SFHCHS205 - SQA Code HD0T 04

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 and 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 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 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 and work with relevant stakeholders or agencies involved in the manufacture
P3 correctly interpret the specification for the manufacture of the rehabilitation or customised equipment, assistive technology or medical device
P4 identify existing manufacturing components for suitability
P5 select the appropriate range of tools and techniques to produce the working/prototype model
P6 select the appropriate materials to meet the prescribed manufacturing specification
P7 determine those aspects of specification which relate to an adaptation of existing equipment and/or device to meet the prescribed customised solution
P8 apply health and safety measures, standard precautions for infection prevention and control and personal protective equipment appropriate to the manufacturing process
P9 manufacture and assembly the component parts to specification
P10 regularly monitor environmental conditions and maintain them at the correct levels during the manufacturing process as required by the procedure
P11 incorporate relevant testing, inspection and risk assessment for the operation o equipment and materials within the manufacturing process
P12 monitor the operation of equipment regularly and where faults or breakdowns occur in equipment during use, take appropriate action to remedy or minimize damage to yourself and others
P13 test the working model or prototype with the individual
P14 make the required adaptations to the working model or prototype within the prescribed specification
P15 confirm that final product meets design specification, prescription and required performance parameters
P16 test the final product with the individual against the prescription and specification and confirm performance within expected parameters and/or make appropriate adjustments
P17 confirm that it product is suitable for the individuals needs and where appropriate offer the prototype for a trial in their home environment
P18 compile user information for the product and make arrangements to review the completed product or prototype with the individual andrelevant others
P19 maintain full, accurate and legible records of information and store in

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 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 to specification

K3 the importance of and how to ensure that the prescription requirement is integrated in the manufacture of the equipment or medical device

K4 the methods for selection, approval and contracting with external suppliers appropriate to the prescription for the equipment or medical device

K5 the range, extent, format and level of detail required within manufacturing information and how to turn the specification into a manufactured product

K6 the range of health and safety measures, infection prevention and control and relevant personal protective equipment, their importance and their application within the manufacturing process

K7 why it is important to know how to assess and manage risks within the manufacturing environment and for the item under construction

K8 the principles of manufacturing techniques, electronic and mechanical engineering and/or biomechanics and their application relevant to the component manufacture

K9 the range of design specifications, purpose and application of the range of equipment or medical devices within your work practice

K10 the range and types of manual and machine operated tools required for the manufacture process and how to operate these in accordance with local policies and protocols within your work area

K11 the type, range, purpose and properties of materials used in manufacture of equipment and medical devices and the indications and contra-indications for use

K12 the range and types of environmental controls and devices used in assistive technology and their application within your work practice

K13 how to conduct the relevant procedures involving direct interaction with the individual and/or relevant others during the manufacturing process

K14 the range of materials available for impression taking and the contra-indications for their use

K15 the use of prototypes and when and where to apply them

K16 how to fabricate equipment and materials and other components to meet the prescription

K17 the requirements for assembly, testing and inspection of relevant components to meet specification

K18 how to communicate effectively in the appropriate medium to meet the

individuals needs and preferences

K19 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

K20 how to check the completed product meets the users and prescribed specifications

K21 the different types of waste generated by the activity and the appropriate methods of handling and disposal for each

K22 the current national legislation, guidelines, local policies and protocols which affect your work practice

K23 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: HWB9 Equipment and devices to meet health and wellbeing needs

The candidate and assessor must only sign below when all Performance Criteria and Knowledge points have been met.

Unit assessed as being complete

Candidate's Name:	
Candidate's Signature:	
Date submitted to assessor as complete:	

Assessor's Name:	
Assessor's Signature:	
Date assessed as complete:	

Internal Verification —

to be completed in accordance with centre's IV strategy

Evidence for this Unit was sampled on the following date/s:	**IV's Signature**	**IV's Name**

This Unit has been subject to an admin check in keeping with the centre's IV strategy.

Date of admin check	**IV's Signature**	**IV's Name**

Unit completion confirmed

IV's Name:	
IV's Signature:	
Date complete:	