

1. PURPOSE

Retirement of computer systems must be carefully planned and implemented. Most important is to ensure that data created and/or processed on the system are readily available on new systems in a form required by regulations and business standards.

2. SCOPE

Retirement of all computer systems used in a regulated environment. The SOP covers all retirement activities from planning and implementation to documentation. The procedure applies to systems with and without stored data that need to be reused. Sometimes the term system retirement is interchangeably used with decommissioning. In this context the SOP also applies to decommissioning of computer systems.

3. GLOSSARY/DEFINITIONS

Item	Explanation
System Retirement	Process to take a computer system out of service and to make sure that data created and/or processed on the system can be reused in a form as required by regulations and internal standards.
Decommissioning	In the context of a computer system decommissioning is interchangeably used with system retirement.

Note: For other definitions, see www.labcompliance.com/glossary.

4. REFERENCE DOCUMENTS

- 4.1. GAMP 4 Guide: "Validation of Automated Systems", ISPE, Brussels, 2001.
Order from www.ispe.org.

6. FREQUENCY OF USE

6.1. When computer systems are retired.

7. RETIREMENT PRINCIPLES

Computer systems create and process lots of data. Data are intermediately stored on the system itself and archived on external storage media when not regularly used. The archival period is dictated by regulations and business reasons and typically defined in company policies. Time frame can range from several years to several decades.

During the archival period data should be maintained such that they can be reused when needed for compliance or business reasons. Usability of data may require migration of data for compatibility to new revisions of application software. When the system is retired data should be able to be reused on new systems. This is relatively easy if all application software on new systems come from the same vendors. Problems can arise with different software from different vendors. In this case compatibility of data from the old systems should be verified. Therefore retirement of computer systems is not only simple decommissioning as known for more simple equipment but also includes the process for migrating to the new system.

8. PROCEDURE

8.1. The system owner develops a retirement plan and initiates a retirement process using the form in Attachment 9.1.

Special consideration should be given to the question whether critical quality and/or compliance data have been processed on the system and if these data need to be reused after retirement of the system.

8.2. QA, IT, Operations and Documentation Departments review and approve the retirement request.

8.3. The system owner collects and reviews all system documentation that may be necessary to demonstrate compliance of the system during the entire record retention period. Use the form in Attachment 9.2.

8.4. If data do not need to be reprocessed after retirement proceed to 8.14.