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Review Article

Understanding GLP Archives: Establishment, Control, Compliance and Future Perspectives

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ABSTRACT

Archives are crucial for regulatory compliance with Good laboratory practice. They ensure the quality, integrity, retrieval of documents, specimens and their support records generated during non-clinical health and environmental safety studies. An effective archival system facilitates the regulatory compliance and allows for the reconstruction of GLP studies. Although the archival management is the responsibility of Test facility management, it requires provide adequate space, authorized access and environmental controls, disaster recovery plans, preventive control measures and assigned responsibilities. The archival systems face significant challenges due to the increasing transition from documents (paper based) to hybrid/digital archives, including data integrity, cybersecurity, and data recovery concerns. This review summarizes operational and regulatory aspects of Good Laboratory Practice compliant archive management with emphasis on archive organization, environmental controls, electronic records, retrieval procedures, and risk-based quality assurance. This review aims to provide a comprehensive understanding of GLP-compliant archival systems based on OECD guidance document No. 15, and to support test facilities in establishing and maintaining effective archive systems in compliance with regulatory requirements.

Keywords: Archive, Archivist, Audit, GLP, OECD, Regulatory.

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INTRODUCTION

Archives preserve records and materials that may be required for future scientific, regulatory, or legal reference. In Good Laboratory Practice (GLP) compliant test facility, archives maintain study-related documents and materials generated during non-clinical health and environmental safety studies. These records provide evidence of study conduct, support reconstruction of experimental procedures, and verification of study plan and final reports against raw data. Test Facilities increasingly manage both paper-based and electronic records, creating additional challenges in data storage, retrieval, data security, and long-term preservation. Consequently, archive management has evolved from a retention (storage-oriented) activity into an integrated component of quality systems and regulatory compliance. The Organization for Economic Cooperation and Development (OECD) Principles of GLP emphasize that records and materials must remain identifiable, retrievable, protected, and accessible throughout the retention period. Archive systems therefore require restricted access, defined roles, in house approved procedures, and structured documentation practices. Inadequate archive management may compromise regulatory compliance, and reconstruction of studies. This review discusses major aspects of archive organization, operational procedures, facility maintenance, electronic data management, disaster recovery, and future perspectives of archive management. The procedures and evaluation pattern or checklist outlined in this review are intended for guidance purposes and may differ based on test facility SOPs, sponsor requirements, and applicable national regulatory requirements.

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ROLES AND RESPONSIBILITIES

Sponsor

The sponsor is responsible for ensuring that non-clinical health and environmental safety studies intended for regulatory submission are conducted in compliance with GLP principles (OECD, 1998). Sponsors should ensure that archived records and materials remain available for regulatory inspection and are preserved under specific conditions that maintain their quality, integrity and accessibility throughout the retention period.

Test facility management

Test Facility Management (TFM) is responsible for providing adequate archive facilities, implementing Standard Operating

Procedure (U.S. EPA, 2007) and appointment qualified personnel for archive operations and management (OECD, 1997). TFM should ensure that archive systems provide controlled access, environmental monitoring, security measures, records and material retrieval procedures.

Study director

The Study Director is responsible for ensuring that all study related raw data and materials are transferred to the archive following study completion (OECD, 1999). These records and materials may include original raw data, study plans, final reports, specimens, slides, paraffin blocks, electronic data, and supporting records associated with specific study. The study director holds responsibility for quality, completeness, reproducibility and regulatory compliance of the study.

QUALITY ASSURANCE UNIT

The Quality Assurance Unit (QAU) plays an important role in monitoring archive operations through periodic facility inspections and risk-based audits (OECD, 2022). These inspections/audits help verify that archival activities comply with regulatory requirements and that documentation remain complete, recoverable, and secured from deterioration or unauthorized access. In general, test facilities shall conduct a risk-based Quality Assurance (QA) programme on a quarterly or half-yearly basis and document it appropriately.

Archivist

Archive operations should be performed according to in house approved Standard Operating Procedure (SOP) to ensure traceability and controlled access (OECD, 2007). The archivist functions as the custodian of archived materials and is responsible for proper indexing and orderly storage; authorized (from TFM) retrieval of archived materials and maintaining controlled environmental conditions for archive facilities.

In facilities managing electronic records, archivists may work closely with information technology personnel to maintain backup systems and electronic data security. This example checklist may serve as a practical reference for archival practices and inspection readiness (Table 1).

OPERATION AND MANAGEMENT OF ARCHIVES

Archive facility

A GLP-compliant test facility should maintain adequate and secure space for the storage of study-related records and materials generated during non-clinical health and environmental safety studies. Archive areas may include dedicated rooms, secured cabinets, lockable storage units, or separate buildings depending on the quantity and type of materials retained. Access to archive facilities should remain restricted to authorized personnel through controlled entry systems (OECD, 2007).

Archive facilities should be designed to minimize the risk of environmental damage caused by fire, flooding, storms, water leakage, or other physical hazards. Archive areas should also be protected from rodents, insects, and pests through appropriate preventive measures and periodic pest control activities. In emergency situations, access by security or maintenance personnel should remain documented to ensure traceability. Basic infrastructure and operational requirements of GLP archive facility are summarized in Table 2.

Access to archive

Access to archive storage areas should remain controlled and restricted primarily to the archivist in order to maintain the security, traceability, and integrity of archived materials. Entry by any other personnel should be permitted only with prior approval from TFM and in the presence of the archivist. All visits to the archive facility should be appropriately documented to maintain accountability and traceability of access activities. For routine submission of study-related records or materials, GLP personnel should generally be restricted to the archive ante room, while access to the main archive storage area should remain limited to authorized archive personnel only.

Archive conditions

Environmental control is an important factor influencing the long-term preservation and integrity of archival materials. Temperature and relative humidity directly affect the stability of paper records, biological specimens, labels, paraffin blocks, and electronic storage media. In general, storage conditions of approximately 22±2°C temperature and relative humidity between 40% and 60% as suitable for environmental conditions for archives (NEDCC, 1999). Any significant deviations from in house approved SOPs should be recorded and evaluated. In wet archives holding formalin-fixed specimens should have sufficient ventilation to prevent formaldehyde accumulation in the surrounding environment (Lull and Banks, 1995). Similarly, samples of test and reference item should be stored in accordance with the label specifications, which may include room temperature, desiccated, refrigerated, or frozen conditions where applicable. Electronic storage media should be protected from dust, moisture, and magnetic interference to preserve integrityand long-term readability of data.

Extreme or fluctuating environmental conditions may adversely affect the retention of archival materials and compromise their quality and integrity.

Low temperature conditions may contribute to moisture absorption in paper materials, fading/smudging of text in raw data, and wet documents increased susceptibility to fungal growth.

High temperature conditions may lead to evaporation of formalin fixatives in specimen, and distortion of paraffin blocks

Table 1: Inspection readiness checklist for archivist.

Sl. No.	Checklist Item
1.	General Archive Management
2.	Archive SOPs are available, approved, and current
3.	Archivist and backup archivist roles are defined
4.	Archive access is restricted and controlled
5.	Entry/exit logbook is maintained
6.	Materials are properly indexed and traceable
7.	Location register is updated regularly
8.	Retrieval and return procedures are followed
9.	Audit trail (manual/electronic) is maintained
10.	Training and competency records are available
11.	Dry Archive
12.	Documents are properly labeled and complete
13.	Cabinets and shelves are labeled and organized
14.	Temperature and humidity are monitored and recorded
15.	Documents are free from dust, moisture, and fungus
16.	Electronic records are readable and accessible
17.	Data backup and recovery systems are functional
18.	Wet Archive
19.	Wet archive area is segregated and controlled
20.	Ventilation system is adequate
21.	Temperature conditions are appropriate
22.	Specimens/Test item are properly labeled and identifiable
23.	Containers are leak-proof and intact
24.	Paraffin blocks and slides are clean and intact
25.	Adequate fixative is present (e.g., formalin) and ensured
26.	Periodic inspection (3 months) is performed
27.	Deterioration findings are documented
28.	Safety and Infrastructure
29.	Fire detection and alarm systems are functional
30.	Fire extinguishers are available and valid
31.	Archive area is protected from flooding/leakage
32.	Pest control programme is implemented
33.	Power supply (UPS/generator) is available
34.	Retention, disposal and Compliance
35.	Retention periods are defined and followed
36.	Disposal is review by QAU and approved by TFM

Score value: 2 -Compliant; 1- Minor Observation; 0- Major Non-Compliance; Interpretation: More than 80% score → Acceptable / Compliant; 60-79% score → Needs Improvement; below 60% score - Critical Non-Compliance.

Low humidity levels may result in drying and brittleness of materials

High humidity levels may cause documents adhesion, smudging of ink, loss of legibility of labels and text, and accumulation of vermin-related contamination.

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Disaster recovery

Archived records and materials should be protected from fire, flooding, theft, and accidental damage through appropriate disaster recovery planning and preventive control measures. Effective disaster preparedness is important for maintaining long-term integrity, and accessibility of archived materials within GLP-compliant test facilities. Archive facility should incorporate fire-resistant construction materials, install smoke/alarm detection systems, portable fire extinguisher and withstands local weather to minimize irreversible damage. Flood protection measures are also important, particularly in areas vulnerable to water accumulation or leakage. Locating archive facilities above ground level and avoiding water pipelines in and around archive facility may reduce the risk of water-related damage. Unauthorized access, theft, and intentional vandalism may compromise the security and integrity of archived materials. Consequently, archive facilities should maintain controlled access systems with lockable storage areas restricted to authorized personnel only. Proper documentation of access activities further strengthens accountability and traceability. The disaster recovery checklist summarized in Table 3 provides practical guidance for recovery drill practices and inspection readiness.

ARCHIVE PROCEDURES

Receipt of materials in the archive

All records and study-related materials transferred to the archive should be accompanied by appropriate depository documentation during archival transfer.

Before accepting materials into the archive, the archivist should verify the completeness and condition of the submitted records and materials. This verification process may include confirmation of labelling, completeness of records and/or materials, pagination of study files, total no. of specimens, slides, and blocks.

For test/reference items appropriate labelling, proper sealing and absence of leakage of test/reference items, availability of a supporting characterization document (OECD, 2018).

For electronic data should be readability and size of electronic data

Following verification, receipt of materials should be formally documented through signed acknowledgment and entry into the archive receipt log. Incomplete records, incorrect/missing labels, or leakage of container or damage are the example of discrepancy

that should not be accepted for archiving until the identified issues are appropriately resolved.

Indexing

Following receipt of materials, the archivist should assign archive numbers, label the materials appropriately, and place them in designated storage locations. Effective archiving facilitates organized storage and rapid retrieval of retention materials; the cabinets, shelves, and compartments should be clearly identified and labelled properly. Archivist shall be planned for separate storage arrangements for office/departmental documents, study-related records/materials, and non-GLP materials further improve retrieval and prevent record displacement. A structured identification or labeling system using unique archive numbers for archived materials as follows:

Office/department-specific records may be identified using designated three letter prefixes combined with three-digit serial numbering systems. For example: Archive-ARC001; Toxicology - TOX001.

Study-related materials, including study files (raw data, reports), specimens, slides, paraffin blocks, test/reference items, and electronic records, should be assigned unique identifiers incorporating material type, study number, and year of archiving. Similar numbering approaches may also be applied to logbooks, equipment-related records, and archive registers to maintain consistency in documentation practices.

Location register should be maintained by archivist for easy tracking and retrieval of archived materials and updated whenever a new archive number is assigned or when the location of materials is changed.

Retrieval of archived material

Original records and materials archived once, it should remain under restricted access. Retrieval of archived materials by GLP personnel for audit or reference purposes should be permitted only with prior approval from TFM. Before issuing archived materials, the archivist should verify the document or materials such as document page count, number of specimens or slides, and quantity of test/reference items or electronic records. Personnel receiving archived materials remain responsible for their integrity and safe handling until return. Upon return, the archivist should verify completeness and document or materials any discrepancies, which should be immediately reported to TFM.

Deterioration check of archived material

Archives require appropriate storage conditions to minimize the deterioration of records and to prevent damage caused by high or low temperature, relative humidity, insects, pests, and data corruption. All test facility records, and materials should be checked quarterly / half-yearly for any signs of deterioration and documented.

Retention of archived material

The primary purpose of retaining archived records and materials is to ensure that non-clinical studies can be reconstructed, verified, and reviewed whenever required by regulatory authorities, sponsors, or QA personnel. Since retention requirements may vary across countries and regulatory systems, retention periods should be established according to applicable national regulations and institutional policies while considering the nature, stability, and storage conditions of archived materials. Study-related records and materials that should be retained in the archives for three inspection cycle (OECD, 2007). The retention period for test facility records and materials may vary depending on the policies of the test facility and the in house approved SOPs.

In document archives- Records to be retained include paper records such as study related records and other test facility records (QA audits, Floor plan, Master schedule, Organizational records, Personnel training, Equipment details etc.,). Electronic records include software programs, hard disks, electronic study data, recorded data from automated instruments, or any other

Table 2: Basic Requirements for GLP Archive Facility.

Sl. No.	Design component	Purpose / Importance
1.	Dedicated archive area	Prevents mixing with operational records and materials
2.	Controlled access	Prevents unauthorized access
3.	Fire-resistant construction	Protects against fire damage
4.	Elevated storage areas	Prevents water damage (flood)
5.	Environmental control	Prevents deterioration
6.	Ventilation systems at wet archives	Reduces moisture and chemical vapour
7.	Pest prevention	Prevents biological damage
8.	Security system	Improves safety
9.	Shelving and storage cabinets	Easy retrieval and indexing
10.	Wet archive segregation	Contamination control
11.	Storage for test/reference items	Maintains sample integrity
12.	Electronic archive protection	Protects digital media
13.	Backup power supply	Protects electronic systems
14.	Fire detection system	Early emergency detection
15.	Disaster recovery system	Supports data recovery

Table 3: Disaster Recovery Checklist.

Sl. No.	Disaster recovery area	What to check	Frequency*
1.	Fire protection system	Fire extinguishers validity, alarm system functionality	Monthly
2.	Smoke detection	Smoke detector working condition	Monthly
3.	Flood risk assessment	Drainage system and floor safety	Quarterly
4.	Backup power	UPS/generator operational status	Monthly
5.	Environmental monitoring	Temperature and humidity records review	Daily
6.	Electronic data backup	Server backup completed and verified	Daily/ Weekly
7.	External hard disk backup	Backup media updated and readable	Monthly
8.	Disaster recovery storage	Offsite backup availability	Quarterly
9.	Access control system	Lock/biometric system functioning	Monthly
10.	Archive key control	Key custody records maintained	Daily
11.	Pest control	Pest activity and control records	Monthly twice
12.	Documents conditions	Moisture, fungus, dust, damage	Half-yearly
13.	Wet specimens check	Fixative level and container integrity	Quarterly
14.	Slides and paraffin blocks	Breakage, fungus, labelling status	Half-yearly
15.	Electronic media	CDs, drives, storage media readable	Monthly
16.	Emergency contact list	Updated emergency contact availability	Quarterly
17.	Disaster recovery SOP	SOP available and updated	Annual
18.	Mock disaster drill	Fire/flood emergency simulation	Annual
19.	Incident documentation	Disaster event records and corrective action	As needed

*- The frequency of checking /responsible may vary depending on the in house approved SOPs of the test facility.

storage media containing data generated during the conduct of a non-clinical health or environmental safety study. In wet archives- Materials to be retained include specimens, paraffin blocks, histological slides, and samples of test/reference items, etc.

Disposal of archived material

Disposal is one of the key procedures in the operation and management of archives and should be performed with appropriate Personnel Protective Equipment (OSHA, 2014). Before the retention period expires, the archivist should inform TFM to obtain sponsor consent for extension, return, or disposal of archived materials. Materials identified for disposal should be reviewed by the QA, approved by TFM, and properly documented before disposal. The materials should be properly packed, labelled, and collected in appropriate color-coded bags as defined in SOPs.

ELECTRONIC RECORDS

The increasing use of computerized systems has transformed archive management within Test facility. Electronic archive requires less storage space, rapid retrieval, and easy accessibility of test facility records. However, electronic archival systems also introduce additional operational challenges that have been increased due to cyber security, unauthorized data access/ deletion, validation of software/hardware (OECD, 2016), readability of electronic data (OECD, 2021) and protected from irreversible data loss or manipulation. Therefore, test facility management and IT personnel should work together to establish additional backup systems (onsite or offsite), enable cyber security measures, and develop recovery plans for incident response and periodic risk-based assessments that support minimizing the risk of irreversible data loss, thereby enabling trust and regulatory acceptance of electronic archival systems (OECD, 2024).

RISK-BASED ARCHIVAL CHALLENGES

Risk-based archival challenges difference between electronic (digital) and documents (paper) based data systems (Danley, 2011). Digital archives are more vulnerable to data corruption, security threats, and technological obsolescence. In contrast, documents archives are more vulnerable to physical decay, environmental degradation, and storage space constraints. Therefore, a risk-based approach integrating digital safeguards and physical preservation measures is essential for effective archival management.

GLP is complex and qualified personnel are involved (Jena and Chavan, 2017) for the management of archives. Nevertheless, archivists may face several challenges in the operation and maintenance of archives as summarized in Table 4.

Table 4: Challenges in challenges in the operation and maintenance of archives.

Challenge	Root cause	Risk	Preventive action
Poor indexing	Improper coding	Delay in retrieval	Unique numbering system
Missing records	Improper handover	Data gap	Depository records
Unauthorized access	Weak access control	Confidentiality breach	Biometric/lock system
Fire hazard	Inadequate protection	Total loss	Fire-resistant archive
Flood damage	Poor facility design	Material damage	Elevated archive area
Pest infestation	Poor maintenance	Record deterioration	Pest control schedule
Temperature and Humidity variation	HVAC failure	Material degradation/ Mold/ fungal growth	Continuous monitoring
Electronic corruption	Media failure	Data loss	Multiple backup
Software obsolescence	Outdated systems	Data inaccessible	Migration validation
Cyber security threats	Weak IT controls	Data breach	Password/encryption
Improper retrieval	SOP deviation	Loss/misplacement	Authorized approval and logs
Incomplete audit trail	Poor documentation	Non-traceability	Audit trail review
Staff turnover	Training gap	Operational error	Cross-training
Disposal error	Poor review	Wrong destruction	QA verification

FUTURE PERSPECTIVES OF ARCHIVE MANAGEMENT

Cloud-based archival systems

Cloud-based archive infrastructure offers scalable storage capacity and secure remote access to study records and test facility records. From a regulatory perspective, cloud systems must comply with data security, confidentiality, and controlled accessibility requirements. Cloud storage can improve disaster recovery capabilities by maintaining offsite backups against fire, flood, or local hardware failure. Test facility must ensure that cloud service providers maintain audit trails, access control logs, and encryption standards. Regulatory acceptance of cloud archives will depend on proper validation, vendor qualification, and data migration controls.

Hybrid archive systems

The hybrid archive system completely maintains records in digital format, which helps effective data management practices for non-clinical health or environmental safety studies. The hybrid archive system supports regulatory compliance by enabling continuity in record identification; avoid data discrepancies, retention, and rapid retrieval regardless of the storage format. Future archive strategies will likely be targeted on harmonizing both systems (paper and digital records) under a unified quality management framework.

Integration with Laboratory Information Management Systems (LIMS)

The archival system integrated with LIMS can improve the complete tracking of data flow from study initiation to study completion (archiving of materials). This LIMS integration supports automatic data management (avoiding discrepancies), audit trail generation, elimination of manual data errors, tracking of samples and study status, and meeting regulatory standards. From a regulatory perspective, integrated systems enhance data integrity and traceability and improve inspection/ audits readiness. Test facilities may rely on validated LIMS-linked archives that can support better life cycle management of records and study materials for end-to-end data governance.

CONCLUSION

Future perspectives of archive systems will likely integrate hybrid storage models, cloud based system, and artificial intelligence technology helps indexing, automated audit trail generation, data management practices, and inspection readiness. However, the increasing adoption of hybrid/digital technologies has expanded responsibilities associated with many challenges in archival operation and management, particularly in areas related to data integrity, cybersecurity, and disaster recovery.

ABBREVIATIONS

ARC: Archive; **GLP:** Good Laboratory Practice; **OECD:** Organization for Economic Co-operation and Development; **QAU:** Quality Assurance Unit; **QA:** Quality Assurance; **TFM:** Test Facility Management; **SOPs:** Standard Operating Procedure; **LIMS:** Laboratory Information Management Systems.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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