

SFHCHS202

Acceptance test products, equipment, medical devices and associated systems within healthcare



Overview

This standard relates to the critical examination of equipment, medical devices, products and any associated system in order to acceptance test. This is to ensure equipment, devices or products are safe and suitable for clinical use.

Acceptance tests may be performed by the manufacturer or by specialist health staff. Individuals undertaking this function will liaise closely with any relevant stakeholders to confirm accuracy of information and compliance with relevant legislation

Users of this standard will need to ensure that practice reflects up to date information and policies.

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Performance criteria

You must be able to:

- P1 work within your level of competence, responsibility and accountability
- P2 liaise with key individuals throughout the acceptance test
- P3 apply appropriate health and safety measures, infection prevention and control and personal protective equipment within the acceptance test
- P4 interpret technical and/or scientific data and instructions to select the appropriate acceptance tests and the required measurement parameters, seek advice if this is outside your competence and level of responsibility
- P5 identify standards of output performance which are applicable to the item, product or system under test
- P6 where equipment is used in the acceptance test, confirm that any warning devices, interlocks or safety cut-off mechanisms are activated and that the equipment is fully operational
- P7 set up and perform appropriate acceptance tests according to recommended operational parameters, standards and guidelines
- P8 obtain the results and compare against expected performance, standards and
- P9 where applicable, apply appropriate statistical methods for tabulating and identifying trends in performance parameters within the acceptance test
- P10 report the findings of the acceptance test at required level of detail for the target audience
- P11 maintain full, accurate and legible records of information and store in the correct location in line with current legislation, guidelines, local policies and protocols

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Knowledge and understanding

You need to know and understand:

- K1 your own level of competence, authority and specialist knowledge base
- K2 where, when and how to obtain technical or specialist advice and support for the acceptance test
- K3 the importance of acceptance tests for equipment, systems, products and their associated systems and any new techniques/methodologies prior to introduction into service
- K4 the clinical setting, intended purpose and expected performance parameters of equipment, medical devices, product and/or associated systems
- K5 the range of health and safety measures, infection prevention and control and personal protective equipment, their importance and application within acceptance tests
- K6 the principles, range and purpose of the different types of tests, measurements and assessments relevant to the acceptance test
- K7 how to liaise and consult with key individuals to specify and devise acceptance tests with protocols at the required level of detail, when none exist
- K8 how to obtain the appropriate test equipment and estimate the time taken for each measurement or test procedure
- K9 the characteristics, capabilities, limitations and expected performance parameters for the acceptance test
- K10 the range and operational details of any associated utility requirements for the specific equipment, device, product and/or associated systems required for the acceptance test
- K11 how to obtain data, estimate errors and where appropriate, perform statistical analyses relevant to the acceptance test
- K12 the current national legislation, guidelines, local policies and protocols which affect your work practice
- K13 the policies and guidance that clarify your scope of practice, accountabilities and the working relationship between yourself and others

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Additional Information

External Links

This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: G2 Development and innovation

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Relevant occupations Health, Public Services and Care; Nursing and Subjects and Vocations Allied; Health Professionals; Healthcare and Related Personal Services

Suite Clinical Health Skills

Key words calibrate, evaluate, procurement
