

Medical Equipment Policy - Safe Use Of Medical Equipment	Policy Registration No. 04066 Status: Public
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Contributes to Care Quality Commission Regulation	Regulation 16, Outcome 11

Consulted With	Individual/Body	Date
	Medical Devices Group	August 2014
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Policy to be followed by (target staff)	All staff involved with the purchase/use/introduction of new equipment or devices for direct use with patients
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Appendix 1 Authority to Invest Form



Appendix 1.doc

1. Purpose

- 1.1 It is the policy of the Mid Essex Hospital Services NHS Trust, (MEHT), to ensure, so far as is reasonably practicable, safety in the selection, purchase, decontamination and use of medical equipment and supplies.
- 1.2 The Chief Executive and the Trust Board are responsible for ensuring that the standards in this policy are met, in line with the Trust's general Health & Safety Policy Statement, so far as reasonably practicable.
- 1.3 The policy and procedures below will comply with the recommendations laid down in the Medicines and Health Regulatory Agency Bulletin, DB2006 (05) 'Managing Medical Devices'.
- 1.4 The Trust is committed to a systematic approach to purchasing, deployment, maintenance, repair and disposal of Medical Equipment.

2. Introduction

- 2.1 The MHRA Device Bulletin (DB 2006 05) provides guidance for NHS Trusts to follow in order to adequately manage all aspects of Medical Equipment.
- 2.2 The aim of this Policy is to ensure that all Medical Equipment are managed as per relevant guidelines, including NHS/PSA/2014/06, and to reduce the risk to patients and staff.

3. Scope

- 3.1 The Policy applies to all directorates and departments who are involved with the purchase, supply, maintenance, decontamination and use of Medical Equipment.

4. Equality & Diversity

- 4.1 The Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.

5. Definitions

- 5.1 **Medical Device** (Equipment) (Directive 93/42/EEC) – any instrument, apparatus, appliance, material or other article, whether used alone or in a combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
 - Diagnosis, prevention, monitoring, treatment or alleviation of disease.
 - Diagnosis, monitoring, treatment or alleviation of or compensation for an injury or handicap.
 - Investigation, replacement or modification of the anatomy or of a physiological process.
 - Control of conception and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.”
- 5.2 **Single use only** – a medical device that is intended for only one episode of use on one patient only. Note: the international symbol, which is a figure 2 with a diagonal line drawn

through it may be used on medical device packaging to indicate 'Do Not Reuse' and may replace any wording.

There are instances where the Trust may decide to use a 'Single Use Only' item on more than one occasion on the same patient, in such circumstances a risk assessment will be undertaken and a local guideline developed to ensure that the patient is not put at risk.

- 5.3 **Single patient use only** – a medical device that is intended for more than one episode of use on one patient only, the device may go through some sort of processing between each use.
- 5.4 **Re-usable medical device** – a medical device that may be re-used on either the same or different patient after it has been through decontamination processing or reprocessing. Note: some accessories of re-usable medical devices may be either for single use or single patient only.
- 5.5 **Central Alerting System (CAS)** - The Central Alert System brings together the Chief Medical Officer's Public Health Link (PHL) and the Safety Alert Broadcast System (SABS). Safety alerts, emergency alerts, drug alerts and medical device alerts are issued via CAS and on behalf of Medicines and Healthcare products Regulatory Agency (MHRA), the National Patient Safety Agency (NPSA) and the Department of Health (DoH).

6. Roles & Responsibilities

6.1 Chief Executive

The Chief Executive is the Executive Director responsible for ensuring there are processes in place to manage the risks associated with the safe use of Medical Equipment, including overseeing the facilitation and successful operation of the Medical Devices Group. This includes overall responsibility for ensuring compliance with all current regulations and approved guidance and best practice, and the implementation of this policy by:

- Communicating the Policy to everyone who works at the Trust
- Ensuring the Policy is implemented by everyone who works in the Trust
- Delegating the performance of some of the duties related to medical equipment to Directors, Directorate Managers under his/her control

6.2 Health & Safety Group

- Approval of this policy.
- Overseeing the activity of the Medical Devices Group and escalating key issues or risks to the Patient Safety and Quality Committee.

6.3 Medical Devices Group

The Medical Devices Group is a multidisciplinary group with responsibility for:

- The scrutiny and monitoring of all equipment management processes including this policy.
- Reporting to Health and Safety Group annually
- Approval of this policy

6.4 Patient Safety and Quality Committee (PSQC)

The PSQC is responsible for:

- Overseeing risks on the Trust Risk Register relating to Medical Devices. Reviewing the distribution and response to safety alerts relating to medical devices distributed under the Safety Alert Broadcast System (SABS).

6.5 Directorate / Department Management Teams

The Directorate or Department Management teams are responsible for the following:

- Procurement – compliance with the policy with regard to documenting a case for need to purchase new equipment by completing an Authority to Invest (ATI) form (Appendix 1) and submitting it to the Investment Group.
- Providing information and responses to the Medical Devices Group regarding risks relating to Medical Equipment.

6.7 Ward Managers/ Heads of Service

- The Ward Managers/ Heads of Service are responsible for ensuring that all staff members adhere to this policy.
- Line managers are responsible for ensuring all medical equipment is purchased and maintained in accordance with this policy working with Procurement to complete the process. This includes completion of the Authority to Invest (ATI) form (Appendix 1). They are also responsible for ensuring any significant risks associated with medical equipment, informs the local risk assurance framework.

6.8 All staff using / operating medical equipment will be responsible for:

- Ensuring they are suitably trained to use the equipment in accordance with the Diagnostic & Therapeutic Equipment Training Policy.
- Ensuring that, where medical equipment is found to be faulty, it is taken out of use, cleaned in accordance with the Trust's Decontamination Policy and reported to the Biomedical Engineering Department (BME).
- Adverse incidents involving medical equipment should be reported using the Trust's Incident Reporting System. Dependent on the circumstances, consideration should also be given to reporting the incident to the MHRA. Where doubt exists, advice should be sought from the Health & Safety Manager.

6.9 Biomedical Engineering Department (BME)

BME maintain the Trust asset register for Medical Equipment using an Equipment Management System (Info health F2).

BME are responsible for:

- Undertaking Acceptance Checks on new equipment based on the MHRA DB 2006
- 'Managing Medical Devices' guidelines. Acceptance tests will be performed as soon as possible after receipt and in the event of Medical Equipment failing acceptance checks, procurement must be notified immediately and the equipment must not be put into use.

6.10 **Medical Devices Safety Officer (MDSO)** support local medical device incident reporting and learning, act as the main contact for NHS England and the MHRA and medical device manufacturers and be a member of the new National Medical Devices Safety Network.

7. Medical Equipment Procurement

7.1 In liaison with BME, departments, directorates or individuals wishing to purchase medical equipment for use within the Trust must document a case for its need using the ATI form (Appendix 1), and submit it to the Investment Group for approval.

7.2 The Trust will seek to reduce the number of different models and types of medical equipment in use in the Trust, as recommended by the National Audit Office (HC475, 'The Management of Medical Equipment in NHS Acute Trusts in England').

7.3 The Trust is committed to a policy of standardisation of Medical Equipment in order to:

- Reduce risk through a common range of equipment.
- Reduce the range of consumables held.
- Reduce maintenance and training costs.
- Reduce purchasing cost by use of competition and purchasing power.
- Reduce lifetime costs.
- Ensure all relevant decontamination issues have been considered as per the Trust Decontamination Policy.
- Improve the quality of patient care.

7.4 When MEHT non-standard Medical Equipment are being considered for purchase, the following must be completed:

- A technical specification,
- An evaluation by users and procurement against predefined evaluation criteria,
- Any required submission to the Health Technology Appraisal Group.

7.5 It is the responsibility of the Procurement and Finance departments to provide commercial and business support to enable the Trust to implement policies and procedures, and meet the responsibilities for the procurement of Medical Equipment.

7.6 The Procurement Department will report quarterly to the Medical Devices Group any exceptions to the procurement process.

8. Equipment Replacement Programme

8.1 The Trust has an Equipment Replacement Programme identifying its Medical Equipment needs. All purchases of medical equipment will follow the Trust's Standing Financial instructions (SFI's) and relevant procurement procedures.

- 8.2 Equipment will be allocated a realistic lifespan based on experience and on information provided by the manufacturer. End of Life monitoring will form part of the quarterly reports to the Medical Devices Group.
- 8.3 The equipment replacement programme will be planned and monitored by BME reporting to the Investment Group fortnightly. All medical equipment will be condition risk assessed and replacement will be based on sound business planning, to ensure that the Trust meets all its obligations in the provision of agreed healthcare services.
- 8.4 Any request for new equipment, either replacement or additional, is required to go to the Investment Group by way of an Authority to Invest Form.

9. Process for Ordering Medical Equipment

- 9.1 The user requirement (the function that the item is required to perform) will be precisely defined by the Department Manager wishing to make the purchase through the preparation of a specification.
- 9.2 Only equipment which staff are capable of using (after provision of training if necessary) will be specified.
- 9.3 Equipment which is more complex than needed for the task required must be avoided.
- 9.4 Departments, Directorates or individuals wishing to purchase medical equipment will ensure that equipment they propose to buy is compatible with equipment and facilities already in use.
- 9.5 The equipment must be CE Marked.
- 9.6 Approval will be sought from the Investment Group for all purchases.
- 9.7 Following approval the Procurement Department will liaise with BME to agree the purchasing plan, including identifying the maintenance costs for the lifespan of the equipment.
- 9.8 The Plan will ensure:
- The Trust's Standing Financial Instructions are adhered to.
 - Electrical Safety checks are carried out to the relevant standard. Pre Purchase Questionnaires will be obtained by BME.
 - The end user, in conjunction with BME, will ensure that an Equipment Competency is in situ or, where necessary, develop a new competency.
 - Best buy product is identified by proper evaluation of products available and how they meet the user's requirements.
 - By identification of all costs likely to be incurred during lifespan of product i.e. maintenance costs.
 - That all appropriate Departments are represented in the Negotiating Team.

- Approval from I.T. on devices with an I.T. interface.

9.9 Any equipment that emits radiation in any form will involve a member of the Radiology Team in the negotiation.

9.10 Orders will only be placed for equipment via the Procurement Department.

9.11 The order will reflect the results of the procurement negotiations.

9.12 All charity purchases must also follow this procedure.

9.13 Donated equipment should not be used under any circumstances until it has been proved to comply with the Trust's specification for that type of equipment. If not, the Trust will refuse to allow the use of such products.

9.14 All financial donations must be routed via the correct route within the Trust. Procurement of the donated equipment must be carried out using the normal procedure. This includes the identification of maintenance funding suitable for the equipment.

9.15 All Medical Equipment **must** be delivered to the BME department for the necessary acceptance procedures to be carried out. BME will ensure that the device is:

- Complete with all necessary accessories and user operating manuals.
- Undamaged.
- In proper working order and operating to the correct specification.
- Allocated and marked with an asset code and included in the appropriate equipment management system (F2).

9.16 No imaging, radiation therapy, laser, ultra violet or intense light source devices will be acquired by the Trust without the approval of the Chair of the Radiation Safety Group and appropriate specialist Adviser. This includes loan equipment, charitable, donated or research equipment. The Supplies Department will not process a purchase without this approval (See Radiation Safety Policy)"

9.17 Any installer or erector of equipment that involves ionising radiation is required under the Ionising Radiations Regulations, 1999, to perform a Critical Examination as defined in Regulation 31(2). This is the supplier's responsibility and arrangements must be confirmed at procurement to ensure this will be done. This applies to new equipment as well as the replacement of major components (e.g. an x-ray tube, image intensifier or automatic exposure control chambers).

10. Equipment Trial/Evaluation

10.1 Any equipment trial must be managed correctly. The user/department must inform Procurement & BME of any intended trial or evaluation.

10.2 Informal visits by sales representatives and leaving equipment behind is not permitted.

10.3 Any equipment that is to be used during an authorised trial or evaluation will be processed the same as loan equipment in section 16.

11. Medical Equipment Maintenance

11.1 The Trust will provide adequate facilities, tools, equipment and staff to ensure the effective and efficient maintenance and repair of medical equipment, and allocate sufficient resources for service and maintenance contracts by external agencies when necessary. The MHRA Guidance document DB2006 (05) will be used for continual reference.

11.2 The Head of BME will ensure:

- Provision of suitably trained and qualified engineering technicians
- The suitability of external contractors
- The technical content of maintenance contracts
- Establishment and operation of a scheduled servicing system for medical equipment throughout the Trust.
- Supervision of scheduled servicing, whether carried out by Trust staff or by contractors including:
 - Authorisation of staff to service medical devices.
 - The availability of service schedules, manuals, diagrams and adequate spares
 - Control of technical training
 - Authorisation and control of work
 - Quality assurance and safety
 - Ensuring that the interests of user and patient are protected
- Maintenance of a systematic Medical Equipment Database to record the medical equipment within the organisation. This will include service history of equipment for the lifetime of that equipment and the retention of records for the period required by the Consumer Protection Act 1987
- Maintaining close liaisons and communications with users
- Tracking change of ownership of equipment across Directorates
- Establishment of appropriate frequency (where appropriate) of servicing and/or calibration for each item of equipment
- Liaising with user departments to ensure that equipment required for servicing is made available
- That action required by MHRA Safety Alerts is carried out
- Condition risk assessments are undertaken for all equipment on the Equipment Replacement Programme

11.3 Scheduled Servicing will encompass the following:

- Comprehensive inspection
- Changing of components and sub-assemblies which require regular replacement
- Calibration
- Performance tests as necessary
- Final functional and configuration check
- Safety check
- Recording of necessary data onto the Equipment Management System (F2)

12. Departmental Equipment Control

12.1 Heads of department are responsible for equipment in their department.

12.2 Responsibilities include:

- Acceptance of equipment into service and attendance at commissioning sessions
- Ensuring that arrangements made for servicing reflect the interests of the user
- Examining of equipment records to ensure that repairs and servicing are carried out regularly and promptly
- Ensuring that the Trust Decontamination procedures are used correctly and documented, including those occasions where equipment is handed over for servicing
- Devising contingency arrangements for use in the event of equipment failure

13. Equipment Failure or Breakdown

13.1 The Trust is committed to ensuring that all medical equipment is fit for purpose and remain so through appropriate maintenance, inspection and repair.

13.2 Medical Equipment maintenance, inspection and repair requirements will be assessed and reviewed in line with the manufacturer's recommendations as well as any legal guidance and best practice recommendations.

13.3 This information will be available on the BME Equipment Management System (F2) such that a planned programme of maintenance occurs. Equipment requiring maintenance will be identified on a monthly basis and a quarterly report to the Medical Devices Group will identify compliance with these requirements and with completion of any required repairs and end of life issues. Where the maintenance or repairs are not undertaken within the agreed timescales, actions will be developed and progress monitored at the Medical Devices Group. This is monitored internally via the BME bi-monthly departmental meetings.

13.4 Staff involved in maintenance, inspection and repair must be suitably trained and qualified. This may include use of outside contractors. Where this is the case, a service level agreement should be arranged to ensure both quality and value for money.

13.5 Single use device accessories used with equipment will – where appropriate – be replaced after any maintenance or repair procedures on the 'parent' equipment.

13.6 Equipment breakdown, when a piece of equipment fails / or is broken, staff must report this to the BME department, via extension 6000. The breakdown is logged on the Equipment Management System(F2). BME will assign an engineer to deal with the device. Ward staff

must decontaminate the equipment and attach the decontamination label to the broken device. BME will attend the ward / department to assess if the device can be repaired in situ or requires a workshop repair. On completion of the repair BME will return the equipment to the ward and will update the F2 system accordingly.

- 13.7 Identified risks associated with medical equipment, which appear on the local risk assurance framework, will be managed in accordance with the Risk Management Strategy and Policy.

14. Decontamination

- 14.1 Using the correct decontamination processes is essential to prevent the spread of infections. By preference, single use devices and accessories should be used wherever practicable.
- 14.2 Single use devices **must not** be re-used under any circumstances.
- 14.3 Single patient devices **must not** be used on different service users. Staff should be aware that reusable medical equipment sometimes have accessories, which fall into the category of single patient devices. These should always be replaced between service users.
- 14.4 Reusable medical equipment should be cleaned, disinfected or sterilised as appropriate and in accordance with the manufacturer's instructions.
- 14.5 It is the responsibility of the user to ensure that medical equipment is decontaminated after use and left in an operational state.
- 14.6 The decontamination process should follow the manufacturer's instructions and or the guidance, policies and procedures provided by Infection Prevention. Please refer to the Trust Decontamination Policy.

15. Loan / Lease or Rental Equipment

- 15.1 All loan / lease and rental medical equipment must conform with all relevant standards pertaining to the type of medical equipment, the location and function for which it is to be used.
- 15.2 Loan equipment / Lease equipment will be subjected to acceptance testing and other medical equipment management procedures accordingly, including indemnity number, equipment competency and maintenance support and included on the Equipment Management System (F2).
- 15.3 Accompanied by appropriate Information and training instructions.
- 15.4 Issued with clear instructions as to when and how it should be returned. Non-electrical devices should be visually checked for signs of wear, tear or damage on return.

16. Reporting Adverse Incidents and Responding to Central Alert System

- 16.1 Any medical equipment can fail, however, an increasing number of incidents which result in significant morbidity or mortality arise out of user/device interface problems or because of poor practice. Central Alert System (CAS) Bulletins highlight problems arising from the use or misuse of medical devices when health or safety, have been put at risk, these include

Medicines and Healthcare Products Regulatory Agency (MHRA) and Department of Health (DOH) notices.

- 16.2 Refer to the Trusts Risk Management Strategy and Policy and Incident Policy. Where necessary the reporting of any adverse incidents to external organisations will be co-ordinated by the Medical Devices Liaison Officer dependant on circumstances.
- 16.3 The Medical Devices Liaison Officer is the identified liaison person between the Trust and Central Alert System (CAS).
- 16.4 The Medical Devices Liaison Officer manages and co-ordinates access and distribution of notices (see below)
- Where there is evidence of a Trust wide initiative arising from a CAS alert, the Medical Devices Liaison Officer will co-ordinate responses concerning compliance with actions as outlined within the alert. The Trust lead (within each section/ward or department) will co-ordinate and monitor any relevant or required action plan until completed and advise the Quality & Compliance Manager of outcomes before action deadline date.
 - The Health & Safety Manager will visit relevant CAS website on a daily basis to ensure the Trust remains up to date in terms of alert information
 - MDA alerts - Electronic distribution of alerts to responsible CAS leads throughout Trust is undertaken by Risk & Compliance. This is undertaken following an initial checking process via the Biomedical Engineering and Procurement teams who will deem whether the alert is applicable to the Trust. A dedicated CAS lead within the BME team will immediately identify whether the alert is applicable to the Trust and where the alert should be sent, this enables the Quality & Compliance Manager to respond to the alert instantaneously. Where an alert is applicable to the Trust an email with all relevant alert details is sent to all relevant the areas of the Trust. Compliance details are sought from each area prior to deadline by the Quality & Compliance Manager.

Patient Safety Alerts (PSAs)– When a rapid response is received the Quality & Compliance Manager will confirm with the Chief Medical Officer to whom/which team the alert should be sent. An email consisting of the alert attachments, guidance/relevant compliance and timescales is then sent to an identified lead for them to manage the Trust's compliance to the alert either individually or within a specific grouping. The Quality & Compliance Manager will develop an action plan, seek feedback at regular intervals to ensure progress is consistent with timescales. Where necessary the PSAs are passed to the Clinical Audit team to be included in the job list for audit.

- Estates and Facilities alert – An alert relating to an estates issue is sent directly to the Deputy Director of Estates and Facilities for immediate onward action. Responses to such alerts are sought in a similar manner to MDA and PSA alerts.
- The Health & Safety Manager is responsible for updating the CAS website with details of compliance and Trust relevance to any given alert. This must be done within the set deadlines as laid down by each individual alert for closure, and by the CAS website for acknowledgement of alert.

17. Medical Equipment Disposal

- 17.1 All medical equipment must be disposed of in a safe and appropriate manner. The disposal of medical equipment is currently not specifically covered under any legislation. However, it is incumbent on the Trust to ensure that any used medical equipment is disposed of correctly following any necessary local regulations or guidelines. Equipment donated for re-use is required to be safe under other national provisions including:

- Consumer Protection Act 1987 (Consumer Safety and Product Liability)
- Sale and Supply of Goods Act 1994
- Health and Safety at Work Act 1974
- Trade Descriptions Act 1968
- The Electrical Equipment (Safety) Regulations 1994
- WEE Directives 2007

Equipment will be disposed of using one or more of the following methods:

- Sale or exchange to external organisation with full indemnity
- Sale via Medical auction house
- Disposal via the WEE Regulations. (collection by manufacturer, waste collectors)

17.2 Disposal will be co-ordinated by the Trust's Procurement Department in conjunction where applicable with BME, I.T. and Estates.

- The BME department will remove the equipment from the Asset Register.
- The I.T. department will ensure that all patient data has been removed prior to disposal.

18. Training

18.1 It is important that staff work within their 'Scope of Practice'. Staff should only use, maintain or manage equipment that they can demonstrate competency in through specific training or through professional knowledge and skills.

18.2 For further details please refer to the Training in the Safe Use of Diagnostic & Therapeutic Equipment Policy.

19. Equipment Maintenance Audit

19.1 An annual sample audit will be undertaken by BME lead with support from the Clinical Audit Team such that all ward areas are visited at least once annually to establish adherence to the processes in place to ensure all reusable medical equipment is maintained and repaired. This will include assessing the following:

- Equipment has been tested for electrical safety
- Equipment has an F2 asset number
- Equipment has been logged on F2
- Equipment appears fit for purpose
- Equipment has been serviced (PPM) in last 12 months either in-house or by external contractor

- Equipment has been maintained as per PPM and within timescales
- Where equipment required repair, this was undertaken within appropriate timescales

19.2 The findings will be reported to the Medical Devices Group and, where deficiencies are identified, actions will be developed to address these with named leads and timescales. Progress will be monitored at subsequent meetings. Where performance is poor, more frequent audit may be scheduled.

19.3 The findings of this review will be reported to the Health and Safety Group.

19.4 Key findings and learning will be shared with the BME team and clinical staff as appropriate.

20. Policy Review

21. The Trust's Medical Devices Group will review the policy on a three yearly basis or at an earlier date in response to national or local initiatives.

21. References

DB2006 (05) 'Managing Medical Devices' Safety Alert Broadcast System (SABS)
 (ECRI-AIMS) Clinical Engineering Database Ionising Radiations Regulations, 1999
 Consumer Protection Act 1987 (Consumer Safety and Product Liability) Sale and
 Supply of Goods Act 1994
 Health and Safety at Work Act 1974
 Trade Descriptions Act 1968
 The Electrical Equipment (Safety) Regulations 1994 ,WEE Directives 2007