prevention and Recovery Plan must be in place. Archived records must be protected from the consequences of smoke, fire or water damage (e.g. alarms/detectors, extinguishers, fire -proof cabinets, etc.).

Information owners or designee in coordination with relevant department personnel are responsible for determining the priority of the records in the event of a disaster.

In the event of a disaster arising, procedures should be provided for:

- The safe removal of records to suitable alternative storage
- Prioritized removal of records relative to importance and time
- Documenting the records removed
- Salvage of records and damage assessment
- Recovery and restoration of records (air drying, copying etc.)
- Special procedures to salvage and restore electronic media and records or other types of records, e.g. photographic materials, reserve samples of test articles
- Documenting the records lost
- Notifying the applicable regulatory authority of loss
- Preparation of an internal report (to include reasons for disaster, consequences, future preventative measures etc.)