

CHS205 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. Version No 1

KNOWLEDGE AND UNDERSTANDING

You will need to know and understand:

- 1.your own level of competence, authority and specialist knowledge base
- 2.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
- 3.the importance of and how to ensure that the prescription requirement is integrated in the manufacture of the equipment or medical device
- 4.the methods for selection, approval and contracting with external suppliers appropriate to the prescription for the equipment or medical device
- 5.the range, extent, format and level of detail required within manufacturing information and how to turn the specification into a manufactured product
- 6.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
- 7.why it is important to know how to assess and manage risks within the manufacturing environment and for the item under construction
- 8.the principles of manufacturing techniques, electronic and mechanical engineering and/or biomechanics and their application relevant to the component manufacture
- 9.the range of design specifications, purpose and application of the range of equipment or medical devices within your work practice
- 10.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
- 11.the type, range, purpose and properties of materials used in manufacture of equipment and medical devices and the indications and contra-indications for use
 - 12.the range and types of environmental controls and devices used in assistive technology and their application within your work practice
 - 13.how to conduct the relevant procedures involving direct interaction with the individual and/or relevant others during the manufacturing process
 - 14.the range of materials available for impression taking and the contra-indications for their use
 - 15.the use of prototypes and when and where to apply them
 - 16.how to fabricate equipment and materials and other components to meet the prescription
 - 17.the requirements for assembly, testing and inspection of relevant components to meet specification
 - 18.how to communicate effectively in the appropriate medium to meet the individuals needs and preferences
 - 19.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
 - 20.how to check the completed product meets the users and prescribed specifications
 - 21.the different types of waste generated by the activity and the appropriate methods of handling and disposal for each
 - 22.the current national legislation, guidelines, local policies and protocols which affect your work practice
 - 23.the policies and guidance that clarify your scope of practice, accountabilities and the working relationship between yourself and others

PERFORMANCE CRITERIA

You must be able to do the following:

- 1.work within your level of competence, responsibility and accountability
- 2.liaise and work with relevant stakeholders or agencies involved in the manufacture process
- 3.correctly interpret the specification for the manufacture of the rehabilitation or customised equipment, assistive technology or medical device
- 4.identify existing manufacturing components for suitability
- 5.select the appropriate range of tools and techniques to produce the working/prototype model
- 6.select the appropriate materials to meet the prescribed manufacturing specification
- 7.determine those aspects of specification which relate to an adaptation of existing equipment and/or device to meet the prescribed customised solution
- 8.apply health and safety measures, standard precautions for infection prevention and control and personal protective equipment appropriate to the manufacturing process
- 9.manufacture and assembly the component parts to specification
- 10.regularly monitor environmental conditions and maintain them at the correct levels during the manufacturing process as required by the procedure

- 11.incorporate relevant testing, inspection and risk assessment for the operation of equipment and materials within the manufacturing process
- 12.monitor the operation of equipment regularly and where faults or breakdowns occur in equipment during use, take appropriate action to remedy or minimise damage to yourself and others
- 13.test the working model or prototype with the individual
- 14.make the required adaptations to the working model or prototype within the prescribed specification
- 15.confirm that final product meets design specification, prescription and required performance parameters
- 16.test the final product with the individual against the prescription and specification and confirm performance within expected parameters and/or make appropriate adjustments
- 17.confirm that it product is suitable for the individuals needs and where appropriate offer the prototype for a trial in their home environment
- 18.compile user information for the product and make arrangements to review the completed product or prototype with the individual and relevant others
- 19.maintain full, accurate and legible records of information and store in correct location in line with current legislation, guidelines, local policies and protocols

ADDITIONAL INFORMATION

This National Occupational Standard was developed by Skills for Health. 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