York Teaching Hospital NHS
NHS Foundation Trust

Medical Devices Management Policy

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Relevant Regulations and Standards	NHSLA RMSAT CQC Essential Standards of Quality & Safety Outcome 11
Links to Organisational/Service Objectives, business plans or strategies	Not applicable

Executive Summary

This Policy sets out the process and responsibilities for safe and effective management of medical devices throughout the York Teaching Hospitals NHS Foundation Trust.

This is a controlled document. Whilst this document may be printed, the electronic version is maintained on the Q-Pulse system under version and configuration control. Please consider the resource and environmental implications before printing this document.

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

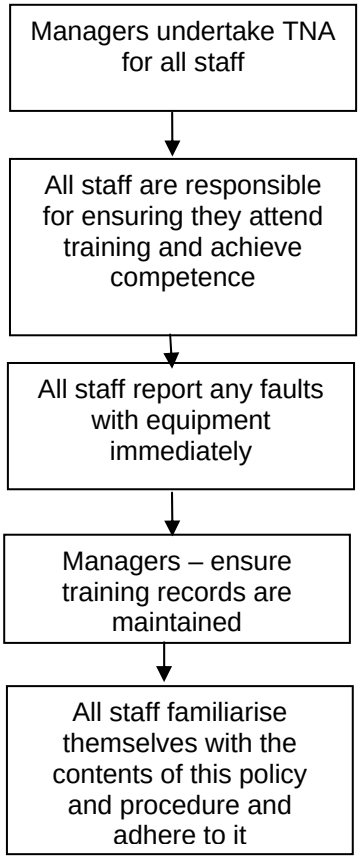
Version	Date Approved	Version Author	Status & location	Details of significant changes
2		Peter Lamb	Horizon	The whole policy has been reviewed to comply with the new template and NHSLA guidelines
3		Graham Barnes	Horizon	Training needs & training profiles
4		Graham Barnes	Horizon	Loans to other organisations added Security of patient data added Training amended following appointment of Medical devices Training Co-ordinator Changes to responsibilities following the merging of the Equipment Manager and Medical Engineering Manager roles

5		Graham Barnes		Escalation of fault reporting to local manager added to A.3.9.8 3.10.6 and 10.0.2 aligned – MEMC to review AIRS twice yearly MDA DB2006/05 added to 13. external references Reporting arrangement changed to Health, Safety & Non-Clinical Risk Group EME accreditation updated to ISO 9001:2008 Requirement for Ward/Dept managers to be responsible for user manuals added to 11.5 Trust Name updated
6		Graham Barnes		Training in the use of Devices moved to Trust's Training

		& David Biggins		Identification Policy (TIP) Requirements for standardised software configurations added A3.1.7 Reference to The Trust's SABS reporting added Requirement for risk assessments prior to introduction of devices added A3.1.4. Availability of user manuals via the Intranet added RIDDOR reporting added to fault/incident reporting A3.10.6

Contents

High Level Process Flowchart



1 Introduction & Scope

1.1 Introduction

Medical devices play a crucial role in the delivery of safe effective care for patients. With advances in technology and the increased use of medical devices, it is paramount that the safety of the patient and staff is maintained.

York Teaching Hospital NHS Trust (The Trust) recognises, and will fulfil its duty to ensure that all medical devices are introduced and used within the Trust in accordance with the recommendations for best practice from NHS England, Medicines and Healthcare products Regulatory Authority (MHRA), and in compliance with the provisions of the Health and Safety at Work etc Act 1974, and in order to meet the requirements of the NHSLA Risk Management Standards, The CQC Essential Standards for Quality & Safety, local Clinical Governance arrangements, and all statutory requirements for the user and the patient's safety.

This Policy describes the processes for:

Introducing Medical Devices to the Trust
Acquisition of Medical Devices
Commissioning Medical Devices
Training staff – (By reference to the Trust's Training Identification Policy)
Use, storage and cleaning
Repair, maintenance and disposal

1.2 Scope of the policy

This policy is to be observed by all staff who participate in the introduction, use and management of medical devices.

It applies to all medical devices which are leased, patient owned, loaned (short-term, long term or permanent), rentals, hire purchase, gifts, consumable contracts, trial /evaluations and includes medical devices purchased through Trust funds, capital funds charitable donations or revenue budgets.

2 Definitions

Medical Devices are defined as:

Any instrument, apparatus, appliance, material or health product, excluding drugs, used for a patient or client for the purpose of:

- Diagnostic, prevention, monitoring, treatment or alleviation of a disease.
- Diagnosis, monitoring treatment, alleviation of, or compensation for an injury or impairment.
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

A more extensive list of products which fall within the definition of 'Medical Device' is provided on the Medicines and Healthcare products Regulatory Authority (MHRA) website at www.mhra.gov.uk.

3 Policy Statement

The Trust recognises and will fulfil its duty to ensure that all medical devices are introduced, managed, and used within the Trust in accordance with the recommendations for best practice from NHS England, Medicines and Healthcare products Regulatory Authority (MHRA), and in compliance with the provisions of the Health and Safety at Work etc Act 1974, and in order to meet the requirements of the NHSLA Risk Management Standards, The CQC Healthcare Standards, local Clinical Governance arrangements, and all statutory requirements for the user and the patient's safety.

Please see Appendix A for the Procedure

4 Equality Impact Assessment

In the development of this policy the Trust has considered evidence to ensure understanding of the actual / potential effects of our decisions on people covered by the equality duty. A copy of the analysis is attached at Appendix 1.

5 Accountability

5.1 Chief Executive

The Trust's Chief Executive is responsible for the implementation and compliance monitoring of this policy.

The Director of Estates and Facilities is the nominated Director with responsibility for medical devices management.

5.2 All Managers

Directorate and Departmental Managers will ensure Medical Devices used within their area of responsibility are managed in accordance with this policy.

They must ensure staff have updated their annual Training Analysis with regards to training on Medical Devices.

They must demonstrate that all staff within their area have received the appropriate training, have demonstrated their competence where required, and that records are maintained.

5.3 The Medical Device Management Group (MDMG)

The MDMG will:

- Review this policy bi-annually and make recommendations for change to the Director of Estates and Facilities, and Health, Safety & Non Clinical Risk Group.
- Monitor compliance with this policy as described in section 10 and report any concerns to the Director of Estates and Facilities, and to the Health, Safety & Non-Clinical Risk Group.
- Monitor any action plans arising from policy audit activity
- Review medical device related incidents
- Promote this policy and its objectives to all Trust staff

5.4 All users

It is the responsibility of each user to ensure that they have received the appropriate training to use medical devices and can demonstrate that they are competent to do so, that they are aware of their responsibility in regards to maintenance and fault reporting as detailed in this document.

It is the responsibility of all users to comply with this document

6 Consultation, Assurance and Approval Process

6.1 Consultation Process

The Trust will involve stakeholders and service users in the development of its policies.

Consultation has taken place with the following stakeholders:

- Wide representation of the Medical Devices Management Group
- Purchasing
- Maintenance departments
- Systems and Network Services
- Risk and Legal Services

6.2 Quality Assurance Process

Following consultation with stakeholders and relevant consultative committees, this policy has been through quality assurance checks prior to being reviewed by the authorising committee to ensure it meets the NHSLA standards for the production of policy and equalities legislation and is compliant with the Development and Management of Policies policy.

6.3 Approval Process

The approval process for this policy complies with that detailed in section 6.3 of the Development and Management of Policies Policy. The approving body for this policy is Medical Devices Management Group.

The Checklist for Review and Approval has been completed and is included as Appendix 2 and the completed Virtual Policy Review Group Checklist is included as Appendix 4.

7 Review and Revision Arrangements

7.1 Process for Reviewing a Policy

On reviewing this policy, all stakeholders identified in section 6.1 will be consulted. The persons responsible for review are:

- Head of Medical Engineering
- Medical Devices Management Group

Subsequent reviews of this policy will continue to require the approval of the Medical Devices Management Group

8. Dissemination and Implementation

8.1 Dissemination

Once approved, this policy will be brought to the attention of all relevant staff working at and for York Hospital NHS Foundation Trust following the completed Plan for dissemination of the policy (See Appendix 3)

This policy is available in alternative formats, such as Braille or large font, on request to the author of the policy.

8.2 Implementation of Policies

This policy will be implemented throughout the Trust by (insert relevant text)

In addition to this the Policy Author will collate the following evidence to demonstrate compliance with this policy:

- Annual Medical Devices Audits
- Medical Devices Management Group Terms of Reference, agendas, minutes and papers
- Training Records Audits
- Sterile Services Audits
- AIRS incident review records

9 Document Control including Archiving Arrangements

9.1 Register/Library of Policies

This policy will be stored on Staffroom, in the policies and procedures section and will be stored both in an alphabetical list as well as being accessible through the portal's search facility and by group. The register of policies will be maintained by the Healthcare Governance Directorate.

If members of staff want to print off a copy of a policy they should always do this using the version obtainable from Staffroom but must be aware that these are only valid on the day of printing and they must refer to the intranet for the latest version. Hard copies must not be stored for local use as this undermines the effectiveness of an intranet based system.

9.2 Archiving Arrangements

On review of this policy, archived copies of previous versions will be automatically held on the version history section of each policy document on Q-Pulse. The Healthcare Governance Directorate will retain archived copies of previous versions made available to them. Policy Authors are requested to ensure that the Policy Manager has copies of all previous versions of the document.

It is the responsibility of the Healthcare Governance Directorate to ensure that version history is maintained on Staffroom and Q-Pulse.

9.3 Process for Retrieving Archived Policies

To retrieve a former version of this policy from Q-Pulse, the Healthcare Governance Directorate should be contacted.

10 Monitoring Compliance With and the Effectiveness of Policies

This policy will be monitored for compliance with the minimum requirements outlined below.

10.1 Process for Monitoring Compliance and Effectiveness

In order to fully monitor compliance with this policy and to ensure that the minimum requirements of the NHSLA Risk Management Standards for Acute Trusts are met, (or key areas of compliance) the policy will be monitored as follows:-

Minimum requirement to be monitored	**Process for monitoring**	**Responsible Individual/ committee/ group**	**Frequency of monitoring**	**Responsible individual/ committee/ group for review of results**	**Responsible individual/ committee/ group for developing an action plan**	**Responsible individual/ committee/ group for monitoring of action plan**
Introduction of devices, Acceptance & Commissioning	Annual audit against policy requirements	Medical Device Management Group	Annual	Medical Device Management Group	Head of Medical Engineering & Medical Engineering Team Manager	Medical Device Management Group
Prescribing of medical devices	Annual audit against policy requirements	Medical Device Management Group	Annual	Medical Device Management Group	Head of Medical Engineering & Medical Engineeering	Medical Device Management Group

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results	Responsible individual/ committee/ group for developing an action plan	Responsible individual/ committee/ group for monitoring of action plan
					Team Manager	
Training in the use of devices	Audit of training records and documentation	Medical Device Training Coordinator	6 monthly	Medical Device Management Group	Medical Device Training Coordinator	Medical Device Management Group
Decontamination of Devices	Audit and Matrons inspections of device visual cleanliness and training records Audit of sterile services/endoscopy decontamination procedures	Decontamination steering group Hospital Infection prevention control group	High risk devices- Annually Low risk devices as per monthly schedule	Decontamination steering group Hospital Infection prevention control group	Decontamination steering group Hospital Infection prevention control group	Decontamination steering group Hospital Infection prevention control group
Loan of devices	Audit of relevant documentation	Medical Device Management Group	Annual	Medical Device Management Group	Medical Device Management Group	Medical Device Management Group

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results	Responsible individual/ committee/ group for developing an action plan	Responsible individual/ committee/ group for monitoring of action plan
Maintenance & Repair and replacement	Monthly Medical Engineering report on maintenance completion status and repair performance sent to Director of Estates& Facilities. Report also reviewed by Medical Devices Management	Head of Medical Engineering	Monthly with annual report to HS&NCR Committee	Medical devices Management Group	Head of Medical Engineering and Director of Estates and Facilities	Medical Devices Management Group
Reporting of Defects, Failures & Incidents (A.3.10)	Audit and review of Medical Device related incidents	Medical Device Management Group	6 times per year	Medical Device Management Group	Medical Device Management Group	Medical Device Management Group

10.2 Standards/Key Performance Indicators

This policy conforms to the requirements identified in the NHSLA Risk Management Standards, Care Quality Commission Essential Standards of Quality and Safety Outcome 11 and Guidance from the Medicines and Healthcare products Regulatory Agency.

11 Training

Any training requirements identified within this policy that are of a 'Corporate Statutory or Mandatory nature will be outlined in the Statutory/Mandatory Training Brochure. This can be accessed via the link on Staff Room, the Q:\York Hospital Trust\Mandatory Training or the organisation's online learning platform.

11.1 Ward and Departmental managers are responsible for ensuring their staff receive appropriate training in the use of medical devices. To aid the assessment of training needs an inventory of ward / department medical equipment is available on request from the Head of Medical Engineering. (Note: The inventory held by Medical Engineering includes medical equipment owned or leased by the Trust but may not include items on loan or single use items.)

11.2 The process and procedure for assessing, delivering and recording the training needs for medical devices is contained in the Trust's Identification Policy which can be found on Trust's Intranet site. For further information on medical device training please contact the Medical Device Training Coordinator.

11.3 A copy of the user instructions will be delivered to the ward/department following commissioning of the equipment. It is the responsibility of the Ward / Department manager to ensure it is kept securely and available to users of the equipment when required. Electronic copies are available on the Trust's Intranet site via the Medical Equipment Management pages

12 Trust Associated Documentation

The Trusts' intranet system, Staff Room, should be consulted for all associated policies.

AIRs Policy

Central Alerts System Policy

Decontamination of Reusable Medical Devices Policy

Decontamination of reusable equipment and the environment policy

Corporate Statutory and Mandatory Training Identification Policy

Procurement Policy

Waste management and disposal policy

Trust Company Representatives Policy

Procedures and guidance on all parts of this policy can be sought from the Medical Equipment Management intranet page and or the Head of Medical Engineering.

13 External References

MHRA DB2006/05- Managing Medical Devices.

NHSLA Risk Management Standards

Care Quality Commission – Essential Standards of Quality and Safety

Health & Social Care Act 2008

Equipped to Care

Health & Safety at Work etc Act etc 1974

14 Appendices

Appendix A – Procedure

Appendix B – Equality Impact Assessment Tool

Appendix C - Summary of Group Roles

Appendix D – Dissemination Plan

Appendix E – Checklist for Review and Approval

Appendix F – Virtual Policy Review Group

Appendix A - Procedure

A.3.1 Introducing Medical Devices to the Trust

A summary of the roles of the Groups involved can be found in Appendix C.

A.3.1.1 All devices being introduced to the Trust must satisfy that they meet the Trust and national standards Where possible devices will be standardised within the Trust.

A.3.1.2 Purchasing Managers / Buyers will ensure maintenance managers are aware of all medical equipment acquisitions.

A.3.1.3 All medical devices purchased directly or indirectly must conform to the Trust's Procurement Policy and this Policy.

A.3.1.4 Prior to the introduction of devices, Directorate Managers must ensure appropriate risk assessments and medical device decontamination checklists have been undertaken and that, where necessary, appropriate controls are in place.

A.3.1.5 All devices being introduced to the Trust will satisfy Purchasing and Maintenance Managers that they meet the Trust and national standards including:

- Electrical Safety Standards
- Infection Control/Decontamination standards
- Medical Devices Directives (93/42/EEC & 90/385/EEC)
- Arrangements for security of any patient data generated by, or stored within the device.
- Consideration has been given to energy usage and sustainability issues.
- Disposal Policy and Waste Electrical and Electronic Equipment (WEEE) regulations (Devices and Consumables)
- Risk assessments, Latex assessment, and Control of Substances Hazardous to Health (COSHH) requirements are in place.
- Appropriate training package is included by the supplier for initial and ongoing training provision.

A.3.1.6 All equipment involving administration of medication technologies (e.g. implanted infusion devices) and any related software must be discussed and agreed with Pharmacy and Corporate Nursing.

A.3.1.7 All requests for equipment which generates and/or stores patient identifiable data must include assurance that appropriate arrangements are in place to ensure confidentiality and security of that data. Advice should be sought from Systems and Network Services (see also A.3.5.1)

A.3.1.8 The software configurations for standardised devices will be agreed with users and the Trust Medical devices Trainer, who will maintain records of agreed configurations.

A.3.1.9 All single use medical devices must be approved by the Medical & Surgical Supplies and Equipment Group (MSSE Group). The Purchasing Department will reject any requests to obtain single use devices not previously approved and will maintain a catalogue of approved devices.

A.3.1.10 Patients may bring their own medical equipment on site, for use at their own risk, and with the approval of the ward / department manager (of the department where the patient is being treated), All electrical devices must be checked by Estates or Medical Engineering before use.

A.3.1.11 When items are permanently re-located within the Trust the maintenance departments must be informed and the asset register updated.

A.3.2 Acceptance testing/commissioning

A.3.2.1 The Purchasing Manager will ensure that the delivery address for new equipment will be to the appropriate Maintenance Department, or ensure they are aware of the pending delivery.

A.3.2.2 The Maintenance Managers will ensure that ‘New to the Trust’ devices which require routine inspection maintenance or service

are logged and added to the Trust inventory and are supplied with a unique asset number. Where practical, the item will be labelled with the asset number to aid future identification.

A.3.2.3 Maintenance Managers will ensure that, as part of the acceptance and commissioning, the maintenance and calibration requirements are assessed and appropriate arrangements are implemented.

A.3.2.4 Maintenance managers will, as part of the commissioning process, ensure the Trust's Medical Devices Training Coordinator is informed of the introduction of any new devices.

A.3.2.5 All staff will ensure that prior to use, any Trust owned Medical Device will have a valid service date and an asset number.

A.3.2.6 All staff have a responsibility to ensure they have received appropriate training and are competent, before using any new device

A.3.2.7 Items on loan to the Trust will be logged on the central log sheet (managed by the medical engineering team manager)

A.3.3 Prescription & Use

A.3.3.1 Prescribing the use of Medical Devices shall only be made by staff who are appropriately qualified, trained, experienced and, where circumstances dictate, authorised.

A.3.3.2 Authorisation to use devices is restricted to staff trained on the respective device, all users have the responsibility to ensure they are adequately trained. (Also see A.3.4 Training)

A.3.3.3 All devices should only be used for their intended purpose. Devices shall not be modified without approval by the Head of Medical Engineering and the manufacturer.

A.3.4 **Training in the use of devices**

A.3.4.1 York Teaching Hospital NHS Foundation Trust (YTHNHSFT) recognises that it is vital that all staff required to use Medical devices as part of their role should be trained appropriately.

A.3.4.2 All managers are responsible for ensuring their staff are competent and receive appropriate training in the use of medical devices.

A.3.4.3 The procedure for identifying the training needs of staff and the process for accessing & recording that training is described in the Trust's Training Identification Policy.

A.3.5 **Security of Patient Data**

A.3.5.1 An increasing amount of medical equipment is based on computer technology and has internal storage of patient data. Wherever possible it is recommended the device should be networked and the data saved on a secure Trust server. Where this is impractical additional encryption or physical security should be considered. Advice should be sought from Systems & Network Services or the Head of Medical Engineering.

A.3.5.2 Patient identifiable data held within equipment will be managed in accordance with Trust policies:

- Information Governance Policy
- Data Protection Policy
- Information Security Policy
- Trust Freedom of Information Policy

A.**3.6 Decontamination**

A.3.6.1 The Infection Control Team or Trust Decontamination Lead will be consulted on all decontamination issues. The team are

members of the Medical Devices Management Group, MSSE Group, and receive details of bids to the Medical Requisitions Group for comment.

A.3.6.2. The decontamination requirements of re-usable devices and equipment will form part of the selection and evaluation criteria when new devices are obtained via the medical device decontamination checklist.

A.3.6.3 The ward/department managers and all users will ensure that re-usable Medical Devices are decontaminated in line with the Trust's Decontamination of Reusable Medical Devices and Decontamination of Reusable Equipment and the Environment Policies and the manufacturer's recommendations. Where appropriate, evidence and records of the decontamination process will be kept.

A.3.6.4 Training in decontamination procedures will form part of the training assessments and user training delivery. (See A.3.4 Training)

A.3.6.5 Devices designated for single use will not be re-used.

A.3.7 Storage/Security

A.3.7.1 All staff have the responsibility to ensure that medical devices are stored appropriately when not in use in such a way that deterioration is kept to a minimum, stock controlled and that any battery re-charging or other ongoing service requirements are maintained- as instructed by the manufacturer.

A.3.7.2 Department Managers must ensure items with a limited life are stored appropriately to ensure adequate stock rotation

A.3.7.3 Department Managers must ensure that all equipment is stored in a secure way and that appropriate storage facilities are provided. All staff are responsible for ensuring equipment is not left vulnerable to theft or loss.

A.3.7.4 All losses must be reported to the Trust Head of Security.

A.3.7.5 As per the Standing Financial Instructions, all losses of medical devices apparently caused by theft, arson, neglect of duty or gross carelessness must be reported to the Director of Finance. These losses should be subsequently reported to the Audit Committee for review and recommendation via the Losses and Special Payments Schedule. The Board of Directors shall ultimately approve the writing-off of losses.

A.3.8 Loan of Devices

A.3.8.1 Where devices are loaned to patients or carers, the person arranging the loan will ensure the patient or carer is given (in a way appropriate to their needs):

- User instructions, preferably written by the manufacturers
- Training on the use of the device
- Control of Substances Hazardous to Health (COSHH) assessment
- Instructions on the care of the device including maintenance requirements / arrangements
- Instructions on cleaning or decontamination requirements
- Advise on how to obtain supplies of any consumables required
- Instructions on action to take in the case of a malfunction/complication
- Instructions on the return of the device
- Complete records of the loan must be maintained and held in the department
- A signed statement by the patient/carer that they understand the basis of the loan and how to use the device must be recorded and stored.

A.3.8.2. Where devices are loaned to an external organisation the person arranging the loan must ensure that details of the equipment, owner, lender and applicable dates are appropriately recorded. Standardised documentation to facilitate this is available from Anaesthetics Directorate Project Manager.

A.3.8.3 When loaned devices are returned to the Trust they must be inspected to ensure they are safe to be returned to use.

A.3.8.4 If single use items have been supplied to an external organisation, records including any batch/serial numbers must be retained by the department supplying the items. Replacement single use items will not be accepted from the external organisation. It is the responsibility of the person agreeing to the supply to arrange for invoicing if appropriate.

A.3.8.5 If single use items are obtained from another organisation and not procured through the Purchasing Dept (e.g. emergency supplies) the person arranging the supply must ensure the items are fit for purpose and record the supply details, including any associated batch/serial numbers. If the items are obtained for a specific patient, details of the supplier and product should be recorded in the patient's medical record.

A.**3.9 Maintenance, Calibration, & Repair**

A.3.9.1 The Trust will take a systematic approach to ensure all medical equipment is maintained and repaired in accordance with the requirements of Health and Safety legislation, manufactures/supplier guidance and established best practice.

A.3.9.2 Trust Maintenance Managers will:

- Provide advice on appropriate maintenance and calibration arrangements (See also A.3.2 Acceptance testing/commissioning)
- Manage and monitor the delivery of safe, effective and timely maintenance, calibration, and repairs, using both in-house labour and external contractors.
- Ensure that the asset register is maintained and updated when, during maintenance or repair activity, assets are found to have been re-located or disposed of.

Note: *In the specialist areas of Radiology and Pathology, the Directorate makes their own maintenance arrangements. In these*

cases the Directorate Manager, or nominated person, will ensure these arrangements comply with the requirements of Maintenance Managers and In-House maintenance departments described in this Policy.

A.3.9.3 All users of medical equipment will:

- Report faults/defects to the appropriate maintenance provider and ensure faulty items are not used.
- Ensure equipment is made available for repairs and planned maintenance when required.
- Ensure any requirements for user maintenance, checks, or calibration prior to use, are carried out in accordance with the manufacturers instructions.

A.3.9.4 The Trust's Medical Engineering Department will be externally audited and accredited to ISO9001:2008.

A.3.9.5 Records of maintenance, calibration and repair history will be maintained by the in-house maintenance departments.

A.3.9.6 Medical Devices will not be used when the service due date has expired (as indicated by the service label) or there is any doubt about the safe working condition. Items found overdue for maintenance should be reported to the appropriate maintenance department.

A.3.9.7 Devices will not be modified or adapted for use for purposes they were not designed for without prior approval of the supplier/manufacturer and Maintenance Managers.

A.3.9.8 If a defect/fault/breakdown could result in an on-going patient risk it must also be reported to the local manager or clinical lead of the area in which the equipment is used, to enable a risk assessment to be carried out to determine whether any further action is required.

A.3.10 **Reporting of Defects, Failures & Incidents**

A.3.10.1 Risk and Legal Services will appoint a nominated officer to act as the MHRA Liaison for the Trust. The reporting of incidents and distribution of incoming safety notices is described in the Trust's Central Alerts System Policy and Procedure managed by Risk & Legal Services

A.3.10.2 All Medical Device faults/defects must be immediately reported to the appropriate in-house maintenance department.

A.3.10.3 All consumable faults must be reported to the Purchasing Department. Where possible, samples will be retained with packaging.

A.3.10.4 Any faulty / defective item must be clearly identifiable, stored safely, and quarantined to ensure it can not be used until the defect is resolved.

A.3.10.5 Incidents involving injury or near miss to patients, visitors or staff must be reported and recorded in accordance with the Trust's Adverse Incident Reporting System (AIRS). This is through the bespoke DatixWeb reporting module.

A.3.10.6 Where required by the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR), incidents involving death or injury to patients, staff or visitors must be reported to the Health & Safety Executive. Further guidance is contained in the Trusts AIRS and Health & Safety policies.

A.3.10.7 The Medical Equipment Management Group will bi-annually review reported incidents

A.3.11 Planned Replacement Strategy

A.3.11.1 Directorate Managers will plan their local replacement strategy and associated funds.

A.3.11.2 The Head of Medical Engineering will plan the replacement of shared equipment managed by the Equipment Coordinators.

A.**3.12 Disposal**

A.3.12.1 Medical Devices must be removed from service when no longer suitable for use.

A.3.12.2 When no longer required Medical Devices will be disposed of as described in the Trust's Waste Management and Disposal Policies. Items with a potential residual resale value will be disposed of through the Purchasing Department's Disposals Officer.

A.3.12.3 The Disposals Officer within the Purchasing Department must be informed of any disposals and a Disposals Form completed.

A.3.12.4 Items must only be condemned as 'unfit for use' and disposed of, following consultation with the appropriate maintenance department and the Purchasing department.

A.3.12.5 Maintenance Managers will be informed of equipment disposals and will update their asset registers accordingly.

A.3.12.6 Any equipment which has been removed from service for disposal must not be returned to use without being re-commissioned by the appropriate maintenance department.

Appendix B Equality Analysis

To be completed when submitted to the appropriate committee for consideration and approval.

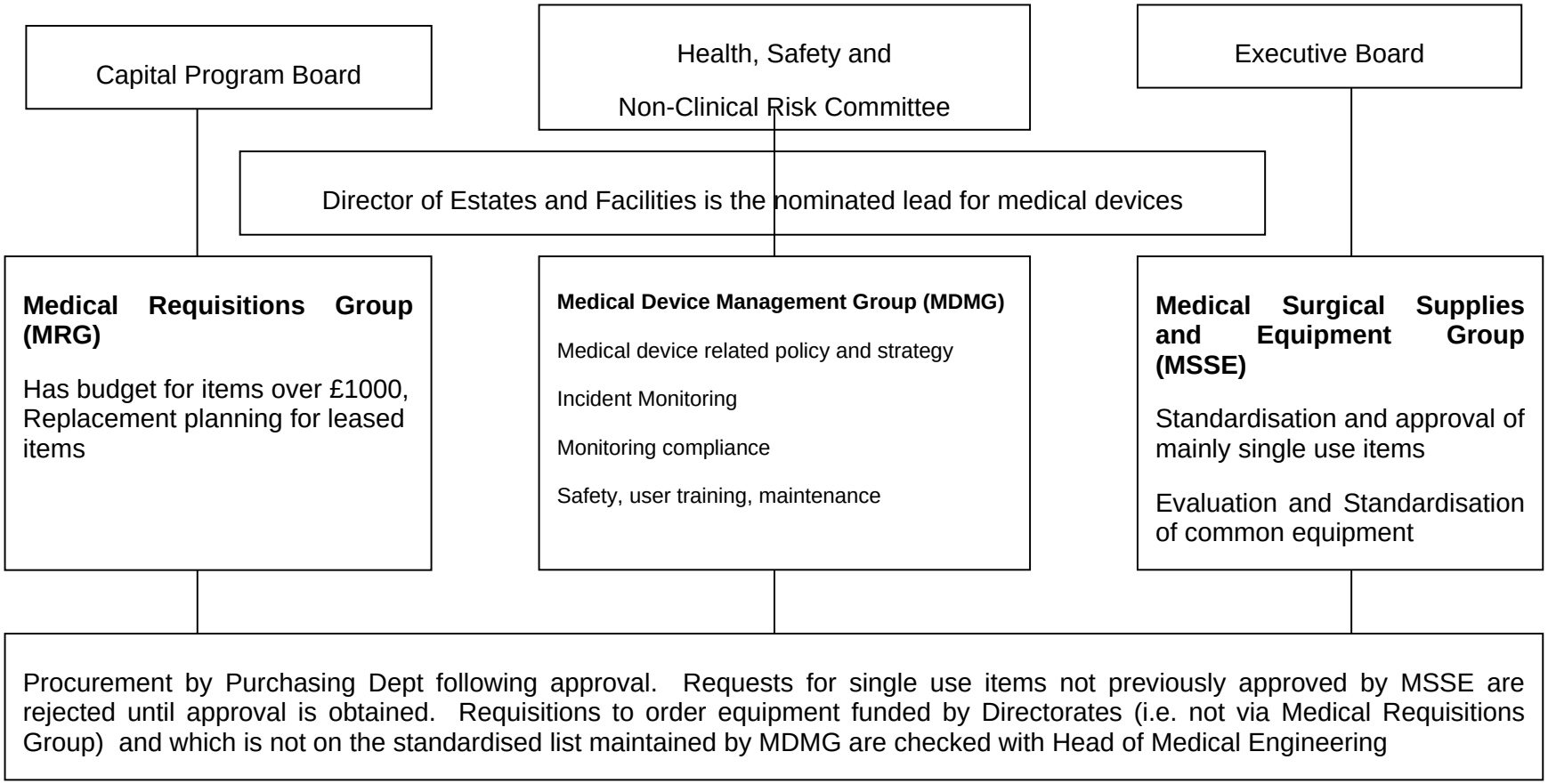
Name of Policy	Medical Devices Management Policy
1.	**What are the intended outcomes of this work?** That all staff are aware of and comply with the contents of this policy and procedure
2	**Who will be affected?** Staff, Patients, Service Users
3	**What evidence have you considered?** MHRA DB2006/05- Managing Medical Devices, NHSLA Risk Management Standards, Care Quality Commission – Essential Standards of Quality and Safety, Health & Social Care Act 2008, Equipped to Care, Health & Safety at Work etc Act etc 1974,
a	**Disability -** This policy is inclusive
b	**Sex -** This policy is inclusive
c	**Race -** This policy is inclusive
d	**Age** - This policy is inclusive
e	**Gender Reassignment** This policy is inclusive
f	**Sexual Orientation -** This policy is inclusive
g	**Religion or Belief -** This policy is inclusive
h	**Pregnancy and Maternity -** This policy is inclusive
i	**Carers -** This policy is inclusive

j	**Other Identified Groups** - This policy is inclusive	
4.	**Engagement and Involvement**	
a.	Was this work subject to consultation?	Yes
b.	How have you engaged stakeholders in constructing the policy	Discussion and circulation of document
c.	If so, how have you engaged stakeholders in constructing the policy	Discussion and circulation of documents
d.	For each engagement activity, please state who was involved, how they were engaged and key outputs All members of the Medical Devices Management Group and the Virtual Policy Review Group have had the opportunity to comment upon the content of the document. Members of specialist services as included in section 6.1 have also had the opportunity to comment and influence the content of the document.	
5.	**Consultation Outcome**	
a	Eliminate discrimination, harassment and victimisation	The policy is inclusive
b	Advance Equality of Opportunity	The policy is inclusive
c	Promote Good Relations Between Groups	The policy is inclusive
d	What is the overall impact?	Safe process for Medical Devices Management
	Name of the Person who carried out this assessment: Graham Barnes	
	Date Assessment Completed **September 2013**	
	Name of responsible Director **Brian Golding**	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Equality and Diversity Committee, together with any suggestions as to the action required to avoid/reduce this impact.

Appendix C

Summary of Committee Roles



Appendix D Checklist for Review and Approval

Authors need to be confident that their policy meets all of the criteria identified below before submitting this to the appropriate committee(s) for consideration and approval.

	Title of document being reviewed:	Yes/No	Comments
1.	**Development and Management of Policies**		
	Is the title clear and unambiguous and meets the requirements of page 3 of the Development and Management of Policies Policy?	Yes	
	Is it clear whether the document is a policy, procedure or protocol?	Yes	
	Does the style and format of the policy meet the requirements of section 3.2 of the Development and Management of Policies Policy?	Yes	
	Does the policy contain a list of definitions of terms used?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are individuals involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with all relevant stakeholders and users?	Yes	
4.	**Content**		
	Is the document linked to a strategy?	No	
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
	Does it meet all of the requirements of NHSLA RMSAT or other relevant body, if applicable?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the	Yes	

	Title of document being reviewed:	Yes/No	Comments
	document identified explicitly?		
	Are supporting references cited in full?	Yes	
	Are local/organisational supporting documents referenced?	Yes	
	Are all associated documents listed and updated?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate, have the staff side committee (or equivalent) approved the document?	Yes	
7.	**Dissemination and Implementation**		
	Does the dissemination plan identify how this will be done and is it clear?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	Yes	
	Does the policy detail what evidence will be collated to demonstrate compliance with it?	Yes	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process for Monitoring Compliance**		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so, is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for coordinating the dissemination, implementation, evidencing, monitoring and review of the documentation?	Yes	

Policy Owner's Approval			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval. (This can be completed electronically with an electronic signature)			
Name	Brian Golding	Date	September 2013
Signature	*Brian Golding*		
Committee Approval			
If the Chair or Vice Chair of the committee is happy to approve this document, please sign and date here and enter the name of the committee/group. The Policy Author will contact the secretary/administrator of the committee/group to obtain a signed copy of this checklist. The Policy Author will then submit this together with the approved policy (ensuring the "draft" watermark is removed) to the Policy Manager for logging and publication.			
Name	G Barnes D Biggins	Date	16 October 2013
Signature	*Graham Barnes* *David Biggins*		
Committee/ Group title	Chairs of the Medical Devices Management Group		

For Policy Manager's use only	
Is there a signed and completed Checklist for Review and Approval accompanying the policy?	Yes
Is the policy logged on Qpulse?	Yes
Has the old version of the policy been archived? (if applicable)	Yes
Has the policy been published on Staffroom?	Yes
Author notified that policy has been published?	Yes

Appendix E Plan for the dissemination of a policy

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Medical Devices Management Policy
Date finalised:	October 2013
Previous document in use?	Yes
Dissemination lead	Graham Barnes
Which Strategy does it relate to?	Not applicable
If yes, in what format and where?	Not applicable
Proposed action to retrieve out of date copies of the document:	**Healthcare Governance Directorate will hold archive**

To be disseminated to:	1) All Staff	2)
Method of dissemination	Team Brief and via Staffroom	
who will do it?	Graham Barnes	
and when?	On approval	
Format (i.e. paper or electronic)	Electronic	

Dissemination Record

Date put on register / library	October 2013
Review date	01 October 2016
Disseminated to	All staff as above
Format (i.e. paper or electronic)	Electronic
Date Disseminated	October 2013
No. of Copies Sent	Not applicable – see above
Contact Details / Comments	Graham Barnes

York Teaching Hospital NHS
NHS Foundation Trust

Virtual Policy Review Group Checklist

All document authors are required to complete the table below, entering ticks or text in the relevant box and to be open and honest about any implications. Failure to identify implications may lead to the document approval process being delayed

Policy Title: Medical Devices Management Policy

Policy Author: Graham Barnes, Head of Medical Engineering

Policy Owner: Brian Golding, Director Estates and Facilities

Date of submission to VPRG 17 May 2013

	Yes	No	Not Sure	N/A	Comments
CLaD Does the policy/procedural document require staff to be formally trained?	Yes				Requires that staff are formally trained in the use of Medical Devices – by reference to the Trust Training Identification Policy
Would the training be classified as Statutory/Mandatory and is this already included in the Statutory/Mandatory Training Brochure?	Yes				
Does training require the learner to access statutory or mandatory learning material/content on line?		Does training require the learner to access statutory or		Does training require the learner to access statutory or	

	Yes	No	Not Sure	N/A	Comments
		mandatory learning material/content on line?		mandatory learning material/content on line?	
Procurement Will the introduction of the document incur additional costs associated with equipment, disposables, maintenance agreements etc?		No			Policy is an update on an existing version with no changes which substantially incur additional costs in this area
What is the likely additional cost associated with the above?		None			
Information Technology Will the introduction of the document require an increase in computer hardware?		No			
Are there any software, IT training or software license requirements associated with the document's introduction? If so, what are the estimated costs associated with this?		No			
Information Governance Are there any information governance issues associated with the introduction of the document?		No			

	Yes	No	Not Sure	N/A	Comments
HR Will there be any impact on staffing levels or any other HR related issues? (If so give details)		No			
Estates and Facilities Will there be any significant impact on Estates and Facilities associated with the introduction of the document? (If so, give details)		No			
Communications Will the introduction of the document require significant communications team input?		No			
Risk and Legal Are there risks associated with the introduction of this document?		No			The update does not introduce any new risks. Failure to comply with the Policy generates risks. There is a new requirement for Risk Assessments to be carried out before introducing new medical devices (A3.1.4)
Are there any legal implications associated with the introduction of this document?		No			
Will the introduction of the document require the production of significant additional or new patient information?		No			

	Yes	No	Not Sure	N/A	Comments
Occupational Health Will the introduction of the document have any potential implications on the OH department?		No			
Health and Safety/Security Will the introduction of the document have any significant health and safety or security implications for the Trust?		**No**			
Corporate Will the introduction of the document have any corporate governance implications for the Trust not covered above?		**No**			
Finance Are there any changes from the proposed document which have a financial impact? If you answered yes to the above question, please provide detail.		**No**			
Does the document require any change in financial processes or arrangements? (e.g. Payroll, Invoicing, Payments etc) If you answered yes to the above question, please provide detail.		**No**			

If you answered yes to the first question, has a business case been submitted? Enter details alongside relevant entry **Submitted and Approved** (Include Business case No.) **Being written** (Please provide planned timeframes for submission) **Saving being Declared** **None of the above** (Please give a brief explanation of the reasons why a business case has not been submitted or savings declared)	