ISPE GAMP

GAMP Good Practice Guide:

Electronic Data Archiving

Preface to the GAMP Good Practice Guide: Electronic Data Archiving

This document, the GAMP® Good Practice Guide for Electronic Data Archiving is intended as a supplement to the Guide to Validation of Automated Systems (GAMP Guide). It is recommended that this Guide be read in conjunction with the main GAMP Guide and the ISPE/GAMP® Good Practice Guide for Electronic Records and Signatures.

It seeks to provide a rational and scaleable approach to electronic data archiving through the development of an archiving strategy. The implementation of this strategy should help organizations to achieve and maintain regulatory compliance, and to more effectively manage electronic records over the long term."

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All used sources are acknowledged and in particular those named in Appendices A, C, and J. Appendix B is based on the Open Archival Information System (OAIS) reference model as provided by Consultative Committee for Space Data Systems (CCSDS).

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1 Introduction

1.1 Overview

The subject of Electronic Data Archiving (EDA) is both large and complex, and one that is rapidly expanding and evolving.

Regulators are increasingly favoring the submission of information in electronic form. The cost of a failed inspection can be substantial, and an EDA mechanism is an important tool in ensuring continued compliance. This, together with the increasing use of computers and electronic data, has resulted in the need for compliant solutions for electronic data archiving.

In August 2003, the FDA issued a guidance document named "Part 11, Electronic Records; Electronic Signatures – Scope and Application." This document contains brief guidance on record retention, reminding readers of the requirement to retain accessibility to records throughout the retention period and allowing the archiving onto non-electronic media, as long as predicate rules are met and the content and meaning of the record is preserved. At the same time, the PIC/S issued its guidance "Good Practices for Computerised Systems in Regulated GxP Environments," which also reminded readers of the requirements to retain records in accessible form, and stressed the media independence of regulatory responsibilities with regard to records and record retention.

At the time of publication, it is generally accepted that there are no commercial off-the-shelf solutions that can comprehensively meet all the demands of the regulated life science sector, and meet security and confidentially criteria over a number of software and technology platform upgrades and changes. Although such commercial solutions are in development, it is unlikely that future archiving needs can be fully addressed using off-the-shelf offerings.

The challenge is to plan and implement changes to processes and systems to enable compliant solutions to the regulatory requirements.

1.2 Purpose

This Guide is intended as a supplement to the main GAMP® Guide, which provides an introduction to record retention, archiving, and retrieval. It has been developed in accordance with the version of the main GAMP® Guide current at time of publication, but every effort has been made to align with planned revisions of that document. It is recommended that this Guide is read in conjunction with the main GAMP® Guide and the ISPE/GAMP® Good Practice Guide for Electronic Records and Signatures, which provide additional relevant information.

It seeks to provide a rational and scaleable approach to electronic data archiving through the development of an archiving strategy. The implementation of this strategy should help organizations to achieve and maintain regulatory compliance, and to more effectively manage electronic records over the long term.

More specifically, this Guide:

- Provides an introduction to the complex subject of electronic data archiving, recognizing the differences from the traditional paper archive
- Provides a process for creating and implementing an archiving strategy
- Highlights considerations in determining an archiving strategy, at an organizational, technical, and regulatory level

- Identifies those aspects of technology that have an impact on the selection of an archive solution, which are independent of specific technical solutions

The intended audience for this Guide consists of those individuals who:

- Need to archive electronic records (particularly regulated records)
- Have accountability for stored electronic records, including the Archivist or Archive Administrator, and those with management responsibility for providing records to both regulators and business users
- Need to access archived electronic records
- Are tasked with implementing an electronic archive (this includes IS/IT specialists and suppliers) and are responsible for the funding of the electronic archive

Therefore, the audience for this Guide will include individuals from many disciplines, as well as IS/IT specialists.

1.3 Scope

This Guide addresses the processes and issues around the long term preservation of electronic data. These include:

- Transfer of data from a live, on-line system to electronic archive storage
- Retrieval of data from archive
- Deletion of data
- Maintenance of an electronic archive system as it approaches obsolescence

Current GxP regulations related to archiving have been taken into account in developing this Guide. The Guide addresses management, planning, development, operational, and compliance issues. Good systems management and other matters covered by the main GAMP Guide are excluded.

The Guide does not cover the digitizing of paper records and the operation of a conventional paper archive. General rules about archiving and the role of the traditional Archivist also have been excluded since these are well-established concepts. Specific technical solutions and research material and concepts are not covered.

E-Mail

While the principles outlined in this document may apply to the retention of email records, their use and retention has not been specifically covered. Some of the issues relating to emails include:

- What constitutes appropriate use of email?
- When should email be considered a business record?
- Difficulties associated with retention of encoded electronic signatures and metadata

It is considered that reliance on emails as records exclusively for GxP purposes is now, and likely to remain, limited. Other regulatory requirements (e.g., Data Protection, Sarbanes-Oxley, Stock Market regulations) which go beyond the scope of GxP and differ from jurisdiction to jurisdiction, apply to email communications and should be taken

into account when considering the retention, destruction, copying, and forwarding of email communications. Therefore, comprehensive guidance in this matter is beyond the scope of this Guide. Regulated companies developing archives of such data should take specific and explicit legal advice concerning the management of those archives.

Web Sites

Given their special nature, Web sites are out of scope. The archiving and preservation of Web sites is difficult, as these often are dynamic in nature and do not have a final form. They are often temporary and they may contain links to other Web sites that are similarly temporary.

Data Warehouses

Data warehouses that are used for data mining purposes, and often contain copies of data held in archives, are not discussed in detail in this Guide, as their main purpose is commercial and their use often is not regulated. However, some of the issues surrounding data warehouses are covered in Appendix D of this Guide.

1.4 Benefits

This Guide aims to assist in the efficient, effective, and compliant development and implementation of electronic data archiving.

Particular benefits of such an implementation include:

- An enhancement of the asset management and retention of Intellectual Property, which represent a significant financial resource to the organization
- Improved business processes through the use of effective data access, enabling data and information reuse. These may assist in shortening the time-to-market for new products.
- Improved regulatory and legal compliance through enhanced search and retrieval facilities, traceability, integrity, and security of records
- Streamlined business processes for the retention of records and their maintenance, based on the use of automated processes
- Reduced business risk through the controlled use of advanced electronic tools for the safe-keeping of records

1.5 Objectives for this Guide

Methods by which electronic data archiving is conducted should be practical and efficient, in addition to meeting regulatory compliance expectations.

To this end, the following objectives applied to the development of this Guide:

- Provide a common understanding and awareness of the issues surrounding electronic data archiving
- Establish the principles of good electronic data archiving practice, supported within the framework of the main GAMP® Guide