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Medical Devices Management Policy

Post Holder Responsible for Policy:	Head of Medical Device Management Services
Directorate Responsible for Policy:	Clinical Support and Family Services Directorate
Contact Details:	Head of Medical Device Management Services
Date Written:	August 2004
Date Revised:	April 2019
Approved By:	Medical Devices Committee (approved) Operational Management Board (ratified)
Date Approved:	Approved: Ratified:
Next Due for Revision:	May 2022
Date Policy Becomes Live:	

Version Information

Version No.	Updated By	Updated On	Description of Changes
1.0	Nicki House	August 2004	New Policy
2.0	Nicki House	October 2007	Minor amendments agreed at the MDC meeting on 12 November 2007.
2.1	Linda Riddell	December 2007	Further minor amendments agreed at the MDC meeting on 3 December 2007.
2.2	Penny Daffurn Gerard Sword	May 2008	Minor amendments.
3.0	Nicki House	October 2010	Formation of new policy for maintenance causing this policy to need amending.
3.1	Kate Stovin-Bradford	July 2013	Review and minor amendments.
4.0	Nicki House	November 2015	Review and amendments to references, new MDSO role, definition of medical devices added and minor amendments.
5.0	Mandy Cripps	April 2019	Review and amendments. New policy names and references. Include more information re TWG's

INDEX

Section

1 Introduction

1.1 The Trust owns and relies upon a large stock of medical devices in order to carry out its function of patient care and treatment. This policy was based upon the requirements of the Care Quality Commission 'Regulation 12: Safe Care and Treatment', and 'Regulation 15: Premises and Equipment'. It is further informed by the Medicines and Healthcare products Regulatory Agency (MHRA) guidance publications 'Managing Medical Devices', and 'Devices in Practice: checklists for using medical devices'.

1.2 The ownership and use of medical devices has a statutory basis within the Provision and Use of Work Equipment Regulations 1998 (PUWER). This policy is the basis by which the Trust complies with PUWER regulations in the use of medical devices.

1.3 The Trust operates and manages this policy through the Medical Devices Committee (MDC). The MDC provides the functions defined in paragraph 2.2 of 'Managing Medical Devices, April 2015' for a medical devices management group. The Terms of Reference of the MDC are included as Appendix A to this policy.

2 Policy Statement

2.1 This policy applies to all grades and disciplines of staff.

2.2 The policy applies to all medical devices which are brought into the Trust, whether purchased through Trust Capital funding, charitable donation, research funding, loaned or donated.

2.3 This policy covers the ownership and use of medical devices in the Trust and includes references to corporate and risk management structures, evaluation and selection of new devices, information and documentation, training, decontamination, maintenance and quality systems.

2.4 The Trust will promote the safe and appropriate use of all medical devices available in the Trust by ensuring that the healthcare professionals who use such devices are aware of the associated risks and have access to training and support to develop and maintain their knowledge and skills

The Trust requires that a formal record be kept of training received.

3 Definition of a Medical Device

A medical device is any product used in the:

- diagnosis, prevention, monitoring and treatment of disease of disability
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy, or of a physiological process
- control of conception.

A full list of examples of medical devices are shown in the MHRA publication *"Devices in Practice, June 2014".*

4 Management Arrangements and Ownership

4.1 There is a Trust Board Director who has executive responsibility for all issues relating to medical devices. This is the Chief Operating Officer.

4.2 The Trust owns and accepts responsibility for all purchased or donated medical devices that have been appropriately brought into the Trust (excluding leased or contracted arrangements).

4.4 Items that have been borrowed, loaned or are on demonstration must be used in accordance with both the policy for Decontamination and the Policy for the Introduction of New Health Technologies within Salisbury NHS Foundation Trust, copies of which are available on Microguide.

4.5 Managerial ownership of a medical device lies with the relevant ward or department manager, who is responsible for ensuring that the item is maintained and used in a safe manner, and that all staff are competent and confident in its use.

4.6 Each ward or department is also responsible for highlighting the need for replacement of medical devices as they approach the end of their anticipated life. Disposal may be organised via Medical Electronics, who should always be informed so that the device can be removed from the asset register. Medical Electronics will also condemn faulty items beyond economical repair.

4.7 The person responsible for co-ordinating the Trust's medical device management is the Head of Medical Device Management Services (MDMS) within the Clinical Support and Family Services Directorate. The MDMS supports the Trust requirement to collate the service information provided by equipment manufacturers after completion of service procedures.

5 Evaluation, Selection and Purchase of Medical Devices

5.1 All bids must be approved by the relevant Directorate Management Committee (DMC) along with a robust business case and risk assessment. The DMC will prioritise their Directorate's bids and forward to MDMS. The capital bidding process is outlined on the Trust intranet.

5.2 The Director of Finance will allocate a capital budget for the use of the MDC each year. This will cover single devices valued at over £5,000 inclusive of VAT.

5.3 For medical equipment items under £5,000 inclusive of VAT in value there is an allocated central budget for Grouped Assets in addition to individual departmental budgets.

5.4 MDMS will ensure that all requests, for the purchase of medical devices are approved and prioritised by the relevant Technology Working Group (TWG) regardless of source of funding. Each TWG is made up of specialists who review bids under the following groupings;

- Critical Devices
- Imaging
- Assistive Technology
- Pathology and Laboratory
- Operating Theatres and Endoscopy
- Consumables

5.5 The bids are then further reviewed by the Medical Device Committee (MDC) regardless of the source of funding. The MDC will be responsible for prioritising the bids to ensure the capital spend is not exceeded

5.6 The Trust's Standing Financial Instructions and Standing Orders will be adhered to at all times.

5.7 MDMS has established a medical equipment loan library for commonly used items of equipment. This allows for economies of scale and ensures that maximum utilisation is obtained from each device. Wards and departments can access items in the library as and when they are needed

6 Acceptance of Devices into Use

6.1 All medical devices must go through an appropriate acceptance test before being put into patient use. Electronic portable items must be sent to Medical Electronics for these tests to be carried out; large or fixed items of equipment e.g. x-ray machines or pathology analysers, should be installed and commissioned in the appropriate manner by qualified personnel. Items owned by the Trust will be recorded on the Trust Asset Register and the Medical Electronics' database as will equipment on long term loan.

6.2 The Acceptance Procedure is attached as an Appendix A to the Medical Devices Maintenance Policy, which can be found on Microguide. This includes an important section of cybersecurity.

6.3 All equipment which connects to the Trust Network must undergo conform to the following standards:

- All companies must have at least Cyber Essentials Certification (see www.cyberessentials.ncsc.gov.uk), Cyber Essentials Plus is beneficial.
- Penetration testing will be conducted on devices after installation and Salisbury Foundation Trust will require staff to take the appropriate action to secure the equipment within one calendar month of installation. Further monthly security scans will be performed against the device - appropriate action will be taken to secure it following identification of any vulnerabilities.
- If remote access is required for support, the Salisbury NHS Foundation Trust standard method of connection and the appropriate multi-factor authentication will be used.
- All software/firmware must be patched for security vulnerabilities regularly during the equipment's lifetime.
- All unnecessary services and processes will be prevented from running on equipment when it becomes live.
- If possible, the anti-malware solution chosen by Salisbury NHS Foundation Trust will be installed on this equipment.
- Security checks will have been conducted on staff who have access to Salisbury NHS Foundation Trust's network.

6.4 MDMS should be advised of all new devices for purchase or trial to ensure indemnity and entry onto the Equipment asset register. Please refer also to the Trust's "Suppliers and their Representatives – Code of Conduct".

6.5 Items of a consumable or disposable nature will be accepted into use by the ward or department manager, or their designate. Where disposable items have a use by date, the manager must ensure that stock is correctly rotated so that items never go out of date.

6.6 New consumable items which are proposed to be introduced to the Trust must be submitted on a new item request form. This is to ensure standardisation can be maintained, risk can be minimised and cost savings can be attained.

6.7 When an item is delivered to a ward or department after having been formally accepted by Medical Electronics, the manager must ensure that any local acceptance tests that should be undertaken are performed. In the case of reusable non-electronic medical devices delivered direct to the ward or department, the manager should ensure that they are asset registered and in good condition and working order. There must also be clear decontamination instructions from manufacturers for staff to follow to ensure safe use for multiple patients. More information can be found in the Trust Decontamination Policy available on Microguide. The manager must advise MDMS of the arrival of all reusable medical devices.

6.8 Managers should review the training needs of their staff when a new medical device is delivered. If the device is unfamiliar to any member of staff then training must be provided for that member of staff and a record kept of the training provided. More information can be found in the "Medical Devices Training Policy" which is available on Microguide.

6.9 When a new medical device is received into a ward or department, the manager must ensure that all staff read the instruction manuals and that these are stored in a place that is familiar and accessible to staff at all times. Instruction manuals for commonly used medical devices will be uploaded onto the Trust's Intranet where possible.

6.10 Managers must arrange for suitable storage of medical devices when they are not in patient use. The storage facilities must take into account any special requirements for infection control, temperature, humidity, exposure to light or other requirements specified by the manufacturer. Any device that has rechargeable batteries must be kept fully charged and in optimum condition by adherence to manufacturer's recommendations.

7 Maintenance and Repair of Medical Devices

7.1 Managers should ensure that appropriate arrangements for maintenance and repair are in place for when the equipment warranty expires. Although Medical Electronics undertake much of the medical device maintenance, there are items which are outside their expertise eg Radiological equipment. It is then the manager's responsibility to ensure that a suitable maintenance contract is negotiated via the Procurement Department.
More information can be found in the "Medical Devices Maintenance Policy" which is located on Microguide**.**

8 Decontamination

8.1 The Trust has a comprehensive Infection Control Policy, and a Decontamination Policy, which include the requirements for decontamination of medical devices. These policies can be located on Microguide.

8.2 It is the ward or department manager's responsibility to ensure that their medical devices are properly decontaminated between patient use.

8.3 Loan library equipment must be properly decontaminated, and have a decontamination certificate attached, before it is returned to the MDMS.

8.4 When equipment is to be repaired by Medical Electronics or returned to a manufacturer or third party maintenance provider, the ward or department manager must ensure that is has been properly decontaminated with a decontamination certificate attached. It is illegal to send contaminated devices through the post. For advice contact MDMS.

8.5 If a device is contaminated internally, and therefore cannot be adequately cleaned before dispatch for maintenance or repair, this fact must be communicated to the technical organisation undertaking the work and the equipment transported in a safe and agreed manner. A decontamination certificate, stating the degree of residual contamination should always be attached.

9 Training

9.1 All healthcare professionals must be trained in the correct use of each relevant medical device and it is their responsibility to ensure they are up to date. It is the ward and departmental manager's responsibility to ensure that training is accessible to all staff for equipment required to provide patient care or treatment. More information can be found in the Trust's "Medical Devices Training Policy".

10 Safety and Incidents

10.1 The safety of patients and staff is paramount at all times. It is the responsibility of all users to ensure that medical devices are used in such a manner that the patient, visitors or any other person is not put at risk.

10.2 Before a new medical device is put into service, the manager responsible for the equipment should undertake a risk assessment to ensure that any possible hazards arising from the use of the device are identified and appropriate precautions taken. Please refer to the Risk Management Policy and Procedure which is available on the Intranet.

10.3 In the event of an adverse event occurring which involves a medical device, the Adverse Event reporting procedure must be followed. This is part of the Adverse Events Reporting Policy, available on the intranet. It is vital that the asset number, serial number or batch/lot number of the device in question is recorded on the incident form. It is important that the affected device, and any associated consumables, are retained by the Trust as it may be required as evidence. Photographs of damaged or failed devices can be attached to the incident report submitted via Datix. If the event requires a report to be made to the MHRA, this will be carried out by Medical Devices Safety Officer (MDSO).

10.4 All Safety Alerts sent from the Central Alerting System (CAS) of the Department of Health will be received and co-ordinated centrally by Medical Device Management Services, and disseminated to all relevant healthcare professionals. The CAS Alerts Review Group is responsible for reviewing the Trust's process for the dissemination and compliance with safety alerts. Please refer to the Trust's CAS Alerts Management Policy. The MDMS Head of Service is the CAS Liaison Officer for the Trust.

10.5 Medical Electronics will receive manufacturer's safety or modification instructions and ensure that they are implemented with appropriate urgency for any medical devices for which they are responsible.

10.6 No modification to any medical device will be permitted unless it has been approved by the manufacturer however some devices require modification to provide bespoke treatment or support for individual patients. In these situations, reference should be made to up to date MHRA advice and guidance; 'Medical devices: the regulations and how we enforce them'.

11 Prescription of Medical Devices

11.1 Any healthcare professional who prescribes medical devices for use by a patient must be qualified to do so.

11.2 Managers of wards and departments must ensure that their procedures include the prescription of medical devices and that these are enforced appropriately.

11.3 Managers must ensure that medical devices are not issued to patients or carers without the issue of the appropriate instructions and training and having ensured that facilities for maintenance and repair have been clarified.

11.4 Users must ensure that a medical device is working correctly before use and not showing any obvious signs of damage.

12 In-House Manufacture of Medical Devices

12.1 The Medical Electronics team do not manufacture medical devices in-house however the Trust recognises that medical devices are manufactured in-house for patient use and that such manufacture is covered by Medical Device Regulations.

12.2 Where a medical device is manufactured for a patient on a named basis, the healthcare professionals involved in the design and manufacture carry the responsibility for the safety and efficacy of the device. It must be designed and constructed to comply with all national and international standards relevant to the particular products.

13 Policy Monitoring and Audit

The implementation of this policy is monitored by the following means:

13.1 Monthly Heads of Service meeting with the Clinical Support and Family Services Directorate Manager for financial, operational (including responsibilities) and resource issues.

13.2 Adverse Events reports via Datix are investigated by MDMS, and monthly figures are presented at the monthly Clinical Risk Group meeting.

13.3 Regular meetings of the TWGs agree the introduction of new devices, and MDMS and Procurement monitor the purchase of items new to the Trust. The TWGs report directly to the MDC.

13.4 Regular meetings of the MDC monitor resource, inventory, maintenance and policy issues. (Appendix A) This group is a subgroup of, and accountable to, the Trust Management Committee (TMC). MDC minutes are recorded and emailed to the TMC.

14 Associated Policies

Medical Devices Training Policy
Medical Devices Maintenance Policy
Adverse Events Reporting Policy
Policy for the Introduction of New Health Technologies
Infection Control Policy
Decontamination Policy
Risk Management Policy and Procedure
CAS Alerts Management Policy
Suppliers and their Representatives - Code of Conduct

15 External References

Care Quality Commission: *"Regulation 12: Safe care and treatment" (2014)*
Care Quality Commission: *"Regulation 15: Premises and equipment" (2014)*
Medicines and Healthcare Products Regulatory Agency: *"Managing Medical Devices, April 2015"*
Medicines and Healthcare Products Regulatory Agency: *"Devices in Practice, June 2014"*
Medicines and Healthcare Products Regulatory Agency*: "Medical Devices: the regulations and how we enforce them, February 2019"*