

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Medical Device Management Policy

Effective from: June 2009

Reviewed: May 2012

1. Introduction

- 1.1 The Trust recognises that the safe and appropriate use of medical devices is critical to the delivery of high quality patient care. This policy promotes the requirement for procedures, the overall objectives of which are to ensure safe, efficient and high quality management of medical devices, thereby minimising the risks associated with the use of such medical devices.
- 1.2 The purpose of this policy is to ensure best practice with regard to medical device management throughout the lifecycle of a medical device; this involves the assessment of medical devices from the justification of the need, through tender/product specification, commissioning, clinical use, staff training and maintenance throughout the life of the device.
- 1.3 This policy defines a clear and systematic approach to the management of medical devices to ensure compliance with Care Quality Commission standards, NHS Litigation Authority (NHSLA) and Medicines and Healthcare products Regulatory Agency (MHRA) requirements for medical devices.
- 1.4 All medical devices purchased through Trust capital funds, department revenue budgets, public donations, lease purchase, hire, loan, consumable agreements and gifts come under the guidance of this policy.
- 1.5 This policy is intended for all managers, healthcare professionals, support workers and maintenance staff who are accountable for ensuring that they interact with medical devices in a safe and effective manner.
- 1.6 Reference should be made to the following publications:
 - Care Quality Commission “Essential Standards of Quality and Safety”
 - Department of Health “Standards for Better Health” (updated April 2006)
 - Medicines and Healthcare products Regulatory Agency (MHRA) device bulletin [“Managing Medical Devices” DB2006\(05\)](#).

2. Organisational Responsibilities

2.1 Chief Executive and Trust Board

The Chief Executive and Trust Board have responsibility for the safety and welfare of all Trust patients, visitors and staff. This includes overall responsibility for medical devices used within the Trust.

2.2 Medical Devices Steering Group

This group reports via the Clinical Governance and Quality Committee to the Trust Board, and is responsible for developing, implementing and monitoring compliance with this policy to ensure best practice. The group is required to produce an annual report and action plan on the efficacy of the Trust's Medical Device Management Policy. See Medical Devices Steering Group "Terms of Reference" (*Appendix 01*).

2.3 Supplies Manager

The Supplies Manager has responsibility to ensure compliance with Trust Standing Orders, Legal Obligations and European Legislation in respect of tendering and contract procedure, to ensure compliance with guidance, codes of conduct and good practice in respect of procurement and supply of medical devices.

2.4 Clinical Governance & Risk Department (CGARD)

The CGARD Department is responsible for overseeing incident and near miss reporting involving medical devices and for disseminating SABS Alerts throughout the Trust via a nominated SABS Officer.

2.5 Head of Estates and Facilities

The Director of Estates and Facilities has the delegated responsibility for the maintenance and repair of medical devices within the Trust. In practice, this responsibility is delegated to the Head of EME Services and the Hospital Engineering Officer.

2.6 Operational Services

The Operational Services Manager has delegated responsibility for the decontamination of re-usable medical devices and is responsible for ensuring that the risks associated with decontamination facilities and processes are well managed in accordance with the relevant regulations.

2.7 Point Of Care Testing (POCT) Committee

The Point Of Care Testing (POCT) Committee is a sub group of the Medical Devices Steering Group chaired by the Point Of Care Testing Manager. The POCT Committee has responsibility for all performance issues relating to POCT devices within the Trust and reports to the Medical Devices Steering Group.

2.8 Ward/Department Managers

Managers are responsible for the safe and effective use of all medical devices within their area. Managers must ensure that all staff identified as using or maintaining medical devices comply with this policy.

2.9 All Staff

It is the responsibility of individual members of staff to ensure that they are conversant with the content of this policy and are appropriately trained and competent to use the medical devices that they are required to use as part of their duties.

3. Definition of a Medical Device

- 3.1 For the purpose of this policy the term “Medical Device” encompasses devices as defined in [MHRA Bulletin 17 “Medical Devices and Medicinal Products” \(amended April 2006\)](#) and can be summarised as:

“Any instrument, apparatus, appliance, material or other article, whether used alone or in 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, 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 principal 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” (*For examples see Appendix 02*).

- 3.2 Inventory. An inventory of all reusable medical devices and equipment is kept by the Trust. All medical devices are added to the Works Information Management System (WIMS) which is managed by the Trust Asset Management Team.

4. Selection Process and Standardisation Approach

- 4.1 The Trust, wherever practical, operates a standardisation approach with regard to the purchase of common ward based medical devices. This ensures that unless there are valid clinical or technical reasons, similar and up to date models of equipment from the same supplier are purchased in order to ensure:

- Ease of user training
- Reduction in risk due to users being familiar with equipment type
- Availability of in-house expertise and ease of servicing
- Cost benefits in terms of purchase of equipment and consumables
- Cost reduction if equipment is to be placed on external contract
- Rapid issue of equipment from the Medical Equipment Loan Library in the event of a major incident.

- 4.2 Reference should be made to the following policies and procedures:

- [Medical Devices Procurement Policy](#).

5. Procurement Process

- 5.1 The Trust has a properly planned approach to the purchase of medical devices taking into account the needs and preferences of health care professionals and end-users. Medical Devices will be selected according to clinical based specifications.

5.2 The following factors will be considered during the selection process:

- User preference
- Whole life costs
- Maintenance processes
- Decontamination processes
- Cost and availability of consumables
- Cost and availability of spare parts
- Supplier product support
- User and service training provision.

5.3 Reference should be made to the following policies and procedures:

- [Medical Devices Procurement Policy](#).

6. Training and Competency Assessment

6.1 It is the Trust's aim to ensure all staff using medical devices are competent in their use. To be competent is to be adequately trained, knowledgeable and capable of operating a device in a safe and effective manner. Education and training is essential to ensure that users of medical devices have appropriate knowledge and skills to operate medical devices.

6.2 This policy aims to support safe practice and does not constrain clinical autonomy what so ever, clinical judgement is to be exercised at all times and as such, clinical need/emergency situations may over ride this policy. In exercising professional judgement, any alteration from this policy must be noted on an incident form. This is important for legal accountability.

6.3 Staff must have completed agreed practice and be deemed competent through self-assessment or by a supervisor/trainer to operate independently.

6.4 It is the responsibility of the ward/department manager to assess all new staff, regardless of experience, as part of their **local** induction to establish their training needs.

6.5 Staff beginning employment with the Trust must complete the Trust **corporate** induction program where the following medical device related topics will be covered:

- Health & Safety
- Safe lifting & handling
- Reporting procedure for adverse incidents
- Infection Control
- Clinical Risk

6.6 The ward/department manager must maintain records of staff training and dates for re-training relating to all medical devices used within that area. These records must be reviewed annually to ensure they are valid and up to date for audit/inspection purposes.

6.7 Training should be provided by a practitioner competent in the functions and operations of the device. Competency assessment tools and further guidance is available on the [EME Loan Library intranet site](#).

- 6.8 Should a member of staff be unable to demonstrate competence, their ward/department manager must arrange re-training before the individual can operate the medical device in a clinical environment.
- 6.9 When a new medical device is introduced into an area, staff should receive training or instruction before using the equipment unsupervised.
- 6.10 In the event of the appropriate training being unavailable from any source, the ward/department manager must raise this with their Directorate Manager. This must be identified as a risk and included on the Trust risk register. Until the issue has been resolved or rectified the device must not be used.
- 6.11 Reference should be made to the following policies and procedures:
- [Policy for Training in the Safe Use of Medical Devices](#)
 - [Trust Induction Policy](#)
 - [Risk Register – Policy for Management and Use.](#)

7. Use of Medical Devices

- 7.1 All medical device selection decisions must only be taken by staff who are appropriately trained and qualified. Devices must be chosen to best meet the requirements of the intended medical procedure or needs of the end user. All users must ensure that a medical device is only used for the purpose for which it was manufactured and not for any other purpose.
- 7.2 Good clear instructions have a crucial role in the safe and effective use of a medical device. It is the responsibility of the ward/department manager to ensure that instruction manuals are available for each medical devices used within their area and that they are readily accessible to all users.
- 7.3 Users must refer to the manufacturers instructions for details of how the device should be used, which consumables are suitable for use with a device, any contraindications and for whom it is suitable.
- 7.4 Users have a responsibility to carry out routine checks, in line with the manufacturer's instructions, to ensure that the device continues to function correctly including:
- Pre-use checks to ensure the device is working correctly
 - Regular cleaning
 - Specified daily/weekly checks
 - Reporting faults or damage and discontinuing use
 - Battery charging.
- 7.5 Users have a responsibility to routinely monitor medical devices while in use, following local guidelines as appropriate.
- 7.6 After use, staff must ensure that all re-usable medical devices are cleaned and stored safely ready for their next use. Single use medical devices should be disposed of in line with the Trust Waste Management Policy.

7.7 Privately owned medical devices - a patient may wish to use his or her own medical device while in hospital. Privately owned medical devices must be subject to an Electrical Safety test by the Electronics & Medical Engineering Department or Estates Department before use on Trust premises.

7.8 Reference should be made to the following policies and procedures:

- [Standard Precautions Policy](#)
- [Cleaning & Disinfection Procedure](#)
- [Trust Waste Management Policy](#).

8. Medical Device Contamination

8.1 It is the responsibility of the Trust to ensure that patients, visitors and staff are not put at risk by unnecessary exposure to biological, chemical or radioactive hazards. The Trust has a duty to ensure, where necessary, decontamination of any medical device is carried out before re-use, submission for maintenance/repair or before being transported to another location.

8.2 Decontamination is the combination of processes, which may include cleaning, disinfection and sterilisation, used to render a reusable item safe for further use on patients and handling by staff.

8.3 The Trust Decontamination Group is responsible for ensuring that decontamination facilities and processes for re-usable devices, (e.g. surgical instruments/endoscopes), are managed and validated in accordance with the relevant requirements of The Health & Social Care Act 2008 - Code of Practice for Health and Social Care on the Prevention and Control of Infections and related guidance, and Health Technical Memorandum 01-01: The Decontamination of Reusable Medical Devices.

8.4 Reference should be made to the following publications, policies and procedures:

- [The Health & Social Care Act 2008 - Code of Practice for Health and Social Care on the Prevention and Control of Infections and related guidance](#)
- [Standard Precautions Policy](#)
- [Cleaning & Disinfection Procedure](#)
- [Decontamination of Healthcare Equipment Prior to Service or Repair](#)
- [Decontamination of Bed Space Policy](#)
- [Control of Methicillin Resistant Staphylococcus Aureus \(MRSA\)](#)
- [Cleaning and Disinfection of Endoscopes Policy](#)
- [Infection Prevention & Control Practice in the Operating Department.](#)

8.5 Special arrangements may need to be made for medical devices that form part of an investigation as a result of an accident or serious incident. Refer to the [Management and Reporting of Accidents and Incidents Policy](#) and seek advice from CGARD and the Control of Infection Department if required.

9. Single Use and Single Patient Use Medical Devices

9.1 **Single-Use** means any medical device that is intended to be used on an

individual person during a single procedure and should then be disposed of appropriately. A single-use device is **NOT** intended to be re-used or reprocessed for another procedure, even if that procedure is on the same patient.

- 9.2 The symbol below indicates single-use only and is used on devices and on packaging to indicate the item is for single-use only. Every item labelled with a single-use symbol must always be disposed of after use in accordance with Trust Waste Management policy.



- 9.3 **Single Patient Use** means any medical device that is intended to be reused by **ONE patient** and must always be disposed of after that patient use (e.g. Oxygen Mask).

- 9.4 Reference should be made to the following publication:

- [MHRA Device Bulletin DB2006\(04\) Single use Medical Devices: Implications and Consequences of Reuse.](#)

10. Medical Devices Acceptance Testing

- 10.1 It is vital that the Trust has an accurate asset inventory, inclusive of medical devices, that forms the basis from which medical device management is developed. It should be recognised that audit and financial management requirements must also be satisfied during this process.

- 10.2 To ensure that all new medical devices, whether purchased, leased, donated, hired or presented as a gift are safe and fit for purpose, all new medical devices will be subject to a formal acceptance and commissioning procedure by the Electronics & Medical Engineering Department or the Estates Department in line with MHRA device bulletin ["Managing Medical Devices" DB2006\(05\)](#).

- 10.3 With the exception of surgical instruments, all devices will be recorded on the Trust Asset Register and a label bearing a unique asset ID number will be affixed to the device:



- 10.4 A member of the user department will be required to sign for the receipt of the device and associated user instructions, this form will be retained as part of the devices service record.

10.5 If the device is to be introduced to the user area for the first time then training will be required and will normally be provided by the manufacturer. Only upon satisfactory completion of this training and competency assessment can the device be put into use.

10.6 Reference should be made to the following policies and procedures:

- EME-P-08 Acceptance Testing – Medical Devices (*Appendix 03*)
- [Policy for Training in the Safe Use of Medical Devices.](#)

11. Medical Device Maintenance and Repair

11.1 It is a duty of the Trust to ensure that medical devices are adequately maintained and therefore fit for purpose. The Trust recognises the benefits of providing in-house service support for medical devices via the Electronics & Medical Engineering(EME) Department and Estates Department. These departments are responsible for managing the maintenance and repair of all medical devices throughout their lifecycle, from acceptance testing of new devices to the disposal of redundant devices.

11.2 The Head of EME Services and the Senior Hospital Engineer have delegated responsibility for ensuring that arrangements are in place to provide appropriate servicing regimes for the maintenance/repair of medical devices and that action regarding MHRA Medical Device Alerts, manufacturers' recalls, updates and modifications are carried out when required.

11.3 Some specialist equipment can prove to be more effectively maintained by manufacturers, suppliers or third party agents, in such cases the EME Department or Estates Department, depending upon the type of equipment, will approve maintenance contracts and liaise with users and the Supplies Department to provide the most appropriate cover.

11.4 Reference should be made to the following policies and procedures:

- [Medicines and Healthcare products Regulatory Agency \(MHRA\) device bulletin "Managing Medical Devices" DB2006\(05\)](#)
- [Decontamination of Healthcare Equipment Prior to Service or Repair](#)
- [Decontamination of Bed Space Policy](#)
- [Medical Devices Procurement Policy.](#)

12. Condemnation and Disposal of Medical Devices

12.1 Having established that the Trust has no further use for a medical device, orderly disposal is vital from a financial, data protection and waste management objective.

12.2 Regardless of the method of disposal, medical devices can only be disposed of through the EME Department, Estates Department or Supplies Department; under no circumstances will users dispose of or negotiate the sale of surplus/redundant medical devices.

12.3 Once agreement regarding condemnation and disposal has been reached the Electronics & Medical Engineering Department and the Estates Department, have the authority to issue a "Replacement/Redundant Equipment Report"

(Appendix 04).

- Medical devices EME Department
- Computer hardware IT Department
- Domestic appliances Estates Department
- Beds and Trolleys Estates Department
- Laboratory equipment Dual responsibility.

Dual responsibility means both Estates and Electronics Departments have equal responsibility and both can condemn an item of equipment depending on who maintains that particular item.

12.4 Prior to disposal, the user must ensure the device is clean and a decontamination certificate, which can be obtained from the Estates Department or the EME Department, is completed to accompany the device for disposal.

12.5 Disposal of medical devices will be carried out in compliance with all applicable legislation with regard to waste management. Disposal of medical devices will be subject to the [Waste Electrical and Electronic Equipment \(WEEE\) Directive](#).

12.6 Reference should be made to the following policies and procedures:

- EME-P-09 Disposal of Redundant/Surplus Medical Devices (Appendix 05)
- [Medicines and Healthcare products Regulatory Agency \(MHRA\) device bulletin “Managing Medical Devices” DB2006\(05\)](#)
- [Trust Waste Management Policy](#)
- [Decontamination of Healthcare Equipment Prior to Service or Repair](#).

13. In House Manufacturer / Modification

13.1 Any Trust manufacture/adaptation of a medical device has safety implications and must only be carried out by authorised personnel following consultation with the manufacturer and a full risk assessment.

13.2 Reference should be made to the following policies and procedures:

- [Risk Register – Policy for Management and Use](#).

14. Medical Equipment Loan Library

14.2 A Medical Equipment Loan Library is provided on the RVI and Freeman sites and is responsible for the management of all common use medical devices. The library provides these medical devices for short-term loan, however high risk areas such as Intensive Therapy Units retain an agreed core stock level.

14.3 The Trust Intranet has a Medical Equipment Loan Library Website, which shows the range of equipment available, user instructions, staff contact details and opening times. Equipment can be requested by contacting the relevant Equipment Library (during opening hours) and through the Portering Service out of hours.

14.4 Equipment is cleaned, checked and internal batteries charged prior to issue;

however, it remains the users responsibly to ensure that the device is suitable for its intended use.

14.5 Reference should be made to the following policies and procedures:

- [Medical Equipment Library – Access to Service.](#)

15. Medical Devices on Loan to the Trust

15.1 It is common practice for medical devices to be brought into the Trust on loan, they may be:

- On trial or evaluation
- Provided for research
- To replace devices that are being repaired
- Provided as part of a disposable procurement arrangement
- From other Trusts.

15.2 Medical devices loaned to the Trust are subject to the same risks concerning patient and user safety and must therefore be managed appropriately. The supplier must indemnify any device before it can be used within the Trust.

15.3 All loan devices must be reported to the EME Department, safety tested and included on the Trust loan equipment register before entering into service.

15.4 All loan devices must only be used by staff that are trained in the use of the equipment. If a representative from the supplier is to demonstrate the device then it is assumed that adequate and appropriate training, and where necessary competency assessment, will be provided for the device users. If no representative is to be present then the ward/department managers must satisfy themselves that adequate user instructions are available to allow for the safe use of the device. In case of doubt, the supplier is to be contacted.

15.5 All loaned items being returned to a manufacturer/supplier must be cleaned/decontaminated prior to release.

15.6 Reference should be made to the following policies and procedures:

- EME-P-04 Medical Devices – On Loan (*Appendix 06*)
- [Decontamination of Healthcare Equipment Prior to Service or Repair.](#)
- [Handling of Surgical Instruments On Loan.](#)

16. Accident or Incident Reporting Involving a Medical Device

16.1 The Trust actively supports the promotion of a positive and non punitive approach to incident reporting. The system for reporting accidents and incidents to patients, staff or visitors is clearly written in Trust policy “Management and Reporting of Accidents and Incidents” accessible to all staff via the Trust intranet.

16.2 In order to manage risk effectively and to meet our statutory obligations, it is necessary to ensure that a rigorous system is in place to identify and report all incidents and near misses within the Trust. Errors, incidents and accidents in

all areas of clinical and non-clinical activity can result in serious harm to patients, staff and other personnel as well as to Trust property and reputation. It is, therefore, essential to ensure that all possible steps are taken to minimise the risk of initial incident occurrence and subsequent recurrence.

16.3 Within the policy, clear levels of accountability and responsibility are identified and the Trust operates a non-punitive philosophy whereby staff are encouraged to report incidents and near misses. Accident and Incident Reporting ensures that incidents involving medical devices are promptly recorded and this information along with the evidence of actions taken enables the Trust to identify areas for improvement.

16.4 Any medical device that was involved in an incident should be isolated until either the EME Services Officer – Electronics & Medical Engineering Department or the Senior Hospital Engineer - Estates Department, has reviewed it. Where possible photographs should be taken to support analysis of the incident.

16.5 Where an incident involves a medical device:

- Do not alter any dials or settings
- Record the setting for future reference
- Retain any disposables e.g. giving sets, in a yellow bio-hazard bag within a sealed and clearly labelled clear polythene bag
- Isolate the device in an area where it can not be accessed by staff who may inadvertently put the equipment back into service
- Do not allow the device to be returned to the manufacturer without the clear agreement of either the Electronics & Medical Engineering Department, Estates Department, Health and Safety Department or CGARD.

16.6 Reference should be made to the following policies and procedures:

- [Management and Reporting of Accidents and Incidents](#)
- [Procedure for Incident Investigation](#)
- [Being Open Policy](#).

17. Safety Alert Broadcast System

17.1 The Trust has a nominated SABS Officer, attached to the Clinical Governance and Risk Department (CGARD), who is responsible for the rapid distribution of Hazard Notices, Device Alerts and Safety Notices including those received from the Medicines and Healthcare products Regulatory Agency (MHRA) and other bodies including the National Patients Safety Agency (NPSA).

17.2 The SABS Officer maintains a record of all alerts, monitors and reports on the implementation of necessary action if required and records when required actions are complete.

17.3 Reference should be made to the following publications, policies and procedures:

- [Safety Alert Broadcast System \(SABS\) Policy and Procedure](#)

- MHRA DB2010(01) Reporting Adverse Incidents and Disseminating Medical Device Alerts.

18. Mobile Phones

18.1 Mobile phones should always be switched off on entering Trust premises as they can interfere with the operation of medical devices.

19. Monitoring

19.1 The monitoring of maintenance of medical devices will include planned preventative maintenance (usually in line with manufacturer's recommendations), user maintenance (often simple maintenance undertaken daily or weekly) and breakdown maintenance. This will be reported to the Medical Devices Steering Group in the Annual Medical Devices Management and Maintenance Report.

19.2 The Medical Devices Steering Group will receive a quarterly report from the DATIX risk management system indicating incident trend data relating to medical devices. Where necessary, the Medical Devices Steering Group will monitor actions as a result of analysis of the incident report.

19.3 The Clinical Governance and Quality Committee will receive the minutes of the Medical Devices Steering Group meetings

19.4 Where appropriate medical devices management will be considered for review by the Trust internal auditors, managers and staff will be required to co-operate with reviews conducted by the auditors.

19.5 Point Of Care Testing devices will be monitored annually by circulation of Quality Assurance material for each type of test. Results of this material will be correlated by the POCT Manager and performance reports distributed to users. Consistent poor performance will be reported to the Medical Devices Steering Group.

Author: EME Services Officer

20. Bibliography

Care Quality Commission (2009) "Essential Standards of Quality and Safety".

Department of Health (2004) "Standards for Better Health".

Department of Health (2009) "The Health & Social Care Act 2008 - Code of Practice for Health and Social Care on the Prevention and Control of Infections and related guidance".

Department of Health (2009) "Health Technical Memorandum 01-01: The Decontamination of Reusable Medical Devices".

European Union Commission (1993) "Medical Devices Directive 93/42/EEC".

HMSO (1974) "The Health and Safety at Work Act".

HMSO (1998) "The Provision and Use of Work Equipment Regulations".

HMSO (2006) "The Waste Electrical and Electronic Equipment (WEEE) Directive".

Medical Devices Agency (2000) "Equipped to Care: The safe use of medical devices in the 21st Century".

Medical Devices Agency (2002) "Devices in Practice - A guide for health and social care professionals".

Medical Devices Agency (2002) "SN2002(17): Management of loaned medical devices, equipment or accessories from manufacturers or other hospitals".

Medical Devices Agency (2006) "DB2006(04): Single-use Medical Devices: Implication & Consequences of reuse".

Medicines and Healthcare Products Regulatory Agency (2006) "Bulletin 17 - Medical Devices and Medicinal Products".

Medicines and Healthcare Products Regulatory Agency (2006) "DB2006(05): Management of Medical Devices".

Medicines and Healthcare Products Regulatory Agency (2010) "DB2010(01): Reporting Adverse Incidents and Disseminating Medical Device Alerts".

NHS Litigation Authority (2007) "Risk Management Standards for Acute Trusts".

Medical Devices Steering Group

Terms of Reference

Purpose

The Medical Devices Steering Group will be an official sub committee of the Clinical Governance and Quality Committee. It will oversee the development and implementation of the Trusts' Medical Devices management systems.

The Medical Devices Steering Group and will be responsible for ensuring the trust meets the requirements of the Care Quality Committee's standards, NHS Litigation Authority (NHS LA) and Medicines and Healthcare products Regulatory Agency (MHRA) requirements for medical devices.

Terms of Reference

The establishment of a Medical Devices Steering Group will improve communication on medical device issues within the Trust.

The Medical Devices Steering Group will identify and implement strategies as required to meet the standards on medical devices set by the MHRA, Care Quality Commission and the NHS LA.

The Medical Devices Steering Group will ensure that the Trust's medical devices management arrangements conform to current legislation and guidance.

The Medical Devices Steering Group will monitor the training and education of staff in medical devices, and medical device issues.

The Medical Devices Steering Group will identify areas of best practice – both within and outside the Trust - and seek their wider implementation across the service; this will encourage improvements in working practices, thereby reducing risk to patients.

The Medical Devices Steering Group will meet bi-monthly or more frequently if deemed necessary by the group.

Initially a Trust Management representative will chair the Medical Devices Steering Group.

Three members of the group will constitute a quorum. Deputies may be appointed to represent members who are unable to attend.

Other Trust staff may be co-opted onto the group when necessary, or may be asked to provide expert advice and help on specific issues that may arise.

The Medical Devices Steering Group will submit minutes and action plans to the Clinical Governance and Quality Committee.

The terms of reference will be reviewed annually in order to monitor the performance and effectiveness of the group.

Common Categories of Medical Device

(Extract from the MHRA's guidance '[Equipped to Care](#)')

The list below is not comprehensive but gives a sense of the wide range of products that are considered medical devices.

Equipment used for diagnosis or treatment of disease, or monitoring of patients, such as:

- Syringes and needles
- Dressings
- Catheters (urinary, cardiac)
- Surgical instruments
- Endoscopes
- IV administration sets and pumps
- Patient monitoring equipment, e.g. Cardiac monitors
- Anaesthetic equipment
- Surgical implants, e.g. orthopaedic prostheses, bone cements, heart valves
- Power implants, e.g. pacemakers, implantable defibrillators
- Ultrasound imagers and CT / MR scanners
- Radiotherapy equipment
- Dental equipment and materials
- Ophthalmic equipment
- Chiropody equipment
- Sphygmomanometers
- Thermometers
- Physiotherapy equipment
- Beds, mattresses and covers
- Examination gloves

Equipment used in life support, such as:

- Ventilators
- Defibrillators

In vitro diagnostic medical devices and their accessories, such as:

- Blood gas analysers
- Blood glucose measuring devices
- Hepatitis and HIV test kits
- Urine test strips
- Pregnancy test kits
- Specimen collection tubes

Equipment used in the care of disabled people, such as:

- External prostheses and orthoses
- Wheelchairs and associated postural seating
- Patient hoists
- Walking aids
- Pressure relief equipment

Aids to daily living, such as:

- Commodes
- Hearing aids
- Urine drainage systems
- Domiciliary oxygen therapy systems
- Incontinence pads
- Prescribable footwear

Equipment used by ambulance services, but not the vehicles themselves, such as:

- Stretchers and trolleys
- Resuscitators

Other examples of medical device include:

- Condoms
- Contact lenses and care products
- Intra-uterine devices (IUDs)

The MHRA are also interested in products which, whilst not themselves medical devices, are used in close conjunction with these devices, e.g.:

- Centrifuges
- Blood tissue storage systems
- Fluid warming cabinets
- Disinfecting and sterilising equipment, e.g. bench top sterilisers

**ELECTRONICS & MEDICAL ENGINEERING DEPARTMENT
PROCEDURE EME-P-08
ACCEPTANCE TESTING - MEDICAL DEVICES**

1. Introduction

The Electronics & Medical Engineering Department has a duty to ensure that new medical devices are processed in accordance with MHRA device bulletin DB2006(05) "Managing Medical Devices." Devices should be delivered to the end user fully documented, labelled and in safe working order. This procedure details the tests and documentation prior to the equipment's delivery to the user department.

2. Equipment process

New equipment is delivered to the Electronics Department from the hospital Main Store. It may be necessary to arrange to have large items taken directly to the user department where the acceptance process will take place. The equipment will be unpacked, examined for transit damage and checked against the delivery note and purchase order. The goods should be booked into the Supplies Department good receipt system and the purchase order is attached to the Field Service Report and filed "awaiting manpower". Any discrepancies or damage must be reported to the supplier immediately and goods will be placed in "quarantine" until all outstanding issues have been resolved.

3. Testing and documentation

In some circumstances, as part of the purchase agreement, a representative of the supplier can commission the equipment. Where no provision has been made for a company representative to commission the new equipment, the EME technician carrying out the acceptance tests will:

- Check that what was ordered has been received, and is complete
- Check boxes and goods for physical damage
- Check all accessories are intact and complete
- Assemble the equipment
- Ensure the mains voltage setting is correct
- Fit a mains plug if necessary
- Carry out an electrical safety check
- Carry out any relevant equipment type specific checks
- Calibrate the equipment as required
- Carry out functional checks
- Ensure the equipment is delivered to the end user with the controls set to default values for the intended application
- Enter the equipment details on the EME Equipment Management System
- Ensure the equipment details are entered on the WIMS asset database
- Fix an asset label to the equipment
- Fix new equipment label (ref: EME-L-03)
- Deliver the equipment and user manuals to the user and obtain a signature of receipt on the Field Service Report (ref: EME-F-30)
- Log any maintenance manuals or users instructions in accordance with procedure EME-P-11
- EME Services Officer should be made aware of all new equipment. It may be necessary to organise service training, service manuals, in house or manufacturer's preventative maintenance programmes

THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST



REPLACEMENT / REDUNDANT EQUIPMENT REPORT

HOSP NAME:	DEL REF: RVI 06102
DEPARTMENT:	DEL DATE:
	TO:
COMMENTS:	FROM:

PART A - DETAILS OF ITEM TO BE REMOVED FROM SERVICE

DESCRIPTION:	ASSET:
MODEL:	SERIAL NO:
MANUFACTURER:	INTO SERVICE DATE:

THE ABOVE EQUIPMENT IS TO BE REMOVED FROM SERVICE :-

- Beyond economic repair
- Physically damaged beyond repair
- Unreliable
- Clinically or technically obsolete
- Spare parts are no longer available

SUPPORTING INFORMATION

AUTHORISED.....

PART B - TO BE COMPLETED BY DEPARTMENT EQUIPMENT OFFICER

WILL THE ABOVE ITEM BE REPLACED? YES / NO

Authorised Signature.....Print.....

Designation.....Date.....

IF YES USE THIS FORM TO SUPPORT REQUISITION FOR REPLACEMENT EQUIPMENT. DEPARTMENT HEADS ARE REMINDED THAT A CAP3 FORM MUST BE SUBMITTED BEFORE CAPITAL EQUIPMENT CAN BE DELETED FROM THE ASSET REGISTER!

PART C - CAPITAL/REVENUE ASSET ADMINISTRATION

- | | |
|-------------------------------------------------------|------------------------------------------------------|
| <input type="checkbox"/> Capital Asset | <input type="checkbox"/> Revenue Asset |
| <input type="checkbox"/> Copy to user with CAP 3 form | <input type="checkbox"/> Copy to user |
| <input type="checkbox"/> Copy to Asset Manager | <input type="checkbox"/> Deleted from Asset database |

CAPITAL ASSET AUTHORISATION.....

PART D - METHOD OF DISPOSAL

- Be offered for sale or disposed of by the Supplies Department
- Be used by the Electronics Department for spare parts
- Be scrapped by the Electronics Department
- Remain in service whilst a replacement is purchased (maximum 6 months)
- Other:- _____

THE ABOVE ITEM HAS BEEN MADE SAFE FOR RETENTION/DISPOSAL

SIGNED.....PRINT.....DATE.....

**ELECTRONICS & MEDICAL ENGINEERING DEPARTMENT
PROCEDURE EME-P-09
DISPOSAL OF REDUNDANT/SURPLUS MEDICAL DEVICES**

1. Introduction

Medical devices that are considered beyond economic repair, redundant or surplus to the user requirement will be disposed of, or redistributed in an organised and safe manner. All such devices should be processed through the Electronics & Medical Engineering Department in accordance with EME-P-13 Field Service Report procedure.

2. Equipment Beyond Economic Repair

All equipment considered to be beyond economic repair should be assessed; taking into account age, general condition, cost of repair, cost of replacement, recommendations from suppliers and the impact of MHRA guidance. A Redundant/Replacement Equipment Report (ref: EME-F-08) should be produced via the asset register and obsolete manuals will be withdrawn from use, and the manuals register updated as appropriate.

3. Redundant/Surplus Equipment

Equipment that is no longer of use to the Trust may have a value to other organisations and will be offered for auction via a Trust appointed auction house. In such cases the Trust Supplies Manager should be notified in writing of the equipment for sale. EME Services Officers will be notified by the Supplies Department if/when the equipment has been sold.

4. Administration

A Redundant/Replacement Equipment report is required for all medical devices that are to be removed from the Trust asset register. The form will be authorised by a Deputy EME Services Officer and the ward/department manager.

For a revenue asset a copy of the form will be sent to the asset register team who will delete the asset from the Trust asset register.

The disposal of a capital asset must be authorised by the EME Services Officer, who will countersign the report. A complete CAP 3 form must accompany the Redundant/Replacement Equipment Report and a copy of both forms will be sent to the asset register team.

The asset team will be responsible for deleting the asset from the asset register.

The Deputy EME Services Officer will determine the most appropriate method of disposal and ensure the Redundant/Replacement Equipment Report is completed accordingly and signed by the technician responsible for ensuring the actions below.

The EME Services Officer will be responsible for keeping a signed original copy of the report.

5. Preparing Equipment for Disposal

The following precautions must be taken by the user before devices can be

disposed of:

- remove all hazardous substances including chemical solutions, body fluids and radioactive isotopes. These should be disposed in accordance with Trust, local authority and COSHH regulations
- decontaminate the equipment and complete a decontamination form.

The following precautions must be taken by the Electronics & Medical Engineering Department before devices can be disposed of:

- remove all hazardous substances including oil, batteries and glassware. These should be disposed in accordance with Trust, local authority and COSHH regulations
- remove all asset labels
- hard disks **must** be wiped of all patient data or physically damaged beyond repair
- scrap equipment must be rendered useless to prevent unauthorised persons attempting to bring back to use
- equipment will be clearly labelled with the Redundant/Replacement Equipment Report reference number, date and any other relevant information.

The Electronics & Medical Engineering Department is responsible for disposing of equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive and all local authority and COSHH regulation.

Date: December 2010

**ELECTRONICS & MEDICAL ENGINEERING DEPARTMENT
PROCEDURE REF: EME-P-04
MEDICAL DEVICES - ON LOAN**

1. Introduction

It is common practice for medical devices to be brought into the Trust on loan, they may be:

- On trial or evaluation
- Provided for research
- To replace devices that are being repaired
- Provided as part of a disposable procurement arrangement
- From other Trusts

Medical devices loaned to the Trust are subject to the same risks concerning patient and user safety and must therefore be managed appropriately.

2. Related documents

1. Standard Form of Indemnity (ref: EME-F-04)
2. Loan Equipment Label (ref: EME-L-01)
3. Register of Suppliers holding Master Indemnity Agreements

3. General procedure

All loan equipment should be delivered (preferably by the company representative) to the Electronics & Medical Engineering Department for checking and documentation prior to entering service. It may be necessary for some equipment that requires assembly at the point of use to be checked in the user department.

Details of the loan equipment and supplier will be entered on the Loan Equipment Register and the equipment will be allocated a reference number.

Electronics Department staff will check the equipment for electrical safety and if satisfactory a Loan Equipment Label will be attached.

The company representative will be asked to complete and sign a Standard Form of Indemnity and the Deputy EME Services Officer will sign on behalf of the Trust. This form will not be necessary if the supplier is on the Register of Suppliers holding Master Indemnity Agreements via PASA.

Every effort should be made to get indemnity cover; if this is not forthcoming, the equipment should not be allowed to enter service.

The Electronics & Medical Engineering Department must be informed when the device is returned to the supplier and the date of removal must be recorded on the Loan Equipment Register.

Date: December 2010

**THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
IMPACT ASSESSMENT – SCREENING FORM A**

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:		Policy Author:	
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems.	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4(a).	Is the impact of the policy/guidance likely to be negative? <i>(If “yes”, please answer sections 4(b) to 4(d)).</i>	No	
4(b).	If so can the impact be avoided?		
4(c).	What alternatives are there to achieving the policy/guidance without the impact?		
4(d).	Can we reduce the impact by taking different action?		

Comments:	Action Plan due (or Not Applicable): N/A
------------------	--------------------------------------------------------

Name and Designation of Person responsible for completion of this form: J.P. Stephenson.....

Date: 15 March 2010

Names & Designations of those involved in the impact assessment screening process: J.P. Stephenson - EME Services Officer, RVI D.Crawford – EME Services Officer, FH.....

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)