

SOP SAM-001: Network Maintenance Guidelines (Sample SOP)

TITLE	Network Maintenance Guidelines (Sample SOP*)
DEPARTMENT	Information Technology
NUMBER	SOP-SAM-001
REVISION	001
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* - NOTE: This is not an effective SOP presently in use by any company; this is a sample of Mike Brannon's SOP writing.

APPROVAL SIGNATURES:

Author	(Not applicable in a sample SOP)
Department Director	(Not applicable in a sample SOP)
Quality Assurance Director	(Not applicable in a sample SOP)

1. PURPOSE

- A. This procedure describes a methodology for Configuration management for a Computerized System.

2. SCOPE

- A. This Standard Operating Procedure applies to all company Computerized Systems, both existing and to be implemented in the future, that will be used to create, modify, maintain, archive, retrieve, or transmit clinical data intended for submission to the FDA, and/or produce records that may be subject to an FDA inspection.

3. RESPONSIBILITY

- A. Information Technology Department – Responsible for the Configuration management and maintenance of the physical network of Computerized Systems.

4. CROSS-REFERENCES

- A. SOP-SAM-002: Inventory of Computerized Systems
- B. SOP-SAM-003: System Change Control

5. ACRONYMS

- A. IT – Information Technology
- B. N/A or n/a – Not applicable
- C. SOP – Standard Operating Procedure

6. DEFINITIONS

- A. Computerized System – Computer hardware, software, and associated documented (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of pre-clinical, clinical, safety trial, etc.
- B. Configuration – The components (e.g., hardware, software, and associated documents) of a Computerized System.
- C. Systems Administrator – Person that is charged with the overall administration and operation of a computer system.

7. PROCEDURE

A. Recordkeeping

- 1. A network binder or electronic equivalent will be established to store all pertinent network information. This binder or electronic equivalent will be stored in the IT Department and can be made available for review as necessary.

B. Establish Baseline

- 1. A System Administrator, in association with the IT Director, or the appropriate designee, will establish a baseline physical network map to guide the schema of the company's internal and external networks.
 - i. The physical network map will detail all internal access points as well as external internet access points to any company facility network.
 - ii. The physical network map will detail all equipment necessary to establish a working network for the facility.
 - iii. The physical network map will detail any redundancies or points of failure in the system.
 - iv. The physical network map will be stored in the network binder or an electronic equivalent.
 - v. Any changes to the baseline network will require the network map to be updated to reflect the current full network.
- 2. The complete physical network map will be used to detail a physical network inventory with detailed information on all components of the functional network. This will include external data networks, routers switches, hubs, firewalls or any other appliance that is not an endpoint on the network. All noted physical hardware will be inventoried on the company's Computerized System manifest and will contain, at minimum, the vendor name, version, release, and model number as outlined in SOP-SAM-002.

C. Changes to Baseline

- 1. A System Administrator or a designee will record changes to baseline network, configuration, or equipment via change control as defined in SOP-SAM-003: System

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Change Control. All change controls for the network system will be stored in the network binder or electronic equivalent. Changes may include the following:

- i. Identification (vendor name and model/version/release number) of new or changed element of hardware, peripheral equipment, software, or supporting documentation.
 - ii. Identification of component being replaced (vendor name and model/version/release number).
 - iii. Reason for addition or replacement.
 - iv. Reference to testing protocol/plan where documented evidence was generated to confirm proper operation of the new/released component.
 - v. Effective date of the implementation of the new or changed component.
2. During the change control process, if a change can effectively impact the primary business of the company or any agreement in place the IT Director may require further testing or verification prior to deployment.
 3. After any change to the network, the physical network map and the physical network inventory will be updated.

D. Review

1. The physical network map and the physical network inventory will be reviewed, at minimum, annually by the IT Director and the System Administrators. Any variations will be verified and recorded in the network binder.

8. ATTACHMENTS

1. None

9. REVISION HISTORY

REVISION	EFFECTIVE DATE	AUTHOR	TITLE	REVISION DESCRIPTION
001	April 15, 2011	M. Brannon	Validation Lead	Original –Writing Sample, not for use, distribution or publication.