Medical Device Management Policy

Policy information

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Summary of document:
A policy for the effective lifecycle management of medical devices in support of safe and effective patient care

Scope:
This Policy applies to medical devices (single-use, single-patient use as well as re-usable) captured by the section medical device definition and interpretation and must be adhered to by all prescribers, users, managers, trainers and personnel involved in the procurement, use, maintenance, reprocessing, validation and performance testing, disposal and information governance for medical devices.

To be read in conjunction with:
011 - Incident and Hazard Reporting Policy (*opens in a new tab*)
012 -New Interventional Procedures Policy (*opens in a new tab*)
013 – Management of NICE and other National Guidance Implementation Policy(*opens in a new tab*)
172 – Confidentiality Policy (*opens in a new tab*)
674 – Risk Assessment Procedure (*opens in a new tab*)
195 - Clinical Record Keeping Policy (*opens in a new tab*)
217 - Ionising Radiation Safety Policy (*opens in a new tab*)
836 – Information Governance Policy (*opens in a new tab*)
268 - Medicines Policy (*opens in a new tab*)
329 – Point of Care Testing Policy (*opens in a new tab*)
390 - Infection Prevention & Control Policy for the Cleaning & Decontamination of Equipment prior to Inspection, Servicing, Repair or Disposal (*opens in a new tab*)
429 - Management & Distribution of Safety Alerts and Notices Policy (*opens in a new tab*)

093 - FP/09/03 - Disposal of Surplus & Obsolete Furniture, Equipment, Sale of Scrap and Other Waste Materials Procedure (*opens in a new tab*)
982 – Incident, near miss and hazard reporting procedure (*opens in a new tab*)
Standard Financial Procedures
674 – Risk Assessment Procedure (*opens in a new tab*)

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Include links to Patient Information Library

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Executive Director of Allied Health Professions and Health Science

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Version 1 – new policy 5.3.2018
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Keywords
Medical Device, Medical Equipment, Single Use Items

Glossary of terms
MHRA – Medicines and Healthcare products Regulatory Agency
MDSO – Medical Devices Safety Officer
SMTL – Surgical Materials Testing Laboratory
CE – Clinical Engineer
NWSSP - NHS Wales Shared Services Partnership: Procurement Service
QSESC - Quality, Safety & Experience Sub Committee

Contents

Executive summary

- Patients of Hywel Dda University Health Board undergoing diagnosis, treatment or alleviation of condition will invariably come into direct contact with medical devices as they progress along their care pathway.
- The Health Board holds a legal duty of care to ensure medical devices used in the diagnosis, treatment or alleviation of condition are fit for purpose, acceptance tested, suitably reprocessed, maintained and; validated and performance tested, and that confidential, personal information is stored and managed securely and staff using these devices are trained and maintain their competency.
- A medical device for the purposes of this policy is defined as any piece of equipment that comes into contact with a patient and has diagnosis, treatment or alleviation of condition as its purpose, including the software that controls the functionality and/or secondary items connected to such devices.
- For medical devices management to be successful the organisation needs to promote a culture of co-operation and co-ordination across planning, risk management and operational priorities such that the stages of selection and procurement, acceptance and commissioning, operational use (including information governance) and maintenance (including cleaning and disinfection) and training can be effectively managed.
- The management processes for effective medical devices management are clearly laid down in guidance produced by Medicines and Healthcare products Regulatory Agency (MHRA).
- Executive Board level accountability for medical devices management rests with the nominated executive director as defined by the scheme of delegation.
- It is an absolute responsibility of medical devices users and their managers to manage all aspects of the medical device during its operational life.
- For the purpose of this policy the term lifecycle refers to the period between the medical device being introduced into service until it is withdrawn and includes processes such as reprocessing, maintaining, validation and performance testing which occur in between periods of operation of the medical device.

INTRODUCTION

Medical devices are a vital component of modern day healthcare delivery and it is difficult to imagine a single patient pathway where a medical device is not involved at some stage. Rapidly advancing technologies mean devices are becoming more and more complex and hence it is imperative to have a robust clinical governance framework underpinning a sound management system for medical devices.

The Health Board holds a legal duty of care (refer to section : legal framework) to ensure that a medical device used in the diagnosis, treatment or alleviation of a condition is suitable for its intended purpose, suitably reprocessed, maintained, repaired, validated and performance tested, and that confidential, personal information is stored and managed securely and staff engaged in using these devices are trained and maintain their competency.

The field of medical devices is extremely broad and multifarious and ranges from a simple bandage to a complex MRI scanner. Such is the breadth of this field it is essential that a robust clinical governance framework exists which underpins the management of medical devices in order that care can be provided to the highest standards and be supported by sound governance and assurance arrangements.

This policy therefore sets out the Health Board's approach and commitment to achieving a safe and assured system for medical devices management.

POLICY STATEMENT

This Policy offers a platform for the continued development of a mature management system to support medical devices management that will in turn improve and maintain standards of clinical governance and hence patient safety and patient outcomes where medical devices are used.

SCOPE

This Policy applies to medical devices (single-use, single-patient use and re-usable) captured by the section: definitions and must be adhered to by all prescribers, users, managers, trainers and personnel involved in the procurement, use, maintenance, reprocessing, repairing, validation and performance testing, disposal and information governance for medical devices.

Whilst the Medical Devices Directive includes *in vitro* medical devices, these are governed by standard laboratory standards and therefore fall outside of the scope of this policy. In addition this also applies to implantable medical devices.

AIM

This Policy aims to set out the Health Board's commitment to medical devices management and provides clear direction and guidance to all involved in the procurement, management, use and upkeep of medical devices with the intention of controlling risk and delivering safe patient care.

OBJECTIVES

The aim of the Policy will be achieved by ensuring:

- That there is a robust inventory of all reusable medical devices.
- That there are effective risk management processes in place to support the deployment of medical devices;

- That there are adequate and effective programmes of training and staff are competent and maintain their competency;
- That there are prudent and effective selection and procurement processes in place when acquiring new and replacement medical devices;
- That there are adequate support mechanisms to ensure medical devices are and remain fit for purpose throughout their lifecycle;
- That there are adequate arrangements in place for the secure management and storage of confidential personal information associated with the use of medical devices, in line with health Board Policies
- That compliance with relevant standards is achieved and where exceptions exist they are escalated to the Quality, Safety & Experience Sub Committee (QSESC);
- That there are effective processes in place to learn from incidents and safety notices;
- That disposal at end of life is executed safely and with due diligence.

MEDICAL DEVICE: DEFINITION AND INTERPRETATION

In line with UK legislation the Health Board defines a medical device as any instrument, apparatus, appliance, material or other article whether used alone or in combination, including the software necessary for delivering the correct functionality as intended by the manufacturer, to be used by human beings for the purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception;
- And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

By way of interpretation the Health Board therefore considers a medical device to be any piece of equipment that comes into contact with a patient and has diagnosis, treatment or alleviation of condition as its purpose, including software that controls the functionality of such devices, and secondary items connected to the medical device. This will include equipment not owned by the organization such as that which has been loaned from another healthcare provider or used as part of a clinical evaluation of equipment and loaned by a manufacturer.

There are 3 categories of medical devices:

- Single-use items: A single-use medical device must only be used on an individual patient during a single procedure and then be discarded. It must not be reprocessed and used again, even on the same patient. It will have this symbol on the packaging or the device;

A few single-use devices are marketed as non-sterile. These may require processing, in line with the manufacturer's instructions, to make them sterile and ready for use. These must not be re-sterilized again.

- Single-patient use items: A single-patient use medical device may be used for more than one episode of use but on one patient only; the device may undergo some form of reprocessing between each patient use, in accordance with the manufacturers reprocessing instructions.

- Re-usable items: A re-usable medical device is a device that undergoes lifecycle processes which means the device can be re-used on multiple patients. The lifecycle processes include reprocessing, maintaining and; validation and performance testing which occur in between periods of operation of the medical device.
  The reprocessing of a medical device for re-use may involve any or a combination of the following processes:
  - Cleaning
  - Disinfection/decontamination
  - Sterilization
  - Refurbishment
  - Repackaging
  - The manufacturer of re-usable medical devices should provide validated reprocessing instructions along with the device.

COMMITMENT TO MEET STANDARDS

The Health Board undertakes to comply with all published statutory and implied statutory standards listed in this section. The Medical Devices Group, will on behalf of the QSESC:

- Ensure that the clinical governance framework for medical devices is in place and remains fit for purpose by incorporating medical device alerts, field safety notices, and all other alerts into the framework.
- Receive reports from the service via the Quality, Safety and Experience Sub-Committees on non-compliance and/or seek assurance from the service that the non-compliance is being managed appropriately; and/or confirm that the clinical governance framework is still fit for purpose and action as appropriate.
- Escalate unresolved non-compliance to the QSESC.

The Quality, Safety and Experience Sub-Committees will monitor compliance and will report any non-conformities giving rise to significant risk as they arise to the Quality, Safety and Experience Assurance Committee as part of standard reporting.

Legal Framework

Statutory obligations

Legislatively the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and Electrical Equipment (Safety) Regulations 1994 made under the Consumer Protection Act of 1987 aim to control the manufacture and supply of medical devices. Given the business functions of the Health Board do not extend to the manufacture of medical products and the Health Board will always procure such products in accordance with NHS procurement rules these regulations will hold little in the way of further notable obligations.

The main legal obligations made under the Health and Safety at Work etc Act 1974 that the Health Board is cognisant of and will comply with in respect to medical devices management are contained in the Management of Health and Safety at Work Regulations 1999, Provision and Use of Work Equipment Regulations 1998, Electricity at Work Regulations 1989 and Ionising Radiation Regulations 2017. These Regulations being largely non-specific to medical devices rely on bespoke guidance to support safe working definitions and interpretations and these are available via specific guidance covered in the section immediately below.

Standards

MHRA Bulletins and Guidance

The principal source of medical devices management reference for users/keepers and their managers is the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA's documentation resource contains many device bulletins issued to the health service which are based on industry best practice and draw on evidence from the wider experiences of the NHS.

Although not strictly mandatory the guidance contained in MHRA device bulletins stands alone as the only published best practice to inform many aspects of medical devices management and as such the Health Board will take all reasonable steps to comply with the advice and guidance issued by MHRA in line with 429 - Management & Distribution of Safety Alerts and Notices Policy (*opens in a new tab*).

Health & Care Standard No. 2.9 – Medical Devices, Equipment and Diagnostic Systems

Internally, governance of medical devices management will be framed around and monitored by way of Health & Care Standard No 2.9.

National Institute for Health and Care Excellence (NICE)

Medical Technologies Guidance (MTG) and other guidance issued by NICE will be implemented by the Health Board in line with 013 – Management NICE and other National Guidance Implementation Policy (*opens in a new tab*). 012 -New Interventional Procedures Policy must be adhered to if the medical device is supporting a new interventional procedure.

National Patient Safety Agency (NPSA)

Previous alerts and safe practice notes issued by the former National Patient Safety Agency remain actively relevant and hence the Health Board will continue in its commitment to meet these requirements on an ongoing basis, in line with 429 - Management & Distribution of Safety Alerts and Notices Policy (*opens in a new tab*)

Safety Notices

Safety notices and alerts issued by medical device manufacturers (Field Safety Notices) and Medical Device Alerts issued by MHRA will be acted on without undue delay in line with 429 - Management & Distribution of Safety Alerts and Notices Policy (*opens in a new tab*)

RISK MANAGEMENT

Any risks associated with medical devices will be assessed, managed and escalated in line with Procedure 674 - Risk Management – opens in a new tab..

Medical devices, which are re-usable, are subject to lifecycle processes (related to the specification, procurement, acceptance, reprocessing, maintenance, repair, validation and performance testing, safety alert action and decommission) and are subject to the risk management processes detailed in this policy.

Medical devices which are for single-use or single-patient use are disposed of immediately after use and do not undergo reprocessing, therefore the application of the full risk management processes for reusable medical devices would be disproportionate and not cost-effective for these items.

MEDICAL DEVICES INVENTORY

On behalf of the Health Board, Clinical Engineering host an overarching Inventory database for re-usable medical devices. To ensure clinical and information governance requirements are met effectively, the Heath Board requires wards/services/departments to ensure the inventory database remains relevant, up to date and accurate. The inventory database identifies the management and maintenance responsibilities (Maintenance Overseer) for each device.

Responsibility for the compiling and maintaining of inventories rests with the relevant directorate working with Clinical Engineering, as defined under the responsibilities section of this Policy.

ROLES & RESPONSIBILITIES

The scheme of delegation as it relates to medical devices management is as follows:

Chief Executive
The Chief Executive carries ultimate accountability for all risk matters arising within the Hywel Dda University Health Board including those relating to medical devices management.

Nominated Lead Executive Director
The Nominated Lead Executive Director holds accountability for the executive portfolio for the clinical governance of medical devices including implementation of this Policy. This accountability will be enacted through the Medical Devices Group.

Chief Operating Officer
The Chief Operating Officer, will make the necessary provisions for adequate information exchange and escalation of risk matters as necessary as it relates to medical devices and to apprise Quality, Safety and Experience Assurance Committee of risks arising and other salient issues

Medical Devices Group
The purpose of the Medical Devices Group is to:

- Ensure that the clinical governance framework for medical devices is in place and remains fit for purpose by incorporating alerts, field safety notices, etc. into the framework.
- Receive reports from the service via the Quality, Safety and Experience Sub-Committees on non-compliance and/or seek assurance from the service that the non-compliance is being managed appropriately; and/or confirm that the clinical governance framework is still fit for purpose and action as appropriately.
- Escalate unresolved non-compliance to the Quality, Safety and Experience Sub Committee.

Operational Directors and Senior Managers
Operational management of medical devices is vested with operational directors and senior managers who will in the majority of cases ultimately report to the Chief Operating Officer. Operational directors and senior managers will invariably carry direct or indirect line management responsibility for users of medical devices and will control budgets that can influence the duties they are expected to fulfil. The Health Board places the obligation to compile and maintain local inventories of re-usable medical devices used in the course of delivering front line patient care services which is delegated to the operational management teams. It is the responsibility of the Service Managers / directorate owners of the devices in use in their respective clinical settings, to ensure they have adequate device replacement planning programmes in place.

Managers

Although users will always retain responsibility for their front-line application decisions, a number of management duties will remain with managers and include procurement, maintenance of the medical devices inventory, maintenance, servicing, calibration and testing arrangements as well as risk management of medical devices. Such duties will apply to a portfolio of medical devices used in the provision of care within the respective clinical service area.

- Ensure sound clinical and information governance, and maintain a local inventory of medical devices under one's control;
- Inform Clinical Engineering Department of the acquisition/arrival of new devices into their clinical services area – regardless of the ownership status.
- Ensure that their staff are suitably trained (with records available) on the medical devices they are expected to encounter as part of their duties.
- Ensure devices are presented for service in good time.
- Have readily available manufacturers' instructions for medical devices in local use.
- Ensure medical devices are cleaned and disinfected after use and a certificate of contamination status filled out and is available to servicing personnel with the medical devices in line with Policy 390 - Infection Prevention & Control Policy for the Cleaning & Decontamination of Equipment prior to Inspection, Servicing, Repair or Disposal.
- Respond to safety alerts and notices relative to their medical device portfolio through the ECRI or equivalent safety alert reporting system used within the Health Board.
- Compile and maintain a medical devices inventory of existing medical devices and link it with other records related to reprocessing, maintenance, repair, validation, performance testing and user competency. In addition, a duty exists to maintain an inventory for medical devices which have been removed from service.

Prescribers of Medical Devices

Authority to prescribe the application of a medical device on a patient is limited to prescribing registered healthcare professionals. When prescribing the use of a medical device, the prescribing healthcare professional must only do so on devices on which they are fully conversant with the intended application and any associated issues/implications of its use.

Users of Medical Devices

A pivotal role in the management of medical devices is that of the user, who will be operationally responsible for ensuring that medical devices used in the diagnosis, treatment, and alleviation of a condition are right for the job, properly validated and commissioned, serviced, maintained and cleaned and are safe to use and that information governance arrangements are in place and that they are competent to use that device in clinical service. User Checks in line with the Electricity at work Regulations 1989 should also be regularly undertaken by the device User at regular intervals. Examples of staff groups which might include users are registered nurses, doctors, dentists, chiropodists, midwives, physiotherapists, radiographers, plaster technicians, phlebotomy staff, audiology staff, occupational therapists, optometrists. This list is not exhaustive.

Users are often referred to as having their 'finger on the button' and hence fulfil a crucial final assurance gateway check that all is in order before the medical device is operated or

applied in clinical use. Users must follow the diagnostic or treatment instructions set out by registered prescribing practitioners and ensure the right device is used on the right patient commensurate with its design purpose.

Patient Users of Medical Devices
Occasionally patients will also be the users of medical devices and in such cases a small number of the duties ordinarily expected of users will not be expected of the patient user. However, in such situations the majority of duties particularly those relating to the selection and preparation of the device prior being put to use and the delivery of suitable and sufficient instruction and information to the patient user will remain a key responsibility of the prescribing healthcare professional.

Medical Device Coordinator
The Medical Devices Co-ordinator will be responsible for the operational quality management and optimisation agenda for medical devices across the Health Board. They shall provide guidance and advise operational teams in all aspects of medical device acquisition, commissioning, clinical governance, information governance, operational management, and control.

Medical Device Safety Officer (MDSO)
As stipulated under MHRA guidance the Health Board should have access to suitable and sufficient human resource in order that it may effectively discharge the duties and functions of Medical Device Safety Officer. This function is presently provided through the Head of Clinical Engineering or nominated individual and includes duties such as review of alerts and safety notices reconciling against the procurement database and distributing as necessary, produce and provide reports to MHRA and SMTL on relevant incidents arising and acting as the principal liaison point between the Health Board and MHRA/SMTL.

Maintenance Contracts Coordinator
Within the Clinical Engineering Department, the Contracts Coordinator role is to ensure devices maintained externally by third parties are on contracts that provide an appropriate level of cover while offering the Health Board optimum value for money.

Medical Device Training Team
The Health Board's Clinical Engineering department employs a medical device training team who have training roles applicable to a wide range of higher risk medical devices.

Radiation and Laser Protection Supervisors
The Health Board has allocated responsibilities to staff in relation to radiation and laser protection as it relates to medical devices; these staff carry the supplementary titles of Radiation Protection Supervisor and Laser Protection Supervisor. These persons are not professional advisers but moreover fulfil a liaison role between the Radiation Protection

Service that is provided by Swansea Bay University Health Board and the current appointed Laser Protection Advisor. All decisions relating to acquisition, in-service life and use and disposal of such medical devices must be supported by the advice of the Radiation Protection Adviser or Laser Protection Advisor.

Procurement
Procurement plays a pivotal role in the medical device lifecycle, from identifying approved and authorised suppliers, for both the purchase and maintenance of medical devices, to associated approval in respect of the disposal processes of devices.

Maintenance Overseers

Due to the plethora of device types that fall within the definition of a reusable medical device, it follows that there are range of different departments (identified below), that are best equipped to manage the maintenance requirements of these – thus the medical device Maintenance Overseer. The Maintenance Overseer for individual devices on the Health Board inventory is identified within each device record.

The duties of the Maintenance Overseer shall include:

- For those devices for which they have responsibility, ensure that all facets of maintenance meet the minimum regulatory requirements.
- Ensure appropriate acceptance procedures including the installation of agreed configuration sets (see Appendix D – Medical Device Configuration Procedure) are followed prior to clinical deployment.
- Ensure appropriate and adequate maintenance arrangements (including QA, performance verification, calibration, electrical safety testing etc.) are in place and undertaken in a timely manner to a level consummate with the inherent function and nature of the device.
- Provide monthly reports to the Medical Device Group on maintenance performance.
- Ensure episodes of repair/unexpected performance are investigated with remedial action undertaken by appropriately trained, skilled and authorised engineers.
- When devices are decommissioned, it is done so following Health Board and nationally accepted policies/guidelines for devices of that nature.
- Robust records are maintained as detailed in Section: keeping of records for a period no less than 11 years following decommissioning.
- Assist the service in identifying surplus devices and/or those approaching the end of their life cycle.
- At least annually, communicate any changes to their portfolio to the Clinical Engineering Department so as to allow the Health Board inventory to be updated.
- Take a lead role in incident investigation.

Clinical Engineering Department
In addition to being the Health Boards primary Maintenance Overseer, the Clinical Engineering Department shall:

- On behalf of the Heath Board, develop and maintain the inventory of reusable medical device and in so doing, assign the role of Maintenance Overseer to each uniquely catalogued device.

- At least annually, provide details taken from the Health Board inventory to other Maintenance Overseers for the devices for which they have responsibility.
- Provide advice and guidance to users of medical devices.
- Promote the practices within this policy.
- Manage the lifecycle of devices from the owning department where they are generally mobile, powered (electrically or hydraulic / assisted) and fit a multitude of criteria commonly used in hospitals.
- This excludes:
    - Point of Care devices
    - Devices that are directly sought from procurement and directly used with the patient such as Manual PCA devices
    - Devices that are loaned directly to patients that the ownership of the device remains with the supplier (such as Hospital @ Home scenarios).
    - Devices that are owned by the patient.

Radiology
Radiology oversee the lifecycle of the fixed infrastructure devices, such as MRI, CT XRAY to name a few. They are responsible for ensuring that the medical device inventory database remains relevant and up to date. This is either via Clinical Engineering, or direct access to the database. This is to ensure that all information in respect of the value, age and need for replacement planning is accurate and current.

Pathology
Pathology are responsible and oversee the lifecycle of Point of Care (POC) devices used by staff and patients. They are also responsible and oversee the lifecycle of Laboratory devices and Mortuary devices. They hold and maintain an inventory database to manage their appropriate devices. They also link with Clinical Engineering in respect of the medical device inventory database, to ensure that all information in respect of the value, age and need for replacement planning is accurate and current.

Hospital Decontamination and Sterilisation Unit (HSDU)
HSDU are responsible and oversee the lifecycle of both Sterilisation and Decontamination infrastructure. They hold an Inventory and traceability system for the devices used for delivery of patient care, such as Theatre instruments and other decontamination devices. They link with Clinical Engineering to ensure their infrastructure systems are on the medical device inventory database, to ensure that all information in respect of the value, age and need for replacement planning is accurate and current.

Endoscopy
Endoscopy are responsible and oversee the lifecycle of the Flexible Endoscopes used within their clinical settings. They work closely with the Clinical Engineering contracts team to ensure that appropriate maintenance arrangements are in place and manage their own record keeping of service history for devices, in line with the MHRA Managing Medical Devices guidelines. They are responsible for ensuring that the medical device inventory database remains relevant and up to date. This is either via Clinical Engineering, or direct access to the database. This is to ensure that all information in respect of the value, age and need for replacement planning is accurate and current.

Theatres / Sterile re-usable device / Instruments service owners
Theatre / departments that own and use sterile re-usable devices / instruments, such as surgical instruments are responsible and oversee the lifecycle of these devices used for invasive procedures.

Podiatry
Podiatry manufacture and modify orthotic medical devices. This team are responsible and oversee these devices.

CardioRespiratory / Cardiac Physiology
CardioRespiratory are responsible and oversee implantable medical devices such as pacemakers. This team hold a record of the devices that have been implanted to patients, should there be a recall or a need to follow up for safety alerts. This team also hold records of devices issued to patients in respect of respiratory devices, such as Constant Positive Airway Pressure (CPAP)

Audiology
The Audiology team are responsible, modify and oversee medical devices such as custom earmould provision used in conjunction with hearing aids issued to patients.

Hard Facilities Management (Estates)
Hard Facilities Management (FM) are responsible and oversee the larger fixed infrastructure devices across most Acute settings. This also includes the medical gas infrastructure in accordance with their policies and procedures.

Clinical Effectiveness
If there is a new device to be used in conjunction with a new process or NICE guideline to adhere to, the Clinical Effectiveness team will need to be involved in the medical device procurement process

Tritech Institute
The TriTech Institute undertake various projects that may include elements of medical device development and evaluation. In such cases, they will do so in accordance with this policy and with the knowledge of the Clinical Engineering Department.

Digital Services
If a medical device requires connection to the Health Board IT network, via Wi-Fi or wired connection, approval from Digital Services is required. Depending on the type of device and information stored or transmitted, review maybe required by various Digital Service Teams, which may include Cyber Security, Information Governance or Infrastructure. Clinical Engineering will liaise with Digital Service during the configuration of the device to ensure approval.

If there are any faults or issues with networked devices whilst in use, then service managers/users are requested to report to Digital Services via the IT Portal.

INCIDENT REPORTING

When an incident involving a medical device occurs, in addition to submitting an incident report via Datix in accordance with Policy 982 – Incident, Near Miss and Hazard Reporting and Management procedure, the Health Board is required to collaborate with MHRA and

the Surgical Materials and Testing Laboratory (SMTL) by sharing relevant incident details for the purposes of collective NHS benefit.

If it is suspected or confirmed that a device is implicated in an incident then together with any associated consumables it should be immediately and securely quarantined as potential evidence and Clinical Engineering notified. The device/s should not be cleaned or subjected to alteration of its settings or programmes as detailed in Policy 982 – Incident, Near Miss and Hazard Reporting and Management procedure. Also view the Hywel Dda Quality, Assurance and Safety Intranet page, with more information.

If the incident involves a medical device accessory, that may require investigation directly with SMTL, then the Health Board Procurement Nurse will also be able to advise and support in addition to Clinical Engineering / Maintenance Overseer.

Link to: Appendix C: Medical Device Training, Safe Use and Operation Procedure

Preservation of evidence
In addition to reporting the incident, the device, together with any associated accessories and consumables (including packaging if available), must be immediately and securely quarantined as potential evidence to facilitate internal and/or external investigation. Not only is this vital to the Health Board's efforts to co-operate with MHRA and SMTL and in the case of a serious incident with enforcing authorities, but also to support opportunities to learn from incidents. This duty extends to decontamination processes which must not be carried out when a device is involved in an incident where enforcing authority investigation is likely to follow. In these circumstances the advice of the appropriate Clinical Engineering/Maintenance Overseer/HSDU team is to be taken on appropriate measures to best preserve evidence.

GUIDANCE FOR USERS WHEN USING A MEDICAL DEVICE

The decision to use one device over another or use a medical device in the first place is a matter of clinical judgement and hence must be taken by the relevant healthcare professional who carries the responsibility for care of the patient.

How such decisions might be arrived at are beyond the scope of this policy and the clinical prescriber and user may be one and the same person whilst on other occasions the prescriber may pass these duties onto another.

Whether the prescriber fulfils the role of user or delegates the duties to use a medical device for diagnosis, treatment or alleviation of condition, the user must satisfy themselves of the following:

- Appendix C: Medical Device Training, Safe Use and Operation Procedure has been followed.
- That it is the right medical device for the required procedure and will be used in accordance with manufacturer's instructions on the right patient.
- That they are competent to use the medical device inclusive of its software and accessories.
- That the medical device is clean in line with Policy 390 - Cleaning and Decontamination of Equipment prior to Inspection, Servicing, Repair or Disposal.
- That the medical device shows no signs of damage or disrepair.

- Where applicable, that all records of use are completed e.g. an infusion monitoring chart, and stored in line with Policies 195 - Clinical Record Keeping (*opens in a new tab*).
- Where applicable, that the medical device bears a next test due date which is in the current month, or the future.
- That the user are aware and act upon any specific instructions or limitations of use instructions that originate from an alert or safety notice.
- That the user follow user checking procedures for the specific device.
- That the patient will be adequately monitored accordingly to clinical needs whilst connected to or in contact with the prescribed medical device.
- That battery packs are sufficiently charged and capable of delivering the function of the device.

KEEPING OF RECORDS

The Health Board expects all of its medical devices users/keepers and their managers to exercise due diligence where keeping of records is required in support of medical device use (including staff competency), reprocessing, repairing, maintaining, validation and performance testing.

Users/keepers or their managers are required to maintain suitable and sufficient records of any actions of relevance taken through the medical devices' operational life which might assist the Health Board and other agencies in identifying incident root causes and to aid any investigations that are commissioned subsequently. These will include but not be limited to:

- Purchasing records
- Commissioning records
- Decontamination and sterilisation records
- Maintenance and repair records
- Calibration, Performance validation and/or Quality Assurance records
  Software and Configuration settings – see Appendix D Medical Device Configuration Procedure
- Records of special safety inspections; for example, those required for medical devices subject to ionising radiation requirements
- Records of any approved modifications carried out (refer to 'MODIFIED / CHANGE OF USE' section on page 24)
- Patient identifiable traceability of usage (where applicable) and in accordance with Information Governance policies and procedures
- Training and maintaining of competency records
- Decommissioning and disposal records
- Risk assessments

It is the responsibility of users/keepers or their managers to ensure that such records are available for inspection at any point or to have arrangements with supporting teams to

maintain such records on their behalf through the device Maintenance Overseer. The default responsibility will however always remain with the users/keepers or their managers.

INTERNAL DEVICE OWNERSHIP

Howsoever acquired, all medical devices that are the property of Hywel Dda University Health Board can be redeployed to any part of the organisation on a temporary or longer term basis as deemed necessary by the needs of the service. The Chief Operating Officer will be the final arbiter of such redeployment decisions. However, the clinical and information governance responsibilities must be agreed between the donating and recipient departments.

In addition, the relevant Clinical Engineering department and/or Maintenance Overseer must be notified of the equipment transfer to ensure arrangements are made for future reprocessing, repairing, maintaining and; validation and performance testing.

SATISFYING CLINICAL GOVERNANCE STANDARDS PRIOR TO PURCHASING MEDICAL DEVICES

For the majority of cases, the need to purchase a medical device will originate from any one of three distinct possibilities (see Appendix A: Clinical Governance & Information Governance Assurance):

- New medical device required to support new clinical interventions;
- Replace a medical device that has become technically and/or clinically obsolete;
  A medical device already in service that has become unserviceable (technically obsolete) or no longer fulfils what could be considered reasonable contemporaneous technological performance (clinically obsolete) may justify a case for replacement provided recent utilisation evidence supports an on-going need for the medical device.
- Increasing the quantity of a medical device already in service;
  A medical device that is presently in service but is not available in sufficient quantity to meet the needs of the service; it may be justified to purchase additional stock but a business case including how the existing stock is used is required.

New Medical Devices

The majority of medical devices purchased will not have been used before. However, there are occasions that the Health Board will purchase second hand equipment (see Section: second hand medical device acquisitions) or borrow equipment from other health providers or manufacturers. The latter is dealt with further on in the Policy.

A medical device is considered to be new when:

- Appearing for the first time in a service;
- Supporting a new clinical intervention in a service*;
- Replacing a medical device which offers substantial technological enhancement;
- A significant quantity of a medical device, from the same manufacturer, is introduced in a short space of time;
- The standardisation profile of a type of medical device is affected (organisation-wide).

* In this case prior approval in support of the clinical intervention must be obtained from the Clinical Engineering Department and the Clinical Effectiveness Team.

Specific Types of Medical Devices
The purchase of some genre of specialist medical devices are covered by separate governance arrangements including those as set out in:

- Ultrasound Clinical Governance in Wales (Refer to Appendix B).
- 329 – Point of Care Testing Policy (opens in a new tab)
- 217 - Ionising Radiation Safety Policy (opens in a new tab)

Pre-purchase process

Before progressing with the purchase of a medical device as defined in ‘New Medical Devices’ & ‘Specific Types of Medical Device’ sections (from the last page and above), both the Maintenance Overseer & the Clinical Engineering Departments for that genre of device will, on behalf of the Health Board, need to satisfy themselves that the necessary clinical and information governance arrangements and required support are in place to safely introduce and maintain the medical device prior to giving final approval to proceed to purchase.

Irrespective of the financing route (e.g. departmental funds, capital bids or charitable funds) the requirement to justify clinically and gain approval, prior to purchase, from both the Maintenance Overseer & the Clinical Engineering Departments is required.

In order for the service to establish pre-purchase approval from the Maintenance Overseer & Clinical Engineering Department, the following questions must be addressed:

- Is the proposed acquisition likely to affect clinical practice to any significant degree?
- Does the proposed acquisition conflict with any declared strategy aimed at delivering improved standardisation across the medical device type in question?
- If a replacement, does the proposed acquisition bring with it a significant advancement in medical devices’ technology?
- Are there any new hazards created by introducing this medical device e.g. ionising or non-ionising radiation, medical gases, manual handling, IT security?
- Are there likely to be any associated consumables product changes brought about through acquiring this medical device?
- For replacement medical devices are lifecycle* costs greater than the pre-existing devices?
- Are any difficulties likely to arise in decontaminating and cleaning the medical device between patient episodes? Manufacturers reprocessing instructions need to be reviewed by the Head of Decontamination prior to purchase, to ensure that the

reprocessing instructions are compatible with United Kingdom decontamination parameters.
- Will the acquisition of the medical device place an increased demand on training resources from that which was evident previously?
- Will the acquisition of the medical device follow an arranged clinical trial?
- Will the acquisition involve using Patient Identifiable Information (PII) in a new way involving the collection, and storage of information?
- Will the new acquisition involve using new technology that individuals may find intrusive to their privacy?
- Will the acquisition involve making automated decisions about an individual's care i.e. where a decision is made without involving a human being?

* The term lifecycle refers to the period between the medical device being introduced into service, until it is withdrawn and includes processes such as reprocessing, maintaining and; validation and performance testing which occur in between periods of operation of the medical device.

If the response to any of the questions above is positive, then a Statement Of Need form (refer to Appendix E – Purchase & Acquisition of Medical Devices Procedure) and a finance proforma (Capital, Charitable funds etc.) will need to be completed and approved by the Head of Clinical Engineering or nominated representative, prior to submitting to the appropriate financing body and/or procurement. In addition, any new device requests must involve procurement early in the process to ensure a compliant route to market.

This Statement of Need form combines the clinical governance standards and the cost of the item and the financial impact likely in respect of maintenance, decontamination, training and consumables costs.

MEDICAL DEVICE FINANCING

Medical device purchases can draw on a number of funding options and it is expected that these options are considered during purchase planning. All medical devices procurements will be undertaken in accordance with the Health Board's - Standing Financial Instructions and inherent procurement procedures including Appendix E: Purchase & Acquisition of Medical Devices Procedure (735).

The most frequently used routes to funding medical devices purchases include:

- Outright purchase using capital or revenue resources as is appropriate to the specific procurement case.
    - A sub-set of this option is the use of charitable funds and for the purposes of interpretation and application of the commitments of this policy, no difference shall exist between the use of charitable funds of any financial magnitude (i.e. Hywel Dda charitable funds or via the support of external partner charities such as Leagues of Friends) and exchequer funding;
- Lease arrangements.
- Amortised purchasing arrangements.

SELECTION AND PROCUREMENT

To avoid abortive purchases and unnecessary risk escalation it is essential that due process is applied to the selection and procurement of medical devices purchases. When medical devices procurement planning aligns with risk mitigation plans then equipment standardisation can be extended and hence patient safety and outcomes improved. Equally medical devices that are not sourced through proper channels can sometimes be found to be incompatible with associated systems and equipment in use across Health Board.

To this end the Health Board does not allow the sourcing of medical devices from suppliers other than those that are included on approved lists held and accessible by NWSSP - Procurement Services. When a medical device is sourced through the proper channels then pre-purchase qualification tests are applied and this process helps reduce risk and can save money through the avoidance of abortive purchases.

Once a Statement of Need has been approved, the requester must contact Procurement to ensure that a compliant route to market can be identified, and lifecycle costs have been considered to ensure value for money.

STANDARDISATION OF MEDICAL DEVICES

Under this Policy the Health Board commits to embrace an appropriate degree of standardisation of medical devices in service where risk considerations overall render it prudent. This however, shall not be at the expense of introducing added risk as a result of overdependence on one supplier.

ACCEPTANCE AND COMMISSIONING

All re-usable medical devices must be formally acceptance tested and certified as fit for use prior to going into clinical service. This is achieved through and coordinated by the Maintenance Overseer & the Clinical Engineering departments and also device suppliers. MHRA Device Bulletin – Managing Medical Devices provides an overview of acceptance testing and commissioning procedures which local teams should enhance and apply as necessary for incorporation into their written procedures. In addition the Medical Devices Co-ordinator can be contacted for advice.

MEDICAL DEVICE CONFIGURATIONS

Along with the formalised acceptance process described above some medical devices may also need to be appropriately configured prior to going into clinical use. The process of medical device configuration involves making hardware and software choices which will be embedded into the medical device and will fundamentally influence the manner in which the medical device responds to user instructions. Configurations must be developed with the involvement of the Maintenance Overseer, Clinical Engineering Department and other stakeholders – refer to Appendix D – Medical Device Configuration Procedure.

MEDICAL DEVICES THAT ARE LOANED

It may, on occasion become necessary to put into clinical use medical devices that are loaned from another health provider or in the case of a trial, a medical device manufacturer or distributor. Trials can take the form of research and development trials (clinical trials or medical devices trials) or equipment evaluation trials prior to procurement of a medical device – regardless of the trial/device type, the same safeguards must be in place. In either scenario the user/keeper and their manager of the medical device must ensure all acceptance checks are in place after consulting with both the Maintenance Overseer & Clinical Engineering Departments. Additionally, in the case of medical devices provided for clinical trials, users/keepers and their managers must ensure all indemnity documentation and written agreements are in place and an application to MHRA is sought through the Clinical Engineering Department in order that the Health Board's interests are protected and liabilities minimised; this must take place before the trial can begin. In the event of uncertainty in this area the Health Board's local Clinical Engineering Department will be at hand to offer advice and guidance.

In the case of devices loaned from other health providers for the continuation of patient care, these devices would be transferred and accepted in such a way that the care and safety of the patient is not compromised. Any lifecycle maintenance and training arrangements should be set up by the Maintenance Overseer and the associated clinical teams managing the respective patient care, as soon as possible.

Medical devices left by company representatives shall not be put into clinical service without first being approved by the relevant Maintenance Overseer & Clinical Engineering Departments in line with their adherence to the Medical Industry Accreditation Scheme.

Medical devices could also be loaned directly to patients in line with the Hospital @ Home / Virtual Ward programmes. In these instances, the devices are fully managed by the loaning organisation. No intervention will be required internally by the maintenance overseer / Clinical Engineering, to manage the device lifecycle. This is on the condition that the loaning organisation appropriately supply evidence of device selection (being compliant in respect of Medical Device Regulations) and are managed in accordance with the MHRA Managing Medical Device guidelines. They must also supply supporting evidence of assurance, such as effective current Master Indemnity Assurance. However, Hywel Dda / Clinical Engineering reserve the right to audit devices issued by the loaning organisation, to ensure continued compliance in respect of the MHRA guidelines managing medical devices. This evidence will be supplied to and retained by the Clinical Engineering Department, from the clinical teams / project leads and is the responsibility of the clinical teams to manage and provide current and updated information, should the device be changed and any when assurances expire.

For devices issued to patients by loaning organisations for Hospital @ Home / Virtual Ward arrangements, Hywel Dda clinical staff must never use the devices that have been supplied to patients, they must use Health Board owned devices supplied to them which are managed by Hywel Dda.

MODIFIED / CHANGE OF USE

Modified medical devices or medical devices subject to CHANGE OF USE (Off Label USE), that are subject to modification will effectively lose the CE marking status they carry as a statutory measure under the Medical Devices Directive. In the eyes of the law the device will in all likelihood be seen as new piece of equipment and hence the manufacturer's product liability will be limited or removed and that liability will be partly or wholly transferred to the Health Board or to the person making the modifications on its behalf and/or the directing mind. The Health Board will only support the modification of medical devices when patient safety is at risk and the provision of care is placed in jeopardy as a consequence of removal of the unmodified device and all other possible solutions have been given prior consideration and the recommendation to modify (which is accompanied by a detailed risk assessment, in line with 674 – Risk Management procedure – opens in a new tab) remains the only reasonable and sensible course of action.

Medical devices that are subject to a change of use which go beyond the scope of application, as intended by the manufacturer, will be effectively classified as modified and the above will therefore apply.

Further information regarding off label use of medical devices can be obtained at

www.gov.uk/government/publications/medical-devices-off-label-use

The Medical Devices Group will seek assurance from the QSESC on all episodes of device modification or change of use and refer to the appropriate specialities as appropriate.

SECOND HAND MEDICAL DEVICE ACQUISITIONS

Ordinarily the Health Board will not procure or receive second hand medical devices for patient care use. If, however, in exceptional circumstances a situation emerges where second hand medical devices purchase is recommended as a reasonable course to take, then the medical device must be accompanied by lifecycle records including commissioning and acceptance data, service reports, parts replaced, usage data, fault logs and a record of contamination status (as relevant). The Medical Devices Group must give QSESC the assurance that the necessary safeguards (as listed above) are in place prior to proceeding with acquisition.

MAINTENANCE AND PERFORMANCE VALIDATION

Maintenance and performance validation testing is an important safety measure aimed at ensuring that medical devices continue to perform in the way the manufacturer intended and the user expects and hence are safe to be used. As with acceptance and commissioning procedures, these are provided/coordinated by the in-house Maintenance Overseer & Clinical Engineering Departments along with others including devices manufacturers or their agents. There must be regular reporting from Maintenance Overseers & Clinical Engineering Departments to the QSESC as well as a monthly report on maintenance performance and compliance status together with related safety information to Medical Devices Group.

It is sometimes the case that decisions can be taken to forego maintenance or performance validation programmes and this situation can be found when a medical device is of low replacement cost and it is considered more cost effective to replace the item outright rather than incur lifecycle servicing costs, or where the manufacturer clearly states that no maintenance is required and do not compromise the Electricity at work Regulations 1989 (in respect of safety testing and User checks) The medical devices that fall into this category are expected to be low risk so far as patients' safety and critical dependency is concerned. In such cases the risk considerations presenting will be documented in accordance with 674 Risk Management procedure – opens in a new tab and reported by the QSESC and assurance provided to the Medical Devices Group.

MEDICAL DEVICES LIBRARIES

The Clinical Engineering medical device libraries present economic opportunities if properly resourced and operated. The facilities provided at all four acute sites offer ready access to a range of devices for the wards and departments at each hospital.

For the Clinical Engineering medical device libraries to be effective co-operation between staff who use and those who support the facilities is essential. The procedures for booking out of medical devices and the prompt return once finished in a clean and serviceable state is therefore a basic requirement. Staff are required to observe the local medical devices' library procedures for booking out and return of stock at every episode.

LOAN OF HYWEL DDA MEDICAL DEVICES

Ordinarily the Health Board does not permit its' medical devices to be used for purposes not directly related to Hywel Dda activity, this includes;

- The removal of any medical devices off Health Board premises for;
    - Clinical use in other NHS organisations;
    - Clinical use in non-NHS organisations;
    - Clinical use on non-Hywel Dda patients;
    - Use by non-Hywel Dda staff.

In exceptional circumstances, permission may be granted via an application to the Chair of the Medical Devices Group who shall evaluate each case on its own merits.

END OF PRODUCT LIFE MANAGEMENT

The Health Board has a duty of care to ensure that medical devices are disposed of safely and with due diligence. The Health Board's actions at the end of a medical device's life should not create unnecessary hazards that could compromise the safety of the public or patients or harm the environment. Equally any medical device that has facility to store Personal Identifiable Information (PII) must have that data securely erased to an appropriate standard (BS ISO/IEC 15408 [24] and British HMG Infosec Standard 5 or IS5 [25].

Prior to disposal, appropriate steps should be taken so as to ascertain whether a need exists elsewhere within the Health Board and whether redeployment is feasible and/or appropriate.

Any service / device owner that receive End of Life / End of Support documentation directly from the Manufacturer have a responsibility to forward all relevant information to the Maintenance Overseer / Clinical Engineering, to ensure the Inventory Database remains accurate.

Disposal of medical devices
The removal from service of medical devices that have been declared obsolete is coordinated by both the Maintenance Overseer & Clinical Engineering Departments and disposed of in line with the Financial Procedure 093 - Disposal of surplus and obsolete furniture, equipment, sale of scrap and other waste materials – opens in a new tab, with any PII information fully removed and rendered forensically irrecoverable. The Maintenance Overseer shall inform the Clinical Engineering Department of the actions taken such that the Health Board inventory is updated accordingly.

Sale or donation as a usable asset
The Health Board recognises that any onward sale or donation of used medical devices requires its compliance with the obligations set out in the Consumer Protection Act, the Sale and Supply of Goods Act, the Health and Safety at Work Act, the Trade Descriptions Act, the Electrical Equipment (Safety) Regulations and the Unfair Contract Terms Act. Given the potential for ongoing and not insignificant liabilities arising from the onward sale or donation of medical devices, specific advice on a case by case basis should be taken from colleagues in NWSSP - Procurement before any irreversible action is taken. Before any used medical devices are donated or sold, assurance must be sought that all Personal Identifiable Information (PII) has been permanently removed from the device prior to any transfer taking place.

RADIATION AND LASER PROTECTION

There are several examples when medical devices used or intended for use at the Health Board will incorporate ionising and non-ionising types of radiation. All acquisition and in-service issues arising in respect to both types of medical devices must be predicated on the advice of a designated specialist in line with general obligations and 217 - Ionising Radiation Safety Policy (*opens in a new tab*)
In the case of medical lasers the current appointed Laser Protection Advisor should be consulted. Access to this person should be through Hywel Dda University Health Board's Laser Protection Supervisor(s).

For all other radiation protection issues the Radiation Protection Advisor working out of Swansea Bay University Health Board Radiation Protection Team should be consulted and access to this person should be through Hywel Dda University Health Board's Radiation Protection Supervisor(s).

TRAINING

All healthcare professionals carry a responsibility for their practice and decisions and for delegation of certain aspects of care to others. There is therefore a general onus on healthcare professionals, particularly in cases where less complex medical devices are

applied that the generally embedded professional training and learning will cover many aspects of their training need. Staff should never feel coerced into using medical devices if they are not or do not feel competent to do so, however they are expected to seek out training at the earliest opportunity.

With more complex 'higher risk' devices, training is provided in a number of ways (refer to Appendix C: Medical Device Training, Safe Use and Operation Procedure). The Health Board employs a dedicated in-house medical device training team who follow a pre-planned schedule of training and retraining aimed at covering all staff needing to maintain competence. In other instances it is usually the case that on purchase of a specific device, a training package will be procured along with the asset particularly with larger items such as major diagnostic equipment. Managers must continuously apprise themselves of which staff are, as well as which staff are not permitted to use specific medical devices and use this information to inform their job and skill-mix planning.

FURTHER INFORMATION

- Medical devices regulation and safety - https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety
- BS ISO/IEC 15408
- Ultrasound Clinical Governance in Wales – Welsh Scientific Advisory Committee – 2012 (Appendix B)
- Hywel Dda University Health Board Procurement Guide for Staff (developed in conjunction with NHS Wales Shared Services Partnership – Procurement Service
- Procurement Processes – Quick Guide
- Health Board Standing Orders and Standing Financial Instructions – Corporate Governance
- MHRA Medical Device Bulletin: Managing Medical Devices - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf
- Medical Industry Accreditation Scheme - https://www.miaweb.co.uk/
- Medical Devices Amendment Regulations 2003 - http://www.legislation.gov.uk/uksi/2003/1697/made
- British HMG InfoSec Standard 5 or IS5 Products & services - NCSC.GOV.UK
- Electricity at Work Regulations 1989
- Medical Devices: Software Applications
- Provision and Use of Work Equipment Regulations 1998 (PUWER)

Appendix A – Clinical governance and information governance assurance

1. Describe the maintenance and support arrangements in place for the medical device.
2. Describe the details of where the medical device is to be used, storage arrangements,
3. Describe the Information Governance arrangements that are in place related to the medical device and the outcome of any Privacy Impact Assessment undertaken
4. Describe the infection prevention & control arrangements required as agreed by the Infection Prevention & Control Team.
5. Where applicable, confirm that the HSDU manager has confirmed that the department is able to re-process the medical device or consumables used with the medical device in the decontaminating machinery they have available.
6. Describe the arrangement in place to ensure the ongoing competency of the user(s) in the use of the medical device.
7. Where applicable, that any special advice from a Radiation Protection Adviser or Laser Protection Adviser has been taken and their recommendations have been implemented or there are clear plans to do so.
8. Confirm that there are no extant MHRA device alerts that would give rise to unacceptable risk should the medical device be put into service.

Appendix B Ultrasound Clinical Governance in Wales

Appendix C – Medical Device training, Safe use and operation procedure

Appendix D – Medical device configuration Procedure

Appendix E – Purchase & Acquisition of Medical Devices Procedure

Appendix F – Maintenance of Medical Devices Procedure