



Information Technology Support Service

Level II

Learning Guide 35

Unit of Implement Maintenance

Competence: Procedure

Module Title: Implementing Maintenance

Procedure

LG Code: ICT ITS2 LO3-LG-35

TTLM Code: ICT ITS2 MO2 TTLM 1019v1

LO 3: Identify and analyze IT system components to be maintained

Instruction Sheet

Learning Guide #35

This learning guide is developed to provide you the necessary information regarding the following content coverage and topics –

- Identifying Equipment and software to be maintained and implemented
- Identifying Vendor documentation, peer organizations or research information
- Obtaining user Requirements
- Documenting maintenance procedure

This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, upon completion of this Learning Guide, you will be able to –

- Identify Equipment and software to be maintained and implemented processes to ensure future acquisitions of equipment and software.
- Identify Vendor documentation, peer organizations or research information detailing best practices in equipment and software maintenance to improve system performance and reliability.
- Obtain Requirements from user in the area of equipment maintenance and reliability.
- Document Procedures for maintenance based upon best practices.

Learning Activities

- 1. Read the specific objectives of this Learning Guide.
- 2. Follow the instructions described below 3 to 6.
- 3. Read the information written in the information "Sheet 1, Sheet 2, Sheet 3 and Sheet 4," in page -3,4, 5,6,7,10,11,13,15 and 17 respectively.
- 4. Accomplish the "Self-check 1, Self-check 2, and Self-check-3, Self-check and Self-check-4 in page 8,12, 14,16 respectively

Information sheet-1 Determining and documenting Warranty Status

1.1. Documenting Warranty Status

- General: Legally binding assurance (which may or may not be in writing) that a good or service is, among other things, fit for use as represented, free from defective material and workmanship, meets statutory and/or other specifications. A warranty describes the conditions under, and period during, which the producer or vendor will repair, replace, or other compensate for, the defective item without cost to the buyer or user. Often it also delineates the rights and obligations of both parties in case of a claim or dispute.
- Contracting: Expressed or implied undertaking that a certain fact regarding the subject matter of a contract is, or will be, true.
 Unlike conditions (the central points), warranties are deemed incidental points, and a breach of warranty is usually not a valid reason for voiding a contract but it entitles the aggrieved party to damages. See also in nominate term and intermediate term.
- insurance: Written pledge by the insured party that a specified condition exists or does not

exist. Breach of warranty entitles the insurer to treat the insurance contract as void even if the actual loss is unaffected by the breach. See also representation.

ICT equipment companies guarantees that all the products undergo backbreaking quality control testing before delivery and installation. In the event that any product of these manufacturers is found to be defective, the company will provide service for product repair and/or component replacement as may be necessary within the warranty period as per the terms mentioned here under.

Ref.

Read more: http://www.businessdictionary.com/definition/warranty.html

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Self-Check 1	Written Test
News	D
Name:	Date:

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

Please ask your trainer the answer key for this Self-Check.

- I. Write True if the statement is Correct and False if the statement is Incorrect
 - 1. A warranty describes the conditions under, and period during, which the producer or vendor will repair or replace defective item without cost to the buyer or user.
 - 2. ICT equipment companies guarantees that all the products undergo backbreaking quality control testing before delivery and installation.
 - 3. pledge by the insured party that a specified condition exists or does not exist

Note: Satisfactory rating - 3 points, Unsatisfactory - below 3 points

You can ask you teacher for the answer key

2.1. Architecture overview

Give general description of the system, from the point of the user:

- In what environment it works (home, near patient bed, operating rooms....)
- Who the users are
- · What it is for
- The main functions
- The main interfaces, input and outputs

If your soft ware is integrated in a large system, you may reference a document that describes this system.

✓ Physical architecture overview

Describe the hardware components on which software runs and their interactions/relationships

Use components diagrams, deployment diagrams, network diagrams, interface diagrams...

√ Hardware Component description

Describe the content of each hardware component in the architecture

- Its identification
- The purpose of the component
- The software component it receives
- Its technical characteristics: type of machine, CPU, RAM, disk and so on.
- Its network hardware interfaces

✓ Logical architecture overview

- Describe the top level software components and their interactions/relationships.
- Use UML package diagrams and/or layer diagrams and/or interface diagrams.
- Describe also the operating systems on which the software runs.

√ Software Component description

Describe the content of each top-level software component in the architecture

The description should contain:

- Its identification
- the purpose of the component,
- Its interfaces with other components,

- Its network interfaces,

The hardware resources it uses, for example: average RAM usage, peak RAM usage and peak frequency and duration, disk space for permanent data, disk space for cache data, average CPU usage, peak CPU usage and peak frequency and duration ...

Software SOUP

If you use SOUP (Software Of Unknown Provenance), list them here.

For each SOUP, describe:

- Its identification and version
- Its purpose
- Where it comes from: manufacturer, vendor, university ...
- Whether it is maintained by a third party or not

If this is an executable,

- What are the hardware / software resources it uses
- Whether it is insulated in the architecture and why
- Its interfaces and data flows
- Which SOUP functions the software uses
- How the SOUP is integrated in the software
- What hardware/software resources it requires for proper use

Note: have a look at FDA Guidance « Off-The-Shelf Software Use in Medical Devices » to determine if you need specific or special documentation for your COTS.

If there is a list of known bugs on your COTS, you may add here this list with a review of their consequences in terms of software failure and patient safety. If there are concerns about known bugs, they should be treated by the risk analysis process.

2.1. Dynamic behavior of architecture

The architecture was designed to answer to functional requirements.

For each main function of the system, add a description of the sequences / data flow that occur.

Use sequence diagrams, collaboration diagrams

Workflow / Sequence 1

Describe here the workflow / sequence of a main function

For example, the user queries data, what happens, from his terminal to the database.

Workflow / Sequence 2

Repeat the patern for each main function of the system

2.2. System architecture capabilities

Describe here the rationale of the hardware / software architecture in terms of capabilities:

- Performances (for example response time, user mobility, data storage, or any functional performance which has an impact on architecture)
- User / patient safety
- Protection against misuse
- Maintenance (cold maintenance or hot maintenance),
- Adaptability, flexibility
- Scalability, availability
- Backup and restore
- Hardware and Software security: fault tolerance, redundancy, emergency stop, recovery after crash ...
- Administration,
- Monitoring, audit
- Internationalization

2.3. Network architecture capabilities

If the medical device uses/has a network, describe here the rationale of the hardware / network architecture:

- Bandwidth
- Network failures
- Loss of data
- Inconsistent data
- Inconsistent timing of data
- Cyber security (see FDA Guidance on Cyber Security of networked medical devices)

Risk analysis outputs

If the results of risk analysis have an impact on the architecture, describe here for each risk analysis output what has been done to mitigate the risk in the architecture.

Use diagrams if necessary, like architecture before risk mitigation and architecture after risk mitigation, to explain the choices.

Human factors engineering outputs

If the results of human factors analysis have an impact on the architecture, describe here for each risk human factors output what has been done to mitigate the risk in the architecture.

Ref.

http://www.ibm.com/ibm/environment/news/epro.shtml. 10 IBM Corporate Responsibility Report 2006. http://www.ibm.com/ibm/responsibility/pdfs/IBM_CorpResp_2006.pdf.

Self-Check 2	Written Test	
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Name:		Date:
Instruction: Answer al	I the questions listed below	v, if you have some clarifications- feel
free to ask	c your teacher.	

Please ask your trainer the answer key for this Self-Check.

- I. Write True if the statement is Correct and False if the statement is Incorrect
 - 1. Physical architecture describe the hardware components on which software runs and their interactions/relationships
 - 2. Software Component description Describe the content of each top-level software component in the architecture
 - 3. Logical architecture overview Describe the hardware components and their interactions/relationships
 - 4. Physical architecture overview Describe the top level software components on which software runs and their interactions/relationships

Note: Satisfactory rating - 3 points, Unsatisfactory - below 3 points

You can ask you teacher for the answer key

Information sheet-3	Identifying	critical	components	and/or	software	and
	documenting recommendations					

3.1. Definition of Critical Components

<u>Critical Components</u> means a component or system of components that, due to their importance in the continued proper operation of the device, have been designated by the manufacturer as requiring special fabrication, maintenance, inspection or operation. To document recommendations first of all we must identify the critical components and soft ware from the followings.

Computer hardware

This is the physical technology that works with information. Hardware can be as small as a <u>smart phone</u> that fits in a pocket or as large as a <u>supercomputer</u> that fills a building. Hardware also includes the <u>peripheral devices</u> that work with computers, such as keyboards, external disk drives, and routers. With the rise of the Internet of things, in which anything from home appliances to cars to clothes will be able to receive and transmit data, sensors that interact with computers are permeating the human environment.

• Computer software

The hardware needs to know what to do, and that is the role of <u>software</u>. Software can be divided into two types: system software and application software. The primary piece of system software is the <u>operating system</u>, such as <u>Windows</u> or iOS, which manages the hardware's operation. Application software is designed for specific tasks, such as handling a spreadsheet, creating a document, or designing a <u>Web</u> page.

Telecommunications

This component connects the hardware together to form a network. Connections can be through wires, such as Ethernet cables or <u>fiber optics</u>, or wireless, such as through <u>Wi-Fi</u>. A network can be designed to tie together computers in a specific area, such as an office or a school, through a local area network (LAN). If computers are more dispersed, the network is called a wide area network (WAN). The <u>Internet</u> itself can be considered a network of network

Ref.

http://www.ibm.com/ibm/environment/news/epro.shtml. 10 IBM Corporate Responsibility Report 2006. http://www.ibm.com/ibm/responsibility/pdfs/IBM_CorpResp_2006.pdf.

Self-Check 3	Written Test
Name:	Date:

Instruction: Answer all the questions listed below, if you have some clarifications- feel free to ask your teacher.

Please ask your trainer the answer key for this Self-Check.

- I. Write True if the statement is Correct and False if the statement is Incorrect
 - Telecommunication component connects the hardware together to form a network
 - 2. Hardware includes the <u>peripheral devices</u> that work with computers.
 - 3. If computers are more dispersed, the network is called a wide area network LAN
 - 4. Critical Components means a component or system of components that their importance is low

Note: Satisfactory rating - 3 points, Unsatisfactory - below 3 points

You can ask you teacher for the answer key