WHITE PAPER

Data storage and preservation

Preserving data from retired systems

Introduction

The system development life cycle, which includes system retirement planning, supports FDA requirements for GxP system validation. Instruments are taken out of service due to migration of use to a new technology or due to retirement of the system by the manufacturer. The legacy data generated by that platform still need to be managed for years, decades, or perhaps indefinitely. Access to the original data and audit trails is required if requested for audit. This becomes a challenge when the data are stored in a proprietary format and can be viewed only by the application software that comes with the instrument, since the software may run on an old, unsupported operating system and hardware.

This white paper evaluates the more frequent strategies taken by organizations to address the challenge of managing data from legacy instruments and how well these approaches support the ALCOA+ principles for data integrity that are currently used by the FDA, MHRA, WHO, and GAMP™ 5 guide [1,2]. The ALCOA+ principles describe data that are attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available [3,4]. Careful consideration of data management strategies is needed to support the ALCOA+ principles.

Printing files

The MHRA data integrity guidelines advise that printing the results or reports does not remove the need for appropriate data integrity controls. Inspectors wanting to see the original file may want to see the original digital data. Under the narrow interpretation of 21 CFR Part 11, the FDA has established that if the business relies on the electronic record to perform regulated activities, the original data must be retained—the printed version of the data is not the original and does not eliminate the need to retain and secure the original data. The printout of the original data will not preclude the need for compliance with the electronic record regulation [5].

Data export

Software systems that control instruments often allow for the export of the data to formats, such as text or PDF, that can be viewed by readily available tools. However, the export process may be laborious and there are concerns about how this strategy complies with the ALCOA+ guidelines. The transformation of the data to a simpler format may result in the loss of metadata associated with the original files so that they are no longer complete. The export location may no longer be under the control of any audit-tracking functionality built into the system software, making data integrity questionable.

Virtualization

Virtualization of the instrument systems allows users to emulate the working environment for access to the original data and allows the application software to be migrated off old, unsupported hardware. Managing the virtual images for long-term data preservation has two further considerations. First, large image files may become corrupted, resulting in the loss of all information. Therefore, they should be maintained in a proactive way to test for data integrity on a regular basis and allow for recovery in case of corruption. Second, as software and hardware to view virtual images evolve, the images created today may not be compatible with the viewing software of the future. To help prevent this scenario, the image files need to be managed and updated as new versions of the virtualization software are released [6]. Audit trails of any updates to the images need to be recorded to ensure traceability back to the original data.

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Data backup

Data backup is traditionally used to provide a recovery strategy for business-critical data. It is not intended to be used as a long-term preservation tool for scientific data. In many cases, backup snapshots are stored for a limited time, although some organizations may implement a process whereby one annual backup is retained indefinitely. In terms of ALCOA+ guidelines, this strategy does not ensure data integrity. Upon detection of data corruption by inspectors, the IT department of an institution will need to restore the data from the backup data. This is not a quick procedure, so a response to the inspectors may be delayed. There is also no guarantee that an uncorrupted version of the data can be retrieved. Proactive testing of data integrity is required to provide robust support of the ALCOA+ guidelines. Maintaining traceability of backups is also a challenge, since the process does not embed the audit trail within the backup.

Scientific data management system (SDMS) and data normalization

Archiving data in normalized XML-based format provides the ability to retrieve original raw data or converted files, allowing prompt response to requests from colleagues, regulatory agencies, or legal bodies. Some SDMS solutions, such as Thermo Scientific™ Data Manager™ Software [7], provide file converters to allow transformation to an XML-based format and will generate the necessary audit trails to support compliance with ALCOA+ guidelines. An SDMS is a good option for data from systems where file converters are available and the SDMS solution has been designed with the specific technologies in mind.

When no file converters are available, or the SDMS solution is not designed for the particular system that is being retired, an alternative strategy is needed since the original application software is required to access the original data. We recommend the following steps to provide support for the ALCOA+ data integrity guidelines and GxP regulations.

- Virtualization of the application server or computer
- Management of the virtual images within a data preservation software solution to provide proactive and frequent data integrity checks
- User acceptance testing (UAT) documentation detailing the data migration process to support GxP compliance
- Professional services to provide necessary updates to ensure compatibility with future versions of virtual image viewing software
- Creation of regular electronic audit trails, allowing for prompt response to regulatory bodies
- Duplication of the archive for disaster recovery

Data preservation service

At Thermo Fisher Scientific, we have adopted these principles to develop a new service for the long-term management of data from retired instruments. Our engineers will perform a full audit of the original system and migrate the application software and data to a structured archive. Data, audit files, and supporting information can then be accessed in accordance with data integrity and compliance requirements.

Key benefits

- Full access to the original application software and data
- Long-term safeguarding and security of data
- Support from on-call and onsite service professionals

For more information on this service, please contact **professionalservices@thermofisher.com**.

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