Long-Term Archiving of Analytical Instrument Data Operational Guidebook

Version 1.0

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Public Interest Incorporated Association Japan
Image and Information Management Association
R&D Data Archiving Committee

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1. Objective.

The purpose of this guidebook is to provide more specific operational methods for long-term archiving at each facility based on the concept of the "Guidance for the Long-Term Archiving of Analytical instrument Data" (hereinafter referred to as "Long-Term Archiving Guidance")1.

2. Scope of Application

This operational guidebook discusses procedures and reliability considerations as a reference for long-term Archiving of measurement instrument data in accordance with the concept of the Long-Term Archiving Guidance. In practice, therefore, each facility is expected to follow its own procedures.

3. Introduction

The R&D Data Archiving Committee (hereafter referred to as "the Committee") has summarized the concept of long-term archiving of analytical instrumental data in a form that can be reprocessed, using high-performance liquid chromatography (HPLC) data as the subject matter, in the form of long-term archiving guidance. In addition, the "Technical Guidebook for Long-Term Archiving of Analytical instrumental Data"2 (hereinafter referred to as the "Technical Guidebook") was published, a standard data specification (standard package) was compiled in consideration of authenticity and cost. This guidebook is intended to serve as a reference material for the actual long-term archiving of analytical instrument data using this standard package.

Prior to the preparation of this operational guidebook, we confirmed that it is possible to reprocess data after long-term archiving according to the technical guidebook using analytical instrument data, analysis software, packaging tools, and cloud-based archiving sites provided by the members of this committee. In addition, in order to enhance the possibility of using the tools in actual laboratories, we distributed the packaged tools provided by the Committee members to volunteer members of Subcommittee 3 of GLP Division of Japan Society of Quality Assurance, which establishes a liaison relationship with the Committee, and conducted a demonstration experiment. Through the demonstration experiment, we clarified the procedures, records to be created, and QC/QA (Quality Control/Quality Assurance) methods necessary to ensure reliability.

4. Long-term Archiving Model for Analytical Instrument Data and Assumed Environment and Risks

4.1. Long-term Archiving Model

Following the concept of long-term archiving presented in the Long-Term Archiving Guidance, the actual operation should define specific procedures from export to reprocessing of data according to the workflow of the standard package (see Figure 1) presented in the Technical Guidebook.

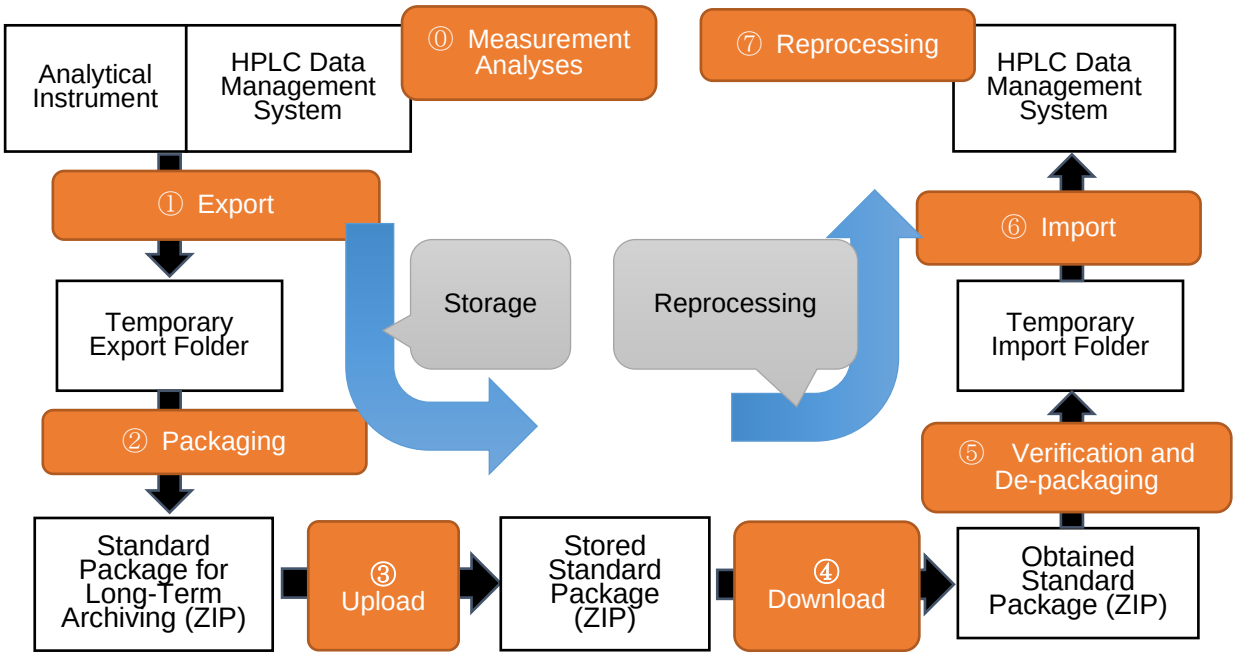

Figure 1. Flow of Analytical Instrument Data

This operational guidebook was prepared with long-term archiving in mind to enable compliance with GxP regulations. A model was developed in which analytical instrument data is stored for a long period of time and goes through seven phases before being reused: (1) export, (2) packaging, (3) upload (write), (4) download (read), (5) verification and de-packaging, (6) import, and (7) reprocessing.

4.2. Assumed Risks

Based on the above model, the reliability assurance risks in each phase are shown in Table 1. Chapter 6 describes measures for each risk.

Table 1　Reliability Assurance Risks in Each Phase

Phase		Risk	Control
①	export	Analytical instrument data required for test reconstruction not exported. Measurement data is falsified or switched during export.	6.1
②	Packaging	Required data are not packaged. Measured data is falsified or switched during packaging.	6.2
③	Upload)	Standard packages are swapped when uploading packages. Standard package is abandoned during the Archiving period.	6.3
④	Download (read)	Can be swapped out when downloading a package.	6.4
⑤	Verification and de-packaging	Unable to verify (e.g., certificate expiration). Unable to de-package (packaging failure, measurement data loss).	6.5

Phase		Risk	Control
⑥	import	AIA file not imported correctly (negligence or intentional). Metadata not set correctly on import (negligence or intentional).	6.6
⑦	reprocessing	Reprocessing results do not exactly match original analysis results.	6.7

5. Preparation for Long-term Archiving of Measurement Equipment Data

5.1. Selection of Analytical Instrument Data

5.1.1. Selecting the Format

The AIA format[1] was used as the standard format for HPLC data in this Operational Guidebook as a representative example of analytical instrumental data; it has been verified by this committee that the AIA format can be exported and read by software from multiple manufacturers. (See footnote 13 in the Long-Term Archiving Guidance.)

5.1.2. Selecting Data to Be Exported

Analytical instrument data that should be stored in packages for long-term Archiving depends on the intended use. The Long-Term Archiving Guidance clarifies examples of analytical instrument data that should be stored in the package, including cases where the data is used for reprocessing for purposes other than regulatory compliance, where the data is subject to the paper-based compliance inspection, and where compliance with GxP regulations is required, which are shown in Table 2.

Table 2 Example of analytical instrument data to be stored in the package

Analytical instrument Data		Reprocessing only	Document-based Conformity inspection	GxP Regulations standard
Original data (data in instrument-specific format)		○	○	○
Standard format (AIA) data		○	○	○
derived data	Results analyzed using original data (peak areas, etc.), etc.	-	○	○
	Calculation results (concentration, etc.), etc.	-	○	○
Analysis Metadata	Sample Schedule	○	○	○
	Instrument Parameters	○	○	○
	Analysis Parameters	○	○	○
audit trail metadata	Related to original data	-	○	○

[1] AIA format: A standard format for chromatographic data such as HPLC, etc., established by the Analytical instrument Association (AIA) of the United States. Different versions may not be readable.

Analytical instrument Data		Reprocessing only	Document-based Conformity inspection	GxP Regulations standard
	Related to Analysis Results	-	-	○
	System related	-	-	-

○: to store -: no need to store

5.2. Packaging of Analytical Instrument Data

The Analytical instrument data necessary to ensure reproducibility are combined into a single package, and long-term archiving guidance is provided to prevent modification to this package. In order to maintain interoperability, the specifications of a standard package with a standardized package structure shall be used. (See Figure 1).

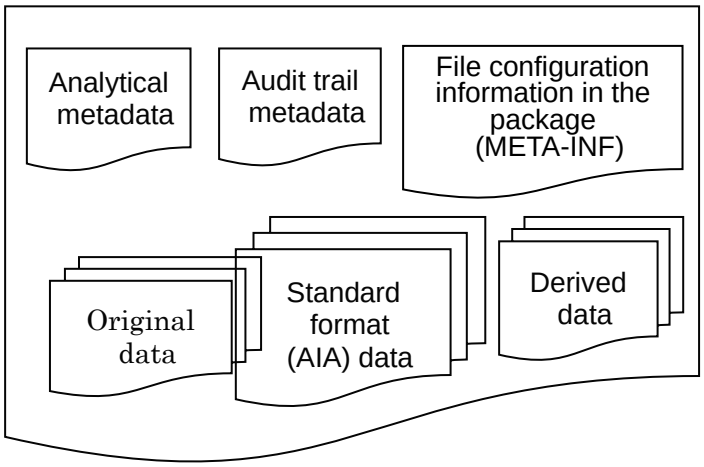

Figure 1 Example of a standard package of analytical instrument data[2]

[2] The meaning of each file is as follows:

- Analysis metadata: includes measurement conditions, analysis conditions, sample schedule, etc.
- Audit trail metadata: includes audit trails related to the original data and audit trails related to the analysis.
- Original data: Electronic data output from a measuring analytical instrument. Often output in an analytical instrument-specific format.
- Standard format data: measurement data converted to standard formats such as AIA and some derived data and metadata.
- Derived data: results of analysis (e.g. peak areas) and calculation results (e.g. concentrations) using the original data.
- In-package file configuration information (META-INF): In addition to the data, a special directory describing the file configuration information in the package.

5.2.1. Standard Packaging Tools

Based on the specifications in the Technical Guidebook, the members of this committee have created AdDataPackager[3] (hereinafter referred to as "the tool"), an open source and free-of-charge packaging tool with standard packaging and de-packaging/verification functions. Since this tool is a Windows version, it must be downloaded to a local computer prior to packaging. This operation guidebook shows the procedure for downloading the tool to the desktop of a local computer and creating the package, but this is only an example and should be done in accordance with the following instructions.0 As indicated in section 5.2.2, please consult with the IT staff at your facility.

Although this operation guidebook was established based on the assumption that this tool is used, a tool created separately according to the specifications of the technical guidebook can also be used to ensure reliable Long-Term Archiving of Analytical instrument data using a similar process.

5.2.2. Reliability Assurance of Standard Packaging Tools

Since this tool is open source, it is recommended that consult with the IT staff at each facility prior to whether or not it can be implemented in terms of internal policies and the internal IT environment. At that time, the following items should be communicated to the IT staff. It is also recommended that the IT staff be advised on the use of this tool.

- Since this tool performs simple hash value calculation and verification, digital signature and verification, and packaging and de-packaging, it is generally unlikely to interfere with other applications.
- The source code is publicly available and can be verified by a third party if necessary.

If the tool is planned to be used under GxP regulations, CSV should be conducted prior to the introduction of the tool in accordance with the regulations related to computerized system validation (CSV) at each facility. (However, even if the tool is not planned to be used under the GxP regulations, the listed items should be selected and considered for implementation.)

- Assign staff involved in the management of this tool (e.g., the tool's administrator) and clarify the roles and responsibilities of each staff member.
- Customize this tool to each facility's intended use as needed.
- Using the data for testing, create and unpack standard packages, perform verification functions, and document the verification results.
- Maintain a manual for the use of this tool.

No measures have been taken to detect program editing in this tool. Therefore, measures must be taken to maintain the security of this tool. Possible measures include:

- The tool (including customized versions) will be stored on an electronic data management system capable of complying with regulations (such as 21 CFR Part 11) related to electronic records and electronic signatures.

[3] It is available at: https://www.ossal.org/salproj/adpack.html.

- If an electronic data management system as described above cannot be prepared, the data may be stored in a location with restricted access permissions (e.g., non-validated Archiving). In such cases, footnote3 It must be ensured that the data has not been modified after downloading from the location indicated in footnote 3.
  - For example, if the tool itself is packaged immediately after downloading and placed in a controlled location, and the hash value is checked before use when downloading to the local computer, it can be shown that it has not been modified since the download.
  - If the location itself has the ability to calculate hash values, it is acceptable to use that. In this case, validation should include the part where the tool is downloaded to the local computer.
  - footnote each time this tool is used instead of storing and using it at the facility in question.3 Instead of saving and using the tool at the facility, it can be downloaded directly to a local computer from the location indicated in footnote 3. In this case, the possibility that the Tool may have been upgraded since the last time it was used should be taken into consideration before considering countermeasures.

6. Long-term Archiving and Operation of Analytical Instrument Data

This chapter describes operational methods to ensure the reliability of the series of operations shown in Figure 1. One of the important things to ensure the reliability of operations is to keep a record of the operations. It is important to keep a record of the operations so that it can be explained to those who are not present that the proper operations were performed. It should be noted that this record of the operation may also be reviewed by QA, sponsor or regulatory personnel. It is useful to have an SOP or template prepared for this purpose.

The following two methods can be used to confirm the reliability of the operation, but each facility should decide which method to adopt.

- A third party (e.g., QC/QA) reviews the above records to determine the reliability of the operation from the records.
- A person other than the operator is present during the actual operation to confirm that the operation is being performed in accordance with the SOPs and records.

In order to support confirmation work by operators and third parties (QC/QA, etc.), a check sheet with examples of specific confirmation methods was prepared and made an appendix to this guidebook (see Appendix).10 Chapter 10). However, this checklist may contain check items that are not applicable depending on the conditions of the facility, so please consider selecting or adding check items when using the checklist.

6.1. Exporting from the Analytical Instrument

When exporting analytical instrument data, the necessary data should be selected for future use (see Table 2).Table 2). For example, if compliance with GxP regulations is required, audit trail

metadata should be exported in addition to analytical metadata.

Generally, it is assumed that the export will take place at the time when the study report is approved, the study is completed, and the study-related materials are stored in the archive, but this is not the case in the following cases.

- If it becomes necessary to provide data to sponsors or other parties during the study period
- If the analysis application of the analytical instrument needs to be upgraded during the study period and data compatibility needs to be maintained

6.1.1. Export Procedure

In general, a single test often involves multiple measurements, so the data exported at the end of a test often includes the measurement results of multiple batches[4] . Therefore, we will explain the export procedure for combining data from multiple batches into a single package (see Figure 2).

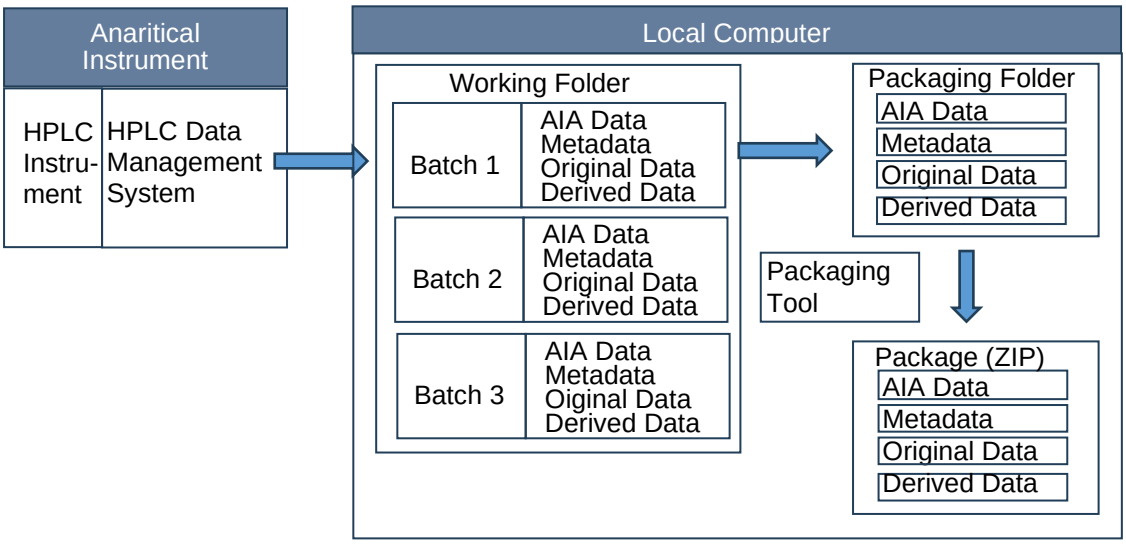

Figure 2　Schematic diagram from export to packaging

① Create a "working folder" on the local computer to store the exported data. Note that this tool is not designed to package data on the server, so it is necessary to temporarily save the data to be packaged to the local computer.

② Output one batch of data (AIA data, metadata, original data, and derived data) in a "working folder". If possible, it is recommended that an output method be selected that allows for detection of data tampering[5] .

③ Create a subfolder in the working folder and move the output data to it. The name of the subfolder

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[4] A batch in this case refers to a single measurement made using an autosampler.

[5] Empower needs to be configured to determine which channels are to be exported with AIA data. An export method can be created that simultaneously exports the report and the AIA data. Exporting using this method will align the save date and time of the exported data set. If the exported data is tampered with under such conditions, the possibility of detecting the tampering is high, since only the relevant data has different modification dates and times.

should be something that makes it easy to identify the measurement batch.

④ Repeat the above steps ① and ② to export all batches to be saved.

⑤ After copying the "working folder," rename the folder and create a "pre-packaging folder.

- Within each measurement batch folder in the "pre-packaging folder," create additional subfolders to organize the data by type, as shown in the example below.
- It is also recommended to store documents (e.g., test reports, etc.) that link the measured sample information with the measured data.
- Store the packaging tools in the "pre-packaging folder" if necessary.
- An example of the hierarchical structure inside a "pre-packaged folder" is shown below.

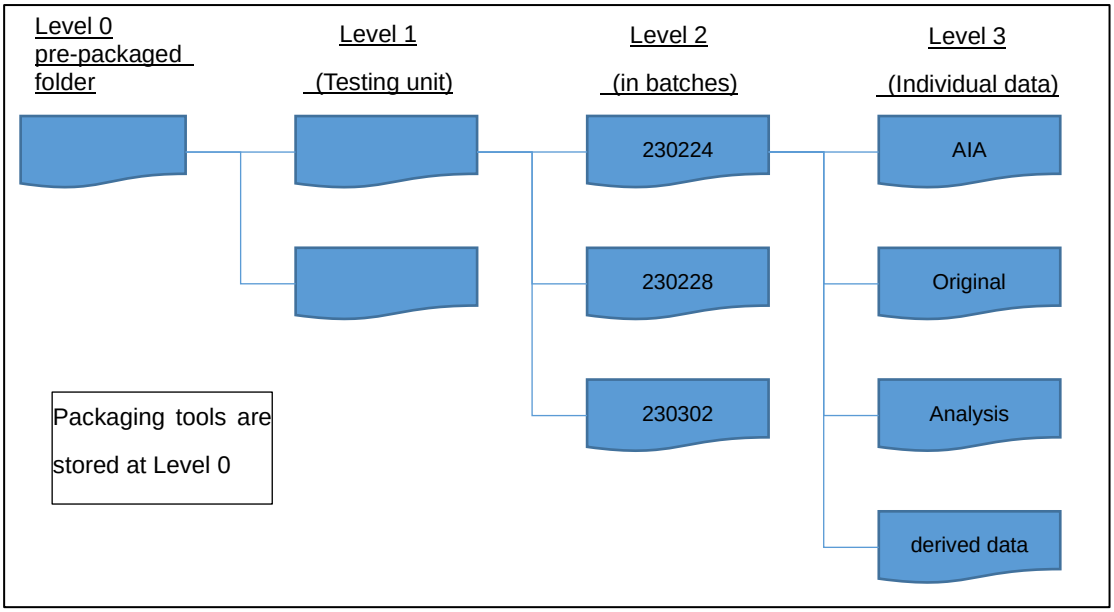

Figure 3　Hierarchical structure of pre-packaged folders

The "pre-packaged folder" including the folder name is stored as a "standard package" for a long time. In addition, using this tool, the structural information in the package (META-INFO) is stored in the top-level folder of the "Standard Package (ZIP)" created by the tool.[6]

6.1.2. Reliability Assurance Considerations for Export

The most important factor in ensuring the reliability of the export process is that all necessary data are exported. Therefore, it is necessary to take measures to prevent omissions in the export of target data or to detect such omissions when they do occur. As a prerequisite for this, it is necessary to identify the data to be saved. For this purpose, the data to be exported can be written in advance in the test report. An example of how to check for export omissions would be to check the number of measurement data to be saved in the test report and the number of measurement data in the "working folder" or after export.

[6] Due to the specifications of the tool, META-INFO is also created in the "pre-packaging folder".

The "pre-packaging folder" is to be created by artificially editing the "working folder", Therefore, the "pre-packaging folder" should be checked for file omissions and tampering prior to the creation of the standard package as indicated in section 6.2. For example, the hierarchical structure inside the "pre-packaging folder" and the Archiving location of the measurement data should be checked to confirm that the number, file name, update date, etc. of the measurement data exported to the "working folder" and those in the third level of the "pre-packaging folder" match. In addition, if packaged tools or test reports are stored, confirm that they are the intended files. Files may be checked visually, but examples of more efficient checking methods include counting the number of files by command or creating a file list[7] .

If there are plans to erase data from the equipment, perform the verification while the data is still available. For example, it may be more efficient to perform the verification of exported data together if subsequent standard packaging and Archiving on media can be performed on the same day.

In this case, it should be determined according to each facility's policy whether the data remaining in the measuring analytical instruments after the standard package is created should be deleted or whether they should continue to be stored.

6.2. Creating a Standard Package

6.2.1. Standard Packaging Procedure

Follow the instructions of this tool to create a standard package, specifying the "pre-packaging folder" from which the package is to be loaded and the directory in which the package is to be created (at the same hierarchy as the "pre-packaging folder").

A standard package (ZIP file) is created in the specified directory. As soon as possible after the standard package is created, it should be moved to an appropriate Archiving location (see0 section) as soon as possible after the standard package is created.

6.2.2. Reliability Assurance Considerations when Creating a Standard Package

When creating a standard package from a "working folder" on a local computer, there is a risk of data mix-up or falsification, so it is necessary to be sure to keep a record of the work with screenshots, etc. so that a third party can verify it. In addition, to prevent misuse, the "working folder" and "pre-packaging folder" created on the local computer should be deleted after verification by non-parties (including QC/QA) is completed. When uploaded to a long-term repository or handed over to an external organization, the "standard package" remaining on the local computer should also be deleted.

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[7] For example, there are two types of measures
- A) Check the number of files with the command dir /A-D/S /B | find /c /v "".
- B) Create a file list with the command tree /F > filename.txt (or dir /b /s > filename.txt) and visually check file consistency.

6.3. Uploading (Write) Standard Packages

The packaged data may be stored in one of the following ways or handed over to an outside agency. The standard package created should be immediately stored in a long-term Archiving location.

a) archiving
   - The data shall be stored on electronic Archiving media and stored in a material Archiving facility.
   - Store on an electronic management system.

b) handover
   - The information is stored on electronic Archiving media and mailed to an outside agency.
   - Handover to external organizations through cloud servers

6.3.1. Reliability Assurance Considerations when Data Is Handed over via a Cloud Server

There are two methods of passing standard packages to external institutions: saving them on media and mailing them to the external institution, or setting up a shared folder that both parties can access. In recent years, more and more institutions have adopted the latter method due to the development of cloud services for file sharing (e.g., box[8]). However, when using such shared folders, it is important to manage staff accounts. It should be noted that it takes more effort than expected to grant access rights to those who need them and to promptly delete access rights of those who no longer need them. In addition, from the viewpoint of information security, it is desirable that the person who uploaded or downloaded the file can be identified and that a history of the upload or download can be kept. In addition, shared folders and cloud services (box[8] When using shared folders or cloud services (e.g., box, Business b-ridge[9]), it is necessary to evaluate the connection to the site and the availability of the service at each facility prior to use.

To ensure that the file handed over to the external agency is the same as the original file, the identity of the file must be verified by performing the operations described in paragraphs 6.4 and 6.5 below to ensure that the file is the same as the original file.

6.3.2. Reliability Assurance Considerations when Storing on Media

The package can be stored on a medium and used for external delivery. If a medium capable of long-term Archiving is selected, it can be used for long-term Archiving. In addition, by storing the

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8 BOX is a cloud service for business-specific file sharing. It stores historical information, but whether the history can be viewed depends on the contract. It also has the ability to send an email for each event.
https://www.box-ctc.com/about_box.html

9 Business b-ridge can build, operate, and analyze business systems that digitize operations across departments and companies, and realize centralized information management and business progress management. The company has experience and know-how in CSV support in the pharmaceutical industry. It can keep a history of uploads and downloads.
https://www.businessbridge.jp/about

version of the tool used for packaging on the same media, the risk of unzipping due to version upgrades can be reduced.

Because of the risk of deterioration and obsolescence of media over time, when media is used for long-term Archiving, consideration should be given to storing at least two copies of the original and two copies of the original, periodically checking legibility, and migrating to a new media.

6.3.3. Long-term Archiving and Reliability Assurance Considerations

Since the standard package is a specification that can be checked for alterations since the time of Archiving, it is necessary to guarantee that the package itself has not been misplaced, lost, or stolen.

If the data is stored in an electronic data management system that has functions for compliance with ER/ES-related regulations and has appropriate CSV, it is assumed that the functions have already been verified and the necessary operational structure has been established, and if the necessary procedures are followed, few problems will arise. One point to keep in mind is that there is a risk that the staff member responsible for the data may be transferred or retire over time. It is desirable to have a system to appropriately maintain the staff responsible for the data.

If the files are stored on a server for archiving that has not been built with the above functions and systems, in addition to the above actions, it would be necessary to add a process to verify that the file update date and time, capacity, etc. have not changed.

6.4. Downloading (Read) Standard Packages

6.4.1. Download Procedure

Describes the procedure for downloading a standard package that has been stored for a long period of time for the purpose of re-analyzing data, etc.

Download or copy the standard package to a local computer so as not to make any changes to the standard package (ZIP) in long-term Archiving. For example, if the standard package (ZIP) is stored in the cloud or on an internal server used for external transfers, it should be downloaded; if the standard package (ZIP) is stored on media, it should be copied.

6.4.2. Reliability Assurance Considerations for Downloading

Since this tool runs only on the local computer, it must be downloaded once in order to perform a reprocessing. Therefore, the standard package in the Archiving location is not edited and a copy is used, thus eliminating the risk of erasure or overwriting of the standard package due to error. Naturally, the appropriate procedure must be followed and a record made of the download. Since the person who uploaded the data may not necessarily download it, appropriate handover is necessary in the event of a change in personnel responsible for the data. As long as it is made clear that the standard package at the Archiving location is the correct one when downloading, there is no need to be concerned about multiple copies of the same data being created.

6.5. Verification and De-packaging

6.5.1. Verification Procedures

Download or copy the tool and standard package to a local computer. Follow the instructions in the tool to perform the verification.

6.5.2. De-packaging Procedure

The standard package after verified by this tool is unzipped with a general-purpose unzip tool to create a "folder for import". Subsequently,0 After that, move the "import folder" to a location accessible from the analysis system according to the procedure described in section 6.6. If downloading to a location accessible from the analysis system, verification, and de-packaging can be performed there, the risk of data mix-ups and import omissions can be reduced because there is no need to manually move the files.

When decompressing with this tool, it is necessary to select the destination drive for de-packaging. Whether or not the de-packaging destination can be specified depends on the environment, not on the tool's functionality. If a location that can be analyzed on the server can be specified, the files will be verified and decompressed there.

6.5.3. Reliability Assurance Considerations for Verification and De-packaging

When decompressing, it is necessary to verify that all necessary data are included in the standard package. If materials clarifying data that should be included in the standard package (e.g., test records, test reports, etc.) are stored in a separate location as test-related materials, etc., the consistency can be checked by comparing the materials and data.

6.6. Importing to the Analytical Instrument

6.6.1. Import Procedure

The import procedure varies depending on whether the analysis application at the time of measurement and the analysis application at the time of reprocessing can be considered equivalent. If the Archiving period is long, it is likely that the analysis application will be upgraded, but in many cases the raw data from the previous version can be used as is. In this case, the relevant supplier should be consulted.

a) If the analysis application is not equivalent
   - The AIA file and the sample information are all that is needed to perform the reprocessing; the sample schedule in the AIA file import setup must be lined up in the sample table for the recalculation to be correct.
   - The data to be imported is AIA data only.

b) If the analysis application is equivalent
   - If the same model is used continuously, it is assumed that data will continue to be migrated

when the analysis application is upgraded, rather than following the method described in this guidebook.

- When transferring data to an outside organization (e.g., from a CRO to a sponsor), the original file can be used directly for reprocessing if they have the same analysis application (e.g., Empower).
- The data to be imported includes the original data as well as analysis parameters and sample schedules.

6.6.2. Reliability Assurance Considerations for Imports

Reliability assurance aspects of each import method will be discussed.

a) If the analysis application is not equivalent
   - We need to consider how to assure that the AIA file capture settings are correct. Identify the data needed for the purpose of reprocessing, select the AIA file for the appropriate channel[10] , and ensure that it is set up in the application.
   - It is necessary to verify that the sample tables for the reprocessing have been correctly entered as set up.

b) If the analysis application is equivalent
   - For example, if data is exchanged between the CRO and the manufacturer, and both have Empower, the hash value can be checked to verify that the file has not been tampered with. Verification is performed using this tool.

6.7. Reprocessing

6.7.1. Reprocessing Procedure

Set the analysis parameters and perform the reprocessing.

It would be useful to type out the sample schedule and tables when they are finalized so that they can be verified with the tables at the time of the initial analysis.

6.7.2. Reliability Assurance Considerations for Reprocessing

The supplier guarantees that the AIA data can be analyzed with the corresponding analysis application. Therefore, it should be confirmed that similar spectra can be drawn after reprocessing and that the analysis parameters can be set so that the peaks detected in the original analysis results are also detected in the new analysis application. If the analysis application is different, or if the analysis application has been upgraded, it is highly likely that the reprocessing results will not exactly match the original analysis results. However, if the data are normalized through internal

[10] Channels: Empower sets a channel for each measurement item to acquire measurement values.

standards or calibration curves, it may be possible to consider the error to be within an acceptable range. Also, since reprocessing is often performed for new purposes (e.g., detection of unknown peaks that are assumed to be metabolites or degradants), it is not necessary to obtain the same results as the original. For example, if the reprocessing is to find micro peaks, etc., it is sufficient to confirm that the sample sequence including the AIA file necessary for the reprocessing has been specified and that the original data has been reproduced.

7. Future Issues

Since the method proposed by this committee requires manual operations of data export, packaging, verification and de-packaging, and data import, it is difficult to completely avoid the risk of erroneous operations or tampering by malicious intent. Therefore, it is expected that the manually performed processes can be automated by applications on the analytical instrument side.

We expect the creation of a download tool as an automated response. Currently, downloading, verification on a local computer, de-packaging, and importing into the analysis system are all performed manually, and there is a large risk of data mix-ups and import omissions. If a specification that reads the standard package from a specified long-term Archiving location, automatically downloads it to the specified location, and then verifies and decompresses it, the number of tasks will be reduced and the risk of data mix-ups and missing imports will be minimized by creating a de-packaging tool.

8. Glossary

Table 3 shows an explanation of the terms used in this operational guidebook.

Table 3　Explanation of Terms

terminology	Description.
import	Importing data generated by other measuring analytical instruments so that they can be used.
export	Exporting the generated data so that it can be used by other measuring analytical instruments, etc.
open source (software, etc.)	Publicly available source code that can be freely viewed, modified, and distributed under the license
analysis parameters	A value that sets the peak waveform processing method, etc. Including baseline setting method, noise elimination method, etc.
audit trail	A secure, computer-generated, time-stamped electronic record that allows the reconstruction of the course of events associated with the creation, modification, or deletion of an electronic record. There are logs of original data generation, audit trails of analysis, and audit trails related to the system.
sample schedule	Analytical schedule when using an autosampler. Identify the order of sample injection, injection volume, etc.

terminology	Description.
normalization (e.g. in floating-point representation system)	To prepare data, etc., according to certain or standardized rules.
channel	Data generated from a single electrical signal from an analytical instrument. Examples: chromatograms (for detectors) or data on the operating conditions of the analytical instrument, such as pump pressure, temperature, flow rate, etc.
File configuration information in the package (META-INFO)	Special file describing the file configuration information in the package
hash value	Message digest generated by hash function
local computer	Computer terminal where data can be stored and operated at hand
CRO	Contract Research Organization, an organization that conducts studies under contract from pharmaceutical companies.
SOP	Standard Operating Procedures, a document that defines standard processes for conducting business.
ZIP	A file format for archives in which multiple files are treated as a single file. Basically, the file extension is "zip", but some files, such as docx, do not have a zip extension.

9. Reference

1. R&D Data Archiving Committee: Guidance for Long-Term Archiving of Analytical instrument Data (Version 2.1, January 31, 2020, Japan Institute of Document and Information Management (JIIMA))
2. R&D Data Archiving Committee: Technical Guidebook for Long-Term Archiving of Analytical instrument Data (Version 1.1, December 31, 2022, JIIMA)

10. Attachment (Check Sheet)

- Attachment 1: Check Sheet for Packaging and Long-Term Archiving of Analytical instrument Data
- Attachment 2: Verification/Reprocessing of Long-Term Stored Analytical Instrument Data Check Sheet

11. Revision History

Date	version number	Revision details
December 20, 2023	1.0	first edition
July 17, 2024	1.0	English edition

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Attachment 1: Check Sheet for Packaging and Long-Term Archiving of Analytical instrument Data

Checklist of processes from download to archiving

Item to be checked	Object to Be Checked	Confirmation Method and Contents	1st Check (Implementer)	2nd Check (Reviewer)	Remarks
System test and evaluation plan or test report	Plan or study report of the study to be preserved	Confirmation of description (Can the test number be identified?)	Pass□ Fail□	Pass□ Fail□	Transcribe the test number and other identifying information here.
	Files to be saved	Verification of description (Checking the plan against the files that actually exist)	Pass□ Fail□	Pass□ Fail□	The materials to be preserved must be comprehensive. Does the data be stored match the study protocol or study report? If not, it can be stated in the data archiving plan.
Data archiving plan (if any)	Documents that summarize the information needed to create the package, etc.	Archiving method, folder structure	Pass□ Fail□	Pass□ Fail□	Folder names should be regular.
	Archiving location	Confirmation of description (Can the archiving location be identified?)	Pass□ Fail□	Pass□ Fail□	Location of analytical data or package Archiving here (Transcription is not required if indicated on the data archiving plan).
Test record data identification	Test record	Check what data files are output when the test is conducted and whether they are eligible for archiving.	Pass□ Fail□	Pass□ Fail□	Check the file name from the test record when the measurement was made. It also needs to be saved if needed as metadata for measurement data.
	Identification of measurement data	Date of measurement	Pass□ Fail□	Pass□ Fail□	Check to see if all measurement dates for the required data are included.
		Is the list (sequence) written? Are the samples selected as planned?	Pass□ Fail□	Pass□ Fail□	To be confirmed from sample listings, etc.
Procedure	Data verification	Confirmation of data archiving location	Pass□ Fail□	Pass□ Fail□	Is the location indicated in the plan, etc.?
		File name confirmation	Pass□ Fail□	Pass□ Fail□	Does the file name match the file name identified in the plan or other implementation record?
		Data type	Pass□ Fail□	Pass□ Fail□	AIA, metadata, measurement conditions, audit trails, etc.
	Exporting data	Create export destination folder	Pass□ Fail□	Pass□ Fail□	
		Exporting	Pass□ Fail□	Pass□ Fail□	
		Confirmation of exported data	Pass□ Fail□	Pass□ Fail□	To be confirmed from measurement records, data types, etc.
	File structure in folders	Is there an appropriate hierarchical structure?	Pass□ Fail□	Pass□ Fail□	
		Appropriateness of confirmation method	Pass□ Fail□	Pass□ Fail□	Examples of reasonable methods: screen shots, visual checks, etc.

Item to be checked	Object to Be Checked	Confirmation Method and Contents	1st Check (Implementer)	2nd Check (Reviewer)	Remarks
	Packaging tools	Download tools	Pass□ Fail□	Pass□ Fail□	If stored on a server, include download location.
		Check version information	Pass□ Fail□	Pass□ Fail□	
	Data packaging	Confirmation of implementation	Pass□ Fail□	Pass□ Fail□	
	File deletion	Exported data	Pass□ Fail□	Pass□ Fail□	
		Downloaded tools	Pass□ Fail□	Pass□ Fail□	
		Packaged data	Pass□ Fail□	Pass□ Fail□	
Condition	Destination to save to	Archiving location on the company's own servers	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	Ensure that the package is stored in the proper location. Also make sure the location is secure.
		Cloud, Upload to	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	Address description, Also make sure the location is secure.
		Media: hardware archiving location	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	Check media Archiving locations. Also check the state of management of the Archiving area.
	Archiving medium	Media: confirmation of use	Pass□ Fail□ /Not applicable□	Pass□ Fail□ Not applicable□	Confirmation that long-term archiving is possible and that rewriting is not possible.
Changes and deviations	Record of changes and deviations	Record check	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	
Signature	Effective date (MMM/DD/YYYY)				
	Signature of the implementer				

Attachment 2: Check Sheet for Verification and Reprocessing of Analytical Instrument Data Archived for a Long Term

Checklist of processes from download to verification/reprocessing

Item to be checked	Object to Be Checked	Confirmation Method and Contents	1st Check (Implementer)	2nd Check (Reviewer)	Remarks
Target test	Information identifying the study to be reprocessed	Are the test numbers, etc. appropriate?			Transcribe the test number and other identifying information here.
	Target Package Name	Name of package, URL, etc.			
Objective.	Data validation / de-packaging	Whether data validation or de-packaging (including reuse) is performed, and why	Verification□ De-packaging□		Purpose and reasons are listed in this column. In cases such as only confirming that the data is complete, only verification is performed. The flow of verification only is assumed to be as follows. Place a copy from the main archiving location to the DL folder, and then verify there (do not unzip)
work location	Creating Folders	Are the folder names appropriate?	Pass□ Fail□	Pass□ Fail□	
Package copy	Compressed copies of test data	Have you copied it to the right place?	Pass□ Fail□	Pass□ Fail□	
Packaging tools	Use the latest version of the tool downloaded from the website	Ensure that there may be minor changes from the tools used to create the package, but that they are acceptable	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	
	Use packaging tools stored at the facility	Ensure that the package is stored in the proper location	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	
	Unpackaging tools (if necessary)	Is there a problem with de-packaging, or is it stored in the appropriate file?	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□□	
Data validation	Validation of data using validation tools	Were there any problems with the verification results?	Pass□ Fail□	Pass□ Fail□	The action to be taken in case of a problem (error) is described in the Remarks.
Data de-packaging	Decompress data using a de-packaging tool	Did you unzip to the proper folder?	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	
Preparation for reprocessing	Prepare sample set* for reprocessing and set analysis parameters	Do you have a place to capture the data? Has a sample set been created for analysis? Does it contain all the data needed for reprocessing? Are the analysis parameters appropriate for the purpose?	Implemented□ Not implemented□ Not applicable□	Pass□ Fail□ Not applicable□	* Case of Empower. Other systems may call it differently. When exchanging with other systems, a sample set dedicated to analysis may be created before importing.

Item to be checked	Object to Be Checked	Confirmation Method and Contents	1st Check (Implementer)	2nd Check (Reviewer)	Remarks
Import into the same application	original data	Are the necessary data imported?	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	Obtain screen captures as needed
Import into different applications, etc.)	AIA formatted data	Are the necessary data imported?	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	Obtain screen captures as needed
Reprocessing	Conduct reprocessing	Did you find any errors?	Pass□ Fail□ Not applicable□	Pass□ Fail□ Not applicable□	
Deletion of data	Data for verification	Delete working data placed in locations* that are inaccessible to the system.	Implemented□ Not implemented□	Pass□ Fail□	* If you worked on a desktop, it needs to be deleted.
Signature	Effective Date (MMM/DD/YYYY)				
	Signature of the implementer				