SFHHCS1
Manufacture samples for quality assurance programmes in healthcare

Overview

This standard relates to the manufacture of quality assurance samples for testing and analysis within both internal and external quality assurance programmes to test the integrity of the procedure and operator competence. Samples may include materials or manufactured products for testing, anonymised repeat testing, anonymised images or data for analysis selected to detect normal, abnormal or unusual results within a wide range of healthcare environments.

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 obtain sufficient materials relevant to the context, complexity and scale of the intended quality test sample/product

P3 confirm materials or repeat samples have been validated against the target specification and conform to relevant financial, ethical, confidentiality, safety and other relevant legislative requirements which affect your work practice

P4 check materials, samples or products are of suitable type, quality, integrity and will remain stable within defined timescales

P5 apply health and safety, infection prevention and control and personal protective equipment and containment measures appropriate to the handling and /or manufacture of the quality test sample/product

P6 where manufacturing processes are required, create the quality test sample/product in line with approved policies, protocols and procedures

P7 quality check the manufactured or acquired sample/product against expected results; where appropriate, take corrective action for variances or non compliance and seek advice if this is outside your responsibility

P8 accurately label the acquired or manufactured product with its unique identifier for traceability in line with local policies and protocols

P9 distribute the quality test sample/product to internal or external recipients in line with local policies, protocols and procedures

P10 where indicated in the quality design programme, retain a portion of the sample/product in the appropriate location and environment for retrospective analysis, serial distributions or audit purposes

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 knowledge base

K2 the relevant financial, ethical, confidentiality, safety and other legislative requirements with regard to the selection of materials, products, samples or repeat testing suitable for your work practice

K3 the importance of following the relevant protocols and methods and resources to acquire or manufacture the required products or samples for quality assurance testing

K4 the acquisition or manufacturing processes required for the quality assurance materials, samples or products required within your work area

K5 the factors which may influence the sources, availability, quality and use of materials or repeat samples

K6 the range of health and safety measures, infection prevention control and the relevant personal protective controls and containment, their importance and application associated with the manufacturing or acquisition of samples for quality testing

K7 the need to select the range of appropriate checks and tests to ensure acceptable outcomes from the manufacture or acquisition process and how to check for variances or non-conformance

K8 the minimum data set for labelling the quality assurance samples for testing

K9 where appropriate, the requirements and conditions for storing and distributing the quality assurance items and unused materials appropriate the type and purpose of the quality tests

K10 the importance of an audit trail to meet the requirements of acquisition or manufacture of quality test samples within quality management systems

K11 the importance and requirements for records relating to the acquisition, manufacture, storage and distribution of quality assurance items

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: HWB10 Products to meet health and wellbeing needs

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