SFHCHS205

Manufacture of equipment or medical devices for individuals within healthcare

Overview

This standard covers the manufacture of customised and/or rehabilitation equipment, medical devices and assistive technology. It relates to working with individual users, their carers and other members of a multi-disciplinary team in the production of prescribed equipment, medical devices and assistive technology.

Manufacture will utilise suitable materials and methods to meet the specification within the prescription. The capacity or social interaction needs of the individual may require a prototype or trial use of the equipment or medical assistive device in the user environment. Equipment and medical devices are initially manufactured to fitting stage; this is to allow a certain amount of adjustment to be made to the fit of the equipment or device for the individual user.

Users of this standard will need to communicate effectively to meet individuals' needs and wishes and work in line with health and safety legislation, policy and practices.

Performance criteria

You must be able to:

P1. identify and agree the roles and responsibilities of yourself and others in manufacturing of equipment or medical devices for individuals within healthcare
P2. provide support to the individual and carers and ensure health and safety measures are implemented at all times
P3. establish consent and access information on manufacturing of equipment or medical devices for individuals within healthcare
P4. liaise and work with relevant stakeholders or agencies involved in the manufacture process
P5. correctly interpret the specification for the manufacture of the rehabilitation or customised equipment, assistive technology or medical device
P6. identify existing manufacturing components for suitability
P7. select the appropriate range of tools and techniques to produce the working/prototype model
P8. select the appropriate materials to meet the prescribed manufacturing specification

P9. determine those aspects of specification which relate to an adaptation of existing equipment and/or device to meet the prescribed customised solution
P10. manufacture and assemble the component parts to specification
P11. monitor environmental conditions and maintain them at the correct levels during the manufacturing process as required by the procedure
P12. incorporate relevant testing, inspection and risk assessment for the operation of equipment and materials within the manufacturing process
P13. monitor the operation of equipment regularly and take appropriate action where faults or breakdowns occur in equipment during use
P14. test the working model or prototype with the individual
P15. make the required adaptations to the working model or prototype within the prescribed specification
P16. confirm that final product meets design specification, prescription and required performance parameters
P17. test the final product with the individual against the prescription and specification and confirm performance within expected parameters and/or make appropriate adjustments
P18. confirm that the product is suitable for the individual's needs and where

appropriate offer the prototype for a trial
P19. compile user information for the product and make arrangements to review the completed product or prototype with the individual and relevant others
P20. dispose of waste in accordance with organisational procedures
P21. Complete all relevant documentation required for manufacturing of equipment or medical devices for individuals within healthcare

Knowledge and understanding

You need to know and understand:

K1. how to access and interpret all relevant work instructions, legislation, guidelines, policies, procedures and protocols needed to manufacture of equipment or medical devices for individuals within healthcare
K2. the scope and limitations of your own competence, responsibilities and accountability as it applies to your job role
K3. specific procedures for reporting issues which are beyond your competence, responsibilities and accountability
K4. how to adapt communication styles in ways which are appropriate to the needs of the individual
K5. the principles, practice and procedures associated with informed consent regarding the manufacture of equipment, medical devices and assistive technology
K6. how to liaise and work with the range of stakeholders, their information needs, roles, responsibilities and capabilities involved in the manufacture of the rehabilitation or customised equipment, assistive technology or medical devices
K7. the importance of and how to ensure that the prescription requirement is integrated in the manufacture of the equipment or medical device
K8. the methods for selection, approval and contracting with external suppliers appropriate to the prescription for the equipment or medical device
K9. the range, extent, format and level of detail required within manufacturing information and how to turn the specification into a manufactured product
K10. why it is important to know how to assess and manage risks within the manufacturing environment and for the item under construction
K11. the principles of manufacturing techniques, electronic and mechanical engineering and/or biomechanics and their application relevant to the component manufacture
K12. the range of design specifications, purpose and application of the range of equipment or medical devices within your work practice
K13. the range and types of tools required for the manufacture process and how to operate these
K14. the type, range, purpose and properties of materials used in manufacture of equipment and medical devices and the indications and contra-indications for use
K15. the range and types of environmental controls and devices used in assistive technology and their application within your work practice

K16. how to conduct the relevant procedures involving direct interaction with the individual and/or relevant others during the manufacturing process
K17. the range of materials available for impression taking or shape capture, and the contra-indications for their use
K18. the use of prototypes and when and where to apply them
K19. how to fabricate equipment and materials and other components to meet the prescription
K20. the requirements for assembly, testing and inspection of relevant components to meet specification
K21. how to communicate effectively in the appropriate medium to meet the individual's needs and preferences
K22. the need to test whether any interim and the completed model meets the individual's requirements and how to adapt the model as necessary within the prescription specification parameters
K23. how to check the completed product meets the individual's needs and prescribed specifications
K24. how to dispose of waste in accordance with organisational procedures
K25. how to complete and safely store all relevant documentation in accordance with organisational requirements

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