Supporting note
Standardisation

Supporting notes are written for CQC's assessors and inspectors, to help them make consistent judgements on compliance with the essential standards of quality and safety. Supporting notes only act to clarify key aspects of some of the essential standards; they do not introduce additional requirements. Providers may find them helpful in assessing how they are meeting the standards.

Purpose of note	This note helps to clarify how risks can be managed through standardisation of equipment where appropriate. It also demonstrates how local and national learning can contribute to a culture of safety.

Main Outcome	11 Safety, availability and suitability of equipment	C
Specific prompt (s)	People are safe because, where equipment is provided as part of the regulated activity, there are clear procedures followed in practice, monitored and reviewed. Wherever necessary these include: • Where risks are identified, a plan for how these are to be managed.	
The note may also be relevant, in part, to the following outcomes	9B	

This note is relevant to the following service types:
All

Detail of the note to the essential standards
The systems and monitoring processes that organisations are advised to have in place to manage equipment and medical devices include: • A senior member of management (preferably at board level) with overall responsibility for medical devices management.

- An advisory group that includes those involved in the use, commissioning, maintenance, decontamination and decommissioning of equipment.
- An organisation-wide equipment and medical devices management policy that covers: acquisition, record-keeping and equipment inventories; availability of manufacturers' instructions for use; training; repair and maintenance; single use devices use; decommissioning; disposal and actions required on manufacturers' corrective action notices.
- Safety-oriented pre-purchase criteria to guide purchasing decisions.
- Records of use, maintenance and tracking for each item of equipment, according to risk.
- Arrangements for monitoring the performance of equipment and medical devices management. Ideally this would include a review of safety incident data to determine the reliability and safety of particular devices/equipment.
- Ensuring that purchasing decisions take account of the user experience represented in the advisory group.
- Having a selection process that rationalises the range of medical device models.

Using trusted and appropriate sources of supply can assure the suitability of products purchased and minimise the possibility of counterfeit or damaged goods being purchased. Approved equipment will be awarded a CE mark, which means that the device meets the relevant regulatory requirements, performs as intended, complies with the necessary requirement covering safety and performance and is acceptably safe. In general, a medical device cannot be marketed in Europe without carrying a CE mark. Custom-made devices and those under clinical investigation do not require CE marking.

Risk assessment is at the core of any safety policy. A risk assessment should be undertaken by staff with a full understanding of the purpose and end use of the product being procured. Risks should be identified and minimised, reporting systems should be available and acted upon and, if normal sources are not available (e.g. in a shortage situation), then alternatives need to be assessed in the light of the increased risk they may present to people who use services.

Human factors research (the study of interactions between humans, the equipment and devices they use, and their environment) indicates the importance of design in reducing the contributory factors that can affect human error and safety. An important aspect of this is standardisation of equipment and work processes.

Standardisation has many benefits for people who use services, staff and visitors. It can help to reduce costs, mental workload and errors. It can also make errors and deviations from normal working easier to detect.

Equipment from different manufacturers, or even different models from the same manufacturer, may have different controls, display functions and modes of operation. This can make it more likely for errors to occur due to unfamiliarity with the design or method of use. The same model may also have different configurations, enabling it to respond differently under the same circumstances.

For example, 15 million infusions are performed in the NHS every year. While the vast majority are delivered safely, at least 700 unsafe incidents are reported to the Medicines and Healthcare Products Regulatory Authority (MHRA) each year, of which 19% are attributed to user error. Some of these lead to serious harm or even death. This led to the publication of a safer practice notice in 2004, the recommendations of which included that:

- The range and number of configurations of devices in use should be minimised.
- A centralised equipment library should be established.

However, providers must also consider the risks associated with restricting supplies to a single manufacturer. Other key considerations include the need to:

- Have a sufficient range of types of equipment available to meet different people's needs (in particular the need to ensure equality for disabled people).
- Ensure compatibility with other equipment in use.

Additional benefits from standardisation include greater flexibility to transfer skills and staff between organisations, and reductions in the requirements for training.

Background and references

National Patient Safety Agency (2010) *Lessons from high hazard industries for healthcare* http://www.nrls.npsa.nhs.uk/resources/?EntryId45=74930

National Patient Safety Agency (2004) Safer Practice Notice 01: Improving infusion device safety http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59788

National Patient Safety Agency (2010) *Design for Patient Safety: A guide to the design of electronic infusion devices* http://www.nrls.npsa.nhs.uk/resources/?EntryId45=68534

Jim Armstrong (2007) Sample document: *Purchasing for safety policy*, available from http://www.cmu.nhs.uk/Purchasingforsafetyinjectablemedicines/Documents/purchasing%20policy%20sample%202.pdf

Medicines and Healthcare Products Regulatory Authority (2003) Device bulletin: Infusion systems, http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON007321

Medicines and Healthcare Products Regulatory Authority (2008) Devices in Practice - A guide for health and social care practitioners, http://www.mhra.gov.uk/Publications/Safetyguidance/Otherdevicesafetyguidance/CON007423