Policy:
Medical Devices Policy

Executive or Associate Director lead	Dr Mike Hunter, Medical Director
Policy author/ lead	Vin Lewin/Maggie Uter
Feedback on implementation to	Vin Lewin, Clinical Risk Lead

Document type	Policy
Document status	V3
Date of initial draft	October 2016
Date of consultation	November 2016
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Ratified by	Executive Directors Group
Date of issue	November 2016
Date for review	30 April 2020 (Extended from 31/10/19)

Target audience	All Directorates, SHSC staff and contractors

Keywords	Medical Devices, procurement, decontamination, maintenance, disposal, use.

Policy Version and advice on document history, availability and storage

This is version 3.0. This policy replaces the previous version issued in November 2006.

This policy will be available to all staff via the Sheffield Health & Social Care NHS Foundation Trust Intranet and on the Trust's website. The previous version will be removed from the Intranet and Trust website and archived. Word and pdf copies of the current and the previous version of this policy are available via the Director of Corporate Governance.

Any printed copies of previous versions should be destroyed and if a hard copy is required, it should be replaced with this version.

Contents

1. Introduction

This policy sets out to establish a framework for the management of medical devices owned and utilised by staff working for and on behalf of Sheffield Health and Social Care Foundation Trust (SHSC). It also sets out, in detail, the role of SHSC services and its relationship with the Medicines and Healthcare Products Regulatory Agency (MHRA) and the procedure to be adopted in the event of an adverse or potentially adverse incident involving a medical device.

Medical devices used by staff and patients must be:

- Procured in line with the organisations procurement procedures as outlined in Appendix I and in line with the Trusts Purchasing Policy for the provision of Goods and Non-Clinical Services;
- Recorded on the organisations central medical device database as part of the procurement process;
- Suitable for (and only used for) its intended purpose and in accordance with British statutory standards;
- Properly understood by users and that staff and patients are appropriately trained and competent;
- Maintained on an annual basis or in accordance with the manufacturers guidance. The device should always be kept in a safe and reliable condition;
- Decontaminated in accordance with the organisations decontamination policy;
- Decommissioned in accordance with the organisations decommissioning policy and / or manufacturers guidance.

In order to mitigate incidents involving medical devices and minimising any recurrence after an initial incident has been recorded, the MHRA collates information on all relevant adverse incidents, and as a result issues Medical Device Alerts (MDA) about hazardous medical devices; associated procedures of which are outlined in the organisations Incident Reporting Policy.

What are medical devices?

The term ‘medical device’ includes any instrument, apparatus, appliance, material or health care product (excluding pharmaceuticals) used by a member of staff on a patient or by a patient, and/ or carer for:

- The diagnosis, prevention, monitoring, treatment or alleviation of disease;
- The diagnosis, monitoring, treatment or alleviation of or compensation for an injury or impairment;
- Custom made appliances used in therapies and dental services.

Examples of medical devices used within the Trust are shown in Appendix G. See also section 3: Definitions.

Provision of personalised care

Medical devices should be used in a manner which has regard to the dignity, comfort and safety of the patient and promotes their independence. This will be achieved by:

- Actively listening to patients’ preferences and thoughts wherever possible about the equipment they need and how it is used. Religious belief will be respected regarding consent to use medical devices. If devices are advised which will result in a running cost to the patient e.g. electrical equipment, but the individual does not want to/is unable to fund the running costs, alternative equipment/care will be determined. It will be recorded in the patient notes if consent is not given for devices for any reason.

- Supporting the patient to understand how and why the equipment is being used. This includes ensuring that information about medical devices will be provided in a format to meet the patient/carer's individual requirements.
- Taking care in the way they use the equipment to make sure the patient is comfortable and safe. Individual requirements such as pregnancy will be taken into consideration if relevant when issuing any medical devices.
- Using the equipment in a way that ensures the person's privacy and dignity. Preference for a male or female health professional will be taken into consideration where required.
- Taking account of the training needs of patients with regard to any equipment they are given to use themselves.
- Using best interest provisions where required (refer to Mental Capacity Act Policy).

2. Scope

- This policy applies to Trust staff and any staff providing services under contract in both hospital and community services who are involved in any aspect of medical devices use and management.
- It applies to medical devices which are used in In-Patient services, in the community and in patients' own homes.

The term 'medical device' (see section 3) covers a wide range of products used every day in health care settings, hospital and care units, residential and nursing homes. A non-exhaustive list of the medical devices used within the Trust is included as Appendix G, which also identifies the main services involved in the use of medical devices.

3. Definitions

The term medical device is legally defined in the Medical Devices Regulations 2002 as an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for the purposes of:

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

Diagnostic equipment is equipment that is used to aid a diagnosis and can include such items as medical imaging machines.

Therapeutic equipment is equipment that is used for the delivery of patient care and treatment.

Single Use - All single use items are clearly marked 'single use only', and by law must only be used once.

Reusable equipment is equipment designed to be used more than once, appropriately decontaminated between patient usage.

Single Patient Use - All items marked by the manufacturer as single patient use must only be used by a single named patient. All the manufacturers' usage guidelines must be adhered to.

Decontamination is a combination of processes, which removes or destroys contamination and thereby prevents microorganisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. This is achieved by cleaning, disinfection and/ or sterilisation.

MDA - Medical Device Alerts.

MHRA - Medicines and Healthcare Products Regulatory Agency.

SHSC – Sheffield Health and Social Care Foundation Trust.

MDSO - Medical Device Safety Officer.

4. Purpose

This policy aims to ensure that all Medical Devices in use within SHSC are suitable for (and only used for) their intended purpose, staff are properly trained and competent in their use, devices are maintained in a safe and reliable condition and they are recorded on a locally held database/register:

- Patient and staff safety is enhanced by the use of processes, working practices and systemic activities that prevent or reduce the risk of harm to patients.
- All risks associated with the acquisition and use of medical devices are minimised.
- All reusable medical devices are properly decontaminated prior to use and that associated risk with decontaminated facilities and processes are well managed.
- The Trust fulfils the requirements of the NHS Standards for Better Health. (National Standards, Local Action. DoH 2004) and the NHSLA standards for Risk Management (NHSLA 2006, Clinical Negligence Scheme for Trusts).

The policy is set within the framework provided by MHRA April 2015 Managing Medical Devices, Guidance for healthcare and social services organisations and the relevant Care Quality Commission Fundamental Standards Regulations 2015.

5. Duties

Chief Executive

The Chief Executive has nominated the Medical Director who is accountable for Medical Devices management who will:

- Assume accountability for medical devices management within the Trust.
- Review allocation of resources to meet identified needs in relation to medical devices management.
- Ensure compliance with the requirements of the Standards for Better Health and Clinical Negligence Scheme for Trusts standards in relation to Medical Devices.

Medical Devices Safety Officer:

The Clinical Risk & Investigations Lead is the Trusts nominated Medical Device Safety Officer (MDSO) with the MHRA. The key purpose of this role is to promote reporting & learning and safe use of medical devices across the organisation and be the main expert resource in this practice area.

Infection Prevention and Control Team:

Has responsibility to provide input into the medical devices working group and to advise accordingly in line with this policy and other related policies and procedures.

Service Directors/ Senior Departmental Managers or their nominated representatives should:

- Ensure that the staff working within their area of responsibility adhere to this policy.
- Establish local procedures to ensure that working arrangements meet the requirements for the procurement, use, decontamination, maintenance and end of life of the equipment of medical devices provided by the manufacturer.
- Ensure that staff undergo training and are competent to use the medical devices within their area of responsibility.
- Monitor training relating to the management of medical devices
- Action any hazard and safety notices (refer to SABS Policy) and comply with any guidance on changes to the use of a device.
- Ensure that single use medical devices are not reused.
- Ensure a live inventory of all medical devices is kept for their service/department
- Ensure clinicians are consulted with respect to the procurement of medical devices.

All staff responsibilities:

It is the responsibility of all staff to:

- Fully implement this policy and bring to the immediate attention of Managers any issues affecting the effective implementation of this policy.
- Deliver personalised care through the use of medical devices in a way that has regard to the dignity, comfort and safety of patients and which promotes their independence and well-being.
- Use best interest provisions where required.
- Take account of the training needs of patients/carers with regard to any equipment the patient/carer is given to use themselves.
- Report incidents and near misses involving medical devices via the Safeguard (IR1) electronic incident reporting system.
- Address any concerns in a timely manner where they identify problems around the safety or suitability of equipment in a patient's own home.
- Use medical devices safely and in the prescribed manner including ensuring that any safety checks required by manufacturers' instructions or procedures/guidance are carried out prior to use of medical devices including safe decontamination.
- Individual staff members must ensure they have received sufficient training i.e. verbal and/or written instructions and hence are competent to use a medical device before attempting to operate it. If there is any doubt, the member of staff should consult their Manager and the manufacturers' instructions.
- All prescribing decisions involving medical devices will be made by staff with appropriate professional qualifications and suitable experience.
- Preserve the Trust's assets and keep unnecessary expenditure to a minimum.
- Every member of staff must have ownership and responsibility for minimising the impact of risk.

Independent contractors

All independent contractors are wholly responsible for the management of risks within their practice. To support Independent Contractors in satisfying this duty the Trust recommends full compliance with this policy. The provision of directly managed Trust services within an Independent Contractor's practice may be dependent on full compliance with all the Trust's

governance policies and procedures. Failure to provide evidence of compliance may result in the withdrawal of direct Trust services.

Sheffield Medical and Therapeutic Devices Group

The Medical and Therapeutic Devices Group will be responsible for:

- Reviewing and updating the Medical Devices Policy.
- Provide assurance that competencies are in place and validated.
- Inform the Service User Safety Group about issues and good practice from the group.
- Act as a forum to discuss complex medical devices alerts.
- Review the Medical Device Safety Officers reports, and other data as available, to identify, prioritise and address medical device risks to minimise harm to patients.
- Identification, development and promotion of the best practices for medical device safety. This will include supporting the
- implementation of external medical device safety alerts and guidance from NHS England, MHRA, NICE, manufacturers'
- FIELD SAFETY NOTICES and other organisations.

Implementation will require co-ordination and support for process and system changes to reduce the likelihood of occurrence and reoccurrence of serious medical device.

6. Process

6.1 Procurement of Medical Devices

Managers will adhere to Standing Financial Instructions in the procurement of medical devices. A Risk Assessment/Evaluation should be completed prior to purchase (Appendix K).

Trust staff may wish to consider seeking advice prior to the procurement of medical devices from the Trust's Head of Procurement and other appropriate people including the Medical Devices Liaison Officer (see appendix H).

On receipt of a new medical device, Department/Team Managers will follow the procedure outlined in Appendix I.

6.2 Modification and Adjustments

Modification or adjustment is only be made by the manufacturer or by someone qualified to do so.

Medical devices are only used for the purpose for which they were designed.

It should be noted that modification of equipment or use of any equipment for other than its intended purpose is a clear breach of the terms of the manufacturer's warranty. If a patient suffers harm in the process the Trust would have no redress, even if the equipment was found to be faulty.

6.3 Commissioning and Use

Medical devices are not used until the full functionality and safety have been validated. Only a person who is competent to fully understand the correct operation of the device and to identify any malfunction or faults in operation will undertake tests and checks.

The test and results of such tests will be recorded in the history log for the device by a nominated person. All tests and checks must conform to the guidance in Medical Devices Agency, Device Bulletin DA DB9801 (Medical Device and Equipment Management for Hospital and Community-based Organisations). www.mhra.gov.uk/

All staff using medical devices have an individual responsibility to be competent to do so and managers should ensure training is undertaken before equipment use. Staff lacking competence to use medical devices necessary for their work must inform their line manager so that the training need can be addressed.

Managers will use the induction and appraisal process to identify training needs in relation to medical devices.

Up-to-date operating instructions and user manuals will be available at all times for any person using the device, and must be followed in relation to use, decontamination, handling, storage and reporting faults.

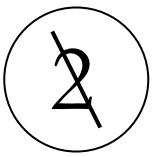
All incidents involving medical devices will be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) by Risk Management Department, on receipt of an Incident Form (using Trust Incident Reporting and Investigation policy)

A defective device will be removed from use, quarantined and must not be tampered with in any way. It will only be handled by an authorised person until the investigation is complete.

If medical devices are loaned or supplied to patients, carers or other health care staff it is the responsibility of the refer/ provider to be assured that the mechanisms are in place to ensure that the end user has appropriate instructions and where appropriate has training and a level of competence in its use and decontaminated before its use.

6.4 Single use items

Devices designated for 'single use' **must not** be reused under any circumstances. The designated symbol for 'single use' is:



6.5 Maintenance and Repair

Managers will ensure that all devices are maintained accordance with the manufacturer's instructions and relevant legal requirements. (For further advice see; MDA DB 2000(02). In-house repairs and maintenance will only be undertaken by staff who are fully trained and competent to do so.

Managers will maintain systems to ensure that all aspects of repair and maintenance are documented accurately, detailed and accessible.

6.6 Decontamination

Decontamination of reusable medical devices will be addressed in line with Trust's Decontamination Policy.

6.7 Disposal of Medical Devices

Medical devices no longer required will be disposed of in a safe manner, in compliance with required legislation.

Disposal of redundant medical devices will be by, transfer of ownership, decommissioning or disposal in line with the Trust policy for waste disposal.

In cases of transfer of ownership - decontamination certificates, maintenance records and operating instructions, will be transferred with the device at the time of transfer.

When devices are decommissioned - decontamination certificates, maintenance records and operating instructions will be retained within departments.

Advice and guidance to be followed as per Trust's Waste Management Policy.

6.8 Medical Device Alerts

The process by which the Trust deals with Medical Device Alerts is outlined in the "Central Alert System (CAS) Policy".

7. Dissemination, storage and archiving (Control)

The issue of this policy will be communicated to all staff via the Communications Digest. Local managers are responsible for implementing this policy within their own teams.

This policy will be available to all staff via the Sheffield Health & Social Care NHS Foundation Trust Intranet and on the Trust's website. The previous version will be removed from the Intranet and Trust website and archived. Word and pdf copies of the current and the previous version of this policy are available via the Director of Corporate Governance.

Any printed copies of the previous version should be destroyed and if a hard copy is required, it should be replaced with this version.

8. Training and other resource implications

All staff joining the Trust will attend Core Mandatory Training as required for their role. The Infection Control session includes a brief overview of decontamination and emphasises its importance in the delivery of care. All staff require Mandatory Training updates; please refer to the mandatory training policy or discuss with your own line manager. Training data will be collected centrally by the Education and Training Department, but each department/team manager is responsible for ensuring that their staff receive training and update any locally held training records.

Staff are reminded that they should seek relevant training and be appropriately trained in clinical procedures e.g. venepuncture or catheterisation where invasive medical devices are used; and maintain their competencies to ensure safe practice.

Should resource implications be identified then appropriate business cases will be produced for consideration.

9. Audit, monitoring and review

Monitoring Compliance Template						
Minimum Requirement	Process for Monitoring	Responsible Individual/ group/committee	Frequency of Monitoring	Review of Results process (e.g. who does this?)	Responsible Individual/group/ committee for action plan development	Responsible Individual/group/ committee for action plan monitoring and implementation
Policy and Process Review	Review	Medical and Therapeutic Devices Group	3 years	Service User Safety Group	Medical and Therapeutic Devices Group	Medical and Therapeutic Devices Group

10. Implementation plan

Action / Task	Responsible Person	Deadline	Progress update
New policy to be uploaded onto the Intranet and Trust website.	Director of Corporate Governance	Within 5 working days of ratification	
A communication will be issued to all staff via the Communication Digest immediately following publication.	Director of Corporate Governance	Within 5 working days of issue	
A communication will be sent to Education, Training and Development to review training provision.	Director of Corporate Governance	Within 5 working days of issue	

11. Links to other policies, standards and legislation (associated documents)

Infection Prevention and Control Policy
Decontamination - Environmental Cleanliness and Reusable Equipment
Incident Reporting and Investigation Policy
Safety Alert Broadcasting System (SABS) Policy

12. Contact details

Title	***Name***	***Phone***	***Email***
Medical Devices Safety Officer	Vin Lewin	0114 2716379	Vin.lewin@shsc.nhs.uk
Health and Safety Risk Advisor	Charlie Stephenson	0114 2716208	Charlie.stephenson@shsc.nhs.uk

13. References

Care Quality Commission (2015) Fundamental standards regulations
MHRA April 2015, Managing Medical Devices, Guidance for healthcare and social services organisations
MHRA Device Bulletin DB 2008 (001) 'Reporting adverse incidents and disseminating Medical Device Alerts'.
MHRA Single-use Medical devices: Implications and Consequences or reuse (MHRA, 2013)
Medical Devices Directive (MDD) 2007/47/EC
The Medical Devices Regulations 2002. Statutory Instrument 2002 No. 618. ISBN0110423178
Safety alerts, rapid response alerts, guidance and directives relating to equipment published by expert and professional bodies including:

NICE
National Patient Safety Agency (NPSA)
Medicines and Healthcare products Regulatory Agency (MHRA)
Royal Pharmaceutical Society of Great Britain
Department of Health
Product Manufacturers

Medical Device and Equipment Management for Hospital and Community-based Organisations. www.mhra.gov.uk/

MDA DB2000 (02) - Medical Device Agency Device Bulletin2000 (02) - medical device and equipment: repair and maintenance provision. www.mhra.gov.uk/
Medical Devices Agency (2002) Devices in Practice, DOH London. www.mhra.gov.uk/
MDA DB2000 (04) - Medical Device Agency Device Bulletin2000 (04)-single-use Medical Devices: implications and consequences of reuse. www.mhra.gov.uk/
MDA DB2000 (04) - Supplement 2. Guidance on the sale, transfer of, ownership and disposal of used medical devices. www.mhra.gov.uk/
MDA DB 9801- Medical Device Agency Device Bulletin 9801-Medical Device and equipment management for hospital and community-based organisations. www.mhra.gov.uk/
Medical Devices Agency (2002) Devices in Practice, DOH London. www.mhra.gov.uk/
Medicines and Healthcare Regulatory Agency Annual Report 2004. www.mhra.gov.uk/
Medicines and Healthcare products Regulatory Agency 2005 (MHRA DB2005 (01). Reporting Adverse Incidents and Disseminating Medical devices Alerts.
Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC)

Appendix A – Version Control and Amendment Log

Version No.	Type of Change	Date	Description of change(s)
3.0	Review / ratification / issue	Nov 2016	Finalised and issued.

Appendix B – Dissemination Record

Version	Date on website (intranet and internet)	Date of "all SHSC staff" email	Any other promotion/ dissemination (include dates)
3.0	Nov 2016	Nov 2016 via Communications Digest	

Appendix C – Stage One Equality Impact Assessment Form

Equality Impact Assessment Process for Policies Developed Under the Policy on Policies

Stage 1 – Complete draft policy

Stage 2 – **Relevance** - Is the policy potentially relevant to equality i.e. will this policy potentially impact on staff, patients or the public? If **NO** – No further action required – please sign and date the following statement. If **YES –** proceed to stage 3

This policy does not impact on staff, patients or the public (insert name and date)

Stage 3 – **Policy Screening** - Public authorities are legally required to have 'due regard' to eliminating discrimination , advancing equal opportunity and fostering good relations , in relation to people who share certain 'protected characteristics' and those that do not. The following table should be used to consider this and inform changes to the policy (indicate yes/no/ don't know and note reasons). Please see the SHSC Guidance on equality impact assessment for examples and detailed advice. This is available by logging-on to the Intranet first and then following this link https://nww.xct.nhs.uk/widget.php?wdg=wdg_general_info&page=464

	Does any aspect of this policy actually or potentially discriminate against this group?	**Can equality of opportunity for this group be improved through this policy or changes to this policy?**	**Can this policy be amended so that it works to enhance relations between people in this group and people not in this group?**
AGE	**No**		
DISABILITY	**No**		
GENDER REASSIGNMENT	**No**		
PREGNANCY AND MATERNITY	**No**		
RACE	**No**		
RELIGION OR BELIEF	**NO**		
SEX	**No**		
SEXUAL ORIENTATION	**No**		

Stage 4 – **Policy Revision** - Make amendments to the policy or identify any remedial action required (action should be noted in the policy implementation plan section)
Please delete as appropriate: Policy Amended / Action Identified / no changes made.

Impact Assessment Completed by (insert name and date) Tania Baxter, Head of Clinical Governance (10/11/2016)

Appendix D - Human Rights Act Assessment Form and Flowchart

You need to be confident that no aspect of this policy breaches a person's Human Rights. You can assume that if a policy is directly based on a law or national policy it will not therefore breach Human Rights.

If the policy or any procedures in the policy, are based on a local decision which impact on individuals, then you will need to make sure their human rights are not breached. To do this, you will need to refer to the more detailed guidance that is available on the SHSC web site
http://www.justice.gov.uk/downloads/human-rights/act-studyguide.pdf
(Relevant sections numbers are referenced in grey boxes on diagram) and work through the flow chart on the next page.

1. Is your policy based on and in line with the current law (including case law) or policy?

X **Yes. No further action needed.**

☐ **No. Work through the flow diagram over the page and then answer questions 2 and 3 below.**

2. On completion of flow diagram – is further action needed?

☐ **No, no further action needed.**

☐ **Yes, go to question 3**

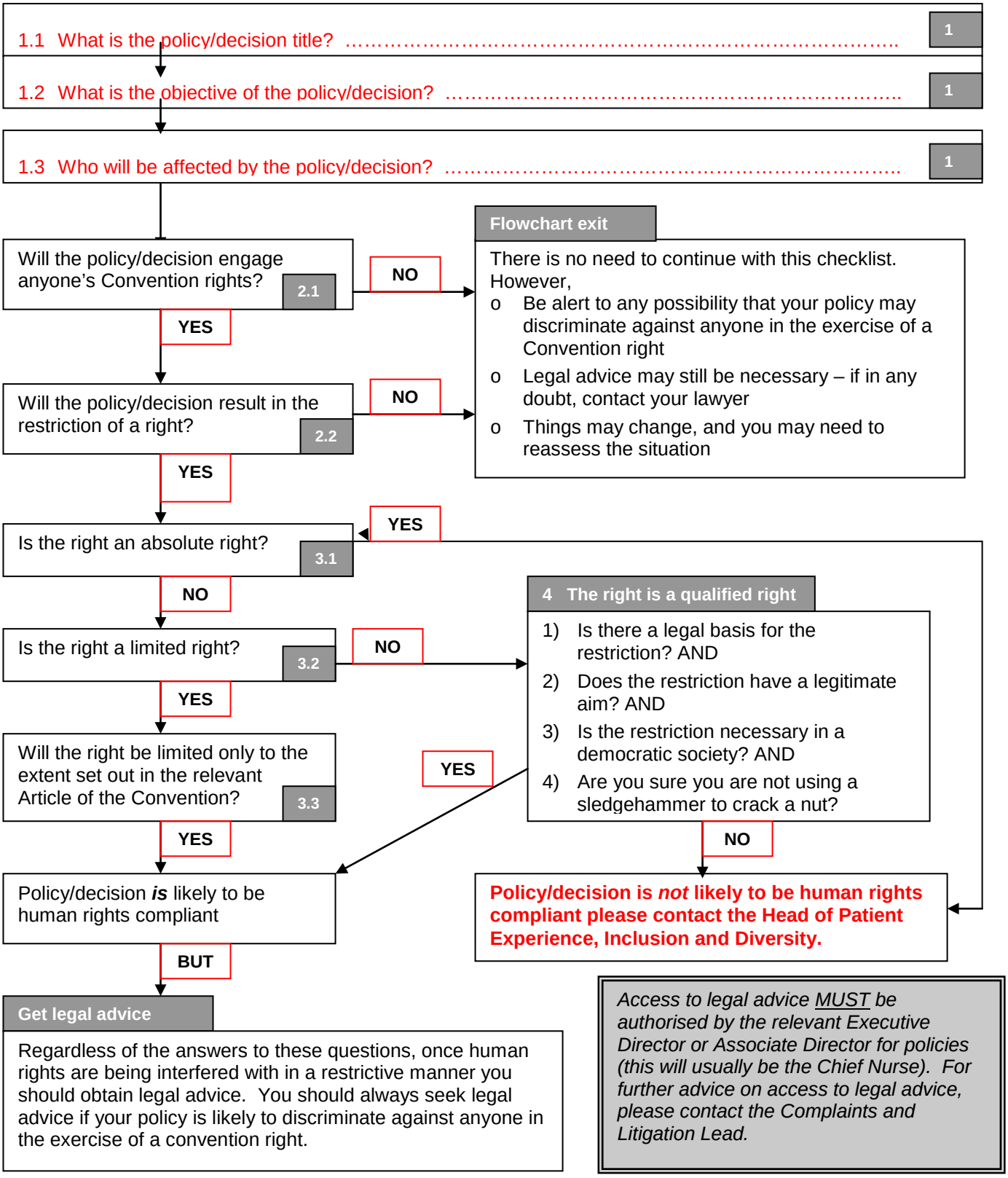
3. Complete the table below to provide details of the actions required

Action required	By what date	Responsible Person

Human Rights Assessment Flow Chart

Complete text answers in boxes 1.1 – 1.3 and highlight your path through the flowchart by filling the YES/NO boxes red (do this by clicking on the YES/NO text boxes and then from the Format menu on the toolbar, choose 'Format Text Box' and choose red from the Fill colour option).

Once the flowchart is completed, return to the previous page to complete the Human Rights Act Assessment Form.



Appendix E – Development, Consultation and Verification

This policy was reviewed and updated as part of an on-going policy review and revision process.

Consultation:
Helen Payne, Director of Facilities Management
Charlie Stephenson, Health & Safety Risk Advisor
Giz Sangha, Deputy Chief Nurse

Changes following feedback from consultation included the onus on directorates to maintain their own log of medical devices and an update.

Verification:
The policy was verified by the Deputy Chair of the Service Users Safety Group.

Appendix F –Policies Checklist

Please use this as a checklist for policy completion. The style and format of policies should follow the Policy Document Template which can be downloaded on the intranet.

1. Cover sheet ✓

All policies must have a cover sheet which includes:

- The Trust name and logo ✓
- The title of the policy (in large font size as detailed in the template) ✓
- Executive or Associate Director lead for the policy ✓
- The policy author and lead ✓
- The implementation lead (to receive feedback on the implementation) ✓
- Date of initial draft policy ✓
- Date of consultation ✓
- Date of verification ✓
- Date of ratification ✓
- Date of issue ✓
- Ratifying body ✓
- Date for review ✓
- Target audience ✓
- Document type ✓
- Document status ✓
- Keywords ✓
- Policy version and advice on availability and storage ✓

2. Contents page ✓

3. Flowchart N/A

4. Introduction ✓

5. Scope ✓

6. Definitions ✓

7. Purpose ✓

8. Duties ✓

9. Process ✓

10. Dissemination, storage and archiving (control) ✓

11. Training and other resource implications ✓

12. Audit, monitoring and review ✓

This section should describe how the implementation and impact of the policy will be monitored and audited and when it will be reviewed. It should include timescales and frequency of audits. It must include the monitoring template as shown in the policy template (example below).

Monitoring Compliance Template						
Minimum Requirement	Process for Monitoring	Responsible Individual/ group/ committee	Frequency of Monitoring	Review of Results process (e.g. who does this?)	Responsible Individual/group/ committee for action plan development	Responsible Individual/group/ committee for action plan monitoring and implementation
A) Describe which aspect this is monitoring?	e.g. Review, audit	e.g. Education & Training Steering Group	e.g. Annual	e.g. Quality Assurance Committee	e.g. Education & Training Steering Group	e.g. Quality Assurance Committee

13. Implementation plan ✓

14. Links to other policies (associated documents) ✓

15. Contact details ✓

16. References ✓

17. Version control and amendment log (Appendix A) ✓

18. Dissemination Record (Appendix B) ✓

19. Equality Impact Assessment Form (Appendix C) ✓

20. Human Rights Act Assessment Checklist (Appendix D) ✓

21. Policy development and consultation process (Appendix E) ✓

22. Policy Checklist (Appendix F) ✓

Appendix G Medicines and Healthcare products Regulatory Agency (MHRA)

Common Categories of Medical Device (this list is not exhaustive. It provides examples of medical devices)

Equipment in the diagnosis or treatment of disease, or monitoring of patients, such as:	In vitro diagnostic medical devices and their accessories, such as:
• Chiropody and podiatry Equipment • Dressings • Examination gloves • Intravenous (IV) administration sets and pumps • Nebulisers • Ophthalmic equipment • Peak flow meters • Surgical instruments • Suction equipment • Syringes and needles • Sphygmomanometers • Thermometers • Ultrasound dopplers • Urinary catheters	• Blood glucose measuring devices • Cholesterol test kits • Pregnancy test kits • Specimen collection tubes • Urine test strips
Equipment used in life support, such as:	**Equipment used in care, such as:**
• Defibrillators • Insulin Injectors • Domiciliary oxygen therapy systems • Ventilators used in home • Pulse oximeters	• Adjustable beds • Lifting poles • Patient hoists • Pressure relief equipment • Stoma care equipment
	Equipment used by people with disabilities, such as:
	• Bathing equipment • Commodes • External prostheses and orthoses • Hearing aids • Incontinence aids • Prescribable Footwear • Standing frames • Urine drainage systems • Walking aids • Wheelchairs and special support seating
	Other examples include:
	• Condoms • Contact lenses and care products • Intra-uterine devices (IUDs)

Medical Devices Agency (2002) Devices in Practice, DOH London

Appendix H

MEDICAL AND THERAPEUTIC DEVICES GROUP

TERMS OF REFERENCE

PURPOSE OF GROUP

- To co-ordinate and direct the Trust with regard to the purchase and use of therapeutic and medical devices, including, but not restricted to, standardisation across the Trust, introduction of new practices, medical device alerts management etc.

- To reflect best practice guidance in relation to the MHRA Managing Medical Devices guidance (April 2014).

MEMBERSHIP

Membership will comprise representatives at a senior level. Additional members will be invited, as and when appropriate. The core membership will be:

Who	Function Required
Deputy Chief Nurse	Chair
Senior Nurse, Infection Prevention Control	Infection Prevention and Control
Senior Nurse, Clinical Training Lead	Training
Investigation Lead	Investigations, Serious Incidents
Procurement Team Manager	Procurement Team Manager
Health and Safety Risk Advisor	Health and Safety and Risk
Medic	Clinical

REMIT

- Agree, develop and monitor a list of standardised therapeutic and medical devices for use within the Trust.
- Manage the introduction of new medical devices into the Trust.
- Review incidents related to such devices for shared learning and improvements in practice and make recommendations, if appropriate.
- Commission policies and procedures in relation to medical devices.
- Identify medical device risks and liaise with the Service User Safety Group.
- Discuss, endorse and advise on Trust responses to emergency planning situations.
- Progress appropriate standards for Infection Prevention and Control and decontamination of medical devices.
- Promote and facilitate education and training in all grades of staff in the use of identified medical devices
- Promote effective communication and joint working with all relevant healthcare providers within the Sheffield area on issues of medical devices
- Respond to medical device and safety alerts as they arise
- Report and make recommendations to the appropriate groups i.e. The Executive Directors Group, the Service User Safety Group, Directorate Senior Management Teams on issues relating the Medical and Therapeutic Devices as appropriate
- Advise the Trust on all aspects of medical devices

FREQUENCY OF MEETINGS

The Group will meet on a quarterly basis. Dates for the meetings are listed below.

AGENDA SETTING

An agenda setting process will be initiated two weeks prior to the meeting by the Deputy Chief Nurse. A formal agenda will be forwarded to all members approximately one week prior to the meeting. The following should be considered as a potential core items:

- Medical Device Alerts/Safety Alerts.
- Medical Device Incidents.
- Areas including: Education; Audit; Surveillance; Decontamination of Environment and Equipment; Policy and procedures.

ACCOUNTABILITY / REPORTING ARRANGEMENTS

The Group will be accountable to the Service User Safety Group and ultimately the Board of Directors. The notes of the Group will be forwarded to the Service User Safety Group for formal notification. The Chair will provide a verbal up-date as necessary.

Appendix I

Procedure for the receipt of a new medical device

Managers will adhere to the following procedure when taking receipt of new medical devices:-

i) Check that the correct product, complete with operating manuals and maintenance instructions has been supplied.

ii) Complete and retain the delivery checklist. (Appendix 4)

iii) Ensure that product items have been delivered in good condition and in working order.

iv) Ensure that a risk assessment relating to the medical device is completed and the risks are managed at reasonable levels.

v) Record the details of the device (product no., serial no., etc.).

vi) Comply with safety legislation

vii) A written decontamination procedure is made available and stored with the records for each piece of equipment.

viii) Determine the correct training requirements for the use and maintenance of each piece of equipment and retain evidence of all training.

ix) Initiate a history for any items requiring service.

x) Ensure that devices are fully functional in line with manufactures', NHS and statutory requirements.

Appendix J

Delivery checklist

A Equipment Details

1.	Decontamination certificate	Yes/No
2.	Date	
3.	Supplier	
4.	Device type	
5.	Delivery note checks with order?	Yes/No
6.	Goods checks with delivery note?	Yes/No
7.	Model/type identification	
8.	Serial Number	
9.	Mains voltage	
10.	Leads supplied	Yes/No
11.	Accessories supplied	Yes/No
12.	User manual supplied	Yes/No
13.	Instructions supplied	Yes/No
14.	Maintenance manual supplied	Yes/No
15.	Warranty document included	Yes/No
16.	Final test certificate supplied	Yes/No
17.	Local serial/inventory number	
18.	Device type new to healthcare facility	Yes/No
19.	- If yes, instructions circulated appropriately	Yes/No
20.	“New Device” sticker attached	Yes/No

B Visual Inspection

1.	Outer packaging undamaged?	Yes/No
2.	Case not dented/broken	Yes/No
3.	Panels etc. secure	Yes/No
4.	No rattles	Yes/No

C Electrical safety

1. Moulded IEC mains connector and mains plug

- Connectors firmly attached Yes/No
- No cores or bare wires visible Yes/No
- Outer insulation intact Yes/No
- Appropriate fuse fitted (see manual) Yes/No
- Fuse holder secure Yes/No

2. Mains lead permanently attached

- Cord grips satisfactory Yes/No
- Fuse value
- Plugs and sockets mate Yes/No
- Clamps and doors latch Yes/No
- Passes PAT test Yes/No

D Functional check

Plug in, turn on (following instruction manual)

1. Indicator lamps light up Yes/No
2. Display as described in manual Yes/No
3. Passes self test routine Yes/No
4. Moving parts operate properly Yes/No
5. Knobs and switches act properly Yes/No

Appendix K – Decontamination Evaluation & Risk Assessment Form

DECONTAMINATION EVALUATION & RISK ASSESSMENT FORM

To be completed at the time of requisition by the requesting area/service

Item: **Requisition form number:**

Briefly describe the item/equipment and its intended use:

Dose <u>any</u> part of the equipment (including accessories) come into contact with the patient/client or their blood or body fluids? YES/NO – *If yes please provide details*

For parts of the equipment <u>not</u> coming into contact with the patient/client or their blood or body fluids:

a) **How is the item to be routinely cleaned e.g. from dust**

b) **Who will carry out this process, how often & where?**

c) **How will the item be decontaminated if inadvertent contact with blood or body fluids occurs?**

d) **Who will carry out this process & where?**

For parts of the equipment coming into contact with the patients/clients <u>intact skin:</u>

a) **How is the item to be cleaned between uses?**

b) **Who will carry out this process, how often & where?**

c) **How will the item be decontaminated if inadvertent contact with blood or body fluids occurs?**

d) **Who will carry out this process & where?**

For parts of the equipment coming into contact with <u>non-intact skin</u>, mucous membranes, blood or body fluids or are to be introduced into sterile body cavities: *(use single use disposable equipment wherever possible)*

a) **How is the item to be cleaned between uses prior to disinfection/sterilisation?**

b) **Who will carry out this process, how often & where?**

c) **How will the item be disinfected/sterilised?**

d) **Who will carry out this process & where?**

If the equipment is to be transferred to another area/location for processing from where it has been used:

a) **Has the department/location that will be cleaning/disinfecting/sterilising the item agreed to this & the methods to be used? YES/NO –** *please provide details*

b) **How will the equipment/item be transported to & from the processing department/location e.g. containers/bags used and by whom?**

Please provide details of the person completing this risk assessment:

Name:

Date:

Position:

Contact details: *(email & phone)*

Please provide details of the person to contact if the reviewer needs to ask further questions or to discuss the situation if the proposed process needs to be referred to the Medical & Therapeutic Devices Group/Medical Devices Liaison Officer/Infection Control Team; if different from the individual named above

Name:

Position:

Contact details: ***(email & phone)***

Please retain a copy for your records. If further advice is required please submit a copy of this to the Infection Control Team. Thank you for your time & assistance.

Decontamination Certificate

Before any equipment is sent for repair/service, transferred between departments or for final disposal both within and outside Sheffield Health and Social Care premises it must be decontaminated and a certificate completed. Please tick:

☐ **Items for service or repair – the certificate must accompany the equipment.**

☐ **Items for final disposal – please complete the certificate and retain in the department/ward/unit area**

☐ **Items transferring between departments – please complete the certificate and give to the receiving department**

Ward/Department:		
Description of equipment:		
Make:	Model:	Serial Number:

Please select **ONE** box and tick accordingly:

To the best of my knowledge this equipment has NOT been in contact with potentially infected material e.g. blood, bodily fluids and therefore has not been contaminated.	
This equipment MAY be contaminated by potentially infected material and has been decontaminated externally on its outer surface as per decontamination policy.	
This equipment MAY be contaminated but could not be decontaminated because, please give details	

The above piece of equipment has been appropriately decontaminated following patient usage and is now ready for repair/service, transfer or final disposal.

Signature_____ Date_____

Name_____ Designation_____

Appendix M Procurement of Medical Equipment/Devices