Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Medical Devices Management Policy

This procedural document supersedes: CORP/PROC 4 v.5 – Medical Devices Management Policy

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Author/reviewer: (this version)	Andrew Leverton - Medical Technical Services Manager
Date written/revised:	July 2019
Approved by:	Medical Devices Management Group
Date approved:	24 September 2019
Date issued:	25 September 2019
Next review date:	July 2022
Target audience:	Trust-wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 6	25 September 2019	• References to care groups changed to divisions • Removal of the Theatre procurement group and Medical equipment management group. • Formation of the Medical Devices Management group • Revised procedures for capital business case submissions • Inclusion of a section on software • Inclusion of the Instrument Review Committee	Andrew Leverton
Version 5	19 November 2015	• Fully revised policy, incorporating **CORP/PROC 1 v.4** - Policy for the Use of Medical Equipment Used 'On-Trial/On-Loan' and **CORP/PROC 5 v.2** - Policy and Procedures for the Maintenance and Repair of Medical Devices – these are now procedures. • Renamed from 'Procurement of Medical Equipment Policy' to 'Medical Devices Management Policy'. • Addition of the Medical Equipment Management Group and Theatre Procurement Group. • Inclusion of Software based Medical Devices.	Andrew Leverton Allison O'Donnell
Version 4	June 2011	• Title change. • Amendment form and contents page added. • Foreword – last four paragraphs removed. • Flowchart - Procedure for Procurement of Items of Equipment Listed in the 'Best Buy' Guide removed. • Flowchart – Procedure for Equipment Procurement for Items Not Listed in the 'Best Buy' Guide removed. • Equipment Evaluation Form removed. • Form of Indemnity – A removed. • Form of Indemnity – B removed. • NHS Delivery Note removed. • Guidance Notes for Staff for NHS Forms of Indemnity and NHS Delivery Notes removed. • Guidance Procedures for the Procurement of Medical Equipment removed. • Item 3 - Equipment Specification – Points f) to l) removed. • Item 4 – Sourcing and Pre-Purchase Questionnaires – paragraph 4 removed. • Item 5 – Business Case – 1st paragraph changed. • Item 8 – Equality Impact Assessment added. • Item 9 – Monitoring of Policy added. • Appendix A - Medical Equipment Flowchart - Equipment Costing > £5k added. • Appendix A - Medical Equipment Flowchart – Equipment Costing < £5k added. • Appendix B – Medical Equipment Purchase Form amended.	Andrew Leverton and Ian Allcock

Contents

Page No.

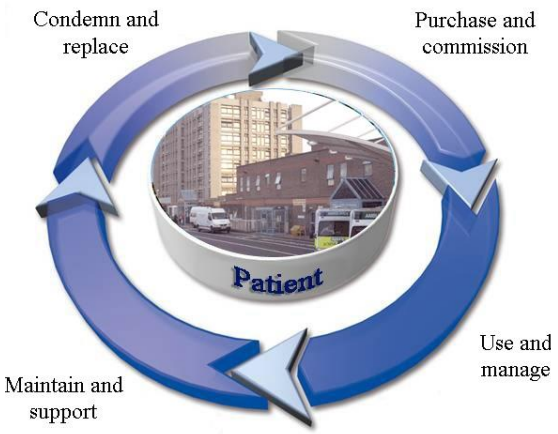
1. INTRODUCTION

This policy has been produced to assist staff in the management of Medical Devices. The Policy should be read in conjunction with the following documents.

- Procedures for the Use of Medical Equipment Used "On-Trial/On-Loan" (Appendix 3)
- Medical Equipment Training Policy – CORP/RISK 2.
- Supplier and Procurement Representative Policy – CORP/PROC 2.
- Selection and Procurement of Medical Devices Policy – CORP/PROC 3.
- Condemnation and Disposal of Trust Assets – CORP/PROC 6.
- Procedures for Maintenance and Repair of Medical Devices. (Appendix 4)

2. PURPOSE

The Trust's Policy for the management of medical devices encompasses each aspect of the devices life cycle as shown below:



The policy and associated procedures are in place to ensure that:

- Procedures for the loan and trial of Medical devices are adhered to.
- Equipment used on the Trust's behalf complies with the recommended standards, particularly those relating to safety.

- An auditable system is in place to ensure medical equipment purchase is verified as appropriate from a clinical, technical and financial standpoint.
- Safe guards are in place to prevent unauthorised downloading, uploading or modification of data in PC controlled medical equipment / systems, for example Intensive care data logging PC.
- Users are aware of the technical, revenue and training implications of their choice of equipment.
- Managers and staff are familiar with and in compliance with the Trusts user training Standard process for recording equipment training records.
- Procedures for the maintenance and servicing of medical devices are understood.
- Users are aware of how to report incidents and faults.
- The process for condemnation, removal and subsequent replacement of medical devices is fully understood.

3. DUTIES AND RESPONSIBILITIES

3.1 **Procurement:-** The head of Procurement is responsible for issues relating to the sourcing and procurement of medical devices ensuring the Trust is compliant with current procurement legislation.

3.2 **User management/Training:-** Ward/department managers supported by their relevant division matrons are responsible for the day to management of the devices under their care and for ensuring staff are trained in accordance with Trust policy.

3.3 **Maintenance and servicing:-** The Trusts Head of Medical Technical services is responsible for ensuring that the Trusts medical devices are maintained and serviced in accordance with a risk assessed program.

A number of specialist groups exist to support staff in the above:

Medical Devices Management Group.

This group meets quarterly and supports wards and departments in every aspect of medical device management. Chaired by the Head of Medical Technical Services it addresses day to day operational issues.

Medical Equipment Group (MEG)

Chaired by the Medical Director and meeting monthly this group receives bids for replacement medical equipment and discusses wider strategic issues relating to medical equipment management. Bids for new and replacement medical equipment will need to be submitted using the appropriate template supplied in appendix 5. Sponsors maybe requested to attend to present their case.

Instrument Review Committee (IRc)

The instrument Review committee meets specifically to assess the needs and requirements of the trusts stock of surgical instrumentation. The committee meets quarterly and is chaired by the Steris Contract manager. Identification and agreement on areas for investment are considered along with reviewing the service support from the off site service provider, Steris.

Corporate Investment Group (CIG)

The CIG will receive those bids for medical equipment that have already been supported by the Medical Equipment Group, and approve purchase accordingly; meeting monthly it is chaired by the Director of Finance. Bids need to be submitted by the agenda deadline and sponsors are requested to attend to present their case.

4. TRIAL AND ON LOAN EQUIPMENT

In some cases there will be a need to trial equipment to ensure that it meets the clinical requirements. It may also be advantageous to have loan devices in the Trust on a long term basis, for instance where devices are provided as part of a consumable deal.

Where this is identified reference should be made to the procedures for on loan/on trial medical devices. Appendix 3.

5. PROCUREMENT

The following procedure has been summarised in flowcharts that can be found in Appendix 1.

This Policy is designed to cover all the sources of acquiring medical equipment such as gift, donation, free issue, in house manufacture, lease and P.F.I.

5.1 Case of Need

A case of need must be established before proceeding with the purchase. The following criteria will need to be taken into account: -

a) Does equipment already exist within the ward or department?
b) Is the equipment a replacement or additional to existing equipment?
c) Does the equipment appear in the list of Trust approved equipment ('Best Buy') Guide*? (At the time of writing the best buy guide is being reviewed, please contact the Head of Medical Technical Services or procurement capital buyer for further information.)*
d) What is the source of the funding and does it require support from the Medical Equipment Group and authorisation from CIG?

e) Where equipment is to be purchased from exchequer funds, is the purchase price of the medical device below £5000 Inc VAT?
f) Does the equipment meet the safety requirements for its type?

Note It is not acceptable practice to alter, modify or cannibalise existing equipment in order to meet a clinical need.

5.2 Equipment Specification

Selection of new equipment can prove to be difficult with a wide spectrum of equipment available on the market today. A number of factors need to be taken into account when drawing up a specification:

a) The users requirements
b) Performance
c) Safety and compliance with standards and information updates
d) Electro Magnetic Compatibility
e) Equipment Standardisation
f) Revenue costs i.e. training, cost of disposables required for use with the equipment, maintenance and spare parts, cleaning and decontamination.

It is advisable to have the specification checked by Medical Technical Services Department or Estates (depending on the equipment) and a clinical specialist to ensure the equipment specified will not compromise or cause incompatibility with existing equipment, services or systems. The specification should also be discussed with Procurement to ensure it is output based and not specified to a Supplier/Brand.
A standard Statement of Requirements (SoR) may be available for equipment on the NHS supply chain framework. Contact procurement for more details.

5.3 Sourcing and Pre-Acquisition Questionnaires (PAQ)

The Procurement Department will source all potential manufacturers/suppliers and request pre-purchase questionnaires. This will provide essential information such as the equipment compliance to standards, warranty, spares availability and maintenance options.

This process may involve the issuance of competitive Tenders in line with the Trust's Standing Orders and Standing Financial Instructions.

The department/ward requesting the medical equipment will be asked to submit an on line medical equipment purchase form (Appendix 2) . This will identify key information and indicate the named individual who will ensure relevant training issues are pursued (this could be the equipment controller, senior nurse or another identified officer). Approximate annual consumable costs are required to be identified and recurring funding agreed to be transferred (if appropriate) following warranty.

5.4 Business Cases

If the medical equipment costs in excess of £5,000 it will be necessary to prepare a Business case for consideration by the Medical Equipment Group (MEG) for new or replacement medical equipment. It may be useful when drawing up such a case to consider the following:

a) Clinical Requirements

Does the equipment augment existing clinical practices?
Does it introduce new procedures and techniques that are approved and safe?

b) Installation

Does the equipment require services not already available?
Are further safety measures required? e.g. laser regulations, COSHH

c) Staffing

Is additional staff required to operate or carry out this service?
Is additional staff training required?

d) Consumables

Does the equipment use additional consumables?
Are they special (i.e. bespoke) or are they readily available from alternative sources?

What is the annual consumable cost?

e) Maintenance

How do you intend to maintain the equipment?
What level of cover do you require, including response time in the event of a breakdown? And how is this to be funded?
Are spare parts readily available?

If you intend to have the equipment maintained "in house" have you spoken to the Head of Medical Technical Services to see if they are prepared to undertake the task?

Does the equipment require calibrating at regular intervals and is special equipment required for this function?

f) Service Manual

Is a full service manual available, complete with circuit diagrams and set up procedures, to allow Trust staff to repair and maintain the equipment in the event of the supplier going into liquidation?

Such service manuals will require being included in the purchase.
Provision must also be made for manufacturers technical updates to be sent to the Medical Technical Services Department, this to be included in the purchase specification.

g) Training

Operating and maintenance training courses need to be included in the purchase.

The Manufacturer/supplier must ensure that all operational updates and alterations to the user's manual are forwarded to the Head of Procurement for onward distribution.

All technical updates and alterations must be forwarded to the Head of Medical Technical Services.

h) Cleaning and Disinfection

Can the equipment be easily cleaned and disinfected in accordance with the Trust's policy – PAT/IC 24 - Cleaning and disinfection of ward based equipment and is there detailed cleaning and disinfection procedures provided in the operator's handbook?

Does the equipment require Sterilisation, if so have Sterile services been consulted? Sterilisation and decontamination of surgical instrumentation is carried out by an off-site facility so allow time to ensure any requirements can be met.

i) Software

In the case of products that are or include networkable software, a review of the product will need to be carried out by the Deputy Director - Information and Communications Technology and the head of Medical Technical Services to check whether the software application is or is not likely to constitute a medical device. Medical software that will be reviewed as to whether compliance is necessary includes Clinical Information systems, Decision Support Software, Information Systems, Communication Systems, Web Monitoring Systems and In-Vitro Diagnostic Systems. If compliance appears to be necessary the Trust will seek appropriate documentation from the manufacturer and in cases of doubt will rely on the opinion of the Medical and Healthcare Products Regulatory Agency (MHRA) as to the applicability of the regulation.

Consideration must also be given to any devices that may have the capability to hold patient identifiable information. Such devices will need to be reviewed before use to ensure such information is not able to be viewed, downloaded or edited by individuals not authorised to do so.

j) Cost

What is the estimated cost likely to be? Procurement should be engaged to review the market and obtain an approximate cost prior to business case submission. Consideration should be given to other options such as lease, hire, managed services, or consumable deals if applicable.

5.5 Business Case Submission for replacement equipment

After completion of the business case it will require submission to the Trusts Head of Medical Technical Services for inclusion in the agenda for the next scheduled Medical Equipment Group meeting. It would be helpful to include all evaluation forms, condemnation forms and any other supporting documentation to assist in the discussion. It may be suggested that the department sponsor be invited to present their submission in person.

5.6 Business Case Submission for new equipment

New medical equipment will require a business case to be submitted to the above group. Again any supporting documentation should be made available for the committee to have as much information as possible. Outline business case templates and supporting information can be found in Appendix 6.

6. USER RESPONSIBILITIES

6.1 Ward Managers/ Heads of Service

- The Ward Managers/ Heads of Service are responsible for ensuring that all staff members adhere to this policy.

- Line managers are responsible for ensuring all medical equipment is purchased and maintained in accordance with this policy working with Procurement and Medical Technical Services to complete the process. This includes completion of the appropriate business cases. They are also responsible for ensuring any significant risks associated with medical equipment are identified and captured in the local risk assurance framework escalating to the corporate trust risk register as and when appropriate.

6.2 All staff using / operating medical equipment will be responsible for:

- Ensuring they are suitably trained to use the equipment in accordance with the Medical Equipment Training Policy CORP/RISK 2.

- Ensuring that, where medical equipment is found to be faulty, it is taken out of use, cleaned in accordance with the Trust's Decontamination Policy and reported to Medical Technical Services promptly.

- Reporting adverse incidents involving medical equipment, these should be reported using the Trust's Incident Reporting System. Dependent on the circumstances, consideration should also be given to reporting the incident to the MHRA. Where doubt exists, advice should be sought from the Head of Medical Technical Services.

- Storing medical equipment safely and kept ready for use. Where equipment is powered by rechargeable batteries these must have suitable charging sockets and be charged in accordance with the manufacturer's instructions.

- Medical Devices that are labelled single use only or single patient use only must only be used in accordance with the manufacturer's instructions.

Single use devices must not be re-used.

Single patient use devices may be reused on the same patient but always confirm the instructions for use as there may be a limited number of times a device maybe re-used even on the same patient.

- Support from Medical Technical services is available weekdays from 8:30 to 16:30 (15:45 Friday). Extension 642135, Emergency on call cover is available weekends and bank holidays via the switchboard.

7. TRAINING/SUPPORT

All Medical Devices will require some form of assessment to determine the level of training required before the device can go into clinical use. Training of staff in the use of medical Devices is fully covered in the Trusts Guideline Strategy - Medical Equipment Training Policy – CORP/RISK 2.

8. HOME USE EQUIPMENT

There will be some occasions where Trust owned equipment will need to be issued out to a patients home for their continuing care or for on-going investigations, for instance 24hr ECG recorders, BIPAP ventilators etc. In order to address the specific issues that arise from issuing these, a separate procedure has been written that includes template forms to record the issuing out and return of equipment to patients in their own homes. Please see appendix 4.

This should not be confused with the loan of medical equipment to aid living at home such as walking aids and frames, commodes etc these are usually organised by the occupational therapists and supplied direct to the patient by an outside agency. At the time of writing, this is NRS.

9. MAINTENANCE AND SERVICING

The maintenance and servicing of medical devices is predominantly managed by Medical Technical Services (MTS). There are some exceptions, including Medical Imaging and Pathology equipment, these are managed directly by their division.

The scope and range of detail required to cover maintenance aspects of medical devices has required a separate procedure which can be found in Appendix 5.

MTS will also be responsible for all acceptance testing of Medical Equipment entering service in the Trust as below:

9.1 Medical Equipment Asset Register

All medical equipment will be entered onto the equipment management database by the MTS department showing:

Unique identifier for service organisation in the form of a barcode;
A full history, including date of purchase and where appropriate when it was put into use, deployed or installed;
Service schedule (if applicable, and to include calibration);
Maintenance schedule;
Supplier and manufacturer;
Serial number;
Purchase date;
Cost;
Warranty period;
The end-of-life date, if specified;
Any specific legal requirements.

Medical equipment must not be put into service unless recorded onto the Asset register by Medical Technical Services, this is to ensure accurate data in the case of equipment recall or safety updates. Likewise medical equipment must not be removed from service unless via Medical Technical Services to ensure database and contract management accuracy.

10. CONDEMNATION AND DISPOSAL

It is extremely important that reusable medical devices are condemned and removed from the Trust premises in a managed and controlled way. Please refer to the Trust's policy on the condemnation and disposal of Trust assets. Condemnation and Disposal of Trust Assets – CORP/PROC 6.

Single use medical devices must never be re-used and should be disposed in accordance with the manufacturer's recommendations and Trust waste management guidelines.

11. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Medical Device Purchasing procedures	Procurement, , Medical Technical Services	Bi-monthly	Medical Devices Management group Medical Equipment Group Corporate Investment Group
Medical Device on/loan procedures	Procurement, Medical Technical Services	Bi-monthly	Medical Devices Management group

Medical Device maintenance procedures	Medical technical Services	Quarterly	Medical Devices Management group Estates and Facilities Compliance meeting

12. DEFINITIONS

Some confusion arises over the definition of a Medical device. In this document the terms 'Devices' and 'Equipment' can be interchanged and it is intended to cover the following:-

All equipment used, for the treatment, diagnosing and the monitoring of patients. It also includes dental and chiropodal equipment, i.e. drills etc. Medical equipment also includes gas regulators; flow meters, wall suction units, gas operated equipment and general Medical and Surgical instrumentation. The policy also covers Pathology and Medical Imaging Equipment. The policy does not include general Estate items or I.T. equipment.

13. EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 7).

14. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

- Procedures for the Use of Medical Equipment Used "On-Trial/On-Loan".
- Cleaning and disinfection of ward based equipment – PAT/IC 24.
- Guideline Strategy - Medical Equipment Training for Trust Staff – CORP/RISK 2.
- Central Alerting System Policy – CORP/RISK 6.
- Representative Policy – CORP/PROC 2.
- Selection and Procurement of Medical and Surgical Products – CORP/PROC 3.
- Condemnation and Disposal of Trust Assets – CORP/PROC 6.
- Procedures for Maintenance and Repair of Medical Devices.

15. REFERENCES

The Medical Devices Regulations 2002. Statutory Instrument 2002 No.- 618
ISBN 0110423178. http://www.opsi.gov.uk/si/si2002/20020618.htm

Electricity at work Regulations 1989
http://www.hse.gov.uk/pUbns/priced/hsr25.pdf

The Waste Regulations 2011
http://www.legislation.gov.uk/uksi/2011/988/contents/made

The Simple Pressure Vessels (Safety) Regulations 2016
http://www.legislation.gov.uk/uksi/2016/1092/contents

Management of Health and Safety at Work Regulations 1999. Statutory Instrument 1987 No.1680 (c.51) ISBN 0 11 0776801.
http://www.opsi.gov.uk/si/si1999/19993242.htm

The Consumer Protection Act 1987 (Commencement No.1) Order 1987. Statutory Instrument 1987 No. 1680 (O.51). ISBN 0 11 0776801.
http://www.opsi.gov.uk/si/si1987/Uksi_19871680_en_1.htm

Lifting Operations and Lifting Equipment Regulations 1998 (LOLER). UK Statutory Instrument: S.I. 2307. (ISBN 0-11-551836-3). (b) 1981 c.29.
http://www.hse.gov.uk/work-equipment-machinery/loler.htm

Non Automatic Weighing Instrument regulations (NAWI). UK Statutory Instrument 2000 No. 3236. ISBN ISBN 0-11-018925-6
http://www.legislation.gov.uk/uksi/2000/3236

Provision and Use of Work Equipment Regulations 1998. UK Statutory Instruments 1998 No. 2306
http://www.legislation.gov.uk/uksi/1998/2306

MHRA Publications

Managing Medical Devices Guidance for Healthcare and social care organisations. April 2015
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf

Other Government Agencies and Healthcare Organisations

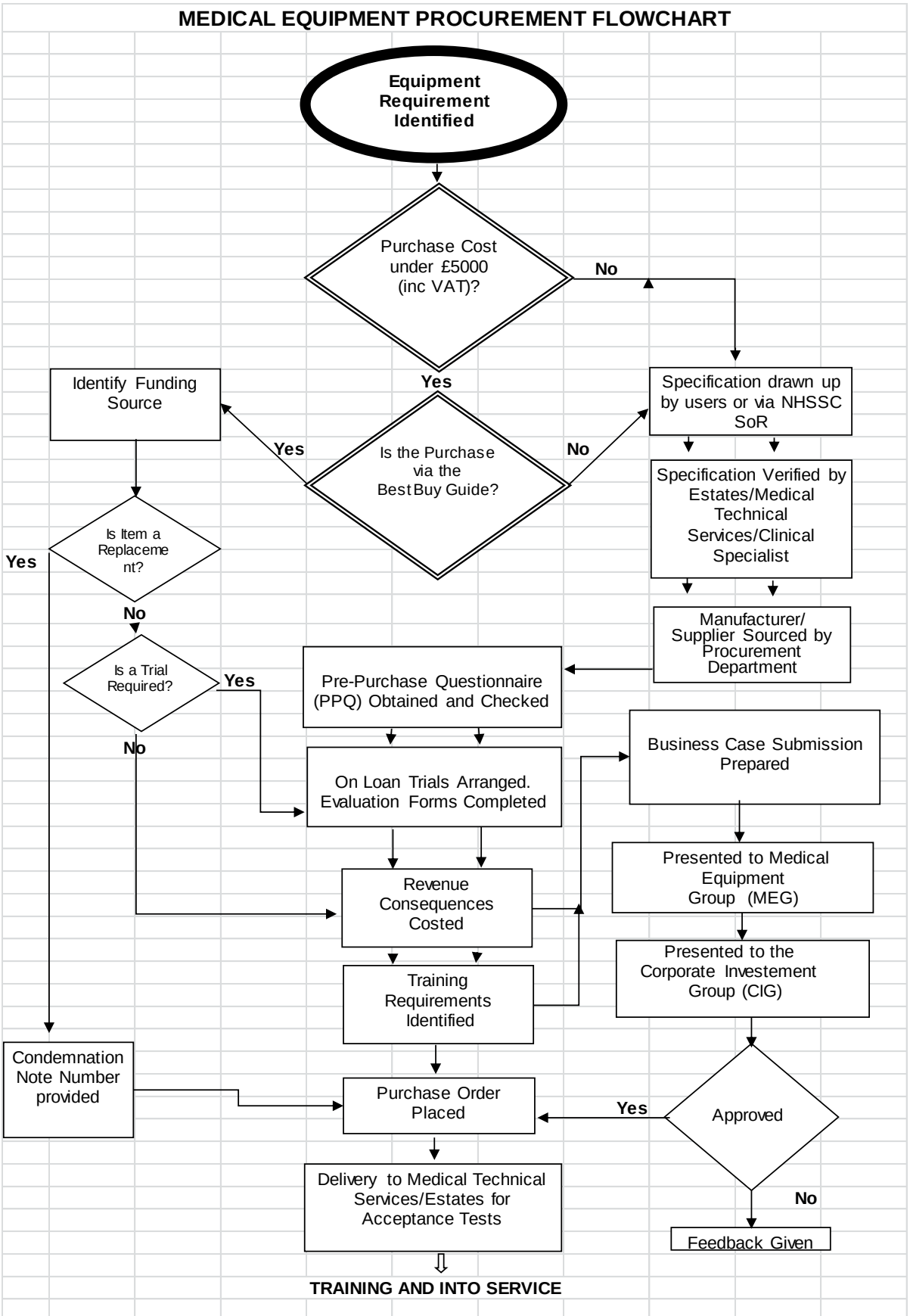
Health and Safety Executive
http://www.hse.gov.uk/

Healthcare Commission. Assessment for Improvement: annual health check. 2005
http://www.healthcarecommission.org.uk

Department of Health. Standards for Better Health, 2004
http://www.dh.gov.uk

NHS Purchasing and Supply Agency (PASA)
https://www.supplychain.nhs.uk/mysupplychain/

APPENDIX 1 – MEDICAL EQUIPMENT PROCUREMENT FLOWCHART



APPENDIX 2 – THE MEDICAL DEVICE PURCHASE FORM

The Medical Device purchase form can now be found on line

Go to the Electronic Forms Icon on your trust desktop or laptop, select Medical Technical Services and use the drop down menu to select the Medical Device Purchase form.

APPENDIX 3 – PROCEDURE FOR MEDICAL DEVICES ON LOAN/TRIAL

Procedures for Medical Devices On Loan/Trial

These procedures can be found on the Medical Technical Services Website under the Device Advice menu

http://DBHMTS/2

APPENDIX 4 – PROCEDURE FOR EQUIPMENT LOANED TO PATIENTS

Procedures for equipment loaned to patients.

These procedures can be found on the Medical Technical Services Website under the Device Advice menu

http://DBHMTS/2

APPENDIX 5 – PROCEDURE FOR MAINTENANCE AND SERVICING OF MEDICAL DEVICES

Procedures for Maintenance and Servicing of Medical Devices

These procedures can be found on the Medical Technical Services Website under the Device Advice menu

http://DBHMTS/2

APPENDIX 6 – BUSINESS CASE TEMPLATES

Business case template for submissions £10k to £50k

Business Case Templates updated O

Business case template for submissions £50k and above

Business Case Templates updated O

APPENDIX 7 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Medical Devices Management Policy	Finance and Infrastructure/ Supplies/Medical Technical Services	Andrew Leverton	Revised Existing Policy	14/08/2019

1) Who is responsible for this policy? Finance and Infrastructure

2) Describe the purpose of the service / function / policy / project/ strategy? Trust wide Management of Medical Devices

3) Are there any associated objectives? To meet standing Legislation in relation to LOLER, NAWI, AORR, Electrical safety at work. PVR

4) What factors contribute or detract from achieving intended outcomes? –

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? No

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4

Date for next review: **July 2021**

Checked by: **Andrew Leverton** **Date:** **19/08/2019**