Torbay and South Devon NHS
NHS Foundation Trust

Medical Devices Management Policy

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Document Information

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Author:	Lead for Medical Devices, Support Services and Non-ionising Radiation Advice Deputy Medical Director Executive Director		
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Approval Route Care and Clinical Policies Group Medical Devices Management Group Quality Improvement Group			
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Members of Medical Devices Management Group		June 2017	
Senior Business Management Group		June 2017	
Care and Clinical Policies Group		20 September 2017	
Links or overlaps with other strategies/policies:			
Incident Reporting Policy 0848			
Procuring a Medical Device			
Infection Control Policy			
Trust Medical Devices Management Procedure			
Trust Procurement Procedure			
Trust Protocol & Guideline; 1112 Decontamination Protocol			
Trust Protocol & Guideline; 0564 Medical Devices Training			
Trust Electrical Safety Policy,			
Trust Waste Management Policy,			

Amendment History

Issue	Status	Date	Reason for Change	Authorised
1	Final	29 November 2012	Adapted from TCT policy and extensive review to reflect the new organisation	Care and Clinical Policies Group
2		27 November 2014	Review and update	Care and Clinical Policies Group
2		24 May 2017	Withdrawn	
3		20 April 2018	Revised	Care and Clinical Senior Business Management Group Medical Devices Management Group

Contents

1 Introduction

1.1 Context

Torbay and South Devon NHS Foundation Trust has a statutory duty to ensure that all medical devices are used safely, and are safe to use. The policy applies to staff employed by Torbay and South Devon NHS Foundation Trust (hereafter called The Trust) who are required to provide assessment and care interventions to patients/service users and also for all staff required to use any type of medical device or therapeutic equipment as part of their work or in the provision of care to residents.

This document provides a comprehensive framework for the management of medical devices within The Trust, to include monitoring control and defines the importance of ensuring staff are prepared and trained to safely operate/use equipment. The Trust seeks to minimise risk when new medical devices are acquired by ensuring they are suitably procured, monitored and controlled.

1.2 Definition of the term "Medical Device"

The term "Medical Device" is defined in MHRA Bulletin 17 as "Medical Devices and Medicine Products" (amended April 2006) and can be summarised as:

> "Any instrument, apparatus, appliance, material or other article whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
>
> § Diagnosis, prevention, monitoring, treatment or alleviation of disease
> § Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
> § Investigate, replacement or modification of the anatomy or of a physiological process
> § Control of conception

1.3 Scope

This policy applies to all staff in The Trust (including seconded, honorary, voluntary, locum, bank and agency staff) as well as all commissioned care settings. An adequate knowledge of the relevant medical devices used and regular updating of basic skills is a requirement for all clinical staff within The Trust.

2 Statement / Objective

2.1 Aims of this policy

The purpose of this document is to outline a standardised approach to purchasing, deployment, maintenance, repair and disposal of medical devices within The Trust and the services commissioned by The Trust.

It is the aim of this Policy to:

§ Minimise the risk of new adverse incidents involving medical devices
§ Reduce the risk of harm to patients, staff, relatives, carers and visitors caused by incorrect or inappropriate use of medical devices.
§ Support patients and staff to make individual decisions around the risks of using medical devices without constraining clinical autonomy. Clinical judgement is to be exercised at all

times occasionally clinical need / emergency situations may over-ride this policy. Any deviation from this policy must be recorded and reported in line with The Trust Incident Reporting Policy and Trust Procedure relating to defective equipment (Appendix VI), and where appropriate in the client / patient records. This is important for legal accountability.

§ Ensure that all staff using medical devices are competent in their use, adequately trained, and capable of using the device in a safe and effective manner (Medical Devices (Equipment) Education And Training Policy Ref 0564)
§ Ensure that managers and individual members of staff are aware of their own responsibilities in relation to the use of medical devices
§ Increase staff awareness of the principles of effective equipment management. The equipment should be:-

- Suitable for intended purpose
- Maintained in a safe and reliable condition
- Used only by competent people

3 Roles & Responsibilities

3.1 Responsibilities

The Chief Executive Officer is ultimately accountable for the safe use and management of all medical devices across The Trust. Various Executive Leads have responsibility depending on the medical device service life cycle, clinical application and effects with delivery of services.

The Chief Operating Officer has delegated accountability and is responsible for the business continuity and service delivery of medical devices across The Trust. The Chief Operating Officer will have delegated accountability from the Chief Executive for this policy.

The Medical Director and Chief Nurse have delegated accountability and responsibility for the clinical applications and safe use of medical devices across The Trust.

The Director of Estates and Commercial Development has delegated accountability and responsibility for the health and safety of staff in connection with medical devices across The Trust.

The Trust Board have corporate responsibility for Medical Device Management. This responsibility has been delegated to Clinical Managers, Heads of Departments and Ward/Unit/Line/Service Managers who are responsible for all aspects of medical device management in their directorates, departments and services within The Trust.

In addition to The Trust Board responsibility, the Medical Devices Management Group has responsibility to develop and regularly review the device management procedure, to ensure that whenever a medical device is used, it is:

§ Suitable
§ Used in accordance with manufacturer's instructions and Trust policies
§ All authorised users of medical devices are trained and competent
§ Maintained in a safe and reliable condition
§ Disposed of appropriately at the end of its useful life

3.2 Arrangements with Contracted/Commissioned Services

All providers of commissioned services should have an equivalent policy or set of guidelines, or agree to work to our policy. This clause should be contained within all contractual agreements. The arrangements are managed through contracted and commissioned services or via Service Level Agreements.

3.3 All Heads of Departments / Managers of users of medical devices are responsible for:-

Training, training and competency records and manuals:

- Ensuring that training is available for all users of devices where training is necessary. All equipment users are properly trained and maintain their competencies. (Medical Devices (Equipment) Education And Training Policy Ref 0564)
- Records will show that users know how to use the device safely, carry out routine checks and maintenance. The dates of the training and relevant refresher training or updates as relevant
- Records of staff training and training updates are kept by ward/line managers with copies forwarded to The Training Department. Good record keeping is essential for the safe management of medical devices. It should include any specific guidance provided in the manufacturer's instructions and supporting information
- Equipment manuals and manufacturing instructions as well as related procedures and protocols are available in each clinical area for medical devices in regular use

An asset register managed through the Medical Devices Support Services, Medical Electronics (hereafter called M.E.) or an approved contracted service provider. The asset register provides evidence of a unique identifier for the device, date of purchase, full history including when brought into use, deployed or installed. Full maintenance schedule, details of repairs and end of life date will also be included.

Ensuring that all medical devices in their areas;-

- Are in safe and good working order.
- Has a label on it detailing retest date or last tested date.
- Is maintained, serviced and calibrated in line with advice from ME and/or the manufacturer/legislation.
- Decontaminated with the required decontamination certificate
- Disposed of according to Trust Policies and National Legislation

3.4 Department control

When a medical device/equipment is allocated to a department, it is essential that all individuals are aware of the medical devices policy and their responsibilities to ensure that medical devices are managed correctly. A named person in each department should be given responsibility for updating the "Asset Register" managed by ME as described in the policy. This person will send the inventory to the ME department annually to keep a Trust wide asset register of Medical Devices. An example of documentation used to record this can be found as Appendix II.

- Risks and fault reporting for ward/area based medical devices
- Each ward / team should have a named person for ensuring that equipment remains in good working order. This will be achieved through regular maintenance and prompt reporting of faults.
- Users must report equipment faults to the relevant team (Appendix I) and complete an incident report if appropriate as per The Trust Incident Reporting Policy. (Ref 0848)

- Any equipment sent must be decontaminated in accordance with The Trust decontamination policy prior to being sent for repair, servicing, calibration, maintenance or disposal by M.E.

3.5 All users of Medical Devices are responsible for complying with this policy.
The following principles apply;-

- Equipment is only used by authorised users who have been appropriately trained, and can demonstrate competence have been trained on its correct use and application.
- Training needs related to use of equipment are discussed with line managers /supervisors and copies of completed training and competence are held by their manager; (Medical Devices (Equipment) Education And Training Policy Ref 0564)
- Individual staff members including agency or locum staff, are responsible for maintaining their competence and keeping their own records up to date
- The equipment is inspected for signs of damage or wear prior to each use and not used if any wear or damage is detected. This defect should be immediately reported to the Ward/Unit/Line/Service Manager or equipment owner.
- Any accessories and or disposables required are recommended by the manufacturer and the procurement department
- User manual / instructions are easily accessible to users of the device
- The equipment has been maintained within the specified period as advised/recommended per the manufacturer's instructions or Medical Devices Support Services.
- If the service/test label shows that the equipment is out of service date, it should be not used and must be reported immediately to the Ward/Unit/Line/Service Manager, service lead, or to the service provider directly if the equipment is in the community or equipment owner.
- The device should be placed in storage and not used until service has been performed.
- Any relevant risk assessments are completed prior to using the device e.g. hoists, on the appropriate Trust risk assessment forms.

3.6 The Medical Devices Management Group is responsible for:

- Developing, implementing and monitoring compliance with this policy to ensure best practice
- The monitoring of training needs analysis and registers at Directorate / Department level
- The monitoring of the audit plan and using this to form the basis of their annual board report

4 Medical Device procurement, Repair, Maintenance, and Disposal

4.1 Purchase, replacement or loan of Medical Devices

When new or replacement medical devices are required or you wish to loan medical devices advice should be obtained from the relevant technical support team/department (Appendix I). See Appendix IV for guidance on the process for procuring medical devices and Appendix III for guidance with the Pre-Acquisition Questionnaire (PAQ).

4.2 The selection of devices for use in clinical areas should only be made after consultation with the relevant technical/professional support department and the Infection Prevention & Control Team. The relevant technical/ professional support departments are in a position to provide advice regarding relevant standards because of their formal communication links with manufacturers and MHRA technical advisory services. The Infection Prevention & Control team need to be consulted about the decontamination of equipment.

4.3 Failure to consult may result in higher maintenance costs or the purchase of unsuitable equipment and placing unnecessary risks on The Trust.

4.4 Repair and maintenance

The Trust will ensure that all medical devices are in good working order and safe for their intended use. It will be the delegated responsibility of Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Managers, Heads of Department, Service Leads etc. to ensure appropriate maintenance and support have been arranged and are being provided for all medical devices within their area of responsibility. Records will need to be kept as evidence of these activities e.g. Trusts Medical Devices Database System, Ward environment log book, service reports from external service providers, Medical Electronic Equipment history sheets etc. If these records are not kept on the ward or within the department a suitable location reference must be made of their point of storage.

A decontamination certificate must be completed and sent to medical electronics along with the piece of equipment to show that the equipment has been cleaned prior to being sent to M.E.

Community based equipment and individually held equipment (e.g. Community Nurse Toolboxes and equipment held by teams) are subject to annual rotation to support decontamination, calibration and maintenance. (The Trust Infection Control Policy and Decontamination Policy to be followed at all times)

Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Managers, Heads of Department, Service Leads etc. are responsible for ensuring that equipment is returned to ME/'The current supplier' promptly when they are requested by ME or 'The current supplier'. This can be for routine maintenance or if there is a MHRA/MDA/NHS England alert on the medical device or equipment.

4.5 Defective Equipment Involved in a patient or staff incident and Medical Device Agency Warning Notices

Medical devices found, or suspected, to be defective should be taken out of circulation and quarantined. The process should be followed as per Appendix VI and an incident report completed

Medical Devices involved in a clinical incident should be taken out of circulation and quarantined. Any consumables must be where practically possible and safe to do so retain for inspection. The process should be followed as per Appendix VI. All communication relating to the incidents must detail the computer generated incident reference.

The mechanism adopted by The Trust for dissemination of Medical Device Agency (MDA) Warning Notices will be via Central Alert System (CAS) alerts and will ensure that all expert technical departments receive this vital information and action is taken as necessary. Records of all alerts reviewed and actioned will be held centrally by The Trust Patient Safety Lead. The information within the safety alert will be further disseminated as required to user departments and / or individuals, where it is deemed appropriate. The Trusts Medical Devices Safety Officer will provide guidance to user, departments and/ or individuals

4.6 Disposal of Medical Devices / Equipment within a ward/department

It is the responsibility of the medical device / equipment user to ensure equipment that is surplus to requirement, no longer required or damaged beyond economic repair is correctly disposed of using the approved procedure:

- For small medical devices / equipment (less than £5,000 including VAT); send to the ME or appropriate technical support department (Appendix I) with a covering memorandum from the Ward/Unit/Line/Service Manager, service lead, or Head of Department requesting disposal. N.B. do not forget to follow the approved Decontamination procedure for medical devices
- For large items / equipment (£5,000 including VAT or more); send a memorandum from the Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads etc. to ME or appropriate technical support department requesting disposal providing as much information about the item of equipment as possible
- The technical support department will respond by completing a *Condemning certificate CA2* as far as possible with the information provided and send this to the Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads etc. to sign, authorising disposal of the medical device / equipment
- Ensure the items of medical devices / equipment are not part of a leasing agreement and therefore are not the property of The Trust. These items are normally returned to the lease company at the end of the lease period
- When the medical device has been fully decommissioned and withdrawn from service the technical support department will advise the Finance department in order that the equipment is taken off the Asset Register (Appendix II), where the item is identified as a capital purchase.

4.7 Disposal of Equipment issued for home/community use.

It is the responsibility of the medical device / equipment Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads and user to ensure equipment that is surplus to requirement, no longer required or damaged beyond economic repair is correctly disposed of using the approved procedure. If the medical device has a ME number, follow guidance in 4.6 (Medical devices with ME numbers are most likely owned by The Trust), all other medical devices and equipment without a ME number:

- If equipment is broken or no longer required the current supplier/provider should be
- For equipment /small medical devices (less than £100) belonging to The Trust and specified in the online catalogue. The current supplier can dispose of these items when they are beyond economic repair in accordance with National Legislation and directives.
- For equipment/medical devices (over £100) in the online catalogue and belonging to The Trust, the current supplier will decontaminate and list the item, the items code together with their relevant faults.
- A competent person must approve the disposal of the item/s prior to them being disposed of according to National legislation and guidelines
- The current supplier removes the item from the asset register and retains any disposal paperwork on file

5 Training

Clear guidance is provided in Medical Devices (Equipment) Education and Training Policy 0564.

The Trust has a statutory duty, and responsibility to ensure that health and care professionals have access to appropriate medical devices training. The Trust will support an individual who identifies that they are not competent to use a piece of equipment until trained to an appropriate level. It is essential that records of staff training are held at both wards / department/zone/locality as well as providing the Training Department with this information.

The Trust recognises the risks to patients, staff and others created by the misuse of medical devices. It therefore intends to ensure that there is a suitable system in place to promote the safe, competent and effective use of medical devices in order to safeguard patients/service users and staff'.

Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, and Service Leads etc. play a pivotal role on ensuring patient safety. They are accountable for ensuring that all staff in their respective clinical and non-clinical areas do not use any medical devices unsupervised unless they have been assessed by a suitable qualified person as competent and are competent in their use and application.

5.4 Staff Groups

The Trust aims to ensure that all users of medical devices are trained and competent in their clinical use and application. Medical Devices (Equipment) Education and Training 0564 policy applies to all staff who use medical devices including registered nurses, midwives, operating department practitioners, allied healthcare professionals, all medical grades, health care assistants and all support staff.

The Trust expects all clinical and non-clinical staff including temporary staff working in The Trust or those working in The Trust from other organisations as well as workers in commissioned care settings where service users are receiving care to adhere to the following principles. Before using any medical devices equipment, practitioners must:

- Not use equipment unless trained and competent to do so.
- Undertake supervised practice with Ward/Unit/Line/Service Manager, service lead,/supervisor until deemed competent to use the device independently
- Always visually inspect the equipment for signs of damage prior to use and carry out safety and functional checks where appropriate
- Know where the medical device user manual / instructions are located
- Seek help where appropriate
- Identify their training needs/requirements with line manager/supervisor
- Provide evidence of training records and competence to the ward/department/section manager to inform their medical devices training needs analyses table at their 12 month performance & development review (PDR).

5.5 Instructions

Good clear instructions have a crucial role in the safe and effective use of equipment. The Medical Devices Regulations stipulate that the manufacturer is responsible for supplying appropriate instructions, taking into account the knowledge and training of the intended user(s)

Any shortcomings in the instructions should be reported to the Medical Devices Safety Officer/ME and the provider of the equipment as an adverse incident (Appendix VI).

Clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users or accessible and, where appropriate, carers. The manufacturer's instructions may need to be supplemented with training.

There should be specific departmental responsibility for keeping track of updates in manufacturer's information, replacing existing instructions with revised versions and updating the content of relevant training.

5.6 Instructions for the end user

All necessary information on storage, pre-use checks, use, maintenance and cleaning should be passed on or made available (trusts or supplier/manufactures website) to the end user following acceptance checks (MHRA Management of Medical Devices April 2015) by ME or an appropriate technical support department, including when the device is issued to a second or subsequent user.

- A failure to pass on to the end user the manufacturer's original or a direct copy may compromise the end user's ability to use the device safely, and may lay the provider/supplier open to legal liability as follows:
- The Consumer Protection Act (in the case of a medical device).
- The Consumer Protection Distance Selling Regulations
- The General Product Safety Regulations (in the case of a consumer product not covered by other specified legislation).
- The common law of negligence

It is important to ensure that the disabilities, medical conditions or cognitive impairment of those using the medical device user manual/instructions/user guides are taken into account and that additional training, adaptions and instructions are made available.

6. Guidelines on Staff Education and Training Procedure

The emphasis on improving the quality of health services is embodied in the requirement for clinical governance arrangements. Making a Difference (DOH, 1999) reinforces the personal accountability of practitioners within a framework for self-regulation, built on maintaining and improving professional knowledge and competence throughout their careers. The Trusts has a legal obligation under Provision and Use of Work Equipment Regulations 1998 (PUWER) to insure equipment training is made available and users competency in the use of medical devices or equipment is managed.

The Medical Devices (Equipment) Education and Training Policy 0564 provides clear guidance for Education and Training to use Medical Devices.

Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, and Service Leads etc. must identify medical device training and assessment needs at appointment, local induction and as part of the annual appraisal. They must ensure that no member of staff should use a medical device unless they are competent to do so, if they are not competent, then they must be supervised in using the device. It is the responsibility of the line manager to ensure that adequate medical device training is given to all staff as required and that

records of this training are held within the department with copies of this information sent to The Trust Training department. Frequency of attendance at specific training must be discussed individually at the annual appraisal or sooner if a problem is identified.

Training should be provided by a suitably qualified person competent in the function and operations of the medical device.

In the event of appropriate training not being available from any source, an incident report should be completed using The Trust incident reporting system. Until competence of the user can be achieved the medical device should not be used.

When a new medical device is introduced into an area, staff should receive training to ensure their competence before using the equipment unsupervised. The local training needs analysis table must be updated to reflect medical devices or equipment changes.

The frequency of the updates on the medical devices should be done in accordance with Trust policies (Medical Devices (Equipment) Education and Training Policy 0564) and standard operating procedures and any MHRA guidance (Management of Medical Devices April 2015).

6.1 New Staff

Medical devices training must be part of the ward/department induction programme and should be achieved as soon as possible and within six months as an absolute maximum period. This will enable staff to be introduced to equipment that they will be using regularly in their practice area and mitigate the risk of misuse of equipment. The Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, and Service Leads etc. must ensure that a training record is recorded and filed in the ward's training folder.

Staff new to The Trust who has evidence of competence/qualification in the use of a medical device/s must be assessed as competent prior to using infusion devices unsupervised. This assessment must be carried out by an assessor who is a recognised assessor of the skill before undertaking the procedure unsupervised. The Trusts medical devices training and education lead will provide guidance on this matter.

Staff who have not been assessed as competent in the use of a medical device must undertake supervised practice until assessed as competent to practice by an assessor who is recognised as an assessor of the skill.

The Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads etc. need to hold records to demonstrate training attended by staff and this is regularly reviewed as part of The Trusts performance development review policy (H6).

6.2 Bank Staff

Medical devices training is part of the Bank Induction Programme, this training will be given by a competent Trust trainer. This will enable staff to be introduced to equipment that they will be using in their practice areas and mitigate the risk of misuse of equipment. Training must be given according to the learner's needs identified from the ward/department training needs analysis.

6.3 Current Staff

In line with The Trust's Risk Management and Health and Safety Policies, it is the Matrons, Ward/Unit/Line/Service Manager, service leads, Service Manager, Heads of Department, Service Leads etc'. responsibility to ensure that staff, for whom they are responsible, receive appropriate

instruction and training in the safe use of all medical devices used in their clinical area. This is to provide assurance that all staff have been suitably trained in the safe use of medical devices (PUWER).

Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads etc. should, as part of individual staff development at appraisals, or at their induction, identify, prioritise, and meet any medical devices learning/ training needs. It is the responsibility of the ward/department manager to ensure that adequate medical device training is given to all staff and records must be maintained.

Frequency of attendance at specific medical devices training must be discussed individually at the staff members annual PDR/appraisal or sooner if a problem is identified and documented. Records must be kept within the individuals personnel file.

Should a member of staff be unable to demonstrate competence, their line manager must arrange re-training before the individual can operate the medical device in a clinical environment independently.

7 Monitoring, Auditing, Reviewing & Evaluation

7.1 Record Keeping

It is the responsibility of the Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads etc.to maintain Medical Devices training records, this record will contain the following information:

a) A register of all medical device equipment used within their own respective clinical and non-clinical areas
b) Identified levels of training required for each piece of equipment for each grade of staff in order that they are able to use the device safely
c) List all ward/department based trainers and assessors and their area of expertise
d) Identified names of Medical Devices Link Persons
e) Records of all staff training, including evidence of competency assessments and outcomes for all staff using medical devices to be held in staff personal files.
f) Evidence of **reassessment of competency** when

- Staff have not used a piece of equipment for six months or more
- Indicated by clinical practice
- An incident has been reported
- A predetermined assessment time scale has been agreed between the assessments and the management team

7.2 Monitoring

The Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads etc. must maintain records of staff training and dates for re-training relating to all medical devices used within that area. These records must be reviewed annually to ensure they are up to date for audit / inspection purposes. The Care Quality Commission (CQC) has the responsibility for monitoring Care Homes and Care Providers and also responsibility for monitoring and inspecting NHS Services.

The training record will include the following elements:

- Equipment type
- Equipment manufacturer
- Equipment model
- Hospital/ community site
- User department
- User level
- Risk level of device
- Training provided
- Competency attained
- How the equipment is to be decontaminated

Matrons, Ward/Unit/Line/Service Manager, service lead's, Service Manager, Heads of Department, Service Leads etc. (or nominated deputies) must ask to see a portfolio of evidence of training and assessment at appointment, local induction and as part of annual appraisals (Performance development review policy H6).

7.3 Audit/Reviews, Monitoring Compliance with the policy

On-going monitoring and compliance of this policy will be the responsibility of Matrons, Ward/Unit/Line/Service Manager, service leads, Service Manager, Heads of Department, Service Leads and Professional groups. They will be responsible for ensuring there is a local system for auditing and reviewing compliance and the effectiveness of this policy.

The monitoring mainly occurs through the day to day management of function, the work of the Medical Devices Management Group and CQC reporting (for the Care Homes etc.). Use is made of existing audit and recording tools e.g. Infection Control audits, Learning and Development records held by Workforce Planning, maintenance and training schedules held by the Medical Devices management service providers.

An annual report is provided by The Medical Devices Management Group to The Quality Improvement Group, providing information on progress, performance and key actions for the following year.

7.4 Contracted Providers

Contracted Providers will be monitored against their Regulatory requirements and guidance as well as any other specified requirements set out in their contracts.

8 References

Statutory

The Medical Devices Regulations 2002. Statutory Instrument 2002.

The Electricity at Work Regulations. Statutory Instrument 1989

The Waste Electrical and Electronic Equipment Regulations 2013

Pressure Systems Safety Regulations 2000.

Health and Safety at Work etc. Act 1974.

The Management of Health and Safety at Work Regulations 1999 Statutory Instrument 1999

The Consumer Protection Act 1987

The Consumer Protection Distance Selling Regulations 2000

The Consumer Protection Act 1987 (Product Liability) (Modification) Order 2000

The General Product Safety Regulations 2005

Employers' Liability (Compulsory Insurance) Act 1969.

Employer's Liability (Defective Equipment) Act 1969

Lifting Operations and Lifting Equipment Regulations 1998

Health and Social Care Act 2012

Health and Social Care (Safety and Quality) Act 2015

The Active Implantable Medical Devices Regulations 1992

MHRA Publications www.mhra.gov.uk

MHRA Managing Medical Devices April 2015

MHRA Medical Devices in Practice Checklists for using medical devices June 2014

MHRA Infusion systems

MHRA Bed rails: management and safe use

MHRA Blood pressure measurement devices

MHRA Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices

MHRA Assistive technology: definition and safe use

MHRA Blood glucose meters: point-of-care testing

MHRA Electromagnetic interference: sources

MHRA In vitro diagnostic point-of-care test devices

MHRA Magnetic resonance imaging equipment in clinical use: safety guidelines

MHRA Single-use medical devices: implications and consequences of re-use

MHRA MDA/2010/001 Medical devices in general and non-medical products. (General) Users should avoid (if possible), off-label use of medical devices, the modification of medical devices and the use of non CE-marked medical devices in clinical settings.

MHRA MDA SN 2002 (17) Management of loaned medical devices, equipment or accessories from manufacturers or other hospitals.

MHRA MDA SN 2000 (18) handling of surgical instrument on loan form another organisation.

MHRA. Medical Devices Alert MDA/2007/001 'Reporting adverse incidents and disseminating Medical Device Alerts'. 2007

MHRA Medical Device Liaison Officer Information page ht

Devices in Practice: A Guide for Health and Social Care Professionals 2001.

DB 2006 (01) Reporting Adverse Incidents and Disseminating Medical Device Alerts. 2006.

Leaving Hospital with a Medical Device.

Medical Devices Agency (2001) *Reporting Adverse Incidents and Disseminating Safety Warnings* MDA SN 2001 (01)

Medical Devices Agency (1998) *Medical Devices and Equipment Management for Hospitals and Community based Organisations* MDA DB9801 1998

Other Government Agencies

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)
http://www.pasa.nhs.uk/

NHSLA "Risk Management Standards for Acute Trusts", NHS Litigation Agency (April 2007)
http://www.nhsla.com

British and European Standards

IEC 60601 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. BSI 2005.
http://www.bsonline.bsi-global.com/server/index.jsp

BS EN ISO 13485 Medical Devices. Quality management systems – Requirements for regulatory purposes. BSI 2003.
http://www.bsonline.bsi-global.com/server/index.jsp

BS EN ISO 9001 Quality management systems. Requirements.
http://www.bsonline.bsi-global.com/server/index.jsp

9 Appendices

Appendix 1a – Community Based (non-hospital) Technical Support Department

Type of Medical Devices
Located – The current supplier Paignton
Telephone 0300 100 0047
Fax
Normal working hours 8.30- 17.00
Outside normal working hours 8.30-21.00 365days per year
Type of Medical Devices : Various

Appendix 1b – The Technical Support Department Contact details

Medical Devices Support Services	
Located	Torbay Hospital, DGH site
Telephone	01803-654751
Email	sdhct.medelec@nhs.net
Normal working hours	Monday – Friday, 8am to 5pm
Outside normal working hours	For emergency assistance call Torbay Hospital switchboard
Type of Medical Devices	Various

Medical Physics department	
Located	Torbay Hospital, DGH site
Telephone	01803-655390
Normal working hours	Monday – Thursday 9:00am – 5:00pm, Friday 9.00am - 4.30pm
Email	
Type of Medical Devices	Ultrasound units and X-ray equipment

Estates Services department	
Located	Torbay Hospital, DGH site
Telephone	01803-654426
Normal working hours	Monday – Friday. 8:30 – 5:00pm.
Outside normal working hours	For emergency assistance regarding relevant equipment in ANY hospital, call the switchboard and ask for the "duty officer".
Help desk	http://sdhbacktraq/TorbayPublish/TorbayBase/btfmWarning.aspx

Procurement Department	
Located	Regents House
Telephone TSDFT - Acute Service	(ext. 53365) 01803 653365
Telephone TSDFT - Community & Social Care Service	(ext. 58488) 01803 210488
E-mail	procurement.tsdft@nhs.net procurement.tct@nhs.net
Normal working hours	Monday – Friday 8am – 5pm
Type of Medical Devices	Consumables
Computer Services Helpdesk	
Telephone	# 6282

Appendix 2 – Local Asset register example

Unique identifier (ME Number)	Description	Item Location	Date of Purchase	Date of last service	Date of start of use	Date of start of installation	Date of start of deployment	Item Acquired	Recommended Service interval	Date of next scheduled maintenance	End of life date	Additional Comments

Appendix 3– PAQ Pre-Acquisition Questionnaire (PAQ Form 2016)

PAQ 2016

PRE-ACQUISITION QUESTIONNAIRE (PAQ Form)

The purpose of this questionnaire is to support the pre-acquisition assessment and approval of proposals to procure Medical Devices and accessories under purchase, exchange, rental, lease, loan, donation or other agreements. Please ensure that all relevant sections have been completed; (questions for which the only available response is 'YES' indicate that this response is a requirement, if the question applies) - and that all supplementary information requested has been provided; (shaded boxes ☐ indicate that supplementary information is required).

Note: The term 'Device', as used here, includes equipment and systems; in the case of systems the requirements below apply both to the individual constituent Devices and to the configured system as a whole. (Accessories within the scope of the return need to be identified under 1(d).)

PART I

to be completed by the device Manufacturer or Authorised Representative

PRODUCT DETAILS:

UDI Device Identifier:		
Device Description: (GMDN Code / Group if available)		
Type:	Make:	
	Model:	
Manufacturer:		
Supplier:		
EU Authorised Representative:		

1 a) When was this Model first placed upon the market ?

b) Is this Model still in production ? NO ☐ YES ☐ If NO, when did production cease ?

c) Any outstanding Field Safety Corrective Actions / Field Safety Notices ? NO ☐ YES ☐ All Issued Notices / Alerts attached to this return ? YES ☐

d) Does this return cover a range of Model variants ? NO ☐ YES ☐ If YES, list of Models attached to this return ? YES ☐

e) Does this return cover Accessories ? NO ☐ YES ☐ If YES, list of Accessories attached to this return ? YES ☐

f) Has a Device brochure and specification been attached to this return ? YES ☐

REGULATORY COMPLIANCE:

2 a) Does the Device meet the Essential Requirements of all currently applicable EC Directives ? NO ☐ YES ☐

b) Which EC Directive/s apply ?

Medical Devices Directive ☐ Classification? ↳ (I, I+m, Is / IIa / IIb / III

Active Implantable Devices Directive ☐

In-Vitro Diagnostics Medical Device Directive ☐ Category? ↳ (general / self-test / List-A / List-B)

Other/s ☐

- which Directive/s?

3 a) Is the Device CE-Marked, for its intended use, to all currently applicable EC Directives ? NO ☐ YES ☐

b) - If YES, have the EC Declaration/s of Conformity been attached to this return ? YES ☐

4 If not CE-marked, (or if 'off-label' use is proposed for a CE-marked Device), then -

a) Is this a Medical Device for 'Clinical Investigation' ? NO ☐ YES ☐

- If YES, quote the MHRA 'no objection' reference

- If YES, has a copy of the MHRA's notice of 'no objection' been attached to this return ? YES ☐

b) Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation' ? NO ☐ YES ☐

- If YES, has a copy of notification to MHRA been attached ? YES ☐

c) Is this a 'custom-made' Medical Device ? NO ☐ YES ☐

- If YES, name the prescribing Medical Practitioner:

d) - If NO to 3(a), and to 4(a) (b) and (c), then provide justification of the Device's status -

5 a) Which EC conformity assessment route/s have been adopted?

☐ full QA ☐ type examination ☐ product verification ☐ production QA

☐ product QA ☐ unit verification ☐ internal control (self declaration)

b) Has this included Notified Body conformity assessment ? NO ☐ YES ☐

- Notified Body identification number & name:

c) Is the manufacturer currently certified to any management system Standards ? NO ☐ YES ☐

- which Standard/s ? ↳ (eg: BSI/ISO-9001, BS/EN 13485, etc)

- Certification Body:

Page 1 of 4

PRODUCT COMMITMENT:

6 a) To what date is product support for this Model guaranteed ?

b) Does this include training; servicing, repair & availability of parts; supply of consumables / accessories ? YES ☐

c) What is the Device warranty period? Have warranty details been attached to this return ? YES ☐

d) Does the manufacturer / supplier have a robust system for notification of Device alerts / upgrades to a named hospital representative ? YES ☐

e) What is the recommended working lifetime for this Device? ← (not applicable for disposable Devices)

f) Have details for end-of-life waste management of the Device been attached to this return ? YES ☐

PRODUCT SUPPORT:

7 a) Can an additional User Manual be provided (electronic format) ? YES ☐

b) Can a Technical Manual be provided (electronic format) ? (Any cost for doing so should be included in the response to 9(a)) NO ☐ YES ☐

c) Is identical equipment normally available as free-of-charge loan in the event of equipment failure ? NO ☐ YES ☐

Commissioning & Deployment

8 a) Has a protocol for post-delivery acceptance testing of Device function and safety been attached to this return ? YES ☐

b) Does the Device have particular installation requirements and / or require ancillary services or other prerequisite arrangements ? NO ☐ YES ☐

- If YES, then have details of all installation requirements been attached to this return ? YES ☐

Technical Support

9 a) Does the manufacturer or an authorised servicing agent provide a maintenance / repair service ? NO ☐ YES ☐

- If YES, then have details of all service contract options been detailed, fully costed and attached to this return ? YES ☐
- where is the servicing facility located ?
- are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform ? YES ☐
- are qualification / competency records of servicing staff available upon request ? YES ☐

b) Is the servicing organisation currently certified to any management system Standards ? NO ☐ YES ☐

- which Standard/s ? ← (eg: EN/ISO-9001, 13485, 17025, etc)
- Certification Body:

c) Do the contract alternatives offered in 9(a) include an option for in-house equipment servicing by hospital staff ? NO ☐ YES ☐

- If YES, have details of the availability of spare / replacement parts to support equipment servicing been attached to this return ? YES ☐
- If YES, have details of information / test equipment / tooling / software required for equipment servicing been attached to this return ? YES ☐

Decontamination

10 a) What level of Device decontamination / reprocessing is required ?

☐ single-use ☐ cleaning ☐ disinfection ☐ sterilisation

b) If not single-use, have validated decontamination protocol/s been attached to this return ? YES ☐

c) For sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ? YES ☐

d) Have all requirements for special reprocessing equipment, tools and materials been detailed in the attached information ? YES ☐

e) Have any special post-processing Device storage requirements been detailed in the attached information ? YES ☐

f) Is there a limit to the number of Device reprocessing cycles ? NO ☐ YES ☐ If YES, what is the limit ?

g) Are Devices uniquely identifiable ? NO ☐ YES ☐

h) Is this an implantable Device ? NO ☐ YES ☐

Data Security

11 a) Does the Device store or transmit patient information that will require information governance measures ? NO ☐ YES ☐

- If YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this return ? YES ☐

b) Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems ? NO ☐ YES ☐

- If YES, then have details of Device IT software / hardware compatibility requirements been attached to this return ? YES ☐
- If YES, then have details of provisions made for Device IT cybersecurity been attached to this return ? YES ☐

Particular Requirements

12 a) Does the Device present particular hazards that require special safety management measures ? NO ☐ YES ☐

(eg: Ionising / non-Ionising radiation; contamination / infection; hazardous materials; hazardous mechanical / electrical energy; etc.)

- Identified hazards:
- If YES, then have details of the nature of identified hazards been attached to this return ? YES ☐

b) Does the Device require particular performance quality assurance measures? (eg: calibration, qualification, PoCT controls, etc.) NO ☐ YES ☐

- QA measures:
- If YES, then have details of quality assurance requirements been attached to this return ? YES ☐

IMPLEMENTATION SUPPORT:

13 a)	Is competency-based user training available from the manufacturer or an authorised provider ?	NO ☐	YES ☐
	- If YES, have details of user training offered (amount / content / assessment / duration / location / cost / etc.) been attached ?		YES ☐
b)	Is competency-based technical (equipment servicing) training available from the manufacturer or an authorised provider ?	NO ☐	YES ☐
	- If YES, have details of technical training offered (amount / content / assessment / duration / location / cost / etc.) been attached ?		YES ☐
c)	Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider ?	NO ☐	YES ☐
	- If YES, have details of decontamination training offered (amount / content / assessment / duration / location / cost / etc.) been attached ?		YES ☐
d)	Are qualification / competency records of training providers available upon request ?		YES ☐
e)	If other additional support facilities are available, (eg: helpdesk, literature, website resources, etc.), have details of these been attached ?		YES ☐

DECLARATION:

Please ensure that all necessary supplementary information, (as indicated by shaded boxes ☐ in the Form above) accompanies this return.

1.c)	All Issued Field Safety Notices / Alerts	ATTACHED ☐	NOT APPLICABLE ☐
1.d)	List of all Model variants covered by this return	ATTACHED ☐	NOT APPLICABLE ☐
1.e)	List of all Accessories covered by this return	ATTACHED ☐	NOT APPLICABLE ☐
1.f)	Device brochure / specification	ATTACHED ☐	
3.b)	EC Declaration/s of Conformity	ATTACHED ☐	
4.a)	MHRA's notice of 'no objection' for Medical Device 'Clinical Investigation'	ATTACHED ☐	NOT APPLICABLE ☐
4.b)	Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performance Evaluation'	ATTACHED ☐	NOT APPLICABLE ☐
6.c)	Warranty details	ATTACHED ☐	
6.f)	Details for end-of-life waste management of the Device	ATTACHED ☐	
8.a)	Protocol for post-delivery Device acceptance testing	ATTACHED ☐	
8.b)	Details of installation requirements	ATTACHED ☐	NOT APPLICABLE ☐
9.a)	Service support contract options for maintenance / repair	ATTACHED ☐	
9.c)	Availability of spare / replacement parts	ATTACHED ☐	NOT APPLICABLE ☐
	Information / test equipment / tooling / software required for Device servicing	ATTACHED ☐	NOT APPLICABLE ☐
10.b)	Validated decontamination protocol/s	ATTACHED ☐	NOT APPLICABLE ☐
10.d)	Requirements for special reprocessing equipment, tools and materials	ATTACHED ☐	NOT APPLICABLE ☐
10.e)	Details of special post-processing Device storage requirements	ATTACHED ☐	NOT APPLICABLE ☐
11.a)	Details of patient information capture / encryption / storage / transmission / deletion	ATTACHED ☐	NOT APPLICABLE ☐
11.b)	Details of Device IT software / hardware compatibility requirements	ATTACHED ☐	NOT APPLICABLE ☐
	Details of provisions made for Device IT cybersecurity	ATTACHED ☐	NOT APPLICABLE ☐
12.a)	Details of particular hazards that require special safety management	ATTACHED ☐	NOT APPLICABLE ☐
12.b)	Details of particular performance quality assurance measures required	ATTACHED ☐	NOT APPLICABLE ☐
13.a)	Details of user training offered	ATTACHED ☐	NOT APPLICABLE ☐
13.b)	Details of technical training offered	ATTACHED ☐	NOT APPLICABLE ☐
13.c)	Details of decontamination training offered	ATTACHED ☐	NOT APPLICABLE ☐
13.e)	Details of any additional support facilities offered	ATTACHED ☐	NOT APPLICABLE ☐

When reference is made to this Form and its attachments within the process of obtaining the specified product/s, we agree that the purchaser will be entitled to rely upon the contents and that subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name:			
Position:			
Company:			
Address:			
Website:			
Email:		Telephone:	
Signature:		Date:	

PART II

for completion by the device Supplier
(eg: Manufacturer, Authorised Representative or other)

Previous sections in PART I provided for general Device information; this PART II addendum provides details specific to particular transaction/s for supply of the product:-

TRANSACTIONAL:

14 a) On what basis will the product be supplied, (including Devices for clinical investigation / research) ?
purchase ? ☐ exchange ? ☐ rental/lease ? ☐ loan ? ☐ donation ? ☐

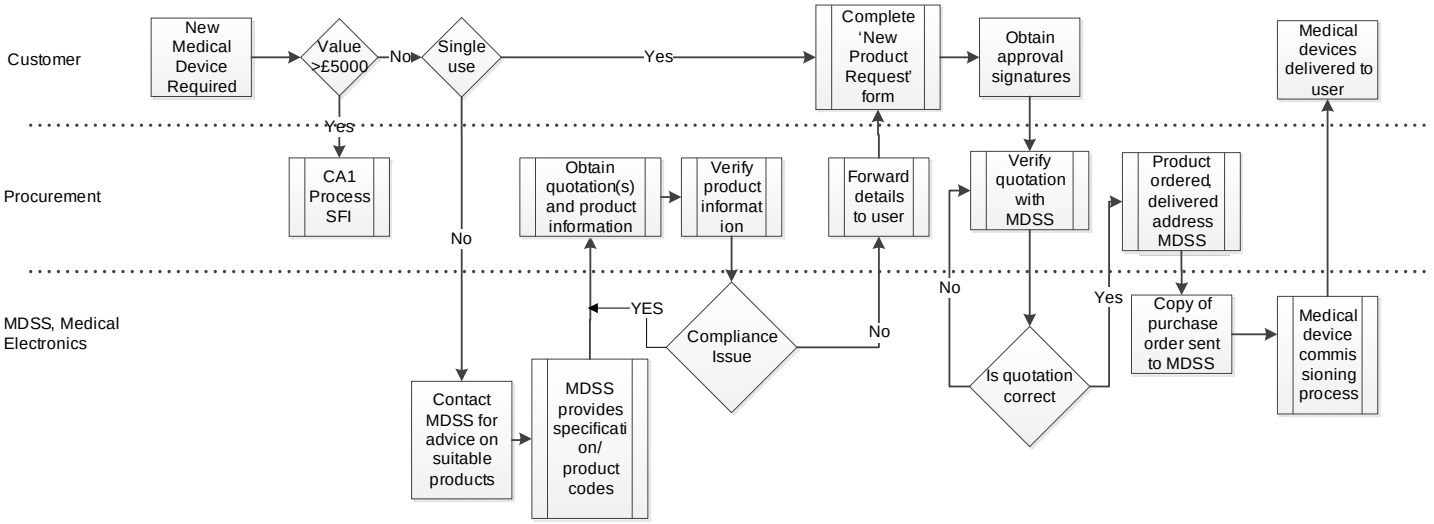
b) For supply by loan or donation, other than Devices for clinical investigation / research -
Has a Department of Health (DH) MIA CallOff Agreement Form been attached ? YES ☐
Is the Supplier on the DH Master Indemnity Agreement (MIA) Register ? * NO ☐ YES ☐
- If YES, then quote DH MIA registration number:
- If NO, has an Indemnity Insurance Certificate (for local indemnity agreement with the customer) been attached ? YES ☐
(* Note: unregistered Suppliers are advised to register for the MIA Overarching Agreement with the DH)

c) For supply by loan or donation of Devices for clinical investigation / research -
Has confirmation of Health Research Authority (HRA) indemnity approval been attached ? YES ☐

d) Is the particular item to be supplied a pre-used product ? NO ☐ YES ☐
- If YES, has usage and full service history been attached with this return ? YES ☐

Name:			
Position:			
Company:			
Address:			
Signature:		Date:	

APPENDIX 4 - MEDICAL DEVICE PROCUREMENT PROCESS



Date 23-06-2016	Required Documentation for any New/Loan/Trial Medical Device				
Information Required	Product information Required for		Purchase	Trial/Loan	Demonstration non-patient
NHS Delivery Note	NHS Delivery Note		N/A	Mandatory	N/A
Insurance (IFA/IFB)	MA Reference Number		Mandatory	Mandatory	Mandatory
Insurance certificate	Insurance certificate £5m Employers Liability		Optional	Mandatory	Mandatory
	Insurance certificate £5m Public Liability		Optional	Mandatory	Mandatory
	Insurance certificate £5m Product Liability		Optional	Mandatory	Mandatory
Product Conformity	Pre-Purchase Questionnaire (PPQ)		Mandatory	Mandatory	Mandatory
	Certificate of Product Conformity (CE/MDD)		Mandatory	Mandatory	Mandatory
Product Information	User Manual		Mandatory	Mandatory	Mandatory
	Operators Manual		Mandatory	Mandatory	Optional
	Service Manual		Mandatory	Optional	Optional
	Spare Parts Listing and Costs		Optional	Optional	Optional
	Warranty Information		Mandatory	Mandatory	Optional
	Maintenance Contract Detail/Costs		Mandatory	Mandatory	Optional
Cleaning Instruction (Infection Control: Decontamination 1112)	Cleaning solutions/strengths	Frequency of cleaning			
	Soap and water/detergent wipes	Daily	Mandatory	Mandatory	Optional
	1000ppm hypochlorite (Actichlor) when in contact with MRSA, ESBL, Flu	Daily Hotel services carry out daily cleaning 1000ppm hypochlorite (Actichlor) to reduce the environmental load of alert organisms	Mandatory	Mandatory	Optional
	5000ppm hypochlorite (Actichlor) when in contact with CDT or norovirus/diarrhoea unknown origin	1. Adhoc cleaning – deep clean 2. Outbreaks- bay or ward closures 3. Potentially daily for equipment specifically purchased for use in side rooms or Allerton ward	Mandatory	Mandatory	Optional
	10,000ppm hypochlorite (Actichlor) when in contact with blood borne viruses (on occasions that it may happen)	Occasionally – used if contaminated with blood However a bed on the labour ward will be cleaned at least daily with 10,000ppm hypochlorite (Actichlor)	Mandatory	Mandatory	Optional
Product Costs	Sales Quotation		Mandatory	Optional	Optional
	Service Contract Quotation		Mandatory	Optional	Optional
	Non Contract Repair Costs, travel, labour		Mandatory	Optional	Optional
Health and Safety	Contractors pass for all staff visiting site		Mandatory	Mandatory	Mandatory
	Completion of contractors information pack		Mandatory	Mandatory	Optional
Device	Device to be checked for electrical Safety		Mandatory	Mandatory	Mandatory
Training	User Training information pack		Mandatory	Mandatory	Optional
	Service Training information pack		Mandatory	Optional	Optional
Mandatory RISK ASSESMENTS	Control of Artificial Optical Radiation at Work Regulations 2010: Written evidence of the hazards/risks and safe working practices to meet the requirements of this regulation.		Mandatory	Mandatory	Mandatory
	Manual Handling Operations Regulations 1992 (as amended) (MHOR): Written evidence of the hazards/risks and safe working practices to meet the requirements of this regulation.		Mandatory	Mandatory	Mandatory
	The Electromagnetic Fields (EMF) Directive: Written evidence of the hazards/risks and safe working practices to meet the requirements of this directive.		Mandatory	Mandatory	Mandatory

APPENDIX 5 Torbay Hospital Trials Procedure / Documentation

If trial isn't for an NHS Supply Chain product - need to check indemnity - Check via PASA MASTER INDEMNITY LIST (http://www.pasa.nhs.uk/MIA/). If the supplier isn't on the PASA Indemnity List you will need to complete Indemnity Form A (for equipment) and / or Indemnity Form B (for consumables).

At all times the procurement department must be involved with communications to suppliers.

The register is to be discussed at the Medical Devices Group Meeting. Produce a benefits report

Is the trial for a product contained in one area or trust wide?

TRUST WIDE Discuss the trial at the Medical Devices Operations Group Meeting to decide who needs to be involved	ONE AREA Discuss the trial with the relevant group i.e. critical care / A&E user group and / or with the area requesting the trial
Email *Clinical Governance Lead & Co-ordinators / Associate Nurse Directors / Infection Control / Training / Med Electronics / Key End Users / Stock Control to flag up that a trial is going to take place.	Email *Clinical Governance Lead & Co-ordinators / Infection Control / Training / Med Electronics / Key End Users / Stock Control to flag up that a trial is going to take place.
Agree areas and timeline for trial and ensure trial evaluation forms are made available?	
Arrange an evaluation meeting with key end users, collect and file feedback forms. Has the trial been a success?	
Yes	No
FORMS TO COMPLETE: Complete savings form with sign off from head of directorates / end users / clinical governance / finance / buyer	Add trial information to Trials Register (procurement) and add reason as to why a product switch isn't viable
Feedback to the Medical Devices Operations Group	
SWITCH AGREED	
FORMS TO COMPLETE: Matman change sheet for stock control. Request email from Logistics team to confirm changeover has been completed	
FORMS TO COMPLETE: Stock usage to Procurement Lead if it's an NHS Supply Chain Product	
Email all areas where product change will take place	
Approved	**VERSION 1**
Date:	
***Email** **Procurement (Acute)** **Procurement (Community and Social Care)** Clinical Governance Lead Clinical Governance Co-ordinator (Medical) Clinical Governance Co-ordinator (Surgical) Clinical Governance Co-ordinator (W,C&D)	procurement.tsdft@nhs.net procurement.tct@nhs.net

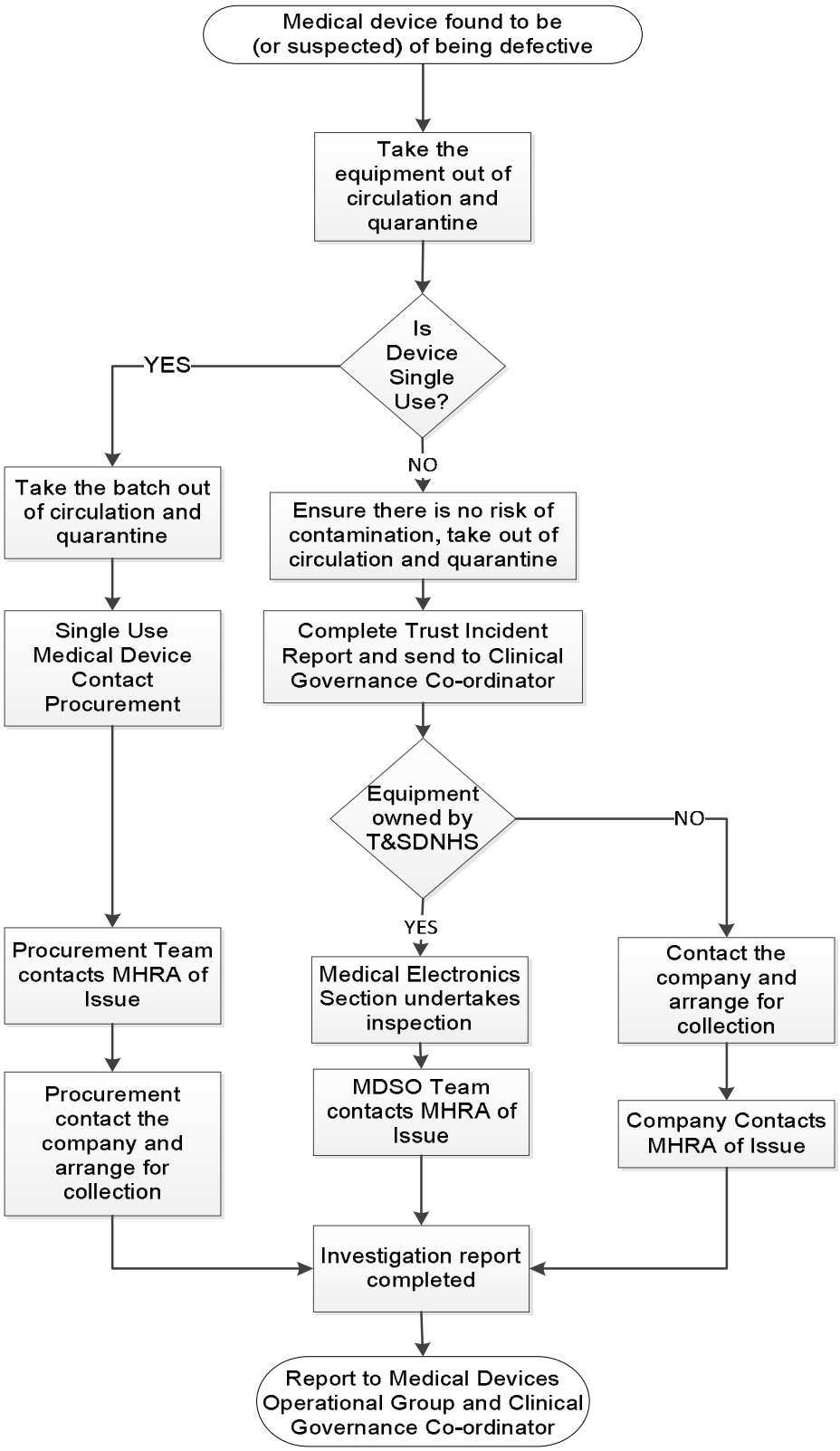
Associate Nurse Director (Medical) Directorate Nurse Manager (Surgical) Associate Director of Nursing (W,C&D) Infection Control Training Medical Electronics Stock Control	

NB: THINGS TO CONSIDER FOR TRIALS

1. Will there be any clinical waste or issues involving the new WEEE Directive? involve The Trust Waste Manager at an early stage -
2. Check whether old / existing equipment that is made redundant by the trial is being leased or is free on loan? - make arrangements to return to supplier
3. Old stock to be used up first
4. If there are new pieces of equipment with the potential to be damaged (i.e. suction jars) provide a replacement list with codes to stock control
5. Can the product switch be rolled out to the community?
6. Does the product get used with a machine and / or existing piece of equipment?

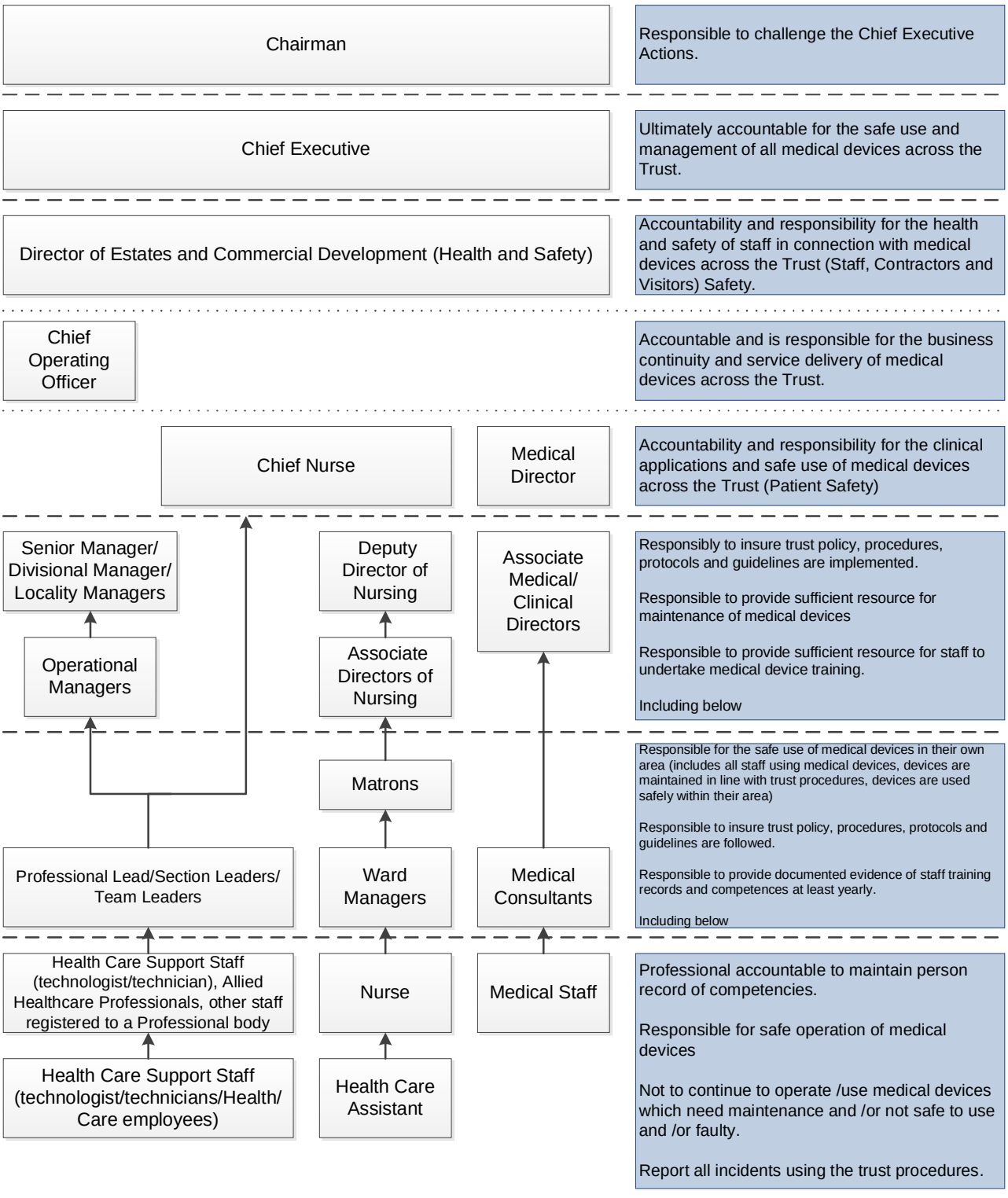
Appendix 6

Flow Chart on how to report a defective medical device



Appendix 7

Line Management of Responsibilities



Individual members of staff have a responsibility too to follow Trust policy(s).
1) Medical Devices only to be used if they are safe and appropriate for the situation.
2) Before staff use any medical device they must ensure that they have received an appropriate level of training in the clinical use and application of that medical device. They must also be able to demonstrate competent use of the medical device.

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

NHS South Devon and Torbay Clinical Commissioning Group Torbay and South Devon NHS NHS Foundation Trust

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)		**Version and Date**	
Policy Author			

An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.

Who may be affected by this document?

Patients/ Service Users ☐	Staff ☐	Other, please state… ☐

Could the policy treat people from protected groups less favorably than the general population?
PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below

Age	Yes ☐ No☐	Gender Reassignment	Yes ☐ No☐	Sexual Orientation	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐	Religion/Belief (non)	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐	Marriage/ Civil Partnership	Yes ☐ No☐

Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)	Yes ☐ No☐

Please provide details for each protected group where you have indicated 'Yes'.

VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion

Is inclusive language[5] used throughout?	Yes ☐ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?	Yes ☐ No☐ NA ☐
Does the policy encourage individualised and person-centred care?	Yes ☐ No☐ NA ☐
Could there be an adverse impact on an individual's independence or autonomy[7]?	Yes ☐ No☐ NA ☐

EXTERNAL FACTORS

Is the policy a result of national legislation which cannot be modified in any way?	Yes ☐ No☐

What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)

Who was consulted when drafting this policy?

Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups) ☐
Staff ☐	General Public ☐	Other, please state… ☐

What were the recommendations/suggestions?

Does this document require a service redesign or substantial amendments to an existing process? ***PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below***	Yes ☐ No☐

ACTION PLAN: Please list all actions identified to address any impacts

Action	Person responsible	Completion date

AUTHORISATION:
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them

Name of person completing the form		**Signature**	
Validated by (line manager)		**Signature**	

Please contact the Equalities team for guidance:
For South Devon & Torbay CCG, please call 01803 652476 or email marisa.cockfield@nhs.net

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net
This form should be published with the policy and a signed copy sent to your relevant organisation.

[1] Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user
[2] Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them
[3] Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
[4] Consider how someone will be aware of (or access) a service if socially or geographically isolated
[5] Language must be relevant and appropriate, for example referring to partners, not husbands or wives
[6] Consider both physical access to services and how information/ communication in available in an accessible format
[7] Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

Clinical and Non-Clinical Policies – New Data Protection Regulation (NDPR)

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU New Data Protection Regulation (NDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

NDPR intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy.

Furthermore, NDPR requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data. The most effective way of being open is through data mapping. Data mapping for NDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the NDPR.

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our GDPR page on ICON.