ARCHIVES:
PHYSICAL VS ELECTRONIC

Matthew Riggsbee

AGENDA

General Overview (EPA & OECD)

- Physical Archives

- Electronic Archives

Considerations for Archives

ARCHIVES

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

EPA GLPS, **§** 160.51

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

OECD Principles on GLP, No.1

ARCHIVES - PHYSICAL
KEY REQUIREMENTS

Storage

Maintain study files, facility records, specimens, retains for test, control and reference substances

Limited Access

Entry limited to personnel authorized by management

Indexed

Maintain orderly storage and (expedient) retrieval

Preservation

Storage conditions do not adversely affect the quality and integrity of the records

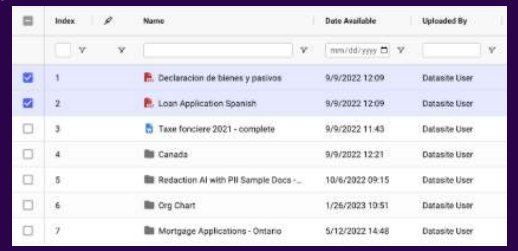
ARCHIVES - ELECTRONIC
KEY REQUIREMENTS

Storage

Maintain study files, facility records, and electronic data with their **associated metadata**

Indexed

Maintain orderly storage and (expedient) retrieval



Limited Access

Access limited to personnel authorized by management

Preservation

Free from magnetic interference and utilizing backup systems for power and data through mirroring and/or cloud storage

PHYSICAL ARCHIVES

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For EPA, requirements outlined in the following locations:
  - §160.31(e) as TFM to ensure there are facilities available
  - Subpart C defines “Facilities” and in § 160.51 specifies space for archives with some details

§ 160.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For EPA, requirements outlined in the following locations:
  - §160.190 and 160.195 outlines what should be retained, how it should be retained, and who manages and accesses the archives

§ 160.190 Storage and retrieval of records and data.

(a) All raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For EPA, requirements outlined in the following locations:
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WHAT & HOW

WHO

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(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For EPA, requirements outlined in the following locations:
  - §160.195 further details retention period (b) and business concerns (g)

§ 160.195 Retention of records.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for whichever of the following periods is longest:

(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For OECD, requirements outlined in the following locations in No. 1:
  - Section I - Definition of GLP

2.1 *Good Laboratory Practice*

1. Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For OECD, requirements outlined in the following locations in No. 1:
  - Section II, 1.1, #2, (b) and (l), TFM to ensure appropriate facilities exist and to identify the archivist

1.1 *Test Facility Management's Responsibilities*

1. Each test facility management should ensure that these Principles of Good Laboratory Practice are complied with, in its test facility.

2. At a minimum it should:

l) ensure that an individual is identified as responsible for the management of the archive(s);

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For OECD, requirements outlined in the following locations in No. 1:
  - Section 3 defines “Facilities” and in 3.4 specifies what should be retained and how it should be retained

3.4 *Archive Facilities*

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For OECD, requirements outlined in the following locations in No. 1:
  - Section 3 defines “Facilities” and in 3.4 specifies what should be retained and how it should be retained

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Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

WHAT

HOW

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For OECD, requirements outlined in the following locations in No. 1:
  - Section 2, 10.1 provides a list of what should be retained

10.1 The following should be retained in the archives for the period specified by the appropriate authorities:

a) The study plan, raw data, samples of test and reference items, specimens, and the final report of each study;

b) Records of all inspections performed by the Quality Assurance Programme, as well as master schedules;

c) Records of qualifications, training, experience and job descriptions of personnel;

d) Records and reports of the maintenance and calibration of apparatus;

e) Validation documentation for computerised systems;

MORE DETAILS ON WHAT (from OECD)

f) The historical file of all Standard Operating Procedures;

g) Environmental monitoring records.

In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For OECD, requirements outlined in the following locations in No. 1:
  - Section 10.2 and 10.3 states the "how"

10.2	Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.
10.3	Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- For OECD, requirements outlined in the following locations in No. 1:
  - Section 10.4 further details business concerns

10.4	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).

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- Additionally, OECD provides further detailed guidance for physical archives:
  - OECD GLP Advisory No. 15, “Establishment and Control of Archives that Operate in Compliance with the Principles of GLP”
  - OECD GLP Advisory No. 22, GLP Data Integrity

PHYSICAL ARCHIVES

Paper, samples, Test Substances

- Other OECD references include:
  - OECD GLP Consensus Document No. 6, The Application of the GLP Principles to Field Studies (coordination to archive between the sites)
  - OECD GLP Advisory No. 11, specifies archive responsibilities for a sponsor if a facility goes out of business
  - OECD GLP Consensus Document No. 13, includes archive responsibilities for the Principal Investigator and multiple sites participating in a study


ELECTRONIC
ARCHIVES

ELECTRONIC ARCHIVES

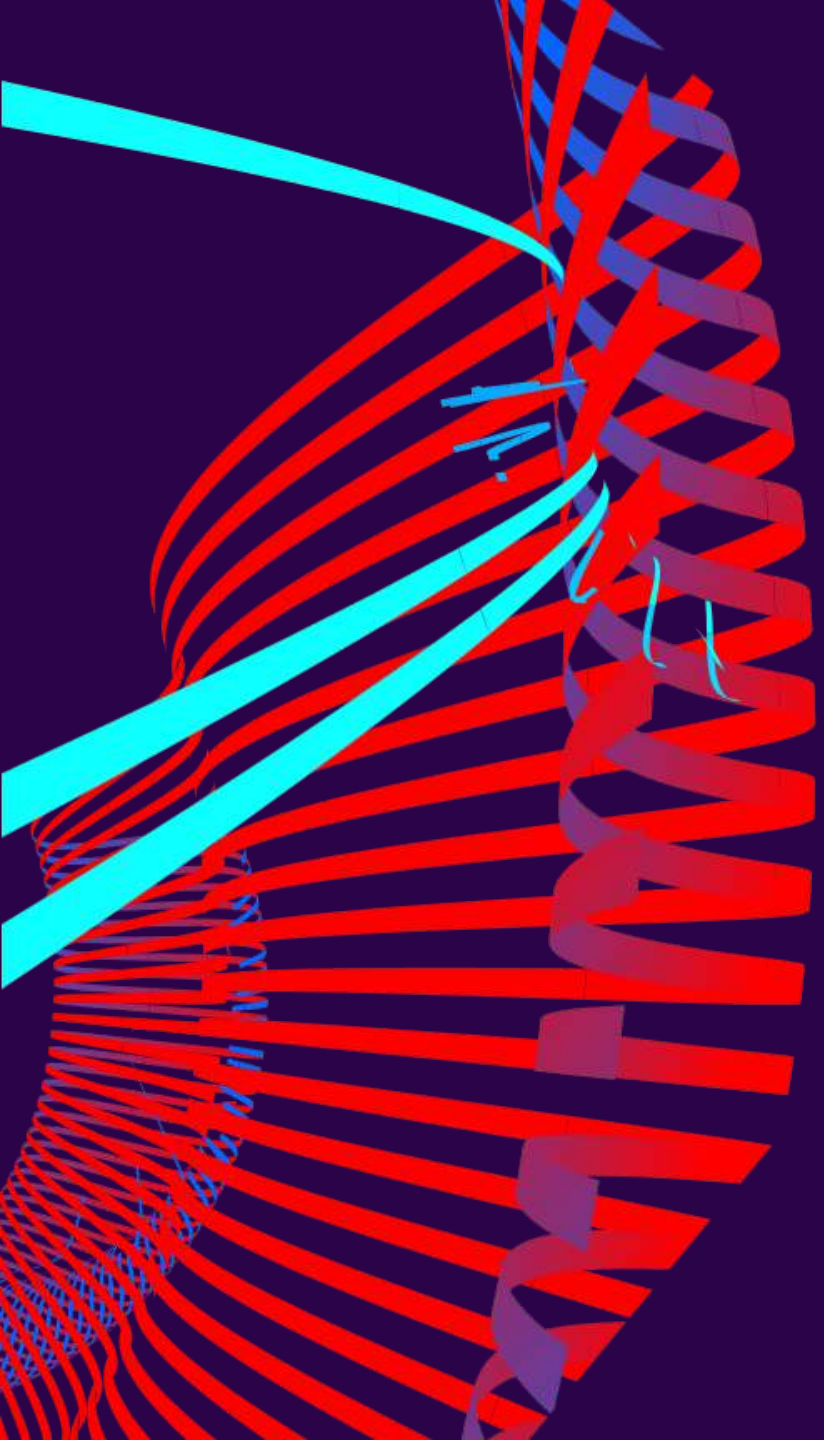
Electronic Raw data and Metadata

- For EPA, the same requirements as that for physical archives:
  - §160.31(e) as TFM to ensure there are facilities available
  - Subpart C defines “Facilities” and in § 160.51 specifies space for archives
  - §160.190 outlines what should be retained, how it should be retained, and who manages and accesses the archives
  - §160.195 further details retention period (b) and business concerns (g)
  - Electronic systems are considered equipment and follow §160.61 and 160.63

ELECTRONIC ARCHIVES

Electronic Raw data and Metadata

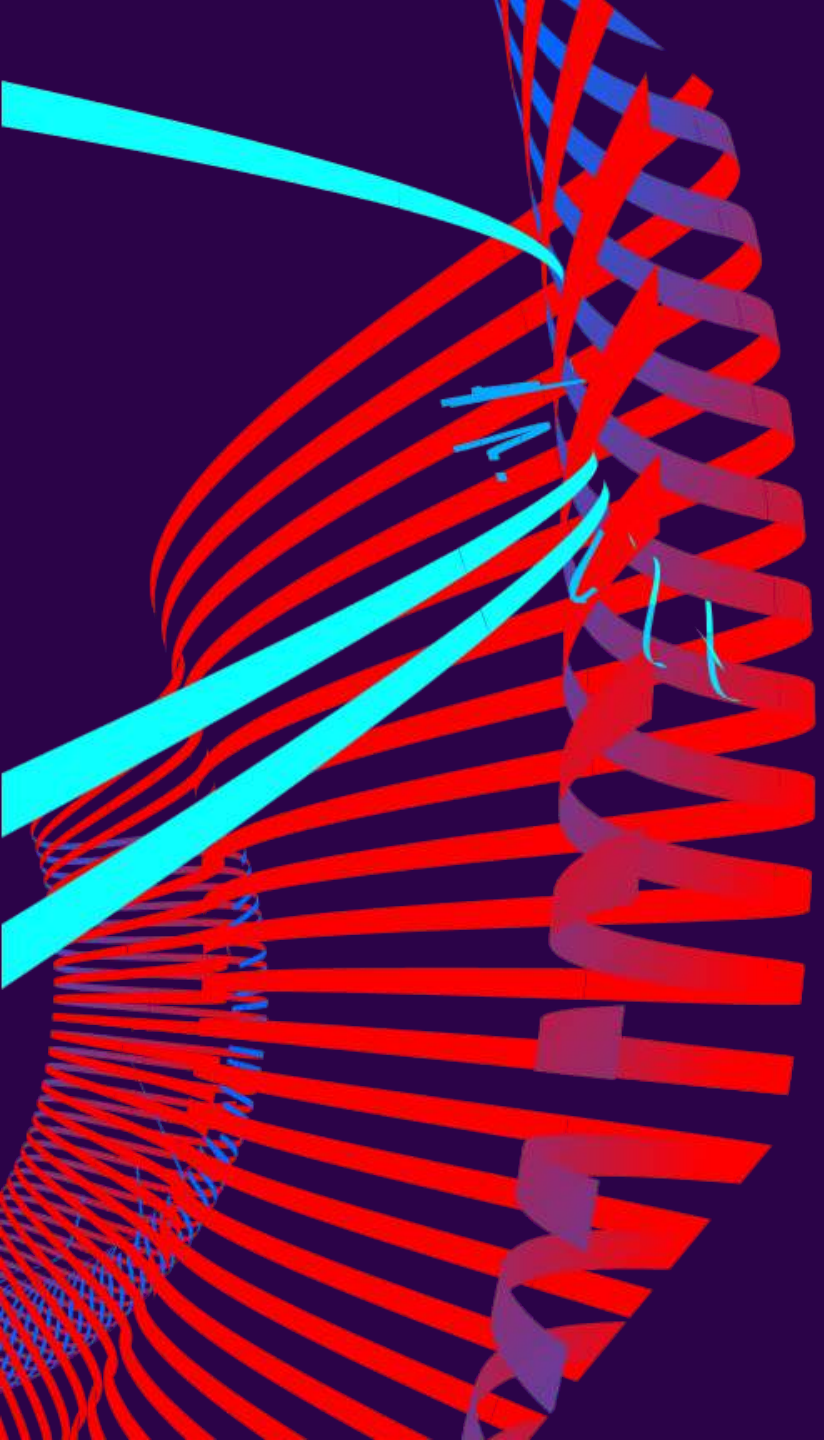
- OECD GLP Principles for e-Archives follow the same as physical archives
- Additionally, OECD provides further detailed guidance:
  - OECD GLP Advisory No. 15, “Establishment and Control of Archives that Operate in Compliance with the Principles of GLP”-> Section 8
  - OECD GLP Advisory No. 17, “Application of GLP Principles to Computerised Systems”
  - OECD GLP Advisory No. 17, Supplement 1, GLP & Cloud Computing
  - OECD GLP Advisory No. 22, GLP Data Integrity (e-data throughout)



THE QAU & THE ARCHIVE

- For EPA, QA requirements can be gleaned from the following:
  - §160.35(a) as QA ensures that facilities are in compliance with the GLPS and existing facility SOPs (including archives)
  - §160.35(c) Retention of QA records with an index
- For OECD,
  - OECD GLP Advisory No. 23, section 10, details QA record retention and archive, and section 11.6, specifies the need for periodic inspections by QA of both archive facilities (internal and external) and the associated archive procedures

QAU



ARCHIVE CONSIDERATIONS

ARCHIVE CONSIDERATIONS

Consideration 1: Business & GLP Operations?

ARCHIVES: BUSINESS AND GLPS

Per EPA GLPS, §160.195(g):

If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.

Notify EPA (Henry) via email: armstead.henry@epa.gov of facility updates

ARCHIVES: BUSINESS AND GLPS

Per EPA GLP Advisory No. 75:

(transfer of archives)

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP) Regulation

GLP Regulations Advisory No. 75

FROM: Rick Colbert, Director
Agriculture and Ecosystems Division
TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Agriculture and Ecosystems Division of the Office of Compliance. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at 202-564-2365.

Attachment

Dear

This is in response to your letter of August 26, 1996 in which you requested compliance assistance with respect to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). You wanted to know who in the EPA should be notified when data are transferred to the archives of a sponsor when a facility that conducts testing or that is contracted to archive data goes out of business. They require this notification under GLPS at 40 CFR 160.195(g).

You specifically referred to X which conducted the field portion of residue studies for Y. According to your letter, X went out of business and the non-study-specific archives were transferred to Y archives. These records were then transferred to a contract facility to provide better accessibility by other sponsors who had contracted with X. You stated that X had assured you that the other sponsors had been notified of the disposition of the records.

Our office is the correct office to notify in writing, as required at 40 CFR 160.195(g), when data are transferred after a facility goes out of business. In your written notification, please identify both the archiving facility and the studies that are affected by the transfer. If the affected archives apply to only the field portion of the studies, please indicate that in your notification

*Notify EPA via email: armstead.henry@epa.gov

ARCHIVES: BUSINESS AND GLPS

Per OECD GLP, **No. 1, 10.4**:

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).

ARCHIVES: BUSINESS AND GLPS

Per OECD GLP Advisory, **No. 15**:

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)".

ARCHIVES: BUSINESS AND GLPS

Per OECD

GLP Advisory,

No. 15:

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.

ARCHIVES: BUSINESS AND GLPS

Per OECD GLP Advisory, **No. 15**:

> ***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.

Per OECD GLP Advisory, **No. 11**:

> **Storage and Retention of Records and Materials:** "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)." (See revised Principles, para. 10.4.)
>
> *Note:* In this case, the sponsor is expected to arrange for an archive for the appropriate storage and retrieval of study plans, raw data, specimens, samples of test and reference items and final reports in accordance with the Principles of GLP.

ARCHIVES: BUSINESS AND GLPS

Business Considerations

- Business closure
- Stoppage or Termination of GLP services
- Acquisition/Transition of Business

ARCHIVES: BUSINESS AND GLPS

Business Considerations

- Business closure
  - ✓ Contact the GLP monitoring authority (GLP MA) such as the EPA, SCC, etc.
    - ✓ Notify sponsors
  - ✓ Transfer the facility's archive
    - ✓ Study records to the applicable sponsor archive
    - ✓ Non-study records should be transferred to a sponsor or a long-term location
    - ✓ Document location(s) of archived records
  - ➢ Inform business partners, family, etc. of plans, procedures, process
    - ✓ Have key contact information centralized (EPA, Sponsors, QA, etc.)

ARCHIVES: BUSINESS AND GLPS

Business Considerations

- Stoppage of GLP services (~ OECD No. 15, section 11.2)
  "test site no longer intends to operate the archive in compliance with the Principles of GLP…"
  - ➢ If suspending GLP operations, consider planned length of time
    - ➢ Archives will need to be maintained to GLP during stoppage
  - ✓ If Terminating, follow guidelines for Business closure
    - ✓ Contact monitoring authority and sponsors
    - ✓ Transfer archives
      - ✓ Study records to Sponsors
      - ✓ Non-study records to an agreed to location (notifying MA and sponsors)
    - ➢ Inform business partners, family, etc. of plans, procedures, process

ARCHIVES: BUSINESS AND GLPS

Business Considerations

- Acquisition/Transition of Business
  - ✓ Contact the GLP monitoring authority (GLP MA) such as the EPA, SCC, etc.
    - ✓ Notify sponsors
    - ✓ Update on new ownership and contact information/name(s)
  - ✓ Review facility procedures archive
    - ✓ Ensure archiving procedures exist
    - ✓ Understand index and locations
  - ➢ Inform business partners, family, etc. of plans, procedures, process
    - ✓ Have key contact information centralized (EPA, Sponsors, QA, etc.)

ARCHIVE CONSIDERATIONS

Consideration 1: Business & GLP Operations

Consideration 2: Original Electronic data (source files, derived, metadata, copies)

ARCHIVES: ORIGINAL E-DATA

Per EPA GLPS, **Definitions**:

"Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

ARCHIVES: ORIGINAL E-DATA

Per EPA GLPS, **§160.190(a)**:

All raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained.

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 1 (Definitions)**:

Raw data means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10, below.

ARCHIVES: ORIGINAL E-DATA

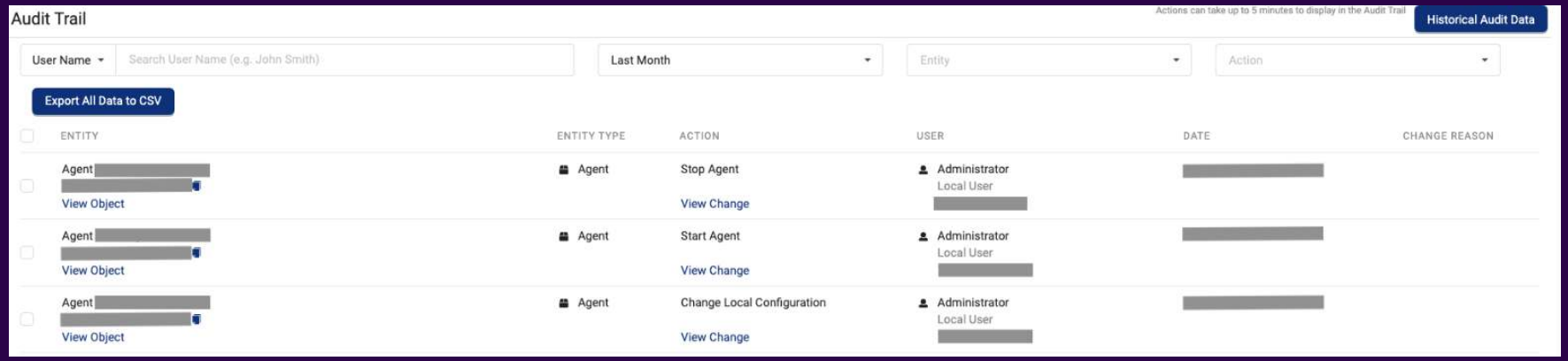
Per OECD GLP, **No. 1 (Section I, 8.3, #5)**:

5. Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 1 (Section I, 8.3, #5)**:

Computerised system design should always provide for the retention of full audit trails to show all changes to the data



ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 15 (Section 8 – Archiving Electronic Records)**:

Audience Participation

What are some examples data storage formats that are no longer used?

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 15 (Section 8 – Archiving Electronic Records)**:

Audience Participation

What are some examples data storage formats that are no longer used?

IBM 3850 Mass Storage System (1974-1986)

ISI WC Optical Storage System (1985 - late 1980s)

Advanced Digital Recording (ADR) (1999 - 2003)

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 15 (Section 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…

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 15 (Section 8.1)**:

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

- Loss due to corruption
- Loss due to advancing technology

https://obsoletemedia.org/data/data-timeline/

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 15 (Section 8.2 – Storage Media)**:

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.

IBM 3850 Mass Storage System
(1974-1986)

ISI WC Optical Storage System
(1985 - late 1980s)

Advanced Digital Recording (ADR)
(1999 - 2003)

https://obsoletemedia.org/data/data-timeline/

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 15 (Section 8.4)**:

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.

- Data is digitally retained in an e-archive
- IT staff assisting with archive should follow archiving procedures and with the archivist being ultimately responsible for the e-archive.
- Reference OECD No. 22, Data Integrity

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 15 (Section 8.5 – Maintenance & Preservation)**:

- 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 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.

ARCHIVES: ORIGINAL E-DATA

Per OECD GLP, **No. 22 (Section 6.16 – Archive)**:

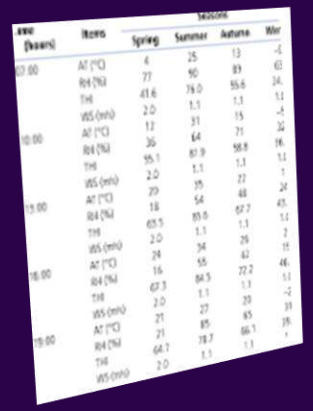
- Data should be archived securely, under the control of the unique archivist, including, where relevant, an appropriate electronic repository whether this is on the original system or elsewhere, subject to suitable controls or in a stand-alone electronic archive.
- All archive sites (physical as well as electronic) associated with the archived data should be identified and documented.
- Archives must be designed to permit retrieval and readability of data and metadata throughout the required retention period.
- If it is impossible to migrate the records to new electronic media it may be necessary to migrate to paper records.

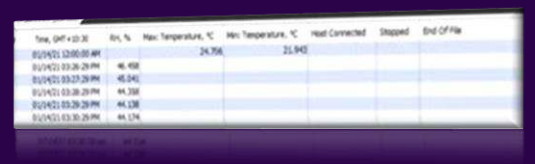
ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- Consider "Derived data" when preparing to archive a study. Ensure that these data are retained and archived.

> ***Derived data***
>
> Derived data are obtained and reconstructed from raw data (e.g. final concentrations as calculated by a spreadsheet relying on raw data obtained from an instrument; result tables as summarised by a Laboratory Information Management System (LIMS), etc.). Derived data are obtained by data processing.





ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- Additionally, Metadata and audit trails should also be retained and archived. From 3.1:

> ***Metadata***
>
> Metadata are data providing information used for the identification, description, and relationships of data. Metadata give data meaning, provide context, define structure, and enable retrievability across systems, and usability, authenticity, and auditability across time. For electronic data, parts of the metadata can be generated in audit trails.
>
> Metadata form an integral part of the data. Without the context provided by metadata, the data have no or limited meaning. The degree of metadata missing reduces the ability to interpret the data.

ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- Additionally, Metadata and audit trails should also be retained and archived.

6.3. Metadata

For raw data to have full meaning the data requires metadata and should be considered as part of the data (see also section 6.13 "Data audit trail").

Metadata should be generated contemporaneously with the data and should be retained with the associated data.

ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- Additionally, metadata and audit trails associated with electronic signatures should also be retained and archived. Also, from 3.1:

Audit trail

The audit trail is a form of metadata that contains information associated with actions that relate to the creation, modification or deletion of electronic data. An audit trail provides an automated secure way of recording life cycle details such as creation, additions, deletions or alterations of information in an electronic record without obscuring or overwriting the original record. An audit trail facilitates the reconstruction of the history of such events relating to the record, including the 'who, what, when and why' of the action.

ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- Additionally, metadata and audit trails associated with electronic signatures should also be retained and archived.

6.16. Archive

dynamic data functionality. It is the TFM's responsibility to assess the impact of such losses and maintain the link between the readable audit trail or electronic signatures and the audited data to an acceptable level.

(See also section 3.11 of OECD Document No 17 (OECD, 2016[4]))

ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- Additionally, metadata and audit trails associated with electronic signatures should also be retained and archived.

6.16. Archive

dynamic data functionality. It is the TFM's responsibility to assess the impact of such losses and maintain the link between the readable audit trail or electronic signatures and the audited data to an acceptable level.

(See also section 3.11 of OECD Document No 17 (OECD, 2016[4]))

115. If an electronically signed record is archived electronically, its integrity should be ensured for the relevant time period. The verification of the integrity of the signed record, the supporting metadata and the electronic signature should be possible and subjected to evaluation within the archiving period. The periodicity of the evaluation should be justified by the test facility management based on risk assessment.

ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- Additionally, metadata and audit trails associated with electronic signatures should also be retained and archived.
  - Docusign envelopes and Certificates of Completion

Signer Events	Signature	Timestamp
John Smith 11-ind@mailinator.com Test Account Security Level: Email, Account Authentication (Required)	John Smith Signature ID: 8B6538B1-830E-4CD6-8606-0D74EB771680 Using IP Address: 10.10.66.37 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 12/16/2015 4:45:15 PM Viewed: 12/16/2015 4:52:14 PM Signed: 12/16/2015 4:53:53 PM
Electronic Record and Signature Disclosure:		

  - Adobe Sign and the accompanying audit report

GlobalCorp Client Services Agreement

Final Audit Report 2018-11-26

Created:	2018-11-26
By:	Casey Jones
Status:	Signed
Transaction ID:	CBJCHBCAABAAxfp3eP

"GlobalCorp Client Services Agreement" History

Document created by Casey Jones
2018-11-26 - 3:02:01 PM GMT- IP address: 192.150.10.202

Document emailed to Io (io@jupiter.dom) for signature
2018-11-26 - 3:02:04 PM GMT

Document viewed by Io (io@jupiter.dom)
2018-11-26 - 3:12:53 PM GMT- IP address: 192.150.10.202

Document e-signed by Io (io@jupiter.dom)
Signature Date: 2018-11-26 - 3:13:16 PM GMT - Time Source: server- IP address: 192.150.10.202

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ARCHIVES: ORIGINAL E-DATA

Considerations of e-data (from OECD 22):

- E-data should be archived and under the control of the archivist
- GLP archive requirements for paper archives apply equally to electronic archives
- Archived e-records must be retrievable and readable throughout the life/retention of the record
- Use version controls when modifying e-records that are to be modified if checked out of the archives
- Ensure that deleted records have history via audit trail

ARCHIVE CONSIDERATIONS

Consideration 1: Business & GLP Operations

Consideration 2: Original Electronic data (source files, derived, metadata, copies)

Consideration 3: Preservation of E-data (backup and recovery)

ARCHIVES: PRESERVATION OF E-DATA

Considerations for preservation of e-data (from EPA & OECD GLPS):

- §160.190(b)… Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens.

- OECD No.1, section II, Item 3.4: Archive design and archive conditions should protect contents from untimely deterioration.

ARCHIVES: PRESERVATION OF E-DATA

Considerations for preservation of e-data (from EPA & OECD GLPS):

- OECD No. 15, section 8.5: e-data should have a preservation process for accessibility, which may require:
  - Appropirate equipment
  - Migration between media*
  - Record duplication (as a method of preservation)*
  - Conversion to paper if unable to perform migration*

* Requires validation (or verification) based on SOPs

ARCHIVES: PRESERVATION OF E-DATA

Considerations for preservation of e-data (from EPA & OECD GLPS):

- OECD No. 22, section 6.15: Back-up and recovery processes for electronic data should be tested where appropriate.
- Consider:
  - Ensuring that back-ups have completed successfully
  - Validate/verify the back-up process/procedure (routine checks)
  - Test via a restoration/recovery check (Disaster Recovery/Business Continuity test)

ARCHIVES: PRESERVATION OF E-DATA

Considerations for preservation of e-data (from EPA & OECD GLPS):

- OECD No. 22, section 6.16: Archive arrangements must be designed to permit retrieval and readability of data and metadata throughout the required retention period.
- Consider:
  - Maintaining hardware and/or software (physical or virtual)
  - Migrate to an alternative file format, retaining data attributes
  - Perform a risk assessment and validation of migration processes

ARCHIVES: PRESERVATION OF E-DATA

Considerations for preservation of e-data (from EPA & OECD GLPS):

- OECD No. 17, section 6.3, Electronic archives in cloud soln

> Measures such as a risk-based back up policy are important. Documented evidence of relevant and efficient back-up and mirroring measures and restoration protocols and a control over those processes by the test facility should be available.

- Consider:
  - Ensuring that back-ups have completed successfully
  - Validate/verify the back-up process/procedure (routine checks)
  - Test via a restoration/recovery check (Disaster Recovery/Business Continuity test)

ARCHIVE CONSIDERATIONS

Consideration 1: Business & GLP Operations

Consideration 2: Original Electronic data (source files, derived, metadata, copies)

Consideration 3: Preservation of E-data (backup and recovery)

Consideration 4: Management of Archives (physical vs. e-data) and archivist vs IT

ARCHIVES: MANAGEMENT OF ARCHIVES

Considerations for managing archives (from EPA & OECD GLPS):

- §160.190(c)… An individual shall be identified as responsible for the archives.

- OECD No.1, section II, Item 1, 1.1, 2(l): ensure that an individual is identified as responsible for the management of the archive(s)

ARCHIVES: PRESERVATION OF E-DATA

Considerations for preservation of e-data (from EPA & OECD GLPS):

- OECD No. 15, section 8.4: the archivist should be the system-owner for the electronic archive system.
- However:
  - the electronic archive system may be managed by IT personnel
  - TFM must ensure that IT works under guidance of the archivist
  - IT follows procedures agreed to by archivist

ARCHIVE CONSIDERATIONS

Consideration 1: Business & GLP Operations

Consideration 2: Original Electronic data (source files, derived, metadata, copies)

Consideration 3: Preservation of E-data (backup and recovery, e.g. Frances' example of data loss in e-archive)

Consideration 4: Management of Archive (phys vs. e-data) and archivist vs IT

Consideration 5: Non-study, facility records (amongst Sponsors)

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

Audience Participation

What are some examples of facility records that should be maintained?

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- §160.195(d): The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by § 160.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.
- §160.195(e): Summaries of training and experience and job descriptions required to be maintained by § 160.29(b) may be retained along with all other testing facility employment records for the length of time…

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- §160.195(f): Records and reports of the maintenance and calibration and inspection of equipment, as required by § 160.63 (b) and (c), shall be retained for the length of time...
- OECD No. 1, Sec. II, item 10.1(b): Records of all inspections performed by the Quality Assurance Programme, as well as master schedules
- OECD No. 1, Sec. II, item 10.1(c): Records of qualifications, training, experience and job descriptions of personnel

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- OECD No. 1, Sec. II, item 10.1(d): Records and reports of the maintenance and calibration of apparatus;
- OECD No. 1, Sec. II, item 10.1(e): Validation documentation for computerised systems;
- OECD No. 1, Sec. II, item 10.1(f): The historical file of all Standard Operating Procedures;
- OECD No. 1, Sec. II, item 10.1(g): Environmental monitoring records.

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- OECD No. 15, item 7.2.2 – Facility records and materials, Examples:
  - QA inspection records (facility or process audits)
  - Master Schedules
  - Organisational charts
  - Floor/site plans
  - CV/Resume, training, and job descriptions
  - Records and reports of the maintenance and calibration of apparatus

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- OECD No. 15, item 7.2.2 – Facility records and materials, Examples:
  - 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

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- OECD No. 15, item 7.1 – Standard Operating Procedures
- Key procedures to consider:
  - Indexing procedures, including electronic records
  - Responsibilities of the archivist and archiving staff
  - Transfer to sponsors or third parties, if applicable
  - Disaster recovery

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- OECD No. 15, item 7.1 – Standard Operating Procedures
- Key procedures to consider:
  - Training requirements for the archivist and archiving staff (+ IT ?)
  - Frequency of archiving non-study specific records
  - Periodic refreshing of electronic records

ARCHIVES: NON-STUDY, FACILITY RECORDS

Considerations for managing non-study records (from EPA & OECD GLPS):

- Business closure or stoppage of GLP services
  - Communicate with Sponsors and applicable customers on plans
  - Develop a plan to get facility records (verified copies or originals) to a GLP archive to manage or to a sponsor or sponsors
  - Notify EPA GLP personnel of this change of status
    - Note: Current notice should go to Henry Armstead at armstead.henry@epa.gov

ARCHIVE CONSIDERATIONS

Consideration 1: Business & GLP Operations

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Consideration 6: Originals vs True Copies -> C. Miles coming up next

REFERENCES

EPA GLPs

https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol24/xml/CFR-2011-title40-vol24-part160.xml

OECD GLPs

https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/good-laboratory-practice-and-compliance-monitoring.html

Obsolete Media and history:
https://obsoletemedia.org/data/data-timeline/

THANK YOU

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