

SFHCHS199

Evaluate new and existing products, equipment, medical devices and associated systems in healthcare



Overview

This standard relates to evaluation of functionality and performance, assessment of risks and benefits of new and existing medical equipment, medical devices, associated systems and products or for new clinical and non clinical facilities.

This standard will be necessary prior to procurement or commissioning or as part of research or review for replacement and may be undertaken in response to a request for new/replacement equipment, facility or as part of a regular review process.

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 with relevant internal and external stakeholders and establish the reasons for the request of new or replacement equipment, medical device associated systems and products
- P3 identify issues which may influence the choice of new emerging technologies or replacement of existing item
- P4 collate relevant information and incident history for the existing or new item or system under evaluation and compare against relevant trends and developments to support the review and decision
- P5 where appropriate obtain additional information from reliable sources to assist the decision making process
- P6 apply suitable evaluation comparator criteria alongside the required product specification to assess the clinical relevance of the item under evaluation
- P7 identify options, which comply with appropriate legislation and guidelines, to meet stakeholder specified needs applicable to complexity, risk and urgency of
- P8 liaise with relevant stakeholders to reach agreement for the recommended action
- P9 provide clear and relevant data and where appropriate include advice and guidance on factors involved in any new purchase or replacement of an existing item and its associated systems
- P10 produce a report of the evaluation or a business case for the preferred option involving key stakeholders as appropriate
- P11 where applicable, produce a product specification for suppliers to respond to when replying to a tender process
- P12 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 scientific, technological or engineering knowledge, trends and developments for evaluating resources appropriate to your work practice and level of responsibility
- K3 the need for new or existing technology evaluation and the factors which affect the whole life cycle including costs and associated systems
- K4 specifications and evaluation criteria for products and the importance of involving key stakeholders to assess functionality of relevant engineering and technical options to meet clinical need
- K5 how to identify, analyse, interpret and recommend action relating to the item or system under evaluation within your level of responsibility
- K6 how to collect information on the clinical area and stakeholders needs on which to evaluate options to support decision making
- K7 the importance of ergonomic factors associated with provision of the existing or new system or item
- K8 factors affecting the health, safety, security and relevant environmental issues regarding the options available and subsequent recommendations
- K9 where and how to access further information to support investigations and decision making to inform the evaluation
- K10 the expected performance parameters of any new or existing item or system under review
- K11 how to prepare a report or business case and seek advice if this is outside your competence and area of responsibility
- 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: G2 Development and innovation

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Suite Clinical Health Skills

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