

Servicing clinical computing equipment

Overview

This standard identifies the competencies you need to carry out servicing activities on clinical computing equipment, in accordance with approved procedures. You will be required to service a range of clinical computing equipment including computerised medical devices, medical devices connected to computers, computers which host medical device software and associated equipment. This will involve dismantling, removing and replacing faulty items, at component or unit level.

You will be expected to apply a range of dismantling and reassembly methods and techniques. You will also demonstrate knowledge of installing and upgrading software packages and perform data back-ups. Computer security is paramount and an understanding of antivirus software, and any other measure that are in place to ensure the computer systems are secure and robust, needs to be demonstrated. This will include electrical, electronic and mechanical units and components, media storage drives, removable storage mediums, magnetic tape, computer infra-structure systems and internet / intranet network security.

Your responsibilities will require you to comply with organisational policy and procedures for the servicing activities undertaken, and to report any problems with the activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people. You must ensure that all tools, equipment and materials used in the servicing activities are removed from the work area on completion of the activities, and that all necessary job/task documentation is completed accurately and legibly. You will be expected to work with a minimum of supervision, taking personal responsibility for your own actions, and for the quality and accuracy of the work that you carry out.

Your underpinning knowledge will provide a good understanding of your work, and will provide an informed approach to applying the correct servicing procedures. You will understand the dismantling and reassembly methods and procedures used, and their application. You will know about the computer equipment being worked on, and component properties, functions and associated defects, in adequate depth to provide a sound basis for carrying out the servicing activities, correcting faults and ensuring that the serviced equipment functions to the required specification and remains compliant with all standards and regulations.

You will understand the safety precautions required when carrying out the servicing activities, especially those for isolating the equipment. You will also understand your responsibilities for safety, and the importance of taking the necessary safeguards to protect yourself and others in the workplace.

Performance criteria

You must be able to:

1. work safely at all times, complying with health and safety legislation and other relevant regulations, directives and guidelines
2. follow the relevant servicing schedules to carry out the required work
3. carry out the servicing activities within the limits of your personal authority
4. carry out the servicing activities in the specified sequence and in an agreed timescale
5. report any instances where the servicing activities cannot be fully met or where there are identified defects outside the planned schedule
6. complete and store all relevant servicing documentation in accordance with organisational requirements
7. dispose of waste materials in accordance with safe working practices and approved procedures and leave the work area in a safe condition

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Knowledge and understanding

You need to know and understand:

1. the health and safety, infection control and de-contamination requirements of the work area and equipment being serviced, and the responsibility these requirements place on you
2. the statutory and advisory documentation relating to clinical equipment (such as warnings and guidance from the MHRA or other regulatory authority standards)
3. the importance of reporting any equipment adverse incidents to the regulatory authority
4. the overall organisation of components within a general computer system
5. how computers store and process data
6. what a "Server" is and how this interfaces with other terminals or computers on a network
7. a "Virtual Computer" and its operation
8. how to ensure that essential IT equipment can be relied upon and the measures put in place to ensure a single fault doesn't compromise the operation of the system
9. the boot-up sequence from power on to the boot loader handing over to the operating system
10. the function of hard drives and the terms "RAID" and "SAN"
11. the design of physical network equipment and how signals propagate in wired and wireless systems
12. the installation standards of a wired IT network system
13. three different ways that data can be transmitted
14. the design of physical network equipment and how signals propagate in wired and wireless systems
15. the installation standards of a wired IT network system
16. what are TCP and IP and explain the function and usage of different types of protocols
17. the following components and their functions (such as: UPS, interface controller/network interface card, repeater, router)
18. the operation of the common types of malicious code such as: Trojan, Logic Bomb, Worm, Spyware and how to remove malicious code
19. the purpose and operation of a "Firewall"
20. the role of the "Operating System" and compare the differences between the major off the shelf systems that are commonly available
21. how systems are backed up and how these back-ups are managed, to include data backup, archive, disk imaging and disaster recovery policies and procedures
22. the concept of a "Relational Database"

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23. the isolation procedure that applies to the servicing activities (such as electrical isolation, removal of fuses, placing of maintenance warning notices)
24. what constitutes a hazardous voltage and how to recognise victims of electric shock
25. how to reduce the risks of a phase to earth shock (such as insulated tools, rubber matting and isolating transformers)
26. the importance of wearing protective clothing and other appropriate safety equipment (PPE) during the servicing activities
27. how to obtain and interpret documents needed in the servicing activities (such as drawings, circuit and physical layouts, charts, specifications, manufacturers' manuals, history/maintenance reports)
28. the working practices of, and the need to respect, the hospital ward and/or patient environment
29. hazards associated with carrying out servicing activities on clinical computer equipment and how to minimise them and reduce any risks
30. the difference between standard hospital computers and ones that are connected to medical devices or computers which host medical device software and computerised medical devices
31. what controls must be put in place when connecting medical and non-medical equipment together
32. the role of the MHRA and the controls required for medical device hardware and software developed "in house"
33. why components within a CE marked medical device should be replaced with like for like components
34. the specific function of each component in a typical computer
35. how internal components communicate with external peripherals
36. common computer ports and the types of peripherals that attach to them
37. the electrostatic (ESD) precautions that must be taken when handling semiconductor, components or circuit boards
38. the different data storage mediums available and how they function
39. network equipment and how signals are propagated in wired and wireless systems using different protocols
40. the cable type and connectors used in a network system
41. security considerations associated with hardware installations
42. how malicious software can access a computer and what is in place to limit this
43. virus protection software and how it is updated and validated to work with medical software packages
44. how passwords are used to protect data, computer systems and personal information
45. how software is installed onto a clinical computer
46. the difference between operating systems, applications and data and why it is desirable to keep them separate
47. how systems are backed up and how these back-ups are managed,

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- to include data backup, archive, disk imaging and disaster recovery policies and procedures
- 48. what medical data transmission protocols exist and typical applications that use them
- 49. the generation of documentation and/or reports following the servicing activity
- 50. the equipment operating and control procedures to be applied during the servicing activity
- 51. the problems that can occur during the servicing activity, and how they can be overcome
- 52. the organisational procedure(s) to be adopted for the safe disposal of waste of all types of material
- 53. the extent of your own authority and to whom you should report if you have a problem that you cannot resolve

Scope/range

1. Carry out all of the following servicing activities:
 1. plan and communicate the servicing activities so as to minimise disruption to normal working
 2. obtain and use the correct issue of organisational and/or manufacturers' drawings and servicing documentation
 3. adhere to procedures or systems in place for risk assessment, COSHH, personal protective equipment and other relevant safety regulations and procedures to realise a safe system of work
 4. ensure that the correct equipment decontamination procedure has been adhered to before and after the servicing activities
 5. ensure the safe isolation of equipment (such as electricity, mechanical, gas, air or fluids)
 6. provide and maintain safe access and working arrangements for the servicing area
 7. carry out the servicing activities, using appropriate techniques and procedures
 8. return the equipment to service on completion of the activities
 9. dispose of waste materials in accordance with safe working practices and approved procedures. and leave the work area in a safe condition
 10. work within the criteria, procedures and SOP identified in the ISO9001 quality management system
2. Carry out servicing activities on all of the following clinical computing equipment:
 1. computerised medical devices
 2. networking systems
 3. computing peripherals
3. Carry out all of the following servicing activities on clinical equipment as applicable to the equipment being serviced:
 1. isolate the equipment
 2. replace appropriate 'lived' items
 3. carry out electrical safety tests
 4. check components for serviceability
 5. dismantle equipment to the appropriate level
 6. disconnect and reconnect wires and cables
 7. attach suitable cable identification markers
 8. remove and replace electrical units/components
 9. remove and replace mechanical units/components

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10. replace damaged/defective components
 11. set and adjusting replaced components
 12. make visual checks before powering up
 13. check equipment operating parameters
 14. functionally test the serviced equipment
 15. install and configure software
 16. install and configure hardware
 17. carry out data back-ups
 18. upgrade software in accordance with suppliers instructions
 19. apply electrostatic discharge (ESD) precautions
 20. fault find on IT computing systems and networks
 21. de bug software faults
 22. interface computing systems
4. Remove and replace / install / configure a range of components and software to include fifteen of the following:
1. power supply
 2. motherboard
 3. memory
 4. hard drive
 5. CD/DVD
 6. battery
 7. connectors
 8. cables
 9. keyboard
 10. mouse
 11. visual display unit
 12. printer
 13. uninterruptable power supply
 14. BIOS
 15. upgrade software
 16. anti-virus software
 17. fans / cooling system
 18. security (malicious software)
 19. network card
 20. servers
 21. KVM switch
 22. back-up drives
 23. operating systems
5. Carry out the servicing activities within an agreed timescale, for all of the following requirements:
1. organisational guidelines, codes of practice and local rules
 2. equipment manufacturers operation range
 3. relevant and current Trust, suppliers, MHRA and QMS documentation
 4. the equipment functions to specification

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5. the equipment remains compliant with all standards and regulations
 6. in accordance with BSEN standards and the equipment's CE marking
 7. data protection, information governance and patient confidentiality
 8. medical device status, compliance and integrity is maintained
6. Complete and store all relevant servicing documentation in accordance with organisational requirements, using one of the following:
1. job cards/PPM update
 2. medical equipment log book
 3. software registration
 4. organisational-specific documentation
 5. electronic reports

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