SEMEM361

Testing medical equipment

Overview

This standard identifies the competences you need to carry out inspections and tests on medical equipment, in accordance with approved procedures. You will be required to carry out tests on a range of medical equipment, such as cardiovascular equipment, physiological monitoring and infusion equipment, anaesthetic and ventilation equipment, operating theatre and surgical equipment, medical imaging equipment, laboratory equipment, dental equipment, therapeutic equipment and mechanical/electromechanical Assisted Technology (AT) equipment, to establish that it is functioning at optimal level and to specification.

You will be required to carry out inspections and tests, which will include open and short circuits, resistance, insulation, earth bonding, pulse width/rise time, AC voltage/current levels, frequency, DC voltage/current levels, logic states, and temperature, pressure and flow measurements.

Your responsibilities will require you to comply with organisational policy and procedures for carrying out the testing activities, and to report any problems with these activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people. 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 the procedures for carrying out the required inspections and tests, and will provide an informed approach to applying the necessary test procedures. You will understand the medical equipment being worked on, the test equipment being used, the various testing procedures and their application, in adequate depth to provide a sound basis for carrying out the activities, correcting faults, and ensuring that the equipment operates safely and correctly to the required specification and remains compliant with all standards and regulations. In addition, you will be expected to review the outcome of the tests, compare the results with appropriate specifications, determine the action required, and record/report the results in the appropriate format.

You will understand the safety precautions required when carrying out the inspection and testing activities, especially those for isolating the equipment, and for taking the

necessary safeguards to protect yourself and others against direct and indirect electric shock. You will be required to demonstrate safe working practices throughout, and will understand the responsibility you owe to 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 appropriate procedures for use of tools and equipment to carry out the required tests
3. set up and carry out the tests using the correct procedures and within agreed timescales
4. complete and store all relevant documentation of the test outcome in accordance with organisational requirements
5. review the results and carry out further tests if necessary
6. dispose of waste materials in accordance with safe working practices and approved procedures and leave the work area in a safe condition

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 medical devices (such as warnings and guidance from the regulatory authority, British and European standards)
3. the importance of reporting any equipment adverse incidents to the regulatory authority
4. your responsibilities under regulations relevant to the medical equipment testing activities being undertaken
5. the isolation procedure that applies to the testing activities (such as electrical isolation, removal of fuses, placing of warning notices, proving that isolation has been achieved and secured)
6. the isolation procedure(s) specific to the medical equipment being tested
7. how to recognise and deal with victims of electric shock (to include methods of safely removing the victim from the power source, isolating the power source) including the difference of AC and DC electrical shock and how this affects the victim
8. how to reduce the risks of a phase to earth shock (such as insulated tools, rubber matting, isolating transformers)
9. the specific safety precautions to be taken when carrying out formal inspection, safety and circuit testing of medical equipment
10. the hazards associated with testing medical equipment, and with the equipment that is used, and how to minimise them and reduce any risks
11. the importance of wearing protective clothing, and other appropriate safety equipment (PPE) during the testing activities
12. the importance of keeping the work area clean, tidy and free from waste and surplus materials
13. how the testing activities may affect the work of others, and the procedure for informing them of the work to be carried out
14. the procedures and precautions to be adopted to eliminate/protect against electrostatic discharge (ESD) when working on sensitive equipment or devices

15. how to obtain and interpret the documentation required in the testing activities (such as drawings, flow charts, tables, logic symbols, circuit diagrams, specifications, manufacturers' manuals, test procedures)
16. the basic principles of how the medical equipment functions, its operating sequence, the function/purpose of individual units/components, and how they interact
17. how to determine the most suitable test points within the equipment
18. how to set up the test equipment for the particular tests being carried out
19. how to check that tools and equipment are free from damage or defects, are in a safe and usable condition, and are configured correctly for their intended purpose
20. how to ensure that the test equipment used is within current calibration dates
21. the various testing methods and procedures, and how to apply them to different equipment and operating conditions
22. the importance of carrying out tests in the specified sequence, and what could happen if you do not
23. what may cause errors or discrepancies with the test results, and how to avoid these
24. whom to seek authorisation from if you need to alter or change the test procedures
25. how to record the results of each individual test, the documentation that must be used and personal information
26. how to interpret test results and make valid decisions about the acceptability of the equipment
27. the types and limits of adjustments that can be made to the equipment on completion of the testing activity
28. the procedure to be followed if the equipment fails to meet the test specification
29. the environmental control requirements and organisational operating procedures relating to functional testing
30. the documentation required, and the procedures to be followed, at the conclusion of the test
31. the extent of your own authority and to whom you should report if you have problems that you cannot resolve

Scope/range

1.

Carry out all of the following during the testing activities:

1.1 plan the inspection and testing activities so as to minimise disruption to normal working
1.2 obtain and use the correct issue of organisational and/or manufacturers' drawings and maintenance documentation
1.3 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
1.4 ensure that the correct equipment decontamination procedure has been adhered to before and after testing
1.5 ensure the safe isolation of equipment where necessary
1.6 provide and maintain safe access and working arrangements for the testing area
1.7 carry out the inspection and testing activities using appropriate techniques and procedures
1.8 take electrostatic discharge (ESD) precautions when handling sensitive components and circuit boards
1.9 return the equipment to service on completion of the testing activities
1.10 dispose of waste materials in accordance with safe working practices and approved procedures and leave the work area in a safe condition

2.

Carry out inspections and tests on three of the following types of medical equipment:

2.1 cardiovascular equipment
2.2 medical imaging equipment
2.3 physiological monitoring and infusion equipment
2.4 laboratory equipment
2.5 anaesthetic and ventilation equipment
2.6 dental equipment
2.7 operating theatre and surgical equipment
2.8 therapeutic equipment
2.9 mechanical/electromechanical AT equipment

3.

Carry out tests on medical equipment, using a range of tools and test equipment, to include all of the following:

3.1 electrical safety analyser
3.2 multimeter
3.3 oscilloscope
3.4 medical equipment simulators
3.5 special purpose testing equipment

Plus two more from the following:

6. residual current (RCD) tester
7. oscilloscope
8. ammeter
9. voltmeter
10. logic analyser
11. signal generator
12. temperature measuring devices
13. logic probe
14. insulation resistance tester
15. flow measuring devices
16. built in test equipment (BITE)
17. pressure measuring devices
18. signal tracer

1.

Carry out thirteen of the following tests/measurements:

1.1 functional check
1.2 pulse width/rise time
1.3 performance tests
1.4 continuity check
1.5 heat dissipation
1.6 condition of assemblies and components
1.7 operating range check
1.8 current leakage
1.9 signal noise/interference levels
1.10 logic states
1.11 power output
1.12 gas/fluid leak tests
1.13 DC voltage/current levels
1.14 protective conductor resistance values
1.15 pressure
1.16 AC voltage/current levels
1.17 flow
1.18 clock/timer switching
1.19 soak tests
1.20 temperature
1.21 earth bonding
1.22 safety device trip speed
1.23 `special-to-type' tests
1.24 open/short circuit
1.25 frequency values
1.26 resistance

2.

Carry out all of the following checks to ensure the accuracy and quality of the tests carried out:

2.1 the test equipment is correctly calibrated
2.2 test equipment used is appropriate for the tests being carried out
2.3 ESD precautions and procedures are applied
2.4 test procedures to be used are up to date and follow laid-down procedures such as those given by manufacturer or local regulations
2.5 test equipment is operated within its specified range

3.

Complete and store all relevant documentation of the test outcome in accordance with organisational requirements, using one of the following:

3.1 preventative maintenance log/report
3.2 organisational-specific reporting procedure
3.3 inspection schedule
3.4 specific test report
3.5 electronic reports

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