Prepare and maintain environments, materials and equipment for the non-routine design and manufacture of custom made devices



Overview

This standard covers establishing the necessary materials and equipment needed to carry out the non-routine manufacture of a custom made device and the preparation and maintenance of the materials and equipment. It also covers the health and safety aspects required, including risk assessment. 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 confirm the prescription and contract with the relevant person and correctly identify the materials and equipment which will be required
- P2 identify any non-routine design and manufacturing processes necessary to produce the device and confirm the acceptability of carrying out these processes
- P3 assess correctly the risks to the worker and others involved in undertaking the design and manufacture of the custom-made devices
- P4 use working methods and systems throughout the process which:
 - P4.1 promote health and safety
 - P4.2 reduce the risk of infection and contamination
 - P4.3 are consistent with the assessed risks
- P5 confirm that the environment in which the work is to be undertaken is in a fit state ready for use and if it is not, take any necessary remedial action
- P6 use suitable personal protective equipment and take the necessary precautions
- P7 select the correct type and quantity of materials specified in the prescription
- P8 confirm that the required equipment is:
 - P8.1 in working order
 - P8.2 clean
 - P8.3 set correctly
- P9 handle any problems with equipment and materials within your responsibility and report problems outside your responsibility to the relevant person
- P10 move and handle equipment and materials in an appropriate, safe manner which is consistent with current legal and organisational requirements
- P11 dispose of waste in a suitable container and in an environmentally safe manner

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Knowledge and understanding

You need to know and understand:

- K1 the reasons for maintaining records throughout the process and of clearly identifying the products during the manufacturing process
- K2 the organisational procedures and requirements for the recording of information about incoming work, work in progress and work delivered, and the purpose of this
- K3 quality audit systems, their purpose, nature and procedures, impact of the relevant regulatory body, currently the Medicine and Healthcare Regulatory Authority, on the recording of incoming work, the detailed design and manufacturing specification and the recording of materials and processes
- K4 the principles of quality assurance, processes and procedures for quality assurance in your workplace
- K5 the methods used for setting and calibrating equipment and of testing that this is correct
- K6 the effects of modifying manufacturers' components and products to meet production/usage requirements on the physical properties of the components/products and the legal implications
- K7 the relevant regulatory body, currently the Medicine and Healthcare Regulatory Authority, in monitoring the progress of devices through the production process
- K8 health and safety at work legislation and related procedures and liability, principles of, and how to apply legislation and regulations
- K9 the characteristics, properties and the processing of the following commonly used materials:
 - K9.1 metals;
 - K9.2 plastics: thermoforming, thermosetting, composites;
 - K9.3 wood:
 - K9.4 leather;
 - K9.5 plaster of Paris;
 - K9.6 adhesives;
 - K9.7 fabrics;
 - K9.8 foams:
 - K9.9 other materials
- K10 the following:
 - K10.1 hand tools: their selection, use and maintenance;
 - K10.2 measuring instruments: use and methods of application;
 - K10.3 machine tools: selection, installation, use and maintenance;
 - K10.4 welding processes and equipment for metals and plastics;
 - K10.5 sewing machines: selection, use and maintenance;
 - K10.6 general equipment: ovens, compressors, vacuum formers, fume and dust extraction apparatus;

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K10.7 workshop layout;

K10.8 health and safety regulations and practice;

K10.9 computers, including CAD/CAM

- K11 the ways in which design and manufacturing processes can be safely and acceptably adapted and modified to accommodate non-routine situations and circumstances
- K12 the roles and responsibilities of the interdisciplinary team
- K13 ethical considerations in rehabilitation technical services
- K14 prosthetics/orthotics/special seating care systems in the UK

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Additional Information

External links

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: Core 3 Health, safety and security

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