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Management of Medical Devices Policy

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Associated Documentation:

Medical Equipment Department - Standard Operating Procedures;

- Commissioning of Medical Devices
- Decommissioning of Medical Devices
- Medical Devices for Service or Repair
- Management of Stores
- Managing Medical Devices Subject to Investigation (joint with A&E Operations)
- Loaning, Trialling Equipment - NHS Indemnity Scheme
- Lifepak 15 Battery Management (joint with A&E Operations)
- Medical Devices Exchange Process
- Decontamination of Medical Devices (joint with A&E Operations)
- MED Risk Management
- MED Responding to CAS Medical Device Alerts & Field Safety Notices
- Lifting and Handling Devices for Service or Repair
- Incident and Serious Incident Policy

Risk Management and Assurance Strategy
Risk Management Procedures
Decontamination of Vehicles and Equipment Procedure
Waste Disposal Policy
Statutory and Mandatory Training Policy & Procedure
Policy for Staff Training on Pre-hospital Diagnostic and Therapeutic Equipment
Health and Safety Policy

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Staff Summary

This policy is part of the Trust's internal control system and aims to mitigate the risks associated with the management of medical devices. Effective implementation of this policy and associated procedures will greatly assist in providing quality patient care and in reducing the potential for harm.
Prior to the purchase of any medical device, the Trust considers the requirements for its intended use and needs of the patients. The primary group tasked with this responsibility is the Trust Procurement Group. All purchases will conform with the Trust Procurement Policy
To reduce the possibility of inappropriate devices being purchased the Medical Equipment Department (MED) will complete a full performance specification of the entire system before any purchases are made.
Finding out that a medical device is broken or inappropriate, only when someone tries to use it for the first time, can delay or interrupt treatment. To mitigate the risk of this happening, the MED make a number of checks on delivery of the medical device.
All medical devices on loan from manufacturers will be subject to a written agreement which defines the device management requirements, responsibilities and liabilities, and will be managed in accordance with the NHS Master Indemnity Agreement.
The Trust recognises that good record keeping is essential for the safe management of medical devices. Records will include detail of the initial order, the results of the delivery inspection, and any safety or functional tests, including who carried these out, when and how.
To ensure safe and effective use of medical devices, staff are provided with training as appropriate and clear manufacturer instructions will accompany each medical device on deployment.
Medical devices requiring repair should be withdrawn from service as soon as possible and replaced. The MED should be contacted to facilitate the necessary repairs or disposal, as appropriate. Repairs should only be undertaken by a competent MED Engineer.
Items subject to inspection, maintenance, repair or disposal, should be decontaminated beforehand. Any loaned items being returned to a manufacturer or supplier should also be decontaminated.
Reporting is essential to ensure that lessons are learnt and adverse events are not repeated. National reporting is essential to ensure that trends are spotted and appropriate action is taken across the country to help ensure the safe and effective use of medical devices.

1.0 Introduction

1.1 Medical devices utilised by the Trust play a key role in patient management, providing an aid to diagnosis, monitoring of patient observations, patient handling and definitive care. This policy and associated procedures outline a systematic approach to the acquisition, deployment, maintenance, repair and disposal of medical devices, and describe the support processes required to safely manage medical devices.

2.0 Purpose/Scope

2.1 The Management of Medical Devices Policy and associated Standard Operating Procedures (SOPs) are designed to provide structure and clarity around the processes for safely and effectively managing medical devices utilised by the Trust. It is intended primarily for staff working in the Medical Equipment Department (MED) that are responsible for the management of reusable medical devices, to help them set up and develop systems that promote the use of the medical devices for safe and effective health care. The Policy is also intended for all those who use medical devices as part of their operational role.

2.2 This policy is part of the Trust's internal control system and provides assurance to the Board that robust procedures are in place to mitigate the risks associated with the management of medical devices. The Trust aims to manage this important resource through effective management, to enable the delivery of quality patient care, clinical and financial governance, including minimising the risks of adverse events. Effective implementation of this policy and associated procedures will greatly assist in providing quality patient care and in reducing the potential for harm.

3.0 Process

3.1 Acquisition

The Trust manages the acquisition of medical devices through the production and implementation of a 5 year investment and replacement plan. This plan includes a prioritised schedule of all short to long term medical device requirements and is monitored against appropriate risk assessment criteria.

In acquiring medical devices the Trust takes account of;

- Safety, quality and performance
- Core objectives, Trust priorities and the needs of patients
- Whole life costs
- The needs and reasonable preferences of all interested parties, including those involved in use, commissioning, decontamination, maintenance and decommissioning
- Consumables are cost effective for the life of the device, if applicable

The Trust recognises that it could be held responsible, under health and safety law and civil liability in the event that a patient or member of staff died or suffered personal injury or damage, as a result of the inappropriate purchase of a medical device.

3.1.1 Methods of acquisition

In addition to purchasing and leasing, which are the most common methods of acquisition, the Trust may also acquire medical devices through loans from manufacturers, as part of a trial or evaluation of a medical device. All devices on loan from manufacturers will be subject to a written agreement which will define the device management requirements, responsibilities and liabilities. In all cases, the agreement will make it clear from the outset who is responsible should a problem arise.

3.1.2 Factors to consider before acquisition

Prior to the purchase of any medical device, the Trust considers the requirements for its intended use and needs of the patients. The primary group tasked with this responsibility is the Trust Procurement Group (TPG), who on considering the procurement of any medical device will take account of;

- Suitability for intended purpose/application by reviewing the manufacturer's description of the intended user, usage and the instructions for use, safety and performance information
- Safety issues and any limitations on use
- Software compatibility with archive systems, as appropriate
- Electronic medical devices which process data needs to be secure; the medical device is validated, as appropriate
- Ease of use
- Has it been designed to minimise accidental misuse?
- Evaluate and assess the readability of manufacturer's instructions
- Training requirements. Availability, type and scope of training
- What advice services does the supplier offer and/or what user-help guides
- Ensuring the operating/environmental conditions of the place where the device will be used are compatible with those of the device
- Decontamination and disposal procedures
- Pre-use set up, testing and installation requirements, as appropriate
- The projected service life of the device and warranty details
- Whole life costs: acquisition and operational, maintenance and consumable, training, renewal and disposal costs
- Maintenance requirements; the user and planned maintenance recommendations for the device (including frequency and type).
- Periodic performance checks which may require specialist test equipment
- Costs associated with medical devices to be stored, maintained and serviced in line with the manufacturer's instructions for use
- Reliability and previous performance. Is there any local knowledge or past history of problems with the device or type of device

3.2 Selection

3.2.1 Factors to consider before accepting new devices

Prior to selecting new medical devices, the Trust considers the requirements for its introduction in operational service. Members of the TPG, with specialist responsibilities, will identify:

- Whether risks associated with using a particular model for the first time have been minimised
- Education and development requirements, including training of end users and maintenance staff.
- Appropriate planned preventive maintenance and performance checks
- Technical support needs of users
- CE marking requirements
- Medicines and Healthcare Products Regulatory Agency (MHRA) safety publications, manufacturer's advisory notices or other relevant publications identifying issues related to the selected device.
- The financial impact on consumable/single use items associated with any new product

3.2.2 Maintenance support services

The Trust ensures that medical devices are regularly checked for functionality prior to use, by the implementation of operational vehicle and equipment checks at the start of each shift.

It is anticipated that during the equipment checking process faults may be identified, and it is also recognised that medical devices will be subject to service maintenance schedules. In selecting medical devices consideration will be given to;

- Are alternative devices available to cover periods when a device is being repaired or serviced?
- What are the proposed servicing intervals?
- Are calibrations required between servicing intervals?
- Are spares readily available, and for how long?
- Is service support guaranteed, and for how long?
- What information is available from the device manufacturer, e.g. circuit diagrams, preventive maintenance schedules, trouble-shooting guides, repair procedures, parts list, and special tools list?

3.2.3 Evaluation

Periodically the Trust will evaluate medical devices that are new or alternative to those that it currently operates. The TPG manage the evaluation process taking account of the factors listed under sections 3.2.1 and 3.2.2. Additional personnel will be included in the evaluation process, as required by the TPG, and tools, such as; questionnaires, scoring matrices and independent reports will used by the Group to facilitate the process.

Medical devices are evaluated in the operational environment and business area of intended use. This will only take place provided that the Trust and the manufacturer/supplier are completely satisfied that the end-user is competent in the operation of the device. Should an issue arise during the evaluation period that could

lead to potential harm, the trial would be stopped immediately.

On completion of the evaluation process the Chair of the TPG will submit a report to the Trust executive, as appropriate, with either a proposal to continue with the procurement process, or reasons why the medical device would not be suitable for procurement.

3.2.4 Documentation

To reduce the possibility of inappropriate devices being purchased the Medical Equipment Department (MED) will complete a full performance specification of the entire system before any purchases are made. For example, with a battery powered device this must incorporate all elements, such as: battery type, charger type, charging process, maintenance and use.

Once the selection process has identified the most suitable medical device, then the final terms and conditions covering all aspects of the acquisition are agreed by all interested parties and documented. Only then will the contract be awarded, the purchase order raised and cleared to proceed. The acquisition will then be managed in accordance with the terms and conditions agreed.

3.3 Acceptance

3.3.1 Delivery Checks

Finding out that a medical device is broken or inappropriate, only when someone tries to use it for the first time, can delay or interrupt treatment, make it harder to establish when and where the problem arose and invalidate warranties. To mitigate the risk of this happening, the MED make a number of checks on delivery of the medical device, which include:

- Checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied
- The specification of newly delivered medical devices matches the purchase order detail or tender specification
- Ensuring that devices have been delivered in good condition and in good working order
- The manufacturer's instructions may specify particular testing, calibration or adjustment before a medical device is used for the first time.

3.3.2 Safety and Calibration Checks

Particular medical devices require calibration as an integral part of their scheduled maintenance programme. These include the following devices; manual defibrillator/monitors, aneroid and blood glucose monitors. Manufacturer's service intervals and procedures will be used and for electrical safety testing then guidance issued by the MHRA will be adopted.

Practical implementation of this aspect of the process is detailed in a supporting *Medical Devices for Service or Repair SOP.* This document includes basic guidance on what checks and tests should cover, and the skills required to carry them out, which are dependent on device type.

3.3.3 Devices on loan from manufacturers

All medical devices on loan from manufacturers will be subject to a written agreement which defines the device management requirements, responsibilities and liabilities. Delivery receipt and pre-use procedures for medical devices on loan should be the same as those for purchased medical devices, unless otherwise specified in this written agreement. The Trust process will be managed in accordance with the NHS Master Indemnity Agreement.

Practical implementation of this aspect of the process is detailed in a supporting *Loaning and Trialling Medical Devices SOP*

3.3.4 Legal requirements in relation to electrical safety testing

The Electricity at Work Regulations (EWR) 1989 and the Health and Safety at Work Act (HASAWA) 1974 form the basis of programmes used by MED engineering staff for the regular electrical testing or inspection of portable electrical equipment.

The HASAWA imposes a duty on employers for:

- The provision and maintenance of plant and systems of work that are so far as is reasonably practicable, safe and without risks to health
- The provision of such information, instruction, training and supervision, as necessary.

The Electricity at Work Regulations state:

- No electrical equipment shall be put into use where its strength and capability may be exceeded in such a way as may give rise to danger
- All systems shall be maintained so as to prevent, as far as is reasonably practicable, such danger.

There is no specific legal obligation, or even guidance, requiring the Trust to carry out any particular test, however; there is a general duty to take necessary steps to protect staff and patients from danger. The Trust will implement electrical safety schedules to comply with this legislation, as appropriate.

Risk assessments will be completed within the department, led by the MED Manager, to ensure that the tests carried out are appropriate or reasonably practical. These will include pre-use testing of new devices in addition to subsequent maintenance tests.

Practical implementation of this aspect of the process is detailed in the supporting *Commissioning of Medical Devices SOP*, and in regard to risk assessments, in the supporting *MED Risk Management SOP*.

Electronic medical devices should be tested against the specific type standard in regulations IEC 60601-1 and IEC 62353 where appropriate.

3.3.5 Re-usable medical device modification

Under no circumstances must a medical device be modified or altered in any way by unauthorised personnel or without prior consent of the manufacturer. No device component of any description must be adjusted, adapted, occluded, re-sited or upgraded without written authorisation.

3.4 Records

Electronic records relating to Trust medical devices are retained within a centralised data management system, located within the MED. During the process of service or repair of medical devices, MED Engineers will generate electronic job cards. These records are also retained within the MED database management system. Practical implementation of this aspect of the process is detailed in the supporting *Medical Devices for Service or Repair SOP*.

Records will include any specific guidance provided in the manufacturer's instructions and supporting information, and include detail of the initial order, the results of the delivery inspection, and any safety or functional tests, including who carried these out, when and how.

The Trust medical device records will also provide evidence of:

- A unique identifier for the device, where appropriate
- The purchase price of the equipment
- A full history, including date of purchase and where appropriate when it was put into use, deployed or installed
- Any specific legal requirements and whether these have been met
- Details of installation and/or where it was deployed
- Risk based maintenance schedule
- Details of service and repairs
- End-of-life date, as appropriate.

Storage procedures will ensure that accurate and complete copies of records, in electronic format, will be made available throughout the retention period of the records for future reference, including; for traceability, for review, inspections, internal audits and investigations. The retention period of records will be in accordance with the Department of Health guidance; *Records Management: NHS Code of Practice 2006.*

3.5 Equipment deployment

Medical devices are primarily deployed within the A&E Operations, Patient Transport Services and on occasions to the Education & Development Department. People working within these areas have primary responsibility for the way in which medical devices are treated and cared for. These responsibilities can also include performance checks before use and routine maintenance, such as charging batteries. Practical implementation of this aspect of the process is detailed in the supporting *A&E Operations SOP.*

To ensure safe and effective use of medical devices, staff are provided with training as appropriate and clear manufacturer instructions will accompany each medical device on deployment. The instructions include all of the necessary information on storage, pre-use checks, use, maintenance and cleaning, and are retained in the document library on the Trust intranet and in hard copy on training premises. The MED Manager will ensure that when manufacturers update their information the document library will be updated and hard copies will be disseminated to training managers, who will facilitate the replacement of existing instructions with revised versions.

The MED will also issue, when required, additional information, such as; contact details for maintenance, consumables or spare parts etc.

3.6 Tracking and traceability of medical devices

Each medical device has a serial number unique identifier which is applied to the device in the form of a label. Each device also has a unique asset tag applied in the form of a label. When a device is allocated to a vehicle, station or personal issue, a location label is applied. Identification details of all medical devices are logged in the MED data management system for reference and to facilitate location when required.

3.7 Maintenance

The Trust is responsible for ensuring that medical devices are maintained appropriately. This includes:

How each device should be maintained, and by whom

- Arrangements for the most suitable persons/providers to carry out the work
- Arrangements to ensure items subject to inspection, maintenance, or disposal are decontaminated beforehand
- The timescales for planned maintenance
- The maintenance database is validated for its intended use and functionality.

The frequency and type of planned preventive maintenance is specified in risk based MED maintenance schedules, which are in accordance with the manufacturer's instructions, and take account of expected usage and the operational working environment.

Trust medical devices are primarily maintained by the MED engineering staff. When demand to maintain medical devices exceeds the resource available to do so within specified maintenance schedules, consideration is given to seeking support from third party service providers, such as; the manufacturer's or other healthcare organisations under contract to provide such support.

A service label is attached to each medical device detailing the next service due date. The service intervals are determined by the MED Manager, taking account of manufacturer's instructions, operating guidelines and risk assessments where applicable.

Staff authorised to use medical devices should ensure that the device continues to function correctly. This entails regular inspection and care, as recommended in the manufacturer's user information and local procedures. Instructions for user maintenance of medical devices will include:

- Checking that it is working correctly before use
- Regular cleaning
- Specific daily/weekly checks
- Noting when it has stopped working properly or when obvious damage has occurred. (In these circumstances discontinue use of the device)
- Reporting faults and damage to the MED.

Minor changes that do not affect the safe working of the device can be recorded for attention during scheduled maintenance sessions.

Practical implementation of this aspect of the process is detailed in the supporting *Medical Devices for Service or Repair SOP.*

3.8 Repair

Even with comprehensive maintenance schedules, breakdowns may still occur.

The Trust is responsible for ensuring that medical devices are repaired appropriately. This includes:

- How each device should be repaired, and by whom
- Arrangements for the most suitable persons/providers to carry out the work
- Arrangements to ensure items subject to repair should be decontaminated beforehand
- The timescale for repairs to be completed
- Arrangements for substituting item for repair with a similar device, as appropriate
- Arrangements for repairs outside of normal working hours.

Medical devices requiring repair should be withdrawn from service as soon as possible and replaced. The MED should be contacted to facilitate the necessary repairs or disposal, as appropriate. Repairs should only be undertaken by a competent MED Engineer.

Particular types of medical devices are covered by specific legislation and this may affect their maintenance requirements. Reference is made throughout this policy to the relevant legislation. The Trust ensures that it, or a third party provider, has adequate insurance or indemnity in place.

Practical implementation of this aspect of the process is detailed in the supporting *Medical Devices for Service or Repair SOP.*

3.9 Decontamination

The Trust aims to keep patients, staff and visitors safe, and have systems with supporting procedural documents in place to ensure that all reusable medical devices are properly decontaminated prior to use or maintenance, and that the risks associated with decontamination facilities and processes are well managed.

Items subject to inspection, maintenance, repair or disposal, should be decontaminated, as required, beforehand. Any loaned items being returned to a manufacturer or supplier should also be decontaminated. Once decontamination has been completed, the items should be labelled accordingly and a declaration of contamination status form completed. In all aspects of this process the Trust will adhere to the legislation and guidance detailed in section 7 ‘References’.

Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the manufacturer for investigation.

Practical implementation of this aspect of the process is detailed in the supporting A&E *Operations and MED Decontamination of Medical Devices SOP.* Reference should also be made to the Trust *Decontamination of Vehicles and Equipment Procedure.*

3.10 Single use medical devices

Wherever possible the Trust will seek to utilise single-use medical devices throughout its clinical operations in order to minimise the risk of infection. The waste disposal of single-use medical devices is the responsibility of the end-user and must be conducted in accordance with the Trust's *Waste Disposal Policy*. It is the responsibility of the end-user to ensure that single-use medical devices are not re-used.

Single-use medical devices may only be re-used for training or demonstration purposes in conjunction with a manikin or other simulated training aid at the discretion of Education and Development department training staff.

3.11 Decommissioning

At the end of their scheduled life expectancy, all medical devices will need to be replaced. The expected life cycle of a medical device is held in the equipment inventory records, which is regularly reviewed against the usage, maintenance and repair records, to determine if the end of life date needs to be adjusted.

A manufacturer's recall of a device will take precedence over other considerations.

3.11.1 Preparation

Medical devices deemed unfit for use by an MED Engineer should be decommissioned. The Trust decommissioning process aims to make medical devices safe and unusable, including decontamination, as appropriate. This is to ensure that an inappropriate person does not use the device and expose themselves and/or others to hazards.

Where necessary the MED Engineers will contact the manufacturer for information on any environmental, disposal, recycling or structural requirements. If the manufacturer has ceased trading, the MHRA should be contacted for further guidance.

3.11.2 Erasing stored data

If a medical device stores patient identifiable data, this should be certified as securely erased before disposal. Data on any device should be forensically unrecoverable, i.e. patient data must be over-written. In all aspects of this process the Trust will adhere to the legislation and guidance detailed in section 7 'References'.

3.11.3 Items for sale or donation

There is no legislation which specifically covers the resale or reuse of medical devices or equipment. However, used medical devices are still required to be safe under other national provisions, including:

- Consumer Protection Act (Consumer Safety and Product Liability)
- Sale and Supply of Goods Act
- Health and Safety at Work Act
- Trade Descriptions Act
- Waste Electrical and Electronic Equipment Regulations 2013
- Electrical Equipment (Safety) Regulations 1994
- Unfair Contract Terms Act.

The Trust will only consider sale of medical devices to auctioneers. A waiver of liability will be required from the auctioneers prior to the sale of any medical device.

3.11.4 Liability issues

Before the sale or transfer of ownership of medical devices, both parties should be clear about their legal liabilities. Under requirement 13b of the Medical Devices Directive (MDD) 93/42/EEC, the Trust has a responsibility to provide; 'all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times'. This information should be available for a prospective purchaser to view before sale and be supplied with the device on its completion.

3.11.5 Disposal

Some waste products need specialised disposal. Examples include:

- Wastes containing certain metals (e.g. mercury above 3%, some batteries)
- Oil wastes (including polychlorinated biphenyls – PCBs)
- Wastes from coolants
- Radioactive waste
- Healthcare wastes from human or animal origin
- Human waste from natal care, diagnosis, treatment or prevention of disease.

When disposing of medical devices, the MED will liaise with other specialists within the Trust, as appropriate to ensure safe disposal and adherence to legislation. MED Engineers will also contact the manufacturer, who should be able to provide details of the current waste disposal techniques and processes applicable to their products.

3.11.6 Transport of medical devices before disposal

When returning medical devices to the manufacturer at end of life, or when transporting devices, MED Engineers will ensure that they are appropriately packaged and secured. They will adhere to the legislation that applies to the transport of goods by road and rail:

- The Carriage of Dangerous Goods by Road Regulations
- The Carriage of Dangerous Goods by Rail Regulations
- Chemicals (Hazard Information and Packaging for supply) Regulations

Practical implementation of the decommissioning process is detailed in the supporting *Decommissioning of Medical Devices SOP.*

3.12 Risk management

3.12.1 Adverse incident reporting

Operational staff are expected to report all adverse incidents relating to a medical device including; user problems with a medical device, software failures, or problems with the instructions for use, in accordance with the Trust *Risk Management Procedures.*

Adverse incidents and near-miss incidents are reported through the Trust risk management data system, which is monitored and managed by the Safety Team. For all incidents relating to medical devices the Safety Team will liaise with the MED Medical Device Safety Officer (MDSO). The MDSO is situated in the MED Workshops, Unit M and can be contacted on 01924 584526 / yas.equipment@nhs.net.

For the effective management of adverse incidents involving medical devices, in support of this policy, the Trust also has in place;

- Clear lines of accountability through the Trust and leading to the Trust Board
- A Trust Procurement Group, with representation from across the Trust, including operational and engineering staff, management and specialists
- A data management system which records the location of medical devices, maintenance schedules, repair and other associated data
- Mechanisms to distribute manufacturer's Field Safety Notices, MHRA Medical Device Alerts, other MHRA safety guidance to the appropriate people in the Trust, and to report incidents to external regulators

Reporting is essential to ensure that lessons are learnt and adverse events are not repeated. National reporting is essential to ensure that trends are spotted and appropriate action is taken across the country to help ensure the safe and effective use of medical devices.

The Safety Team report all adverse incidents involving medical devices to the MHRA which receives reports of all adverse incidents across the country. This enables the MHRA to identify emerging problems, reducing the risk of repeat incidents and patient harm.

The Trust *Risk Management Procedures / Incident and Serious Incident Policy* describe the process for the escalation of incidents to serious incidents. For all serious incidents involving medical devices reference should be made to the *A&E Operations and MED Managing Medical Devices Subject to Investigation SOP.*

3.12.2 Patient Safety Alerts and Field Safety Notices

Patient safety alerts are a crucial part of NHS England's work to rapidly alert the healthcare system to risks and provide guidance on preventing potential incidents that may lead to harm or death. These incidents are identified using a reporting system to spot emerging patterns at a national level, so that appropriate guidance can be developed and issued to protect patients from harm.

Patient safety alerts specific to medical devices are published as Medical Devices Alerts (MDA's), which are the prime means of communicating safety information to the Trust and other healthcare organisations on medical devices.

MDA's are issued via the Central Alerting System (CAS), a web-based cascading system for issuing alerts, important public health messages and other safety critical information and guidance.

A Field Safety Notices (FSN) is a communication sent by medical device manufacturers, or their representatives, in connection with a Field Safety Corrective Action (FSCA). FSNs outline actions to be taken to reduce the risk of death or serious injuries associated with the use of medical devices, and are used by manufacturers to tell their customers about them.

The Safety Team manage the process for responding to MDA's and FSN's in liaison with the MDSO. MDA's and FSN's are tabled at the TPG meetings and presented by the MDSO who is a member of the Group.

The practical application of this process is detailed in the supporting *MED Responding to CAS Medical Device Alerts & Field Safety Notices SOP*.

3.12.3 Risk Assessments

The MED management use a range of risk assessments to identify and manage risks within the department, including; risk register risk assessments, general risk assessments and health & safety departmental risk assessments. The practical application of these risk assessments are detailed in the supporting *MED Risk Management SOP.* Reference should also be made to the Trust *Risk Management Procedures.*

3.12.4 Risk Register

The MED has a risk register which records risks specific to the department and which is recorded on the Trust risk management data base.
The risk register is reviewed at each monthly department staff team meeting and changes made to the risk register, as appropriate. The practical application of this process is detailed in the supporting *MED Risk Management SOP.* Reference should also be made to the Trust *Risk Management Procedures.*

4.0 Training expectations for staff

4.1 Legal requirements relating to staff training

The Health and Safety at Work Act 1974 requires the Trust to ensure employees are adequately trained. The Trust ensures that through effective education and development programmes that all MED engineering staff are adequately trained and competent on medical devices and have sufficient work experience of the medical devices they repair and maintain. On completion of training programmes, medical engineer competencies are checked and signed off as competent for each medical device covered.

The Trust will not allow those without adequate training to repair or maintain medical devices and equipment. MED Engineers undertaking repair and maintenance will be expected to produce written evidence of appropriate and up-to-date training, when required. They will also be expected to demonstrate that they are up to date on new maintenance techniques, consistent with the medical devices they are servicing. Staff performance reviews are usually undertaken on a biennial basis, however; additional reviews can be undertaken if any concerns relating to performance are identified.

4.2 Education and development

4.2.1 Operational staff

Healthcare professionals working for the Trust have a professional duty to ensure their own skills and training remains up to date. To enable them to do this the Trust provides a range of opportunities for continuous professional development, from initial basic training and throughout their service.

Training for operational staff on the use of medical devices is delivered as specified within the Trust Training Needs Analysis (TNA). Training on medical devices is primarily included within other programmes, such as; basic and paramedic training and clinical updates. On occasions, such as the introduction of a new medical device, specific bespoke educational programmes will be developed, and will be delivered both in the Education and Development Centres and locally, using a range of methodologies.

Training for operational staff will consider how to operate the medical device safely and effectively, and how to recognise when faults have occurred and how to report them. Training will also consider requirements to carry out routine maintenance, such as; cleaning, decontamination, and how to remove, change and insert batteries correctly in accordance with the manufacturer's instructions.

Reference should also be made to the Trust *Statutory and Mandatory Training Policy & Procedure* and the *Policy for Staff Training on Pre-hospital Diagnostic and Therapeutic Equipment.*

4.2.2 Engineering staff

MED Engineers are recruited with a requirement to hold specified minimum educational and professional qualifications. On appointment MED Engineers will receive induction training and bespoke training programmes specific to the medical devices they will be expected to service and repair.

Training takes into consideration;

- The need for adequate training programmes, including initial training and periodic review or retraining, as required
- The training methodology (face-to-face, e-learning, competency based etc.)
- Who should receive the training offered by the manufacturer?
- How will everyone else be trained, and by whom, and when?
- Inclusion of all those involved in maintenance and repair services as appropriate
- Continuing professional development
- Planned training before a new medical device is introduced to the Trust
- Appropriate record keeping of training
- Access to manufacturer's instructions for all users
- Future training needs
- How will training updates be managed for device/software upgrades?
- Post training competency assessments

MED Engineers will also receive statutory and mandatory training in accordance with the requirements of the Trust TNA.

4.2.3 Administration/Parts specialist staff

In addition to induction, and statutory and mandatory training, administration and parts specialist staff will receive training, as required, enabling them to perform their tasks safely and effectively.

4.2.4 Driving staff

Driving staff will receive training, as the administration staff. In addition, driving staff will periodically have their driving standards assessed and will receive update training, as required.

4.2.3 Manufacturer instructions

Good clear instructions for use have a crucial role in the safe and effective use of medical devices. Training includes reference to manufacturer's instructions. A readily accessible register of user manuals is available on the Trust intranet to all operational staff and in addition hard copies are available on all training premises. Operational and training managers will ensure that their availability is known and periodically checked.

When manufacturers update their information, the Trust will be informed. The MED Manager will maintain records of all sets of instructions held in the department and will update these as updates are received. The MED Manager will also liaise with the Education and Development department to enable replacement of existing instructions with revised versions. The Education and Development department will then update the content of relevant training, as required.

5.0 Implementation Plan

5.1 The latest approved version of this Policy will be posted on the Trust Intranet site for all members of staff to view. New members of staff will be signposted to how to find and access this guidance during Trust Induction.

6.0 Monitoring compliance with this Policy

6.1 The MED Manager will ensure overall compliance with this Policy and all associated SOP's. The Trust Procurement Group will note any failings in the monitoring compliance process for this procedural document and note any associated actions in the minutes of the Group, as required.

Requirement	Methodology	When
A systematic inventory is maintained recording all activity relating to Trust medical devices	An audit of the data management system, including accuracy and completeness of records	Annually
Adherence to maintenance schedules	Reports including KPI's	Quarterly
There are effective service and repair processes in place.	User survey to be completed by operational users of medical devices on the repair and maintenance process.	Annually
Adherence to MED Standard Operating Procedures	Audit of key elements of the processes described in the department SOP's	Annually
All staff receive statutory, mandatory and update training, in accordance with the TNA, Trust policy and manufacturer guidelines, as appropriate.	A review of training records, discussion with staff and the provision of attendance certificates/qualifications.	Quarterly
There are effective risk management arrangements in place.	A review of the department risk register, risk assessments and incident reports.	Monthly

In addition, random checks will be made by the MED Manager on all elements of maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to.

The MED holds monthly team meetings to ensure that there is a mechanism to obtain regular feedback; this should include the reporting of even apparently minor problems as these might lead to major failure unless remedied.

7.0 References

7.1 Care Quality Commission. Guidance for providers on meeting the regulations. March 2015

Medical Devices Regulations 2002 (as amended)

Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC

MHRA Document - Managing Medical Devices. April 2015

NHS England and MHRA. Improving medical device incident reporting and learning. March 2014

Department of Health. Records Management: NHS Code of Practice. 2006
MHRA. Devices in Practice

BS EN 62366:2008 Medical devices. Application of usability engineering to medical devices

Department of Health. NHS Master Indemnity Agreement. June 2015

The Electricity at Work Regulations 1989

Health and Safety at Work etc. Act 1974

BS EN ISO 13485:2012 Medical devices. Quality Management Systems. Requirements for regulatory purposes.

The Waste Electrical and Electronic Equipment Regulations 2006 as amended in 2007

Carriage of Dangerous Goods by Road Regulations 1996

Chemicals (Hazard Information and Packaging for supply) Regulations 2009

The Electrical Equipment (Safety) Regulations 1994

The Control of Substances Hazardous to Health Regulations 2002

The Employers' Liability (Compulsory Insurance) Regulations 1998

Management of Health and Safety at Work Regulations 1999

The Provision and Use of Work Equipment Regulations 1998

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

IEC 62353 Edition 1: Medical Electrical Equipment

IEC 60601-1Medical Design Standards

Appendix A - Definitions

Medical Device

Any reference to a medical device indicates a unit of equipment that is owned by the Trust, operated by a suitably trained clinician and used for the purpose of clinical care under the jurisdiction of the Trust. Such devices fall into two main categories; single patient use and reusable.

Single Patient Use

A medical device which is only used once for its designated purpose. They are almost exclusively contained in an air-tight package, have a designated 'shelf-life' and must be disposed of appropriately after first use. Such devices are controlled in consumable stock and are not identified as Trust capital assets. They are not regarded as 'serviceable' items.

Re-usable

A medical device which is used for its designated purpose on multiple occasions for the duration of its operational life. They are not regarded as consumables but may incorporate single-use items as ancillary devices for the purpose of application. Most devices are expensive and are registered as Trust capital assets. They are regarded as 'serviceable' items and therefore require a scheduled inspection, test or calibration.

Patient monitoring devices

These medical devices are almost exclusively re-usable but are often operated in conjunction with single-use ancillary devices. They are generally used in order to monitor the patient's condition of health. The clinician will often use the information indicated by the device to determine any further course of action. Such devices can be expensive, often contain electronic components and are serviceable devices, such as:

- Manual Defibrillator/ECG Monitors
- Automated External Defibrillator/Monitors
- Blood Glucose Monitors
- Tympanic Thermometers
- Otoscope/Ophthalmoscope
- Manual Sphygmomanometers
- SPO2, and Capnography Equipment

Resuscitation Devices

These medical devices are almost exclusively re-usable but are often operated in conjunction with single-use ancillary devices. They are generally powered by gas, be it oxygen or ambient air. Most devices are used to assist the respiratory recovery of a patient. The devices are serviceable, can be expensive and contain electronic components, such as:

- Oxygen Flowmeters/Pipeline Systems
- Suction Units
- Pneumatic Resuscitators
- Ventilators
- Bag/Valve/Mask Resuscitators

- Lifting and Handling Equipment

These medical devices are re-usable and are utilised for the safe movement, immobilising and handling of patients. Stretchers may contain electronic components and hydraulic systems for operating the device. The devices are generally serviceable and can be expensive, such as:

- Stretchers
- Carry Chairs
- Wheelchairs
- Scoops
- Spinal Boards
- Straps

Appendix B- Roles and Responsibilities

The Trust Board

The Trust Board provides leadership within a framework of practical and effective controls in the management of health, safety and risk issues including those related to the management of medical devices. This responsibility is subsequently delegated through the Trust Board, by the Chief Executive, to the Executive Directors.

The Trust Procurement Group

The remit of the Trust Procurement Group is to;

- Improve communication about medical devices within the organisation
- Ensure involvement of clinicians, technical staff and users in relation to the procurement of medical devices
- Define persons responsible for device management tasks, training and safe device operation
- Define and review the *Management of Medical Devices Policy*
- Review incidents relating to medical device management.

Incident Review Group

The Incident Review Group is a working group that is responsible for reviewing and instigating appropriate action to address issues identified in relation to incidents, potential serious incidents and near misses, including those that are specific to the management of medical devices.

Executive Director of Finance

The Executive Director of Finance is the executive lead responsible for the management of medical devices and ensuring the effective implementation of the *Management of Medical Devices Policy*. The Executive Director of Finance is also responsible for ensuring compliance with all statutory responsibilities and regulatory standards associated with the management of medical devices.

Medical Equipment Department (MED) Manager

The MED Manager has delegated responsibility for the management of medical devices and ensuring the effective implementation of the *Management of Medical Devices Policy* and all associated Standard Operating Procedures, and for ensuring department compliance with all internal and external regulatory standards.

The MED Manager has responsibility for ensuring that there are systems in place to ensure reporting of device issues including:

- The effectiveness of the medical devices management system
- The condition and performance of medical devices including: device failures and issues; utilisation, performance, maintenance; repair and calibration history
- The execution of investment, replacement and disposal plans.
- Medical Device Safety Officers (MDSO)

The MDSO supports the management activity of MED Manager and is the primary link to the Safety Team in the management of risk and incident reporting, including the reporting of adverse incidents to the MHRA and other official agencies.

Locality Directors, Managers and Supervisory Staff

Locality Directors, Managers and Supervisory Staff are responsible for the ensuring that the *Management of Medical Devices Policy* is adhered to within their area of responsibility. They are also responsible for ensuring that suitable medical devices are provided, that they remain functional and readily available for operational staff under their areas of responsibility. They are expected to actively encouraging staff, within their area of responsibility, to report medical device related incidents and near misses.

MED Engineers, Drivers and Parts Specialist

MED Engineers, Drivers and Parts Specialist are responsible for the practical implementation of technical processes as described in the *Management of Medical Devices Policy* and all associated Standard Operating Procedures.

MED Administrator

The MED Administrator assists the MED Manager in the maintenance of the medical devices data-base and provides all necessary administrative processes for the department.

Operational staff

All employees have a personal responsibility for health, safety and risk and have a duty of care toward other persons affected by their acts or omissions. Operational staff who use medical devices during the course of their work are expected to follow the guidance provided in *Management of Medical Devices Policy* and all associated Standard Operating Procedures, manufacturer's operating instructions and operational updates.