

Management of Medical Devices Policy V7.0

Policy Statement:

All Medical Devices in the Trust must be managed in accordance with this policy and associated procedure.

Key Points

* This policy applies to the management of re-usable and single use medical devices.
* This policy is for all staff working within or for Heart of England NHS Foundation Trust who use, manage, decontaminate, maintain or purchase medical devices.
* The purpose of this policy is to minimise the risks associated with the use of medical devices by ensuring that the procurement, cleaning, maintenance, use and training is appropriate, consistent and safe.

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Corresponding Author: Medical Devices Manager

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| **Relevant External Standards/ Legislation & Guidance** | * National Healtlh Service Litigation Authority (NHSLA) Acute Risk Management Standards for Acute & Community providers - 5.4 & 5.5 * Care Quality Commi*ss*ion (CQC) Outcome 11*,* (section 20 regulation 16 of Health & Social Care Act 2008) * Health & Safety at Work Act 1974 * Management of Health & Safety at Work Regulations 1999 * Provision and Use of Work Equipment Regulations 1998 * Managing Medical Devices. Guidance for healthcare and social services Organisations MHRA DB2006 (05) November 2006 * National Patient Safety Agency (NPSA) guidance * Control of Substances Hazardous to Health Regulations (COSHH), 2004 (amendment) * Health Act 2006 Decontamination of Equipment * International Electro–technical Commission (IEC) 60601-1 * Waste Electrical and Electronic Equipment Regulations * Electricity at Work Regulations 1989 * Electrical Equipment (Safety) Regulations 1994 * EC Medical Devices Directives * MHRA Directives Bulletins |
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# **Circulation**

This policy applies to the following:

* This policy applies to all staff working within or for Heart of England NHS Foundation Trust who use, manage, decontaminate, maintain or purchase medical devices.
* All staff includes permanent, temporary, locum, agency, volunteer, contractors, students and all grades and professions working within Acute & Community sectors of the Trust.

# **Scope**

**Includes:**

* This policy applies to the management of re-usable and single use medical devices and to all staff working within or for Heart of England NHS Foundation Trust which includes permanent, temporary, locum, agency, volunteer, contractors, students and all grades and professions.

**Excludes:**

* This policy excludes the management of Point of Care Testing equipment. Please refer to the Point of Care Testing Policy for more information.
* This policy excludes the management of Radiology Imaging equipment. Please refer to Ionising Radiations Regulations 1999 (IRR99) *ref 1*

# **Definitions**

The term Medical Devices encompasses both re-usable and single use items. The European Commission (EC) and the Medicines and Healthcare products Regulatory Agency (MHRA) define a medical device as

“any instrument, apparatus, appliance, material or healthcare product, excluding drugs, used on a patient or client for the purpose of:

* Diagnosis, prevention, monitoring, treatment or alleviation of disease
* Diagnosis, monitoring, treatment, or alleviation of, or compensation for an injury or disability
* Investigation, replacement or modification of the anatomy or of a physiological process
* Control of conception

and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means”

*Ref 2 - Medical Devices Directive 93/42/EEC*

# **Reason for development**

Medical Devices are an integral part of the diagnosis, treatment, support and care of patients. The Trust recognises the risks to patients, staff and others that may arise in the use of medical devices and that it has an obligation to minimise the risk of using medical devices. This Policy outlines mechanisms to ensure that the entire life cycle of all medical devices within the Trust are appropriately managed. Only the most appropriate equipment for purpose are selected for use, staff are trained to competently and safely use equipment, devices are cleaned / decontaminated and maintained correctly and disposed of in an appropriate manner.

# **Aims and Objectives**

The purpose of this policy is to enable the effective deployment, monitoring and control of medical devices throughout the Trust and to minimise the risks associated with the use of medical devices by ensuring that the procurement, use, decontamination, maintenance, and training is appropriate, consistent and safe.

This policy aims to ensure that the Trust has systems in place to:

* Ensure that medical devices are managed safely and effectively, and that their management complies with statutory and regulatory requirements
* Ensure that there is a standardised, systematic approach to identify, assess, and record medical device training needs and competence through the ongoing development and maintenance of a Trust Medical Equipment Training Database & Staff Training Competency Records
* Provide staff with details of roles and responsibilities
* Monitor compliance with the requirements of this policy

# **Standards**

## Procurement of New Medical Devices

All new medical devices are legally required to comply with EU directives and the relevant UK legislation for performance and safety. All medical devices must hold a CE mark. Medical Engineering, Procurement & the Medical Devices Manager **must approve equipment prior to procurement.**

The process outlined in the Trust Medical Devices Procedures document for the procurement of a new medical device must be followed.

## Incidents involving a Medical Device

If an incident occurs which involves a medical device it is the responsibility of staff to report the event in line with the Trust Incident Reporting Policy. Guidelines for management of incidents involving medical devices are included in the Medical Devices Procedures document.

**6.3 The Central Alert Safety (CAS) Reporting System**

CAS is an electronic system developed by the Department of Health, with the MHRA, NHS Estates and the National Patient Safety Agency (NPSA). Specific types of safety alerts are emailed to Trusts for processing at a local level. The Health and Safety Department undertakes this activity for the Trust which involves dissemination, central recording of responses, monitoring of responses and updating the CAS website of Trust compliance. It is absolutely essential that allocated leads respond in a timely fashion to the Health and Safety Department about CAS alerts.

Please refer to the Trust Management of Safety Alerts received via the Central Alert System Policy for further information.

# **6.4 Decontamination of Medical Devices**

The Trust’s Decontamination Policy provides an appropriate, rational and cost effective basis for the control of microbial contamination of medical devices and the environment within Trust premises, additionally highlighting responsibilities for maintaining a safe environment. It is the user’s responsibility to ensure that equipment is cleaned according to protocol after use and before being sent to maintenance departments for repair.

Please refer to the Trust’s Decontamination Policy for further information.

## 6.5 Modification of Medical Devices

**No** medical device is to be customised without formal agreement from the Medical Devices Committee and the knowledge and agreement of Medical Engineering.

Modifying or using medical devices for purposes not intended by the manufacturer “off label use” has serious safety implications and liability may be partly or wholly transferred to the person or organisation making the modifications if the device is implicated in an incident.

## 6.6 Introduction of Novel Medical Devices

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

Devices and products which are of novel action and may require approval from both a pharmacy/medicines and a medical device perspective must be considered by the New Techniques Committee to decide the appropriate and safest route for approval before use in the Trust.

Please refer to the New Techniques & Interventional Procedures Policy for more information.

## 6.7 Re-use of Medical Devices / Single Use Medical Devices

Current general guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) is contained in DB2006 (04) In the key points summary, it states *‘a device designated for ‘single use’ must not be reused under any circumstances’*. (Ref 3). This is consistent with the Department of Health Service Circular 1999/179, action point (iv) *‘never re-use medical devices designated for single use'*.(Ref 4).

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

## 6.8 Loaning in, trials, prescribing and loaning out of Medical Devices

The process for the loaning in, prescribing, trials and loaning out of medical devices is described in the Medical Devices Procedures document and must be followed.

All medical device suppliers and company representatives must conform to the Trust Protocol which is available on the Medical Devices Management Intranet page and included in the Medical Devices Procedures document.

<http://sharepoint/medicaldevices/default.aspx>

# **6.9** [**Maintenance**](#_Maintenance) **and repair**

Maintenance and repair of medical equipment is the responsibility of the Trust's Medical Engineers and is performed in accordance with their Quality Management System. Procedures described in the Quality System include scheduled preventative maintenance, repair of faulty equipment and retention of maintenance records. Planned maintenance schedules and details of maintenance, repairs and calibrations performed by Medical Engineers are recorded in the relevant equipment database.

Where directorates have external contracts for maintenance the contract should represent good value for money and managers must ensure that contracted work is carried out satisfactorily. Advice on maintenance contracts is available from Medical Engineering and the Trust’s Procurement Department.

When malfunction of an item of medical equipment is identified or suspected, the item should be removed from service immediately and labelled clearly to prevent further use. The user department should ensure that the item is referred to its normal maintenance agency for testing or repair. Items for repair must be accompanied by a completed Decontamination Status Certificate. Copies of the Decontamination Status Certificate are available from the Medical Devices Management page on the intranet and from Medical Engineering Departments.

## 6.10 Replacement

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

Please refer to the Risk Management Policy & Procedures for further information.

# **6.11 Disposal**

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

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

When equipment is disposed of through an internal maintenance department it will be recorded as disposed. When equipment is disposed of directly by the user (e.g. traded in or scrapped), the relevant maintenance department should be informed. When capital items of equipment are disposed of, the Capital Manager must be informed.

## 6.12 [Records](#_Standards)

Medical Device records will be accurately maintained and will include the following:-

**Manuals/instruction sheets**

Manuals and Instruction sheets for medical devices are available on the Medical Devices Website intranet site.

<http://sharepoint/medicaldevicestraining/default.aspx>

All staff must have access to these documents, either through the intranet or alternatively the documents can be downloaded into an electronic or paper folder. If a folder is utilised for this purpose it must be updated annually to ensure that current versions are held.

**Medical Equipment Training & Competency Records**

A record of training and competency assessments of staff using medical devices will be maintained electronically by the Faculty of Education.

**Maintenance Records**

The Medical Engineering department will keep central records which will provide evidence that any medical device has been maintained in good condition and calibrated as appropriate.

# **[Responsibilities](#_Responsibilities)**

The Trust Board, managers and staff are responsible for establishing, maintaining and supporting a coordinated approach to medical devices management in all affected areas of their responsibility. Some members of staff and Committees have particular specialist functions in relation to medical devices management as described below:

## Individual Responsibilities

**7.1.1 Medical Director**

The Medical Director has executive responsibility for the management of medical devices within the Trust and for ensuring compliance with this policy. He/She will provide reports to the Trust Board as required and delegates operational responsibility to the Head of Operations, Clinical Support Services.

**7.1.2 Head of Operations, Clinical Support Services**

The Head of Operations, Clinical Support Services, on behalf of the Medical Director, is responsible for ensuring the implementation and monitoring of this policy and supporting the operational management of the Policy.

**7.1.3 Medical Devices & Decontamination Manager**

The Medical Devices & Decontamination Manager is responsible for:

* Ensuring the Trust has in place medical devices systems, processes, policies and procedures which achieve compliance with statutory and regulatory requirements and result in an integrated approach to medical device management
* Development of monitoring systems to ensure compliance with procurement standards and requirements
* Developing and implementing a Trust wide risk management programme which minimises the risks associated with the use of medical devices
* Leading the initiative to standardise medical devices where appropriate
* Co-ordination of regular audit of this policy and the Medical Devices Procedure document
* Compiling an Annual Report on Medical Devices
* Reviewing & investigating incidents reported ( IR1) relating to Medical Equipment
* The Medical Devices Manager is the Trust’s Medical Device Liaison Officer to the Medicines & Healthcare products Regulatory Agency (MHRA)
* The Medical Devices Manager also fulfils the role of Trust Local Decontamination Lead for Medical Devices across the Trust

**7.1.4 Director of Safety & Governance**

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

**7.1.5 Health & Safety Manager**

The Health and Safety Manager is the nominated person who receives MDA, NPSA and Estates, safety alerts issued by the Department of Health, Central Alert System.

Please refer to the Trust Management of Safety Alerts received via the Central Alert system Policy for full details of the processes that are in place; in principle the health and safety manager will:-

* Receive the alert
* Identify an appropriate senior manager within the trust to manage the alert
* Ensure that the Central Alert System is updated in a timely manner
* Compile a monthly status report and ensure that it is widely circulated across the trust
* Provide exception reports to the trust Safety Committee
* Escalate exceptions to the Director of Medical Safety.

**7.1. 6 Procurement Director**

The Procurement Director is responsible for ensuring that medical devices are procured in accordance with Trust standards and relevant guidance from the MHRA.

**7.1.7 Director of Asset Management**

The Director of Asset Management is responsible for directing the Trust’s Facilities and Estates Department, which includes responsibility for the Medical Engineering Department, and will ensure that a rolling programme of maintenance activities is carried out by the Medical Engineering Department in accordance with MHRA and statutory requirements.

**7.1.8 Medical Engineering Manager**

The Medical Engineering Manager is responsible for

* Management of Medical Engineering Trust wide
* Developing & implementing a Trust wide maintenance, calibration & repair programme for ensuring the safe operation of Medical Devices
* Monitoring maintenance, calibration & repair of Medical Devices using the medical engineering QMS
* Ensuring the safe disposal of Medical Devices at the end of their life cycle
* Ensuring adherence to IEC 60601-1 (2005)
* Ensuring that all staff undertaking commissioning and / or repair and maintenance of equipment must be able to produce written evidence of appropriate training and demonstrate that they are up to date on techniques, consistent with the equipment they are servicing.

**7.1. 9 Clinical Equipment Resource Centre (CERC) Manager**

The CERC Manager is responsible for:

* Ensuring that sufficient stock of medical equipment is available to meet client’s needs
* Ensuring all transactions with clients are accurately recorded
* Receiving and accurately reacting to specific equipment requests
* Ensuring that quality standards and customer care standards are maintained at all times
* Ensuring that medical equipment held by CERC is adequately maintained
* Ensuring that all equipment is fit for purpose and is cleaned and decontaminated in line with the Trust's Infection Control & Decontamination Policies.

**7.1.10** [**Faculty**](#_8.1_Medical_Equipment_Training Co-o) **Educators Medical Devices (FEMD)**

Faculty Educators Medical Devices (FEMD) will facilitate the organisation and delivery of education and training in the use of medical devices. FEMD will maintain & update the Trust Medical Equipment Training Database as a centralised record of staff competency and training in the use of medical equipment.

**7.1.11 Clinical Directors and Heads of Operations**

The Clinical Directors and Heads of Operations are responsible for ensuring that medical devices within their areas of responsibility are managed in accordance with this policy and the Medical Devices Procedure. They are responsible for ensuring that procurement of medical devices is compliant with Trust policy and procedures.

Clinical Directors are responsible for ensuring relevant medical staff within their directorate are competent in the use of medical devices. They will ensure that competency records are completed by relevant individuals and will provide updated information regarding any staff or equipment changes to the Faculty Educators Medical Devices in order that the Medical Equipment Database is accurately maintained. Where training needs are identified, they are responsible for ensuring that the individual accesses training Clinical Directors should ensure that Medical Devices Management is included at local induction and undertake an annual review and audit of medical staffs training competencies , as part of the annual appraisal process.

**7.1.12 Matrons & Lead Nurses**

Matrons & Lead Nurses are responsible for ensuring nursing staff within their remit are competent in the use of medical devices. Matrons & Lead Nurses may delegate day-to-day responsibility for medical devices competency to Ward Managers.

**7.1.13 Ward / Department Managers**

It is the responsibility of ward / department managers to ensure that in their department they:

* Ensure all relevant staff are competent to use equipment, releasing staff to attend appropriate training in a timely manner.
* Ensure all equipment is adequately stored, charged and maintained prior to and when in use
* Request planned maintenance when required from Medical Engineering
* Ensure all incidents involving medical devices are reported following the Trust’s Incident Reporting Policy
* Ensure all safety alerts and bulletins are brought to the attention of staff in their area
* Ensure equipment is cleaned and decontaminated in line with the Trust's Infection Control & Decontamination Policies.
* Ensure that competency records are completed by individuals and provide updated information regarding any staff or equipment changes to the Faculty Educators Medical Devices (FEMD) in order that the Medical Equipment Training Database records are accurately maintained.
* Review medical device self assessment forms as part of the annual appraisal process and record this on the appraisal tracker. Where staff have not assessed themselves as competent within 3 months of completing training, agree an action plan that enables staff to achieve competence.
* Where training needs are identified, the Ward / Department Manager is responsible for ensuring that the individual accesses this, e.g. by liaison with FEMD.
* Senior Sisters/Ward Managers are responsible for organising training, and for monitoring and recording attendance on training courses.
* Ensure that Medical Devices Management is included at local induction and undertake an annual review and audit of ward / dept. staffs training competencies.
* Will oversee & co ordinate with FEMD on the provision of locally based Core Trainers where appropriate.
* Ensure that Core Trainers inform FEMD of any training they have delivered promptly

**7.1.14 Core Trainers Responsibilities**

* Core Trainers are only required for high risk devices ie: pumps. *Please see appendix 6, attachment 2 of the Medical Devices Procedures Policy for device categorisation.*
* Core Trainers will be appointed where required by Ward / Department Managers in collaboration with FEMD.
* Core Trainers will be locally based and must be verified as Competent / Proficient Practitioners by FEMD or a Professional Clinical Educator.
* They will provide training & educational support in their speciality and will liaise with FEMD on behalf of the Ward / Department Manager.
* Where specialist training (“train the trainer”) is provided, Core Trainers will cascade train other staff in their area. E.g when new equipment is introduced.
* Inform FEMD of any training they have delivered promptly

**7.1.15 Staff Responsibilities**

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

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

* Users must not use devices they are not trained to use safely and effectively
* Users may use devices that they have been trained to use acknowledging their own professional accountability in delivering safe care .
* Users must report lack of training to their Line Manager so patient care is not delayed
* Clinical equipment must not be used until training has been received

All Staff have a responsibility to ensure that they comply with this policy. They must ensure the following:

* Only use devices that are within service or “use by” date. Should a date not be visible the device must **NOT** be used
* Report any device with an expired or missing maintenance date to the Medical Engineering helpdesk, labeland remove the device from service
* Report any defects or faults with equipment to Medical Engineers immediately
* Report untoward incidents as soon as possible, identifying the involvement of medical devices and where appropriate record the name and identification number of the equipment, i.e. asset/serial number
* Access relevant medical device training, provided either Trust wide or locally
* Update locally held records of training on medical equipment & self assessment of competency documents annually
* Ensure equipment is cleaned and decontaminated in line with the Trust's Infection Control & Decontamination Policies
* Ensure appropriate training and written guidance is provided to support a patient and/or carer (the “ End-User”) when being prescribed a medical device for use away from the clinical environment

## Board and Committee Responsibilities

**7.2.1 Trust Board**

The Trust Board has overall responsibility for ensuring that appropriate systems are in place for the management of medical devices, and for ensuring a programme of risk management activities are in place. It delegates responsibility for monitoring assurance of the implementation and effectiveness of this Policy to the Safety Committee and operational responsibility for Medical Devices to the Medical Devices Committee.

**7.2.2 Safety Committee**

The Safety Committee is responsible for monitoring assurance of the implementation and effectiveness of this Policy and receives biannual reports from the Medical Devices Committee.

**7.2.3 Medical Devices Committee**

The Medical Devices Committee is responsible for providing a corporate approach to all aspects

of medical device management under one integrated policy and for the overall implementation and monitoring of the Trust Medical Devices Policy and Procedure and reports to the Safety Committee on a biannual basis. The Committee is the organisational focus for advice and best practice with regard to the management of medical devices including acquisition, training, decontamination, maintenance & repair, incident & risk management.

and disposal of medical devices.

* It will monitor this policy in liaison with appropriate stakeholders within agreed timescales and is responsible for ensuring there are systems in place to minimise the risks associated with the use and management of medical devices throughout the organisation
* Any associated risks brought to the attention of the Committee are actioned.

**7.2.4 Site Management Committees**

Site Management Committees are responsible for ensuring all directorates within their areas of responsibility have clear arrangements in place for the management of medical devices, and that directorates comply with the requirements of this policy. Site Management Committees receive reports and risks related to their areas from the Medical Devices Committee.

# **Medical Device** [**Training**](#_8.2_Training_Providers)

The training process can be found in the Medical Devices Procedures document.

FEMD will oversee the organisation and delivery of education and training in the use of medical devices, maintaining a centralised register of training and competency electronically.

This register includes an equipment inventory and employee training competencies for all areas using medical equipment across the Trust. Updates to this information must be forwarded to FEMD in order to maintain the accuracy of the core database.

# **[Monitoring & Compliance](#_Monitoring_&_Compliance)**

Compliance with the medical devices policy and associated procedure will be monitored to ensure that the aims and objectives of this policy are met. The following mechanisms will be used:

* Annual Report from the Medical Devices Committee to the Trust Board
* Quarterly status reports to the Safety Committee from the Clinical Compliance

Department highlighting current issues and risks

* Reports from the Medical Devices Committee to the Group Management

Committees when issues arise relating to their clinical areas

* Medical Engineering’s QMS effectively ensures that reusable medical devices and

equipment are properly maintained, calibrated and repaired within specified time frames.

* Incidents reported involving medical equipment will be reviewed by the Medical

Devices Manager and reported to the MHRA if appropriate

* All incidents related to the incorrect use of medical equipment will be reviewed by

FEMD to ascertain if training was a factor. Training issues will be addressed as appropriate.

* Audits of locally held records for Medical Equipment Training and Medical Device

Instructions for Use will be undertaken by FEMD biennially for all areas. Verification of self assessment of competency will be undertaken by line managers annually as part of appraisal process.

# **References**

# Ionising Radiations Regulations 1999 (IRR99)

# Medical Devices Directive 93/42/EEC

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

# Department of Health Service Circular 1999/179

# **Attachments**

Attachment 1: Equality Impact Assessment (EIA)

Attachment 2: Consultation and Ratification

## Attachment 3: Launch & Implementation PlanAttachment 1: Equality Impact Assessment (EIA)

|  |  |
| --- | --- |
| **Policy/Service Title: Management of Medical Devices Policy** | **Group 4** |
| **Name of person/s auditing/developing/authoring a policy/service: Medical Devices Manager** | |
| **Aims/Objectives of policy/service: To manage the risks associated with medical devices** | |

|  |
| --- |
| **Policy Content:**   * For each of the following check the policy/service is sensitive to people of different age, ethnicity, gender, disability, religion or belief, and sexual orientation? * The checklists below will help you to see any strengths and/or highlight improvements required to ensure that the policy/service is compliant with equality legislation. |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Check for DIRECT discrimination against any group of SERVICE USERS:** | | | | | | | |
| **Question:** Does your policy/service contain any statements/functions which may exclude people from using the services who otherwise meet the criteria under the grounds of: | | **Response** | | **Action required** | | **Resource implication** | |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
| **1.1** | Age? |  | **√** |  | **√** |  | **√** |
| **1.2** | Gender (Male, Female and Transsexual)? |  | **√** |  | **√** |  | **√** |
| **1.3** | Disability? |  | **√** |  | **√** |  | **√** |
| **1.4** | Race or Ethnicity? |  | **√** |  | **√** |  | **√** |
| **1.5** | Religious, Spiritual belief (including other belief)? |  | **√** |  | **√** |  | **√** |
| **1.6** | Sexual Orientation? |  | **√** |  | **√** |  | **√** |
| **1.7** | Human Rights: Freedom of Information/Data Protection |  | **√** |  | **√** |  | **√** |
| If yes is answered to any of the above items the policy/service may be considered discriminatory and requires review and further work to ensure compliance with legislation. | | | | | | | |
| **2. Check for INDIRECT discrimination against any group of SERVICE USERS:** | | | | | | | |
| **Question:** Does your policy/service contain any statements/functions which may exclude employees from operating the under the grounds of: | | **Response** | | **Action required** | | **Resource implication** | |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
| **2.1** | Age? |  | **√** |  | **√** |  | **√** |
| **2.2** | Gender (Male, Female and Transsexual)? |  | **√** |  | **√** |  | **√** |
| **2.3** | Disability? |  | **√** |  | **√** |  | **√** |
| **2.4** | Race or Ethnicity? |  | **√** |  | **√** |  | **√** |
| **2.5** | Religious, Spiritual belief (including other belief)? |  | **√** |  | **√** |  | **√** |
| **2.6** | Sexual Orientation? |  | **√** |  | **√** |  | **√** |
| **2.7** | Human Rights: Freedom of Information/Data Protection |  | **√** |  | **√** |  | **√** |
| If yes is answered to any of the above items the policy/service may be considered discriminatory and requires review and further work to ensure compliance with legislation. | | | | | | | |
| **TOTAL NUMBER OF ITEMS ANSWERED ‘YES’ INDICATING DIRECT DISCRIMINATION =** | | | | | | | |
| **3. Check for DIRECT discrimination against any group relating to EMPLOYEES:** | | | | | | | |
| **Question:** Does your policy/service contain any conditions or requirements which are applied equally to everyone, but disadvantage particular persons’ because they cannot comply due to: | | **Response** | | **Action required** | | **Resource implication** | |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
| **3.1** | Age? |  | **√** |  | **√** |  | **√** |
| **3.2** | Gender (Male, Female and Transsexual)? |  | **√** |  | **√** |  | **√** |
| **3.3** | Disability? |  | **√** |  | **√** |  | **√** |
| **3.4** | Race or Ethnicity? |  | **√** |  | **√** |  | **√** |
| **3.5** | Religious, Spiritual belief (including other belief)? |  | **√** |  | **√** |  | **√** |
| **3.6** | Sexual Orientation? |  | **√** |  | **√** |  | **√** |
| **3.7** | Human Rights: Freedom of Information/Data Protection |  | **√** |  | **√** |  | **√** |
| If yes is answered to any of the above items the policy/service may be considered discriminatory and requires review and further work to ensure compliance with legislation. | | | | | | | |
| **4. Check for INDIRECT discrimination against any group relating to EMPLOYEES:** | | | | | | | |
| **Question:** Does your policy/service contain any statements which may exclude employees from operating the under the grounds of: | | **Response** | | **Action required** | | **Resource implication** | |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
| **4.1** | Age? |  | **√** |  | **√** |  | **√** |
| **4.2** | Gender (Male, Female and Transsexual)? |  | **√** |  | **√** |  | **√** |
| **4.3** | Disability? |  | **√** |  | **√** |  | **√** |
| **4.4** | Race or Ethnicity? |  | **√** |  | **√** |  | **√** |
| **4.5** | Religious, Spiritual belief (including other belief)? |  | **√** |  | **√** |  | **√** |
| **4.6** | Sexual Orientation? |  | **√** |  | **√** |  | **√** |
| **4.7** | Human Rights: Freedom of Information/Data Protection |  | **√** |  | **√** |  | **√** |
| If yes is answered to any of the above items the policy/service may be considered discriminatory and requires review and further work to ensure compliance with legislation. | | | | | | | |
| **TOTAL NUMBER OF ITEMS ANSWERED ‘YES’ INDICATING INDIRECT DISCRIMINATION = 0** | | | | | | | |

# 

**Signatures of authors / auditors: Date of signing:**

## Attachment 2: Consultation and Ratification

|  |  |
| --- | --- |
| **Title** | Management of Medical Devices Policy |

|  |  |  |
| --- | --- | --- |
|  | **Ratification checklist** | **Details** |
| 1 | Is this a: Policy | |
| 2 | Is this: Revised | |
| 3\* | Format matches Policies and Procedures Template (Organisation-wide) | Yes |
| 4\* | Consultation with range of internal /external groups/ individuals | Medical Directors  Heads of Nursing  Operations Directors  Clinical Tutors  Director of Governance & Standards |
| 5\* | Equality Impact Assessment completed | Yes |
| 6 | Are there any governance or risk implications? (e.g. patient safety, clinical effectiveness, compliance with or deviation from National guidance or legislation etc) | NHSLA related standards  Reviewed by Governance Manager – up 4 |
| 7 | Are there any operational implications? |  |
| 8 | Are there any educational or training implications? | Training aspects of the policy approved by the Faculty Educators Medical Devices |
| 9 | Are there any clinical implications? | Yes  Medical Directors consulted |
| 10 | Are there any nursing implications? | Yes  Heads of Nursing consulted |
| 11 | Does the document have financial implications? | No |
| 12 | Does the document have HR implications? | No |
| 13\* | Is there a launch/communication/implementation plan within the document? | Yes |
| 14\* | Is there a monitoring plan within the document? | Monitored by the Medical Devices Committee |
| 15\* | Does the document have a review date in line with the Policies and Procedures Framework? | 3 year review |
| 16\* | Is there a named Director responsible for review of the document? | Head of Operations, Clinical Support Services |
| 17\* | Is there a named committee with clearly stated responsibility for approval monitoring and review of the document? | Medical Devices Committee |

Document Author / Sponsor

Signed ……………………… ………….…………

Title……Medical Devices Manager……………………………………………

Date……Sep 2013 ……………….………….………….……

**Approved** by (Chair of Trust Committee or Executive Lead)

Signed ……………………… ………….…………

Title……Associate Medical Director………..………………

Date……Sep 2013……………….………….………….……

**Ratified** by (Chair of Trust Committee or Executive Lead)

Signed ……………………… ………….…………

Title………Chair of Medical Devices Committee…………

Date………Sep 2013 …………….………….………….……

## Attachment 3: Launch and Implementation Plan

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

|  |  |  |  |
| --- | --- | --- | --- |
| ***Action*** | ***Who*** | ***When*** | ***How*** |
| Identify key users / policy writers | Matrons / Sisters / Head Nurses / Department Managers / Clinical Directors | Sep 2013 | Medical Devices Committee  Medical Devices Manager |
| Present Policy to key user groups | Medical Devices Committee |  | Communications email |
| Add to Policies and Procedures intranet page / document management system. | Governance Gatekeeper | Oct 2013 | Medical Devices Manager |
| Offer awareness training / incorporate within existing training programmes | Medical Devices Co Ordinator | Sep 2012 | Medical Devices Management Intranet page |
| Circulation of document(paper) | N/a |  |  |
| Circulation of document(electronic) | Medical Devices & Decontamination Manager | Sep 2013 | Added to Governance Trust Policies Intranet & Intranet page for Medical Devices Management |

Acknowledgement: University Hospitals of Leicester NHS Trust.