Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

11-Jun-2007

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Cancels & replaces the same document of 04 June 2007

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING
Number 15

Advisory Document of the Working Group on Good Laboratory Practice

Establishment and Control of Archives that Operate in Compliance with the Principles of GLP

JT03228850

ENV/JM/MONO(2007)10
Unclassified

English - Or. English

OECD Environment, Health and Safety Publications

Series on Principles of Good Laboratory Practice

and Compliance Monitoring

No. 15

Advisory Document of the Working Group on Good Laboratory Practice

Establishment and Control of Archives that Operate in Compliance with the Principles of GLP

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2007

ALSO PUBLISHED IN THE SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING

- *No. 1, OECD Principles of Good Laboratory Practice (as revised in 1997)*
- *No. 2, Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (1995)*
- *No. 3, Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (1995)*
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This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

FOREWORD

The OECD Working Group on Good Laboratory Practice, at its 17th meeting in 2003, established a drafting group under the leadership of the Netherlands (Mr. Theo Helder), with participation by Germany, Italy, Sweden, Switzerland the United Kingdom and the United States. After reviewing existing material on archiving in a GLP environment, the group develop a first draft document, which was reviewed by the Working Group at its 20th meeting in 2006.

The Working Group agreed that it would circulate the draft for comment to stakeholders in industry and receiving authorities and that Members would prepared consolidated national comments. Comments were received from Australia, Belgium, Denmark, Finland, Germany, Ireland, Israel, Italy, Japan, Korea, Netherlands, Slovenia, Spain, Sweden, Switzerland, and United States. The Working Group then reviewed, amended and endorsed a revised version of the document at its 21st Meeting in 2007.

The Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology endorsed the document on 25 May 2007and agreed that it be declassified and published in the *OECD series on GLP and Compliance Monitoring* as an Advisory Document of the Working Group on GLP.

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Advisory Document of the Working Group on GLP

ESTABLISHMENT AND CONTROL OF ARCHIVES THAT OPERATE IN COMPLIANCE WITH THE PRINCIPLES OF GLP

1. INTRODUCTION

The archiving of records and materials generated during the course of a non-clinical health or environmental safety study is an important aspect of compliance with the Principles of Good Laboratory Practice (GLP). The maintenance of the raw data associated with a specific study and the specimens generated from that study are the only means that can be used to reconstruct the study, enabling the information produced in the final report to be verified and the compliance with GLP of a specific study to be confirmed.

The purpose of the guidance contained in this document is to assist in conforming to the requirements of the OECD Principles of Good Laboratory Practice as they relate to archiving.

This guidance does not supersede any requirement set out in national regulations and/or legislation, e.g. pertaining to the timeliness of archiving or retention periods.

2. SCOPE

This document is intended for use by test facilities that are required to operate in compliance with the Principles of GLP, for organisations that supply support, e.g. contract archives, contract quality assurance units or IT services and for sponsors, GLP compliance monitoring authorities and receiving authorities.

Organisations should ensure that they evaluate applicable regulatory requirements against their business needs. Certain aspects of archive construction and operation may have implications for compliance with building regulations or legislation regarding public health and safety. Guidance on these aspects is outside the scope of this document.

Test facilities and other organisations, engaged in archiving GLP records and material, might benefit from the use of recognised archiving management standards including those concerning metadata.

3. DEFINITION OF TERMS

Archive: A designated area or facility (e.g. cabinet, room, building or computerised system) for the secure storage and retention of records and materials.

Archive Staff: Individuals who work under the supervision of the archivist and who are responsible for the routine archive operations.

Archivist: An individual designated by test facility or test site management to be responsible for the management of the archive, i.e. for the operations and procedures for archiving.

Electronic archives: Facilities and systems provided to maintain electronic records as required by the Principles of GLP.

Electronic record: All original laboratory records and documentation, including data directly entered into a computer through an instrument interface, which are the results of original observations and activities in a study and which are necessary for the reconstruction and evaluation of the report of that study.

Metadata: Data that describe the attributes of other data. Most commonly these are data that describe the structure, data elements, inter-relationships and other characteristics of electronic records.

Migration: The transfer of electronic records from one format, media or computerised system to another.

System Owner: The manager, or designee, of the department that is most impacted by, or is the primary user of, the system.

4. ROLES & RESPONSIBILITIES

4.1 Sponsor

The sponsor is assumed to play an active role in confirming that all non-clinical health and environmental safety studies are conducted in compliance with GLP.

The sponsor therefore should ensure that materials and records in support of regulatory studies are retained and maintained under conditions that ensure their integrity and continued access. Also if records and materials are transferred into the sponsor's possession, storage should be in archives that meet the requirements of the Principles of GLP**.** The sponsor should also ensure that such material and records are retained for as long as required by relevant authorities. The archive and retained materials and records should be available for inspection during normal office hours. If electronic records are kept, it should be possible to make them available in human readable form.

4.2 Test Facility Management

Test facility management is responsible for the provision of archive facilities. Test facility management is also responsible for the appointment of an individual and, if necessary, additional archive staff for the operation of the archives. A back-up archivist should also be appointed to perform the duties of the archivist in the event that the archivist is unable or unavailable to perform the archivist's duties. These appointments should be documented. When appointing the archivist and the back-up archivist, test facility management should avoid possible conflicts of interest through incompatibilities of functions.

Test facility management should ensure that the records and materials generated in the test facility that are necessary to reconstruct studies, and the documentation required to demonstrate the GLP compliance of the test facility, are archived.

Test facility management should ensure that appropriate archiving procedures are established.

Test facility management should ensure that only selected authorised personnel shall have access to the archive(s). Access should be controlled and the accessing procedure should be documented. Security and technical personnel should be granted access only when necessary (e.g. in case of emergencies) also in a controlled and documented manner.

Test facility management might be expected to inform sponsors on GLP requirements and the responsibilities of the sponsor regarding archiving where necessary.

4.3 Archive Contracting Facility

If a sponsor or test facility management uses a contract archive for the storage of records and/or materials for a GLP study, the contracting parties should ensure compliance with the relevant sections of the Principles of GLP.

4.4 Test Site Management

Test site management has the same responsibilities as test facility management with regards to archive facilities and procedures at their own site.

4.5 Study Director

The Study Director is responsible for ensuring that during or immediately after completion (including termination) of a study, all study related records and materials are transferred to the archive(s). The Study Director is responsible for the completeness of the study records and materials and for assuring that all materials are archived before or at the close of the study.

4.6 Principal Investigator

A Principal Investigator should ensure that records and materials for which he/she is responsible are sent to the Study Director, or transferred to an agreed archive location latest upon completion of the study or phase of the study. The Principle Investigator should inform the Study Director about the date of transfer or archiving.

4.7 Archivist

The archivist is responsible for the management, operations and procedures for archiving in accordance with established Standard Operating Procedures, and the Principles of GLP.

The archivist should therefore, inter alia,

– ensure that access to the archive is controlled;

– ensure that the orderly storage and retrieval of records and materials is facilitated by a system of indexing; and

– ensure that movement of records and materials in and out of the archives is properly controlled and documented

Where there is a need for several staff to perform archiving duties, staff should work under the direction and supervision of the designated archivist. It is recognized that in certain circumstances it may be necessary for the archivist to delegate specific archiving tasks, for example management of electronic record. Respective tasks, duties and responsibilities have to be specified and detailed in SOPs.

4.8 Information Technology (IT) Personnel

IT personnel involved in archiving operations (such as ensuring integrity of electronic records) should be adequately trained and their activities should conform to GLP requirements. Since activities pertaining to archiving are the primary responsibility of the archivist, these IT personnel ideally should work under the direction and supervision of the archivist. Because it is recognised that such organisational structures are not feasible in modern companies, the co-operation between the archivist and IT personnel should be ensured in other ways, for instance in SOPs or written service level agreements.

4.9 Quality Assurance (QA) Personnel

QA personnel are responsible for inspecting all aspects of archiving for compliance with the Principles of GLP. This includes the inspection of archiving operations and procedures, including procedures for electronic records, facilities, stored records and materials.

5. ARCHIVE FACILITIES

The archive facility should be suitably designed and constructed to accommodate the archived records and materials. This may be one or more buildings, rooms, safes or lockable cabinets or other locations that provide suitable security. The archive facility should be physically secure to prevent unauthorised access to the retained records and materials. The use of locks or electronic entry systems is required. The components that provide storage of unique electronic records should also be physically secure. The computerised archive facility should have processes to prevent unauthorised access and virus protection.

The building(s) or room(s) that house the archive should be constructed to withstand the elements of local weather, etc. Consideration may need to be given to specific local conditions such as a risk of flooding. The archive design should protect the contents from untimely deterioration for example by leakage of running water pipes in the archive areas. The risk of fire and explosion should be minimised. In most circumstances it will be necessary that an automated fire and/or smoke detection system be installed. Management may also consider an automated fire suppression system that minimises the risk of damage. If there is a risk of flooding, a water detector and/or water drain should be considered.

The archive facility should be designed to prevent the entry of rodent and insect pests. Where appropriate, pest control procedures should be in place.

Where necessary, back-up electrical power should be provided for all temperature-critical equipment (e.g., refrigerators and freezers).

5.1 Archive Conditions

Storage conditions should be designed to preserve and not adversely affect the quality and integrity of retained records and materials. Special storage conditions may be required to maintain the integrity of some retained record(s) and material(s) for the specified retention period(s). For example, it might be appropriate to store wet tissues, blocks and reserve samples of test items separate from paper and histology slides.

Special storage conditions may be required for particular materials. Examples are materials required to be stored frozen, refrigerated, desiccated, etc., or free from dust or magnetic interference in the case of electronic media. The need for special storage conditions should be defined in relevant test facility Standard Operating Procedures.

If special storage conditions have been defined, environmental monitoring procedures should be implemented within archive storage areas to confirm that specified conditions of storage are being achieved.

Where continuous (automated) monitoring systems are used (which may also act as alarms that are activated in the event that defined conditions are outside specified limits), these systems should be regularly maintained, tested, and verified, and records thereof retained, as required by the Principles of GLP.

5.2 Disaster Recovery

Test facilities and contract archives should have procedures in place to minimise damage to archived records and materials caused by adverse events. Some of the more common adverse events to be considered include fire, electrical failure, extreme weather-related damage, flooding, theft, and sabotage.

The procedures may cover protective measures that may be implemented, as well as the recovery and/or restoration of lost or damaged records and materials and re-establishment of security. The plan should include useful and emergency contacts, the location of necessary equipment, and the records that should be made (e.g., documentation of the event and the steps taken to resolve and/or restore).

6. SECURITY

6.1 Physical and Operational Security

The archive facility should be both physically and operationally secure to prevent unauthorised access and changes to or loss of retained records and materials. Test facility management should ensure security by implementing appropriate measures that should be described in the test facility's SOPs.

The security controls necessary to restrict access to electronic records will usually be different from those applied to other record types. Since many electronic storage media can be re-used (e.g. overwritten), measures should be implemented to ensure that records cannot be altered or deleted.

6.2 Access to the Archive

With normal archive operations, access to the archive should be controlled by and restricted to the archivist and archive staff. For emergency access (especially during off-hours or for safety reasons), emergency personnel may enter and/or operate the archive unaccompanied. Otherwise visitors should be accompanied by the archivist or a member of the archive staff. The procedures for access to archive storage areas should be documented. The record of such visits should be retained. For electronic archives the above mentioned restrictions might not be applicable, but as a minimum deletion or alteration of electronic records in electronic archives should be avoided. Management might authorise read-only access on electronic records to a broader community.

7. ARCHIVING PROCEDURES

7.1 Standard Operating Procedures

The following issues should be addressed in the Archive Standard Operating Procedures, where applicable:

- Access to the archives
- Definition and description of the archive
- Indexing procedures, including electronic records
- Conditions under which records and materials should be stored
- Procedures for the receipt of records and materials to be archived
- Procedures for accessing, removal and return of records and materials
- Responsibilities of the archivist and archiving staff
- Security of the archive facility and the records and materials retained
- Climate control
- Retention period
- Disposal of archived records and materials
- Contract archiving services, if applicable
- Transfer to sponsors or third parties, if applicable
- Disaster recovery
- Training requirements for the archivist and archiving staff
- Frequency of archiving non-study specific records
- Periodic refreshing of electronic records

7.2 Records and Materials to be retained

Records to be retained include paper records, photographs, microfilms or microfiches, computer media, dictated observations, recorded data from automated instruments, or any other storage medium containing the data generated in the conduct of a non-clinical health or environmental safety study.

Materials to be retained include wet tissues, paraffin blocks, specimens, slides, smears, test materials / retention samples, etc. Records and materials may be study-specific, or relate to more than one study.

7.2.1 Study-specific records and materials

These are the records and materials generated during the conduct of a single study in accordance with the study plan. The Study Director is responsible for ensuring these records and materials are transferred to the archives latest after study completion. These records may be inspected for verification of the results reported from a specific study and for the general assessment of the compliance of the study with Principles of GLP. The following are examples of study-specific records and materials that should be retained in the archives.

- Study plan, raw data, and the final report of each study
- Other study related documents and communication such as e.g. delivery receipts, phone notes, faxes etc.
- Samples of test and reference items
- Specimens
- Certificates of Analysis

7.2.2 Facility records and materials

These are records and materials that are generated by a test facility/site, and may be specific to one or more studies performed at the facility/site. Such records and materials may be inspected for the reconstruction of a study and for the general assessment of the continuing compliance of a test facility with Principles of GLP. Management should address in an SOP how and by whom the archiving of these records and materials should be carried out.

The following are examples of facility records and materials that should be retained:

- Records of all inspections performed by the Quality Assurance
- Master Schedules
- Organisational charts
- Floor/site plans
- Records of qualifications, training, experience and job descriptions of personnel
- Records and reports of the maintenance and calibration of apparatus
- Validation documentation for computerised systems
- Historical files of all Standard Operating Procedures
- Environmental monitoring records
- Samples of test and reference items, if used for more than one study
- Certificates of Analysis, if used for more than one study

7.3 Indexing

The Principles of GLP require that records and materials retained in the archives be indexed so as to facilitate orderly storage and rapid retrieval. The system of indexing employed should facilitate the retrieval of all information required to reconstruct a study from both the study and the facility records.

7.4 Placement of Records and Materials into the Archives

On completion (including termination) of a study the Study Director is responsible for ensuring that all study documentation, data and related records and materials are archived in a timely manner. The Study Director retains responsibility for the integrity of study documentation, data and related records and materials until they are accepted into the archive. Test facility management is responsible for maintaining the integrity of the records and materials once they are transferred to the archives. Test facility management should ensure that a time period for the transfer of material from the Study Director to the archivist is defined that is in compliance with national regulatory requirements, where existent.

Prior to transferring records and materials to the archive, the Study Director is responsible for establishing an inventory to be archived, confirming completeness of records and materials, and ensuring that these records and materials are transferred in their entirety to the archive. The archivist or archive personnel should check the completeness of records and materials upon their arrival by comparison with the inventory list and acknowledge receipt.

Test Facility Management should ensure that non study specific (facility) records such as maintenance records, staff training records, organisational charts, etc. are archived on a regular basis defined by test facility SOP. Procedures for archiving these records and materials should be similar to those employed for study records and materials.

In multi-site studies, procedures for archiving records and materials generated at individual test sites should be agreed upon and documented prior to/ or at the initiation of the study.

The Principal Investigator should notify the Study Director of the transfer of study materials to the archive.

7.5 Transfers

On occasion it may be necessary to transfer archived records and materials from one archive to another at a different physical location. The archivist transferring the records and materials, including electronic records, should ensure that there is a documented agreement and transfer plan between test facility management, management at the receiving facility and the sponsor before any transfer occurs. The documentation should include details of the records and materials to be transferred, the contact details/address of the receiving facility, and the means of transfer between locations.

Records and materials to be transferred should be clearly described in appropriate chain of custody documentation prepared by the archivist. The transportation of the material, and associated paperwork, between the two locations should be undertaken in such a way as to minimise the risk of loss or damage of the records and materials.

The recipient of the transferred records and materials should check that they correspond with the associated chain of custody documentation, and once accepted, the recipient becomes responsible for ensuring that anything is maintained and preserved appropriately. All parties involved in the transfer

should retain copies of the chain-of-custody documentation. Transfer of archived materials between computerised archive systems should be documented and conducted according to a migration plan.

7.6 Retention Period

Retention periods should be, and in some countries are, defined by regulatory (receiving) authorities. The retention period defines the minimal period of time that data must be retained and must be available for review if the safety studies that support the registration of new products or marketed products need to be verified. It is strongly recommended that records and other sustaining material associated with such safety studies be retained for as long as regulatory authorities might request GLP audits of the respective studies.

When performing routine test facility inspections that include the carrying out of study audits, monitoring authorities and/or their inspectors will normally select studies completed or performed since the previous inspection or, in some countries, the two previous inspections. If the retention periods have not been defined by an applicable regulatory authority, it is highly recommended that records and materials should be retained for at least three inspection cycles so that inspectors can evaluate the compliance of the test facility with the Principles of GLP. For those studies that will not be submitted to regulatory authorities it may be acceptable (if justified) to dispose of the study specific records and materials after this period.

The Principles of GLP state: "*a sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies*". Samples of test and reference items may however be discarded when the quality of the material no longer permits evaluation. Obviously the storage conditions should be optimal for these samples. When samples of test and reference items or specimens are disposed of before the end of the required retention period, the reason for disposal should be justified and documented.

Perishable specimens, such as blood smears, freeze-dried preparations and wet tissues, may also be discarded when they can no longer be read or evaluated. For non-perishable specimens the general guidance will apply.

Electronic media may be discarded when the media itself no longer permits evaluation (due to hardware or software issues) provided the disposal is authorized, documented, and electronic records are migrated and any record losses documented.

7.7 Retrieval

Appropriate procedures should be established for retrieval of archived records and materials. These procedures should define the circumstances under which they may be removed from the archive (e.g. for inspection/ regulatory purposes, by sponsor, etc.). The procedures should also describe in detail who is permitted to withdraw records and materials, who can authorise removal of records and materials and the timeframe within which records and materials should be returned to the archives.

Viewing electronic records without the possibility of alteration or deletion of the archived electronic record or replicating within another computerized system does not constitute "retrieval" of a record.

The Principles of GLP require that movement of records and materials in and out of the archives should be properly recorded. There should be mechanisms in place to enable the archivist to track the movement of records and materials from and back to the archive and to identify any records and materials

not returned within the specified timeframe. On return to the archive, the records and materials should be verified by the archivist or a designed member of the archive staff to be complete and unaltered. Management should be informed of any discrepancies.

7.8 Disposal of Records and Materials

Test facility management's and, if applicable, the sponsor's authorisation should be obtained before the disposal of any archived records and materials. The reasons for disposal should be recorded. It may be appropriate to inform QA. The disposal of archived records and materials should be documented.

8. ARCHIVING ELECTRONIC RECORDS

Requirements for the archiving of electronic records are the same as those for other record types, but there are additional features, which are addressed below. It is therefore important that management ensure that appropriate Standard Operating Procedures are established for the archiving of electronic media in a secure GLP environment.

8.1 Decision to Retain Records Electronically

The decision to retain records in electronic form has important implications. The long-term retention of electronic records may influence the choice of storage medium since deterioration of storage media can lead to permanent loss of records. Computer technology is developing rapidly and devices capable of reading storage media in common use today may not be available in the future. Electronic records should be stored in a format that is readable for the duration of the applicable record retention period.

8.2 Storage Media

Records may be migrated from a computerised system onto a storage medium, e.g. magnetic tape, diskette, CD or optical disk that can be placed in a physical archive. Archive procedures should include the consideration of additional controls for the migration of electronic records from old to new media of these records. Consideration should be given to future access to the data or records stored on these media. There may be a need for special storage conditions, e.g. protection from magnetic fields.

8.3 Defined Archive Area on a Computerised System

Electronic records may be moved from the production part of a computerised system to a discrete, secure archive area on the same computer system (physically separated, e.g. file record systems), or explicitly marked as archived (logically separated, e.g., database record systems). Records should be "locked" such that they can no longer be altered or deleted without detection. Records archived in this way must be under the control of a designated archivist and be subject to equivalent controls to those applied to other record types.

8.4 Dedicated Electronic Archive System

Records may be migrated from the computer system that captured or manipulated them into a separate dedicated electronic archive system. All data associated with the reconstruction of the study needs to be migrated. This includes, but is not limited to raw data, metadata, audit trails, e-signatures and associated hardware and software that allow availability of all records in the future.

Where ideally the archivist should be the system-owner for the electronic archive system, it is recognised that the electronic archive system is likely to be managed by information technology (IT) personnel. The archivist, being ultimately responsible for managing the archive, has an important role in helping to ensure that regulatory requirements are met. Test facility management should, therefore, take care that the co-operation and co-ordination between the archivist and information technology personnel is ensured.

These IT staff should follow procedures agreed with the archivist and/or test facility management.

8.5 Maintenance and Preservation of Electronic Records

Electronic records are at risk without a preservation process to ensure that these records are available in the future. Procedures should be in place to ensure that essential information remains complete and retrievable throughout the specified retention period. If the record medium requires processing in order to render the retained records into a readable format, then the continued availability of appropriate equipment should be ensured. If availability cannot be guaranteed, the possibility of migrating data from one medium to another should be considered.

If electronic record migration is necessary, the process of migration should be fully documented, and validated to ensure complete and accurate migration of the original records before they are lost or destroyed. If it is impossible to migrate the records to new electronic media it may be necessary to migrate to paper records. Duplication of electronic archives should be considered as part of an archive preservation plan.

9. QUALITY ASSURANCE

Archive facilities and processes constitute an important component of a GLP compliant test facility. These aspects should, therefore, be subject to routine quality assurance (QA) inspections and audits. When archived records and materials are transferred, the transfer process should be monitored by the conduct of directed QA inspections.

10. CONTRACT ARCHIVE SERVICES

The Principles of GLP require that a test facility has an archive to provide secure storage of records and materials. This will usually consist of archive facilities within the test facility itself, but the use of contract archive facilities is not precluded. In this situation, the guidance contained within this document should equally apply to the contract archive facilities. Contract archive facilities are involved in processes dealing with GLP studies and thus should be subject to inspections by Quality Assurance Programs, and by Monitoring Authorities, to assess the compliance with the GLP Principles.

The following factors need to be considered when using contract archive facilities:

10.1 Contracts and/or Service Level Agreements

There should be a formal agreement that details the level and conditions of service to be provided by the contract archive facility. This agreement should cover the description of the records and materials to be archived, the transportation of records and materials to the archive, chain of custody, access to stored records and materials by the contract archive, services provided (e.g. regular check of containers for wet tissues), safety, storage conditions, duration of storage, method of retrieval/access and method of return/disposal, QA activities and responsibilities, and other considerations as addressed in this document. The contract archive organisation should follow relevant SOPs, either their own, or, in their absence, those provided by test facility management. This should be specified in the agreement.

10.2 Access Arrangements

Procedures should define how, and when, stored records and/or materials can be accessed by the depositor of the records and/or materials. Any such access should be approved and documented.

10.3 Conditions of Storage

The conditions of storage and the procedures followed by the contract archive facility should be the same standard as those expected of a test facility archive which is operated in compliance with the Principles of GLP. This will include the appointment of a suitably qualified archivist, written and approved SOPs describing archiving related activities and the provision of suitable storage areas to prevent deterioration or loss of stored records and materials.

10.4 Inspections

Periodically the contract archive facility should be inspected by Quality Assurance from or on behalf of the test facility or the sponsor, where applicable, to ensure that the conditions of the service level agreement are being met and that the systems and procedures operated by the contract archive facility comply with their SOPs and the Principles of GLP.

11. CLOSURE OF AN ARCHIVE

11.1 Principle

The OECD Principles of Good Laboratory Practice (in Section 10.4) state: If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s)".

11.2 Measures to be Taken

If a test facility or test site no longer intends to operate the archive in compliance with the Principles of GLP or goes out of business, the following measures have to be taken:

- The applicable national GLP compliance monitoring authority should be informed in a timely manner by the test facility.

- Test facility management should ensure that sponsors are informed as soon as possible once a decision is made to close the archive or if the facility goes out of business. Sponsors should ensure that all study-related records and materials are transferred to an alternate GLP compliant archive and retained for the period specified by the appropriate authorities.

- For non study specific (facility) records or records which relate to studies of more than one sponsor and that should be retained according to the Principles of GLP, test facility management should agree with the sponsors on how to ensure that these records and materials are archived in a GLP compliant archive after the closure of the test facility or archive for the period specified by the appropriate authorities. Access of the sponsors to these study- related records and materials should be agreed upon and documented.

11.3 Inspections by Monitoring Authorities

After the transfer to a new archive facility has taken place the GLP monitoring authority will normally inspect the new archive. In case records or materials are transferred to facilities located in another country, the GLP monitoring authority in that country should also be informed.

12. REFERENCES

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