POLICY FOR THE ACQUISITION, USE AND MAINTENANCE OF, AND TRAINING FOR, MEDICAL DEVICES AND EQUIPMENT

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<td>RELATED DOCUMENTS:</td>
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<td>Safety Alert Broadcasting System Procedure</td>
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Summary of the Medical Devices Policy

The policy sets out how medical devices should be procured, maintained and the related training processes required for the safe use of the devices. It focuses on the need for all staff to understand their responsibilities in relation to medical devices, and the need for managers and clinicians to work corporately with key players, e.g. Procurement, Clinical Engineering, medical devices training manager and clinical specialists, to ensure devices are appropriately procured, based on sound evidence, provide value for money and staff are trained effectively to use them.

It identifies the traffic light system for risk classification linked to training, and places an onus on staff to maintain their competency through self assessment where appropriate. It contains flow charts showing processes for procuring devices, sample documentation required, and terms of reference of relevant Trust groups.

It has been developed in line with NHSLA standards.

Areas of the policy are set out as below:

Section 1 - 4: These provide definitions of key words and phrases used in the policy, and identify the scope and relevant stakeholders.

Section 5: This details individual staff groups' responsibilities for medical devices for procuring, maintaining, decommissioning and identifying training related to medical devices.

Section 6: This describes in detail how devices should be procured, linked to clear flow charts in appendix, as well as managing equipment on loan, processes regarding registration of devices, repair, maintenance, and sets this out simply as an excellent reference. It also includes how MHRA alerts and the decommissioning and disposal of equipment should be managed.

There is a major section on how training should be identified before procurement, how it should be developed, delivered and recorded, and staff duties regarding this.

Section 7: This covers implementation of the policy, and how audit and reporting are undertaken.

Appendices: These contain terms of reference for relevant groups, flowcharts of procurement processes and sample documentation for ward care visits etc.
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1. **INTRODUCTION**

Safe, well maintained medical equipment used by staff trained to do so, is vital for ensuring patients receive high quality safe care. This policy defines how this must be done, to ensure the Trust’s primary duty to maintain patient safety is adhered to, and associated risks are minimised. This Policy describes processes to ensure the safe acquisition, use, maintenance and training for, medical devices and equipment that will help maintain quality care and reduce risk.

The National Health Service Litigation Authority (NHSLA) and the Care Quality Commission also require acute Trusts to reduce the risks related to medical devices and equipment, in order to protect patients and staff from any harm.

2. **SCOPE**

This policy applies to all staff employed by the Trust, whether permanent or temporary, who acquire, use, or maintain medical devices and equipment.

3. **DEFINITIONS**

3.1 **Medical Devices** (including equipment) can be defined as all products, except medicines, used in health care for diagnosis, prevention, monitoring or treatment. This includes the alleviation, or compensation for an injury or handicap, the investigation, replacement or modification of the anatomy or of a physiological process, and the control of conception. Under the amended European Commission Directive 2007 the term Medical Device now includes software products, and not only software required for the normal functioning of a device.

In some circumstances certain devices, although classified as devices, should also be treated as medicines, and follow Trust medicines policies and procedures in addition to this policy. Examples include the bladder irrigation cystostat and hyaluronic acid, which require approval by the Medicines Committee.

Medical devices fall into the following 2 categories:
- Commissioned devices that are recorded on the Clinical Engineering database, AIMS.
- Single use devices such as equipment accessories that are not registered on the database and are low value, low maintenance and low risk items.

3.2 **AIMS** is a central equipment database management programme which:
- Registers new items of equipment onto the database.
- Records the service / repair history of all items on the inventory while it is part of Trust property.
- Records the de-commissioning and de-registering of equipment prior to disposal.
- Runs reports on equipment activity / servicing etc.
- Manages external service contracts, and links these to the items of equipment on the inventory.
- Provides a parts inventory for all spares used in the maintenance and repair of equipment.
- Logs all equipment loans from the equipment library.
- Contains an inventory of all equipment used in the Trust, with the exception of glucometers, which are held in Pathology.

3.3 **MAPS** is a Manpower Analysis and Planning System, which is an electronic rostering system, able to:
● Model staff demand including specific skills / competencies, eg regarding medical devices required for safe delivery of care for each roster
● Record staff details of both permanent and Bank staff, against which competencies are recorded. A recorded competency signifies successful completion of training,
● Record staff leave for training
● Record status, including expiry of staff competencies, for permanent staff, which enables managers to review their own staff status

The system is currently being implemented in most clinical areas, and has been developed to include an ability to record medical device training for general areas.

3.4 **ISO 9000 (International Organisation for Standardisation) is:**

A series of international standards that define, establish and maintain an effective quality assurance system for manufacturing and service industries. This provides the main quality assurance mechanism for all the Trust Clinical Engineering Department activity.

3.5 **Point of care testing (POCT) is** the performance of pathology tests by healthcare professionals close to the patients and outside of the main pathology laboratory. It is a valuable technique that is capable of providing rapid pathology results and already accounts for a considerable proportion of pathology testing performed within the hospital environment.

3.6 **Trust medical devices risk classification system is:**

This is a classification of device risk is based on the European Standards, according to severity of consequence of incorrect usage or failure of the medical device, and against which the level of required training is agreed. Decisions regarding level of classification are made initially by clinicians and ratified by the Medical Devices Committee.

- **High risk device:** Potential to cause serious harm or death if misused or fails.
- **Medium risk device:** Potential to cause significant impact on patient care if misused or fails.
- **Low risk device:** Unlikely to cause serious consequences if misused or fails.

4. **STAKEHOLDERS**

This policy has been developed by a core group from Clinical Engineering, the Centre for Clinical Practice, Procurement, clinicians input and the Medical Devices Committee. The Medical Devices Committee has been actively involved at all stages in the development of the policy, and has endorsed this document.

5. **DUTIES**

5.1 **The Organisation**

The Trust Board will have overall responsibility for ensuring that Trust wide medical device risks are appropriately managed or mitigated against, in order to maintain patients and staff safety.

5.2 **Capital Programme Board**

Duties include to:

- Receipt of capital applications for new medical devices.
- Decisions on funding and assignment of budgets for capital
- Reviewing of progress of capital equipment acquisition projects.

5.3 **Procurement Department**

Duties include to:

Procurement should be involved at the earliest possible opportunity where consideration needs to be given on the sourcing of equipment, the procurement of goods and services, and the development of a supplier relationship in support of long term maintenance and servicing of equipment and devices. Procurement will advise on the most cost effective, whole life value for money solution for the Trust. In addition, Procurement will provide advice and support on the following areas:

- Establishing the most suitable route to market to deliver the required outcome. This will include identifying whether local and or national framework agreements are available and whether this route presents the best whole life value. Inclusive of consumable and maintenance if applicable.
- Supporting the sourcing of suppliers and in the development of a supplier relationship strategy
- Ensuring adherence to local rules (standing financial instructions (SFIs) and national and European legislation, including whether a full OJEU process should be undertaken
- Understanding any interdependencies, either with other equipment or with IT systems
- Drafting of the contract to ensure robust terms and conditions are in place;
- Ensuring that the other relevant parties involved and impacted in the introduction of any new equipment (e.g. Clinical Engineering, medical device training manager, Infection Control,) have been fully consulted and / or informed and have been given the chance to evaluate the equipment and the implications on their role of its introduction

Please refer to flowcharts as indicated: Appendix 4 – Purchase of Capital equipment and Appendix 5 – Purchase of Sub capital equipment.

5.4 **Manufacturers/suppliers**

Duties include to:

- Collaborate with Procurement Department to provide equipment as per contract agreement, including for capital projects.
- Comply with NPSA or MHRA guidelines where applicable.
- Provide relevant information related to a specific medical device, access to operating manuals (paper & electronic). Where available, access to helpline for specific medical device.
- Conform to the Trust training plans and agreed procedures.
- Provide agreed devices training as per contractual agreement, which may include ongoing training.
- Communicate and liaise with the Trust’s Medical Device Training Manager for all device training needs and supply this to them and other relevant personnel.
- Inform / liaise with Clinical Engineering and the Medical Devices Training Manager regarding all equipment trials, evaluations and implementations and training resources.
- Train the Trust’s Medical Devices Training Manager and identified Trust Clinical Skills Lead on a new / identified device, and conduct specialist training on a specific device as per agreement with the Chelsea and Westminster Hospital Foundation Trust where required.
- Communicate and liaise with Infection Control team / decontamination department for all device cleaning / sterilising needs.
• Adhere to the trust’ Rep Access Policy.

5.5 Director of Estates & Facilities
The General Manager for Estates & Facilities has overall responsibility for the management of the Clinical Engineering Department, as well as other contracted out service suppliers.

Duties include:
• Overall responsibility for the Clinical Engineering function, and achievement of its activity, standards and budgets..
• Review of internal audit and formation of any Business plans for Clinical Engineering as required.
• Approval for de-commissioning of devices from the AIMS database.
• Final sign-off for MHRA closures

5.6 The Clinical Engineering Department
The role of the Clinical Engineering Department is to assist the Trust to optimise availability and use of safe and effective medical equipment to support patient diagnosis and treatment whilst minimising costs of ownership, (MHRA Managing Medical Devices, DB2006 (05).

Duties include to:
• Accept and commission newly purchased medical equipment.
• Register all commissioned medical equipment onto the medical equipment AIMS database
• Lead with the Medical Devices Training Manager and clinical leads on the identification and labelling of medical devices according to the agreed Trust traffic light system of risk
• Alter status on AIMS of old/obsolete equipment on the database and subsequent disposal.
• Provide a systematic preventive maintenance, repair and calibration service for agreed device types. (See section 6.8)
• Provide a management service for external maintenance contracts.
• Undertake a programme of annual Ward Care Visits, including preparation and follow up with ward managers, and ongoing monitoring.
• Be a source of advice regarding preferred makes and models of Trust generic devices for staff. .
• Provide expert opinion on equipment purchase proposals from charitable organisations.
• Provide a medical equipment library for the loan of generic equipment used throughout the Trust.
• Provide user training on Trust generic equipment in liaison with the medical device training manager
• Support medical device education and training.
• Co-ordinate Medicines and Healthcare products Regulatory Agency (MHRA) safety action bulletin (SAB’s) distribution and receipt of responses to alerts.
• Maintain logs of all alerts and feedback responses on behalf of the Trust CAS Liaison Officer for closure with the MHRA.
• Ensure all aspects of the Department’s functions are carried out under an ISO 9001 quality system that is audited annually.

5.7 Equipment Library Manager:

Duties include to:
Provide an efficient and responsive system for the commissioning (including acceptance testing), delivery, and management of library equipment, and out of hours deliveries for the equipment library service across the Trust.

Develop and maintain an effective tracking system for loans, and maintain a current Trust database for this purpose.

Respond to clinical need for various library devices, liaising with colleagues as appropriate.

Be responsible for the specification and delivery of planned maintenance of library medical equipment.

Operate the Department procedures for decommissioning and disposal of equipment.

Proactively work with staff to ensure all equipment is appropriately used and decontaminated, in accordance with Trust policy, and be responsive to challenges identified by them.

Train staff who use Trust generic medical equipment.

Work closely with the Medical Devices Training Manager to deliver a structured programme of medical device training.

5.8 Pathology

Duties include to:

- Be responsible for the support and maintenance of point of care testing equipment (POCT) within the Trust.
- Manage POCT equipment that is covered under a service level agreement with Imperial College Healthcare NHS Trust.

- Maintain an accurate inventory of all glucometers, as these are not recorded on the Clinical Engineering inventory.
- Provide advice on the procurement, quality assurance and documentation of all POCT equipment at Chelsea & Westminster Hospital.
- Provide standard operating instructions, and standard operating procedures for all POCT equipment.
- Advise on training issues and train trainers and staff, where appropriate, as per POCT contract.
- Liaise with the medical devices training manager, regarding POCT training, deliver training in accordance with the Trust risk classification system, and ensure records of training are incorporated into the Trust recording systems for medical devices, eg MAPS.

5.9 Point of Care Testing Committee

Duties include to:

- Advise the Trust when preparing a business case for the acquisition of new POCT equipment.
- Advise on the clinical utility and implementation of all new applications for POCT devices.
- Ensure that Standard Operating Procedures / Standard Operating Instructions are developed for POCT, where it is performed.
- Ensure that all POCT services within the Trust are subject to accreditation procedures.
- Ensure that the performance of all POCT devices is monitored by appropriate Quality Control and External Quality Assessment so as to satisfy Clinical Pathology Accreditation requirements.
- Develop a system of audit to ensure compliance with this policy for the safe use of POCT devices.
- Ensure that Health and Safety and Infection Control procedures for POCT are implemented.
- Ensure effective training records are maintained.
- Ensure that clinical users and laboratory staff receive adequate training in POCT devices.
- Ensure that systems exist and are maintained for the accurate recording of all POCT patient data.
- Report and investigate all adverse incidents and near misses associated with POCT.
- Receive reports on actions taken in response to MHRA Alerts relating to POCT equipment
- After liaison with the Risk Management Committee remove any POCT device from service that is being persistently misused.
- Report to the Trust Executive for Clinical Governance through the Trust Risk Management Committee.

5.10 **Radiology Department**

Duties include:

- Be responsible for the specification, tendering and ordering of all radiology equipment, in conjunction with Procurement.
- Ensure that all Radiology equipment is maintained under contract with the manufacturer and is maintained according to the manufacturer’s specifications.
- Ensure all service records for radiology equipment are kept by the Radiology Department.
- Ensure all Radiology equipment using ionising radiation or MRI are inspected by Imperial College Radiation Physic departments in accordance with IR(ME)R regulations. Maintain responsibility for the training and education of radiology equipment and maintain and provide records, eg competency checklists, held on the Radiology shared drive.

5.11 **Decontamination Committee**

Duties include:

- Ensure decontamination programme is implemented and that it takes proper account of relevant national guidelines
- Ensure decontamination of reusable surgical instruments takes place in the Sterile Services department
- Ensure decontamination of flexible endoscopes takes place in the Endoscope Decontamination Unit
- Ensure decontamination equipment is maintained, tested and validated according to the current standards
- Ensure that surgical instruments and flexible endoscopes are tracked through the decontamination process and to relevant patient
- Ensure staff are trained in decontamination process and hold appropriate competencies for their role
- Ensure medical devices are decontaminated in accordance with the manufacturer’s instructions and current guidelines
- Ensure newly acquired medical devices are compatible with decontamination processes prior to orders being placed

5.12 **Medical Devices Committee**

Duties include:

- Ratify, disseminate and promote adherence to, the Medical Devices policy to the appropriate staff.
- Lead on the corporate arrangements for agreeing sourcing and procurement -of new medical devices, and ensuring involvement of procurement at appropriate stage.
- Liaise with the Clinical Skills Team regarding the need for education and training requirements for medical devices.
• Be responsible for the monitoring of compliance to the policy in order to ensure patient safety, and in line with NHSLA and Care Quality Commission standards, and the audit of the compliance.
• Ensure that the Trust provides the support and resource to the Committee in order to meet the policy requirements.

For Terms of Reference, see Appendix 1

5.13 Medical Devices Training Manager

Duties include to:

• Work with the Clinical Skills Lead to develop, maintain and support a system of medical device training and expertise across all professional groups
• Work with others to develop and maintain a Trust training record system that enables systematic and realistic medical device training to be managed across the Trust.
• Support those promoting device training, e.g. super users, education facilitators etc. to ensure high quality delivery of training to where appropriate
• Work with managers and clinicians to ensure all device users are appropriately trained according to the Trust Medical Devices Policy, including the coordination of specialist training with device suppliers.
• Collaborate with others in identifying staff training needs, ensuring that training occurs, and provide reports on this to the Medical Devices Committee as a standing agenda item, with associated action plans. An annual report will also be submitted on progress and actions.
• Deliver elements of core training on devices to a variety of staff groups.
• Work clinically with others to assist in the development and evaluation of competence, and identify and address further training needs as necessary.
• Work with managers to ensure accurate central recording of staff / device users who have undergone or require medical device training related to specific equipment.
• Provide regular audit reports to the Medical Devices Committee on device training, and identify issues and actions from these.

5.14 All staff using medical devices

This will include mainly nursing, medical and therapy staff, but covers anyone using medical devices. For every device used, staff must ensure they follow these duties.

Duties include to:

• Familiarise themselves with the device manufacturer’s written user instructions or guidance.
• Receive adequate training according to the “traffic light” system outlined in this document.
• Be competent using the device.
• Not use the device if unable to affirm the above 3 points
• Use the device for its intended purpose, without alteration or modifications
• Ensure that the device is free from obvious defect before use.
• Decontaminate, or arrange for decontamination of, the device between patients and prior to servicing / repair, according to manufacturer’s instructions
• Ensure single patient use devices are not re-used and single use items are not re-used.
• Report defective devices to Clinical Engineering via the agreed procedure (6.8.1)
• Report adverse incidents involving devices to Risk Management and Clinical Engineering.
• Isolate any device that is involved in an incident and is suspected to have played a part in the outcome of the incident.
• Return any items that have an expired licence that are discovered by staff to Clinical Engineering for checking and re-licensing.
5.15 **Divisional representatives for medical devices:**

These are staff chosen by the Divisions to represent the Divisional view and needs regarding medical devices, and to promote adherence to the policy within their divisions.

Duties include to:

- Be a member of the Medical Devices Committee, (MDC), regularly attending and contributing to MDC meetings
- Be well briefed to provide responses and challenges to the MDC from the Division
- Regularly communicate with Divisional colleagues information regarding medical devices, eg new purchases, changes, training issues etc.

5.16 **General Managers, Clinical Directors, Directorate Risk Leads**

Duties include to:

- Ensure compliance for this policy and associated policies throughout their areas of responsibility, particularly in procurement and training
- Review adherence to device training for all their staff, and action deficits accordingly.
- Ensure that both general managers and lead clinicians are involved in the discussion and agreement regarding the procurement of new medical devices
- Ensure that all new medical devices are approved by Clinical Engineering and/or Medical Devices Committee and that Procurement has been appropriately involved in the sourcing of equipment.
- Ensure all operating and consumable costs have been considered when making procuring new devices.
- Ensure all MHRA alerts are acted upon across Directorate
- Receive incident reports, and ensure action and follow up are undertaken appropriately
- Ensure that clinical governance, information on decontamination and training are in place for each device used in areas of responsibility

5.17 **Senior Managers**

Senior Managers include Service Directors, Divisional and Directorate Nurses, Divisional Medical leads, Matrons, Head of Midwifery, Clinical Site Managers

Duties include to:

- Lead on effective dissemination / sharing of policy with all relevant staff within the Division/Directorate
- Work with ward managers and lead clinicians to ensure Procurement, Clinical Engineering and training requirements are included in all decisions to procure devices and Trust policies adhered to, including when purchasing from charitable sources.
- Articulate and ensure all nurses are aware of their roles and responsibilities in relation to medical devices
- Ensure escalation of any concerns to the Medical Device Committee and / or Clinical Engineering / Risk Management as appropriate, in a timely fashion
- Provide leadership and support to enable appropriate actions to be taken in relation to medical device alerts
- In conjunction with ward managers / lead clinicians, ensure that all staff receive agreed medical device training on all devices used by them within their clinical area.
- Ensure ward managers and lead clinicians, in conjunction with Clinical Engineering Department, accurately and appropriately monitor and record medical devices within their area and associated training undertaken.
• Ensure that incidents and near misses, related to the use of medical devices are investigated to establish cause, and instigate solutions where necessary e.g. training in accordance with the Trust risk management policy
• Provide well briefed appropriate Divisional representation at Medical Devices Committee to reflect Divisional progress, challenges etc.

5.18 Departmental / Ward Managers & Local Areas

General duties include to:

• Utilise the inventory of all medical devices used within their area, which is updated following each ward care visit for each area, and sent to the manager.
• Utilise MAPS for nurses, midwives and healthcare support workers to regularly review their staff device training uptake, and action deficits. For other staff groups, utilise their local training records to achieve this,
• Seek advice from Procurement and Clinical Engineering Department (CED) before the purchase of all new equipment.
• Be responsible for the safe working of all medical devices, and liaise with CED regarding commissioning of new equipment, repairs, maintenance etc.
• Support CED when carrying out Ward Care visits through good preparation and accessibility of equipment and follow up actions.
• Follow up actions from ward care visits, including retrieval of devices not found
• Ensure all staff are appropriately trained to safely use and decontaminate devices.

Duties related to medical device training include to:

• Identify which staff need to be trained for which item of equipment
• Identify device training required, according to the agreed Trust risk classification
• Identify and support local trainers / super users for specific devices where this may be required, to ensure local training demands are met
• Liaise with the Trust Medical Device Trainer, or other person as appropriate, if risk classification requires this level of training
• Ensure staff have easy access to user manuals for all equipment, either in hard copy or electronic form, and utilise this for training if appropriate for the level of risk classification of the device
• Ensure new staff attend induction programme for devices training within their mandatory induction programme
• Maintain records of training for medical devices on appropriate systems eg MAPS , local databases, and local area medical devices training record folders.
• Managers in all areas where medical equipment is used will maintain a list of their staff who are verified as competent/non competent to use devices include names, type of devices, certification dates and where applicable date for updating/training, using their current agreed system of recording
• Information regarding staff training will be recorded locally on the MAPS system, where available or on local databases, and must be supplied on request
• Check that staff medical devices training is current and updated as required, using MAPS
• Local managers will support Medical Device Trainer’s role in device training of ward staff and advocate the importance of medical device training in relation to e.g. NHSLA , NPSA and MHRA
• Regularly review the device training status of their staff through MAPS or other local system to ensure that training needs for permanent staff have been met.
6. CORE ELEMENTS

6.1 Aims

The primary aim of this policy is to ensure patient safety when devices are being used. It identifies how the Trust meets its obligations regarding the acquisition, use and maintenance of medical devices. The policy outlines procurement procedures for medical devices both single use and reusable commissioned devices, and identifies procedures for staff training and support.

It explains how the Trust as an organisation meets and complies with the NHS Litigation Authority Risk Management Standards (standard 5) and the Care Quality Commission outcome 11 of the Essential Standards of Quality & Safety. The aim of both of these is to lead to the reduction of risk and incidents related to medical device incidents.

6.2 Acquisition / Procurement (Commissioned database equipment)

Medical devices purchased from new for the Trust will follow one of 3 pathways:

- Items over £5000 will be considered for purchase by the capital programme board, with business cases submitted by directorate leads. (Appendix 4). However Procurement must be fully involved at the earliest opportunity to ensure the most appropriate route to market is taken, and that the process followed is fully compliant. This section includes devices required in major capital projects, with a separate Capital Project Board.
- Smaller (sub capital) value items will be purchased in line with Trust procurement procedures. (Appendix 5)
- Purchase of medical equipment from charity funds. Any purchase from charitable funds must follow the same process as for funding from Trust funds or capital allocations. It is the Trust’s fiduciary responsibility to adhere to the correct process regardless of the source of funding.

The Medical Devices Committee will give consideration to the purchase of all high volume, and standardised medical equipment

See the purchase of new equipment flowchart, (Appendix 4).

Where appropriate, consideration should be given to the possible use of a New Procedure Application if the device is being used as part of a new procedure.

Capital, sub capital and charity bid applications for new medical equipment will include the following considerations:

- A needs analysis
- A selection process that takes account of the need to standardise and control whole-life costs, particularly consumables
- Assessment of training needs, including support and resources required, and proposed risk classification.
- Assessment of maintenance needs, and impact on revenue budget of department which owns equipment
- Assessment of funding needs
- Assessment of life expectancy and replacement need
- Assessment of the impact the equipment may have in terms of patient case mix, the need for additional electrical sockets, power or uninterruptible power supplies, gas supplies, other complementary equipment or additional staffing
- Availability of adequate instructions for decontamination, and a check that these are possible for the Trust to follow
- Emergency capital bids, eg for a sudden major device failure, with no backup option, an overlooked high priority etc
In order to ensure proper control of purchasing, and to ensure that the necessary audit trails are produced, all requisitions for medical equipment will be intercepted by the purchasing and supplies staff and reviewed by the Clinical Engineering Department to ensure compliance with this policy. Procurement must be involved at the earliest point in any consideration of new equipment to ensure the best possible financial outcome for the Trust.

6.2.1 Capital equipment purchases

- Divisions will consider the need for planned replacement programmes in cases where ageing or inadequate equipment causes clinical problems or is no longer supported by the manufacturer.
- There will be an annual round of capital bids (over £5K), overseen by the Capital Programme board. Clinical Directors, General Managers and Divisional / Directorate Nurses will co-ordinate the process for their own directorates, and prioritise bids, and complete the relevant business case form.

6.2.2 Sub capital equipment purchase (Under £5K)

- Sub capital items will be funded from individual Divisional budgets. A requisition will be raised on the PECOS electronic requisitioning system.

6.2.3 Charitable purchase of medical equipment

- The various charities that provide medical equipment to the Trust where other funding is not available should initially provide a completed charity needs analysis form (CF01 appendix 6) from the ward / Department seeking funding to Clinical Engineering. It is essential Trust purchasing processes are adhered to for charitable purchases in the same way as for all other purchases.

6.3 Acceptance of new commissioned equipment

All new equipment received into the Trust should be delivered directly to Clinical Engineering, with a copy of the delivery note, before it is put into use, in line with MHRA guidance DB 2006 (05).

The equipment will be unpacked, tested, labelled and added to the database by Clinical Engineering.

New equipment will only be issued to clinical users when training needs have been identified and met. The Acceptance Check Form CE15 (Appendix 2) attached will be completed by the Clinical Engineering Team Leader to ensure that training needs have been identified by the ward manager or person managing ward equipment.

6.4 Equipment loaned to the Trust

Equipment loaned to the Trust by a company must be accompanied by a signed indemnity form. The indemnity form includes statements about the lender’s liability for training. The indemnity form must also be signed by a Trust representative who will assume responsibility for the safe use of the equipment. All indemnification forms should be kept in Clinical Engineering and a log kept of all loan items. Equipment loaned to the Trust should also be accompanied by a decontamination certificate if not new.

The ward or loan company should inform Clinical Engineering when the equipment has been removed from the Trust.

Equipment that companies ‘donate’ for long term use or provide free of charge needs to be assessed before its introduction to ensure it satisfies and complies with the Trust financial,
environmental and maintenance and training requirements.

Substitute equipment loaned to the Trust whilst repairs are being carried out is marked by the Clinical Engineering Department with a loan sticker, so that clinical staff know this. A record of this is also kept on the history of the device under repair.

6.5 Equipment loaned by the Trust

In all cases where equipment is loaned out, it must be sent out with a certificate of decontamination to be downloaded from the Decontamination Committee Intranet site. The borrower must complete a fresh certificate before the equipment is accepted as returned. Recording of details regarding such loans is maintained locally by the specialist providing the equipment, e.g. Tissue Viability for vacuum pumps.

6.6 Off-Label use of medical devices

Off-Label use is defined as the use of a device to treat a disease or condition not listed on label, or used in such a way that is not outlined in the label, (Medical Devices Agency, 2010). This is sometimes referred to as non-approved or unapproved use.

Where it has been decided to use a medical device for an off-label indication the healthcare professional or organisation should:
- complete and document a risk assessment
- consider and document the ethical and legal implications
- implement suitable precautions to minimize the risk
- review the risk assessment at suitable intervals
- inform the patient during the consent procedure and a note to be made in the patient’s record

Once the above have been completed, the use of the device should be agreed by the Consultant in charge of the patients care and this is to be documented in the patient’s notes.

6.7 Inventory of diagnostic and therapeutic equipment

An inventory of all equipment used in the Trust is held and stored on the AIMS database, which is managed and kept up to date by the Clinical Engineering Department (see 3.2 for more details).

6.8 Process for maintenance and repair

6.8.1 Breakdowns
If equipment breaks down or malfunctions, users should fill in a form from their Clinical Equipment Fault Report Book, and send the faulty equipment, with the form, to the Clinical Engineering Department, where any necessary repairs will be carried out under a quality system, either in-house or using approved service providers. All equipment must be cleaned prior to sending to the Clinical Engineering Department and the documentation includes a decontamination certificate. All work carried out on equipment will be recorded on AIMS as part of its service history.

The monitoring of repairs from initial identification to completion of work is registered on AIMS. Individual reports are identified by job numbers, and outstanding repairs are identified for monitoring purposes, so that information regarding progress can be communicated to managers.

6.8.2 Accessory replacement
Clinical Engineering will replace commonly used equipment accessories on a new for old basis for items such as Oxygen saturation sensors and non invasive blood pressure cuffs etc. If additional accessories are required the wards are advised to
order these from their own budget. Clinical Engineering will normally supply these and cross charge, or order on the ward cost centre. Under the new SLA all items that are replaced because they have been lost, will be paid for by the wards.

6.8.3 Repair cost limitation
The Clinical Engineering Department will fund repairs to equipment up to 40% of the original purchase price. If the cost of repair is greater than 40%, the ward is advised that they should either pay for the repair from their own budget, or consider buying a replacement. Clinical Engineering will also take into account the age of the equipment as to whether it is worth repairing.

6.8.4 Ward care visits: process and monitoring
During the course of the year all wards are visited in a systematic programme of ward care visits. A schedule of all ward care visits is held by Clinical Engineering Department, to enable progress to be monitored. Preparation ahead of visits will be coordinated by CED, with the ward / department. Managers will ensure staff know about the visit, and cooperate so that equipment is made accessible where possible. The ward care visit programme is a continuous cycle of inspections of all medical equipment in all ward areas, and ensures ward managers know their equipment is safe to use. It comprises the following elements:

- Inspection of all:
  - Gas cylinder regulators and their trolleys cylinders
  - Flow meters and suction regulators
  - Mains operated suction units
  - Mobile equipment and attached roll stands
  - Sphygmomanometers
- Confirmation that the ward has a Clinical Engineering fault report book
- Confirmation that the ward has a medical devices competency file
- Confirmation that the resuscitation daily check list is being completed by ward staff
- Inspection of any mains extension leads being used for medical equipment.

The ward care technician will have a printed list of the ward inventory of devices, which is extracted from the AIMS database. The information is transferred onto a CE98 ward care form (appendix 7) where confirmation that the equipment is still on the ward, its condition and cleanliness, is recorded. All items of equipment from the list that are found on the ward will undergo appropriate checks, calibration and maintenance, which will be recorded on the appropriate Preventive Maintenance (PM) inspection form for the device type (appendix 8). This information is recorded on AIMS for each individual item by the CED administrator, so that there is evidence that the equipment has been inspected.

All items inspected will have the green licence label renewed and any other stickers appropriately replaced. Devices found that belong elsewhere will also have the necessary PM work carried out, and will normally be returned to the appropriate ward. Equipment with a white “Contractor” asset label is checked to see if it has an in-date service label from the contractor. This is recorded on the quality assurance inspection sheet CE 53 (appendix 5).

Items that cannot be found by the ward care technician are referred to ward staff, for further help to find them. Those that still cannot be found are recorded on the CE98 sheet, and the number of missing items is recorded on the care visit compliance certificate (CE 54, appendix 6). Details of missing items and outlining of the manager responsibility for these is provided.

Identification of other issues, eg any shortages of equipment manuals, storage conditions of equipment and any reliability issues are also recorded. The back of the Service performance satisfaction, both generally of CED and of the care visit are also recorded. Discussion will then take place with the manager regarding issues and challenges related to devices, which will be recorded on the form. It is the
responsibility of the manager to follow up issues and agreed actions including retrieval of devices not found. CED will then follow up any issues identified, eg training issues to the Medical Devices Training Manager. Ongoing concerns will be reported back to the Medical Devices Committee via the CED report. Electronic copies of all CE 98 forms are kept on the CED shared drive, for each year of the rolling programme. After each visit, the care programme spreadsheet is updated with the completion date, date next due and the number of missing items. Missing items are entered onto AIMS under a status of “not found in ward care visit”, unless there is evidence from AIMS that it has been seen recently on another ward. Subsequent searches on AIMS for the next annual visit will look for items that have a status of “in service” and “not found in ward care visit”. Items that have a status of “not found” after 2 ward care visits, and the annual audit of all medical equipment, the Big Count, are deemed to be permanently missing, and will have their status changed to “out of service”. These items will not be searched in any future ward care visits or audits, unless they subsequently reappear, in which case they will have the necessary checks performed and a new licence label attached.

Items of equipment sent to CED for repair that are due for a PM check at the same time will have the required PM done at that point.

6.8.5 No fault found
Items of equipment that are sent to Clinical Engineering for repair that subsequently are found to have no fault are recorded on AIMS as ‘no fault found’. Reports can be generated for these instances to identify any wards where there appears to be persistent problems. This data would point towards a training deficiency in the use of the device and it may be necessary to notify the relevant Department’s manager in order to arrange relevant training.

6.8.6 Outsourced contractors
Outsourced maintenance contractors are asked to provide Clinical Engineering with all service reports for work carried out in order that the equipment history on AIMS can be updated. Service agents are requested to attach clearly visible labels to all equipment they service to indicate its service date.

6.8.7 Obsolete equipment
This is equipment no longer supported by the manufacturer in terms of spare parts etc. Clinical Engineering’s Quality Procedures incorporate expert assessments of devices’ condition. Devices are recommended for replacement according to structured protocols, either subsequent to breakdowns or during the course of Ward Care Visits. Ward managers are advised regarding obsolete equipment and are asked to sign ‘notice of obsolescence’ form CE19. These items of equipment will be marked with a yellow label.

6.9 Decommissioning and disposal of equipment
In order to keep an up to date record of the Trust medical devices, obsolete or replaced old equipment must be sent to Clinical Engineering for de-commissioning and eventual disposal. All equipment must be cleaned prior to this, and have an accompanying decontamination certificate. It must be disposed of following local regulations or guidelines. This applies also to any equipment that is being traded in against the purchase of new equipment. The Clinical Engineering Departmental administrator is responsible for the entry and removal of devices from the AIMS database once the appropriate paperwork has been filled in. All items that are to be de-commissioned are approved for removal by the General Manager for Estates & Facilities.
6.10 Risk Management

- Equipment involved in an adverse incident should be removed from service and quarantined, along with any associated accessories.
- Trust Incident Reporting Procedures should be adhered to with the standard incident form completed and white copy passed to the Risk Management Department.
- A green equipment fault form should be filled in, with the addition of the incident form reference number. It should be sent with the equipment and the pink copy of the incident form to Clinical Engineering as soon as possible.
- The Risk Management Department will notify the Clinical Engineering Team of any incident involving medical equipment.
- All equipment device types will be classified according to the Trust’s Risk Classification system.
- The Risk classification is recorded on AIMS for each device.
- Monthly reports will be sent from Risk Management to CED and the Medical Devices Training Manager regarding device incidents. Any general issues requiring action by others will be reported back to the MDC via the Clinical Engineering and medical device training reports. The relevant manager of the area will follow through all other device incidents using the normal Trust risk management process. Where issues are ongoing, these will be included in the MDC bi monthly reports to the Risk Management Committee.

6.11 MHRA safety alert bulletins

The Trust’s incident reporting procedure is used in respect of all incidents involving medical devices and all such incidents are considered for reporting to the MHRA in accordance with their guidelines.

No device is ever risk free and for this reason the MHRA have a safety broadcasting system that disseminates safety notices regarding issues that have been identified through use of these devices.

A cascade process is in place for the distribution of Safety Warnings and Hazard Notices issued by the MHRA and other external organisations.

These include:

- Alerts via the Central Alerting System (CAS) (previously called Safety Alert Broadcasting System, SABS)
- Field Safety notices
- Estates & facilities alerts
- Manufacturer’s recall notices

The process for dissemination of alerts is as follows:

- All warnings and notices are acknowledged in the first instance by the CAS Liaison Officer, (the CED Administrator)
- They are then sent onto Procurement to identify if any of the devices are present in the Trust and their location. The Clinical Engineering administrator and Clinical Engineering team leader agree on an appropriate distribution group as to who to forward the alert to
- The Clinical Engineering administrator collates responses from the distribution group and chases up responses near to the closure date.
- The administrator is responsible for keeping accurate records of Medical Device and other alerts and sees that actions are implemented appropriately.
- The administrator, on behalf of the CAS liaison officer, ensures that CAS alerts are closed on time, and that a full log of responses is kept for each alert. These are ultimately signed
off by the Head of Estates and Facilities. The CED administrator closes the alerts on the CAS system.

- A report on the status of alerts will be presented at each Medical Devices Committee by CED

Divisions will ensure that risks associated with medical devices are methodically reviewed and a risk register maintained in accordance with the Trust’s Risk Management processes.

### 6.12 Medical Device Training

Staff training on equipment is essential to ensure devices are safely used on patients. A significant number of adverse incidents involving medical devices can be caused by training deficits. NHSLA Risk Management Standards also require hospitals to reduce the risk to patient safety associated with the use of medical devices, by implementing systems to ensure staff are trained and authorised to use medical devices. The importance of robust system of training is also recognised and promoted by the National Patient Safety Agency, MHRA and is an identified standard within the CQC monitoring process. Personal professional accountability underpins all self assessment of device competency.

#### 6.12.1 Identification of training needs according to Trust risk classification for devices:

(see Departmental/Ward Managers duties relating to medical devices training (5.17).

The training required for medical devices is identified according to the Trust risk classification system for medical devices. This has been developed in accordance with European Standards, (2007), and agreement with clinical experts across the Trust. Clinical experts within and across Directorates will continue to be involved in such arrangements, under the leadership of the Medical Devices Committee, where appropriate. The decision of an appropriate risk classification for new devices will be ratified by the Medical Devices Committee, following clinical agreement by the relevant clinicians beforehand. In practice a small sub group of the MDC will agree the decision and report back to the full Committee for ratification.

In line with the Point of Care Testing policy (POCT), all POCT devices are classified as medium risk and require documented competency training before use.

The Trust has a colour coded risk classification system for medical devices, which describes the criteria for authorisation of use of devices, and has been developed for easy identification of risk levels and categories of training required for medical devices:

- **High risk device:** potential to cause serious harm or death if misused or fails. Do not use, unless you have received training for this device from a recognised trainer. This may be a super-user. These are staff in local areas who have been trained as a trainer on specific devices. Complete an assessment of medical device competence (where available).

- **Medium risk device:** potential to cause significant impact on patient care if misused or fails, and all POCT devices. Seek training or instructions for use from a trained member of staff. Complete an assessment of medical device competence (where available).

- **Low risk device:** unlikely to cause serious consequences if misused or fails. Review user manual, user guide or instructions. Continue then using your own professional judgement.
The Trust AIMS database holds an inventory of all medical devices in the Trust, and will indicate Trust risk category for each device registered. A local inventory is available to all managers locally for their area via the most recent ward care visit report from CED, and also is updated after each annual Big Count for all areas if required.

6.12.2 Procurement linked to training:

The procurement process must always include a needs analysis of training to be provided by the supplier for implementation and ongoing training, regarding both user and technical training. Before any device of whatever type is purchased, the manager must discuss and identify with clinical colleagues, CED and procurement, if there is a training element to its purchase.

Where large numbers of devices are being purchased e.g. infusion pumps, the Medical Device Committee will advise the Trust to purchase the same type and support an organisational approach to making such informed decisions, in line with the agreed flow chart, (appendix 10). The Trust Medical Devices Training Manager will always be involved in these corporate discussions.

6.12.3 Responsibility for training:

The Trust recognises its responsibility to ensure medical device users are appropriately trained, and will work according to the Trust’s medical devices policy to achieve this. It is imperative on managers that their staff who use devices are trained according to this policy before using equipment. Registered professionals also take personal accountability for any non-compliance (NMC, 2010).

Formal training must be delivered by a recognised trainer, and an assessment of competency completed and recorded where formal training is required. A recognised trainer may be any person who has received super user training on the required device, or trained by the medical devices trainer or the relevant company trainer for the device being used, against a competency assessment which has been recorded. Formal training is also delivered on some medium / low risk devices on induction, and for these only, a self assessment of competency is completed.

The Equipment Library manager has responsibility for training on Trust generic medical equipment and works closely with the medical devices trainer to deliver a structured programme of medical device training to all staff requiring this. This includes medical staff as well as nurses, midwives, therapists etc.

Part of the Clinical Engineering New Equipment Commissioning Procedure requires recipients of new devices to confirm by signature that they have identified any training needs required for the device they are taking delivery of, (see Section 6.3).

Where patients are admitted to the Trust with unfamiliar equipment already in situ, receiving staff should exchange these for equivalent Trust equipment at the earliest opportunity. Any delays to the administration of a prescribed medicine as a result of an unfamiliar device should be escalated in line with the Trust Medicines Policy.

Trust staff supplying medical devices or instructing patients in their use will be appropriately qualified and experienced in the use of the particular device to instruct others.

6.12.4 Frequency of updates:

The underpinning principles of maintaining and updating competence are:
The importance of the recognition of the individual's professional accountability for recognising learning deficits and requirements for updating
- The notion of self assessment as the best way of taking accountability, and of recognising, assessing and individualising need
- The manager role in supporting or challenging decisions made regarding accountability of staff members, where performance or patient safety might be an issue
- Frequency of usage of the device.

Competency identifies ability to use equipment safely, and training is required when a deficit in competency or knowledge is identified, or where the policy deems this to be mandatory.

Criteria for method of update will be linked to the Trust risk classification system for identifying training for each medical device, and then as follows:

**High risk (red):** Competency self assessment every 3 years, recorded on MAPS, or centrally held spreadsheet.
**Medium risk (orange):** Competency self assessment every 5 years, recorded on MAPS or centrally held spreadsheet
**Low risk (green):** Update only if equipment changes or the staff member changes their working environment.

Competency assessments have been developed using an agreed Trust wide competency framework, (appendix 11) and are used on all initial formal training sessions, and for self-assessment.

**6.12.5 Process of identifying which staff are authorised to use equipment, medical device training required, and the accessing and recording of training:**

Any staff that are deemed competent to use certain equipment are authorised to use that equipment. A Trust system for risk classification is in place that links outcomes of misuse or failure to the corresponding training requirements to help managers and staff identify the training required, see 6.12.1.

A flow chart, (appendix 9), describes the process for identifying need and accessing training. A mandatory comprehensive device training and competency assessment programme is in place for all new staff who use such devices, during induction.

**6.12.5.1 Accessing training:**
Using the Trust risk classification system, managers will:

- Utilise their local inventory of devices in use within their area. This information is updated and sent to managers with their ward care visit report, also annually following the Big Count audit of all devices held in the Trust, and also when new devices have been registered through CED.
- Identify the type of training required according to the Trust risk classification system on the local inventory.
- Identify which staff need to be trained for which item of equipment, according to clinical need and designation.
- Ensure new staff attend mandatory device training as part of their centrally arranged induction programme
- Liaise with the Trust Medical Devices Training Manager as necessary, or other person as appropriate, eg super user, local trainer etc to arrange training, other than induction as needed.
- Ensure staff have easy access to user manuals for all equipment, either in hard copy or electronic form, and utilise this for training if appropriate for the level of risk classification of the device
- Identify and implement other forms of training as required, including identification of super users locally if required
- Ensure device users are released to attend required training and that they understand that they will take accountability for their own professional updating, whether formal or informal.

6.12.5.2 Recording of training:
Training is recorded for all high risk and POCT devices and any medium /low risk devices where formal training has been undertaken, eg at induction. This is recorded on the competency sheets which are scanned and held centrally by the Medical Devices Training Manager, as well as in the medical devices folders held in the clinical areas.

a. For nurses, midwives and HCAs:
Competencies will be uploaded onto MAPS for nurses, midwives and health care assistants and kept in folders centrally held for medical staff currently. MAPS reports can be viewed by managers via the monthly mandatory training reports on Qlikview. The MAPS system identifies imminent expiry of competency, those without competency etc.

Device training that is mandatory by policy must be attended, and if sessions are missed staff, they are required to attend, the next available session. Managers must use MAPS or their local recording system to review staff training status and ensure adherence to policy for training is maintained.

When the staff member leaves the Trust, or moves department, their competency documents are to be taken with them. The local manager must ensure local training folders are utilised appropriately, and the medical devices training manager will update these folders, as competencies are completed, eg post mandatory induction.

b. For medical staff:
FY1s, FY2s: Will receive training on relevant high risk devices on induction, and this is recorded on centrally held spreadsheets.

CT/ST grades: Training will be identified for them by the Clinical Tutor for their area from the local agreed inventory of devices, and delivered accordingly. It will be recorded on centrally held spreadsheets when managers have provided attendance details. This training is also recorded on their e-portfolio, and also held by the department area,

For consultants: Devices requiring evidence of competency to use will be identified from the agreed local inventory for the area. They will either self-certify their competency or attend training. Either way this will be recorded centrally on spreadsheets currently, and also locally, which will feed into their appraisal documentation under mandatory training and for revalidation.

Therapists will retain local records of training required and completed, as most of their devices are low risk, (green), and the representative on the MDC will report back any issues.

Training uptake will be monitored by ward managers through reviewing their MAPS status and their monthly Qlikview reports, and actions taken as required. Divisional Medical Devices representatives will be responsible for reporting back at each Medical Devices Committee meeting about overall Divisional issues and challenges, and also working with the Medical Devices Training Manager to address these.

For medical staff, where training in medical devices and equipment is specialty specific, the training is determined by a training committee on behalf of the Deanery. This training is monitored and signed off by the individual and the trainee’s supervisor.

For all new staff:
New nurses and midwives requiring formal device training will be identified according to their area of work by the Medical Devices Training Manager, and invited to mandatory training sessions as part of their induction programme. This will be recorded centrally on MAPS. For all FY1s and FY2s, device training will be delivered as part of their medical induction programme. For senior medical staff, it will be identified by the clinical lead on commencement of employment, according to their clinical area.

Advice on where training can be accessed and dates may be available in the clinical area or via the Medical Devices Training Manager.

Please note: Training arranged locally must be in liaison with the Medical Devices Training Manager to ensure central recording.

6.13 Availability of equipment

The Equipment Library will ensure that medical equipment that is generic to the Trust will be available when requested. The Library will also ensure that its equipment stock is fully serviced, decontaminated, and has fully charged batteries when it is loaned out.

Each ward is sent a catalogue of what is available to them, and updated as new types of equipment become available in the library. This list is maintained by the library manager.

Other items of ‘backup’ generic equipment, eg; blood pressure machines etc; are kept in the library in case of failure of such items while in use.

Equipment is requested via the portering helpdesk, and delivered by portering. It is collected when use is complete by Clinical Engineering, and must be decontaminated before return.

6.14 Re-use of medical equipment

Re-usable medical devices are to be cleaned in accordance with the Trust decontamination policy.

All staff using these devices need to be aware which devices are re-usable, and which are single use, (MDA (2000) Single use Medical Devices: implications & consequences of reuse).

Single-use devices must not be reused under any circumstances. These are identifiable by a single use label on the packaging. Add symbol

Decontamination certificates are part of the Clinical Engineering Fault report form, and must be filled in when sending items for repair. Incomplete forms are likely to be sent back to the ward along with the equipment without any inspection taking place.

6.15 Equipment Trials

Any trials of new medical devices that are not CE marked must have ethical approval and be authorised by the Medical Devices Committee. Associated training needs and patient safety concerns should also be taken into account.

Non CE marked equipment should not be purchased by the Trust. Alternative CE registered products should be sought out instead.

7. DISSEMINATION

The document will be disseminated by publication on the intranet in the Trust wide Policies and Procedures section, and under Departments / Estates and Facilities / Estates and Facilities / Clinical Engineering / Clinical Engineering Policies, and also by circulation of its release by Trust wide email.
Support and advice regarding the policy will be available from the Clinical Engineering Team, Medical Devices Training Manager and Medical Devices Committee as required.

8. MONITORING, IMPLEMENTATION AND EFFECTIVENESS

8.1 Auditing of equipment
All items of commissioned medical equipment that are identified on wards during the annual Ward Care Visits are audited and re-licensed as part of the process in 6.8.4. Local action plans are devised from each Care Visit, which are the responsibility of the ward manager to ensure are completed. Items not found on the visit are identified and communicated to the area by the Clinical Engineering team and followed up.
The ward care visits schedule is audited annually, to assess that all clinical areas have been visited at least once, as required.
An annual “Big Count” event takes place once a year, where the Clinical Engineering team carries out a two day audit of all devices within the Trust. This data is recorded on AIMS, and enables the local inventories held on AIMS to be updated and circulated to ward managers. A report and action plan on this is communicated to the Medical Devices Committee via the CED report.
Items not found over 2 annual Big Counts will have their status amended to “out of service” on the asset register.
The schedule and progress of Care Visits and action plans is reported back to the Medical Devices Committee as part of their standing agenda item.

Issues of continued concern from both the “Big Count” and the Care Visits are reported to the Risk Management Committee as part of the Medical Devices Committee report.

8.1.2 Auditing of maintenance
An annual audit of care visits is undertaken by CED, which identifies due dates and completion dates, equipment numbers, and missing numbers of items. A report and action plan from this inform the ongoing schedule work, and also areas of concern, eg missing items. This audit is reported back to MDC through the standing CED reports.

8.1.3 Auditing of repairs
The repair of all devices is recorded on AIMS as part of the service history, and an audit of a sample of clinical equipment fault report forms is conducted to check repairs have been completed, and reported via the CED report to the Medical Devices Committee, with appropriate actions if required.

8.2 Auditing and reporting of Clinical Engineering Department function
The Clinical Engineering Department is audited annually as part of its National Quality Assurance (NQA) to conform to its ISO 9001 quality system. The ISO system has been extended to test local systems and to include audit, so this can be used to inform other monitoring processes.

Action plans for the Department are developed from these audits. The outcomes of these audits are reported as part of the Clinical Engineering Department report to the Medical Devices Committee.

The Clinical Engineering Department report is a standing item on the Medical Devices Committee’s agenda. Non conformity with this policy and other issues are reported through this report. Issues arising of concern form part of the MDC report to the Operational Risk Committee.

Monitoring of repairs is undertaken by Clinical Engineering, as described in section 6.8.1
Monitoring of the maintenance programme is undertaken by Clinical Engineering as described in section 6.8.4
8.3 Auditing and reporting of device training

Training will be audited as follows:

- All managers will utilise the monthly Qlikview reports, which will record both training attended and the outcome of training where appropriate, and will highlight when updates are needed. Managers will report any major deficits / issues regarding training to the Medical Devices Training Manager and to the relevant Divisional devices lead for action by the Division. Local issues e.g. non attendance or non completion will be managed by the manager locally.

- Managers are also able to continually review the device competency status of their staff via MAPS.

- The Medical Devices Training Manager will undertake quarterly audits via Qlikview on device training and report back to the Medical Devices Committee, highlighting concerns, successes and actions required. Major issues, e.g. resourcing etc., will form part of the Committee’s action plan. These will be reported to the Risk Management Committee via the quarterly MDC reports, if of major concern or where there is no resolution.

- For consultants, monitoring of their device training will be done through the device documentation under mandatory training, in their annual appraisals, and reported back to the Trust via the appraisal system. It will also be recorded on OLM.

- Clinical Tutors will monitor uptake of training for STs and others in their area via their locally held records

- Divisional and overall organisational uptake will be reported annually by the Medical Device Training Manager in their annual report to the MDC, who will highlight deficiencies, develop strategic action plans and make appropriate recommendations to the Medical Devices Committee prioritising high use, high risk device training.

- The Medical Devices Training Manager will report training issues, concerns and developments to the MDC as a standing agenda item.

- The analysis of student feedback forms from training sessions will also provide information and recommendations, which will be agreed and implemented by the Medical Devices Training Manager.

8.4 Other monitoring:

- The Medical Devices Committee will report monthly to the Risk Management Committee, highlighting issues of major concern, progress reports, achievement etc.

- The Medical Devices Committee will monitor the monitoring of general compliance annually, reporting back to the Trust Risk Management Committee
REFERENCES

Department of Health, (2008), Definition of Medical Devices, accessed at www.dh.gov.uk on 25/6/08


Care Quality Commission, Outcome 11, (section 20, regulation 16, Health & Social Care Act 2008)

NHS Litigation Authority, Risk Management Standards

Health and Safety at Work Act, 1974

Provision and Use of Work Equipment Regulations (PUWER), 1998

Management of Health & Safety at Work Regulations 1999

MHRA Guidance:

DB2006(05) Managing Medical Devices

DB2006(04) Single Use Devices – implications and consequences of reuse

DB2007(01) Reporting adverse incidents and disseminating device alerts

DB2003(05) Management of medical devices prior to repair, service or investigation
APPENDIX 1

Terms of Reference of Medical Devices Committee

Introduction

Medical Devices are all products, with the exception of medicines except in exceptional circumstances, used in healthcare for diagnosis, prevention monitoring or treatment. The use of these devices is integral to the daily workings of the Trust, and requires a rigorous approach to their procurement, use, maintenance and training to ensure patient and staff safety when using them.

Aim

The aim of the Medical Devices Committee (MDC) is to provide assurance to the Trust Board through the Risk Management Committee that there are robust governance systems in place to manage the risks associated with the acquisition and maintenance of medical devices.

The procurement, use, training and maintenance of medical devices impacts on a wide range of clinical and non-clinical staff, and this fact will be reflected in the committee’s membership.

Responsibilities

To ensure that there is a robust framework for medical device management the MDC will:
- ensure the development and systematic review of an accurate asset register of all reusable medical devices and equipment used within the organisation
- contribute to the ongoing development of a policy for the procurement, use and maintenance of medical devices; this will include clear criteria to support all staff authorising requisitions
- lead on the corporate arrangements for agreeing the purchase of new medical devices, through the Capital Bids process, and other arrangements for sub capital equipment
- support and oversee a rolling programme for the procurement and replacement of medical devices
- work with Procurement to ensure best value and legal compliance, in line with Trust’s standing financial instructions and relevant public sector/ EU regulations
- develop and maintain a Clinical Product group, to address procurement of consumable devices
- introduce a governance process for the trialling and evaluation of medical devices
- liaise with the Medical Device Trainer and others to establish and monitor the education and training for all staff using medical devices (NHSLA 2.7)
- monitor medical devices education and training activity within each directorate using agreed systems (NHSLA 3.7)
- establish and maintain standardisation of medical devices where appropriate
- develop and monitor key indicators showing improvements in medical devices management
- receive quarterly reports from MAPS via Medical Devices Trainer regarding uptake of training and develop recommendations and action plans as required
- support the development and service provided by the Equipment Library
- ensure that there is a comprehensive programme identifying the extent of compliance across the organisation with national alerts issued via the Central Alerting System (formerly Safety Alert Broadcasting System) (NHSLA 3.7)
- Consider relevant reports from external organisations, such as the MHRA, and action accordingly.
- produce regular reports to the Operational Risk Management Committee on all issues related to medical devices as agreed with the Committee chair (NHSLA 3.7)
- support the organisation in preparation for external visits and inspections as required
Reporting to

Operational Risk Management Committee

Membership

There will be a core group, whose attendance or suitable alternative representation is vital for the Committee to function effectively and in a representative manner. There will be agreed co-opted members who will be required to attend as required.

Core group

Director of Operations (Executive Sponsor)

Representatives from:
Risk Management
Procurement
Clinical Engineering
Medicine & Surgery Division
Clinical Support Division
Womens and Childrens, HIV and GUM Division
Emergency Department
Anaesthetics & Imaging Directorate
Resuscitation
Therapies
Critical Care
Decontamination / Sterile Services
Medical Devices Training Manager
Administrator, Clinical Engineering, (minutes)

Co-opted members:

Representatives from:
Clinical Skills Team
Pharmacy
Theatres: Technician / Senior Operating Department Practitioner
NICU: Technician / Clinical Nurse Lead
Radiology
Infection Control

Role of Committee Members

Committee members will be expected to:

- attend the committee meetings, or send a fully briefed representative
- read the committee papers prior to the meeting, and actively participate in committee meetings
- represent their departments
- undertake actions i.e. data collection, audits, participating in tendering processes etc, as agreed at meetings
- disseminate information within their departments

Committee Meetings

Committee meetings will take place bi-monthly; however, the frequency may be increased as and when required.
**APPENDIX 2 - Clinical Engineering Acceptance Checks for New Equipment CE15**

**Additional items listed over * □**

<table>
<thead>
<tr>
<th>Control No*:</th>
<th>Serial No*:</th>
<th>Manuf:</th>
<th>Ward Name:</th>
</tr>
</thead>
</table>

**Action Code:** ACCP  
**Date:** ....../........./........  **Initials:** ............  **Time taken Hrs / Mins:** ....../.....

**Device type:**

<table>
<thead>
<tr>
<th>Acceptance check</th>
<th>Comment</th>
<th>Pass</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the equipment itself CE marked or damaged in any way?</strong></td>
<td>If yes to any of these questions, reject the equipment. Inform the following: Supplier; User; Quality Controller.</td>
<td>pass/fail</td>
</tr>
<tr>
<td>Does it fail to power up or complete its self test?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>This equipment will need planned maintenance. Does a generic service template exist?</strong></td>
<td>If no, contact the Quality Controller.</td>
<td>pass/fail</td>
</tr>
<tr>
<td><strong>Does the equipment have a pre fitted 13 amp mains plug?</strong></td>
<td>If no, fit a resilient 13 amp mains plug with a suitably rated fuse. <em>(5A if equipment uses a normal IEC mains lead)</em></td>
<td>pass/fail</td>
</tr>
<tr>
<td><strong>Has an instruction manual been supplied?</strong></td>
<td>If no, obtain one prior to licensing the equipment</td>
<td>pass/fail</td>
</tr>
<tr>
<td><strong>Has the user identified any training that will be required on this device?</strong></td>
<td>If no, ensure that staff are aware that they should organise suitable training.</td>
<td>pass/fail</td>
</tr>
<tr>
<td><strong>Does the equipment pass all of the above conditions?</strong></td>
<td>If yes, deliver the equipment to the User. If no, give reasons below.</td>
<td>pass/fail</td>
</tr>
</tbody>
</table>

**Reasons for not delivering equipment:**

**Corrective action taken:**

**Team Leader**

- □ This equipment will be maintained in house
- □ This equipment replaces existing equipment which I have removed from service. Therefore funding from the old equipment can be used for the new.
  - Control number(s) decommissioned: 
- □ This equipment requires an out-sourced maintenance contract. *(Data entry clerk to forward copy to Operations manager)*
- □ This is additional to existing equipment and will therefore require extra funding.
- □ In my judgment, a specialist Infection Control opinion is not necessary.

I am satisfied that I have made arrangements for the ongoing maintenance of this device. The equipment may now enter service.

**Signed**

**Name**

**Date**

**Professional User:** I am satisfied that the equipment(s) and operators manual(s) is (are) correctly supplied and that I have identified any training needs, and will ensure it is carried out. I will ensure the equipment is used as directed in the manufacturer’s instructions.

**Signed**

**Name**

**Designation**

**Date**

**Note:** This form should be signed by a senior member of staff who will have responsibility to ensure that staff receive training in its use.

---

This form can be used for multiple entries for batches of equipment with the same manufacturer and model. Additional Control Numbers and Serial Numbers should be listed on the back of the form.

Last Revised 22 July 2005  
Printed 10 September, 2014
APPENDIX 5

Clinical Engineering

Out sourced Quality Assurance Inspection CE53

<table>
<thead>
<tr>
<th>Location:</th>
<th>Aux Ref</th>
<th>Action code: QA</th>
<th>Date:......../......../........</th>
<th>Assignee: ..........</th>
<th>Time taken Per Item Hrs/Mins: ...../.....</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control No.</td>
<td>Description</td>
<td>Serial No.</td>
<td>Last service date / service status</td>
<td>In date sticker from outsourced contractor Y / N</td>
<td></td>
</tr>
<tr>
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</tbody>
</table>

The above items are either satisfactory or I have raised any non compliance issues with the Quality controller at the regular monthly meeting.
Signed Team Leader: ..............................................

Check:
- With the user if there are any known faults or problems with the equipment or contractors.
- Equipment is still being used. *If not consult with Team Leader.*
- Cleanliness of instrument. *All old labels removed, instrument clean.*
- For evidence of servicing. *Either by service report or appropriate labelling on instrument. Indicate in last column.*
- Instrument appears to be in good working order.
## Clinical Engineering

**Ward care & quality compliance certificate CE54**

<table>
<thead>
<tr>
<th>Ward Name:</th>
<th>Start date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior sister / ward manager name:</td>
<td>Ext:</td>
</tr>
</tbody>
</table>

### Tasks completed during equipment care visit

- Cylinder Regulators are correct for the gas they are supplying and within their service duration
- Cylinder holders / trolleys are suitable and in good working condition
- Oxygen therapy equipment is in good working condition
- Vacuum equipment, wall and electric, is in good working condition
- Medical gas / suction facilities sufficient for patient bedsides
- Monitors properly mounted e.g. *bedside; trolley; roll stand*
- Aneroid sphygmomanometers have been rationalised to a suitable quantity and are all in good working order. (Any remaining Mercury sphygs to be removed from the ward)
- All medical equipment is in good working order, with 12 months licence or longer.
- No broken equipment remains on the ward
- Confirmation of Fault Repair Book e.g. *adverse incident labels*. (supply new book if necessary)
- Confirmation of staff medical device competency file
- Confirmation that the Resuscitation Station Daily Checklist has been regularly completed

### Please note any issues you wish your team leader to raise during the final care visit with the ward manager/ sister: *Carried out by Technician*

<table>
<thead>
<tr>
<th>Equipment Training outstanding needs, include fault reporting, adverse incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating manuals and Warning Posters</td>
</tr>
<tr>
<td>Current and future service needs developments moves &amp; changes</td>
</tr>
<tr>
<td>Obsolescence advance notice yellow licence</td>
</tr>
<tr>
<td>Reliability of existing equipment discuss any persistent problems</td>
</tr>
<tr>
<td>Equipment storage Take Photographs if poorly stored Batteries charging?</td>
</tr>
<tr>
<td>Equipment diversity</td>
</tr>
<tr>
<td>Number of devices identified on CE 98 census form</td>
</tr>
<tr>
<td>Number of devices NOT found during ward care visit</td>
</tr>
</tbody>
</table>

To the best of my knowledge equipment on this ward has been inspected and is in a good and safe working condition.

I understand that the Clinical Engineering Quality Controller may carry out an audit

Signed ____________________ Print name ____________________ Date ___________.
APPENDIX 7

CLINICAL ENGINEERING WARD CARE FORM CE98

<table>
<thead>
<tr>
<th>Control No</th>
<th>Device type</th>
<th>Serial #</th>
<th>Location</th>
<th>Contaminated?</th>
<th>Obsolete?</th>
<th>Damaged?</th>
<th>Broken?</th>
<th>Not found</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Y / N</td>
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</tbody>
</table>
## General Equipment Performance Testing Record

<table>
<thead>
<tr>
<th>Item No</th>
<th>Manufacturer</th>
<th>Serial No</th>
<th>Location</th>
<th>Job Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

**Memo:**

**Pass**

### Visual Checks
- Check with the user if there are any known faults or problems
- Cleanliness of instrument: *Remove old labels, clean instrument.*
- Casters/brakes: Must operate freely
- Mounting and fastenings *must be secure*
- Chassis/casing *must be undamaged with all fixing points intact*
- Accessory cables/modules/probes/chargers *Must be free from visual damage*
- Particulate air filters *Where fitted must be inspected cleaned or replaced use discretion*
- Controls/Displays *Must function correctly*

### Electrical safety
- Mains plug wiring correct and secure.
- Check fuse rating: _____ Amps
- Inspect mains cable for mechanical damage to outer sheath
- Inspect IEC connector or mains cable entry to instrument for damage
- Inspect instrument case for cracks or missing fixings
- Earth bonding resistance: 0. ......... Ohm.

---

<table>
<thead>
<tr>
<th>Item No</th>
<th>Manufacturer</th>
<th>Serial No</th>
<th>Location</th>
<th>Job Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>As Above</td>
</tr>
</tbody>
</table>

**Memo:**

**Pass**

### Visual Checks
- Check with the user if there are any known faults or problems
- Cleanliness of instrument: *Remove old labels, clean instrument.*
- Casters/brakes: Must operate freely
- Mounting and fastenings *must be secure*
- Chassis/casing *must be undamaged with all fixing points intact*
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### Electrical safety
- Mains plug wiring correct and secure.
- Check fuse rating: _____ Amps
- Inspect mains cable for mechanical damage to outer sheath
- Inspect IEC connector or mains cable entry to instrument for damage
- Inspect instrument case for cracks or missing fixings
- Earth bonding resistance: 0. ......... Ohm.

**Printed:** 2 October 2013
APPENDIX 9

Point of Care Testing Committee
Terms of Reference, Composition and Remit, These are being reviewed in the light of the new pathology contract.

Introduction

Point of Care Testing (POCT) is the analysis of pathology specimens performed outside the main pathology laboratory and close to the patient, usually by non-laboratory personnel, such as doctors and nurses. Typical POCT equipment includes blood gas analysers, blood glucose meters and coagulation meters. Visually read strips, such as urine test strips, are also POCT devices.

The POCT committee will cover all Point of Care testing performed within Chelsea and Westminster Hospital. Representatives from other groups, from both within and outside the hospital, may be invited to attend as appropriate.

Membership

Representatives from the following departments will be invited to attend the steering group:
- A&E
- Beta cell Unit
- CCU
- Clinical Chemistry
- Clinical Engineering
- Corporate Nursing
- Finance
- Purchasing
- Haematology
- ICT
- ICU/ITU
- Infection Control
- Microbiology
- NNU/SCBU
- Nursing
- Obstetrics
- Pharmacy
- Primary Care Trusts
- Respiratory Medicine
- Risk Management
- Theatre
- HIV / GUM

Aims

The POCT committee will:
- Ensure users are trained and certified in the use of POCT devices and are fully aware of any contraindications.
- Ensure that effective records of training are maintained and that refresher training is provided, in accordance with Trust policy.
- Ensure that effective maintenance and quality assurance procedures, including Quality Control and External Quality Assessment, are in place for all POCT devices.
- Ensure appropriate infection control and risk reduction strategies are in place for all POCT devices.
- Ensure appropriate recording and storage, including the use of computerised systems, for all POCT patient results.
- Ensure an external accreditation body assesses the POCT service.
- Report instances of non-compliance to the Clinical Governance Committee.
- Ensure no POCT device is used in Chelsea and Westminster without the approval of the POCT committee.
- Advise the trust when preparing a business case for the acquisition of new POCT equipment.
- Consider the clinical utility of all new applications for POCT devices, irrespective of the source of funding, and advise on their implementation.
- Aim to standardise POCT equipment across the Trust in order to reduce clinical risk and achieve economies of scale.
- Aim to establish a clear audit trail between the person performing the POCT test and the POCT committee.
- Receive reports on actions taken in response to MHRA Alerts relating to POCT equipment.
- Receive reports on investigation of issues, including clinical incidents, relating to POCT equipment and its use.
- Aim to establish ward-based POCT link nurses, following approval by the Nursing Directorate.
- Establish systems for continuing audit and assessment of POCT.
- Look into and advise the group of future developments and their suitability for use.

**Reporting to:** Medical Devices Committee that reports to Operational Risk Management Committee

**Contacts:**
Neither of these people are responsible for POCT any more.

1. **Reference**

Review date: March 2010
HOW TO ACCESS MEDICAL DEVICE TRAINING - GENERAL

Clinical Area
Local Medical Device Inventory with Risk classification identified

High Risk
POCT

New staff member – Attend Medical Device training as part of Trust Induction Programme
-Further Medical devices training needs to be identified and organised by Managers as part of Local induction

Medium Risk
Seek Training locally from:
-Super User
-Competent Registered healthcare professional
-Complete Competency assessment where available

Low Risk
Seek Training locally from:
-Super User
-Competent Registered healthcare professional
-Complete Competency assessment where available

Existing Consultants, ST’s, CT’s – formal training via MDTM or self-certification of competency

Formally recorded centrally on MAPS if an identified competency exists

APPRAISAL
APPENDIX 11

HOW TO IDENTIFY AND ACCESS TRAINING REQUIRED FOR A NEW MEDICAL DEVICE

NEW MEDICAL DEVICE

CLASSIFY RISK with Local Clinical Lead, MDTM, and CED & ratified with MDC

Competency Assessment developed by Local Clinical Lead liaising with MDTM

Formal Training led by:
- Local Clinical Lead
- Super user
- MDTM
- Company

Record on MAPS or centrally held spreadsheets
APPENDIX 12
Application for charitable funding CF01
For medical devices

Please complete all sections below before submitting your application.

This form is to be used for all applications for funding for medical equipment for ANY charity within Chelsea & Westminster NHS foundation Trust. Send all completed forms to the Team Leader, Clinical Engineering. Contact: Richard Aldridge Ext 8140

All applications will be reviewed by the Medical Devices Committee and / or the Clinical Engineering Department. (CED)

1. Equipment details
   Equipment type: ____________________________________________________________
   Model: __________________________ Manufacturing: ________________________
   Supplier / distribution agent: _____________________________________________
   (Only if different from manufacturer)
   What will the equipment be used for?
   ______________________________________________________________________
   ______________________________________________________________________
   Is this a Trust standard item of equipment? Y / N
   Is this going to replace any other equipment? Y / N
   If so what?
   ______________________________________________________________________
   Have you contacted CED about this purchase? Y / N
   Have you evaluated this device? Y / N

2. Costs
   Purchase cost £__________ Confirmed by purchasing? Y / N
   Disposables cost: £__________ per use £__________ P/A
   Servicing / calibration cost: £__________ P/A
   (Contact supplier or clinical engineering)

   Will a service contract be required after the first years warranty has expired? Y / N
   (Contact supplier or clinical engineering)
   If so, how much will it cost? £__________ P / A

3. Funding
   Have you already applied for funding within your ward / Department? Y / N
   Have you applied for capital funding? Y / N
   (Items over £ 5K only)
Please indicate which charity you are seeking to support your application:

- Friends of Chelsea & Westminster
- Chelsea & Westminster Healthcare NHS Trust charity
- Children’s hospital Trust fund
- St Nicholas Fund
- Children’s fire and burns Trust
- St Stephens AIDS Trust
- Dan’s fund for burns
- Other (Please specify)

4. Training

Does this equipment require training? Y / N

If YES, please explain how you will implement a training programme:

__________________________________________________________


5. Additional requirements

Does the device require any Special decontamination? Y / N

If YES have you contacted TSSU or infection control? Y / N

Please explain what is required:

__________________________________________________________

Does the device need any special connections to water, gas, waste etc? Y / N

If YES please specify:

__________________________________________________________

Does this device require routine calibration and or QA checks performing on it? Y / N

(POCT, Point of care testing equipment may well require routine quality assurance checks to be performed by Clinical chemistry)

If YES, please indicate who will perform these checks:

Clinical Chemistry / ward staff / on site technical staff
6. Your details
Your name: ____________________________ Date: / / 
Your ward or Department: ____________________________
Your directorate: ____________________________
Contact number: ____________________________ Email: ____________________________

Signature: ____________________________

General Manager's name ____________________________
I approve of this application

Signature: ____________________________ Date / /

(For Medical devices group and charity use only)

1. Application approved by CED / Medical devices __/__/__ Signature____________
2. All costings taken into account
3. Charity identified
4. Training needs addressed
5. Special Decontamination needs addressed (if required)
6. Additional requirements addressed
7. Clinical chemistry approved (If required)

Application to Charity date: / / Approved / Declined

Approved by: ____________________________

Signature: ____________________________ Date: / /
This form should be completed if you are seeking funding for a development / purchase with a value exceeding £5,000 whether it is revenue or capital funding or a combination. This should also be used for bids for replacement capital.

Chelsea & Westminster Hospital NHS Foundation Trust

BUSINESS CASE TEMPLATE (Part 1 of 2)

SUMMARY

1.1 Title of Business Case:

1.2 Brief Description of Proposed Development / Capital Purchase:

For Capital Schemes Only:

Is this a Replacement Capital Bid? If so please state which asset is being replaced, including its location and serial number.

If this is a New or Replacement Capital Bid, please give details of the expected life (in years) of the new equipment / building and list the assets to be capitalised.

Please note: If this bid is for an item of capital equipment, do not approach suppliers or sales reps directly for quotes but contact the Procurement Department for an indicative cost.

1.3 Service and Directorate:

Is this item on the Trust risk

Yes / No
### DETAILED PROPOSAL

#### 2.1 Context:
(include from the following list as relevant)
- Market analysis – both quantitative (e.g. likely population size x incidence rate) and qualitative (e.g. competitor offerings, clinical or technological advances that affect demand)
- Clinical drivers – e.g. patient safety, new NICE guidelines
- Relevant legislation – e.g. European Working Time Directive, OJEU if spend likely to exceed £93K)

#### 2.2 Current service:
(brief overview of current service including staffing, management structure, activity/financial information and strengths/weaknesses)

#### 2.3 Reasons for change:
(Clinical benefits, service improvements etc. Include reference to compliance with clinical drivers / legislation from 2.1 if appropriate)

#### 2.4 Proposal:
(favoured option put forward for approval)

#### 2.5 Consequences of Doing Nothing:
(identify consequences if proposal is not pursued)

#### 2.6 Options Considered:
(outline other options considered, evaluation method used and reasons for selecting proposal)
2.7 Benefits:
(Identify and quantify all benefits of the proposed development, particularly clinical safety, national plan targets, efficiency, effectiveness, strategic service development; outline how expected benefits will be monitored)

2.8 Impact on Patient Care:
(Please specify in particular what impact this development will have on patient safety and quality (per Trust Corporate Objectives for 2009-10)).

2.9 Impact on Other Directorates:
(Please specify what impact this development will have on other Directorates/Services within the Trust.)

2.10 Impact on PCTs:
(If this proposal involves changes in activity, which PCT(s) is this expected to impact on – e.g. local, London wide or other. Please also give details of the discussions that have taken place with PCTs to agree this development. Do you anticipate that this development may result in CQUIN payments being applicable?)

2.11 Risks:
(Including any risks associated with the proposal as well as an assessment of their likelihood and severity and any planned mitigations)

2.12 Implementation plan:
(Including
• high level plan with timescales, key milestones and major dependencies with other projects;
• overview of any procurement processes;
• key challenges and approach, including dealing with any likely recruitment issues)

2.13 Benefits Realisation
(Please provide details of how you intend to demonstrate that the objectives of this development have been achieved post implementation, together with timelines.)
2.14 Financial Analysis

See Appendix 1- Please ensure all financial schedules are completed prior to obtaining signatures in Section 3 below.

The Table below contains a summary of each financial schedule on Appendix 1.

<table>
<thead>
<tr>
<th>Year</th>
<th>2009/10</th>
<th>2010/11</th>
<th>2011/12</th>
<th>2012/13</th>
<th>2013/14</th>
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<tr>
<td>Net Surplus/(Deficit) by Monitor Category</td>
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<td>Net Surplus/(Deficit) by Directorate</td>
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<td>Capital Expenditure Total</td>
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<td>Total NHS Activity</td>
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<td>Total other Activity</td>
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<td>Total Workforce (WTE)</td>
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SECTION 3: AUTHORISATION

3.1 SCHEME SPONSOR (Executive Director/General Manager, as appropriate)

Name:

Position:

Signature:

3.2 SCHEME OWNER (i.e. the member of staff submitting the bid)

Name:

Position:

Signature:

3.3 BUSINESS ANALYST

Name:

Position:

Signature:

3.4 GENERAL MANAGER (If different from Scheme Sponsor)

Name:

Position:

Signature:
<table>
<thead>
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<th>Name:</th>
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<td>Position:</td>
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<td>Signature:</td>
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</tbody>
</table>

### 3.5 DIRECTOR OF IM&T (For bids with an IM&T component only)

| Signature of Director of IM&T: |  |

### 3.6 FACILITIES GENERAL MANAGER (For bids with an Estates component only)

| Signature of Facilities General Manager: |  |

Policy for the acquisition, use and maintenance of, and training for, medical devices and equipment Sept 2013