University Hospitals Birmingham
NHS Foundation Trust

CONTROLLED DOCUMENT

Medical Devices Policy

CATEGORY:	Policy
CLASSIFICATION:	Governance
PURPOSE	To set out the principles and framework for the management of Medical Devices.
Controlled Document Number:	082
Version Number:	9.0
Controlled Document Sponsor:	Chief Transformation Officer
Controlled Document Lead:	Trust Medical Engineering Manager
Will this Controlled Document impact upon any contracts held by the Trust?	☐ Yes[1] ☑ No
Approved By:	Chief Executive
On:	April 2020
Review Date:	April 2023
Distribution: • **Essential Reading for:** • **Information for:**	 All Users of Medical Devices All Directors, Senior Managers and Departmental Heads

[1] If this Controlled Document will have an impact on any contracts held by the Trust, once approved, this will need to be sent to the Procurement Team requesting that it be added to the Procurement Policy Portal

Contents

1. Policy Statement

1.1 Medical Devices are an integral part of the diagnosis, treatment, support and care of patients. The Trust recognises the risks to patients, staff and others that may arise in the use of Medical Devices and that it has an obligation to minimise the risks associated with the use of Medical Devices.

1.2 The aim of this policy is to outline mechanisms to ensure that the entire life cycle of all Medical Devices within the Trust are managed safely and effectively and that their management complies with statutory and regulatory requirements.

1.3 The aims of this policy are to ensure that:

1.3.1 All Medical Devices are fit for purpose.

1.3.2 All Medical Devices are cleaned/decontaminated and maintained correctly.

1.3.3 All Medical Devices are disposed of in an appropriate manner.

1.3.4 Staff are trained to competently and safely use Medical Devices.

1.4 Only Medical Devices conforming to the required standards and specifications may be used within the Trust.

2. Scope

2.1 This policy covers all aspects of the management of Medical Devices, including patient and staff safety, procurement, specification, training, decontamination, maintenance, contracts, disposal, infection control, tracking and tracing, documentation and certification.

2.2 This policy applies to the management of all re-usable and single use Medical Devices used within the Trust and to all staff working within it which includes permanent, temporary, locum, agency, bank, contractors, students and all grades and professions

2.3 This policy excludes specialist information relating to the management of Radiology Imaging equipment. Please refer to Ionising Radiations Regulations 12017(IRR17) and Ionising Radiation (Medical Exposure) Regulations 2000 ref 1& 2 (last updated 2017).

2.4 This policy excludes details regarding the management of Point of Care Testing equipment. Please refer to the Point of Care Testing Policy for more information.

3. Definitions

Medical Device	The term Medical Device encompasses both re-usable and single use items. The European Commission (EC) and the Medicines and Healthcare products Regulatory Agency (MHRA) define a medical device as: “Any instrument, apparatus, appliance, material, pre-filled syringe or healthcare product, **excluding** drugs, used on a patient or client for the purpose of: Diagnosis, prevention, monitoring, treatment or alleviation of **disease.** Diagnosis, monitoring, treatment, or alleviation of, or **compensation** for an injury or disability. Investigation, replacement or modification of the anatomy or of a **physiological** process. Control of conception and which does not achieve its principle intended action in or on the **human** body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means”. *Ref 3 - Medical Devices Directive 93/42/ EEC as amended 2007/47/EC*
Medicines and Healthcare Regulatory Agency (MHRA)	The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK’s regulator of medicines, Medical Devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness. Recognised globally as an authority in its field, the agency plays a leading role in protecting and improving public health and supports innovation through scientific research and development. The MHRA is an executive agency of the Department of Health.
Central Alerting System (CAS)	CAS is a web-based cascading system, developed by the Department of Health, for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. Alerts include safety alerts, CMO messages, drug alerts, Dear Doctor letters and Medical Device Alerts.

4. Framework

4.1 This section describes the broad framework for the management of Medical Devices throughout the Trust. Detailed operational instructions for the implementation of this policy are contained in the associated Procedure for the Management of Medical Devices and the Procedure for Medical Devices Training.

4.2 The Chief Transformation Officer shall approve all procedural documents associated with this policy and any amendments to such documents, and is responsible for ensuring that such documents are compliant with this policy.

4.3 Equipment Strategy Group

4.3.1 The Equipment Strategy Group is the organisational focus for advice and best practice with regard to the management of Medical Devices including acquisition, training, decontamination, maintenance & repair, incident and risk management and decommissioning of Medical Devices.

4.3.2 It will monitor this policy in conjunction with appropriate stakeholders. It is responsible for ensuring that there are systems in place to minimise the risks associated with the use of Medical Devices and ensure the safe, effective management of Medical Devices throughout the organisation.

4.4 Procurement of Medical Devices

4.4.1 All new Medical Devices are legally required to comply with EU directives and the relevant UK legislation for performance and safety. All Medical Devices must hold a CE mark.

4.4.2 All Medical Devices acquired by or on behalf of the Trust must be procured through the Procurement Department, which must be involved in the procurement of Medical Devices from the start of the process when a requirement is first identified. This applies to all Medical Devices to be used within the Trust, irrespective of the funding source to be used. This includes Trust funds, endowment funds, leased or donated equipment and charity donations.

4.4.3 When procuring Medical Devices, a pre-acquisition questionnaire (PAQ) must be completed, which shall include the following:

a) CE Marking

b) Management System Standards

c) Safety Standards

d) Service/Spares/Installation

e) Decontamination/Reprocessing

f) Warranty

g) Information Governance

4.4.4 The process outlined in the Procedure for the Management of Medical Devices must be followed for the procurement of a new medical device. If the correct process is not followed, equipment will be quarantined until assurance is received and the correct procurement process completed.

4.5 Modification of Medical Devices

4.5.1 **No** Medical Device is to be customised without formal agreement from the Equipment Strategy Group and the knowledge and agreement of Medical Engineering.

4.5.2 Modifying or using Medical Devices for purposes not intended by the manufacturer ("off label use") has serious safety implications, and liability may be partly or wholly transferred to the person or organisation making the modifications if the device is implicated in an incident.

4.6 Introduction of Novel Medical Devices

4.6.1 Medical Devices constructed in or custom made for the Trust must be risk assessed and receive approval before clinical use. Approval is obtained through the Equipment Strategy Group. Transfer of ownership to a separate legal entity of any working medical device designed, constructed, modified or manufactured by the Trust is equivalent to putting the medical device on the market. Such transfers shall not be made unless the Equipment Strategy Group approves the transfer and the transferee accepts the arising liabilities.

Devices and products which are of novel action and require approval from both a pharmacy/medicines and a medical device perspective must be considered by the Trust Medicines Management Advisory Group (MMAG) and the Equipment Strategy Group.

4.7 Re-use of Medical Devices/Single Use Medical Devices

4.7.1 Current guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) is contained in their publication Single-use Medical Devices v2.1 (December 2013) In the Executive Summary 1. key points , it states:

A device designated as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded.
The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk. *(Ref 4*).

4.7.2 Devices labelled as "single use" must be used within the marked "use by" date and this must be checked prior to use. Packaging must be checked to ensure sterility and damaged packs or devices must not be used.

4.8 Loaning in, trials, prescribing and loaning out of Medical Devices

4.8.1 The process for the loaning in, prescribing, trials and loaning out of Medical Devices is described in the Procedure for Loaning and Borrowing of Medical Devices and the Procedure for the Trials and Evaluation of Medical Devices, which must be followed.

4.8.2 All Medical Device suppliers and company representatives must conform to the Trust Protocol, which is available on the Medical Devices Management intranet page and included in the associated Procedure for Loaning and Borrowing of Medical Devices.

4.9 Use of Medical Devices

4.9.1 Medical Devices must be used so that patient and staff safety is ensured at all times by means of appropriate control measures, which include:

a) Traceability

b) Instructions for Use

c) Safety Notices

d) Use of Safety Mechanisms

e) Training

f) Maintenance and repair

g) Cleaning and decontamination

h) Replacement

i) Disposal

j) Medical Device Compatibility and Inter Connection of Medical Devices

k) Patient Data Confidentiality

4.9.2 Traceability

a) The Trust shall maintain systematic inventories or asset registers of all reusable Medical Devices within the Trust. These records provide evidence that all reusable Medical Devices have been maintained in good condition and calibrated as appropriate. There are asset registers in use within clearly defined clinical areas or device categories, each with clear management and ownership responsibilities. These registers form a record of all reusable equipment within the Trust. Further detail on the management of these asset registers can be found within the Procedure for the Management of Medical Devices.

b) On procurement, a medical device will be assigned to one of the medical device inventories either by Medical Engineering, Renal Engineers, Estates, Laboratory Medicine or Radiology. This will be dependent upon the device type.

c) Re-usable Medical Devices must be asset-tagged in accordance with the Procedure for the Management of Medical Devices.

4.9.3 Instructions for Use

a) Manufacturer's Instructions for Use documents (IFU) must be obtained at the point of procurement and will be available with all new Medical Devices when training is provided. Where possible, these will be stored and made available on the Trust intranet.

b) All users of Medical Devices must have access to these documents, either through the intranet or, alternatively, the documents can be downloaded into an electronic or paper folder.

4.9.4 Safety Notices

a) If the Trust is notified via CAS or becomes aware of a risk or safety alert associated with a medical device that is in use within the Trust, any staff likely to use such a device must be notified immediately of the risk by the Datix Safety

Alert System which is managed by the Clinical Risk and Compliance Department.

b) Please refer to the Procedure for Dissemination and Implementation of Central Alert System (including National Patient Safety Alerts) for further information.

c) The Trust Medical Engineering Manager is the designated Medical Devices Safety Officer (MDSO) for the Trust. They will receive and disseminate safety notices direct from Manufacturers, the MDSO email system or other external and internal sources. The MDSO will issue internal Medical Device Alerts (MDAs) in response to internal medical device incidents as appropriate and will report incidents to the MHRA on behalf of the Trust.

4.9.5 Safety Mechanisms

Safety mechanisms provided either by the Trust or a Manufacturer, as part of a medical device to improve clinical or staff safety, MUST be implemented when using that device. Failure to comply with this requirement will result in formal disciplinary action being taken against any staff found to be bypassing any safety aspect of a medical device. Examples of this would include: breaking off needle guard devices intended to reduce needle stick injuries and non-activation of dose error reduction software for IV drug infusions when the required infusion protocol exists within the pump template.

4.9.6 Training

a) All new Medical Devices (i.e. of a type/model that is not in current use in the Trust) shall be assessed to identify any risks associated with their use by the Medical Devices Training Group. Please refer to the Procedure for Training in the Safe use of Medical Devices document for further information on Training and risk classification of Medical Devices (low, medium and high).

b) Save in an exceptional/life-threatening emergency, no member of staff may use a medical device unless:

- They have been appropriately trained or assessed as competent in the use of the particular device.
- They are doing so under supervision as part of such training or assessment.

- They have self-verified their competence to use the particular device.

c) All training requirements must be met in accordance with the Procedure for Training in the Safe Use of Medical Devices.

4.9.7 Maintenance and Repair

a) Maintenance and repair of medical equipment under the remit of the Medical Engineering Department is performed in accordance with their Quality Management System.

b) The maintenance requirements for each medical device will be assessed and, where a manufacturer service contract is not provided, a scheduled maintenance programme will be assigned. Checks will be made to ensure maintenance is carried out in accordance with manufacturer and Trust schedules.

c) Where external service contracts for maintenance exist, they should represent good value for money and managers must ensure that contracted work is carried out satisfactorily. Further advice on external service contracts is available from Medical Engineering and the Trust's Procurement Department.

d) When malfunction of an item of medical equipment is identified or suspected, the item should be removed from service immediately and labelled clearly to prevent further use. The user department should ensure that the item is referred to its normal maintenance agency for testing or repair i.e. Medical Engineering, Estates Team or Renal Engineers. Items for repair must be accompanied by a completed Decontamination Status Certificate.

4.9.8 Cleaning and Decontamination

All re-usable Medical Devices must be cleaned/decontaminated following Trust guidelines and Manufacturer's instructions for use. Medical Devices must also be cleaned/decontaminated before and after clinical use, between patients, and prior to inspection, servicing, repair, decommissioning or on transfer to other areas, in accordance with the associated Procedure for Decontamination of Re-usable Medical Devices.

4.9.9 Replacement

a) The Trust makes provision for capital replacements including medical and scientific equipment as part of the annual block allocation, approved by the Capital Prioritisation Group. Replacement of equipment not possible due to funding issues should be placed on the relevant risk register.

b) Please refer to the Risk Management Policy and Procedures for further information.

4.9.10 Disposal

a) Disposal must comply with relevant Health & Safety legislation, European Union Directives and WEEE (Waste Electrical and Electronic Equipment) legislation. The relevant asset register holder must be informed of any disposal.

b) Medical equipment which is worn out, broken or damaged beyond safe or economical repair must be removed from the Trust and scrapped. Equipment which is clinically or technically obsolete or surplus to requirements may still have some residual value. Such equipment should be disposed of in a way which maximises the financial return to the Trust as required by financial regulations. This may involve trading in for new equipment or selling through tender or auction. In some circumstances, it may be useful to retain technically obsolete equipment as a back up to new equipment where it is safe to do so. For information and advice contact Capital Finance and Medical Engineering.

c) Prior to disposal Medical Devices any sensitive clinical or patient data must be removed to protect Trust and patient data confidentiality.

4.9.11 Medical Device Compatibility and Inter Connection of Medical Device

a) Connection of any device not owned by the Trust to a Trust-owned medical device or of any device not intended to be linked or connected by the Manufacturer must be pre-approved by Medical Engineering and IT Services. This includes any USB port/WiFi access of a medical device and any interrogative equipment from an external or internal source.

b) This is in order to maintain security, integrity and confidentiality of data and to ensure full compatibility of Medical Devices. Failure to follow this requirement may impair the function of equipment and may void any manufacturer's liability and indemnity responsibility to the Trust and our patients.

c) The procurement process for Medical Devices that have IT compatibility must follow the process as described in the Management of Medical Devices Procedure.

4.9.12 Patient Data Confidentiality

All patient identifiable information must be stored on Medical Devices in a safe manner and removed prior to decommissioning/disposal of the medical device. Contact Information Governance, IT Services and Medical Engineering for further advice/support.

5. Duties

5.1 Chief Transformation Officer

The Chief Transformation Officer is responsible for the management of Medical Devices within the Trust and for ensuring compliance with this policy. Any serious concerns regarding the management of Medical Devices shall be brought to the notice of the Chief Executive or the Board of Directors, as appropriate.

5.2 Director of Corporate Affairs

The Director of Corporate Affairs is responsible for facilitating investigations into serious incidents involving Medical Devices. They will also provide specialist risk management and health and safety advice in relation to Medical Devices and oversee the Trust Central Alert System (CAS).

5.3 Director of Facilities

The Director of Facilities shall chair the Equipment Strategy Group and ensure that any significant governance and/or safety issues or serious instances of non-compliance with this policy are reported to the Chief Transformation Officer. This includes responsibility for the Medical Engineering Department. They will ensure that a rolling programme of maintenance activities is carried out in accordance with MHRA and statutory requirements.

5.4 Director of IT Services

5.4.1 The Director of IT Services is responsible for providing assurance

that medical equipment approved for connection to the Trust network meets local procedures for interoperability and IT security management as part of Trust-wide implementation.

5.4.2 They will ensure that users do not permit any unauthorised party to connect any device to the Trust network, without prior authorisation from the IT Services Department.

5.5 Divisional Management Team

5.5.1 The Divisional Management Team are responsible for ensuring that Divisions have clear arrangements in place for the management of Medical Devices, and provide assurance of the compliance with the requirements of this policy and its associated procedures to the Chief Transformation Officer.

5.5.2 They will monitor the risks related to Medical Devices within their Division when escalated by the Equipment Strategy Group.

5.5.3 They will also provide assurance that all Medical Devices used within their Division are procured appropriately and have overall responsibility for ensuring all contracts for the routine maintenance of Medical Devices are formulated and implemented in liaison with the Medical Engineering Department or Estates Department.

5.6 Head of Procurement

5.6.1 The Head of Procurement is responsible for ensuring that all Medical Devices are procured in accordance with Trust standards and with relevant guidance from the Equipment Strategy Group.

5.6.2 They shall ensure that:

a) No medical device is purchased without prior approval from the Equipment Strategy Group.

b) Requirements for all Medical Devices are notified to the Equipment Strategy Group where necessary providing the specifications, manufacturer's instructions, decontamination instructions, training needs, location and division of use, funding for maintenance and compatibility.

5.7 Trust Medical Engineering Manager

The Medical Engineering Manager is responsible for:

5.7.1 Ensuring the Trust has in place medical device systems, processes, policies and procedures which achieve compliance with statutory and regulatory requirements and result in an integrated approach to medical device management.

5.7.2 Development of monitoring systems to ensure compliance with procurement standards and requirements.

5.7.3 Developing and implementing a Trust-wide risk management programme which minimises the risks associated with the use of Medical Devices.

5.7.4 Leading the initiative to standardise Medical Devices where appropriate.

5.7.5 Co-ordination of regular audit of this policy and the associated procedures.

5.7.6 Developing & implementing a Trust wide maintenance, calibration & repair programme for ensuring the safe operation of medical device.

5.7.7 Monitoring maintenance, calibration and repair of Medical Devices using the medical engineering Quality Management System.

5.7.8 Ensuring the safe disposal and decommissioning of Medical Devices at the end of their life cycle.

5.7.9 Maintaining an inventory of Medical Devices within remit, used within the Trust, regardless of monetary value.

5.7.10 Managing, negotiating and monitoring performance against external service maintenance contracts for Medical Devices within remit.

5.7.11 Ensuring the provision of appropriate training for all relevant Trust staff in the safe and competent use of Medical Devices, and to monitor the attendance of staff at such training.

5.7.12 The Trust Medical Engineering Manager is the Trust's Medical Device Safety Officer (MDSO) and is the point of contact for any reportable incidents to the Medicines & Healthcare products Regulatory Agency (MHRA).

5.8 Estates Site Managers

Estates Site Managers shall maintain an inventory of all Medical Devices (other than single use items) used within the Trust and which are managed by them, and shall ensure that this policy is implemented and monitored, ensuring that all equipment held on their asset register is safe and fit for purpose.

5.9 Renal Engineering Manager

The Renal Engineering Manager is responsible for maintaining an asset register of all Renal Unit dialysis equipment. They will ensure that this

policy is implemented and monitored in regard to these devices, ensuring that all renal equipment held on their asset register is safe and fit for purpose.

5.10 Respiratory Engineering Manager

The Respiratory Engineering Manager will ensure that this policy is implemented and monitored in regards to respiratory devices, ensuring that all equipment is safe and fit for purpose. They will also ensure that all respiratory equipment patient loans are documented and traceable.

5.11 Imaging (Radiology) Group Manager

The Group Manager for Imaging is responsible for:

5.11.1 Ensuring Trust compliance with Ionising Radiation Regulations 2017 (IRR17), Ionising Radiation (Medical Exposure) Regulations 2000/2006/2011/2017 and any other statutory and regulatory requirements relevant to imaging. Reference 1 & 2.

5.11.2 Maintaining an asset register of all imaging equipment as per Regulation 10 of the Ionising Radiation (Medical Exposure) Regulations 2000.

5.11.3 Ensure that this policy is implemented and monitored in regards to these devices, ensuring that all imaging equipment held on their asset register is safe and fit for purpose.

5.11.4 Authorising procurement for all Trust imaging equipment to ensure the appropriate specification, usage and governance framework is in place to comply with IRR99 and IR(ME)R2000 and any other statutory and regulatory requirements relevant to imaging.

5.12 Medical Devices Training Lead

The Medical Devices Training Lead will oversee, audit and co-ordinate the facilitation and recording of the training of all relevant staff in the safe and competent use of Medical Devices, and monitor that the Trust complies with the Procedure for Training in the Safe Use of Medical Devices.

5.13 Associate Medical Directors

They shall ensure the facilitation and recording of the training of all trainees medical staff in the safe and competent use of set core Medical Devices during junior doctor induction. Training on devices specific to specialties is the responsibility of the Clinical Service Leads for those specialities. The Associate Medical Directors shall do likewise for all other medical staff.

5.14 **Medical Equipment Library Manager**

The Medical Equipment Library Manager is responsible for ensuring that:

5.14.1 Sufficient stock of medical equipment is available.

5.14.2 All transactions are accurately recorded.

5.14.3 Receiving and accurately responding to specific equipment requests.

5.14.4 Quality standards and customer care standards are maintained at all times.

5.14.5 Medical equipment is adequately maintained.

5.14.6 All equipment is fit for purpose and is decontaminated in line with the associated Infection Prevention and Control Policy and the Procedure for the decontamination of reusable Medical Devices prior to patient use, inspection, servicing, repair or return to departments or organisations.

5.15 **General Managers, Clinical Service Leads, Matrons, Ward and Department Managers**

General Managers, Clinical Service Leads, Matrons, Ward and Department Managers have responsibility for the day to day implementation of this policy and procedure. They shall:

5.15.1 Ensure that any Medical Device is appropriate and sufficient for its intended use and that it complies with all regulatory requirements and guidance.

5.15.2 Ensure all medical equipment is available for use, adequately stored, charged and maintained appropriately.

5.15.3 Check and identify external service contract maintenance needs of Medical Devices and liaise with appropriate departments, notifying the needs to the Divisional Director of Operations.

5.15.4 Ensure that all Medical Device incidents are reported on Datix and in accordance with the Policy for the Reporting and Management of Incidents, including Serious Incidents Requiring Investigation, and those incidents are immediately escalated to the appropriate personnel.

5.15.5 Ensure all safety alerts and bulletins received are brought to the attention of staff in their area and that required responses are timely.

5.15.6 Ensure that satisfactory arrangements for all appropriate tests,

checks, validation, commissioning, verification and paperwork are carried out before installation and use of Medical Devices. Assurance can be obtained from the relevant departments such as Medical Engineering and the Estates Team.

5.15.7 Be involved in identifying needs and requirements for all Medical Devices by developing specifications and providing these to Procurement.

5.15.8 Managers are responsible for ensuring that the use of medical equipment as required by a role and/or department must also form part of the Local Induction process for all new starters/transfers/secondments and temporary staff to the Trust.

5.16 Staff/All users of Medical Devices

5.16.1 Healthcare professionals are individually accountable for their practice and for the delegation of care delivery to others in line with their contract with the Trust and the code of practice from their regulatory/professional body.

5.16.2 They have a responsibility as part of their professional development to acquire, maintain and demonstrate knowledge and skills in the use of Medical Devices relevant to their area of practice.

5.16.3 Users must not use devices they are not trained to use safely and effectively.

5.16.4 Users may use devices that they have been trained to use acknowledging their own professional accountability in delivering safe care.

5.16.5 Users must report lack of training to their line manager so patient care is not delayed.

5.16.6 All staff have a responsibility to ensure that they comply with this policy and associated procedures.

6. Implementation and Monitoring

6.1 Implementation

This policy will be available on the Trust's intranet site. The policy will also be disseminated through the Trust's management structure.

6.2 Monitoring

Appendix A provides full details on how the policy will be monitored by the Trust.

7. Relevant External Standards/Legislation

Ionising Radiation Regulations 2017 (IRR17)

Ionising Radiation (Medical Exposure) Regulations 2000/2006/2011/2017

Health & Social Care Act 2008 (Regulated Activities), Regulations 2014 Regulation 15 (Premises & Equipment)

Health & Safety at Work Act 1974

Management of Health & Safety at Work Regulations 1999

Provision and Use of Work Equipment Regulations 1998

Managing Medical Devices. Guidance for healthcare and social services Organisations MHRA April 2015

Medical Devices Regulations 2017

Control of Substances Hazardous to Health Regulations (COSHH), 2002

Waste Electrical and Electronic Equipment Regulations 2006 as amended 2007

Electricity at Work Regulations 1989

Electrical Equipment (Safety) Regulations 1994

LOLER 1998 – Lifting Operations and Lifting Equipment Regulations

Regulating Medical Devices in the event of a no-deal Brexit 2019

8. References

Ionising Radiations Regulations 2017 (IRR17)

Ionising Radiation (Medical Exposure) Regulations 2000 (updated 2017)

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

MHRA Single Use Devices – implications and consequences of reuse (Dec 2013)

9. Related Policy and Procedural Documentation

Procedure for the Management of Medical Devices

Procedure for Loaning and Borrowing of Medical Devices

Procedure for the Trials and Evaluation of Medical Devices

Procedure for Training in the Safe Use of Medical Devices

Policy for the Reporting and Management of Incidents including Serious Incidents

Policy for the Introduction of Novel Therapeutic Interventions

Procedure for the decontamination of reusable Medical Devices prior to patient use, inspection, servicing, repair or return to departments or organisations

Infection Prevention & Control Policy

Point of Care Testing (POCT) Procedures

Risk Management Policy & Procedures

Procedure for Dissemination and Implementation of Central Alert System (including National Patient Safety Alerts)

Appendix A Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Monitoring of Medical Devices throughout their lifecycle to include: 1. Maintenance schedules, 2. Personal Identifiable Information, 3. External maintenance contracts, and 4. Disposal of devices	Trust Medical Engineering Manager, Technical Manager – Renal and Estates	Equipment Strategy Group	Provide quarterly reports which include the Planned Preventative Maintenance stats for completed Planned Preventative Maintenance over a 12 month period, highlight any not completed and implement actions if necessary to rectify those not completed within the period.	Quarterly
Auditing of Medical Devices using the Active and Passive RFID Tag system	Trust Medical Engineering Manager	Equipment Strategy Group	Provide on an annual basis audit of Medical Engineering's equipment that has been located within the previous 12 months and highlight any devices that have not been located and potentially could be lost. Issues will be escalated to the Chief Transformation Officer.	Annual